

**The economics of patient safety and incident reporting
systems: translational evidence**

The economics of patient safety and incident reporting systems: translational evidence

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Thesis submitted for the degree of Doctor of Philosophy

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Statement of originality

I hereby declare that the work presented in this thesis is original and I confirm that I have performed this research myself. Collaboration and relevant input from other individuals are declared in the respective chapters.

.....

Alexander W. Carter

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Abstract

The aim of this thesis is to expand current knowledge of the economics of patient safety, with a focus on the costs and consequences of incident reporting systems. Intellectual enquiry into these closely aligned topics is demonstrably inadequate for policy development, which was the core motivation for conducting the research. To address these inadequacies, a systematic review of papers focusing on the economics of patient safety is presented, comprising 17 high-quality economic evaluations of patient safety that were published between 2007 and 2018. The findings indicate that few digital interventions for patient safety have been evaluated using methods from health economics, which explains why a rigorous conceptualisation of incident reporting systems and the economic issues surrounding them is required. A process map of the national incident reporting system in England was then developed and validated using semi-structured interviews, followed by a large survey conducted with 168 NHS staff participants, whose numerical responses facilitated the design of the resultant conceptual model. This model was considered valid based on the analysis of respondent scores and was therefore used to perform a time-driven activity-based costing study. A total of 103 NHS staff members with experience of incident reporting and management then estimated the time spent on each activity. The deterministic estimate of £956 million per annum of economic activity, needed to operate incident reporting systems, is a novel finding that exceeds previous low-quality estimates given in the literature. However, the economic costs of these systems do not encompass the consequences (and benefits) they may have for the English NHS. For this reason, an interrupted time series analysis using ten years of registry data from the Myocardial Infarction National Audit Project (or MINAP) was used to evaluate the impact of feedback reports produced by these systems. Using the most robust design, which incorporated a Scottish control group, no effect of feedback reports on bleeding rates in heart attack patients was detected. This finding, together with those described in each chapter, represents an important advance in the application of methods that can address economic questions of intrinsic importance to patient safety. Several methodological challenges emerge from this thesis, and these can be addressed by the research community to estimate the cost-effectiveness of incident reporting systems, along with other complex interventions for patient safety.

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List of abbreviations

The use of abbreviations was deliberately limited in this thesis. Abbreviations that were used are listed below.

ABC =	Activity-Based Costing
AC =	Agreement Coefficient
ACS =	Acute Coronary Syndrome
ADE =	Adverse Drug Event
AE =	Adverse Event
AHRQ =	Agency for Healthcare Research and Quality
AMI =	Acute Myocardial Infarction
ANOVA =	Analysis of Variance
BMJ =	British Medical Journal
CABG =	Coronary Artery Bypass Graft Surgery
CHEERS =	Consolidated Health Economic Evaluation Reporting Standards
CPRD =	Clinical Practice Research Datalink
DALY =	Disability-Adjusted Life Year
DES =	Discrete Event Simulation
DVT =	Deep Vein Thrombosis
EbP =	Evidence-based Practice or Policy
EED =	Economic Evaluation Database
HAI =	Hospital-Acquired Infection
HES =	Hospital Episode Statistics
HLY =	Healthy Life Year
HMIC =	Healthcare Management and Information Consortium
HRO =	High-Reliability Organisation
HTA =	Health Technology Assessment
ICD =	International Classification of Diseases
ICU =	Intensive Care Unit
IHTT =	Institute for Health Technology Transformation

ISD =	Information Services Division (Scotland)
ISPOR =	International Society for Pharmacoeconomics and Outcomes Research
ITSA =	Interrupted Time Series Analysis
LIC =	Low-income country
LMIC =	Lower-middle-income country
LMWH =	Low Molecular Weight Heparin
LOS =	Length of Stay
MeSH =	Medical Subject Headings
MINAP =	Myocardial Infarction National Audit Project
MRSA =	Methicillin-Resistant <i>Streptococcus Aureus</i>
NHS =	National Health Service
NICE =	National Institute for Health and Care Excellence
NPSA =	National Patient Safety Agency
NRLS =	National Reporting & Learning System
NSTEMI =	Non-ST Elevated Myocardial Infarction
OECD =	Organization for Economic Cooperation and Development
OLS =	Ordinary Least Squares
OPCS =	Office of Population Censuses and Surveys
PCI =	Percutaneous Coronary Intervention
PE =	Pulmonary Embolism
PICO =	Population, Intervention, Comparator, Outcome
PRISMA =	Preferred Reporting Items for Systematic Reviews and Meta-Analyses
QALY =	Quality-Adjusted Life Year
RCT =	Randomised Controlled Trial
RoB =	Risk of Bias
ROI =	Return on Investment
RR =	Relative Risk / Risk Ratio
SD or St.Dev =	Standard Deviation
SMS =	Safety Management System

SRA =	Segmented Regression Analysis
Std.Err =	Standard Error
STEMI =	ST-elevated Myocardial Infarction
TDABC =	Time-Driven Activity-Based Costing
UK =	United Kingdom
USA =	United States of America
VAP =	Ventilator-Associated Pneumonia
VTE =	Venous thromboembolism
WHO =	World Health Organization

Acknowledgements

Conducting academic research is a privilege and, as I see it, it is rare to be given time to reflect, refine, and focus on producing evidence that could benefit others. For this reason, I am extremely grateful to Professor Ara Darzi for giving me the opportunity to contribute to patient safety research and, also, to be given the time to grow intellectually at the Institute of Global Health Innovation at Imperial College London.

Professor Elias Mossialos has had the greatest influence on my strategic, scientific, and communicative approach to answering pressing questions in health economics and policy during this PhD. For the time he has given to my personal and professional development, I will be forever grateful.

This research was partly funded by the National Institute for Health Research (NIHR) via the NIHR Imperial Patient Safety Translational Research Centre (PSTRC). I am grateful for their long-term support for research on the economics of patient safety.

Hundreds, if not thousands, of people have contributed to this thesis in one way or another. I would like to express my sincere thanks to the research participants and colleagues at Imperial College London and the London School of Economics and Political Science, and especially my mentors and supervisors.

Preface

This thesis originated from discussions in 2013 between the author, senior academics, and health policy leaders in the National Health Service (NHS). A succinct and pertinent question asked during these discussions was: “Is incident reporting in the NHS cost-effective?” Whilst simple to ask, the answer, as for most scientific endeavours, is difficult to postulate with a high degree of certainty. The enquiries developed in this thesis have therefore been made to reduce the entropy of information surrounding this question, to generate more certainty regarding the answer, and to support policymaking efforts in the United Kingdom (UK).

As will become clear, several themes coalesced in the production of this research. It is primarily concerned with improving patient safety in the UK and across the world. Policymakers have prioritised patient safety in high, middle, and low-income countries, justifying investment based on clinical improvement, health promotion within the population, and economic benefits. Investments at each of these levels are intrinsically linked; however, policy efforts have primarily focused on addressing prominent clinical care failures in acute care settings. As such, twenty years of policymaking in this area directed the perspective of this thesis towards patient safety in the acute sector of the NHS.

Over the past decade, the economics of patient safety has become a discipline within a discipline. Policy research is shaped by the need to measure the economic costs and benefits of system, organisation, and clinical level interventions. This has been driven by post-recession austerity which – although not as severe as it was during the immediate aftermath – may have propagated long-term economic spill-overs. Whilst the cause and effect of austerity in the NHS and health systems in other major economies represent a separate subject in health economics, the consequences for researchers do not. Confronted with a budget deficit of approximately £27 billion by 2030, the NHS in England must initiate, develop, and implement policies that drive short-term efficiencies and promote long-term sustainability. Given the burden of avoiding harm to citizens and patients, the economics of patient safety combines two clear objectives for health policymakers: better population health and cost containment.

New and existing markets for technology are emerging and expanding at an unprecedented rate across all sectors of globalised economies. Health technology has benefited from renewed attention from investors over the past five to ten years. Data and technology goods and services in health systems have the potential to address the core concerns of policymakers; however, unless evidence regarding the long-term value of technology is regularly estimated, rising

expenditure on these goods and services may perpetuate or exacerbate the economic challenges they encounter.

Techniques for estimating the value of information systems are therefore explored in this research. The methodological approach is developed from economic evaluation frameworks that are commonly employed in the evaluation of technology in the UK and elsewhere. Methods derived from systems thinking, operational research, industrial engineering, and policy evaluation are built around these frameworks to generate research output that provides policymakers with precise recommendations on how to redesign systems to maximise their value to society. Theories drawn from other topics in economics are referenced to convey the universality of the concepts explored in this thesis. The development of information systems in patient safety is replete with challenges that mirror digitisation in wider society; in both settings, digitisation is a means of economic growth and parallels between digitisation for macroeconomic development and health system strengthening need to be drawn to achieve intellectual and policy-making coherence.

To this end, the fundamental concept of value is examined and defined. Incident reporting systems constitute an information management technique developed to reduce avoidable harm in health systems. In 2002, the English National Health Service (NHS) expanded the scope of these systems to form a connected national system called the National Reporting and Learning System (NRLS). The emphasis on incident reporting systems grew alongside their development and implementation. The clinical and cultural effect of these systems received a considerable amount of attention in the latter half of the 2000s; nevertheless, the economic impact on patient safety has never been measured.

The methods employed in this research are a novel combination of approaches employed in several fields that were aligned to generate high-quality information on the value of incident reporting systems in the NHS. To fully appreciate the rationale and longevity of this approach, which is rooted in total quality management, readers are encouraged to adopt a forensic attitude to understanding processes. This approach is partly inspired by particle physics, systems physiology, and quantum mechanics, which are respectively concerned with the precise observation of entities, feedback between afferent and efferent connectors, and state-based strings between entities observed in complex systems. Readers should visualise a production line of data that originates from the unobserved information surrounding us. How efficient is this production line? What is its value to society?

At a time when Western economies are transitioning from the knowledge-based economies of the late twentieth century to technology-based economies, the relationship between knowledge production and technology requires empirical evidence to support growth. The potential for such growth in health productivity is best realised using evidence-based policies. Ultimately, evidence-based policymaking is the factor driving this thesis, the final goal of which is to maximise the future health of the UK population.

Chapter one: Literature review of interdisciplinary concepts and theories

Background

In the wake of high-profile failures in healthcare delivery (1), the need to implement technologies and processes and enhance workforce skills that improve patient safety remains high. The NHS has adopted several measures across the system to improve safety with the aim of reducing poor outcomes that distress citizens and result in increased expenditure on care. According to initial estimates provided in 2002, the number of adverse events in acute NHS settings alone is estimated to be between 550,000 and 1,400,000 per year, leading to high resource use (2,3) and litigation settlements (4). Given the well-documented fiscal challenge facing the health service in England (5,6) and after more than a decade of policy effort, there is insufficient evidence available to inform decisions as to how to optimally use scarce NHS resources and address the economic burden of poor care that threatens the safety of patients. This doctoral work aimed to determine the impact of patient safety policies introduced at various levels of the system on health and economic outcomes, with a focus on incident reporting systems.

Incident reporting systems are important because they are considered the most valuable part of the modern patient safety movement (3,7). Providers worldwide are encouraged to promote a culture of incident reporting in their institutions. However, recent evidence from the Organisation for Economic Co-operation and Development (OECD) suggests their perceived value (assessed using an impact: cost ratio) is likely to be low because their perceived impact is relatively small and the cost of developing these systems is high. According to Slawomirski, Aaraaen and Klazinga (2017) (8), Low Income Countries (LIC) and Lower-Middle Income Countries (LMIC) should expect higher value from introducing and promoting the use of these systems, although empirical evidence to support this view is limited. The resource implications of developing national incident reporting and learning systems, which add to the marginal cost of the endeavour, must also be carefully considered. Therefore, evidence is needed to support rational resource allocation to incident reporting systems within the wider framing of policy options and interventions to improve patient safety.

The predominant quality framework against which the research contained herein was conducted is the original and widely accepted definition by Donabedian (9–11) which encompasses seven pillars: efficacy, effectiveness, efficiency, optimality, acceptability, legitimacy, and equity. In this definition, safety is implicit and “indistinguishable” from high quality care (12). This framework has been applied in recent reforms that have aimed to move

the health system away from a model of regulation or “command and control” to one of quality improvement driven by providers and patients (13). The consequences of this paradigm shift are multifaceted; however, an important component is the cultural shift towards openness and teamwork. Therefore, the origination and development of the NRLS in 2002 and other similar interventions, such as the World Health Organization (WHO)’s surgical safety checklist in 2008 (14), represent policy milestones on a journey towards better quality care in the English NHS and elsewhere. Health systems need evidence-driven solutions to adapt to shifts in population demographics that are generating an increasing number of patients with chronic and multiple diseases (15,16). In these settings, quality of care is at risk owing to the increasing demands placed on healthcare providers by complex technologies and broader organisational issues (17).

In this context, the lack of economic evidence regarding patient safety (18) and shortcomings in the present understanding of the efficiency of health systems constitute a significant gap in knowledge. In a systematic review of the US literature (no equivalent UK study has been published), Hussey et al. (19) demonstrated that the association between healthcare quality and cost in this age of quality improvement and cost containment remains unclear. The implications of the pursuit of improved quality must be better understood and, in broad terms, policymakers need to know whether improving quality means higher care costs (20). As other scholars have explained, the relationship is unlikely to lie at an extreme as the cost-quality relationship is likely to depend on the intervention or context of spending (21). Hussey et al. also explored the heterogeneity between methodologies and found that most studies were conducted at the hospital (meso) level, rather than a regional level (19). Hospital level studies were more likely to report a positive relationship between cost and quality, whereas the opposite is the case for regional analyses. Thus, quality improvement interventions are not comparable at each level, although this finding does highlight the ambiguity inherent in the relationship between cost and quality with respect to intervention type, outcome, or quality measures employed, and the economic perspective (level of analysis) adopted. Regional and system (macro) level economic analyses of healthcare quality (and safety) are lacking.

Hussey et al. did not assess the impact of (different types of) quality improvement strategies on care costs, as the primary endpoints used by the authors were quality measures. The need to understand the impact of different forms of quality or safety interventions is therefore high because this type of evidence is essential for policy formulation. The development of patient safety interventions is often based on clinical improvement (and therefore a focus on outcomes

or positive activities is directed towards this), rather than efficiency improvement, which explains why evidence may indicate a misalignment between cost and quality. The main challenge for policymakers and researchers is to retrospectively assess the effectiveness of system-level policies delivered since patient safety emerged as a prominent policy topic (3). Such interventions vary in form and purpose, although all generally attempt to reduce the number of patient safety incidents, which by definition have or could have caused harm to patients (22).

Contemporary reflections on the economics of patient safety

The economics of patient safety is a relatively immature field of health economic research. Broadly, it includes studies on the economic burden of harm in society, cost-of-illness studies, cost analyses of safety interventions, and full economic evaluations of treatment costs and effects, which take the form of cost-effectiveness or cost-utility analyses. Evidence is needed to improve rational resource allocation decisions in health systems, which is optimally achieved using economic evaluation methods. However, contemporary appraisals of the scope and quality of economic evidence are lacking. This is discussed thoroughly in the next chapter. High-quality evidence is urgently needed so that policymakers can make efficient resource allocation decisions, especially because patient safety is continuing to grow as a health policy priority in the face of an adverse situation caused by resource constraints.

Evidence on the economic burden of harm

Compared with the full scope of economic analyses required to inform rational policymaking, evidence on the clinical and economic burden attributable to patient safety incidents is relatively advanced (23). In the economics of patient safety, the economic burden from various harms needs to be estimated first so that resources can be directed towards reducing the incidents most costly to society. This burden is measured using several indicators from multiple global datasets. The impact of interventions or policies on patient safety can therefore be measured using validated indicators, provided the data are accessible. For instance, Hauck et al. utilised a translation of Agency for Healthcare Research and Quality (AHRQ) patient safety indicators (24) from routine administrative data taken from Hospital Episode Statistics (HES) collected in England from 2005 to 2010. These data contain well-documented limitations that must be considered with respect to the measurement of patient safety and the economic burden this presents (25). Nevertheless, use of these datasets is growing (26–29) and these analyses are vital because they provide policymakers with additional information about the most problematic and costly areas of care to address.

Hauck et al. measured the number of preventable incidents for six conditions: pressure ulcers, Deep Vein Thrombosis/Pulmonary Embolisms (DVT/PE), central line infections, hip fractures from falls, post-operative sepsis, and death in low-mortality procedures (23). The researchers deliberately utilised indicators with high false negative (low specificity) rates to derive conservative estimates of healthy-life years lost and excess bed-days between 2005 to 2010. They found that pressure ulcers and DVT/PE exert the highest burden. This research constitutes one of the most robust methods employed to measure harm in the UK; however, there are several limitations associated with Hauck et al.'s findings. Firstly, administrative datasets rely on the institutional coding of clinical care, including diagnoses of harm, and these measurements are subject to bias and gaming. The magnitude and direction of coding bias remain difficult to estimate. Secondly, the observation period for this analysis coincided with major payment reform in England (30), which might have affected coding practice (as an exogenous shock) and estimations of the scope and size of harm. Moreover, wider institutional reform and technological progress has taken place in England since 2010, which reduces the generalisability of these findings. Thirdly, policymakers need more evidence on the burden of a broader tranche of patient safety incidents than the six presented by Hauck et al. This will ensure resources are directed to high-need and not simply “high-evidence” areas.

To achieve this, several challenges need to be addressed. These include the definitional and normative aspects of patient safety, which are transient and require a robust consensus as to what constitutes harm. This varies for several reasons, such as the diffusion of new technologies that change the likelihood of harm or the production of evidence about a previously unknown harm. In particular, the impact of existing interventions on the clinical and economic burden of harm needs to be determined to inform policy, process, and product investment. Whilst the use of patient safety indicators in routine administrative data is an important methodological development, several other types of dataset are required to measure the burden of harm and the impact of strategies designed to reduce this.

In an editorial published in 2012, health economist David Meltzer described the economic evaluation of interventions in patient safety as a “neglected necessity”(18). This means that substantial resources are now being deployed to improve patient safety; however, stakeholders have neither a sufficient understanding of the economic impact nor the opportunity costs associated with the use of these resources. This is important because resources need to be allocated in a manner that minimises the burden of harm at the lowest possible cost. To achieve this, research on the economics of patient safety requires taxonomies from which to build

evidence. For instance, in 2010, patient safety interventions were identified by Waring et al. through a thematic analysis of UK-based research (31). The researchers classified intervention-based research in patient safety as either people-based, encompassing individual or group healthcare staff behaviours in a system; organisation-based, which describes studies or interventions related to “latent” organisational factors, such as system design, organisational culture, and management; or technology-based, which relates to the implementation and use of technologies to improve safety. Incident reporting systems can be viewed as part of each category because they comprise a blend of sociotechnical components that are continuously combined at system, organisation, and individual levels.

Within this framing, incident reporting systems are also learning systems. This loop has operated in various forms of clinical practice for decades, if not centuries, and over the last twenty years electronic systems have replaced earlier methods of identifying safety incidents and learning needs. One notable incident reporting software system in the UK is provided by Datix, which interfaces with the NRLS (32,33). The Department of Health pioneered the development of the NRLS in 2002 (34) to initiate a feedback loop for learning between local and national incident reporting systems. Research and development on learning health systems is now an established scientific field (35) and ideas from this discipline should be applied to incident reporting systems as a means of developing methods that facilitate an understanding of their economic impact. The learning system for incident reporting is conceptualised in Figure 1.1. However, this forms only a small part of wider research on incident reporting systems, the processes they comprise, and investigations into best practices for achieving better patient safety. For example, Benn et al. identified the process of reporting and learning as comprising nine discrete steps that feedback on themselves: detect, capture, classify, analyse, prioritise, investigate, formulate, implement, and monitor (36). This process is rooted in High Reliability Organisation (HRO) theory (37), which is a branch of systems research that has been successfully applied in industries such as chemical processing, offshore oil exploration, and the aviation industry. HRO theory combines systems thinking and human factors approaches to risk management; incident reporting systems in these sectors thus reflect the successful¹ operationalisation of this theory.

A critical determinant of the success of incident reporting systems is the demonstrable utility (38) of feedback. This has been studied qualitatively by researchers, indicating that the

¹ “Successful” as it is used here refers to demonstrable improvement in catastrophic loss of life in these industries.

implementation of feedback and measurement of its impact should be a focus of research on the economics of incident reporting systems (39). Feedback is the essential link between data generation, the production of which has an opportunity cost, and quality improvement, which encompasses improvements in efficiency and effectiveness. The impact of feedback and evaluation in other industries has been summarised extensively in a range of studies (40–43). However, to improve patient safety through incident reporting systems, further impact evaluation is required. This aligns with general principles underpinning the way research and development on incident reporting systems should be conducted. In 2013, Noble et al. argued that there is an urgent need to adopt a public health approach to incident reporting systems, citing the requirement for an epidemiological approach to patient safety research (44). Impact evaluations of incident reporting systems should therefore draw on established public health evaluation methods using, for example, logic models (45).

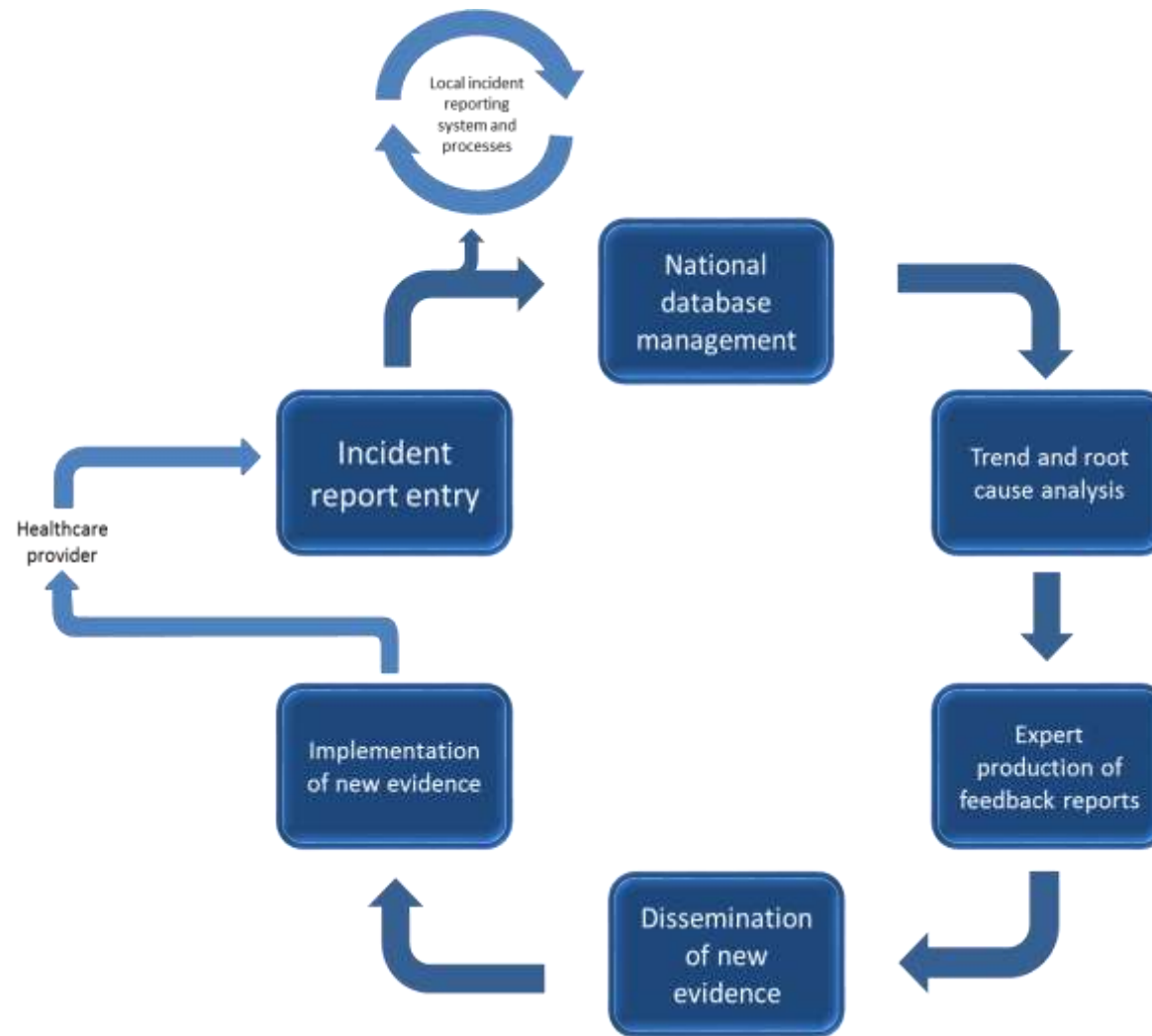


Figure 1.1. A conceptual view of nationwide incident reporting systems. The essential characteristic of this linear model of the system is that it operates in a closed loop. The representativeness of the model depends on the extent to which these activities resemble the real world and the degree to which the information loop is closed; these two essential aspects of system modelling have not previously been estimated. The output of “Expert production of feedback reports” is presented in Figure 1.4 as an example time series of feedback reports published by the NRLS in England (Carter et al. 2015)(46).

Systems thinking applied to translational economic research on incident reporting systems

This thesis explains the state of economic analysis in relation to patient safety, the lack of evidence available to inform quality improvement, and the need for further evidence to improve the development of incident reporting systems in the UK and internationally. It highlights the efforts of policymakers to develop system-level patient safety interventions in the absence of relevant evidence and addresses this gap by adopting appropriate methods that provide evidence on the impact of these systems, points of influence in the management of information, and the value of the outputs they produce. As the previous section indicated, existing clinical and health economic literature does not provide a harmonised theoretical and methodological framework from which to draw upon.

There are several methodological challenges that need to be considered in the analysis of information systems, such as the NRLS and local incident reporting systems. Systems thinking is defined by Trochim et al. (2005) as “a general conceptual orientation concerned with the interrelationships between parts and their relationships to a functioning whole, often understood within the context of an even greater whole” (47). The application of methods that align with this framing depend on the aims of a study and the availability of indicators that link the components of a given system. In other words, although “big data” in the form of routine administrative data and registries may exist, if these measure only a small proportion (albeit with multiple observations) of a large, interconnected system, then the flow of information will always be constrained by the boundaries set by their design. Therefore, mixed method designs rooted in systems thinking are needed to bridge the gaps left by routine administrative data and information.

The conceptual approach to systems thinking is well-established, yet there is a lack of methodological guidance on how to apply the concept to dynamic health information systems. In health economics, the inputs of a system are the basis for analysing the cost of healthcare activities and these methods are well-established (48); without them, accurate estimation of resource utilisation is not possible. A full economic costing of nationwide incident reporting systems, such as the NRLS, has not yet been performed, which is an unmet research need because the economic consequences of reporting (at a given production volume) could be detrimental. Such research is essential for capturing the costs of developing and implementing feedback reports. As the literature review of guideline implementation strategies demonstrated, economic evaluations tend to omit these costs, which means that estimates of their economic

impact tend to underestimate them. This problem is more than academic and provides an important insight into the diffusion (or lack thereof) of new policies or system-level interventions.

As this thesis highlights, the value of information hinges on the closure of feedback loops: health systems that can achieve this are likely to be more efficient and, accordingly, provide higher quality care to patients. The structure or inputs of these information loops must first be identified before the frequency of their closure and magnitude of effect are estimated. The narrative review of incident reporting systems did not identify any papers that formally adopted a societal perspective. Moreover, no studies adopted a systems thinking framework as they focused on arbitrarily identified reporting activities. In addition, the dynamics of the system, such as the flow of information between discrete processes, was not reflected in the economic analysis employed. Overall, these studies may underestimate the level of resource use in incident reporting and management and do not facilitate the redesign or optimisation of these systems. Therefore, an approach is required that will improve the estimation of resource use in these systems and facilitate the translation of evidence into more cost-effective practice.

The systems thinking and dynamics approach positions information attached to patients as the entity of interest. This choice of focus shapes the conceptual and analytical framework employed in this study, which is a novel and necessary contribution to health information valuation, and the relevant methods that have been described at a high level by Gartner, a leading IT consultancy and infrastructure firm (49). In this report, information is considered a business asset that can be valued across 6 domains: 1) Intrinsic Value of Information, 2) Business Value of Information, 3) Performance Value of Information, 4) Cost Value of Information, 5) Market Value of Information, and 6) Economic Value of Information. This business-centric and market-level conceptualisation of information as an asset should be incorporated more formally and regularly into the economics of health information systems because it facilitates the translation of systems thinking into operational and academic models.

The development of this framework requires the synthesis of theories and methods from several disciplines beyond economic evaluation and systems thinking. Thus, operational research, implementation science, process engineering, system dynamics, and systems biology are needed to derive translational evidence that can be used to redesign incident reporting systems in the NHS. The same framework can be applied to information management systems in any sector. In the chapters that follow, the components of this framework are described sequentially

from inputs to outcomes. Operational researchers employ quantitative methods to understand and augment management models and, in association with this, implementation science is a growing field that aims to enhance the translation of Evidence-based Practices (EbP). Similar approaches are required to bridge the gap in the translation of health economic evidence (50). The need for implementation theories rooted in process theory has been discussed by implementation scientists investigating the factors that determine the success or failure of complex interventions in healthcare, resulting in novel frameworks for researchers and decision makers (51,52). To accommodate the anticipated needs of the latter, the framework employed in this doctoral work aims to highlight where each discipline interlocks with others. This is necessary because the translation of the research is improved by credible multi-stakeholder buy-in, which is considered part of the scientific implementation of EbP, as exemplified by Greenhalgh et al.'s synthesis of evidence on the determinants of successful implementation (53).

Implementation science is defined by Eccles et al. as the scientific study of methods used to promote the systematic incorporation of research findings and other EbPs into routine practice to improve the quality of health services and care (54). Process evaluation and process models are important components of implementation science. The former refers to the characteristics of the use of an EbP before, during, and after implementation, which can be studied using an observational design (55,56). The latter is the operationalisation of a theory as a simplified depiction of a complex world that draws on relatively precise causal assumptions and the people and resources comprising a system (57).

Adopting principles from translational health economics

The approach adopted in this doctoral research was developed between 2014 and 2016. Health economics and, more specifically, the techniques employed in economic evaluation lie at the core of the mixed methods employed (around which the science of implementation and systems is built). This methodological approach is congruent to that of “translational health economics”, which was recently defined by Price et al. (2018) as an approach that facilitates the translation of findings from established tools of economic evaluation in healthcare, such as cost effectiveness analysis, into routine practice (50). The need for health economic evidence that can be applied has long been established and the paper by Price et al. signifies a step-change for economists to embrace translational methods. Given the need to reduce the evidence-practice gap, translational health economics aims to provide implementable evidence for optimal resource utilisation in the delivery of healthcare. The result of effective translational

research in this field should be value-for-money for stakeholders, such as policymakers and health administrators, and an identifiable return on investment (ROI). These approaches are increasingly needed to elucidate and demonstrate the value of health economics in enhancing productivity growth.

The conceptual, theoretical, and practical developments described above are also reflected in several strands of economics that have recently grown in popularity, particularly after the Great Recession of 2008. Minsky economics is one such strand and implicitly adopts a rejectionistic stance on classical and neoclassical schools of economic thought. In other words, current models for studying economics and welfare are deemed suboptimal at a fundamental level; hence, novel frameworks of thinking are required if scientists, economists, and policymakers are to acquire the predictive capabilities needed to steer economies and health systems away from the misfortunes of the past. The post-Keynesian economist Steve Keen has developed theories and system dynamic models of economies that represent a continuation of works by Minsky (58). This research is one such example of the direction in which economic science is developing, which is in a manner akin to the ideas now codified as translational health economics. These new approaches are reflected in the growing utilisation of behavioural science and behavioural economics in healthcare to address the underlying complexity of social systems.

A framework for the economic evaluation of (health) information systems

At the core of the framework developed for this doctoral research are patients and the information they “contain”, as they are the source from which information emanates, generating health(care) demand and, consequently, the supply chains that serve expressed needs. Information about a patient is observed or unobserved and, as such, the entropy of information may be infinite or partially (but never fully) reduced because of its complexity. Unobserved information equates to known unknowns, which are variables associated with patient-level phenomena that are yet to be discovered. Although other variables may have been discovered, the data are unobserved contemporaneously (temporal factors) or in situ (spatial factors), which amounts to an unknown known. An unknown known is a variable of interest that is not measured by an observer and adds further, partially explained, complexity. Known unknowns are variables of interest that are unknown to the observer. Observed information is the known known, which is information that is observed within the arena of agreed knowledge. The transformation of latent data into observed data and information (observations) should reduce the entropy of information. In so doing, the generation of economic benefit is facilitated.

In this respect, duplication of effort when generating information is strictly non-negentropic, which means that economic benefit is improbable or impossible. The translation of unobserved information into observed information incurs economic costs that might impact infrastructural or human elements. Theoretically, these can be measured. At an empirical level, several statistical assumptions need to be made. If these data do not generate an economic benefit to society in the short or long term (or both), then the resources employed to generate data confer a net cost to society, such as in the case of duplication. Alternatively, data that generate an economic benefit to society without incurring excessive costs confer a net benefit, as measured through, for example, an improvement in population health that leads to economic growth (59). If the resources employed to generate information and data impede the next generation from performing the same activities, then these activities (or goods and services) are unsustainable.

A value chain that includes production costs

Economic theory contains several, often disparate, strands of theory from which economists, scientists, and policymakers can draw. Figure 1.2 summarises these strands to establish the context for this thesis. Outside of general-equilibrium theory, the flow of finance and funds has been explored in an explicit theoretical strand that attempts to explain macroeconomic instability and the ensuing disequilibria in the short and long term. Several theorists can be credited with this line of thinking, including the economists Hayek, Schumpeter, and Minsky (60,61). More recently, the application of a funding flow framework to predict instability was powerfully demonstrated by Godley et al. (1999) and Godley and Lavoie (2007), who warned of the Great Recession against the tide of official thought and forecasting (62–64). The central importance of balance sheets and debt as a predictor of outcomes induced the “accounting approach” in economics. The accounting approach is described by Minsky and involves the use of “accounting identities” to analyse stocks and flows through the financial system (61). Similarly, Godley and Lavoie (2007) created the accounting framework for macroeconomics. Godley and Cripps (1983) explained that because money stocks and flows must reach a form of accounting equality in individual budgets, a fundamental law of macroeconomics exists that is analogous to the conservation of energy principle in physics. This macroeconomic principle applies to microeconomics, which in relation to economic evaluation places greater emphasis on the stocks and flows of funds as predictors of cost-effectiveness estimates. Put simply, the problem lies in the detail; stocks and flows of funds reveal more to analysts and decision makers than traditional economic frameworks, such that less uncertainty leads to greater economic stability. In terms of economic evaluation, this amounts to mapping value chains in the

production of healthcare, with formal measurement of the transactions executed along that stream. These time-dependent interactions occur at the level of the ‘accounting entity’. The use of “entity” rather than Minsky’s “identities” orientates this school of thought towards the existing terminology employed in the microeconomic analysis of systems and production lines.

Linking these economic theories to quality improvement in health systems, there is a lack of empirical evidence on the development, implementation, and treatment costs of guidelines in healthcare (18). Similarly, there is a dearth of evidence on the development, implementation, and treatment costs and benefits associated with feedback reports produced by incident reporting systems. This highlights the absence of Minsky’s accounting approach in analyses of health information production processes. Hence, there is the potential to adopt a dynamic systems perspective on incident reporting systems (and all other health information systems), which should improve our ability to predict the impact of the system and, therefore, design it in a manner that improves allocative efficiency.

This type of approach to incident reporting systems represents a radical departure from previous research. Most studies employ qualitative designs that employ relatively static process change endpoints, rather than the clinical processes and outcomes or economic outcomes needed to understand the dynamics of information production in these systems (65–67). Using the NHS staff survey, Hutchinson et al. (2009) identified a positive correlation between incident reporting volume and safety culture in the English NHS. Using Spearman’s correlation, they also found a negative association of -0.21 between reporting volume and recorded “slips, trips and falls” (95% confidence interval between -0.37 and -0.05 , $p = 0.015$) (32). Safety culture is an intangible benefit of incident reporting systems, which provides a reason to encourage the use of such systems on the frontline of provider organisations. Whilst this is encouraging evidence for the scale-up of incident reporting, it does not consider the resources associated with increasing reporting rates and the likelihood of diminishing returns on marginal growth in incident reports. Further compounding these issues, the marginal return from an incident report is likely to be small compared with other forms of incident identification due to shortfalls in data quality. This was demonstrated by Sari et al. who compared incident identification methods and found that only 5% of all admissions where a safety incident occurred were detected using a routine reporting system (68). These amount to measurement errors that reduce the value of incident reporting system data and, subsequently, the feedback reports generated from that data.

The state of current evidence on incident reporting systems presents researchers with an opportunity to apply an expansive suite of methodologies to underdeveloped evidence on the effectiveness and efficiency of incident reporting systems. A dynamic approach should, by extension, consider equilibria within closed-loop information systems. This is a natural evolution of the accounting approach in macroeconomics, which in health information economics is known as health information-equilibrium theory.

The measurement of costs and benefits that interact within incident reporting systems represent the mathematical notation of information-equilibria. The costs and benefits of incident reporting systems in other industries and sectors provide more informative methodological advice than is currently available in healthcare. As demonstrated in other sectors, a focus on the outputs from these systems is needed to estimate their cost-benefit or cost-utility to economies. This means experimental approaches revolve around feedback reports, which are the synthesis of an elusive but lengthy supply chain in patient safety. The cost of goods needs to be determined before the overall impact on quality and societal utility can be estimated.

To achieve this, feedback reports need to be characterised according to the Population, Intervention, Comparators, and Outcomes (PICO) they influence so that the health outcomes can be estimated in terms of economic utility. Clinical expertise is therefore required to determine the most likely causal pathway between the introduction of feedback reports and subsequent changes in related outcome(s). Each feedback report is likely to influence (several) different care pathways, which is why these should be considered complex interventions. For the same reason, the selection of appropriate conceptual and operational indicators to measure their impact is a challenge because clinical sequelae manifest across different time horizons and settings. Similarly, the heterogeneity of studies that would be produced is a further barrier to estimating the aggregate impact of feedback from incident reporting systems. The latter can best be understood through Pham et al.'s discussion of data limitations inherent in incident reporting systems (69).

A second methodological consideration concerns the hypothetical magnitude of effect, which differs depending on the care pathway and intervention under investigation. The former National Patient Safety Agency (NPSA) states that a more clinically significant impact is derived from high priority alerts than lower priority guidance. In this case, the likelihood of positive clinical findings regarding the impact of alerts is greater. These observations are also

more likely to be statistically significant. However, as stated previously, the ability to measure these outcomes strongly depends on the availability of datasets.

Sustainability and value as concepts applied to health information systems

Information and data generated today should not hinder the next generation from acquiring that information, unless codification, curation, or censorship mechanisms (data servers, libraries, education programmes) fail for uncontrollable reasons. The sustainability of information generation and data production therefore refers to the macroeconomic impact of knowledge, which is measured as an economic return *vis-a-vis* the opportunity cost of resources employed. For single payer health systems, particularly those reliant on tax-based financing mechanisms to fund the production of health information, the opportunity cost of generating health information should not exceed the economic returns to health from tax yields foregone from other sectors of the market. In this case (*ceteris paribus*), a Pareto optimality is foregone. Relating these concepts to the definition of the value-based design of health information systems, the notion of efficiency is one of normative economics and utility is implicit to this definition. The conceptual discussion thus far has not explicitly considered society's willingness to pay for health information, which is an instrumental objective towards achieving the final goal of population health. Willingness to pay thresholds vary geographically and temporally and are largely unconscious decisions constrained by funding thresholds in real-world decision making. The threshold under which the English and Welsh NHS is willing to pay for medical technologies, estimated from benefit analyses conducted for drugs and devices, is £20,000 to £30,000 (70) for one Quality-Adjusted Life Year (QALY), which is equivalent to 1 year of full health. The budget impact of this investment depends on the volume of access to a technology, which equates to £20m if 1,000 individuals can access a technology at a willingness to pay of £20,000 per QALY. Value therefore depends on the willingness to pay threshold. The approximate value to society of discrete (productised) health information and data generation should be within this range. If assumptions about information and data goods and services vary, which will depend on the type of information being generated, then it is reasonable to expect willingness to pay to be (equivalently) lower or higher. When productised appropriately, the value of information can be judged according to the cost per outcome achieved (retrospectively) or expected (prospectively).

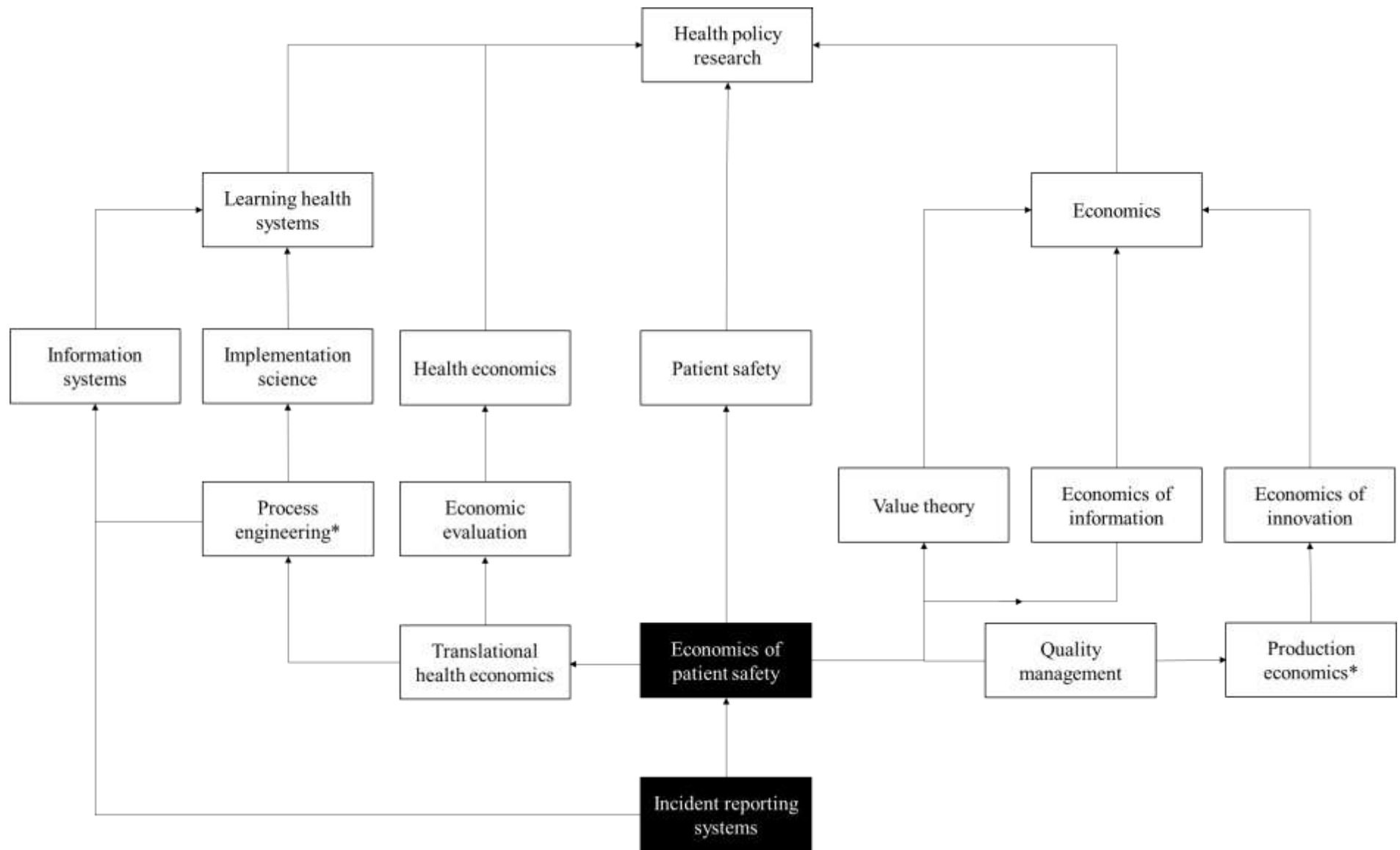


Figure 1.2. Strands of theory informing research on healthcare incident reporting systems and the economics of patient safety, as discussed in Chapter one. *Production economics and process engineering are concepts from related fields of science. Process evaluation and process modelling are methods common to both.

Broader applications of the methods and findings investigated

The application of these concepts to harmonised frameworks that can be used for information valuation is not widespread. However, as markets for information continue to grow, the dynamic relationship between data and economic growth requires an advancement of the methods employed to estimate these interconnections and their implications for society. The same applies to data and productivity growth in health systems. Existing methods rarely apply end-to-end or integrated approaches to evaluate health technologies, often due to resource constraints. Nevertheless, in the case of information systems, the lack of studies characterising the transformation of latent data into goods and services may be explained by the intangible or abstract characteristics of information and data. Data processing is a hidden production line that requires routine human resources, unless the process is fully autonomous in which case machinery and artificial intelligence are the resources required. The lack of evidence on information production lines in health is profound because the structures and functions of a health system, such as service delivery, the workforce, medical technologies, health financing, and leadership and governance, are connected by health data and information (71). Data are thus the element that binds these structures and, of the three final goals of health systems, have immense potential to improve the responsiveness of health systems.

If evidence is derived to inform EbP, its ability to facilitate the achievement of health system goals and the instrumental goal of efficiency through better procurement of information technology is likely to be strong. In popular science, the academic Evgeny Morozov developed the notion of “technological solutionism” (72) which denotes the near-compulsive adoption of often high-cost technologies to solve a problem that could be addressed using frugal and more effective methods. This bias will prevail unless alternative evidence-based solutions are presented with the tangibility of a new technology. This could be through better visualisation of abstract concepts, such as the flow of information through expansive systems. In this way, research acts to bring “known unknowns” into the arena of “known knowns” with which decision makers can interact to identify the most cost-effective rather than the most technological solutions.

Non-health sectors have been more proactive in applying these ideas. Hence, the potential for academic research that values (the components of) information systems is itself high because information systems can be designed that are superior to their predecessors. When applied to healthcare incident reporting systems, the first formal enquiry into network(s) of information governing health systems theoretically adds the most value (there are diminishing marginal

returns with each subsequent enquiry) (73). For these reasons, this thesis contributes direct evidence to inform patient safety policy and practice worldwide and, in doing so, anticipates spill-overs in the form of methodological guidance for the digitisation agenda in patient safety. The dearth of evidence on the economic value of stalwarts of patient safety is addressed in this document, with a deliberate focus on incident reporting systems because they represent a large gap in patient safety evidence.

Review of the economic evidence on incident reporting systems

A narrative review was conducted to assess the state of knowledge on the economics of incident reporting systems in healthcare. To handle the potential breadth of evidence, several terms were employed to capture the two concepts of interest: incident reporting systems and economic analyses. The aim of the review was to summarise findings on the economics of incident reporting systems.

Methods

A search was conducted of health and economic science databases to capture themes and terms related to the input (reporting activities), processing (investigation and management), and output (feedback and learning) components of incident reporting systems. Economic consequences were identified, including clinical outcomes caused by the outputs from these systems. Health and economic perspectives were explored through a search of databases that specialise in both topics. The health-related databases were Medline, Embase, Psych Info, and HMIC, whereas economics literature was obtained from the EconLit, and Business Source Premier databases. Terms were tested individually to ascertain their accuracy in detecting relevant literature. The search was limited to titles only.

Eligibility

Articles were eligible if they were written in the English language or were human-only studies published until 2019. Given the paucity of evidence, the results were not restricted by the type of publication because any peer-reviewed evidence on the topic can inform research on English incident reporting systems. Therefore, systematic reviews, original research, and opinion pieces were all included.

Overall, 409 records were identified and screened, including 85 non-health sector papers that were identified manually using Google Scholar. The search did not yield any information on the economic or patient outcome impact of feedback produced from reporting systems. The search strategy is summarised in Figure 1.3 and the eight eligible papers (40-48) that provide

economic evidence on clinical incident reporting systems, including data on their clinical effectiveness, are presented in Table 1.1

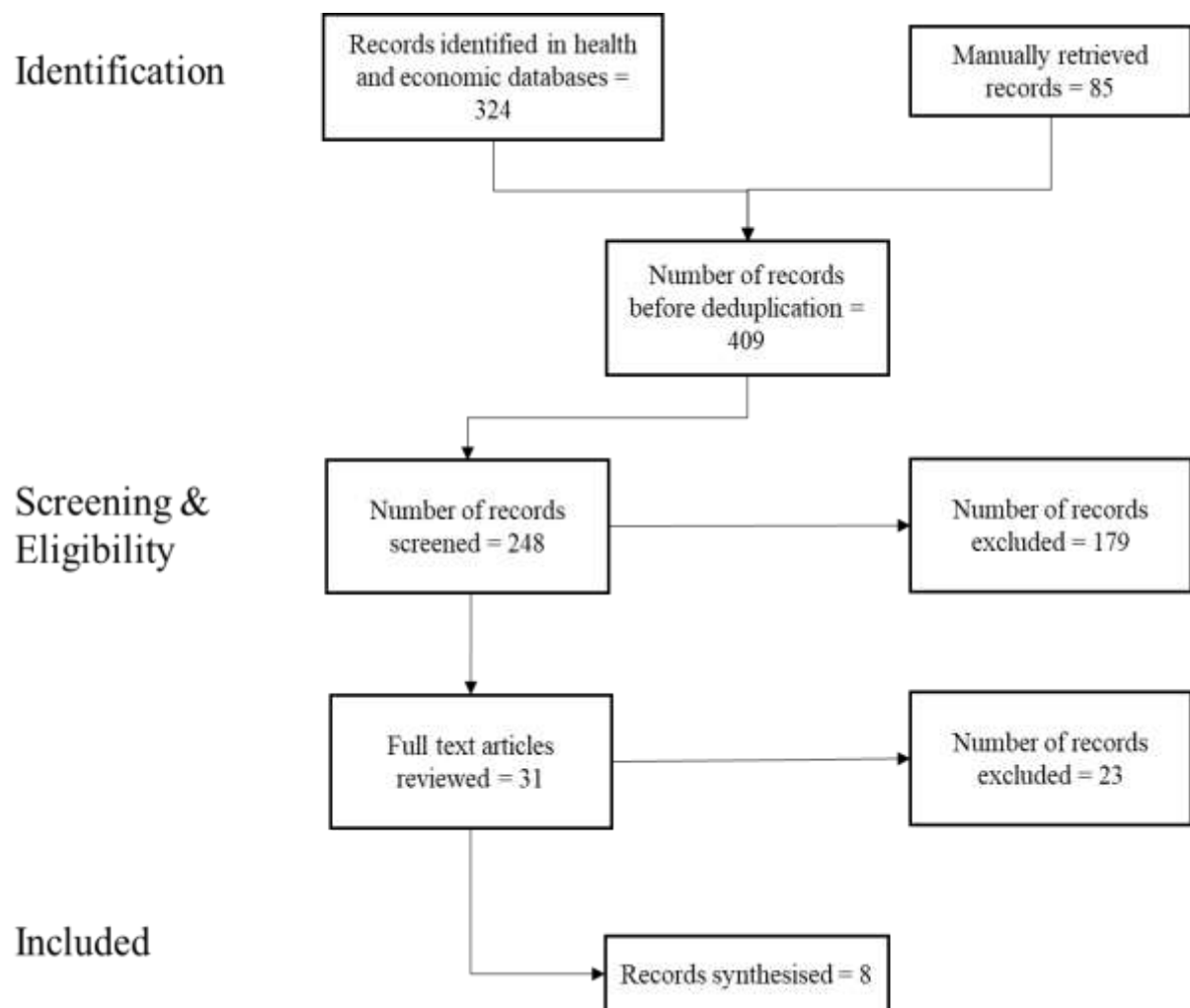


Figure 1.3. PRISMA summary of search strategy and results for papers on the economics of incident reporting systems since 1950. Eight eligible studies remained after deduplication and screening. These papers are summarised in Table 1.1.

Author	Title	Origin	Design	Summary	Results
Atherton 2002 (74)	Description and outcomes of the Doctor Quality incident reporting system used at Baylor Medical Center at Grapevine.	USA	Pre-post	Implementation of a web-based error reporting system coupled with educational and cultural interventions to improve error reporting and increase patient safety.	Post-implementation reporting of events increased. Costs for reporting, data collection, analysis, and management decreased. Time taken to track errors and initiate improvements was reduced.
Boyle et al. 2001 (75)	Quality-related event learning in community pharmacies: Manual versus computerised reporting processes	Canada	Survey	Mail-based survey to determine pharmacists' perceptions of manual versus computerised quality-related reporting.	Pharmacists reported that both computerised and manual incident reporting were cost-effective, easy to complete, and of low risk to operations. Rather than report a formal economic evaluation of a manual versus computerised reporting process, the study relies on staff perceptions only.
Goldsmith et al. 2015 (76)	Do clinical incidents, complaints and	UK	Cohort study	Retrospective review of incident reporting, patient complaints, and medico-legal claims in a single centre in the NHS.	Most complaints and medico-legal claims are not associated with a prior clinical error. One single author described the incident reporting process, concluding it to be efficient and

	medicolegal claims overlap?				working effectively. Approximately 1.5 full time equivalent staff administer the incident reporting system (Datix), with each incident investigated by trained staff from each department. These are supplemented by a patient safety team, constituting an additional 1.6 staff.
Renshaw et al. 2008 (77)	Clinical incident reporting: wrong time, wrong place.	UK	Opinion	The authors estimated the time spent on incident reporting based on the reporter, line manager, and patient safety office spending one hour per incident.	Overall, 44,000 hours per month are spent on incident reporting. The cost of the [incident reporting] system is estimated to be equivalent to 1,184 UK National Health Service (NHS) employees spending all their time each month completing incident forms. The system is described, and an estimate given for completing an incident report form. This translates into a crude economic cost estimate of £31 million per annum for this activity.
Savage et al. 2005 (78)	Utility of an online medication-error-reporting system.	USA	Cross-sectional	Survey exploring the utility of an online medication-error-	The system provided a tool for root-cause analysis and aided the identification of problems related to medication errors.

				reporting programme in 550 hospitals.	Overall, 66% of staff were satisfied with the impact of the system. Respondents estimated the staff, equipment, and training costs. Combined with the subscription cost, implementation was estimated to cost 16,756 dollars+/-21,108 dollars per annum.
Shah et al. 2015 (79)	Incident reviews in UK maternity units: A systematic appraisal of the quality of local guidelines.	UK	Cross-sectional	Systematic appraisal of the quality of guidelines for conducting incident reviews in UK maternity units and how incidents are reviewed, analysed, and disseminated for quality improvement.	Local guidance for the review of maternity incidents was mostly of good or high quality. Stakeholder participation in guideline development could be widened, and editorial independence more clearly stated.
Sinclair et al. 2017 (80)	Investigating the cost and efficiency of incident reporting in a specialist paediatric NHS hospital and its impact on patient safety.	UK	Observational	A retrospective analysis of medication incident reports in a single centre was conducted to determine the costs of reporting and highlight potential areas for improvement. Time was captured in five-minute blocks measured for three activities: 1) individuals' or colleagues' time spent on 'completing an incident form	A total of 262 staff were involved on 2942 occasions, with a calculated estimated cost (based on staff time) of £337.16 per incident. The analysis demonstrated the labour intensity of the process, with areas for improving efficiency highlighted. However, there is a lack of available data determining the costs of incident reporting in the literature. This translates into a crude

				entry'; 2) time spent processing an incident when notified by email; 3) average time spent by safety teams discussing a particular incident.	economic cost estimate of £43 million per annum for this activity.
Stavropoulou et al. 2015 (67)	How effective are incident-reporting systems for improving patient safety? A systematic literature review.	UK	Systematic review	Systematic review of the effectiveness of incident reporting systems in improving patient safety.	Studies compared IRS effectiveness with other methods of reporting or settings, structures, and outcomes for improving patient safety. No strong evidence demonstrated the superiority of IRS over other reporting methods and, furthermore, longer term research is required to determine the translational benefit of generated reports. IRS should be employed as a component of wider safety programmes, and providers should carefully consider the opportunity costs of IRS.

Table 1.1. Summary of studies on the economics of clinical incident reporting systems. Five studies originate from the UK, two from the USA, and one from Canada. Overall, the quality of the available evidence is poor because structural assumptions informing economic costing methods are defined narrowly and lack validation. Furthermore, the methods adopted to measure economic costs in two UK papers are not rigorous micro-costing approaches; only one paper (Sinclair et al., 2017) designed a questionnaire to estimate the ward-level costs of reporting and investigating incidents. These findings suggest that a harmonised methodological framework is needed to improve the methods employed to estimate the cost-effectiveness of incident reporting systems.

The UK-oriented peer-reviewed evidence is mixed. Renshaw et al.'s opinion-based estimates of the cost of incident reporting, which is narrowly defined as the process of completing an incident report form, is the least rigorous approach identified. Goldsmith et al.'s opinion-based estimate expands on Renshaw et al.'s approach by including an estimate of time spent on incident investigation. Sinclair et al. developed a questionnaire-based instrument to measure the amount of time staff spent on completing an incident form, responding to notifications, and discussing incident details in the patient safety team. These activities are embedded in the system at ward-level, which is likely to be narrow given the escalation of different categories of incident across organisational hierarchies. Of the remaining studies, the costs of an incident reporting system were measured only by Savage et al. through a cross-sectional survey of staff who estimated the implementation costs of an online medication reporting system. The authors combined these measurements with the estimated subscription costs for the software intervention procured.

In a pilot study that preceded this thesis, the start-up costs of the NRLS were estimated using accounting data in combination with expert opinion. This study was not published and is therefore not presented in Table 1.1., but it reported that total centralised expenditure on developing the NRLS until 2012 was £268M (inflated to 2018 prices) while annual expenditure, based on the historical accounting records extrapolated from 2012, is approximately £1.1M per annum (inflated to 2018 prices). The reduction in centralised costs illustrates the maturation of the business operation from its relatively high start-up costs to routine operational costs. There are several limitations to these estimates. The main assumption, which was derived from five study participants recruited from the (former) NPSA and its affiliates, was that approximately 80 per cent of the net parliamentary funding received by the Agency was allocated to the start-up and management costs of developing and managing the NRLS (81). This assumption may not be reliable as accounting records did not delineate NRLS development costs in the general ledger, but was the best estimate that was available. More significantly, accounting costs do not capture all relevant economic costs and do not consider the decentralised components of the NRLS. The consequence of adopting a multi-site system in the design of the NRLS is that it heightens the complexity of the system. This is desirable if the marginal gain from the additional information collected and analysed exceeds the costs of procuring it. In this framing, the economic costs must include the additional resources employed for the administration and coordination of information. Thereafter, the

extent to which this resource is rationally allocated can be estimated using tangible and intangible benefits from incident reporting systems.

Other global studies identified in the search did not measure costs (or effects) directly, instead providing opinions on the cost-effectiveness of local systems. Qualitative evidence on the impact of incident reporting systems differs substantially from the economic evidence, which is sparse in comparison

To address this gap, high-quality evaluations of incident reporting systems are needed. Several investigations that use state-of-the art methods are needed to generate data about their clinical and economic impact. According to recent international consensus, Health Technology Assessment (HTA) is a “multidisciplinary process that uses explicit methods to determine the value of a health technology” (82). Whilst not a study design *per se*, HTA encompasses several study designs that can employ various methods to generate clinical effectiveness (and health-related quality of life), safety, cost, and economic data. When considering these dimensions in the context of incident reporting systems, the pressing requirement is for evidence on their clinical effectiveness. In this area, randomised controlled trials are the gold-standard design, although quasi-experimental designs can complement RCTs when they are considered too costly to perform (83). Therefore, quasi-experimental designs can be used to assess the clinical effectiveness of incident reporting systems, particularly because they are already established interventions. The requirements for these designs are more restrictive because longitudinal data on clinical outcomes, such as adverse events, are needed *a priori* and conditions for establishing causality need to be met. However, when causality is verifiable, quasi-experimental studies are an appropriate alternative to RCTs for generating evidence on the effectiveness of incident reporting systems and their outputs. Clinical effectiveness data would be one dimension of an HTA. Cost and economic data form another, yet these two types of data should be distinguished. Cost data are financial or monetary estimates of resources committed to incident reporting systems and, over time, accounting records for incident reporting systems can be used to estimate expenditure. By contrast, economic data includes resource use in a non-monetary form; for example, labour productivity or production time. Cost and economic data provide a complete picture of the economic consequences associated with a health technology, which is why they form another dimension of an HTA. The advantage of focussing on effectiveness and economic data is that these can be used to model the cost-effectiveness of a health technology, which is the cornerstone of HTA.

Overall, evidence on the economics of incident reporting systems does not consider the multi-level and multi-stakeholder nature of these systems. This is a key limitation as the generalisability of evidence is weak and offers little opportunity for policymakers to optimise these systems by identifying viable targets for improvement. In addition, none of the studies identified attempted to measure the benefits of learning or feedback; therefore, no information was provided about the magnitude of closure of feedback loops and the inherent economic impact. There is a paucity of system-oriented evidence on the economic costs and benefits of incident reporting systems. Measurement methods that embrace the systems-thinking perspective are required so that target areas for optimisation can be identified and actioned with an appreciation for the upstream and downstream activities and interactions that influence activity-based costs.

As the summary of studies in Table 1.1 indicates, there is a global dearth of high-quality evidence on the cost-effectiveness of incident reporting systems. This reflects a broader lack of economic evidence on the costs and effects of information systems in health and social care. This indicates a need for the interdisciplinary development of theories and methods to study the economic impact of health information systems. For this reason, the following section combines concepts from health economics, information systems, and learning health systems into a novel conceptual framework.

Examples of economic evidence from the aviation sector

A ROI study on aviation safety was identified through a manual search of the grey literature. In this paper, Lercel et al. (2011) discussed ROI in relation to aviation safety management systems (84). Like other interventions in healthcare, modern incident reporting systems developed from those applied in the aviation sector. In this paper, the disutility to airlines of not operating Safety Management Systems (SMS) is discussed, citing falls of up to 25% in the valuation of firms after a major accident, and subsequent slow rates of financial recovery that might result in bankruptcy. The identification of incidents is seen as an effective risk reduction strategy that creates long-term savings by reducing costly reputational damage and the litigations that often follow safety malpractice.

The author addressed the claim that “the aviation industry has not extensively tracked the financial benefits of safety programs” by proposing a hypothetical model for ROI. A piecemeal approach was proposed whereby for each incident:

$$\text{return on investment} = \frac{(\text{cost of safety incident avoided}) - (\text{cost of preventive action})}{\text{cost of preventive action}}$$

Thus, this approach considers the value of incident reporting systems to be the aggregate costs of individual incidents avoided minus the investment costs of preventive action for that incident divided by the cost of investment in the same incident. Individual incidents are aggregated to derive an estimate of ROI from the implementation of an overarching aviation safety programme, in this case an aviation SMS. The formula assumes that in a “large [aviation] organisation, there will be multiple functions that [will] fall under SMS”. There are also likely to be spill-over effects from investment in individual incidents which, over time, justify reductions in the initial investment as organisational learning or memory is adopted. Educational materials that are deployed across an organisation, such as NRLS feedback reports, are outputs that are likely to generate spill-overs, such as learning applicable to other incidents in the short term and the accumulation of tacit knowledge of how to operate a safer system in the long term. For this reason, feedback reports are best viewed as complex educational interventions – justifying the earlier assertion that incident reporting systems are complex interventions (85).

Spill-overs are a particular challenge when measuring benefits and, in turn, estimating long-term value from incident reporting systems. In the ROI example, the authors also propose a weighting of the costs and benefits, measured, or estimated, from an aviation safety programme to account for the learning curve of an organisation. These weightings should be research-driven; however, numerical estimates of long-term learning from healthcare incident reporting systems do not exist.

Short-term ROI is easier to estimate and the financial benefits of operating an SMS in aviation is an example of a tangible, measurable benefit. For instance, Lu et al. (2011) provide anecdotal evidence that a flying school received an immediate insurance premium reduction of \$25,000 per year after implementing their SMS (86). The challenge of estimating long-term savings is amplified by the fact that long-term tangible costs and benefits are not easy to observe. This is because economic benefit is derived from incident reporting systems when no incidents occur, and therefore a counterfactual scenario is needed to estimate the excess costs that are removed from the system. Given that these costs are hypothetical and potentially not causally associated with the outputs of an incident reporting system, the measurement of tangible benefit tends to

be associated with several scientific limitations. Moreover, such limitations are exacerbated when measuring and incorporating intangible costs and benefits from incident reporting systems. Intangible costs could relate to a positive safety culture that is created by the existence of incident reporting systems that, by definition, are difficult or impossible to measure, but are nevertheless important for economic evaluations.

Given these challenges, a more convenient notation for economic cost measurement in the long term may be a probabilistic risk assessment, which was proposed nearly 20 years ago as a means of informing health systems design for patient safety (87). Risk reduction estimates provide a means of constructing counterfactuals at an organisational level; therefore the value of incidents (avoided) can be combined to estimate their total value. The formula proposed by Lercel et al. can be reorganised as follows to express the tangible and intangible outcomes from incident reporting systems in a healthcare organisation or whole system:

$$\text{return on investment} = \frac{(\alpha)B_{O1} + (\beta)B_{O2} + (\gamma)B_{O3} + (\tau)B_{On...}}{C_{O1} + C_{O2} + C_{O3} + C_{On...}}$$

Where, O = outputs (1, 2, 3, ...n) from an incident reporting system; α , β , γ , and τ are weightings that capture diminishing marginal returns from each unique output, manifested due to the amortisation of information contained in each output and the limited return for organisational learning, such that the effectiveness of learning from an output rarely reaches 100%; B = the tangible and intangible benefits that arise because of the output; C = the cost of identifying the root cause of an incident and then developing, implementing, and adopting the subsequent output.

For mature reporting systems in large organisations, the number of patient safety programmes and outputs may be immense, which is a major difficulty in terms of estimating, with a strong causal inference, the net benefits of such systems. Nevertheless, Lercel et al. demonstrated that to understand the total utility of reporting systems, a piecemeal approach that involves evaluating the impact of individual outputs is needed. Modelling the past or future utility (or costs and benefits) of incident reporting systems should therefore incorporate a function for diminishing learning (as institutional memory improves). The piecemeal approach offers another advantage for research and development on information systems for patient safety, which is that the characteristics of individual outputs, such as their design characteristics or the intended clinical target, can be associated with (the largest) benefits to society. Evidence of

this nature will promote the production of increasingly impactful outputs and the downregulation of those which are ineffective.

The aforesaid methods have not been applied to healthcare incident reporting systems; this is partly explained by the absence of any empirical estimates of the clinical, financial, or economic impact of their outputs. The advice from the aviation sector is therefore additive to the long-term investigation of the economic impact of incident reporting systems as ideas that can be applied to health sector research. The findings from high-reliability organisations, such as those in the aviation sector, are expansive and extend beyond the scope of this thesis. However, the components of any economic analysis of incident reporting systems must be identified to inform both this and future research on the topic.

In broad terms, health system researchers have focused on empirically estimating the impact of clinical guidelines produced by professional bodies and non-governmental agencies in terms of clinical and economic outcomes. In the absence of methodological information and empirical evidence on the impact of incident reporting systems, literature investigating the impact of clinical guidelines on outcomes was therefore explored to inform the methods adopted for this thesis.

Methods for evaluating outputs from incident reporting systems

Literature on the development of guidelines for quality improvement was identified because the methods employed in these studies can best inform approaches to evaluating educational outputs in healthcare, such as feedback reports from incident reporting systems. System-level investigations into the impact of clinical guidelines on economic endpoints that assessed the development, implementation or adoption of new guidelines were also identified. This evidence addresses a gap in methodological guidance on best practices for estimating the effectiveness and economic impact of feedback reports.

Two authoritative papers on this topic were identified. The first was a systematic review of economic evaluations and cost analyses on guideline implementation strategies by Vale et al. (2007)(88). The second paper was a systematic review by Hoomans et al. (2007) (89) which synthesised the methodological quality of economic evaluations of guideline implementation strategies. The authors adopted an international perspective in their review and included studies that were reviewed on the basis of four criteria: study design, intervention, participants, and outcomes. Randomised trials and Interrupted Time Series (ITS) analyses that measured process

change and/or patient outcomes following the implementation of guidelines were summarised by the authors.

Of the 11 types of implementation strategy identified by Vale et al., 49% comprised either the delivery of educational materials, educational meetings, or audit and feedback, which are similar to those produced by the NRLS. Drawing on the guidelines developed by Drummond et al. (1996) (90), the authors attributed the poor methodological quality of studies in this area to a loose interpretation of what constitutes an economic evaluation. Only 4 of the 63 studies identified provided satisfactory quality resource use and cost data on the development and implementation of guidelines, which may not affect the overall result in studies where the cost savings from guidelines are expected to be sufficiently large. However, this review highlights the importance of capturing economic evidence on the guideline development processes, rather than the process/practice changes detailed with the guidelines. This is particularly pertinent in light of findings indicating that evidence-based guidelines may not be as effective as intended (88), along with entrenched concerns that nationally-derived guidance, such as that produced by the National Institute for Health and Care Excellence (NICE), may not represent efficient practice at a local level (89). Hence, it is becoming increasingly important to determine whether disseminating and/or actively implementing guidelines is worthwhile. This was discussed by Severens (2003), who suggests that measuring the cost-effectiveness of quality improvement initiatives requires complex frameworks of thinking and measurement (91). Ideally, process and patient outcomes should be employed as cost effectiveness measures so that professional behaviours and healthcare processes can be better understood and augmented. In terms of economic evaluations, guideline dissemination strategies demonstrate the need for methods more complex than those currently used to assess the net benefits of medical interventions such as drugs. Moreover, in the case of incident reporting systems (and information systems), economic evaluations encounter the added challenge of disentangling the complexity associated with feedback reports as a property of the system within which outputs are produced and delivered (92). As Severens explained, the cost analysis forms the main component of economic evaluations of quality improvement strategies because the human capital costs associated with healthcare processes must be estimated and this is a more intensive exercise than estimating unit costs of drugs or devices (91). The complexity of the system itself must therefore be addressed.

Hoomans et al. found that cost analyses of guidelines tend to be incomplete with respect to the scope of costs, which signifies the intensity of research required to complete a full cost analysis

of the implementation of guidelines. Only 63% of studies reported the costs of developing guidelines, whereas all the studies reported the costs of implementing quality improvement strategies (89). The authors were unable to critically appraise the quality of the costing methodologies used; nevertheless, only a few of the studies identified adopted a health system or societal perspective (13% and 8%, respectively), which, by extension, suggests that most studies do not consider the allocative efficiency of guidelines. Similarly, only 10 of 63 studies in the Vale et al. review reported the perspective adopted and, of these, four adopted a health system perspective and one a societal perspective (93). Vale et al. were only able to identify two studies that reported the costs of the development, implementation, and treatment of guidelines (93,94). These reviews indicated that there is a large gap in the literature for high-quality economic evaluations or, more specifically, cost analyses on the development, implementation, and routine use of guidelines.

The effectiveness of guidelines, particularly their implementation, is a key component of a Health Technology Assessment (HTA) and needs to be considered as part of any economic analysis of incident reporting systems (95). A key distinction in HTAs of guidelines, rather than of drugs or devices, is the need to address wider costs and effects (96,97). Research can be employed to advocate for the promotion of guidelines based on both clinical effectiveness and cost-effectiveness to ensure new practices have the potential to improve frontline efficiency (98,99). In this vein, feedback reports from incident reporting systems should be generated and then promoted based on their potential to improve efficiency.

In summary, these reviews are informative because they demonstrate that although several studies have evaluated the cost-effectiveness of new guidelines across various disease areas, few high-quality studies have investigated the efficiency and effectiveness of guidelines from a health system or societal perspective. The overall poor methodological quality of existing studies suggests there is scope for conceptual development of the problem, along with methodological improvements that address the question of guideline utility and the reasons for their problematic adoption. Specifically, this evidence base can be used to inform methods for investigating the economic impact of feedback reports produced by incident reporting systems. The paucity of equivalent evidence on the clinical and cost-effectiveness of the NRLS feedback reports constitutes a gap in understanding wider than that which exists in mainstream clinical guidelines, such as those produced by NICE and other professional bodies. For this reason, research on this topic addresses an unmet need for global health systems.

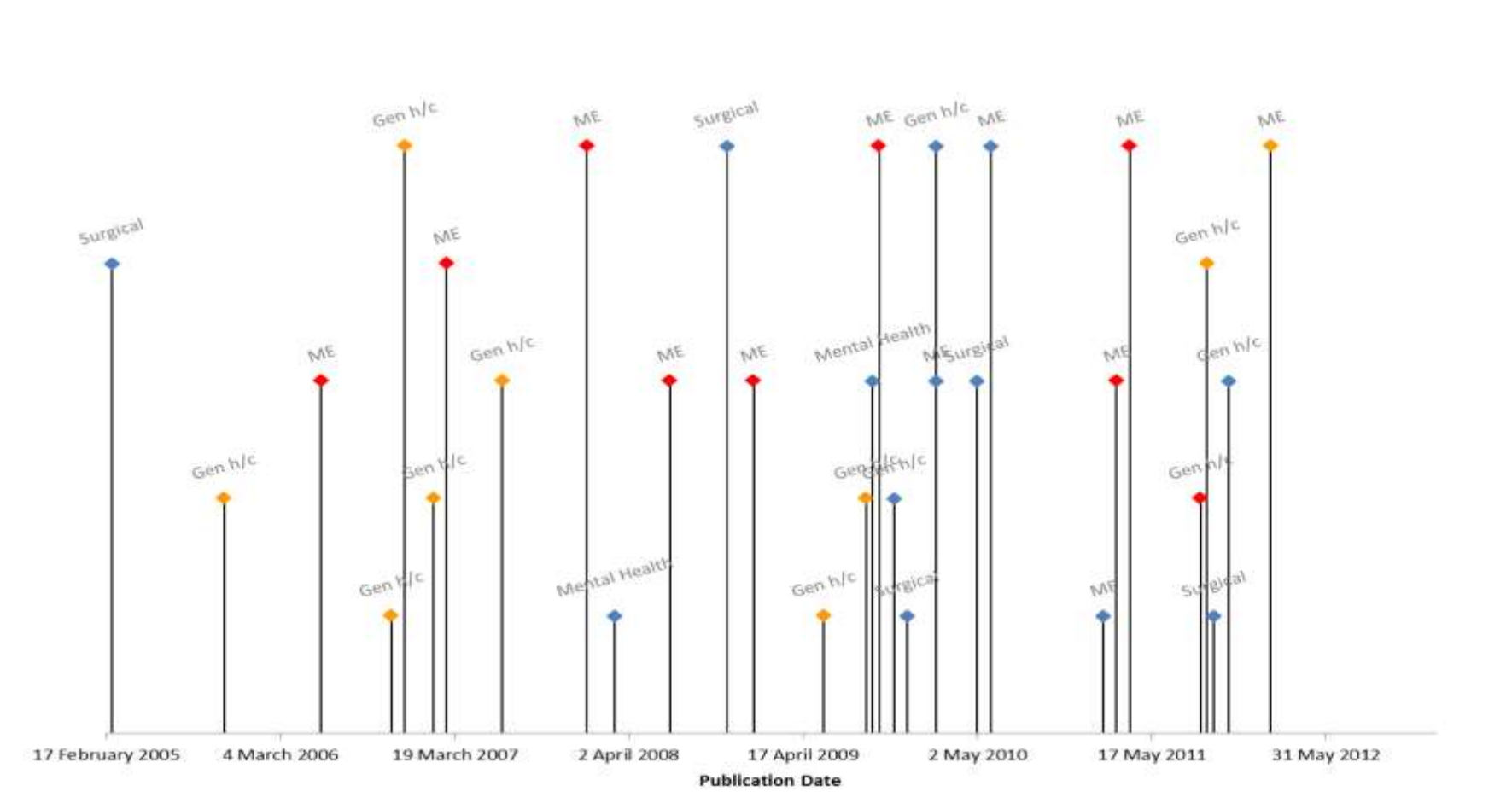


Figure 1.4. The output of feedback reports generated by the NRLS in England and Wales from 2005 to 2012 (author’s analysis). The feedback reports given in this timeline target never events, which have been organised according to the target adverse event within the never event list. Each output represents a structural break in the timeline that exerts an associated effect on clinical and economic outcomes. Legend: “ME” refers to medication errors; “Gen h/c” refers to feedback targeting all acute care settings; “Surgical” refers to surgical errors; “Mental health” refers to feedback targeting all mental healthcare settings.

Motivations for this thesis

The lack of peer-reviewed literature on the economics of incident reporting systems can be viewed in two ways: the first is that the topic is unimportant, which explains the lack of attention paid to it; the second is that the topic is important but is yet to be conceptualised sufficiently for academic and policy audiences to engage with, promote, and conduct research on. The first explanation would be a rarity in health policy because health economics is integral to decision making; methods for addressing economic questions in health systems have evolved since seminal work in the early 1960s and the establishment of several institutions over recent decades demonstrates this (100). Moreover, since the turn of the century, demand for health economists has been expected to grow (101), although at a time when health systems encounter larger economic challenges, it is possible that the supply of these economists will not be sufficient to meet the existing demand. This means that high priority policies may not always be evaluated using methods from economic science. In the case of incident reporting systems, there is a dimension of these systems that aligns with a fundamental concern of economists, which is the marginal cost of production. For decades, policy makers have encouraged healthcare workers to report incidents using the electronic systems provided. This is undoubtedly essential for learning lessons and preventing harm, but the law of diminishing marginal returns must also be acknowledged such that the marginal costs of producing reports does not exceed the value created, given there are other ways in which resources could be deployed to produce health. An uncomfortable but essential question to ask is: what number of incident reports is deemed excessive, given resource constraints? The answer may be that there is no limit, in which case current policy is rational; the answer might also cite the (expected) diminishing costs of producing incident reports and subsequent feedback or guidelines. In the absence of a formal enquiry into this question, the policy itself may become harmful, because a willingness to commit resources to one healthcare process implicitly means withholding them from another. This could compromise the quality of care patients receive elsewhere in a health system. As such, this question is fundamental to health economics and patient safety, and the case for not exploring possible answers is weak given the ethical implications of not doing so, which would amount to wilful ignorance.

The paucity of evidence and methodological guidance needed to address the economics of incident reporting systems means that mixed methods should be explored; indeed, this is essential because the conceptual foundation upon which modelling assumptions are built has not been formalised in this area. To address these gaps, key research themes are presented in

Table 1.2, in which a research problem, a hypothesis, potential methods, and data sources are given.

Table 1.2. Thesis themes and mixed methods for addressing them. These themes ensure that a robust conceptual foundation is created for research on the economics of incident reporting systems.

Chapter	Problem	Guiding principles	Method	Dataset
Two	A search on the economics of incident reporting systems could miss important forms of methodological guidance from broader literature on the economics of patient safety.	A broader search strategy that encompasses the economics of patient safety will reveal methodological approaches that can be built upon in this thesis.	A novel systematic review of economic evidence on patient safety to ensure recently introduced technologies and methods for evaluating them are captured.	Health and economic literature databases, as these are easy to access.
Three	In the absence of methodological guidance specific to the economics of patient safety information systems, a conceptual model is needed. Data from incident reporting software vendors is difficult to access and a conceptual model may be biased by the fields of activity collected for commercial purposes.	A conceptual model must reflect expert opinion, which is achieved if the model has face validity. The value of the model will be higher if it reflects real-world experience. This is equivalent to the “identify” step in cost analysis. The conceptual model should incorporate multidisciplinary ideas from contemporary science.	Process mapping is a technique used in quality improvement to identify a set of activities and their sequencing. It can be employed to conceptualise a set of (economic) decisions within a system and is the first step in an economic evaluation.	Prospective data collection: interview study, followed by a face validity survey with NHS staff (known as users) with knowledge of incident reporting systems; however, it is difficult to access a large sample.
Four	A conceptual model alone does not provide a quantification of resource use. There is no existing dataset on the costs associated with incident reporting systems.	A conceptual model can be used to develop decision-analytic models and simulations of the processes it describes. In the absence of any other cost dataset, the model can be used to derive costs. The parameters measured in an initial cost analysis can be re-estimated by other researchers. This	Time-Driven Activity-Based Costing (TDABC) is a micro-costing technique that supports ideas in the emerging field of translational health economics. It is one method for estimating the marginal and average costs of production. Without costs or prices from established data sources, time estimates must be	Prospective data collection: unit costs or prices for discrete activities estimated using a structured questionnaire administered to NHS users; however, it is difficult to access a large sample.

		approach is equivalent to the “measure” and “value” steps in cost analysis.	collected from experienced NHS users.	
Five	There is no existing conceptual framework from which the effectiveness of complex interventions such as incident reporting systems can be evaluated. Experimental methods using population-level data have not been employed to estimate an effect size attributable to the outputs from incident reporting systems.	The effectiveness of incident reporting systems is translated into economic benefits or utility production. Population-level effectiveness must be measured using an experimental method. This is necessary because the NRLS is a population-wide initiative.	Multi-group interrupted time series analysis is growing in popularity because it enables large datasets to be exploited to measure effect size(s). The outputs produced by incident reporting systems in England must first be identified; these define the structural breaks in a time series from which causal inferences can be drawn,	Published feedback reports need to be identified and categorised retrospectively. The Myocardial Infarction National Audit Project (MINAP) is a nationwide registry that provides patient safety outcomes. A control group can be constructed from equivalent Scottish data, but this may be difficult to access.

The absence of established datasets to both inform and estimate the cost-effectiveness of incident reporting systems means that a broader approach using mixed methods is needed. The outputs from this thesis can be used to strengthen the rationale, conceptual approach, and development of datasets used to evaluate the cost-effectiveness of incident reporting systems, along with other information systems aimed at improving patient safety. For these reasons, the mixed methods proposed above are appropriate and necessary to ensure scientific progress that can be translated into practice. The consequences of the approach outlined above are summarised in Chapter six, table 6.2.

Summary

In this chapter, a wide-ranging review of the literature was presented, drawing on the interdisciplinary fields of health and economic science. A systematic search for literature on the economics of incident reporting systems yielded just two relevant articles on the economic cost of operating these systems. As explained in detail in the next chapter, a systematic review of literature on the economics of patient safety is therefore needed to better orientate research on incident reporting systems. This substantiates the reason for synthesising disparate strands of literature that can inform this and future research on the economics of such systems. Systems thinking guides the conceptual and theoretical discussion on how best the economics of patient safety and incident reporting systems should be investigated. The complementarity that exists between process engineering and production economics, even though these disciplines originate from different scientific strands, demonstrates why a broad base of literature is needed to conceptualise research on incident reporting systems. Moreover, the notion of translational health economics is new, as it was only formalised by Price et al. in 2018 (50); therefore the toolkit health economists should utilise to derive such translational approaches is in its embryonic stages. The inherent challenge in performing translational economic evaluations of complex interventions, like incident reporting systems, is that novel, impactful approaches first need to be formulated.

Chapter two: A systematic review on the scope and quality of economic evidence relating to patient safety

Introduction

The research presented in this thesis centres on the value derived from incident reporting systems in relation to patient safety. The context for studying these systems is set by methods and existing evidence on the economics of patient safety, as well as the interdisciplinary strands synthesised in Chapter one. As a separate discipline within the broader field of patient safety, economic analysis in patient safety is relatively immature. Increasingly, however, evidence on this aspect of patient safety is required by policymakers seeking evidence-based recommendations on how to improve safety efficiently and sustainably. Within the wider definition of quality improvement given by Donabedian (9), efficiency is a pillar of quality that should not be neglected. Sustainability is defined as a set of activities performed in the present that do not hinder future generations from undertaking the same activities (102). For Western health systems facing financial deficits into the next decade, efficiency and sustainability are an essential concern. In conjunction with patient safety policy, the potential for achieving substantial marginal gains by generating and acting upon high-quality evidence is immense.

The achievement of this policy objective depends on measuring patient safety outcomes across clinical, health, and economic dimensions. As discussed in Chapter one, the economic dimension can include costs or financial outcomes. In cost-effectiveness (or cost-utility) analysis, clinical outcomes can be expressed as a rate or absolute number of adverse events (AEs) observed; an AE can be expressed in terms of life years gained, lost, or unchanged by these events, which might reflect a population's total gain or loss of life years, and can be used to capture health outcomes. Life years can be adjusted using standard methodologies for incorporating estimates of Health-Related Quality-of-Life (HRQoL). In extra-welfarist economics, these measurements can be combined to derive standard economic indicators such as Quality-Adjusted Life Years (QALYs) and Disability-Adjusted Life Years (DALYs). The range of ways in which effectiveness (or utility) can be measured is broad, which is reflected in both the health economic literature and national guidelines (103). These indicators reflect "health" as a multidimensional phenomenon that includes physical, mental, and social dimensions and not simply the absence of disease (104). Therefore, the evidence requirements that apply to patient safety (policy) around the world differ according to national guidelines, which reflect norms and preferences for measuring economic outcomes. Consequently, there is no definitive taxonomy of economic indicators for patient safety because those employed in

economic evaluations in general are applied. This partly explains why financial outcomes are often reported in global literature on the economics of patient safety; cost-based indicators are easier to interpret, and can be compared across regions, care settings, AEs, and other diseases.

Recent evidence on the burden of patient safety indicates that adverse events are the 14th leading cause of DALYs worldwide and that this burden falls disproportionately on low and lower-middle income countries (105). In high-income settings, the AE rate is between 3.7% and 16.6% (106,107) with between 27.6% and 72.5% of errors being preventable (106,108). In England, Vincent et al. (2001) (109) estimated that 10.8% of all hospital admissions lead to an AE, half of which are considered preventable, and this endures as the primary estimate of harm in the NHS (4). An alternative estimate of the economic burden of harm in the English NHS was discussed in the previous chapter, where research by Hauck et al. (2017) (23) estimated that Healthy-Life Year (HLY) losses from six common and preventable AEs amounted to 36,000 HLYs per annum, which is equivalent to the HLYs lost to multiple sclerosis.

Current state of knowledge

Systematic literature reviews lie at the top of the hierarchy of evidence when performed well (110). In 2012, Etchells et al. (111) and de Rezende et al. (112) conducted peer-reviewed literature reviews on the economics of patient safety; the former was a systematic review with a quality appraisal using validated instruments, whereas the latter was a narrative review. The reviews were published as complementary investigations by BMJ Quality & Safety and were the first global reviews of their kind. Their findings provided policymakers with quality appraised evidence and recommendations on cost-effective solutions in patient safety at various willingness to pay thresholds. In the same year, Mittman et al. (2012) (113) performed a systematic review on the economic burden of patient safety targets in acute care. Although cost-effectiveness analyses were reviewed, the aim of this research was to determine the quality of literature in costing the economic burden of patient safety targets. Therefore, this article was restricted to economic burden studies and did not include quality appraisals of full economic evaluations.

Etchells et al. identified five high-quality studies containing seven comparisons of patient safety interventions in acute care. Cost-effective interventions included a care bundle of drug administration error reduction versus standard of care (114), chlorhexidine gluconate replaced by povidone-iodine for catheter-site care (115), the Keystone ICU bundle intervention versus standard of care (116), and standard surgical sponge counts or bar-coded sponges for use in surgery versus no strategy (117). The use of erythropoietin to reduce transfusion-related AEs

in critically ill patients was not considered cost-effective because of the high incremental costs involved, even though the economic evaluation was deemed to be of high quality (118).

Using a different search strategy, de Rezende et al. identified three types of economic analysis incorporating policy-relevant information that was not restricted to the acute care sector. The authors categorised studies as either an assessment of economic burden, cost analysis of patient safety practices, or a full economic evaluation. Five high-quality economic evaluations were identified, and their methods and findings summarised. One was an infection control initiative in the UK, which suggested that a deep cleaning programme was not cost-effective (119); the second compared drug-related AE safety practices and reported a slightly negative to high net benefit depending on the practice used (120); the third implemented a strategy to reduce the impact of a nosocomial pertussis epidemic by vaccinating healthcare workers, which was found to yield significant cost savings (121); in the Netherlands, a “search and destroy” policy to reduce nosocomial Methicillin-Resistant *Streptococcus Aureus* (MRSA) in a healthcare organisation was found to be cost-saving (122); finally, the introduction of electronic medical records in primary care as a strategy for reducing prescription errors was also found to be cost-saving, albeit with the risk of generating net costs (123). Together, these two reviews represent the most authoritative scientific output on the economics of patient safety for use by policymakers. However, the patient safety outcomes addressed by the literature are limited to nosocomial infections, drug-related adverse events, transfusion-related injury, and retained-foreign objects.

The paucity of AEs for which cost-effective interventions can be recommended contrasts with the plethora of literature on the clinical effectiveness of patient safety interventions. In addition, the lack of broad economic evidence on safety interventions is a risk to efficient resource allocation at a time of resource constraints (124). Economic research to help improve decision making is, therefore, essential. Solutions in patient safety are attractive to health systems; according to the Lord Darzi Review of Health and Care by the Institute for Public Policy Research (124), which used historical trends to estimate the difference between expected demand for care and consequent NHS expenditure (growth) and anticipated NHS funding, the annual cost of harm amounts to ten per cent of the NHS’s anticipated efficiency shortfall by 2030. Nevertheless, according to Meltzer (2012) (18), whose editorial accompanied the findings by Etchells et al. (2012) (111) and de Rezende et al. (2012) (112), the development of economic evidence on patient safety appears to have been neglected between 2000 and 2011. Only four patient safety strategies were recommended by Etchells et al. based on their cost-

effectiveness, although it is important to note that the authors restricted the scope of their search to 15 safety-related outcomes and six patient safety strategies. De Rezende et al. identified three out of 18 burden studies, three out of three intervention cost studies, and five out of 12 full economic evaluations that were of high quality. Together, these papers provide peer-reviewed evidence that can be incorporated into the resource allocation decisions of policymakers. In total, the evidence provided nine solutions for five target AEs: one for hospital-acquired infection, three for medication errors, and one for retained foreign objects.

Since 2012, two prominent literature reviews on the economics of patient safety, encompassing cost-effectiveness analyses, were published; one by Zsifkovits et al. in 2016 (125) and the other by Slawomirski, Auraen and Klazinga in 2017 (8) on behalf of the European Commission and the OECD, respectively. Both reviews cited the studies by Etchells et al. and Rezende et al. as they were contemporary, but neither report replicated the formal quality appraisal by Etchells et al., which included an assessment of both clinical evidence and full economic evaluations.

In the report by Slawomirski, Auraen and Klazinga (2017), literature on the economics of patient safety was synthesised unsystematically and novel evidence was generated using a nominal group technique to generate expert consensus on value-based investments in patient safety. The survey was administered to a sample of 25 international experts in patient safety who scored 42 interventions based on their perceived cost and impact. The highest averaged impact rating was attributed to “Digital technology solutions for safety” which, alongside “Electronic Health Record (EHR) systems”, was also awarded the highest averaged cost rating by the participants. Value was expressed as an impact/cost ratio for each of the 42 interventions, resulting in “Venous Thromboembolism (VTE) prevention protocols” as the highest value intervention. The survey provides novel findings related to the economics of patient safety, but the core limitation of this exercise is that the measurement of value does not conform to the frameworks and guidelines used for value-based decision making in developed health systems.

The report by Zsifkovits et al. (2016) included a systematic review on the costs of unsafe care and cost-effectiveness of interventions. However, importantly for this chapter, it did not appraise the quality of economic evaluations using a validated instrument, such as that employed by Etchells et al. (2012). The authors utilised a Delphi process that involved asking 15 expert participants to derive a list of all relevant AEs for their systematic searches, but noted that this panel had limited knowledge of AEs at the aggregate level, namely their knowledge was largely specific to one or a few AEs. Recommendations were drawn from the evidence

generated by the literature review in what is best described as a deliberative fashion. The report is expansive and advocates the use of relative cost-utility as the ideal measure for value-based investment decisions, which is consistent with decision making processes in several European states. Moreover, the authors state that the quality of economic evaluations is too low to apply these principles to decision making. Moreover, the quality appraisals were not presented at the level of each study and, as mentioned before, a formal appraisal of economic evaluations was not provided.

The extent to which the scope and quality of evidence has changed since 2011, when it was assessed systematically using validated quality appraisal tools, now constitutes a gap in knowledge. Moreover, given the acceleration of healthcare digitisation since previous studies were conducted and in light of the survey findings reported by Slawomirski, Aaraen and Klazinga (2017) (8), the scope of methods and findings relating to the cost-effectiveness of information systems and digital interventions for patient safety now represent another gap that needs to be addressed.

Relationship between patient safety and information

The economics of information management systems used in patient safety has become increasingly important for the digitisation of health systems. Pharmaceutical and medical device interventions have been subject to regulatory approval and compliance for several decades, which has had a significant impact on the procurement of these technologies, nuanced by the policies of each market. However, relatively little work has been undertaken to transpose these frameworks in order to appraise the safety and effectiveness of information technologies. This should be of concern to policymakers given the resources that continue to be allocated to digital transformation. Thus far, de Rezende et al.'s appraisal of an article on the impact of electronic medical records in primary care (123) is the only economic study to be systematically identified and appraised in the context of information systems and patient safety.

As discussed previously, evidence on the economics of patient safety draws on a plethora of indicators. Nonetheless, there are few explicit recommendations as to which economic indicators should be used in the context of patient safety, other than those referred to in general by Zsifkovits et al. (2016). (125). In another study that was conducted prior to this thesis, a framework of economic benefits which embodies the relationship between patient safety and information was developed to capture economic outcomes from the NRLS (81). This framework is presented in Figure 2.1 and illustrates the breadth of economic benefits that can be provided by the NRLS and, by extension, incident reporting systems. Changes to care

practices in the form of pathway or process improvements and/or the use of safer drugs and devices translate directly into better patient outcomes measured, usually, by fewer AEs. Fewer AEs are a positive patient or clinical outcome that precedes economic outcomes, such as cost savings or more cost-effective practices. However, this is just one dimension of the potential economic benefits derived from incident reporting systems and, indeed, other patient safety interventions. According to this framework, other economic benefits could manifest through culture change, which might lead to quality improvement beyond patient safety alone. These include benchmarking and monitoring harm, which leads to the development of standards against which progress can be monitored over time; improved risk assessment capabilities that improve prioritisation capabilities, which is essential in resource constrained systems; and peer regard, which refers to reputational gain, internationally and regionally, that attracts investment into a health system. The dimensions of economic benefits described by the framework implicitly involve improved patient outcomes, because economic value is determined, initially at least, by reductions in harm to patients. Nevertheless, the extent to which economic benefits have been measured empirically across all dimensions is unclear, although previous reviews suggest that evidence on the economic impact of direct care practice improvements only exist in the patient safety context (8,112,113,125,126). This means that the economic benefits of investing in information systems for patient safety may be underestimated for the simple reason that broad benefits have not been measured empirically.

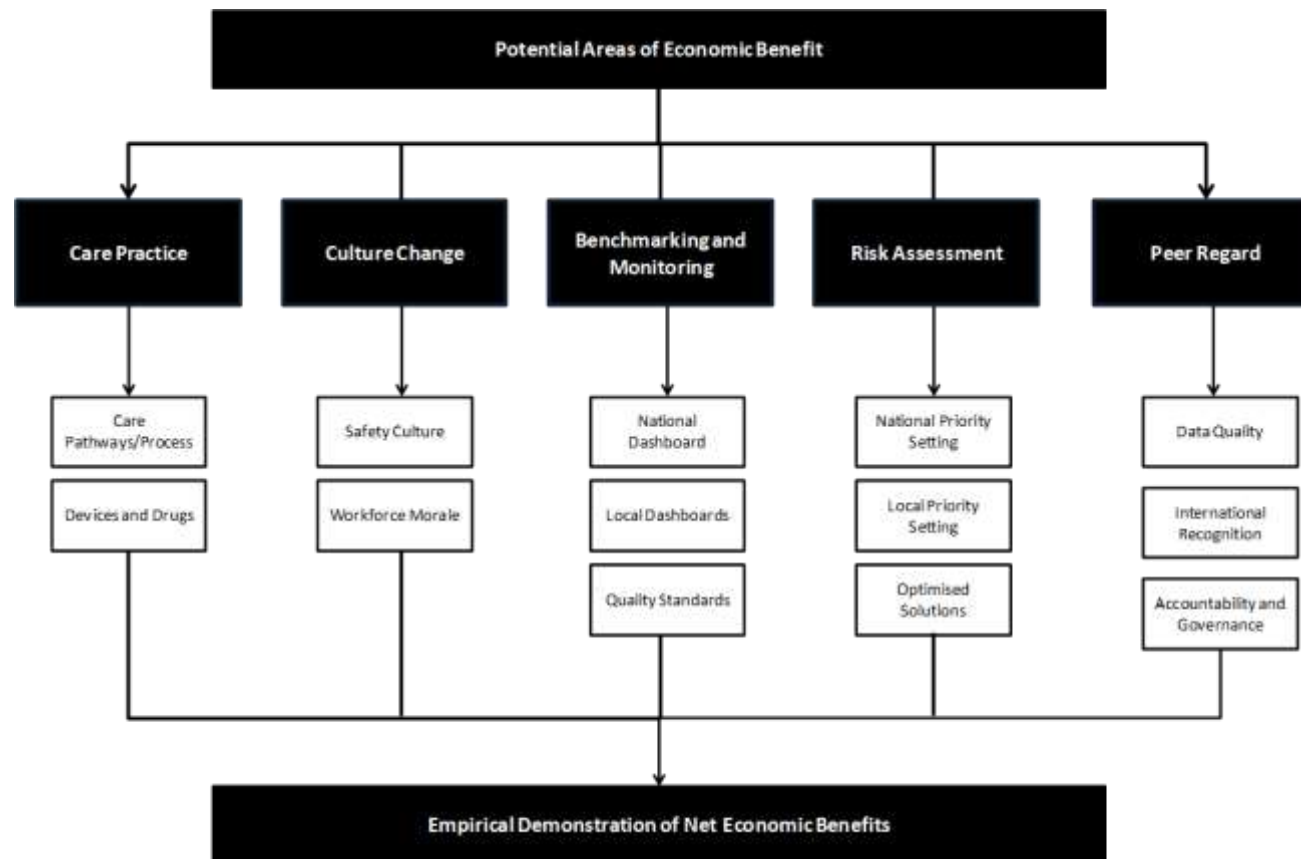


Figure 2.1. Framework of economic benefits derived from the NRLS, developed by Carter in 2013 in conjunction with incident reporting experts. “Care Practice” refers to evidence of clinical benefits derived from information contained in NRLS feedback reports; “Culture change” refers to benefits of improved organisational safety culture; “Benchmarking and Monitoring” refers to the benefits of sharing organisation-level performance; “Risk assessment” is a benefit of information that facilitates prioritisation of effort and resources; “Peer Regard” encompasses the behavioural incentive for NHS organisations to collect high quality information and be seen as accountable. It also encompasses the indirect benefits of being international leaders in safety improvement methods.

Aim

Consistent with the protocol published by Carter et al. (2017) (127) (PROSPERO: CRD42017057853), this study aimed to assess the methodological quality of evidence on the economics of patient safety and to compare the scope of available evidence with findings from previous reviews.

Methods

To ensure a novel contribution is provided by this systematic review, reference lists of the reports by Zsifkovits et al.(125) and Slawomirski, Auraaen and Klazinga (8) were scrutinised. Similarly, articles that cite these reports and those by Etchells et al.(111) and de Rezende et al.(112) were also reviewed. This research followed the guidelines in the Cochrane Handbook for Systematic Reviews of Interventions (128) for the conduct of systematic reviews and meta-analyses. The results are reported using the Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) guidelines (129). First, a search strategy was developed to determine the scope and quality of literature on the economics of patient safety. This strategy was designed to address the limitations of the designs employed by Etchells et al. and de Rezende et al., and to enhance the reproducibility of the method used to search for literature. The methods employed for this study have been described in previous works (127).

The two themes for the search were “economics” and “patient safety”. Terms were derived to capture all permutations of these themes, using previous reviews conducted on the topic and expanding on relevant Medical Subject Headings (MeSH) terms. The patient safety terms are presented in Table 2.1. Emulating Etchells et al. (2012), Medline, Econlit, and the NHS Economic Evaluation Database (EED) were searched using patient safety MeSH terms and the economic evidence search strategy specified by Neyt and Chalon (130) for work published from January 2007 to August 2018. Econlit and the NHS EED were searched using modified MeSH terms.

Patient safety themes	
MEDLINE & NHS EED	Econlit
patient harm/ or patient safety/ or safety management/ or accidental falls/ or accident prevention/ or infection control/ or antisepsis/ or asepsis/ or blood safety/ or sterilisation/ or disinfection/ or sanitation/ or decontamination/ or medical errors/ or diagnostic errors/ or medication errors/ or inappropriate prescribing/ or medication reconciliation/ or near miss, healthcare/ or	(patient harm) or (patient safety) or (safety management) or (accidental falls) or (accident prevention) or (infection control) or antisepsis or asepsis or (blood safety) or sterilisation or disinfection or sanitation or decontamination or (medical errors) or (diagnostic errors) or (medication errors) or (inappropriate prescribing) or (medication reconciliation) or

venous thromboembolism/ or pulmonary embolism/ or pressure ulcer/	(near miss) or (venous thromboembolism) or (pulmonary embolism) or (pressure ulcer)

Table 2.1. Summary of patient safety terms used to search each database in combination with Neyt and Chalon’s (130) procedure for searching MEDLINE. A similar procedure and economic terms were not required for searches of Econlit and NHS EED.

The primary outcomes were clinical and economic endpoints in patient safety research expressed as net monetary benefit, net health benefit, incremental cost-effectiveness, or economic costs. Only AE-related outcomes were extracted from articles; primary outcomes were therefore disregarded unless they related to patient safety.

Inclusion criteria

Studies including individuals of any age or gender, all index admissions, and all health system settings where patients were at risk of experiencing safety-related AEs were identified. Specific interventions were not chosen because the aim was to ascertain the scope of interventions studied in the literature. Interventions refer to any care process designed reduce the incidence of safety-related AEs. All forms of comparative analyses were considered, including standard(s) of care, medical and surgical procedures, drugs, devices, and policies administered separately and/or as treatment bundles.

Exclusion criteria

Systematic reviews, book chapters, conference abstracts, grey literature, unpublished studies, protocols and methodology papers, non-English language articles, and opinion pieces (letters, editorials, and commentaries) were excluded. Studies that did not report economic data or address a patient-level or patient safety outcome were also excluded, as were investigations of falls, health security interventions (sanitation, infectious disease control) and other clinical conditions existing outside a provider setting or which pertained to public health. The following keywords: harm, avoidable, preventable, iatrogenic, nosocomial, patient safety, safety, and in-hospital were searched in full text articles investigating falls in order to ascertain whether these were studied in the context of public health or within healthcare provider settings.

Studies that modelled outcomes using hypothetical cohorts rather than an observed population were excluded. Economic analyses of policy reforms and coverage decisions were excluded unless they referred to policies explicitly targeting patient safety improvement. Studies on physician decision making that related to patient safety but did not include patient level outcomes were also excluded.

Search strategy and data extraction

The results of the search were deduplicated using an Endnote™ procedure (131) and the remaining duplicates were manually removed. This sample was then evenly distributed for independent screening by an academic clinician and an academic economist (the author) using title and abstract entries. The author reviewed all exclusions before proceeding to full text analysis.

To derive a dataset, background information including the year and key information about the study, such as population, intervention(s), outcome(s) of interest, and study design(s) for clinical and economic outcomes, were extracted from the eligible papers identified after screening. The country of origin was also extracted and matched to World Bank income status. With reference to the previous reviews by Etchells et al. and de Rezende et al., the sensitivity of the search strategy was assessed as the proportion of eligible papers (published after 2006) that were retrieved using our search strategy.

For the purpose of comparison, eligible interventional studies were categorised using OECD definitions for the following levels at which interventions were administered: system level interventions (strategies, programmes, and initiatives that are best approached and implemented across an entire system, typically requiring legislative or high-level policy levers); organisation level interventions (programmes, initiatives, or practices that, while often aimed at particular clinical areas or patient types, should be implemented across entire healthcare organisations or institutions); and clinical level interventions (practices that may span organisations but are optimally initiated at practice level and managed within the clinical microsystem with patients and their surrogates, and administrative staff working with practitioners and patients) (8). Interventions were categorised by type: drug, device, national guideline, behavioural, diagnostic or treatment protocol, informatics (information + communication technologies), education or training, surgical technique, bundles (for multiple errors), non-specific interventions, staff-oriented process change(s), and medical equipment (not implantable or wearable devices). The target AE was categorised using definitions provided by the Agency for Healthcare Research and Quality (AHRQ) (132) and previous reviews (111,112). Intervention definitions were aligned to those given in the report by Slawomirski, Auraen and Klazinga (8). The type of economic analysis reported was in line with de Rezende et al.'s definitions (112), with the addition of ROI analyses and legal costs as categories. The ROI category was assigned to articles using the Centers for Disease Control definition (133), which distinguishes ROI analyses from cost-benefit analyses (cba) based on

perspective: for instance, ROI analyses do not explicitly adopt a societal perspective, whereas cba do. If reported, the funding source of studies was extracted.

To account for changes in the number of articles published between the two unequal periods (2007 to 2011 (period one) = 60 months and 2012 to 2018 (period two) = 80 months), the average output per year was calculated. The normalised differences in output were then used to calculate output changes by dividing the normalised output for period two by that of period one.

Quality assessment

The quality of evidence on the economics of patient safety was estimated by first applying the hierarchy of evidence to the scope dataset. Randomised controlled trials (RCTs) were considered the highest-quality evidence (134) and the internal validity of these was assessed using the revised Cochrane risk of bias assessment tool (RoB 2.0, version 2016, available at www.riskofbias.info)(135). Cluster RCTs were assessed using the cluster extension questions provided by Cochrane (136). The two reviewers independently assessed risk of bias in all RCTs that included full economic evaluations. As recommended, outcomes from intention-to-treat analyses were assessed to reduce bias in our interpretation of superiority (rather than noninferiority) trials (137). Disagreements between the assessors were identified and recorded using the discrepancy analysis feature. These were resolved through discussion. For economic evaluations that were informed by more than one trial, the overall risk of bias was deemed either to be low, raises some concerns, or high.

Details on the perspective, time horizon, decision model, costs, quality of life indices, and incremental analysis, as well as the approach to the sensitivity analyses and their results, were documented. Economic evaluations informed by low risk of bias clinical data were independently assessed by two academic economists (led by the author) using the 35-item Drummond checklist (138). The quality of economic evaluations was given as a score out of 35. If scores were within five points, then the higher of the two scores was taken. Discrepancies of five or more points between assessments were discussed and resolved by the reviewers. The Drummond checklist was selected as the quality appraisal instrument because it had been employed in the previous review by Etchells et al. and was therefore considered a better tool for comparing findings; however, this represents a trade-off from not using the contemporary CHEERS statement (139), which was published after the Etchells et al. review and has stronger expert support for its use than the Drummond checklist.

The Drummond checklist is used to determine the presence or absence of a reporting parameter and includes “not clear” and “not applicable” criteria. For instance, models with one-year time horizons do not (usually) need to apply discounting; therefore, the reporting parameter would be marked as “not applicable”. A total of 35 “yes” ratings indicate that a study contains all the items that constitute a good economic evaluation. The final score for each economic evaluation was the average of the scores of the individual assessors; studies that scored lower than 20 out of 35 were then excluded from the final synthesis.

Statistical and comparative analysis

The annual output of evidence, organised by clinical and economic categories, was compared visually pre- and post-2012. The quality of evidence from 2000 to 2018 could not be compared directly using a statistical method because different quality appraisal instruments were employed by Etchells et al.; therefore, descriptive comparisons were made. Cohen’s kappa statistic (140) and Landis and Koch’s (1977) agreement thresholds (141) were applied to assess inter-rater reliability for the independent ratings (round one) of risk of bias and the Drummond assessment (138), and the ratings given after discussion (round two). For risk of bias, agreement was assessed at the level of each of the five domains. For the Drummond assessment, agreement was determined using assessor ratings for each of the 35 items.

A meta-analysis was then performed to investigate and visualise the overall clinical effect of patient safety interventions using STATA/SE 15. Following convention (142), between-study heterogeneity was tested using the I-squared index and a value above 25% was taken as evidence of heterogeneity. A random effect meta-analysis was then conducted, and the results presented as Forest plots, using risk ratios for effect sizes. We did not calculate time-to-event outcomes because high heterogeneity between studies was observed. Therefore, instead of deriving a pooled estimate of effect sizes, a Forest plot was used to visualise individual intervention effects.

For economic literature, the “economics” terms were replaced by a peer-reviewed method for searching MEDLINE which was published by Neyt and Chalon (2013) (130). The “patient safety” MeSH terms were combined with the search output using “AND” for Boolean combinations. Because Econlit is configured to search for economic literature, this database was searched using “patient safety” MeSH terms only. The same approach was adopted to search for relevant literature in NHS EED. The search period selected was from January 2007 to August 2018. The partial overlap with previous systematic reviews, which is described here as the first period, allowed for cross-checking of the search strategy against previously

identified studies and therefore supported a comparative analysis of literature in the second time period. English language-only publications, peer-reviewed papers, and original articles were included. Conversely, reviews, book chapters, opinion pieces, letters, editorials, commentaries, conference abstracts, guidelines, case reports, and study protocols were excluded.

The population of interest was citizens at risk of harm or citizens exposed to actual harm. The population was defined in accordance with the “patient safety” theme, which included all regions of the world. Except for literature reviews, the population was not restricted to predetermined patient safety incidents, interventions, comparators, or study designs.

Findings

The search strategy retrieved 75% of all the articles captured by previous reviews. Specifically, compared to Etchells et al. (2012) (111) and de Rezende et al. (2012) (112), 3/3 (100%) and 7/12 (58%) of eligible papers were captured in the overlapping search period.

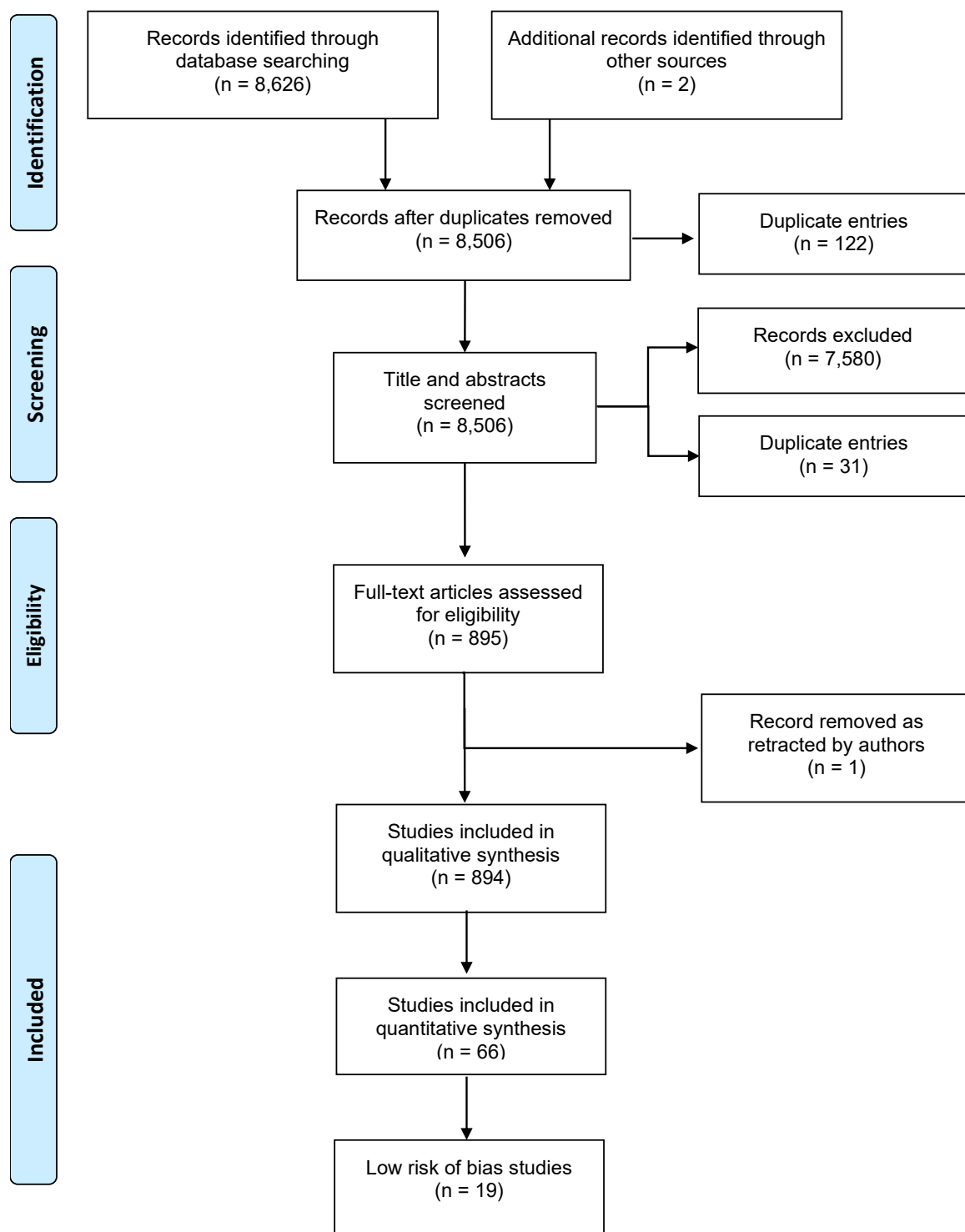


Figure 2.2. PRISMA diagram describing the search strategy and results. 894 articles were included in the scope assessment and 66 articles were included for the risk of bias appraisal and quantitative synthesis. After accounting for articles that included multiple randomised controlled trials, risk of bias was appraised for 76 studies.

As indicated by the PRISMA diagram in Figure 2.2 (129), 8,626 papers were retrieved using the search algorithm and, following de-duplication, 8,506 titles and abstracts were screened. A total of 7,581 papers were excluded because they did not include patient-level (clinical) data, did not measure a patient safety-related outcome (for instance, they focused on health security policy and not patient safety), did not measure economic (cost or utility) outcomes, or the patient safety outcome studied could not be considered iatrogenic as the study was performed in a non-provider setting. One paper was removed because it was retracted by the authors in 2016. This left 894 full text articles that were eligible for the scope analysis.

Assessment of scope

A total of 40 patient safety outcomes from 58 countries were identified. Overall, 827 (93%) articles derived from high-or upper-middle income countries. Of the 894 eligible articles, 86 were RCTs containing some form of economic analysis, of which 66 included a full economic evaluation. As shown in Figure 2.3, research output increased from a normalised output of 51 studies per year (period one) to 95 studies per year (period two), an increase of 1.9x (637 versus 257 articles). Of these, research on seven AEs with the biggest increase in output accounted for 80% of the total volume of evidence. Although the normalised output of articles on surgical error, blood safety, misadventure, and central-line associated bloodstream infections grew markedly, these four AEs accounted for only 6% of the total volume of evidence.

Figure 2.4 presents the output for the economic analyses of interest; these were economic burden studies, complete economic evaluations, cost analyses, ROI studies, and studies on legal costs associated with patient safety targets. Research output on cost analyses in relation to patient safety increased by a 2.5x from 2007 to 2011(189 papers versus 57 papers), followed by ROI studies (2.2x, 34 versus 13), legal cost studies (2.0x, 103 versus 41), complete economic evaluations (1.6x, 123 versus 58), and economic burden studies (1.6x, 183 versus 87).

The proportion of RCTs grew from 6% to 11% between periods one and two, indicating a shift towards higher quality designs over the last decade. Most of this growth appears to be driven by industry sponsorship of patient safety investigations (see Appendix B.1). However, the proportion of all interventional studies that were performed at a clinical level increased from 50% to 63% between period one and period two. Only a slight growth in system-level evidence was observed (7.6% to 7.8%).

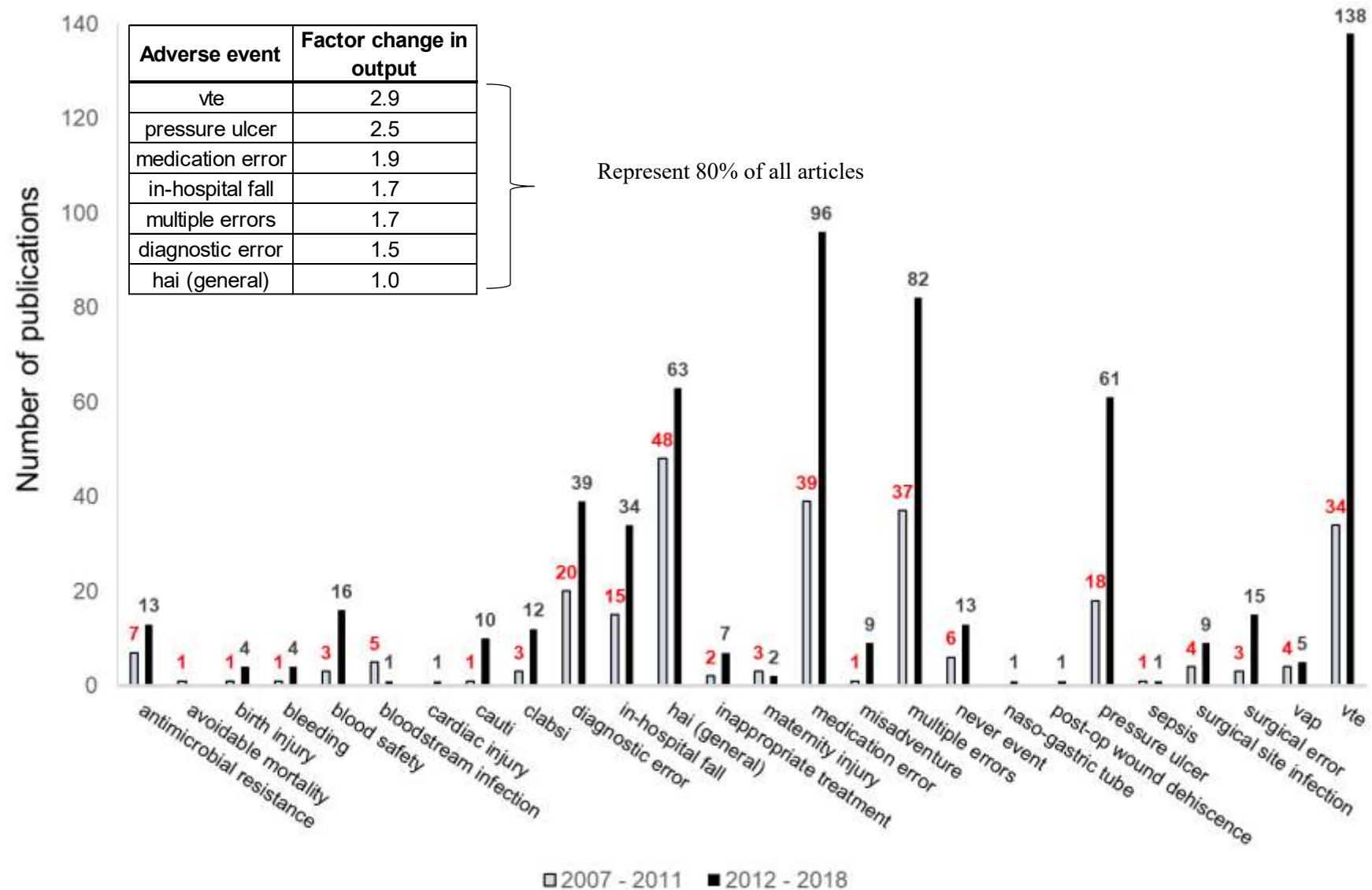


Figure 2.3. Output of all economic analyses of patient safety between 2007 and 2011 (grey bars) and 2012 and 2018 (black bars) by AE. The breadth of AEs retrieved illustrates the scope of the available literature. This demonstrates that effort has been concentrated on seven AEs, which account for 80% of all articles produced. As shown, based on average annual output, VTE articles have increased more than any other target AE (3.0x).

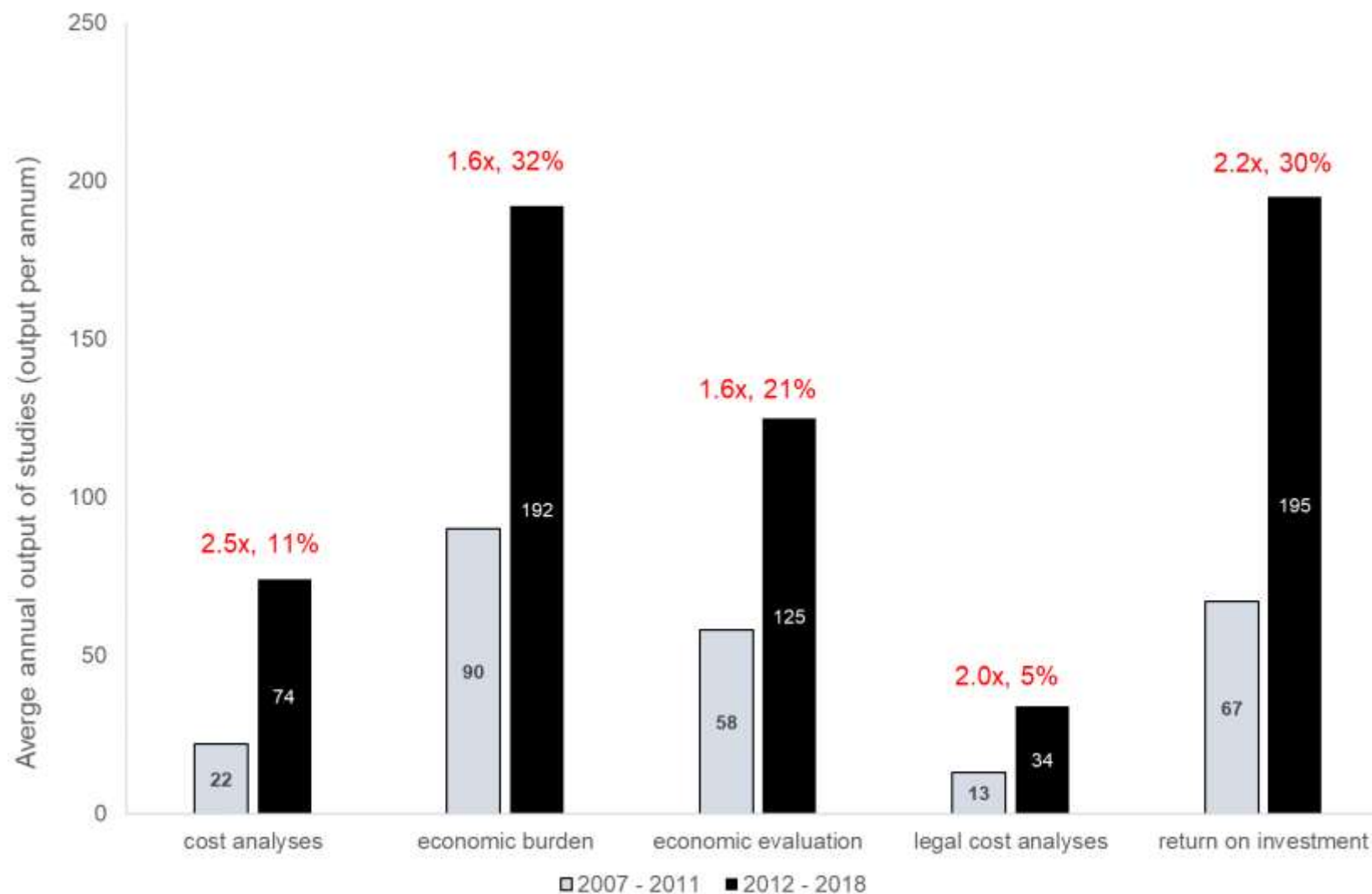


Figure 2.4. Growth in the annualised output of the five main types of economic analysis used to study patient safety between 2007 to 2011 and 2012 to 2018. Based on average annual output, cost analyses of interventions have increased more than the other forms of analysis (2.5x), whereas the output of economic burden and economic evaluation studies has increased least (1.6x). The volume of high-quality economic evaluations in patient safety is low and, of those studies identified, the majority (80%) target only seven AEs. This limits the breadth of investment recommendations that can be made with a strong evidence base.

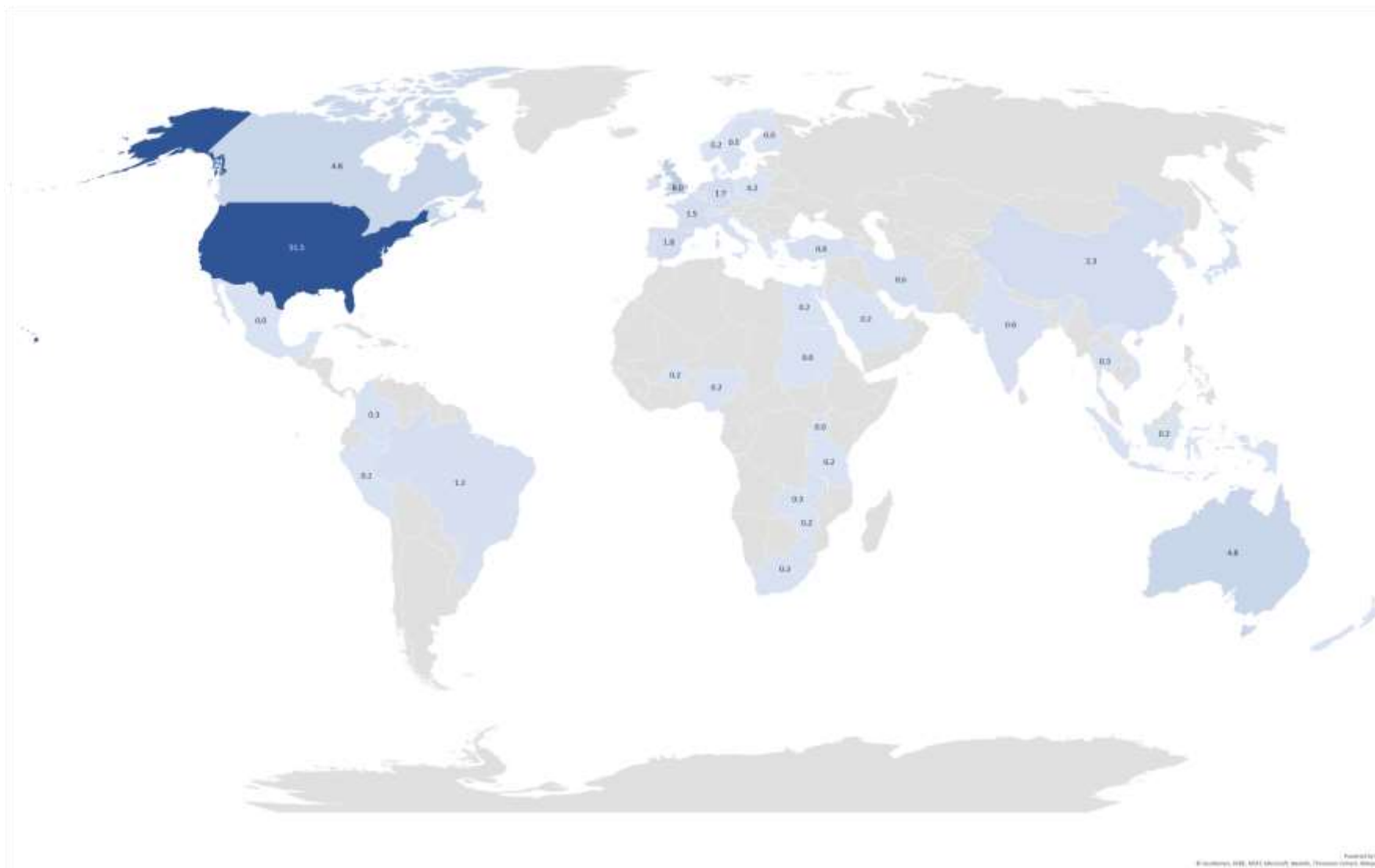


Figure 2.6. Geographical heat map of the normalised annual output of articles on the economics of patient safety from 2012 to 2018. The United States of America dominated output during this period (dark blue shading), followed by the United Kingdom and Australia. Growth in this period compared with that of 2007 to 2011 was highest in China (11.25x), followed by Germany (8.25x). This graphic excludes multi-national studies.

Table 2.2. Interventional studies organised by system level and publication period.			
Study level, interventional research	2007 - 2011	2012 - 2018	Grand Total
Clinical	50.31%	62.76%	59.39%
Organisational	42.14%	29.27%	32.76%
System	7.55%	7.96%	7.85%

The smallest amount of interventional evidence originated from the system level (7.9%), followed by the organisational level (33%). Clinical level interventional studies on the economics of patient safety dominate the scope of the literature (59.4%) for both periods.

Quality assessment

A total of 76 RCTs were appraised for risk of bias as several economic evaluations included multiple studies in their analyses. The overall risk of bias in these trials was low for 21 studies, with some concerns for 30 studies, and high for 25 studies. The root cause of a high risk of bias assessment (Figures 2.7, 2.8.1 and 2.8.2), by domain and in descending rank order, was “Measurement of the outcome” and the “Randomisation process”(equal) followed by “Missing outcome data”, “Deviations from intended intervention”, and “Selection of reported result”. A total of 13 cluster RCTs were identified and, from the cluster-specific questions, one article was found to be at high risk of bias and two had some concerns.

After the first independent review of all trials, the Cohen’s kappa statistic was 0.86 (indicating near perfect agreement), with the largest discrepancy between reviewers evident in the “Missing outcome data” domain (kappa = 0.75, substantial agreement). Following discussion, a kappa statistic of 0.9 (near perfect agreement) was obtained. After the first independent review using the Drummond checklist, the Cohen’s kappa statistic was 0.44 (SD ± 0.19) which indicates moderate agreement. Following discussion of the aggregate scores (out of 35), a kappa of 0.46 (SD ± 0.21) was obtained.

Of the 76 RCTs, 19 were considered to have a low risk of bias and these corresponded to 17 articles with full economic evaluations. All 17 eligible articles (Table 2.3) provided high quality economic evaluations between 2007 and 2018; only one study was from period one (143). Overall, 11 of these articles studied the effect of an intervention on VTE, whereas the remaining six articles each targeted one of six different AEs, namely pressure ulcers, falls, medication errors, nutrition and hydration support, diagnostic error (missed diagnosis), and hospital-acquired infection. The mean methodological score for these articles was 25 (SD ± 3). These articles contained 25 comparisons, 12 of which related to VTE outcomes. Of these, 11

articles were drug interventions and one was a computed tomography protocol. The remaining articles were a care bundle, a digital technology solution, a patient education solution, and three care protocols.

Authors	Origin	Funding source	Target AE	Provider setting	Intervention	OECD intervention category	Result	Certainty (comment)	CHEERS score
Amin et al. 2014 (144)	USA	Private	VTE(145–150)	acute medical	drug	VTE prevention protocols	+	66.7% to 100% (net benefit)	23
Amin et al. 2015 (151)	USA	Private	VTE(145–150)	acute medical	drug	VTE prevention protocols	+	100% (net benefit)	23
Browne et al. 2017 (152)	USA/UK	Private	VTE(145)	acute medical	drug	VTE prevention protocols	+	-	28
Coyle et al. 2017 (153)	CA	Public	Diagnostic error(153)	hospital - radiology	protocol	Clinical care standards	-	21.6% to 28.3% (wtp, \$30,000 to \$50,000)	25
de Jong et al. 2017 (154)	NL	Private	VTE(145)	hospital - ward	drug	VTE prevention protocols	+	100% (wtp, €20,000/QALY)	31
Dijkman et al. 2012 (155)	NL	No statement	HAI(155)	surgery - general surgery	protocol	Peri-operative medication protocols	+	91.5% (net benefit)	27
Elias et al. 2016 (156)	UK	Private	VTE(145,157)	acute medical	drug	VTE prevention protocols	+	89% (probabilistic ICER)	30
Elliott et al. 2014 (158)	UK	Public	Medication error(159)	general practice	informatics	Digital technology solutions for safety	+	59% (wtp, £20,000/QALY)	29
Fowler et al. 2014 (160)	USA	Public	VTE(161)	critical care	drug	VTE prevention protocols	+	78% (net benefit)	25
Haines et al. 2013 (162)	AUS	No statement	Falls(163)	hospital - ward	patient education	Fall prevention programme	±	52% (ICER)	27
Kilonzo et al. 2007 (143)	UK	Private	Patient hydration and nutrition standards(164)	general practice	protocol	Patient hydration and nutrition standards	-	1% (net benefit)	27
Lanitis et al. 2017 (152)	UK	Private	VTE(145,157)	acute medical	drug	VTE prevention protocols	+	94% (wtp, £20,000/QALY)	31
Pineo et al. 2011 (165)	USA	Private	VTE(166)	acute medical	drug	VTE prevention protocols	+	100% (net benefit)	24

Pineo et al. 2012 (167)	USA	Private	VTE(166)	acute medical	drug	VTE prevention protocols	+	>50% (net benefit)	25
Preblich et al. 2015 (168)	USA	Private	VTE(148)	acute medical	drug	VTE prevention protocols	+	67% (wtp, \$50,000/QALY)	28
Revankar et al. 2013 (169)	CA	Private	VTE(170–172)	surgery - orthopaedic	drug	VTE prevention protocols	+	74% to 91% (wtp, \$50,000/QALY)	29
Whitty et al. 2017 (173)	AUS	Public	Pressure Ulcer(174)	hospital - ward	bundle	Pressure injury (ulcer) prevention protocols	±	55% (wtp, A\$3,786 per HAPU)	29

Table 2.3. Summary of RCTs with full economic evaluations deemed at low risk of bias using the Cochrane risk of bias tool. Overall, 17 of these studies also include high quality economic evaluations (scoring >20 out of 35 when appraised using the Drummond checklist). The number of studies deemed high quality in our study is higher than that given by Etchells et al. (2012). This is because our search was not restricted to specific AEs and the overall output of evidence on the economics of patient safety has expanded since previous reviews.

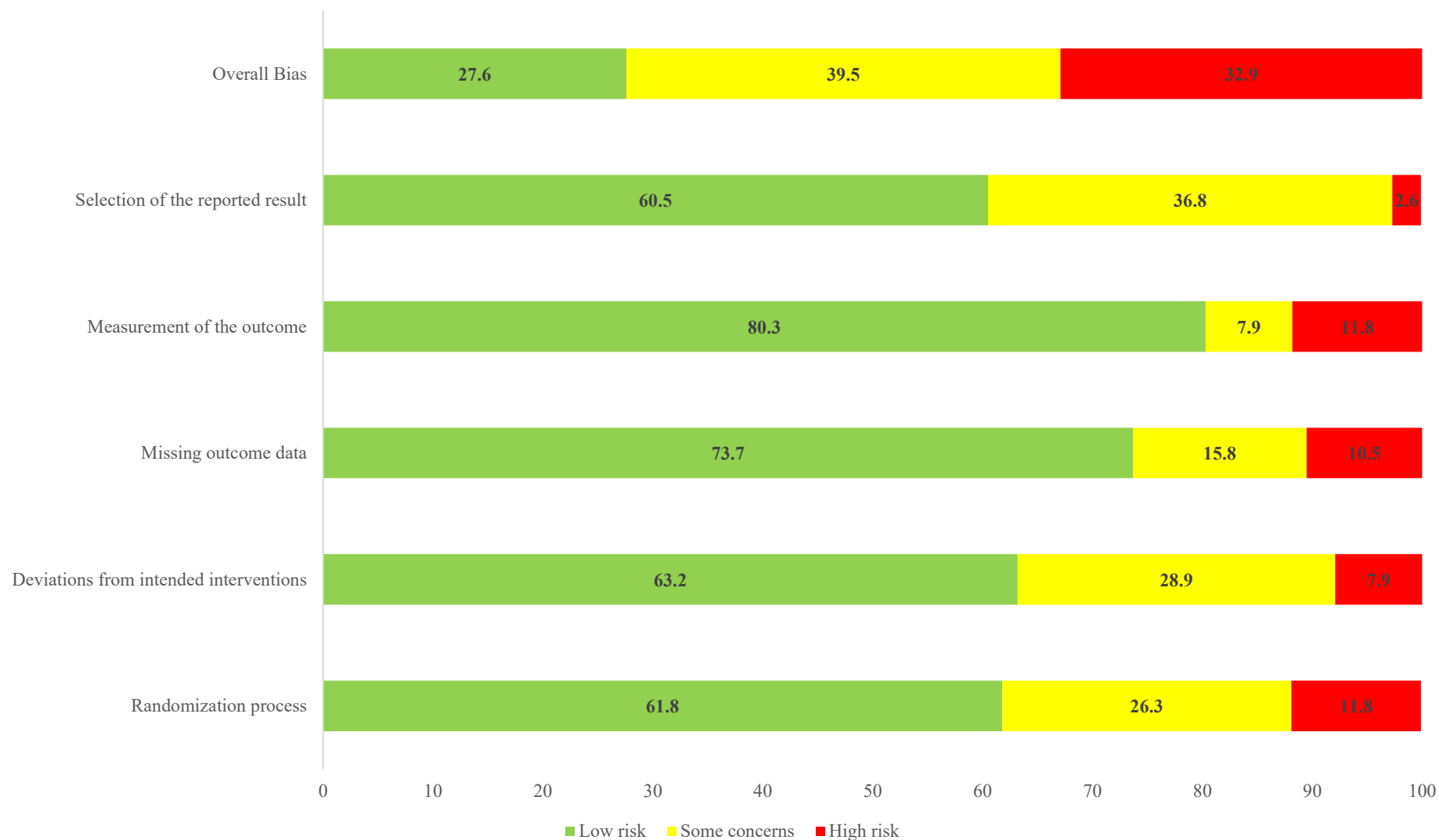


Figure 2.7. Summary by domain of the risk of bias for intent-to-treat outcomes from RCTs informing economic evaluations of patient safety. The figures given in bold are the percentage(s) of all trials that were assessed as low risk, some concerns, and high risk by domain. “Randomisation process” and “Measurement of the outcome” were the domains most frequently awarded a high-risk assessment

Authors	Outcome	Randomisation process	Deviations from intended interventions	Missing outcome data	Measurement of the outcome	Selection of the reported result	Overall Bias
Agnelli et al 2013 (AMPLIFY)	VTE	+	+	+	+	+	+
Carrier et al 2015	Cancer screening and missed diagnosis	+	+	+	+	+	+
Cereda et al. 2015	Pressure ulcer area	+	+	-	+	+	-
Dennis et al. 2013 (CLOTS 3)	VTE	+	?	+	+	+	!
Colwell et al. 2010	VTE	-	?	+	+	?	-
Dwivedi et al. 2016	Dimensions of pressure ulcer	-	?	?	+	+	!
EINSTEIN-DVT	Recurrent VTE	?	+	+	+	+	+
EINSTEIN-VTE	Recurrent VTE	+	+	+	+	+	+
EINSTEIN-PE	Recurrent VTE	+	+	+	+	+	+
Fowler et al. 2014	VTE	+	+	+	+	?	!
Frankenthal et al. 2014	Falls	?	?	?	-	?	-
Gilling et al. 2013	Rate of UTIs	-	+	+	-	?	-
Gundre & Iyer 2012	Wound infection	?	+	+	+	?	!
Hokusai-VTE 2013	Recurrent symptomatic VTE	+	+	+	+	+	+
Kline et al. 2014	Radiation exposure to chest	+	?	+	+	+	!
Konstantinides et al. 2002	30-day mortality, post-randomization	+	+	+	+	+	+
Lee et al. 2003 (CLOT group)	Recurrent symptomatic VTE	?	+	+	+	+	!
Markle-Reid et al. 2006	Functional health status	?	+	+	-	?	-
Markle-Reid et al. 2010	Reported falls at 6-month follow-up	+	?	-	-	+	-
Markle-Reid et al. 2011	HRQoL and functioning	+	?	?	+	?	!
O'hura et al. 2011	Pressure ulcer size	?	-	+	+	?	-
O'Sullivan et al. 2015 (cRCT)	Adverse Drug Reaction	?	?	+	+	+	!
Perez-Parra et al. 2010	<i>Clostridium difficile</i> infection	-	+	?	?	?	!
Pittman et al. 2012	Pressure ulcer staging	+	?	+	?	?	!
Pittman et al. 2012	Incontinence-associated dermatitis	+	?	?	-	?	-
Rantz et al. 2017	Falls	?	?	+	+	?	!
Eriksson et al. 2008 (RECORD1)	Non-fatal VTE or death at 36 days	+	+	+	+	+	+
Kakkar et al. 2008 (RECORD2)	VTE or all-cause mortality at 30-42 days	+	+	+	+	+	+
Lassen et al. 2008 (RECORD 3)	VTE or post-surgery death within 13-17 days	+	+	?	+	+	!
Schulman et al. 2009 (RE-COVER)	VTE and related deaths at 6 months	+	+	+	+	+	+
Schulman et al. 2014 (RE-COVERII)	Objectively confirmed VTE and related deaths	+	?	+	+	+	!
Schulman et al. 2013 (RESONATE)	Recurrent VTE	+	+	+	+	+	+
Roos et al. 2011	Post-operative infectious complications	+	+	+	+	+	+
Logan et al. (2010)	Falls	+	+	+	-	+	-
Sahota et al. 2014 (REFINE)	In-patient bedside falls	?	+	+	+	+	!
Santamaria et al. 2013 (BORDER)	Pressure ulcer	+	+	+	?	+	!

Figure 2.8.1. Individual risk of bias assessments of RCTs (2007 to 2018), part 1, informing economic evaluations. Legend: green = low risk of bias; yellow = some concerns; red = high risk of bias.

Timsit et al. 2009 (Dressing Study)	Major catheter-related infections	?	+	+	+	?	!
Shannon, Browne & Chakravarthy 2012	Pressure ulcer	-	?	+	+	?	-
Sherman et al. 2007	VTE or fatal PE	+	+	+	+	+	+
Souliotis et al. 2016	Healing time of stage III and IV pressure ulcers	+	-	+	+	+	-
Stern et al. 2014 (cRCT)	Pressure ulcer healing time	-	?	-	+	+	-
Rozzelle et al. 2010	Shunt infection within 6 months of procedure	+	?	+	?	?	!
Tang et al. (2017)	Post-operative VTE	+	?	+	+	?	!
Terry et al. 2009	Time to heal pressure ulcer or wound	?	-	+	+	?	-
Milne et al. 2012 (Waycaster & Milne 2013)	Days to epithelialisation of a pressure ulcer	?	+	+	+	?	!
Webster et al. 2007 (DRIP)	Unplanned cannula removal	+	+	+	-	?	-
Chuangsuwanich et al. 2011	Pressure ulcer (grade III-IV)	+	?	+	+	?	!
Haines et al. 2011	In-hospital falls	+	+	+	+	+	+
Irvine et al. 2010	Falls in the community	+	?	-	?	+	-
Avenell et al. 2005	Antibiotic overuse	+	+	+	+	+	+
Pirmohamed et al. 2013	Therapeutic INR range 2.0-3.0	+	+	+	+	?	!
Verhoef et al. 2013 (EU-PACT)	Therapeutic INR range 2.0-3.0	+	+	?	+	+	!
Drahota et al. 2013 (cRCT)	Fall injury rate	+	-	+	+	+	-
Elliott et al. 2014 (cRCT)	Clinical error when prescribing NSAID, beta blocker, ACEi	+	+	+	+	+	+
Lopez-Picazo et al. 2011 (cRCT)	Drug interactions	?	?	-	+	?	-
Moore et al. 2011 (cRCT)	Pressure ulcers rate at 28 days	?	+	+	+	+	!
O'Connor et al. 2016 (cRCT)	In-hospital adverse drug reaction	?	+	+	+	?	!
Snooks et al. 2014 (SAFER 1)	Fall service referrals	+	+	?	+	+	!
Snooks et al. 2017 (SAFER 2)	Emergency department attendances at 6 months	+	+	?	+	+	!
Jiang et al. 2014	Deep vein thrombosis	?	-	+	+	?	-
Payne et al. 2009	Pressure ulcer	?	?	?	+	?	!
Olson et al. 2015	VTE	?	+	+	+	?	!
Chaboyer et al. 2016 (INTACT cRCT)	Hospital-acquired pressure ulcer	+	+	+	+	+	+
Agnelli et al. 2013 (AMPLIFY-EXT)	Symptomatic recurrent VTE or death	+	+	+	+	+	+
Eriksson et al. 2007 (RE-MODEL)	VTE and mortality	+	?	-	+	+	-
Siddiqi et al. 2016 (PiTSTOP)	Delirium rate (missed diagnosis)	-	?	+	?	?	-
Ashby et al. 2012	Time to pressure ulcer healing	-	+	+	-	?	-
Cadman et al. 2017	Length of stay from unintended discrepancies in medicines reconciliation	-	+	-	+	-	-
Wallentin et al. 2010 (RE-LY)	Time in therapeutic range using INR, stroke and systemic embolism events	+	+	+	+	-	-
Eriksson et al. 2007 (RE-NOVATE)	VTE	?	+	+	+	+	!
Patel et al. (2011) (ROCKET-AF)	Systemic embolism	+	+	+	+	+	+
ADVANCE trial (2007)	Major or minor microvascular event	+	+	+	+	+	+
Lassen et al. 2010 (ADVANCE 3)	Composite of deep vein thrombosis, nonfatal pulmonary embolism, or death	+	+	?	+	+	!
Cook et al. 2011 (PROTECT trial)	Proximal leg deep vein thrombosis	+	+	+	+	+	+
Conroy et al. 2010	12-month fall rate	+	+	?	-	+	-
Eveleigh et al. 2017 (PANDA trial)	Successful discontinuation of antidepressant use at 1-year	?	-	-	+	+	-

Figure 2.8.2. Individual risk of bias assessments of RCTs (2007 to 2018), part 2, informing economic evaluations. Legend: green = low risk of bias; yellow = some concerns; red = high risk of bias.

Meta-analysis

The random effects meta-analysis of the risk ratios for the patient safety interventions of each of the 18 RCTs (one exclusion) is presented in Figure 2.9. The average risk ratio was 0.68 [Conf. Int = 0.58 – 0.79], indicating mostly positive findings from high-quality RCTs on the economics of patient safety. The I-squared was 82% ($p < 0.0000$), indicating high homogeneity between studies. This limits the statistical comparisons that can be made, which is expected given the breadth of patient safety outcomes synthesised.

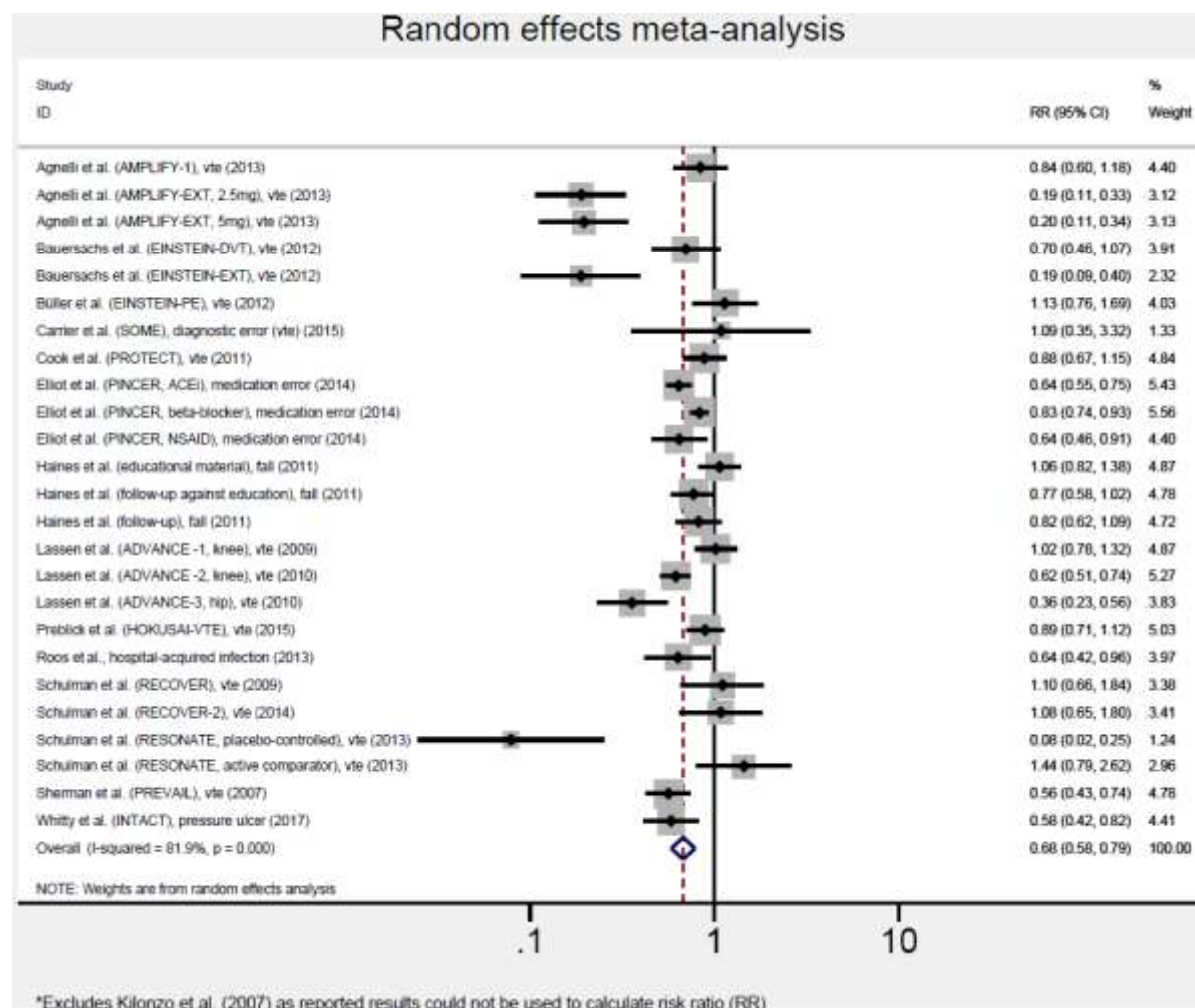


Figure 2.9. Random effects meta-analysis of 18 randomised controlled trials that informed 17 high-quality economic evaluations of patient safety interventions.* Risk ratios (RR) for all AE-related comparisons between the experimental and control arms of each trial are shown. A high I-squared of 82% indicates a large between-study variation, which is partly explained by the breadth of AEs targeted in these articles. These results do not take account of time-to-event outcomes. An overall RR of 0.68 (confidence interval, 0.58 - 0.79)

was found which explained this limitation. Legend: CI = confidence interval; RR = Risk Ratio; vte = venous thromboembolism.

Discussion

This study was designed to estimate changes in the scope and quality of evidence on the economics of patient safety, with the aim of synthesising these findings to inform decision making. Between 2007 and 2018, interventions targeting either VTE, pressure ulcers, medication error, in-hospital falls, multiple error targets, diagnostic error, and hospital-acquired infection dominated the literature. When the output of articles was normalised, the highest growth in economic evaluations of one patient safety target was for VTE (output from 2012 to 2018 was 2.9 times higher than the average annual output from 2007 to 2011). This trend may be due to the emergence of research on the economic burden of VTE during this period (175). The findings align with those by Etchells et al. to the extent that 2/5 of the comparative analyses they identified related to hospital-acquired infections (115,116) and 1/5 related to adverse drug events (114). However, the current research offers a more expansive view of high-quality evidence on the cost-effectiveness of patient safety interventions, which is required by policymakers.

The literature is dominated by economic burden studies (32% of total output) followed by ROI analyses (30%), yet the largest increase in study outcomes has been from cost analyses. Thus, since the previous review by de Rezende et al. (112), there has been an increasing shift in focus away from economic burden studies, which accounted for 55% of their sample, towards cost analyses, which constituted 9% of their sample. Complete economic evaluations, however, are less prominent, accounting for 21% of the articles we identified, compared with 36% for de Rezende et al. If ROI studies were included in the economic evaluation category, economic evaluations would comprise 51% of the high-quality studies found. The largest output of studies on the economics of patient safety came from the USA, the majority of which were ROI analyses. Related to this, the dominance of research from high- or upper-middle income countries (Figures 2.5 and 2.6) is inversely related to evidence on the global burden of patient safety incidents, two-thirds of which is borne by low-income countries (99).

Recent policy evidence suggests an inverse relationship between the volume and quality of this evidence at the clinical, organisational, and system levels and the number of expert investment recommendations given in the OECD survey by Slawomirski, Auraen and Klazinga in 2017 (8). For instance, the consensus on high-value patient safety investments from experts fell disproportionately at the system level, whereas the lowest volume and poorest quality

economic evidence for patient safety investment was found in this study. This suggests that more evidence needs to be produced from a system-level perspective, involving greater use of economic evaluations that adopt a societal perspective (cost-benefit analysis, cost-effectiveness analysis, and cost-utility analysis). Growth in ROI analyses of patient safety is a useful illustrative example, as it demonstrates that more attention has been given to the cost-effectiveness of safety practices in recent years. In the years to come, ROI analyses, which are useful for developing organisation-level business cases, should evolve into system or societal cost-effectiveness analyses to provide the necessary evidence for policy development. This has additional importance because ROI is not the “gold-standard” for making resource allocation decisions in healthcare (176).

As publications by the European Commission and OECD have indicated, the identification of high-value interventions to improve patient safety is a global priority; yet the suite of evidence-based options remains limited and uncertain. Of the non-drug interventions identified in this review, the likelihood of interventions being cost-effective ranged from 1% to 92.1%. The intervention most likely to be cost-effective (92.1%) was selective decontamination of the digestive tract for elective gastrointestinal surgery (177), followed by 59% for pharmacist-led information technology (158), 55% for a patient-centred care bundle for reducing pressure ulcers (173), 52% for a falls prevention programme (162), 21.6% for limited occult cancer screening with CT scan after VTE (153) and 1% for multivitamin and multimineral supplements (143). Of these studies, only one tested the effect of digital technology on patient safety improvement (158), providing evidence for the gap in knowledge of the impact of these types of intervention on the economics of patient safety.

Pharmaceutical interventions for VTE (and bleeding) avoidance dominated the literature in general and within the high-quality sub-group. This aligns with the proliferation of technologies for VTE and cardiovascular care from 2007 to 2012. More generally, these studies are part of a wider effort to provide safe VTE prophylaxis to inpatients; however, associated evidence for non-drug interventions appears weaker than that identified in this study. For example, an economic analysis of guidelines for VTE prophylaxis was based on effectiveness estimates from an uncontrolled before-and-after study at a single site. This assumed that the implementation of guidelines would be 100% effective, with no incremental costs beyond the cost of administering prophylaxis (178).

Deeper knowledge of the economics of patient safety improvement strategies will inform decisions about health policy and patient safety research programmes. Most of the studies identified only considered the economic perspective of an acute care hospital; they need to go further than this. Economic evaluations should explicitly consider all the costs of improvement strategies such as development, implementation, and maintenance, as well as economic consequences from multiple perspectives and time frames.

Limitations

The main limitations associated with this study relate to the comparison with previous efforts by Etchells et al. and de Rezende et al. We made every effort to replicate key aspects of their study designs whilst reducing bias towards pre-selected patient safety targets, increasing the rigour of the quality appraisals, and improving the reproducibility and transparency of our findings. However, in doing so, we reduced the strength of the comparative analysis. This is perhaps reflected in our observation that our search was not 100% sensitive when retrieving articles previously identified by de Rezende et al. Similarly, by restricting our search period to 2007 rather than 2000, we generalised our estimation of the proportional changes in the output of eligible articles from period one to period two. A further limitation of our comparison with de Rezende et al. is our use of two additional categories of economic analysis and potentially differing definitions of “complete” or “full” economic evaluations. To illustrate, if economic evaluation and ROI studies are counted together (as those that consider costs and benefits), then it is these, rather than economic burden studies, that dominate the literature. Furthermore, estimates relating to the change in research output between the periods may over or underestimate changes observed since 2012. A further limitation is that the search strategy was biased towards English-language articles. The principal finding regarding the geographic spread of articles on the economics of patient safety, in which the USA, UK, and Australia were identified as leading producers, is partly explained by this search strategy. Nevertheless, the detection of an 11-fold increase in English-language articles from China is indicative of the potential for increasing collaboration on this topic with institutions in this country. The extent to which the search strategy is biased by bibliographic referencing practices is another limitation. Given the practice of authors providing keywords for their articles, which inform database referencing, the search strategy is biased towards authors’ self-assessment of their articles as relevant to patient safety. This means that some patient safety articles may not align with the global expert consensus as to what constitutes patient safety. It also means that articles that align with this consensus may not have been captured owing to the keywords used to curate

them. The extent to which definitions of patient safety in the literature on the economics of patient safety align with expert consensus is an area for further investigation. An additional limitation of this systematic review concerns the choice of databases that were searched, as these did not include EMBASE. Whilst justified by the design adopted by Etchells et al. (2012), a consequence of this decision is that relevant biomedical studies may have been missed because EMBASE includes approximately 3,000 more journals (179).

The extent to which our assessment of the risk of bias reflects actual bias in the RCTs appraised is unknown. Based on previous research, risk of bias assessments that rely on publications may omit key information (180) at the expense of identifying important methodological aspects of studies (181,182). To address this, we included both trial protocols and original research articles. More broadly, our search strategy utilised the same databases as Etchells et al. (111); however, these do not encompass the full extent of the literature on the economics of patient safety and therefore our strategy may have been systematically biased towards these databases and the cataloguing of articles. For instance, articles related to the economics of patient safety that are not referenced would not necessarily be retrieved unless they were part of the MeSH terms listed in Table 2.1. Furthermore, we performed a quality appraisal of RCTs, which is different from the appraisal of quality improvement studies conducted in previous reviews (111,112). This also limits the comparability of the results; nevertheless, the use of a more rigorous appraisal for high quality evidence demonstrates progression in the evidence as it indicates an improvement in the internal validity of articles.

Nevertheless, the systematic review generated several new insights into the scope and quality of literature on the economics of patient safety. A secondary aim of the research was to characterise the types of digital interventions whose cost-effectiveness was assessed in the context of patient safety. Among the high-quality studies, only one digital intervention was identified. This was a cost-effectiveness analysis by Elliott et al. (2014) which compared a pharmacist-led information technology-based intervention (intervention group) for reducing medication errors with simple computerised feedback (control group) in general practices to manage patients at risk of potentially hazardous prescribing. The intervention groups experienced lower prescribing error rates for all outcome studies; however, the cost-effectiveness of the intervention was not guaranteed as the likelihood of it being cost-effective was 57%. Elliott et al.'s study handles the challenge of studying a complex educational intervention to improve patient safety extremely well. At the root of its successful methodological approach is the cluster randomised controlled trial design, which Meltzer (18)

recommended in 2012 as a necessary advancement for research on the economics of patient safety.

With respect to the cost-effectiveness of incident reporting systems, no directly equivalent studies that could inform those in this thesis materialised from the systematic review. In addition, no studies were found that developed methods from translational health economics, re-affirming the need for novel methods that draw on existing studies of digital interventions, such as that by Elliott et al.

Conclusion

The research conducted suggests there has been a significant increase in the number of studies focusing on patient safety interventions since 2012. While this is primarily due to the increase in the number of studies in the field of VTE, there is an overall improvement in the extent of evidence on patient safety economic evaluations across all patient safety targets. This research provides quality appraised and assured evidence that can be immediately adopted into practice by policymakers and hospital decision makers. Encouragingly, the findings identified an acceleration in addressing the “neglected necessity” of estimating the economic impact of patient safety on society and health systems. Most importantly, more interventions have been appraised for their cost-effectiveness (value for money).

Chapter three: Inputs: process mapping incident reporting systems in the English NHS

Introduction

The previous chapter established an increase in growth in the scope and quality of evidence on the economics of patient safety. However, it also identified a lack of evidence on the cost-effectiveness of information systems or digital technologies in patient safety and in studies that adopt methods derived from translational health economics (50). This gap relates to broader difficulties in evaluating the value of digital products, which evolve at a rate that often exceeds both evaluation and regulation reaction times (183). The utilisation of a conceptual framework to guide an empirical approach to estimating costs and benefits has been absent in studies on the cost-effectiveness of incident reporting systems in healthcare. These costs and benefits must be measured across complicated feedback loops that are not easily identified given the size of the workforce and the infrastructure encompassing these systems. Chapter one introduced the conceptual approach needed to reduce the uncertain outcomes of these processes and drew parallels to research conducted on incident reporting systems in the aviation industry. The emphasis of research conducted by Lercel et al. in the aviation sector was on the adoption of piecemeal methods to elucidate the relationship between resource inputs, processes, and outputs, and the outcomes they generate (84). Using equivalent methods from several disciplines, as described in Chapter one, the same approach is needed for healthcare incident reporting systems.

The development, implementation, and routine use of many healthcare interventions are shaped by the sociotechnical elements of a health system. Therefore, the success of a technology strongly depends on how frontline staff interact with it. From a systems perspective, the routine use of incident reporting systems by healthcare workers has not been formally studied, which represents a gap in peer-reviewed literature seeking to improve the design of such systems. The importance of addressing this gap is rooted in key principles of total quality management, which preceded quality improvement in healthcare, in that knowing a process necessarily precedes any attempt to improve it. For instance, W. Edwards Deming is famous for having claimed: “if you cannot describe what you are doing as a process, you don't know what you are doing.”

To estimate process models for systems as complex as incident reporting systems is a substantial research challenge. According to Shannon's theory of information entropy (73), in the absence of evidence the marginal gains from reducing the uncertainty (or entropy) surrounding the process of incident reporting is high. In this chapter, the process of incident

reporting and downstream activities are investigated because these marginal gains should manifest at least as a means of performing activity-based costing (184) of the entire system in the English NHS. Time-driven activity-based costing can be employed to derive economic costs used in economic evaluations and, in light of growing healthcare costs, is seen as an important part of the solution to limiting healthcare costs (185).

Theoretical grounding and development

Process engineering, mapping, and modelling are techniques employed in industrial engineering that are concerned with (optimising) continuous production processes. In healthcare, process engineering converges with methods used for quality improvement and peer-reviewed investigations have increasingly combined the two (186). Incident reporting systems form a continuous production process whereby raw information collected on harm or potential harm to patients is converted into data-driven guidelines, which can be viewed as goods and/or services to the NHS. For the NRLS, feedback reports are the product of this complicated system of data production; however, the exact activities that feed this production line, and the characterisation of potential variability between and within acute care organisations in England, have not previously been mapped using peer-reviewed methods. This needs to be rectified so that the system can be understood from an operational, rather than conceptual, perspective. In theory, the transformation of raw information into data-driven guidelines by incident reporting systems is designed to correct the market failure of patient harm. From a process engineering perspective, the efficiency of the production process is a function of the extent to which the minimum quantity of inputs is combined to derive the output. The productivity of production processes is a function of the rate at which these inputs are combined and the rate at which outputs are produced. This differs from the economic perspective, which strives to understand the costs of production and the value of the goods and services produced. The quality improvement perspective seeks to improve the entire system so that it delivers higher quality care.

The transformation of raw information into data has the same characteristics as other supply chain and manufacturing processes, although these are less perceptible if the information held in information systems is intangible. This can be the case if information is not viewed as part of a value production process owing to gaps in knowledge, for example in understanding real-time information production in incident reporting systems. From a systems modelling perspective, the production line that follows data entities must be studied in order to optimise flow. From an economic perspective, the cost of that production line should also be understood

to identify cost efficiencies. These principles are aligned to theories of value, production, competition, and prices, which were first described in pre-classical and classical economics.

Valuing the products of information systems

The tangible and intangible value of data and guidelines can, theoretically, be estimated. However, the theoretical underpinnings of economic value are seldom discussed in sufficient detail for the concept of “value” to be understood and, subsequently, defined according to a branch value theory. The labour theory of value developed by Petty explicitly attributes value to the production costs (inputs) from labour and land, which aligns with Smith’s division of labour in the production of goods. The Marxist theory of value extends the idea that the profits achieved from the land are the surplus produced after labour inputs have been expended. The consequence of a labour-driven notion of value is that rents become excessive, negatively impacting on workers whose wages are reduced to the lowest marginal cost per unit produced. The concept of redistributive value was developed by Marx to establish a position whereby workers are compensated according to the economic benefit derived from their activity, which requires redistribution mechanisms that incentivise capitalists to forego excessive rents. This notion of redistributing profits to workers is fundamental for feedback-loop based information management systems. A share of the profits, or at least a position whereby the marginal cost of labour equals the marginal benefit derived from it, is also the concern of behavioural economics. The motivation of labour and therefore its quality depend, in part, on wage rates, which are incorrect if monetary and/or experiential compensation for workers is suboptimal (187). Workforce capacity and skills need to be more sophisticated for complicated production processes, which is the case in the production of data from complex systems and large data sources (188). The neo-classical theory of value extends the notion of value to the post-production phase by asserting that the value of goods and services is set by the marginal utility gained by the individuals that consume them. Value, therefore, is not set entirely by production costs. In the case of information systems, the value of information should be determined by the production costs, the utility gained by workers in the production process, and the marginal utility of information to society or, as in this research, the NHS. Economists have deliberated extensively over the nature of information as a good (or not). For instance, Bates characterises information as something that (a) can be transferred, (b) has some utility (usefulness), and (c) can have a value attached to it (189). Inherently though, information is socially inefficient owing to uncertainty surrounding the precise outcome from the production or exchange of information, the infinite reproducibility of information, and the inability to diminish the stock

of information held by the first holder after its transfer to others (190,191). These inefficiencies can be reduced if the production and flow of information are understood as discrete entities that interact with discrete events.

The research presented in this thesis combines several theories of value and production, integrating production factors (inputs from land and labour) with the post-production notion of value, which is measured as marginal utility. The extra-welfarist conceptualisation of utility in health and care has generated methods for measuring *utils* gained or lost from economic activity. The health-related returns on health resource use are captured as quality of life (QoL) gains or losses, and survival. In the current stage of economic evolution, health information systems should be characterised as production processes in which data are produced from (observed) raw information obtained from patients or workers. This process causes health systems to incur production costs, which need to be estimated if inputs and processes are to be optimised. Such optimisation depends on the utility yielded by data outputs in society, measured as QoL and survival gains or losses. The feedback-loop exists when information flows into data that have a utility to citizens. The value of the feedback-loop depends on the production costs and quantity of utility yielded by the closed-loop. This paradigm is synonymous with cost-effectiveness frameworks, which establish whether the costs of production warrant resource allocation given the expected outcomes for population health and the willingness-to-pay threshold. In this theory, open-loop trajectories yield zero utility but incur production costs. Closed-loop trajectories yield the commensurate utility of the data generated from the production costs. The value of an open-loop trajectory is by default negative, generating a net economic loss to society, whereas the value of a closed-loop trajectory is a function of the production costs and utility yielded for a given discrete entity of information and data. At a given willingness-to-pay, resources are allocated to the production process if the net economic benefit is realised or expected.

The economics of information suggest that a reductionist approach to valuing health information should be used cautiously. For equal information entities, it is possible that, given the infinite reproducibility of information, the information produced by one health information system closes loops that other systems do not. In such cases, the net economic yield to society becomes a question of efficiency in the production of equal data. Duplicated effort is notable for being socially inefficient; therefore, to reduce these inefficiencies it is important to identify the division of labour in a production process and measure resource use. This aspect

incorporates economic theory into lean production methods and, in healthcare, firmly marries health economics with management science.

Process mapping in healthcare

The first step towards understanding the inputs and processes involved in incident reporting systems is the identification of sequential activities. Mapping a production process of this scale is rarely attempted given the heterogeneity of production methods. To derive a useful process map that supports further quantitative analysis and quality improvement, a valid description of the production process is needed. This is achieved using both process mapping methods and validity analysis. Novel production processes can be mapped prospectively and engineered efficiently from the outset. The resources used at each stage of production can be more easily measured and controlled at this stage of production design. In scenarios where a process is mature and tacit knowledge of the rationale for the production design is lost, it is necessary to observe and document the process retrospectively.

Process maps are conceptual models of a system that combine observations and hypothesis into organised estimates of the “real-world”(192). Conceptual models are qualitative description of real systems whose value depends on their precision with respect to the real-world and their interpretability by stakeholders. One application of process mapping is the identification of value and non-value steps in a production process, also known as value stream mapping (193). In lean management, it is employed to design systems that promote value steps in a process and remove resource intensive, low value steps (194,195). The importance of process mapping was described in a recent investigation on the benefits of this approach for quality improvement projects (196). Antonacci et al. (2018) identified the following eight benefits of process mapping through interviews with project managers, clinicians, and researchers: breaking down complexity and developing a shared understanding of reality; identifying gaps and improvement opportunities from a systems perspective; engaging stakeholders in a project; identifying and aligning project objectives and fitting interventions to the context; identifying responsibilities and monitoring project progress; learning about good practice; increasing empathy amongst stakeholders; and offering an easy to use method with a simple research outcome - a process map (196). The authors concluded their qualitative study by arguing that there is no consensus on best practice for process mapping and, furthermore, appropriate methods depend on the scope of the project, the setting, and organisational and behavioural factors. The authors warn that the more complex a process, the more likely it is that the organisational knowledge will be fragmented, and that stakeholder agendas and

interests will conflict. However, quality improvement projects will also benefit from the reduced uncertainty provided by process mapping.

The process mapping of patient pathways was described by Trebble et al. (2010) (197) in a “Practice” paper published by the British Medical Journal (BMJ). Seven steps are described that emphasise the continuous nature of this method. The first is to determine the condition or intervention for pathway redesign; the second is to agree the project aims and identify an evidence base; third, team member roles need to be agreed in conjunction with methods, research time frame, and locations; fourth, data collection needs to be performed (walk the journey or observe the pathway); fifth, the process map should be drawn from the data collected, missing data gathered, and the analysis conducted; sixth, the pathway needs to be redesigned from the simulation generated; and seventh, the new pathway should be implemented and the process mapping study repeated (197). Waiting episodes or bottlenecks are sections of the process that slow the rate of an entity’s progress through the process, typically because resources (capacity) are lacking. A recent example of process mapping in a patient safety context was provided by Holbrook et al. (186) who investigated the process of reconciling admission medicines in a single hospital system in the USA. The authors included a validation stage in their method. In their study, frontline staff were shadowed by process engineers who mapped activities from the triage of patients in the emergency room to their discharge. Activities that were performed by staff 80% of the time and after a sufficiently long period of observation were considered the norm and tasks were timed wherever possible; however, a benchmark for what constituted “sufficiently long” was not provided.

The International Society for Pharmacoeconomics and Outcomes Research (ISPOR) developed guidelines on modelling healthcare systems, using a series produced by an expert task force (198). This task force advocated for steps to improve model transparency and validation as a means of improving the usefulness of (economic) evaluations. Methods for achieving transparency and validity are not provided by the authors or from citations, suggesting that more formal development of these methods is needed (199). In modelling and simulation, validated process maps can be translated into quantitative descriptions or mathematical evaluations of the system they represent. If entities or their interactions change over time, the mathematical models are considered dynamic.

Dynamic models can be stochastic or deterministic; if randomness that amounts to parameter uncertainty is considered, then the model is stochastic, whereas if the transition of entities,

costs, and consequences are considered fixed, and only structural elements are changed to estimate different scenarios, then the model is deterministic. Both stochastic and deterministic aspects of a model can be changed simultaneously. By contrast, static models rely on assumptions about the structure of a system that are considered to remain constant over time (200). These modelling techniques can be applied in health economic evaluation; alongside the other attributes of process models, these techniques have the potential to improve the translational aspects of economic evaluations.

Rationale for process mapping incident reporting systems

Despite the attention given to incident reporting systems in academic and policy research, the volume of peer-reviewed evidence on the structure, processes, and outputs generated from these systems is generally underwhelming. The rate at which academically scrutinised evidence has been produced is slow, despite calls in 2008 for a debate about the value of incident reporting systems (77). Anecdotal and global peer-reviewed evidence suggests there are fundamental process-related problems with incident reporting systems that are related both to their design and the design of the outputs they generate (201). This indicates that an easy solution or “workaround” has not yet prevailed, which is why a renewed, systematic, and scientific focus on these systems is required to identify the parts of the process that need to be improved. Historically, incident reporting systems were developed in secondary care settings and it is only in the last decade that efforts have been directed towards developing systems for primary care (202). There is an equal need for process maps to be developed in the primary care context, for the same reasons that are outlined here. However, research in secondary care is the priority given the maturity of these systems in this setting and the potential for translating design and development lessons into primary care settings.

A systems modelling approach is thus required to improve our understanding of the factors associated with the successful local development and implementation of incident reporting systems. At a national policymaking level, these factors were identified for medication error reporting systems by Holmström et al. (203) using a global expert-driven approach. Among the success factors cited were “international and governmental support, and resources”. Moreover, within this dimension, a shortage of financial and human resources was seen as a barrier to the development and implementation of systems. For this reason, the cost of operating national incident reporting systems needs to be determined to facilitate the earmarking of resources. In combination with validated process maps, activity-based costing methods can be used to estimate these costs (204). Bottom-up methods for deriving estimates of local processes

and costs are key to user buy-in because they facilitate the implementation of future recommendations by creating local ownership of both the problem and solution(s) (205). Moreover, the Delphi-driven findings by Howell et al. demonstrate that hospitals should take responsibility for creating safety solutions at a local level (206); nevertheless, hospitals often lack the expertise and resources to do so (199, 200). This problem extends specifically to systems modelling methods. Pitt et al. describe these methods as an important and potentially underestimated means of quality improvement that are rarely applied owing to a lack of technical training and capability in health organisations (209).

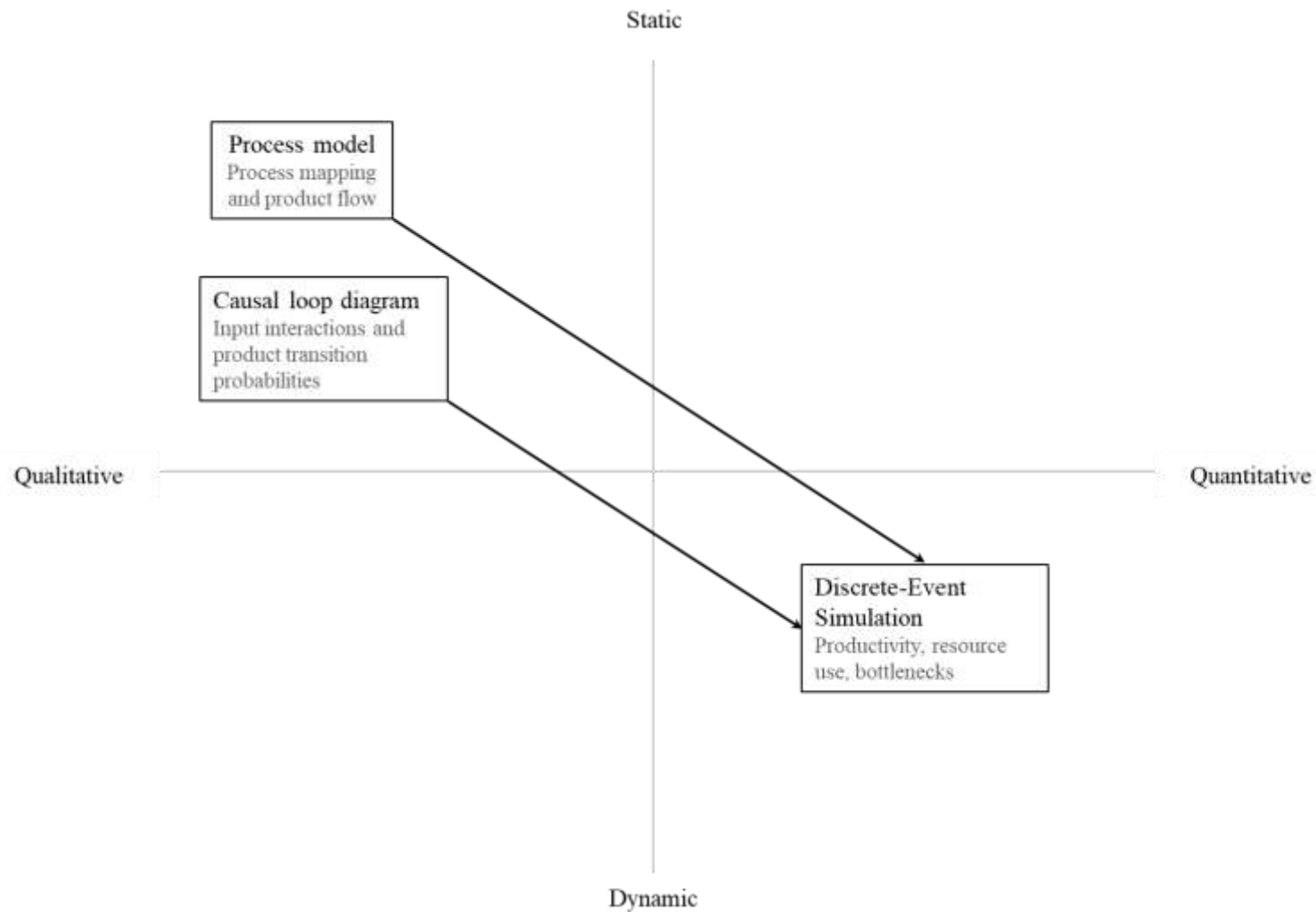


Figure 3.1. Engineering discrete-event simulations. Static qualitative process models are the precursors to dynamic quantitative simulations (adapted from Rus, Neu & Münch, 2003 (210)). Discrete-event simulation is used in health economic evaluation (211), the translational attributes of which are emerging.

Aim

The aim of this research was to derive a validated process model of incident reporting systems in the secondary care setting of the English NHS. Secondary aims were to identify both variability in the activities performed and isolate potentially low value activities.

Methods

Study design

Process mapping was undertaken in two stages. The first stage was a semi-structured interview-based study at one NHS Trust, while the second stage was a validity analysis performed across multiple NHS Trusts. Stage one involved NHS staff from a Trust in North West London encompassing five hospitals serving a population of approximately 2.4 million people. Stage two involved NHS staff from seven Trusts encompassing 25 hospitals serving a population of approximately 8.7 million people across three geographical regions: Central London, Greater London, and East England.

Stage one

Item selection and development of the questionnaire

A questionnaire was developed after reviewing methodological literature that informs process mapping. A semi-structured interview guide was developed, and a topic guide piloted with NHS clinicians ($n = 3$), following which minor amendments were made, including the rewording of five items to enhance understanding. The pilot period preceded the recruitment phase of the main study; therefore, pilot participants were academic clinicians from within a local research network. Links to corporate and departmental risk managers were developed latterly as part of the recruitment strategy, which emphasised limiting the data collection burden for patient safety practitioners. As part of this strategy, the decision was made to limit risk managers' involvement to the main data collection phase.

Participants

Participants were recruited by asking departmental leads and line managers for initial approval to approach any member of NHS staff because, theoretically, incident reporting systems are available for voluntary use by all members of staff. In addition, the lack of peer-reviewed evidence meant that a formal segmented sampling approach could not be adopted *ex ante*. Interviews were then arranged with NHS staff ($n = 15$) through a snowball sampling method initiated with risk managers, clinical leaders, and corporate managers.

Inclusion criteria

Participants who provided full, informed consent to partake in the study and had interacted with or experience in using incident reporting systems.

Exclusion criteria

The two exclusion criteria were incomplete consent after recruitment and no interaction(s) or experience with NHS incident reporting systems at the time of recruitment.

Data collection

Data were collected between February 2015 and February 2016. After giving informed consent, the participants were interviewed at a time and place of their choosing, usually in their work unit(s). The interviews were recorded, and participants were invited to extend or shorten the duration of sessions in accordance with their preferences. The topic guide consisted of 3 sections: 1) participant demographics and level of experience; 2) training in patient safety and incident reporting systems; 3a) the incident reporting process; and 3b) the development and implementation of feedback. The aim of the guide was to determine the sequence and interrelation of activities involved in incident reporting and management in the NHS. Participants were asked to score the level of patient safety at their organisation on a scale of one to ten, whereby one meant it was among the worst organisations in the NHS and ten meant it was among the best. This served as a steering question directing participants to think critically about patient safety programmes in their organisation. As a comparative indicator, this question has limited validity because conceptually similar questions have been developed in validated questionnaires such as the Hospital Survey on Patient Safety Culture (HSOPS)(212); nonetheless, it facilitated broader and deeper participant responses to subsequent questions and scored their perception of organisational patient safety in a conventional manner.

The interviews were semi-structured and open-ended to enable the researcher to ask additional questions and seek further explanation from participants when further elaboration on potentially valuable information was required (213). The topic guide was not adapted during the study. During interviews it was necessary to use impartial, objective language when checking the interpretation and understanding of the processes described by participants. At any stage of an interview, if participants expressed discomfort while disclosing the tasks they perform, the researcher's language was adapted to re-emphasise impartiality. This was necessary despite the informed consent procedure, which emphasised the confidential nature of data collection.

Data analysis

Interviews were transcribed verbatim and qualitative data analysis methods employed to develop a process map (214). This process map is a visual representation of a set of clinical services (215–217) that provides stakeholders in the services, or those analysing or planning an intervention within them, with detailed models of existing care pathways and clinical processes to give an overall picture of how a service is currently provided (218).

Coding and theme development were undertaken using open and axial coding methods derived from grounded theory (219). Data were analysed using a thematic approach that identified the stakeholders and discrete processes in incident reporting systems. Data collection and analysis was cyclical as later interviews were informed by the findings from the first five interviews. This facilitated the additional elucidation of detail as it allowed the topic guide to be amended. The transcripts were arranged into initial themes and sub-themes by systematically searching for discrete events and linkages between events. Contradictory activities and linkages were given a coding category. The coding of themes and sub-themes was reviewed three times. Sub-categories were used for each code to identify sub-activities in the sequence. In an inductive and then deductive process, categories of codes (activities and linkages) were grouped and linked. Saliency analysis was used to identify activities relevant to the primary research objective. Data were collected and analysed until no new activities emerged. The analysis produced a set of incident reporting and management processes that occur at the principal organisational levels of an NHS Trust. These were sequenced according to participants' responses: where linkages were not described or were contradictory, the author modified the structure of the sequence to ensure it was rational and logical. For instance, if two participants referred to different activities that are linked but were not described as such in the transcripts, the author derived such linkages.

Once the set of activities and linkages were identified, a process map was constructed using MS Excel's "Flowchart" package for visualisation. To facilitate interpretation of the process map for use in the stage two study and subsequent research directed towards quality improvement, the process map was constructed to be as simple as possible whilst preserving its utility.

Ethical approval

This research involved NHS staff participants which meant that ethical approval was required. This was obtained from the Joint Research Compliance Office at Imperial College London (IRAS ID: 153350) and informed consent was given by all participants.

Stage two

The aim of this study was to derive a valid archetypal process map of incident reporting systems in the English NHS. A novel questionnaire was therefore developed to estimate which elements of the process map derived in stage one were valid. This was then administered to a generalised sample of NHS staff in researcher-facilitated sessions. The methods described are an efficient approach to collecting data on real-world activities that would otherwise require a large team of observational researchers.

Participants

Participants were recruited using the same sampling method employed in stage one. Snowball sampling was performed with the approval of departmental leads and line managers. Stage one participants were then invited to partake in stage two. The structured questionnaire consisted of three sections: 1) participant demographics and level of experience; 2) training in patient safety and incident reporting systems; 3) Likert scale ratings of the activities and connections displayed on the stage one process map. Each data collection session began with a brief researcher-led presentation about the economics of patient safety, a background to the current incident reporting study, and instructions for completing sections one to three. The latter involved a “walk-through” of the process map to ensure that the description of the activities and the direction of information flow through the map were understood before ratings were given.

Inclusion criteria

Participants who provided full, informed consent to partake in the study and had interacted with or had experience of incident reporting systems.

Exclusion criteria

The two exclusion criteria were incomplete consent after recruitment and no interaction(s) or experience with NHS incident reporting systems at the time of recruitment.

Data collection

Data were collected between February and November 2018. Figure 3.2 depicts the data collection tool (developed in stage one), which was administered as a paper-based bundle to ensure that a) computer accessibility was not a hindrance to data collection, and b) the process map could be viewed in its entirety without the need for scrolling or zooming. Participant exposure to the entire system model was essential because researchers were unaware of participants’ real-world experience of the system. Moreover, a whole system view was needed

to ensure that participants' point of reference was consistent, thereby reducing the potential for context bias within the cohort and between participants.

Participants estimated their level of agreement with each activity or connector proposed in the stage one model using a Likert scale; similar approaches have been adopted in other health research fields (220,221). The instructions asked participants to assess the extent to which the model represented the "current state" on a scale of 1 to 4 where 1 = strongly disagree; 2 = disagree; 3 = agree; and 4 = strongly agree. A "neither" option was not available because, as experts in the incident reporting and management processes (relevant to them), unequivocal knowledge was expected (222). Although 4-point Likert scales are permissible in consensus building research (223), they provide less information than the 5, 7, or 9-point scale. However, a 4-point scale was used to reduce respondent fatigue given the cognitive burden associated with the exercise. Participants were discouraged from responding to elements of the model that estimated real-world processes of which they had no experience. The researcher explained that a "no response" would be interpreted as a lack of experience in a given element of the model. The following definitions were provided to enhance participants' cognitions and orientation to the task:

- **Incident reporting systems** are a set of reporting, investigation, feedback, and learning activities undertaken in response to patient safety-related incidents.
- An **"incident"** is defined as any event that has caused potential or actual harm or injury, patient dissatisfaction, or damage/loss of property.
- **"Patient safety"** is defined as the avoidance and prevention of patient injuries or adverse events resulting from healthcare delivery processes.
- **"Reporting"** is defined as the process leading up to, and including, the entry of an incident report into incident reporting software.
- **"Management"** is defined as the activities performed by the individuals and teams responsible for formally responding to the incidents reported. This includes investigating incidents and providing feedback to relevant staff and departments in their respective Trust.

Data analysis

Participant responses were transcribed and the themes then aggregated into MS Excel, generating a 3-part data frame of demographic, work experience, and process and connector-specific variables. The mean ($\pm$ -standard deviation) and median scores for each participant (rows) were calculated by variable (columns). The denominator for estimates of the sample mean was normalised to the number of observations given per participant: missing data were not included in the estimate of row means. Participants who did not provide formal consent were removed from the sample. Participant observations for the reporting or management process variables were omitted if they indicated they had no experience with incident reporting systems. Ratings given as a range were entered as the midpoint; for example, 1 to 2 was entered as 1.5. A rule for accepting or rejecting variables in the final (archetypal) process map was adopted before analysis, which was that mean or median scores below 2.5 conferred rejection of the variable (an activity or connector between activities). The process map for incident reporting and management was considered valid if the aggregate average score exceeded 2.5.

Potentially low value activities were identified as those that were duplicative in nature and could be avoided (193). Given the limitations inherent in individuals defining such activities, they were identified for exploration in future research and quality improvement work.

Statistical analysis

Means, standard deviations, medians, and minimum and maximum values were used to summarise scores for all activities and connectors, and activity-specific scores. Correlations were then calculated between respondents' validity scores and demographic variables with continuous properties (years of clinical experience, perception of organisation safety, and annual hours of patient safety training). Frequency tables were constructed to explore associations between categorical demographic characteristics (age group, incident reporting experience, time since last use of an incident reporting system, and type of incident reporting training received). They were also generated for a binary variable derived from the analysis following an invitation during data collection sessions; this indicated whether respondents annotated the process maps with suggestions about the process. For categorical variables, Fisher's exact test was used to compare means when less than five observations were present, otherwise Chi-squared tests were used. A significance level of 0.05 was used to inform sample comparisons.

Multiple linear regressions were performed to explore associations between demographic information (predictors) and average scores for each activity or connector (response variable).

Despite controversies around the use of parametric methods, including linear regression, with Likert scale data, these have recently been considered robust with respect to statistical interpretation (224).

Inter-rater agreement was tested using Gwet's agreement coefficient (AC) with a threshold of 0.7 for good agreement and a coefficient of 0.5 indicating acceptable agreement. Gwet's AC is more robust than Cohen's kappa for quantifying agreement between raters (225) as it can handle any number of raters, any number of rating categories, any level of measurement, and missing values(226). A higher coefficient of 0.70 is considered acceptable for new instruments such as those used in this study (227). All statistical analyses were conducted using STATA/SE 15.

Findings

The stage one dataset was generated from semi-structured interviews with a total duration of 654 minutes (11 hours). The 15 participants comprised nine clinicians (seven medical doctors and two practicing nurses), including five NHS consultants and two specialty-training junior doctors, and six administrators, including three risk managers (formerly practicing nurses or midwives) and three corporate patient safety managers. The mean interview length was 44 minutes ($SD \pm 12$, $n = 15$). Nine participants were 36 – 59 years of age and five were 26 – 35 years of age. Data for the other participant were missing. Ten out of the 15 participants were female. The mean number of years of experience in the NHS was 19 ($SD \pm 11$ years) for the departments represented, comprising surgery and anaesthetics ($n = 4$), paediatrics ($n = 3$), the patient safety corporate team ($n = 3$), maternity care ($n = 2$), neonatology, psychiatry, and general medicine ($n = 1$, respectively). Participants worked in one of three different NHS hospitals.

Twelve participants had reported an incident within the previous seven months. Two had reported an incident within the previous 36 and 60 months, respectively; however, both indicated that part of their role involved routine incident reporting system-related duties. One participant had not reported an incident within the previous 13 months and did not indicate their involvement in routine incident reporting system-related duties. The only incident reporting software used in the three months prior to the interview was Datix, although three participants were aware of the NRLS, two participants cited awareness and use of a risk register, one participant reported awareness of another incident reporting software called “Good Gas”, one participant cited software called “Risk Assessment”, one participant reported awareness and use of the “Raising Concerns” policy, one participant was aware of the Strategic

Executive Information System (StEIS) system, one participant was aware of “Safeguard”, one participant was aware of a paper-based “yellow form” alternative, and one participant was aware of a paper-based “yellow card” for prescribing errors. The average workplace safety rating score was 6.7/10 (SD $\pm$ 1.4).

Thematic analysis

A summary of the themes generated by participants that were translated into discrete events is provided in Table 3.1. A full list of the unconsolidated processes that were identified from the interview transcripts is provided in Appendix C.2.

No.	Theme	Participant data
1	Pre-report deliberation and discussion of incident details and severity	<i>“So, things like information collecting and what actually happened, I kind of went over the notes...getting feedback from my colleagues, things like that, it probably took another 10 minutes” (id1)</i> <i>“I mean, when I report personally, I would discuss with the team...there” (id5)</i>
2	Completion of Datix incident reporting form	<i>“Datix is a very clunky designed thing...I would say it takes at least 15 minutes to put anything reasonable in...the report goes to the server and it’s read by someone...whose permanent job it was [to] read all of these Datix reports and do something with them” (id2)</i> <i>“If I do think that there is something that needs to be reported...then it’s usually either I’ll report it myself or I ask my juniors or my trainees to report it” (id5)</i> <i>“...the serious incident would be entered onto the system...at moderate harm/major harm/extreme harm” (id9)</i>
3	Post-report deliberation and discussion of incident details and actions	<i>“Report the incident and then escalate it. I would escalate it straight to the chief of service and...there are other people who should know...I may also call on my friend the risk nurse...I suppose it probably would take about 15-20 minutes to just talk things through” (id4)</i> <i>“In terms of discussing [an incident], I have discussed it at handovers”(id5)</i> <i>“They came to me and asked me to write another statement and I thought, well, it’s just as well I’ve done the incident report”(id15).</i>
4	Discuss incident with patient and/or relatives	<i>“Obviously, you manage the situation. You talk to the family and make sure everything is fine at that point” (id4)</i>
5	Find a computer to enter an incident report	<i>“Get onto a computer, logged in at the sister’s office, accessed Datix and then just basically followed the instructions and filled in the appropriate boxes” (id11)</i> <i>“I think incident reporting, it’s always helpful to have a computer that’s accessible...if you don’t have computer systems at hand, it’s very hard to fill in an incident report” (id15)</i>

6	Allocate submitted Datix incident reports to investigators	<i>“...when somebody else completes that [incident] form and it comes to me. So, in the morning I have on average six to ten incidents sitting in my inbox. It probably takes me 20 minutes to just open those up, allocate the correct person and just do the housekeeping” (id3)</i> <i>“I’ll think, you know, I know who that needs to go to. If it’s an instrumental delivery with a tear, I’ll send it to the consultant”(id13)</i> <i>“The first thing that I do is whether that incident is relevant to my domain...if it’s a medical issue then yes, I would look into it. If it’s a nursing issue I prefer not to” (id5)</i>
7	Local meeting: risk managers’ discussion of incident details and actions	<i>“I had an individual meeting once a month with [the] ward manager to help with the investigation process...A weekly meeting, our meeting with the manager so that’s...five hours a week. A monthly local risk meeting” (id3)</i>
8	Review or development of guidelines, policies, and feedback	<i>“On an average no harm incident, to review the lessons learned, the group would meet and we’d look at what happened” (id3)</i> <i>“We actually have an old guideline group...if we do think that...a new guideline needs to come into practice, we would get somebody appropriate to write that guideline” (id5)</i>
9	Production of patient safety information materials	<i>“If there wasn’t the guidance there in the first place...you know it’s kind of that the guideline was out of date and non-complied with...that created a whole body of work to make sure there was the best guidelines...compliant with...national publications” (id3)</i> <i>“I produce a lessons learnt report” (id3)</i> <i>“If something’s happened, [risk management midwife] will include it in the Risky Business newsletter ...we have hot topics...we put out a reminder” (id13)</i>
10	Implementing existing or new guidelines or policies	<i>“If it’s somebody’s guidance, then we make sure that guideline is relaunched across the floor” (id3)</i> <i>“Once that’s [guideline] approved...we actually again go through an implementation process, which means we decide whether this needs an education package...more posters or just marketing” (id5)</i>

		<i>"A lot of it for us is putting that information out and getting people to understand why we might chance something, and helping them implement it, and auditing it...I send out my risk management meeting minutes...we have done posters in the past, staff meetings if we need it sometimes" (id14)</i>
11	Datix incident report management: update supporting information	<i>"Then I involve...managing and chasing the incident across teams and remit. That takes considerably longer" (id3)</i> <i>"They [risk managers] just want to see all of [regraded incidents], just because it has been graded as that and just to see that it isn't moderate...you have a little investigation to go outside Datix" (id12)</i> <i>"There is a mini root cause analysis that I would need to do for a grade 2 pressure ulcer...on top of the Datix and I'd add an appendix into the Datix" (id12)</i> <i>"If you haven't already, you validate names, you go into the page that says investigation...it will say lead investigator. So, I'll always like type her name...I literally just copy what's written on that...then outcome of investigation...and click report full to [National Reporting and Learning System]" (id13)</i> <i>"If it's going to the NRLS because it's patient safety, we then validate it on Datix" (id14)</i>
12	First formal investigation of Datix incident report	<i>"...we pull a report of all incidents that are reported...and they are sent by division to each division...the divisions attend a meeting with the associate medical director...they present their incidents" (id9)</i> <i>"Sometimes people when they submit incidents, they grade it as absolutely catastrophic, whereas actually he doesn't know what happened at all...anything moderate or above immediately triggers the upper medical director's office. So, if there is something on moderate you just want to downgrade it" (id12)</i>
13	Second formal investigation of Datix incident report (for serious incident)	<i>"Sometimes you've investigated a case very thoroughly, you've done a local investigation and then get told by the trust that this has to be a [serious incident]...then the entire process is repeated again, which I find a waste of time...the chief investigator would then sit down with the risk manager and...interview every person who was involved in that incident" (id5)</i> <i>"There are four outcomes...[the incident] has been downgraded...this patient did die but they died of their natural condition...or they weren't harmed to the extent that we thought they were" (id9)</i>

14	Informal Datix incident reporting training	<i>"There was encouragement, but there's no formal training and there's nothing...maybe I just can't remember it" (id11)</i>
15	Local meeting: Local Negotiating Committee discussion of patient safety	<i>"I'm just trying to think of my deputy of the Local Negotiating Committee...we're talking about safety...the meetings are about every three months...we have a lot of discussions from those" (id6)</i>
16	Local meeting: Joint Staff Committee discussion of patient safety	<i>"...one [meeting] is just the medical union, and then...on the Joint so it's double that, nearing six hours every three months...the majority of it is patient safety"(id6)</i>
17	Local meeting: medical union meeting discussion of patient safety	<i>"...one [meeting] is just the medical union, and then...on the Joint so it's double that, nearing six hours every three months...the majority of it is patient safety"(id6)</i>
18	Local meeting: audit or MDT or M&M	<i>"If there seems to be any inconsistency, then...investigate it. Where I find the answers are not very good, we do have twice monthly meetings" (id5)</i> <i>"At the audit meetings, if your particular incident isn't reported, you can bring it up if you want...they have M&M [mortality and morbidity meetings] to present incidents" (id7)</i> <i>"We would go through patient safety issues at the MDT once a month" (id11)</i> <i>"If it's a moderate [harm incident], within 48 hours you've got to have this MDT meeting" (id14)</i>
19	Data preparation for performance reporting to NRLS	<i>"We have a very nice binder that we use...the last one I produced was 400 pages. That was for one meeting...half was pretty much relating to [incident reporting]" (id8)</i>
20	Incident investigation management	<i>"We should be able to review [incident investigation] and quality assure it...not for every single [serious incident], but for some of them we are saying, 'Okay, can I see a copy of the statements or the interviews'" (id9)</i>

21	Corporate meeting: Serious incident panel review 2 (corporate team)	<i>"The division is responsible for investigating the [serious incident]...the report should come to the corporate team one week before the panel...the panel meetings are chaired by [associate medical director for safety and effectiveness]" (id9)</i>
		<i>"If you've had a [serious incident] or are unfortunate enough to have a [serious incident] investigation, you will get invited along" (id12)</i>
22	Production of organisation performance report for NRLS	<i>"We have a very nice binder that we use...the last one I produced was 400 pages. That was for one meeting...half was pretty much relating to [incident reporting]" (id8)</i>
		<i>"We send our incidents to [National Reporting and Learning System]" (id9).</i>
23	Trust training: Statutory Mandatory Training on patient safety	<i>"It's probably not a lot actually...there's part of [statutory and mandatory] training which covers parts of patient safety, so that's done every three years" (id12)</i>
24	Datix investigator training	<i>"Anyone who has access to the data system has to do some training...there's online training and safety-first training and then loading the password...it's not a long process e-learning. Datix, two hours maybe" (id3)</i>
25	Trust training	<i>"As part of the implementation of the [Central Alerting System], the safety alerts process, effectively I've been teaching people how to capture it" (id10)</i>
26	Datix training update	<i>"You do [Datix training] as a one-off and then...in 2014 we had an update. It's not recurring training" (id12)</i>
27	Maintain, upgrade, or downgrade severity of incident reported	<i>"You've done a local investigation and then get told by the trust that this has to be a [serious incident] ...then the entire process is repeated again" (id5)</i>
		<i>"One of our main jobs ...is making sure the coding's right. That's really important because anything moderate or above...So we recode...We downgrade quite a lot" (id14)</i>
28	Production of organisation performance report for commissioner	<i>"It will be reported as [a serious incident] ...and it needs to be externally reported to our commissioners, and so it will go onto StEIS"(id9)</i>

29	Third formal investigation (level 1 concise investigation)	<i>“...they then have...a level one concise investigation so they have a formal report and investigation done, but it is done divisionally, and it is signed off by the divisional director...it’s for divisional management” (id9)</i>
		<i>“We escalated one two weeks ago that we felt was a serious incident, should go external...the panel came back with more questions...it has now gone external...there’s two formats for doing the reports...level one in-house and then you do external [serious incident with commissioner]” (id14)</i>
30	Datix optimisation by technician	<i>“I’ve actually implemented the safety alerts module, so I’ve written a policy, the standard operating procedure, and a Datix training manual around the process” (id10)</i>
31	Division meeting: Serious incident panel review 1	<i>“We should be able to review [incident investigation] and quality assure it...not for every single [serious incident], but for some of them we are saying, ‘Okay, can I see a copy of the statements or the interviews’”(id9)</i>
32	Close investigation and disseminate findings using Datix	<i>“What happens is the report is attached to this Datix incident form so that all of the managers who have access to that Datix incident form can view the [serious incident] report in its entirety” (id9)</i>
		<i>“I close off reports rather than report on them” (id12)</i>
33	Surveillance of latest patient safety information	<i>“We would advocate using safety alerts and national guidance...through the central alerting system...it’s literally a copy and paste job”(id9)</i>
		<i>“We get the MEA/MHRA alerts and patient safety alerts, and we get them from governance rather than having to go and look at them for ourselves” (id12)</i>
		<i>“We get the [Central Alerting System] alerts that come from the governance team...then we go off and have a look and see if it’s relevant” (id14)</i>
34	Local performance management of individuals	<i>“Certainly, with drug error I think everyone’s prone to a mistake...just sit down and chat with somebody. And then discuss how you might take that forward...with the same nurses on a simple incident I just said, ‘Don’t do it again’, but if the same thing keeps happening...we probably need to do something, i.e., some training or some performance management” (id12)</i>

		<i>"The consultant will pick up again if that doctor does the same [patient safety-related] thing again...we have concerns about midwives with medication errors, you know they could speak to the supervisor of midwives" (id13)</i>
35	Ward meeting: patient safety incidents and feedback	<i>"I have a senior staff meeting every month and I have a general staff meeting every three months, and then I have a team day every month, I'll probably pick anything up in those meetings and feedback with that as well, and it'll also be over email as well...as well as handover in the morning" (id12)</i> Interviewer: <i>"I said I was going to come back to the clinical meetings...So there's a quality and safety meeting?"</i> Participant: <i>"Yeah quality and safety, critical review...local risk management meeting...risk and audit team meeting...divisional health and safety...local Datix meeting" (id13)</i>
36	Retrospective incident surveillance	<i>"We have our coders, once they get the notes and they pull notes for us...they'll have a list of [incidents]...they put them aside for us to collect...yesterday I picked up three sets of notes, two of them weren't even on Datix" (id13)</i>
		<i>"We have a trigger list and I try and pick up Datix that were missed...I went to look at their notes, got the information, put it onto Datix and submitted it...Our other fallback for missing triggers is coding...they will pick out certain cases and keep them aside for us" (id14)</i>
37	Production of incident investigation report for commissioner	<i>"It will be reported as an SI which means this is what happened, it is bad and it needs to be externally reported to our commissioners, and so it will go onto StEIS" (id9)</i>
38	Ward level investigation*	<i>"If there's any investigations around safety or complaints or whatever, I also investigate that as well. So, I'm running around trying to put the systems into place as well to prevent things happening as well... you have a little investigation to go outside of the Datix. So, then you would regrade – look at the grading system...to say the incident has started to investigate it."(id12)</i>

Table 3.1. Themes regarding the process of incident reporting and management in one urban acute NHS Trust *This process was added by the researcher as it was an activity separate from the formal investigations revealed by respondents.

Process mapping

The thematic analysis revealed 121 processes involved in NHS incident reporting systems for all participants (see Appendix C.2). These were translated into a thematic framework of 119 processes, of which 37 were common between all participants (see Table 3.1).

The process map derived from the stage one study is presented in Figure 3.2. In total, 30 discrete events were identified by removing processes that did not represent the discrete events involved in the reporting and management of incident information. The 7 events that were removed are summarised in Table 3.2. Participants cited between 2 and 17 (mean = 6, n = 15) incident reporting and management events and between 1 and 4 (mean = 2, n = 15) training-related events. The mean number of IRS activities and training events identified by clinical participants was 5 and 2, respectively, and by healthcare managers was 9 and 3, respectively.

- | |
|--|
| <ul style="list-style-type: none">➤ Informal Datix incident reporting training➤ Trust training: Statutory Mandatory Training on patient safety➤ Trust training: Datix investigator training➤ Trust training: Patient safety topics➤ Trust training: Basic Datix training➤ Incident reporting system user optimisation➤ Local meeting: medical union meeting and discussion of patient safety |
|--|

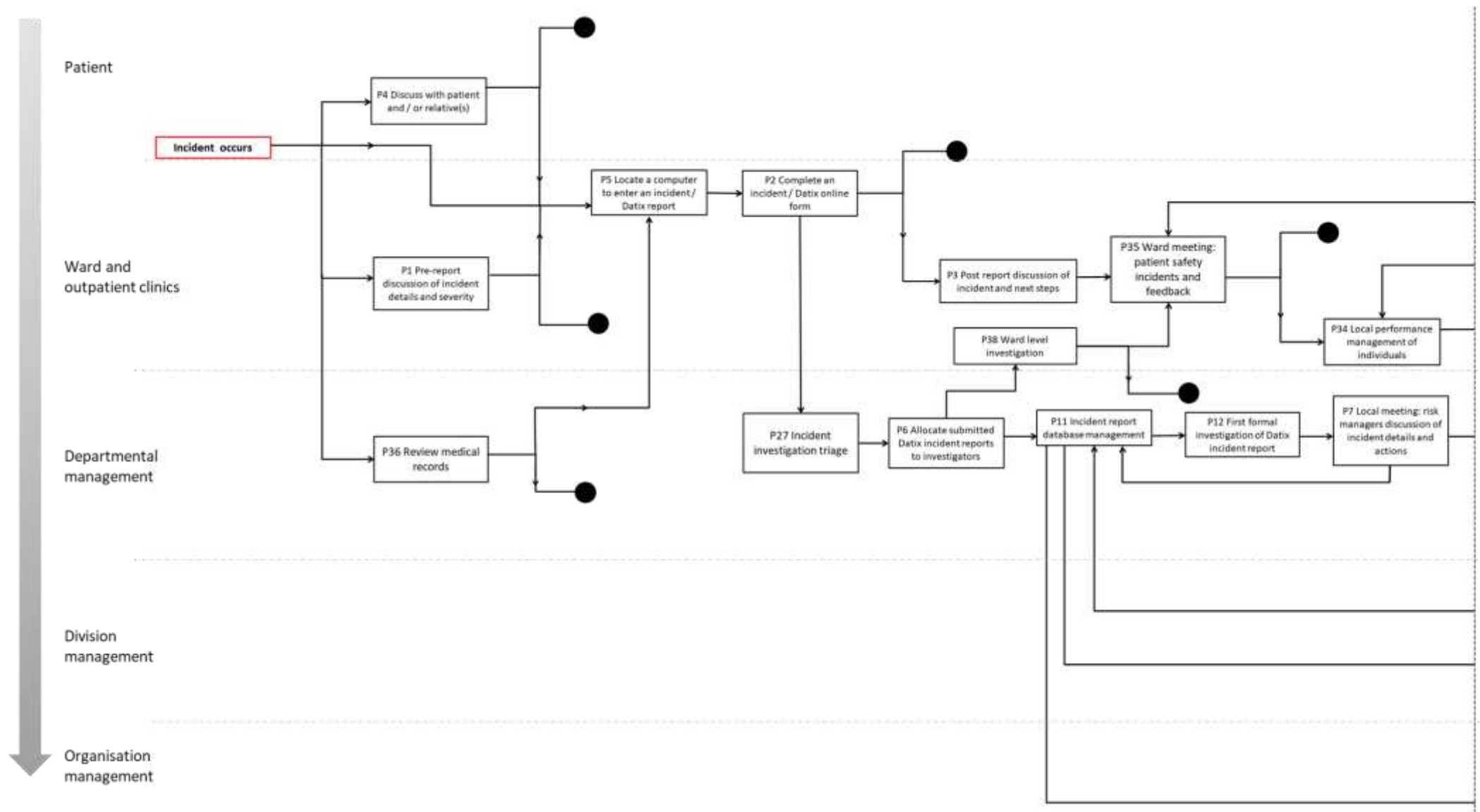
Table 3.2. Non-discrete events removed from the stage one process map. Although these processes are important resource-using events, they are not part of the chronological flow of incident information.

Four events summarised as “reporting” activities relate to the phase between an incident occurring and information being entered into the reporting system, and 17 events summarised as “management” relate to the phase between information about an incident being entered in the report form and the completion of an investigation and sign off by accountable individuals or leadership teams. Three events relate to reporting investigation findings and the number and nature of incident reports, and five events relate to the feedback and implementation of learning(s).

In the incident reporting system, staff referred to 119 affiliated individuals or groups who were involved in the events or training identified (see Appendix C.2), (mean = 8, range = 3 – 21, n = 15). Of these, 33 (28%) were identified by two participants (1 ward-level risk manager and 1 corporate patient safety manager). Several respondents provided estimates of time spent on some of the activities; these are summarised in Appendix C.3.

Low value activities

Three potentially low value activities were identified; these were “Locate a computer” to enter an incident report, “Second formal investigation of Datix incident report”, and “Third formal investigation”.



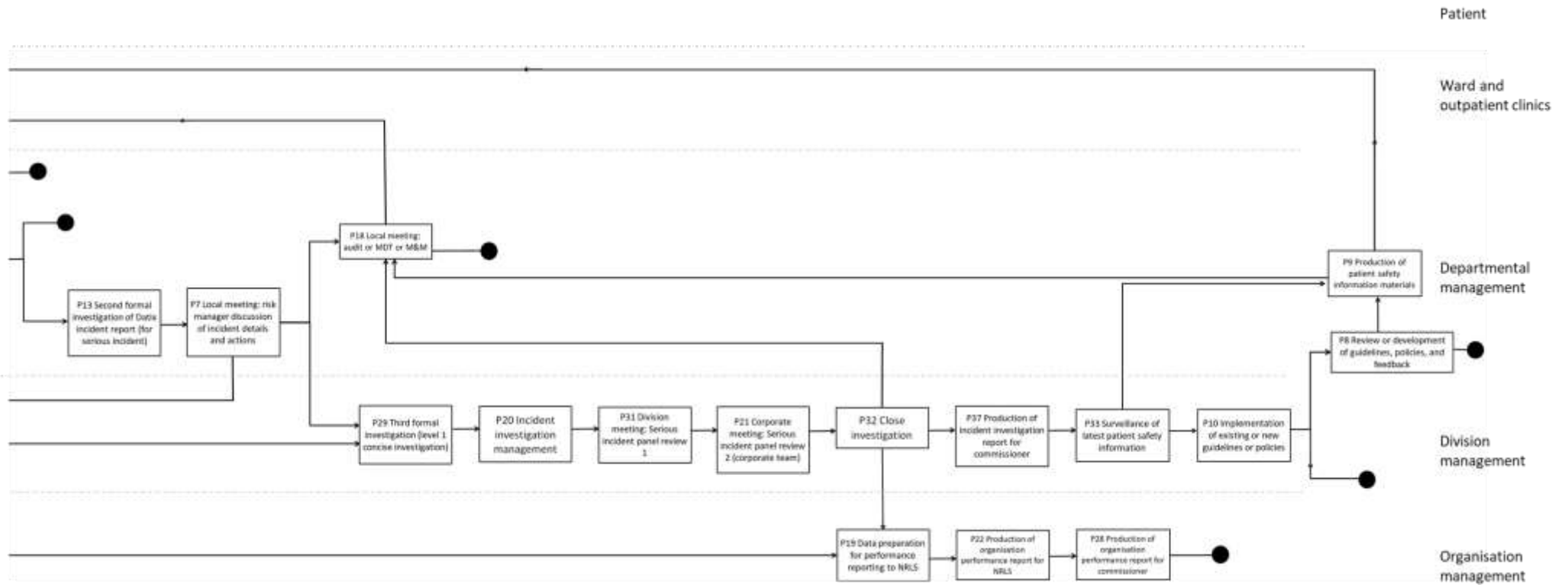


Figure 3.2. Process map of an incident reporting system, derived from the stage one semi-structured interview study

Validation and development of the process map

To test the external validity of the process map derived in stage one, a validity analysis was performed. Overall, 168 participants gave full consent for their responses to be used, whilst 16 did not. All results therefore use data from fully consenting participants only. As summarised in Tables 3.3 and 3.4, the mean NHS experience in the sample was 5.0 years (min = 0.8 years, max = 30 years, median = 3 years). The mean safety rating was 7.3 (SD $\pm$ 1.4) out of 10. The mean score given to all process items generated from the stage one process map was 3.2 (SD $\pm$ 0.42, N = 157). Most participants were 36 – 59 years of age (98/168 or 58%), followed by those 26 – 35 years of age (48/168 or 29%). Most respondents were nurses engaged in clinical practice (49/164 or 30%) or quality managers (49/164 or 30%), including service leaders, educators, auditors, and patient safety managers who may or may not have engaged in clinical practice. Of the 164 respondents, 16 (10%) were consultants, 28 (20%) respondents were doctors (foundation or core trainee), and 11 (7%) had unclear job roles. In terms of demographics, these results suggest broad equivalence of the stage two sample to the stage one sample; however, the stage two sample included a larger proportion of nurses and quality managers. Overall, 90% of the sample were engaged in frontline NHS roles that are strongly associated with the reporting or management of incidents.

A total of 124 participants out of 151 (82%) had used their incident reporting system in the previous 6 months, while 21 (18%) participants had no direct use of the incident reporting system in the previous 6 months; 17 participants did not respond. A total of 115 out of 130 participants (88%) reported being indirectly involved in their incident reporting system in the previous 6 months, while 15 (12%) of participants reported having no indirect involvement in the previous 6 months; 38 participants did not respond. These responses indicate that the sample adequately captures insights from individuals in the English NHS who have been active in incident reporting, management, and investigation processes. At least 80% of the responses came from NHS staff who had engaged in direct use of incident reporting systems within the previous 6 months, which reduces the risk of recall bias in the sample.

A total of 151 participants out of 168 (90%) reported some form of annual patient safety training and 17 participants did not respond. The mean reported duration of this training was 1.7 hours (SD $\pm$ 1.0 hours, min = 0.5 hours, max = 3 hours). The most frequently reported type of training was statutory mandatory training, which was given as an exclusive answer by 68 out of 157 participants (43%), followed by “Other” training types by 64 (41%) participants. Only 5 (3.2%) participants reported having received Datix or incident reporting software

training and 17 participants did not respond. These characteristics indicate that the sample captured NHS staff with standard training in patient safety and incident reporting systems.

Table 3.3. Respondent characteristics summarised using frequency tables		
Variables	Count	Per cent
Age (in years)		
18-25	13	7.70%
26-35	48	28.60%
36-59	98	58.30%
60+	9	5.40%
Total	168	100.00%
Presence of incident reporting system experience		
No	49	29.20%
Yes	119	70.80%
Total	168	100.00%
Last use of incident reporting system		
Less than 6 months ago	124	82.10%
More than 6 months ago	27	17.90%
Total	151	100.00%
Last involvement in incident reporting system		
Less than 6 months ago	115	88.50%
More than 6 months ago	15	11.50%
Total	130	100.00%
Type of patient safety training received		
Statutory mandatory	58	37.90%
General patient safety	11	7.20%
Datix software	5	3.30%
Other	62	40.50%
Multiple entries	17	11.10%
Total	153	100.00%
Annotations added to process map		
No	142	84.50%
Yes	26	15.50%
Total	168	100.00%

Descriptive statistics

The mean response for all variables was 3.2 (N = 157, SD $\pm$ 0.42, min = 1.6, median = 3.1, max = 4). Process variables tested for validity received a mean score of 3.2 (N = 157, SD $\pm$

0.43, min = 1.6, median = 3.2, max = 4) while connector variables received a mean score of 3.0 (N = 121, SD $\pm$ 0.7, min = 1, median = 3, max = 4). Only two processes and one connector scored less than 3.0 and these are summarised in Table 3.4. The evidence for removing these processes and connectors from the process map was not strong and the lowest mean score was 2.8 (SD $\pm$ 0.84, min = 1, median = 3, max = 4) for “Local performance management of individuals”, which is numerically closer to “Agree” than “Disagree”.

Table 3.4. Validity analysis: summary statistics for consenting participants

	Obs.	Mean	St. Dev	Min	Median	Max
Length of experience (in years)	165	5.0	5.8	.08	3	30
Perceived organisation safety rating (1-10)	165	7.3	1.4	3	8	10
Annual Training in patient safety (in hours)	151	1.7	1.0	.5	1	3
Discuss incident with patient and/or relative(s)	148	3.3	.73	1	3	4
Pre-report discussion of incident details and severity	143	3.0	.87	1	3	4
Locate a computer to enter an incident report	152	3.4	.74	1	4	4
Complete an incident report online	153	3.5	.74	1	4	4
Post-report discussion of incident and next steps	142	3.0	.84	1	3	4
Ward-level investigation	131	3.3	.73	1	3	4
Ward meeting: patient safety	138	2.9	.95	1	3	4
Local performance management of individuals	132	2.8	.84	1	3	4
Review medical records	140	3.4	.77	1	3.5	4
Incident investigation triage	132	3.3	.80	1	3	4
Allocate submitted incident reports to investigators	133	3.4	.70	1	3	4
Incident report database management	123	3.3	.67	1	3	4
First formal investigation of incident report	128	3.3	.68	1	3	4
Local meeting: risk managers' discussion of incident details and actions	126	3.3	.59	2	3	4
Second formal investigation of incident report (serious incident)	118	3.2	.76	1	3	4
Local meeting (2): risk managers' discussion of incident details and actions	117	3.1	.75	1	3	4
Local meeting: audit or MDT or M&M	119	3.2	.70	1	3	4
Production of patient safety information materials	91	3.0	.80	1	3	4
Review or development of guidelines, policies, and feedback	102	3.2	.80	1	3	4
Third formal investigation (level one concise investigation)	105	3.0	.90	1	3	4
Incident investigation management	107	3.2	.74	1	3	4
Division meeting: serious incident panel review one	105	3.3	.65	1	3	4
Corporate meeting: serious incident panel review two	100	3.3	.64	2	3	4
Closure of investigation	101	3.4	.68	1	3	4
Production of incident investigation report for commissioner	100	3.3	.72	1	3	4
Surveillance of latest patient safety information	95	3.1	.76	1	3	4
Implementation of existing or new guidelines or policies	107	3.2	.70	1	3	4
Data preparation for performance reporting to NRLS	87	3.3	.73	1	3	4
Production of organisation performance report for NRLS	83	3.2	.74	1	3	4
Production of organisation performance report for commissioner	82	3.3	.73	1	3	4
Connect: 'Allocate submitted incident reports to investigators' with 'Ward-level investigation'	72	3.2	.68	1	3	4
Connect: 'Local meeting: risk managers' discussion of incident details and actions' with 'Incident report database management' (after first formal investigation)	83	3.1	.74	1	3	4
Connect: 'Local meeting (2): risk managers' discussion of incident details and actions' with 'Incident report database management' (after second formal investigation)	73	3.2	.8	1	3	4
Connect: 'Local meeting: audit or MDT [meeting] or M&M [meeting]' with 'Local performance management of individuals'	74	3.1	.65	2	3	4
Connect: 'Production of patient safety information materials' with 'Ward meeting: patient safety'	73	3.0	.78	1	3	4
Connect: 'Production of patient safety information materials' with 'Local meeting: audit or MDT or M&M'	74	2.9	.83	1	3	4
Connect: 'Review or development of guidelines, policies and feedback' with 'Production of patient safety information materials'	86	3.0	.83	1	3	4
Connect: 'Closure of investigation' with 'Local meeting: audit or MDT or M&M'	67	3.3	.59	2	3	4

Connect: ‘Surveillance of latest patient safety information’ with ‘Production of patient safety information materials’	77	3.0	.78	1	3	4

Correlations were also generated to explore associations between demographic characteristics and participants’ responses (see Appendix C.13). No significant associations were found between years of experience and any of the activities or connectors; only a moderately positive association (0.42) was found between participants’ perception of organisational safety and the activity labelled “Implementation of existing or new guidelines or policies”. Very strong positive associations between measures of agreement were found for a small proportion of the incident reporting processes, as shown in Table 3.5.

Table 3.5. Correlations between incident reporting processes

Activity	Pearson’s Rho	Interpretation
Ward-level investigation with Local meeting: risk managers’ discussion of incident details and actions	0.66	Strong association
Ward-level investigation with Division meeting: serious incident panel review 1	0.65	Strong association
Ward meeting: patient safety with Allocate submitted Datix incident reports to investigators	0.68	Strong association
Ward meeting: patient safety with Incident report database management	0.65	Strong association
Production of patient safety information materials with Implementation of existing or new guidelines or policies	0.71	Strong association
Review or development of guidelines, policies, and feedback with Surveillance of latest patient safety information	0.71	Strong association
Review or development of guidelines, policies, and feedback with Implementation of existing or new guidelines or policies	0.72	Strong association
Third formal investigation (level 1 concise investigation) with Incident investigation management	0.62	Strong association
Division meeting: serious incident panel review 1 with Corporate meeting: serious incident panel review 2	0.64	Strong association
Closure of investigation with Surveillance of latest patient safety information	0.66	Strong association

Surveillance of latest patient safety information with Implementation of existing or new guidelines or policies	0.68	Strong association
Data preparation for performance reporting to NRLS with Production of organisation performance report for NRLS	0.92	Very strong association
Data preparation for performance reporting to NRLS with Production of organisation performance report for commissioner	0.90	Very strong association
Production of organisation performance report for NRLS with Production of organisation performance report for commissioner	0.88	Very strong association

Two-way tables were used to test the likelihood that differences in scores between participant groups were due to chance (Table 3.6). For the age group variable and the variable identifying whether participants had any experience of incident reporting systems, statistically significant differences at $p < 0.1$ were found for four variables and $p < 0.05$ for another four variables. For the variable measuring when participants last used an incident reporting system, two variables were statistically significant at $p < 0.1$, while for the variable indicating when participants were last involved in an incident reporting system, three variables were statistically significant at $p < 0.1$. For the type of patient safety training received, five variables were statistically significant at $p < 0.05$, while for the variable indicating whether participants provided annotations to the process map given, four variables were statistically significant at $p < 0.1$ and one was statistically significant at $p < 0.001$.

Table 3.6. Results of Pearson's Chi-squared test for differences in agreement between groups

Statistical significance		
Age group	$p < 0.1$	
	$p < 0.1$	$p < 0.05$
	Complete an incident report online	Third formal investigation (level one concise investigation)
	First formal investigation of incident report	Production of organisation performance report for NRLS
	Data preparation for performance reporting to NRLS	Production of organisation performance report for commissioner
	Connect: 'Local meeting: risk manager discussion of incident details and actions' with 'Incident report database management' (after first formal investigation)	Connect: 'Local meeting: audit or MDT or M&M' with 'Local performance management of individuals'

Presence of incident reporting system experience	Discuss incident with patient and/or relative(s)	Connect: 'Allocate submitted incident reports to investigators' with 'Ward-level investigation'
	Incident report database management	
	Production of organisation performance report for NRLS	
	Connect: 'Local meeting: audit or MDT or M&M' with 'Local performance management of individuals'	
Last use of incident reporting system	Ward meeting: patient safety	Connect: 'Local meeting: risk manager discussion of incident details and actions' with 'Incident report database management' (after first formal investigation)
Last involvement in incident reporting system	Ward meeting: patient safety	Connect: 'Local meeting: risk manager discussion of incident details and actions' with 'Incident report database management' (after first formal investigation)
	Allocate submitted Datix incident reports to investigators	
Type of patient safety training received	Discuss incident with patient and/or relative(s)	Connect: 'Production of patient safety information materials' with 'Local meeting: audit or MDT or M&M'
	Locate a computer to enter an incident report	
	Complete an incident report online	
	Connect: 'Local meeting: risk manager discussion of incident details and actions' with 'Incident report database management' (after first formal investigation)	
Presence of annotations on process map	Discuss incident with patient and/or relative(s)	Implementation of existing or new guidelines or policies ($p < 0.001$)
	Review or development of guidelines, policies, and feedback	
	Third formal investigation (level one concise investigation)	
	Connect: 'Closure of investigation' with 'Local meeting: audit or MDT or M&M'	

Interrater Agreement

Gwet's AC was above 0.7 for responses associated with echelons 3, 4 and 5; however, for echelons 1 and 2 (combined), Gwet's AC was 0.64, which indicates satisfactory interrater agreement. These results are summarised in Table 3.7.

Table 3.7. Gwet's AC for all activity variables and all connector variables									
Gwet's AC	# of subjects	Avg. ratings per subject	Min, max ratings per subject	Coef.	Std. Err.	T	P> T	(95% Conf. Interval), clipped at upper limit	
All process variables	157	22.548	1, 30	0.7055	0.0220	32.13	0.000	0.6621	0.7489
All connector variables	121	5.6116	1,9	0.8091	0.0423	19.11	0.000	0.7253	0.8929

Interrater agreement between participants was measured using Gwet's Agreement Coefficient (AC) for all process variables and all connector variables. Statistically significant agreement, i.e., agreement not due to chance, was observed in both components of the validity analysis, which indicates the process model was statistically robust.

Multivariate linear regression models

Multivariate linear regression models provided more detailed information on the associations between demographic variables and responses given to each activity and connector variable and, separately, by echelon. Regressions where the response variable was the average score for each activity and connector are presented in Appendices C.11 and C.12. Regressions where the response variable is the average score for each echelon of the process map are presented in Table 3.8. In all regression models, the variable denoting “last incident reporting system involvement” was removed from equations due to collinearity with the variable denoting “last incident reporting system use”. Of the six models presented in Table 3.8, between 13 and 33% of the variation in scores given for each echelon was explained by the predictor (demographic) variables.

The coefficients indicate that a one-point increase in the perception of organisational patient safety was associated with a 0.068 higher agreement score in echelon 2 ($p < 0.05$). In the same echelon, participants over 60 years of age gave scores -0.7 points lower than those in the 18 to 25 age group ($p < 0.05$). A weaker association was found for echelon 3 as scores were -0.5 points lower in the over 60 age group ($p < 0.1$). Participants who received general patient safety training provided significantly lower scores across all activities in echelons 2, 3, and 5 ($p < 0.01$, $p < 0.1$, $p < 0.05$, respectively) than participants who received statutory training only.

Table 3.8. Linear Regression with Robust Standard Errors: Consent Only

VARIABLES	Avg. of processes Echelon 2	Avg. of processes Echelon 3	Avg. of processes Echelon 4	Avg. of processes Echelon 5	Avg. of connectors Echelon 3	Avg. of connectors Echelon 4
Clinical or NHS experience (in years)	0.002 (0.010)	0.004 (0.009)	0.004 (0.012)	0.001 (0.014)	-0.000 (0.015)	0.012 (0.015)
Safety rating	0.068** (0.034)	0.040 (0.028)	0.055 (0.039)	0.064 (0.067)	0.123* (0.063)	0.057 (0.047)
Annual training (in hours)	-0.035 (0.041)	0.014 (0.037)	0.139** (0.059)	0.058 (0.066)	0.079 (0.077)	0.089 (0.079)
1.age	-0.276 (0.219)	-0.243 (0.217)	0.116 (0.480)	0.091 (0.525)	-0.026 (0.391)	0.124 (0.405)
2.age	-0.311 (0.210)	-0.197 (0.219)	0.156 (0.491)	0.301 (0.552)	0.451 (0.408)	0.604 (0.408)
3.age	-0.684** (0.266)	-0.456* (0.275)	0.068 (0.614)	-0.084 (0.800)	0.269 (0.477)	-0.164 (0.617)
1.irsexp	0.156 (0.170)	-0.091 (0.139)	0.055 (0.259)	-0.184 (0.288)	0.343 (0.247)	-0.172 (0.361)
1.lastirsuse	0.241 (0.148)	0.075 (0.116)	-0.135 (0.247)	-0.425 (0.302)	0.469* (0.251)	-0.198 (0.398)
1.training	-0.405*** (0.151)	-0.283* (0.169)	-0.064 (0.241)	-0.382** (0.172)	-0.120 (0.250)	-0.193 (0.260)
2.training	0.006 (0.217)	0.241 (0.221)	0.061 (0.246)	0.786*** (0.273)	-0.476* (0.251)	0.002 (0.533)
3.training	-0.038 (0.109)	0.027 (0.093)	-0.073 (0.126)	0.064 (0.193)	-0.094 (0.179)	-0.524*** (0.182)
4.training	-0.292** (0.136)	-0.145 (0.110)	-0.259 (0.258)	-0.000 (0.271)	-0.541** (0.241)	-0.757*** (0.278)
1.annotated	-0.041 (0.119)	-0.001 (0.108)	0.157 (0.163)	0.067 (0.208)	-0.012 (0.192)	0.145 (0.237)
Constant	2.922*** (0.321)	3.180*** (0.302)	2.400*** (0.549)	2.666*** (0.666)	1.429** (0.611)	2.516*** (0.506)
Observations	116	113	94	75	95	71
R-squared	0.174	0.127	0.130	0.149	0.245	0.325

AdjR-squared	0.0692	0.0124	-0.0115	-0.0320	0.124	0.171
Robust standard errors in parentheses						
*** p < 0.01, ** p < 0.05, * p < 0.1						

Assessing convergence: mean agreement scores during the study period

To improve the interpretation of the overall mean agreement score of 3.2, the evolution of agreement during the study was examined visually for all echelons. The extent to which agreement with the processes and connectors in each echelon converged over the course of the study was then plotted. As shown in Figure 3.3 (for each of echelon 2, 3, 4, and 5), the responses given by participants do not appear to converge towards the end of the study. This demonstrates that the study design was implemented consistently and that even though participant feedback was incorporated into questionnaires during the study period, agreement with the process map was not reduced. The aim of the study was to generate greater convergence because this would further validate the resultant process model.

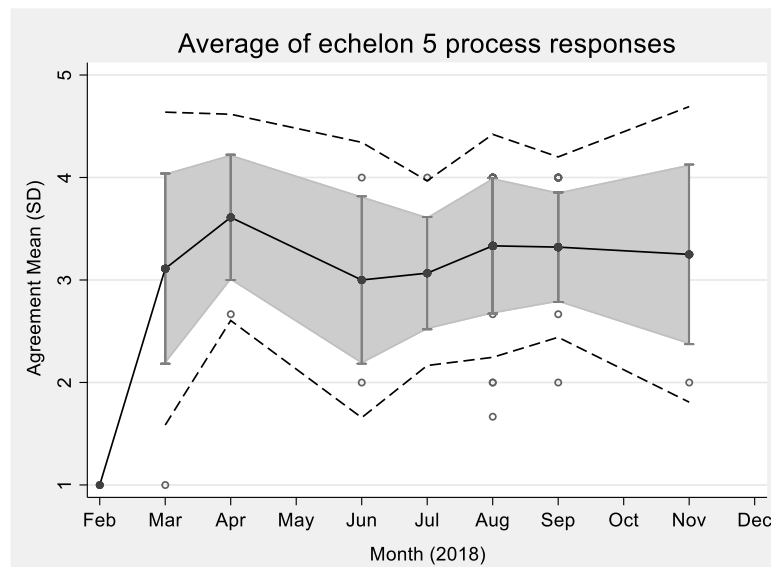
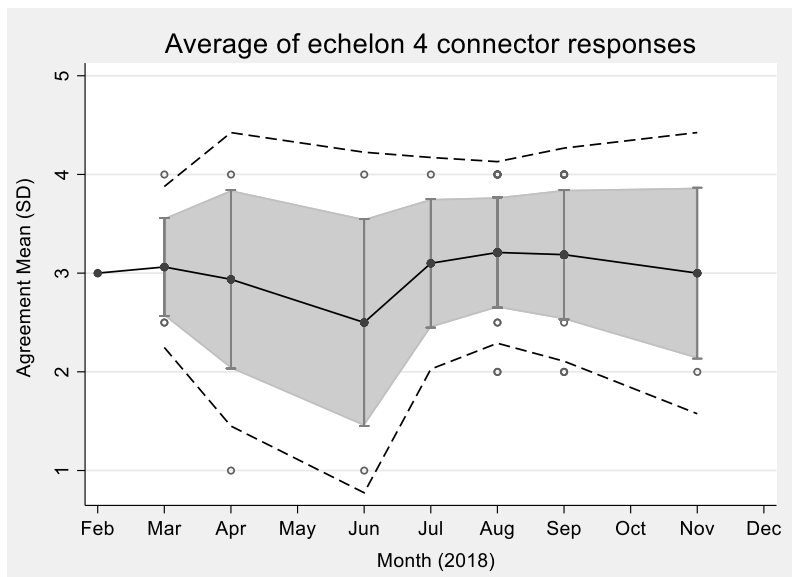
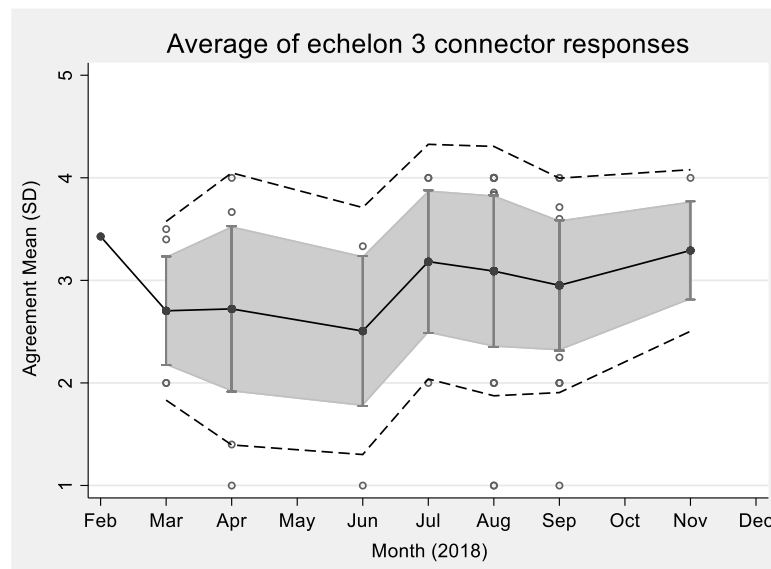
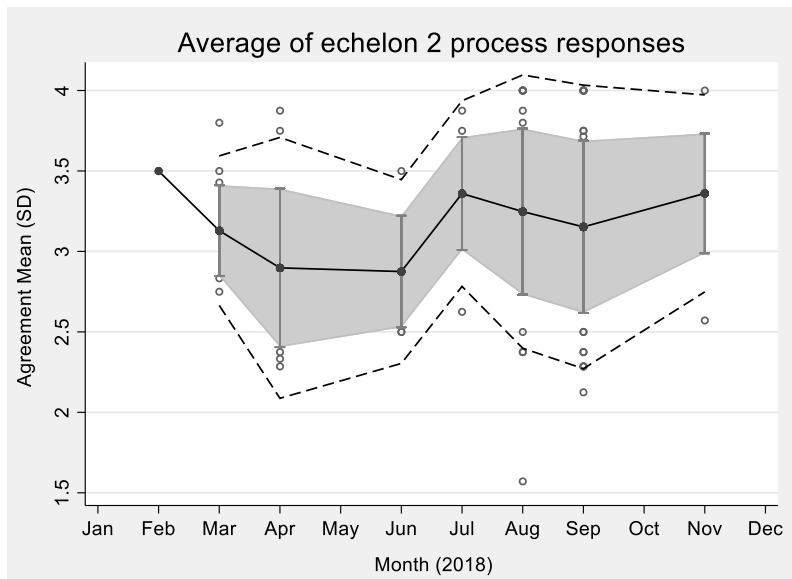


Figure 3.3. Mean $\pm$ St. Dev of participants scores by echelon, over the time frame of data collection. Outlier scores (white circles) depict the size of the variability in terms of average scores.

Discussion

Antonacci et al. (196) describe the use of process mapping in the NHS and present 8 case studies in which the perceptions of users were investigated. The authors identified the following eight benefits of process mapping: developing a shared understanding of the reality; identifying improvement opportunities; engaging stakeholders in the project; defining the project's objectives; monitoring project progress; learning; increased empathy; simplicity of the method. They also identified the following five keys to successful process mapping: simple and appropriate visual representation; information gathered from multiple stakeholders; facilitator's experience and soft skills; basic training; adopting an iterative approach to process mapping.

The aim of this chapter was to derive a validated process map that constitutes an archetype of the inputs and processes involved in incident reporting systems. Reflecting on some of the benefits identified by Antonacci et al., this research makes the following advances: firstly, it initiates the process of gaining further consensus on the reality of incident reporting systems in the English NHS; secondly, it facilitates further improvement of the system, as subsequent chapters will demonstrate; thirdly, it is an effective way to engage NHS stakeholders, which is necessary for any subsequent redesign effort; fourthly, the research and quality improvement priorities can now be more easily defined; and, finally, the process map enables NHS staff to orientate themselves in the wider system, which supports both learning and empathetic stakeholder engagement. In terms of the five "keys to success", the research method employed combined a relatively simple visual representation of incident reporting systems, as described by multiple stakeholders in stage one, with additional, relatively efficient data collection from a larger sample of diverse stakeholders in stage two. To construct the archetypal process map, an iterative approach was used throughout stages one and two. The reproducible methodology adopted makes a novel contribution to the literature on process mapping, which is particularly useful in the context of translational health economics. The utilisation of a validity analysis is a strength because it produced a quantitatively measured consensus on the inputs and processes involved in incident reporting systems. The methods adopted in factor analysis can be applied using this type of study design, which is critical for the transparent reporting of several model assumptions used in economic evaluation.

This is the first use of a validated process mapping method to identify the flow of information entities in incident reporting systems in the English NHS. It is also the first step towards quantitatively identifying problems and inefficiencies and suggesting priorities for the redesign

of these systems. Because data were collected for both stages over three years, the results integrated any structural changes that could confound the findings regarding the process map. The agreement that was built over this period indicates that perceptions of the incident reporting and management processes did not change significantly during these years, suggesting that these processes are relatively static (albeit complicated). The process map can be used as an archetype from which variability in incident reporting and management within NHS Trusts can be mapped and compared. In due course, these local maps can be integrated with the process map derived in this chapter to effectively build an extended system or series of sub-systems that describe incident reporting systems in the NHS. NHS Trusts can also use the archetype as a foundation for quality improvement work. The investigation of associations between participant demographics and levels of agreement provides some evidence of an age group effect that suggests older participants are less likely to agree than younger age groups. Moreover, the linear regression models also suggest that the level of agreement is associated with the type of patient safety training provided. Regarding the responses to the three echelons, participants who reported receiving general patient safety training were less likely to agree with the activities proposed than participants who received simple statutory mandatory training. Interpreting these findings is problematic due to the limitations of the regression models, which do not explain all the variance in the validity scores. The findings suggest that the likelihood of achieving strong agreement for a process map may be lower among research participants with more clinical experience and patient safety-specific training.

The research has several implications for decision modelling in health economics. For instance, economic evaluations of healthcare interventions, particularly clinical level interventions, are conceived from conceptualisations of real-world decision problems. These must approximate the real-world without creating an unnecessary computational burden. Caro et al. (2012) (228) asserted that “validity should not be sacrificed for simplicity” should be adopted as a guiding principle for conceptual modelling. In the extended series on modelling for economic evaluation produced by ISPOR in 2012, checking the face validity of decision models is consistently recommended as best practice in economic evaluation (191, 217–221). This explains the essential need for a validated process map for incident reporting systems. However, the authors of the first six papers in the series do not elaborate on the different types of validity checks that might be appropriate for modelling different systems; consequently, there is no definitive guidance on how to validate models of non-medical interventions. This gap transcends both the articles in this series, and extends to the article by Severens (2003) on

the particular challenges involved in performing economic evaluations of quality improvement initiatives compared to traditional medical intervention (91), as well as the added challenges associated with modelling complex interventions such as information systems. The seventh paper in the ISPOR series is dedicated to model transparency and validity and explores validation methods in more detail from both a definitional and practical point of view; however, the expert group of authors (199) do not recommend any specific methods for particular interventions or modelling scenarios. Vemer et al. (2013) provided a useful commentary on this article, which explains the origin of model validation in engineering and computer science. They emphasised the need for continuous validation of models, stating that the validation process starts from the outset of a modelling project so that inaccuracies can be identified and efficiently addressed throughout (233). Citing research informing model verification and validation, the central lesson on model validation, according to Roza et al. (2013), is that methods should be “traceable, reproducible, transparent and documented” (234) although this guidance is seldom followed (235). Cross-validation and external validity (generalisability) are cited as the two most important forms of model validation by Eddy et al. (2012) (199). In the current chapter, the quantitative data generated from a relatively broad sample of NHS healthcare workers demonstrates that both forms of validation have been transparently documented for use in subsequent studies of incident reporting systems.

Problematic areas of incident reporting and management areas were also identified in the research. In the stage one study, participants consistently described the difficulties associated with completing incident report forms electronically. This theme continued in supplementary comments given in the stage two study and supports findings from other studies on incident reporting systems (69). It appears that, despite years of knowing that incident report forms are cumbersome, some NHS staff in this sample still perceive this activity in a negative light. Second, the investigation of incidents is hindered by the incorrect allocation of investigations to lead clinical investigators, which resulted in up to three “restarts” of investigative activities. This step is rate limiting for downstream activities. The stage two study found there was less support for a third re-allocation of incidents to lead investigators, which indicates that only one reallocation should be incorporated into the archetype. This means that most staff have observed a single re-allocation of investigations and, on occasion, have done so twice. Moreover, there may sometimes be re-categorisation of an incident during incident report triage from the reporting database or during a formal investigation. The stage two study found that this is unlikely, because only a weakly positive consensus was found for this activity. The

identification of these activities and the location of effort duplication informs the generation of hypotheses for further investigation.

As alluded to earlier, the throughput of information entities from the source (a safety incident) is attribute-sensitive in that low harms are most likely to be investigated informally in the ward or unit in which they occurred. Moderate or more severe harms are most likely to be investigated and managed in a formal organisational procedure. The amount of resources consumed in the management of each of these information attributes is likely to differ, with more consumed for moderate or more severe harms due to the engagement of extra personnel.

Time-Driven-Activity-Based-Costing (TDABC) (184,185) represents one essential application of process maps to cost-effectiveness analysis, which is conceptually similar to micro-costing. To enhance its utility, TDABC can be integrated with dynamic simulation methods and this could be an area for future research on incident reporting systems.

Limitations

There are several limitations to this study that need to be addressed. First, it is possible that not all events relevant to incident reporting systems were captured during the study period; therefore, the process model should be viewed as a validated but incomplete estimation of real processes. Whereas the stage one study was conducted in one large English acute NHS Trust with five teaching hospitals, the quality of the process map was immeasurably improved by involving several large acute NHS Trusts in the stage two study. Despite the considerable scope of participation, the sample size falls short of that needed to represent, in statistical terms, the full NHS workforce ($n = 365$). This limits the generalisability of the incident reporting system process map derived in this research. Instead, the map should be viewed as the most authoritative scientifically derived model of incident reporting systems in the NHS, which the validity analysis indicates is internally valid. It does not, therefore, represent other permutations of the whole system or parts of the system (sub-systems) that exist in the real world (as experienced in the “true” NHS population). A clear example of the structural bias of the process map is the lack of detail on feedback and learning, which involves change management steps, and intervention-specific implementation and adoption steps that were beyond the scope of this research. Feedback and learning cycles have been characterised in detail elsewhere and specifically with respect to incident reporting systems by Benn et al. (36); however, the process map identified a smaller number of processes that have previously been characterised. For instance, a process evaluation of the implementation of feedback and learning was not performed in studies in other clinical settings (36). For this reason, the process map is biased

towards the incident reporting and management steps. Therefore, a prospective, observational study conducted over several years, with a larger research team, could identify inputs and processes not captured by our cross-sectional study. These processes are likely to add to the use of resources associated with incident reporting systems in the NHS.

The process model represents a trade-off between complexity and interpretability, which is another reason why the archetype developed is defined as such. To capture additional detail at the first attempt would therefore be prohibitive and, as described by Antonacci et al. (196), would conflict with the final recommended success factor (adopting an iterative approach). Iterations are preferred in process mapping; however, a reasonable degree of saturation should be achieved given the resource constraints of the research. In this study, an aggregate score of 3 (“agree”) from the whole sample was taken as the saturation threshold. However, further iterations and a larger sample size may be needed to achieve a higher level of agreement, if it exists, among expert NHS stakeholders. In addition, the practical implementation of the process map (i.e., translational research) is yet to be tested in the NHS, which may require a higher threshold for consensus if it is to fulfil the intended purpose of supporting further research and improving patient safety through system re-design. Such testing may reveal the dynamic nature of incident reporting systems in the real-world, which is likely given the heterogeneity of processes adopted for the same output and outcomes in the NHS. In this case, the amortisation rate of research evidence may need to be reduced by employing more resources to conduct further studies.

Modeler bias is present in all models of the real-world and, as such, is a source of structural uncertainty in this model and the studies that follow. Although this limitation is difficult to avoid in most process mapping efforts, the intention of the validity analysis was to reduce the “opaqueness” of several process maps present in the peer-reviewed literature. In contrast to focus group methodologies, which risk several forms of social bias, and in-depth interview studies, which are resource intensive when targeting statistically valid sample sizes, the 2-stage methodology balances potential modeller bias with that of participant bias.

This is a topic for ongoing research and the findings presented in this chapter can be challenged using the same methodology, which acute NHS Trusts can reproduce locally. This process mapping study was a necessary first step in understanding the use of resources associated with incident reporting systems in the English NHS, which comes with an opportunity cost. In addition, the process map defines the boundaries of the system we are interested in and the

interactions that occur within it. This provides a more holistic view of the system, alleviating the likelihood of adopting new practices without considering downstream effects. Health economists have advocated adopting this type of approach in research informing resource allocation (236). Furthermore, operational researchers have expressed the fundamental need for a valid conceptual model of a system that is neither overly simple nor over-complicated for discrete event simulation and system dynamic models that can be utilised to optimise resource usage (237).

In computer science, Raffo and Vandeville advocated the use of process feedback in a software development project as a means of improving the predicative (real-world) performance of discrete event simulations (238) 2006). This is the scientific justification for the approach and results described in this chapter. Future models of incident reporting systems can be iterated from the detailed and validated model of the system derived in this study. The predictive power of models of these systems has been enhanced by reducing the uncertainty surrounding the inputs and interactions that occur in the NHS incident reporting system, which will be of value to several research disciplines. Although systematic approaches to developing process models have been promoted in these non-health disciplines (210), they are rarely applied in health contexts (196). As such, the methodology employed in this study is novel and reproducible. It provides a platform for the precise measurement of economic costs and benefits caused by incident reporting systems and constitutes a step towards assessing their relative value when compared with competing activities relating to patient safety. This remains a high priority question that is addressed in the next chapter.

Conclusion

This process mapping study provides valuable information for improving the quality, safety, and efficiency of incident reporting systems in the English NHS. The process map derived is an archetype of the reporting and management process that can be used to obtain more accurate measurements of health resource usage and (opportunity) costs. Cost-effectiveness analysis frameworks, in the vein of translational health economics, can adopt the assumptions provided by the process map to enhance the empirical estimation of incident reporting systems. Healthcare planners can use the process map to standardise and therefore optimise incident reporting systems with respect to persistent sociotechnical idiosyncrasies.

Chapter four: Measuring resource usage in the operation of incident reporting systems in England

Introduction

Chapter one presented research on the economic costs associated with incident reporting systems in the English NHS. The research by Sinclair et al. (80) represents the most detailed attempt in the peer-reviewed literature to measure the costs and efficiencies of operating incident reporting systems; however, the findings are not generalisable due to the low number of staff respondents ($n = 36$), the specialist setting (paediatrics), and the focus on incident reporting processes rather than end-to-end activities. In 2013, Carter (81) conducted a thematic analysis of semi-structured interviews and micro-costing to estimate current NRLS centralised costs and identify wider sources of economic cost. This analysis was combined with a retrospective review of public NPSA accounting records to determine the level of central funding committed to the NRLS since its inception. NRLS specific accounting records were unavailable; therefore, based on expert advice, NRLS expenditure was assumed to be 80% of total NPSA annual expenditure. On this basis, the central costs of operating the NRLS were estimated as a cost per feedback report of £26,000 and an annual recurrent cost of £1.2M. The main limitation of this estimate is that it does not include the frontline costs associated with operating national incident reporting systems, which are managed by NHS Trusts and interface with the NRLS. This lack of evidence on the national frontline costs of incident reporting systems constitutes a significant gap in understanding. The demands on frontline staff and organisational resources because of this technology need to be understood to inform design efforts aimed at maintaining high quality care in the face of growing risks to such quality (17). In addition, in combination with process modelling methods, measurement of resource usage is needed to quantify sources of inefficiency in incident reporting systems. Moreover, a cost analysis is required to inform economic evaluations of these complex systems, which in the long run should help policymakers decide how to allocate scarce resources. This realm of research is part of a general movement towards the economic evaluations of quality improvement interventions, such as healthcare guidelines (89). These forms of economic evaluation are inherently more complex than those conducted on medical interventions (91) and the application of methods to incident reporting systems requires several foundational studies.

From a global perspective, information systems have burgeoned over the last decade and there is a growing need to value data rather than simply collect it. In line with the growth in

information creation between 2000 and 2007, the amount of stored data grew from 50 exabytes (10^{18} bytes) to 300 exabytes (239). To put this in context, this is 1.2 million times more information than was stored by the US Library of Congress in 2011. The potential utility that can be derived from the information collected by economies is unprecedented, which is one reason for the explosion in data collection and storage. However, such utility depends on analytical capability, accurate interpretation, and the implementation or application of the units of knowledge mined from the data. This chapter investigates the resource usage implications of operating incident reporting systems, which is a necessary step towards valuing the data they generate for society.

The need for health data: the necessity of measuring its productive efficiency

Health systems are creating exponentially more data each year. For instance, the Institute for Health Technology Transformation (IHTT) estimated that US healthcare organisations had generated 150 exabytes of data by 2011 (240). Furthermore, the IHTT estimated that correctly leveraged health information could save US systems up to \$300 billion (241), but such systems are struggling to manage and analyse data to achieve efficiency savings. In light of this, the WHO has created a framework for monitoring “health information systems” (242). This framework sets out good practice for the collection and analysis of data to improve population health and exemplifies the need for information systems to generate reliable information to support better decision-making. However, no peer-reviewed evidence describes the resource usage associated with the input of data into health information systems in the UK; as such, there is no information on the opportunity costs borne by using current or alternative systems. The economic cost is likely to be significant and further evidence is needed to inform the development of systems in an increasingly knowledge-based economy and health system.

Nationwide incident reporting systems are information systems that were first developed during this era of unprecedented information growth. Nevertheless, economists have not evaluated their efficiency in order to determine whether the scarce resources consumed by the input and analysis of data results in an overall marginal gain in utility. For these reasons, the resource usage associated with both nationwide systems and local reporting systems needs to be captured through an economic analysis. This research thus offers a unique opportunity to capture resource usage for the first time using a transparent methodology.

Economic evaluation frameworks tend to be either deterministic or stochastic and static methods (with a Monte Carlo simulation as a solution for handling uncertainty). By combining dynamic DES models with time-driven activity-based costing (TDABC) (204), the flow of

information and resource usage implications of this flow can be estimated. This leads to a more dynamic, actionable evaluation of health and social care schemes.

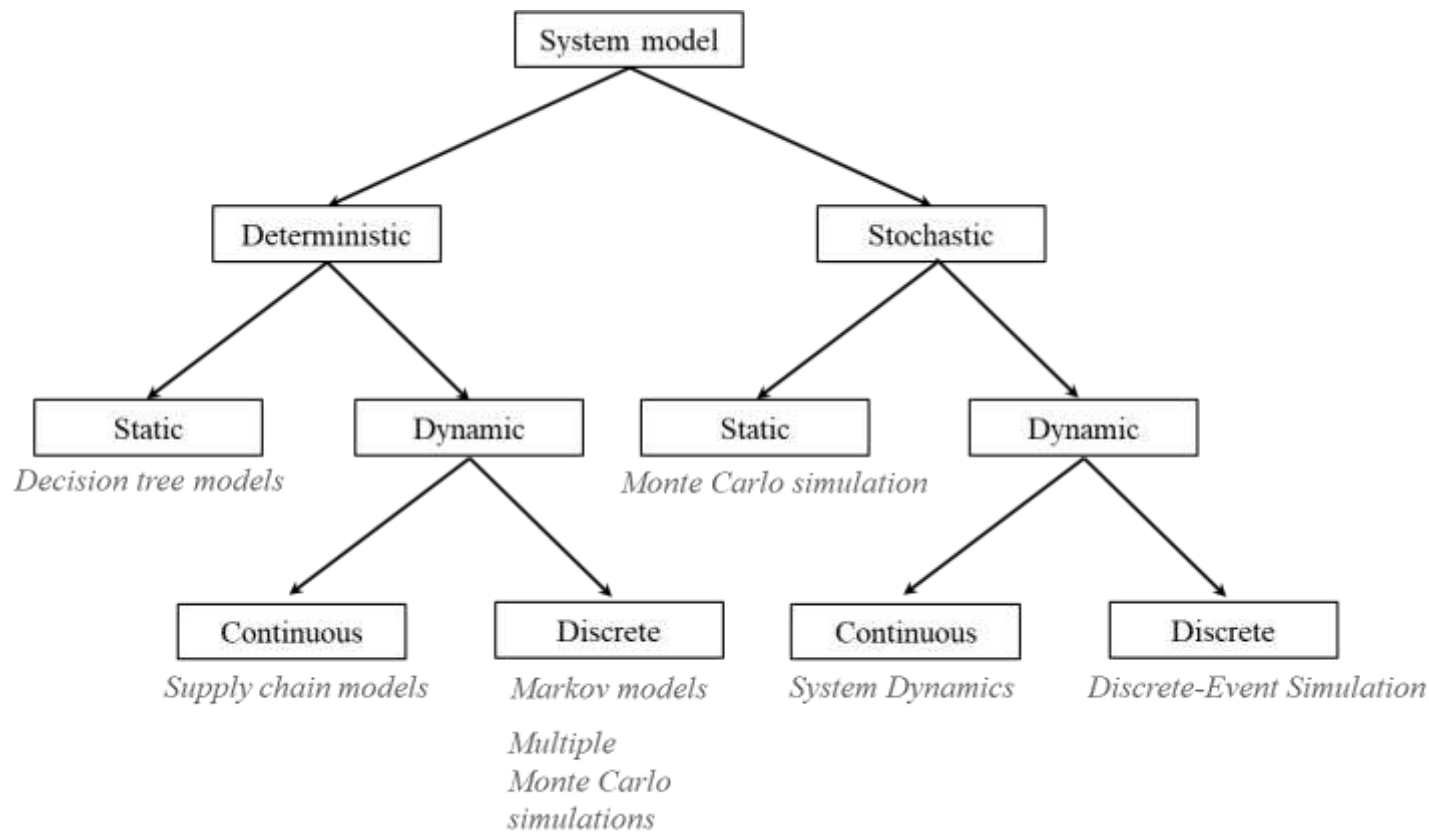


Figure 4.1. Choosing a system model according to research objectives. This is primarily driven by the problem characteristics and availability of data. Economic evaluations routinely use decision trees for short-term, relatively fixed problem-choice scenarios. Markov models support long term decision modelling of the disease state occupancy of entities. Both models can use Monte Carlo simulations to model randomness; however, time is not treated continuously (i.e., transitions are not time dependent). Alternatively, system dynamics and discrete-event simulations offer dynamic alternatives that integrate randomness. The choice to treat events in a continuous time horizon or as time-dependent depends on data availability and modeller assumptions.

Using qualitative research to generate quantitative evidence

There has been an enduring need for operational and translational research in complex, adaptive health systems. The production of evidence is a continuous process with effects on health and economic development. The need for research on the delivery of health services is a core theme in both developed and developing health systems (243) which can be traced back to the landmark Alma Ata Declaration in 1978. Gruen et al. (244) explain the value of framing research efforts in terms of dynamic systems and adopting operational research. In a provocative systematic review on the science of sustainability, the authors report that from the outset, sustainable health programmes have been regarded as complex systems “encompassing programmes, health problems targeted by programmes, and programmes' drivers or key stakeholders”, which interact dynamically within any given context. Sustainable solutions therefore require a mix of qualitative and quantitative evidence to generate the evidence base needed to support reform. This further reinforces the systems thinking approach, the ecological basis (245,246) of which requires qualitative research that complements quantitative analysis.

Systems thinking lies at the core of methodological developments in economic modelling and examples in public health provide a useful introduction to wider applications. Economic models that address systemwide problems are desirable; however, the full landscape of a given system under study is rarely captured, often due to resource constraints. Increasingly, health economic modellers need to be aware of systems thinking paradigms, which originate from the General Systems Theory proposed by Bertalanffy in 1928. In this theory, systems consist of interrelated and interdependent components, and display certain traits to a greater or lesser extent. Simple systems contain relatively few interdependent components with interrelations that are linear and predictable, whereas complicated systems contain several interdependencies with relatively linear and predictable interrelations. Complex systems exhibit many non-linear, dynamic interrelations and interdependencies that create unpredictability and instability (247,248). To construct useful models, mixed methods are needed to address what Trochim et al. (47) identified as the eight practical challenges in supporting effective systems thinking and modelling work in public health.

Aim

The first aim of this chapter is to measure the resource usage associated with incident reporting systems in the English NHS. The second aim is to optimise the use of resources by identifying cost drivers.

Methods

A cost analysis of incident reporting systems was conducted using the process maps derived in the previous chapter. Following convention, three steps were adopted for the cost analysis: identification of cost sources, measurement of resources employed, and monetary valuation of resources (249). The activities derived in chapter three provided the framework for identifying the resources involved in their execution. Frontline resource usage in the NHS in England was then measured and valued. A human capital approach was adopted that involved using the archetypal process map of activities (or discrete events) to value the generation and production of information flows in incident reporting and management.

Identification

The configuration of teams at each of these stages was based on estimates in Chapter three, observations from the stage two study, and proformas completed by clinical governance staff in two NHS Trusts.

Measurement

A structured survey was developed to capture frontline NHS perspectives on the time spent performing the activities contained in the process map. A deductive approach was employed to derive the minimum information requirements for the lowest possible participant response time during facilitated sessions. To achieve this, the process map was consolidated by collapsing or expanding some activities into one or multiple activities. The structure of the questionnaire was amended to improve the efficiency of data collection, primarily by reducing the number of activities inviting participants to respond. This reduced the cognitive burden of data collection and improved face validity based on participant feedback; however, the definitions of the activities and their association with other activities contained in the system were unchanged from those presented in Chapter three.

A total of 107 participants were recruited from three geographical areas: Central London, Greater London, and North England. Following previous studies on patient safety (250), recruitment from geographically and organisationally distinct NHS study sites was attempted to capture a representative sample of the NHS; this reduced sample bias towards organisations in and around London. Participants from the studies in Chapter three were approached for this study and more general recruitment efforts involved advertising across patient safety networks in England and Wales. Snowball sampling was performed with the approval of departmental leads and line managers between January and March 2019. Participants who participated in stage two were invited to take part in stage three. The structured questionnaire consisted of

three sections: 1) participant demographics and level of experience; 2) perceptions of patient safety culture and incident reporting at the work unit/department level; 3) estimations of the lowest and highest amount of time spent on incident reporting activities derived in stage two and stage 3; 4) additional comments on incident reporting system research. To assess participants' perceptions of patient safety culture and incident reporting behaviour in their organisations, the questions in sections one and two were taken from the HSOPS. Each data collection session began with a brief presentation on the economics of patient safety. The process map was introduced to participants by the lead researcher, who briefly presented the validation findings from Chapter three and explained the flow of incident information through incident reporting systems. The facilitated sessions were designed to reduce cognitive dissonance with respect to the definition of activities and the direction of information flow through the map. A glossary of terms was distributed to all participants.

Inclusion criteria

Participants who provided full, informed consent to take part in the study and had interacted with or had experience in using incident reporting systems.

Exclusion criteria

The two exclusion criteria were incomplete consent after recruitment and no interaction(s) or experience with NHS incident reporting systems at the time of recruitment.

Appendix D.8 presents the data collection tool, which was administered as a paper-based bundle to ensure computer accessibility was not a hindrance to data collection and that the process map could be viewed in its entirety without the need for scrolling or zooming. Figures 4.2 and 4.3 were provided to each participant as A3 sized documents and as A0 posters. In-person sessions were also provided so that researchers could observe participants, receive direct feedback on the data collection method, and correct any misunderstandings. Participants were asked to estimate the time spent on activities for which they had experience, either through observation or direct action. To aid researchers' interpretation of the responses, participants were asked whether they had experience in reporting incidents, managing incidents, or both at any echelon of the system. Participants were directed to estimate time spent on activities that corresponded to their experience; hence, experience in reporting and management indicated that more variables would be estimated by participants. This reduced the cognitive burden of responding by ensuring responses were directed to recognisable parts of the system.

Participants were also asked whether their experience occurred less than six months ago, less than 12 months ago, more than 12 months ago, or was unknown.

Time estimates were entered as continuous data and participants could select time units in minutes, hours, or days for each activity. Participants were instructed to estimate the time spent on each activity for one incident only. Low and high estimates could be entered for each activity and participants were instructed that low estimates would be assumed to correspond to a near miss or no harm, low harm, and moderate harm incidents. High estimates were therefore assumed to correspond to severe harm and death, except for activities occurring in the management and investigation of an incident report that escalates to a formal investigation. For these activities, low and high estimates correspond to the amount of time spent on severe harm and death incidents.

Based on qualitative feedback from participants in Chapter three, delay nodes were introduced into the process map and integrated into the questionnaire. These were introduced between high-priority activity connections by the researcher to test otherwise unobserved or unmentioned bottlenecks that do not incur direct resource usage but indicate perceived inefficiency by participants in the system.

Research definitions

The following definitions were given to all participants to improve orientation to the task:

- **Incident reporting systems** are a set of reporting, investigation, feedback, and learning activities undertaken in response to patient safety-related incidents.
- An **“incident”** is defined as any event which has caused potential or actual harm or injury, to patient dissatisfaction, or to damage/loss of property.
- **“Patient safety”** is defined as the avoidance and prevention of patient injuries or adverse events resulting from the processes of healthcare delivery.
- **“Reporting”** is defined as the process up to, and including, the entry of an incident report into incident reporting software.
- **“Management”** is defined as the activities performed by the individuals and teams responsible for formally responding to incidents reported. This aspect includes investigating incidents and providing feedback to relevant staff and departments in their Trust.

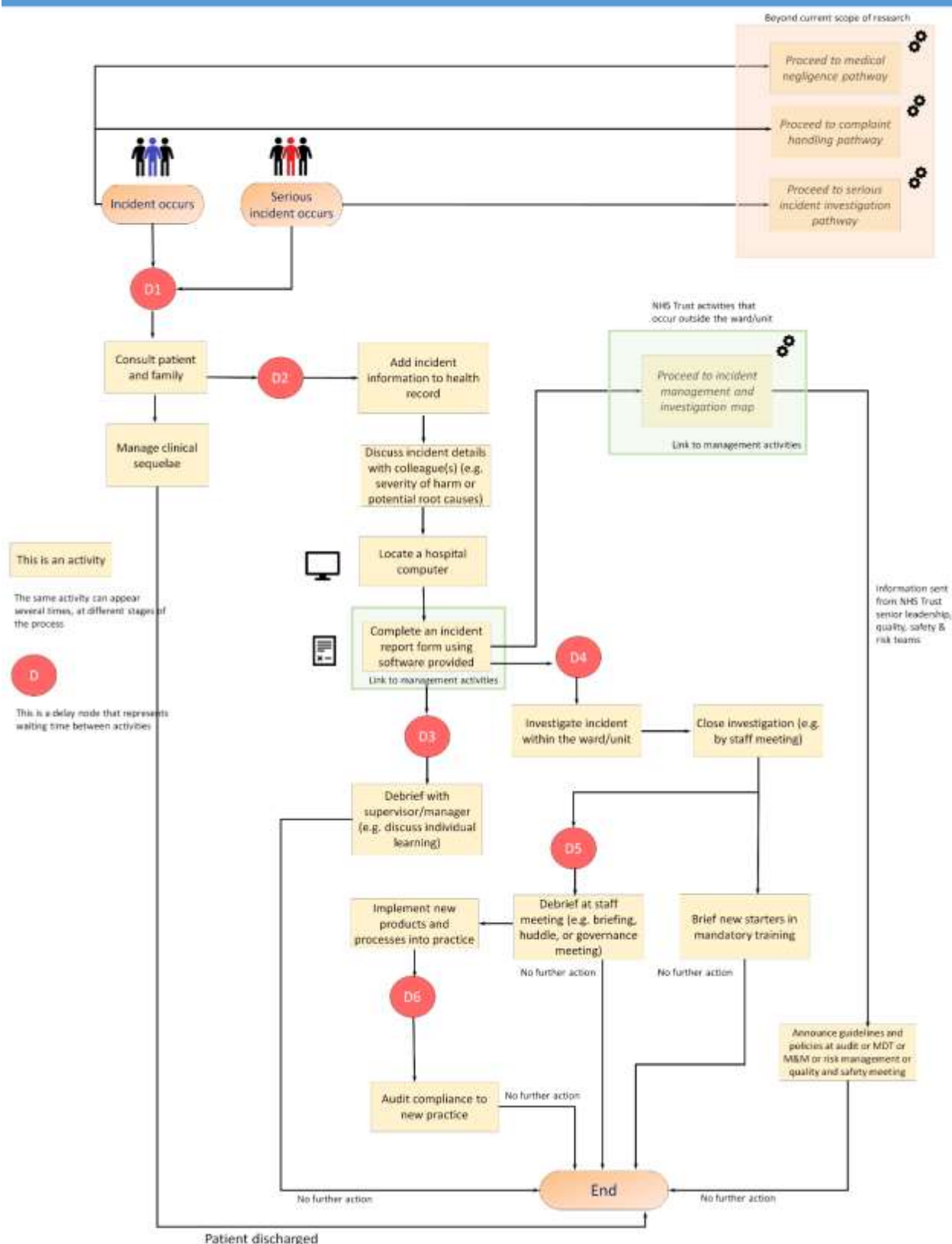


Figure 4.2. Data collection tool for time-driven activity-based costing of incident reporting systems (denoted as “reporting” activities, which encompass patient, ward, and departmental management activities). This schematic was presented to healthcare worker participants from the NHS to facilitate estimates of the time spent on each activity given. These schematics were provided as large posters and within the questionnaire bundles given to participants during facilitated sessions.

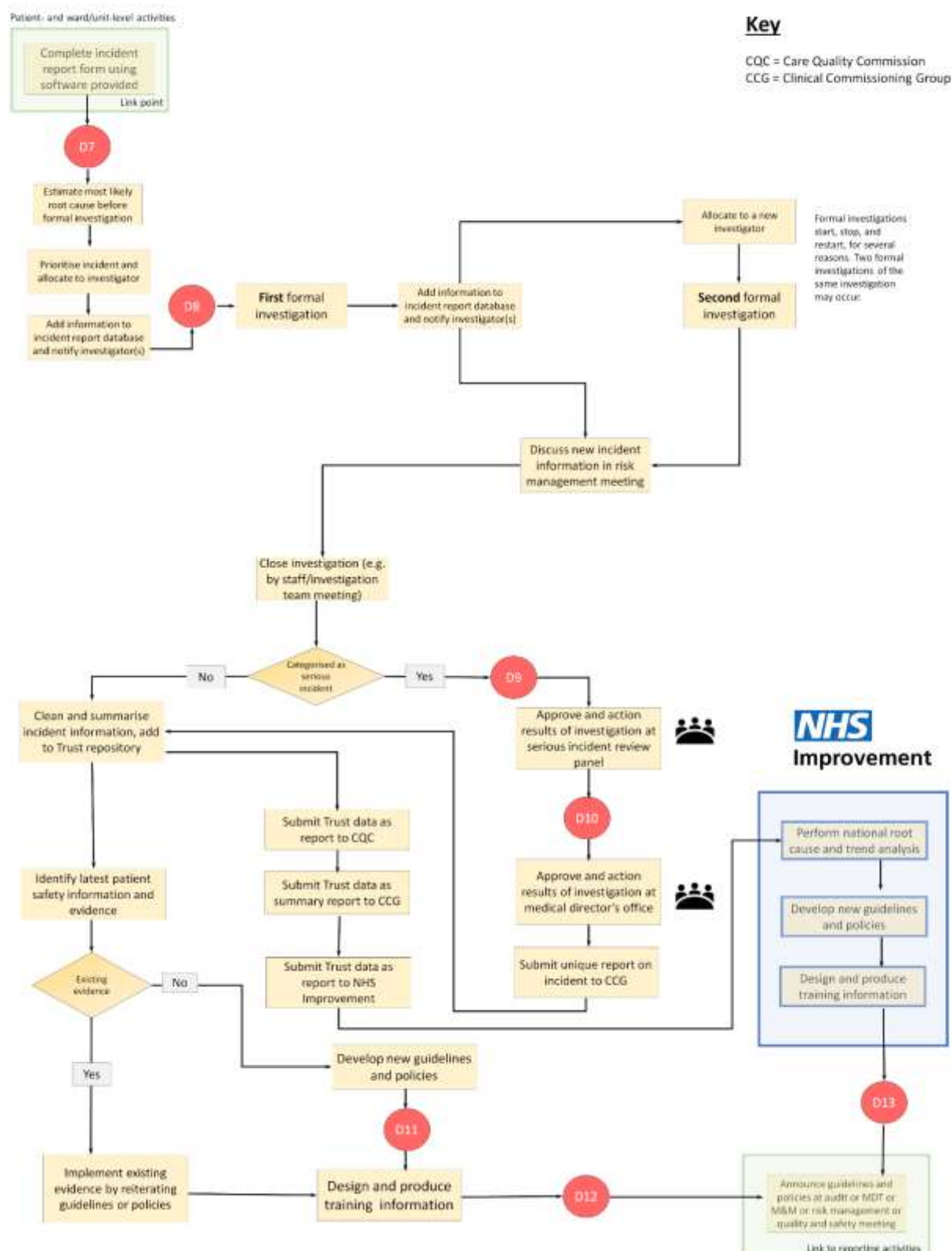


Figure 4.3. Data collection tool for time-driven activity-based costing of incident reporting systems (denoted as “management” activities, which encompass division and organisation-level management activities). This schematic was presented to healthcare worker participants from the NHS to facilitate estimates of the time spent on each activity given. These schematics were provided as large posters and within the questionnaire bundles given to participants during facilitated sessions.

Valuation

The value of activities was estimated by multiplying time-based estimates by the expected hourly wage of the users of incident reporting systems. NHS salary data from the NHS Agenda for Change, which provides the pay schedule for most NHS staff, and the British Medical Association (BMA), which pays NHS doctors' salaries, were used for 2018 to 2019. Salaries for each pay band were converted into minimum and maximum hourly wages for each pay band (from one to nine) or scale (from junior doctor to consultant) and the median was used as a measure of central tendency. Consultants were assumed to be paid under the terms of the General Medical Services contract 2003 and the NHS Medical and Dental Staff contract 2016. Hourly pay was calculated using the number of hours per week worked in the UK in 2018 according to the Office of National Statistics (251). Full time employment was assumed. Total working hours were estimated with an adjustment for a median NHS holiday allowance of 29 days per annum and bank holidays. Minimum, median, and maximum hourly pay was calculated for each pay band or scale by dividing annual salaries by the number of working hours per annum. All resource usage was valued in monetary terms, and unit costs were reported in pounds sterling for the financial year 2018/19. Where necessary, all costs were inflated to 2018/19 prices levels using the Hospital and Community Health Services pay and price inflation index (252).

The mean hourly salary of NHS staff in England was calculated as a weighted average. The number of potential frontline roles with direct involvement in incident reporting systems in the acute sector of the NHS were retrieved from public accounts provided by NHS Digital for the year 2018 to 2019 (253). This included nursing, midwifery, medical, surgical, and allied health professionals, and administrative or management support roles. The proportion of the workforce and the most likely pay band for each role was estimated using guidance from professional bodies.

Analysis of time-based estimates

The time-based data were digitised and converted to standard hour units using Python™. Descriptive statistics for demographic information, perceptions of patient safety culture and incident reporting, and time-based estimates were then calculated, following which the mean and confidence intervals (95% confidence level) for the cost per incident report produced and the average cost per annum of producing incident reports in England were derived. Using strategic cost management methods (254), the cost of each activity was ranked to identify cost

drivers in incident reporting and management with and without an adjustment for the likelihood of their occurrence in practice.

For the time-based estimates, non-parametric bootstrap re-sampling with replacement using median hours was performed using STATA/SE 15. To maximise value from the sample, 1,000 bias-corrected bootstrapped samples were drawn from the original sample (255,256) and resamples taken from participants who provided full consent, whose last incident reporting system experience was less than 12 months ago, and who had relevant experience in incident reporting or management activities. For example, time-based estimates of management activities were excluded if participants only had experience in reporting activities.

Confidence intervals with a 95% limit around the bootstrapped medians were calculated for each activity by multiplying the standard error (SE) by ± 1.96 . Time-based bootstrapped estimates therefore provide a 95% probability that the true population mean for each variable lies within the interval. Skew is an indirect measure of the extent to which the given sample distribution lacks symmetry about the mean, with positive and negative skews indicating that the data are concentrated below and above the mean, respectively. Kurtosis is a measure of whether data are heavy-tailed or light-tailed with a high positive value indicating a sharp peak and a high negative value indicating a flat distribution; to assess closeness to normality, both should be at or close to zero. Quantile-Quantile plots were used to inspect the normality of each variable from the original and non-parametric bootstrapped samples.

Simulations

A deterministic cost analysis was estimated using conservative assumptions and parameter estimates. Lower estimates of time spent on activities were employed and an average hourly monetary cost of £11.50 for all incident reporting system users was assumed, as was the throughput of incident reports in the English NHS from October 2018 to September 2019. To calculate the base case annual monetary cost of incident reporting systems, these bootstrapped time estimates, expressed in hours, were valued by multiplying time by the hourly monetary cost of that time. The hourly cost represents a fixed cost per hour of the reporting and management production line in the NHS, which is a simplification because it does not capture the full range of capital costs employed in the activities. Using the lower estimates provided by participants, the lower confidence interval was the parameter assumed for each variable. All incidents, irrespective of severity, were presumed to follow the activities given in Figure 4.2 and an assumption that all these activities are followed 80 per cent of the time, and are thus

reflected as 80 per cent of the potential cost, was tested. This assumption is arbitrary but was implemented into the base case analysis to reflect the unlikelihood of all processes being performed for all incidents that are reported and managed. The frequency with which each event is performed individually and in aggregate should be considered in resource use estimates; in production economics, this assumption is used as part production capacity estimation. The proportion of incidents that follow management activities was taken as the national throughput of severe harm and death incidents with the same base case assumption that all these activities are followed 80 per cent of the time.

A probabilistic cost analysis was performed using a Monte Carlo simulation with 1,000 trials of the possible annual costs of incident reporting in the English NHS; detailed assumptions are available in Appendix D.1 – D.6. To address the limitation associated with using a fixed hourly cost of capital in the deterministic cost analysis, the hourly monetary cost was varied using parameters derived from NHS salary data, assuming a gamma distribution for nursing, midwifery, medical, surgical, and allied health professionals, and administrative or management support roles for all grades. This hourly cost is higher than that used for the deterministic cost analysis because NHS salary data indicate that the general hourly cost of capital for these staff is greater than £11.50. The mean and median hourly cost using these data is higher and, additionally, the gamma distribution models the probability that the hourly cost could be much higher, such as when many “standard” staff or one or two very senior staff are tasked to handle one activity. This represents the potential for any member of staff to report and/or manage an incident through the incident reporting system based on the assumption that mid-tier and junior employees report and manage incident reports more frequently through the system. The probability of an activity occurring was estimated using information taken from the validity analysis study (Chapter three). The dispersion of responses around the parameter estimate for the level of agreement was assumed to be normally distributed and random draws were selected, which were bounded between one and four. Each random draw was converted to an instantaneous probability of occurrence of that activity by dividing the result drawn by four. This technique maximised the use of information available to inform real world costs and reduced the potential to overestimate costs by assuming that all activities occur all the time. Moreover, it ensured that structural uncertainty in the process model was accounted for whilst maintaining sufficient certainty to derive time-driven activity-based costs. Throughput was not estimated probabilistically because several years of data exist, providing modellers with relative certainty. Therefore, the probabilistic cost per incident report was multiplied by the

expected throughput of incidents through the reporting or management pathways. Consistent with the assumptions communicated to participants, near misses, no harm, low harm, and half of the moderate harm incidents recorded from October 2018 to September 2019 were assumed to follow the reporting activities, which were estimated probabilistically. The remaining moderate harm, severe harm, and death incidents were assumed to follow the management activities probabilistically, although evidence informing these components of the model is limited. These assumptions were informed by NRLS data describing the proportion of all incidents that were categorised as near misses, no harm, low harm, moderate harm, severe harm, or death. Management activities in incident reporting systems involve corporate investigations, which do not take place for all incident categories and may include some moderate harm incidents, namely lower severity incidents may be investigated at a ward or departmental level of the system only. As such, some moderate harms may also be investigated at a corporate level and, for this reason, the volume of incidents that enter the management component of the system should be adjusted. Severe harms and deaths enter the management processes by default; hence, they are part of the throughput of incident information into this part of the system.

A strategic cost analysis was performed to establish the cost driver activities within incident reporting systems. For this analysis, activities were aligned to Benn et al.'s "individual stages of the safety-feedback loop" (36), which were consolidated as "Detect & Capture", "Classify – Investigate", "Formulate", "Implement", and "Monitor". Unweighted costs for each activity were used to estimate the proportion of all costs that originate from these categories, expressed as percentages. Weighted costs were applied separately to explore the cost drivers based on the likelihood of activities occurring in the real world. The weightings and explanations for each of these analyses are presented in Appendix D.6.

Analysis of associations with time-based responses

Multivariate analyses were performed to investigate associations between demographic information, participants' perceptions of incident reporting and patient safety culture in their organisation (independent variables), and individually aggregated time-based estimates (dependent variable) using non-parametric methods. Median values were used, and Kruskal-Wallis ANOVA and median tests were performed for each independent variable derived from participants' responses to the demographic questions. This included tests for statistical associations between participants' unit/department of work, years of experience, professional role or position, NHS pay band (to infer annual salary), clinical specialty, years of specialty-

specific experience, and NHS trust type (NHS foundation trust, mental health trust, acute trust, community health trust). Questions taken from the HSOPS that refer to perceptions of unit-level patient safety culture and incident reporting volume yielded responses for which associations with individually aggregated time-based estimates could be explored. Using two-way tables, Spearman's correlation coefficient was calculated to explore the magnitude and direction of association between independent and dependent variables.

Findings

Sample characteristics

Overall, 103 out of 107 participants consented to take part in the study after the recruitment phase, 74 of whom provided at least one time-based estimate. Of these, 59 participants had experience of incident reporting or both reporting and management, and 43 had experience of incident management or both reporting and management; two participants did not provide a response. A total of 52 participants had experience of either reporting, management, or both components of the system within the last 12 months. Conversely, 22 participants had experience of the incident reporting system more than 12 months ago or did not provide a response. Of the non-missing time-based estimates, participants gave a total of 686 and 720 observations for the low and high estimates of time spent on each activity, respectively. As mentioned previously, the low estimates of time spent are used herein to derive costs.

Most participants identified as belonging to a surgical department ($n = 15$). The next largest representation by unit was radiotherapy and medical physics ($n = 14$), followed by risk, governance, quality management, and corporate departments ($n = 9$). Six participants reported belonging to several different units, six others did not provide their unit affiliation, and five identified themselves as belonging to an anaesthetic unit. The remaining participants identified themselves as belonging to education management, reproductive medicine, neurosciences, and oncology departments.

Most participants had between one and five years of NHS experience ($n = 11$). In addition, more than six years of NHS experience was reported by ten participants and less than one year of NHS experience was reported by six participants. Similarly, most participants had between one and five years of experience in their current unit or department ($n = 14$). Six participants reported over six years of unit or departmental experience and the same number reported under one year of unit or departmental experience. Regarding NHS and unit or departmental experience, 47 and 48 missing observations were identified, respectively. All participants gave

their years of experience with respect to their specialty in the NHS. Of these, the most frequent number of years of experience was between one and five (n = 19), followed by over 21 years (n = 15), 16 to 20 years (n = 12), 6 to 10 years (n = 11), 11 to 15 years (n = 10), and less than one year (n = 7).

The most frequently reported position was an administrative or management role (n = 14), followed by registrar (n = 13), and allied health professional (n = 10). Eight participants identified as consultants and seven as registered nurses. The remaining positions were clinical practice educator (n = 6), matron (n = 3), clinical scientist (n = 2), radiotherapy physicist (n = 2), core or foundation medical trainee (n = 2), pharmacist (n = 2), and risk manager (n = 2). A total of 57 participants indicated their pay band, most of whom were on band seven or eight of the Agenda for Change pay schedule (n = 15, for each). Ten participants were on at least band 8b and ten participants were on or below band 6. Seven participants identified the pay band as inapplicable because they were paid under a general medical contract or junior doctor contract. Finally, 50 participants were affiliated to an acute NHS trust and 19 were affiliated to a foundation NHS trust.

Summary statistics for the time estimates given by participants are presented in Tables 4.1 and 4.2.

Activity	Obs.	Mean	Std. Dev.	St. Error	Median	Skewness
Consult patient and family	30	6.22	16.11	2.94	0.50	3.68
Add incident to health record	25	13.07	48.64	9.73	0.25	4.33
Discuss incident details with colleague(s)	26	9.85	23.82	4.67	1.00	3.47
Locate a hospital computer	27	0.98	2.53	0.49	0.02	2.46
Complete an incident report form...	35	1.59	3.43	0.58	0.33	2.80
Debrief with supervisor/manager	28	6.38	18.06	3.41	0.50	4.59
Investigate incident within the ward/unit	22	21.18	29.28	6.24	8.00	1.89
Close investigation on ward	14	50.32	73.37	19.61	8.00	1.61
Debrief at staff meeting	28	55.98	159.11	30.07	6.00	3.43
Brief new starters in mandatory training	9	215.11	203.62	67.87	8.00	1.86
Audit compliance to new practice	24	248.38	318.04	64.92	192.00	1.89
Announce guidelines and policies at audits...	22	204.56	268.24	57.19	84.00	1.37
Implement new products and practices	9	59.06	82.54	27.51	8.00	1.25

Table 4.1. Summary statistics for time estimates for incident reporting systems by activity classed as “reporting” (N = 52)

Activity	Obs.	Mean	St. Dev	St. Err	Median	Skewness
Estimate most likely root cause before...	13	43.01	131.79	36.55	0.50	3.13
Prioritise incident and allocate...	14	4.41	3.57	0.95	5.00	-0.24
Add information to incident report database...1	15	6.24	14.15	3.65	1.00	3.17
First formal investigation	12	54.33	134.95	38.96	8.00	2.94
Allocate to a new investigator	6	10.51	14.84	6.06	7.00	1.58
Second formal investigation	5	62.80	121.78	54.46	8.00	1.48
Add information to incident report database...2	9	6.47	12.93	4.31	1.00	2.23
Discuss new incident information in risk...meeting	7	10.31	20.39	7.71	1.00	1.95
Close investigation	11	47.84	82.17	24.78	16.00	2.26
Approve...results of investigation at serious incident...	10	123.02	174.64	55.23	24.00	1.14
Approve...results of investigation at medical dir...	5	153.80	207.00	92.57	40.00	0.86
Submit unique report on incident to CCG	4	186.50	223.20	111.60	132.00	0.51
Clean and summarise incident information...	5	36.00	47.83	21.39	24.00	1.37
Submit Trust data as report to CQC	4	182.04	358.66	179.33	4.04	1.15
Submit Trust data as summary report to CCG	5	194.00	261.10	116.77	8.00	0.41
Submit Trust data as report to NHS Improvement	3	163.00	274.55	158.51	8.00	0.71
Identify latest patient safety information..	5	200.60	255.54	114.28	40.00	0.40
Develop new guidelines and policies	4	284.00	344.43	172.22	204.00	0.40
Implement existing evidence by reiterating...	5	368.10	286.06	127.93	8.00	-0.15
Design and produce training information	7	382.86	381.98	144.37	160.00	0.26

Table 4.2. Summary statistics for time estimates for incident reporting systems by activity classed as “management” (N = 52)

Deterministic model

Using the time-based estimates provided by participants to derive a bootstrapped sample, the median cost of reporting an incident using incident reporting systems is £3,655 with a lower confidence limit of £600 and an upper confidence limit of £10,332. The base case annual monetary cost of reporting incidents in the English NHS, based on the total number of incidents reported from October 2018 to September 2019 (1,581,073), is £949M per annum. Using the bootstrapped median cost per incident reported and the upper confidence limit, the annual cost is £5.8B and £16.3B, respectively. These valuations reflect the underlying distribution characteristics of the bootstrapped sample, which is non-normal. As such, using these parameters of the distribution produce much higher costs per incident, which translate directly into higher annual costs when multiplied by the annual incident report volume. The median cost of managing an incident using incident reporting systems is £12,424 with a lower confidence limit of £1,721 and an upper confidence limit of £62,345. The base case annual monetary cost of managing incidents that escalated due to the severity of harm, based on the total number of incidents for the same period (4,982), is £8.6M per annum. Using the bootstrapped median cost per incident reported and the upper confidence limit, the annual cost is £62M and £311M, respectively.

Combining the reporting and management costs for incident reporting systems in the English NHS therefore gives a lower confidence limit annual cost of £956M, a median cost of £5.8B, and an upper confidence limit annual cost of £16.6B. Applying the assumption that all reporting and management activities take place in 80 per cent of incidents thus reduces the lower confidence limit to £765M, the median cost to £4.64B, and the upper confidence limit to £13.3B per annum.

Probabilistic model

Using bootstrapped medians and confidence intervals, 1000 trials based on probabilistic assumptions regarding the frequency of reporting activities and hourly wages resulted in a median cost of reporting an incident of £978 and a mean cost of £1,130. If only near miss, no harm, low harm, and moderate harm incidents follow the reporting component of the system, a total of 1,562,339 incidents were reported between October 2018 and September 2019, the median annual cost of which was £1.5B and the mean annual cost was £1.8B. The lowest cost derived from the simulation was £142 per incident, which is £223M per annum; the highest cost was £5,502 per incident, which is £8.6B per annum. The distribution of simulation results for the reporting component is presented in Figure 4.4.

Similarly, probabilistic assumptions relating to management activities resulted in a median cost of £36,000 and a mean cost of £40,500 for managing an incident that escalated due to the severity of harm. If management activities apply only to severe or death incidents (18,735 incidents for the same period), the median annual cost to the English NHS was £674M and the mean cost was £758M. The lowest cost derived from the simulation was £8,136, which is £152M per annum; the highest cost was £167,991 per incident, which is £3.1B per annum.

Combining the probabilistic estimates for reporting and management components for incident reporting systems in the English NHS results in a median cost of £36,951 and a mean cost of £41,591 per incident. These estimates translate into a median and mean annual cost of £2.2B and £2.5B, respectively. The lowest cost derived from the simulation was £8,315, which is ££432M per annum; the highest cost was £172,616 per incident, which is £10.4B per annum.

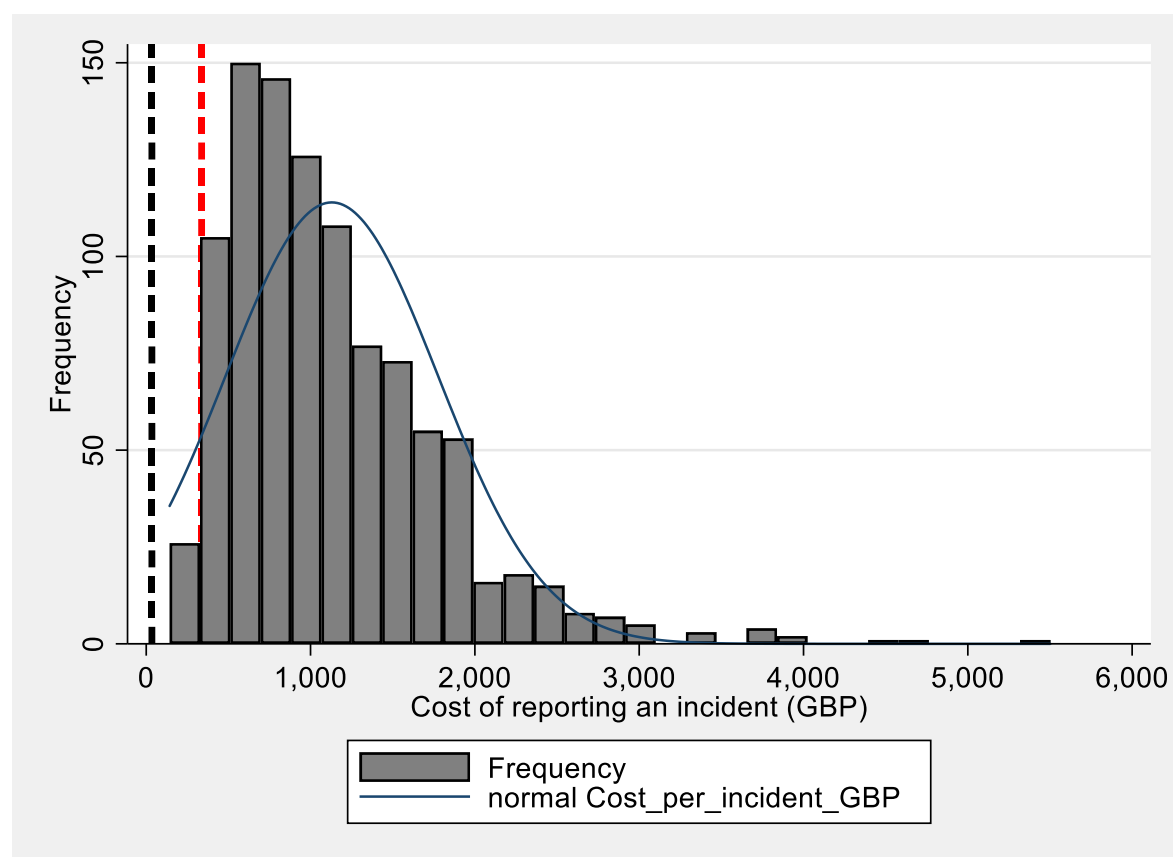


Figure 4.4. Cost of reporting an incident in the English NHS (distribution). Results obtained from a Monte Carlo simulation of frontline staff time-based estimates for the reporting component of incident reporting systems. The black dashed line indicates a conservative estimate of per incident costs of £34.50 by Renshaw et al. (2008) while the red line is an estimate of £337 by Sinclair et al. (2017). This distribution indicates a stronger likelihood of

higher costs per incident reported, which is driven by the identification of more activities requiring resources that comprise the system.

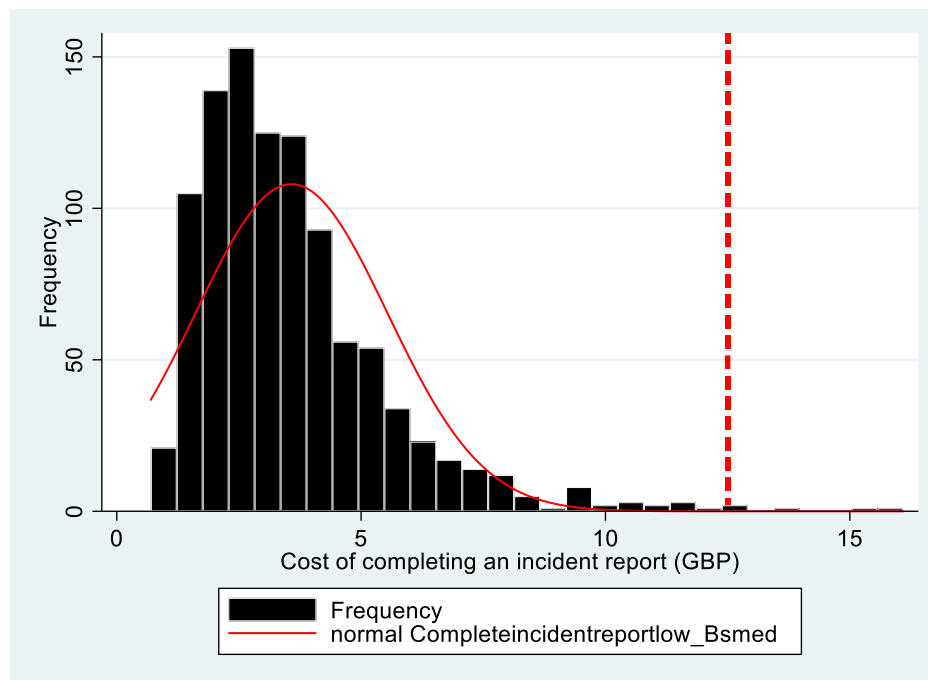


Figure 4.5. Histogram showing the cost of completing an incident report form using the bootstrapped (N = 1000) median taken from the original sample (N = 52). The red dashed line indicates the implied cost of completing an incident report form given by Sinclair et al. (2017).

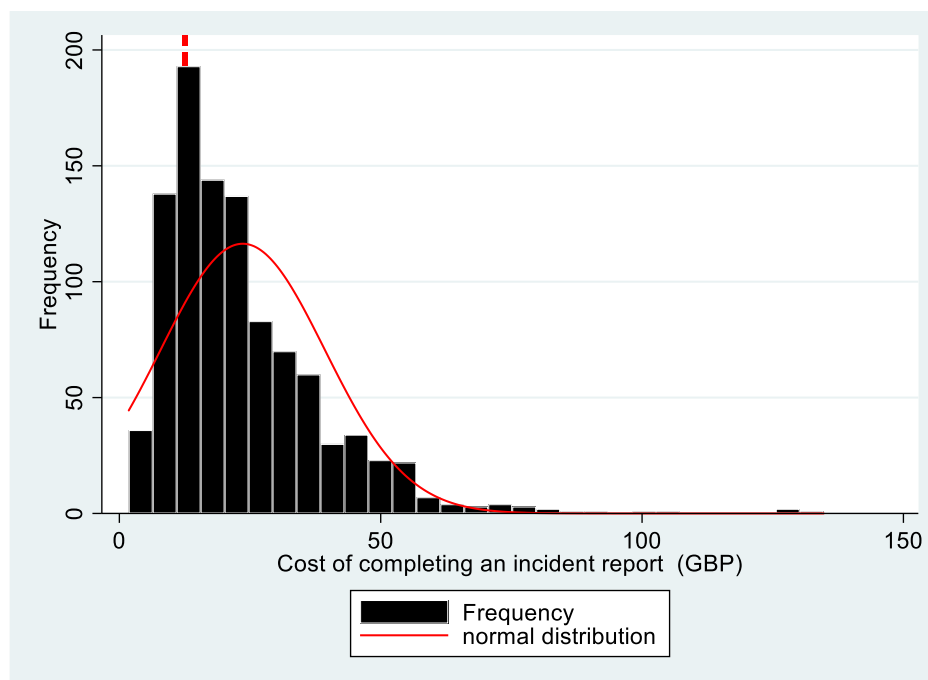


Figure 4.6. Histogram showing the cost of completing an incident report form using the bootstrapped (N = 1000) mean taken from the original sample (N = 52). The red dashed

line indicates the implied cost of completing an incident report form given by Sinclair et al. (2017).

	min	max	Mean	Std. Dev.	Median	1st Perc.	99th Perc.
Cost of completing an incident report (BS mean)	1.794	134.754	23.602	15.714	19.918	4.303	78.276
Cost of completing an incident report (BS median)	.697	16.097	3.576	1.962	3.151	1.012	10.996

Table 4.3. Bootstrapped summary statistics using sample mean and medians for time estimates of completing an incident report form

Analysis of associations with time-based responses

A multivariate analysis was then performed of participant characteristics and perceptions of patient safety culture and incident reporting behaviour. A strong positive association was found between agreement (with the frequency of occurrence) with the statement “We are informed about errors that happen in this ward/department” (comms3) and time spent on incident management. Moderate positive associations were found between agreement with the statement “In this unit, we discuss ways to prevent errors from happening again” (comms5) and “When a mistake is made, but is *caught and corrected before affecting the patient*, how often is this reported?” (repv011). A moderately negative association was found between management time and agreement with the response “Staff are afraid to ask questions when something does not seem right” (comms6). Finally, in this cohort a weak negative association was found between the number of incidents reported in the last 12 months of any severity and time spent on reporting and management activities.

Table 4.4. Multivariate analysis of associations between time estimates for incident reporting and management activities and demographic variables

Variables	(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)	(12)	(13)	(14)
(1) Reporting	1.000													
(2) Management	0.229	1.000												
(3) comms1	-0.161	0.385	1.000											
(4) comms2	0.250	0.374	0.350	1.000										
(5) comms3	-0.019	0.612*	0.384	0.226	1.000									
(6) comms4	0.038	0.085	-0.080	0.371	0.247	1.000								
(7) comms5	0.402	0.241	0.491*	0.092	0.278	-0.001	1.000							
(8) comms6	0.009	-0.449*	-0.488*	-0.406	-0.267	-0.178	-0.055	1.000						
(9) repvol1	0.433*	0.232	0.304	0.072	0.261	-0.143	0.406	-0.323	1.000					
(10) repvol2	0.323	-0.045	0.118	-0.120	0.051	-0.014	0.294	0.019	0.624*	1.000				
(11) repvol3	0.106	0.076	0.285	0.227	0.112	0.100	0.109	-0.167	0.620*	0.644*	1.000			
(12) safety rating	-0.143	-0.121	-0.180	-0.271	-0.394	-0.343	-0.317	0.253	-0.435*	-0.288	-0.558*	1.000		
(13) repnum1	-0.202	-0.341	0.120	0.030	-0.005	0.037	0.043	0.355	-0.013	-0.127	0.117	-0.240	1.000	
(14) repnum2	-0.245	-0.216	-0.118	0.096	0.037	-0.203	-0.203	0.195	-0.013	-0.237	-0.102	0.080	0.442*	1.000

Spearman rho = 0.442, *p < 0.05, Obs. (21)

As shown in Table 4.5, there is strong evidence ($p < 0.05$) that the overall time estimates and time estimates provided for the reporting component of incident reporting systems differed significantly between staff groups. Evidence that differences in time estimates were driven by years of experience in participants' specialty was weaker for reporting estimates alone ($p < 0.1$, median test); however, when time estimates for reporting and management activities were combined, the differences were stronger ($p < 0.05$). Weak evidence was also found of differences between responses to the question "When a mistake is made that *could harm the patient*, but does not, how often is this reported?" (Reporting volume 3) and reporting and overall time estimates ($p < 0.1$), and between management time estimates and communication quality within ward units. There was also weak evidence to suggest that participants' perceptions of the safety of their organisations was associated with differences in the magnitude of overall time estimates ($p < 0.1$). The statistical outputs for these associations are reported in full in Appendices D.9 to D10.

		Test for between group differences	
Component	Obs.	Kruskal Wallis rank test significance (p value)	Median Test significance
Reporting			
Position	49	0.01	0.03
Specialty years	50	>0.1	0.08
Reporting volume 3	46	0.06	0.09
Management			
Comms 3	40	>0.1	0.03
Comms 4	40	0.09	0.1
Comms 6	40	0.05	0.1
Safety rating	39	0.2	0.08
Overall			
Position	66	0.01	0.02
Specialty years	67	0.02	0.04
Reporting volume 3	60	0.06	0.09
Safety rating	61	0.08	0.08

Table 4.5. Kruskal-Wallis, ANOVA, and median test results for between group differences in time spent on three components of incident reporting systems. At $p < 0.05$, evidence of statistically significant between-group differences in estimated time spent on each activity was found for Position and Specialty Years (years spent as a qualified specialist).

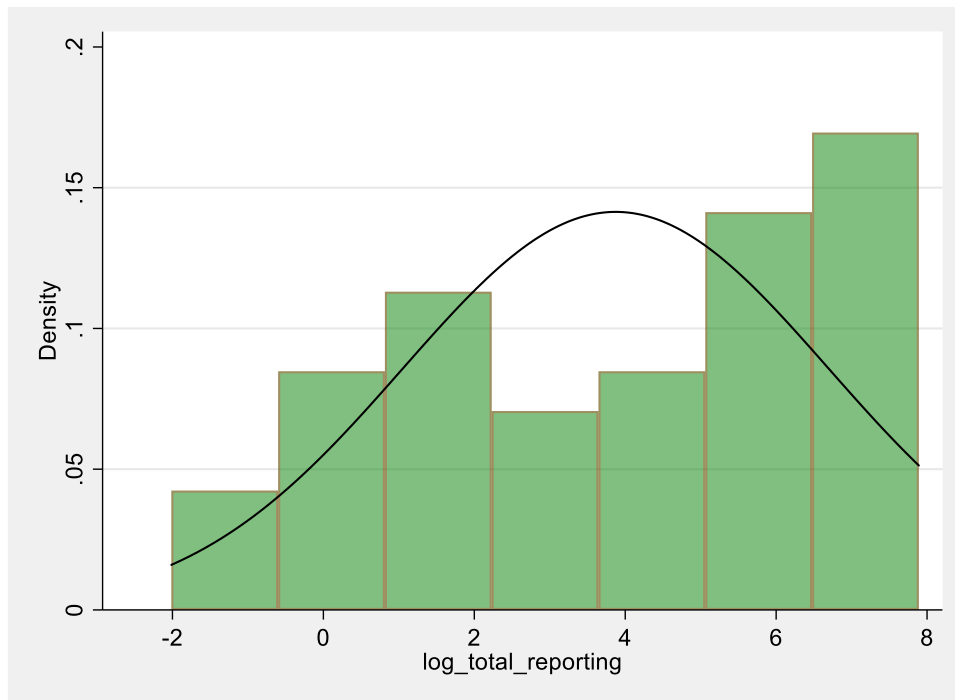


Figure 4.7. Log transformed time estimates for total reporting, which is the sum of individual estimates, by activity, given by participants ($N = 52$). The non-normal distribution confirms that non-parametric statistics are more robust for association tests.

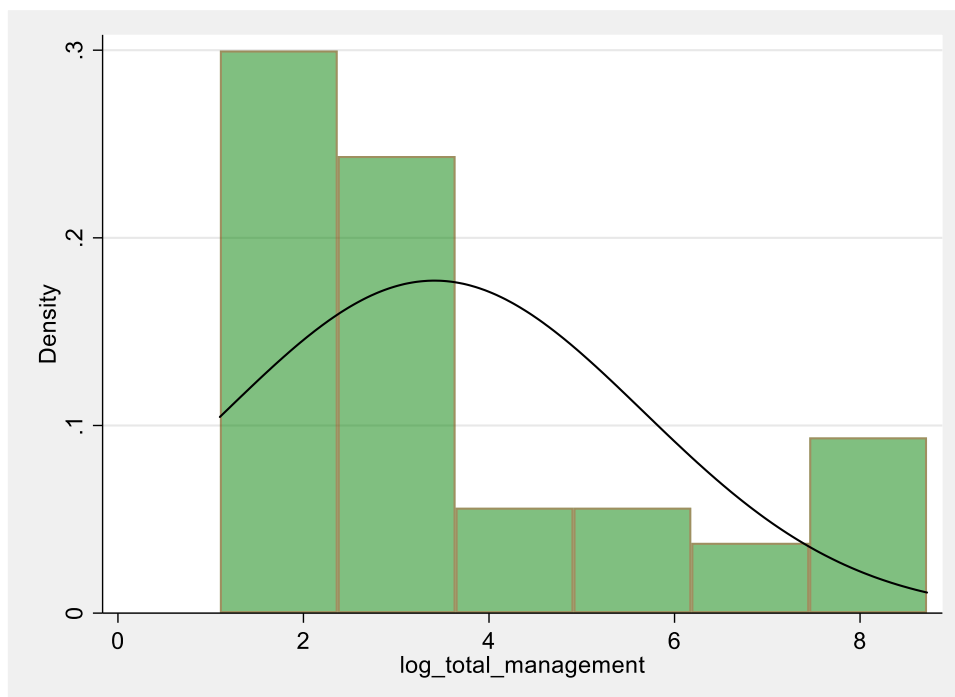


Figure 4.8. Log transformed time estimates for total management, which is the sum of individual estimates, by activity, given by participants ($N = 52$). The non-normal distribution confirms that non-parametric statistics are more robust for association tests.

Strategic cost analysis of incident reporting system activities

A strategic cost analysis was performed to identify the activities that comprise incident reporting systems which have the highest resource usage. Using the mean or median values derived from the Monte Carlo simulation (1,000 trials) did not change the ranking of cost drivers. The highest cost activities, without adjusting using weightings for likelihood of occurrence, were “Formulate” activities (41% of resources consumed), which are activities relating to the development of new guidelines or policies in response to findings from formal investigations (Figure 4.9). These activities only occurred in the upper echelons of the system, namely departmental management and above. The next highest cost activities were “Detect & Capture” (24% of resources consumed); followed by “Implement” changes in work systems (19%) then “Classify – Investigate” activities (12%) and, finally, “Monitor” (4%). For the entire system, ward-level activities (see Figure 4.2) accounted for only 13% of all costs; the remaining costs were incurred in departmental management echelons and above (see Figure 4.3). Overall, 65% of all costs in these echelons were incurred by performing “Formulate” (41%) and “Detect & Capture” (24%) activities; the latter refer to organisational reporting to NHS institutions.

The subsequent weighting of the cost of each activity based on likelihood of occurrence resulted in a different ranking of the categories (see Figure 4.10). “Detect & Capture” comprised 52% of all costs, followed by “Classify – Investigate” (34%) then “Implement” (7%). “Formulate” activities accounted for 5% of all costs when adjusting for the likelihood of these activities occurring, which is lower than when we assume these activities only follow the occurrence of moderate harms or death-related incidents. “Monitor” activities once again constitute the lowest proportion of costs in the ranking, although without decimal points this is the same proportion as “Formulate” activities (0.5%). With weighting, the cost of activities in the patient and ward-level echelons is 28%, leaving the remaining portion of all costs (72%) in the upper echelons.

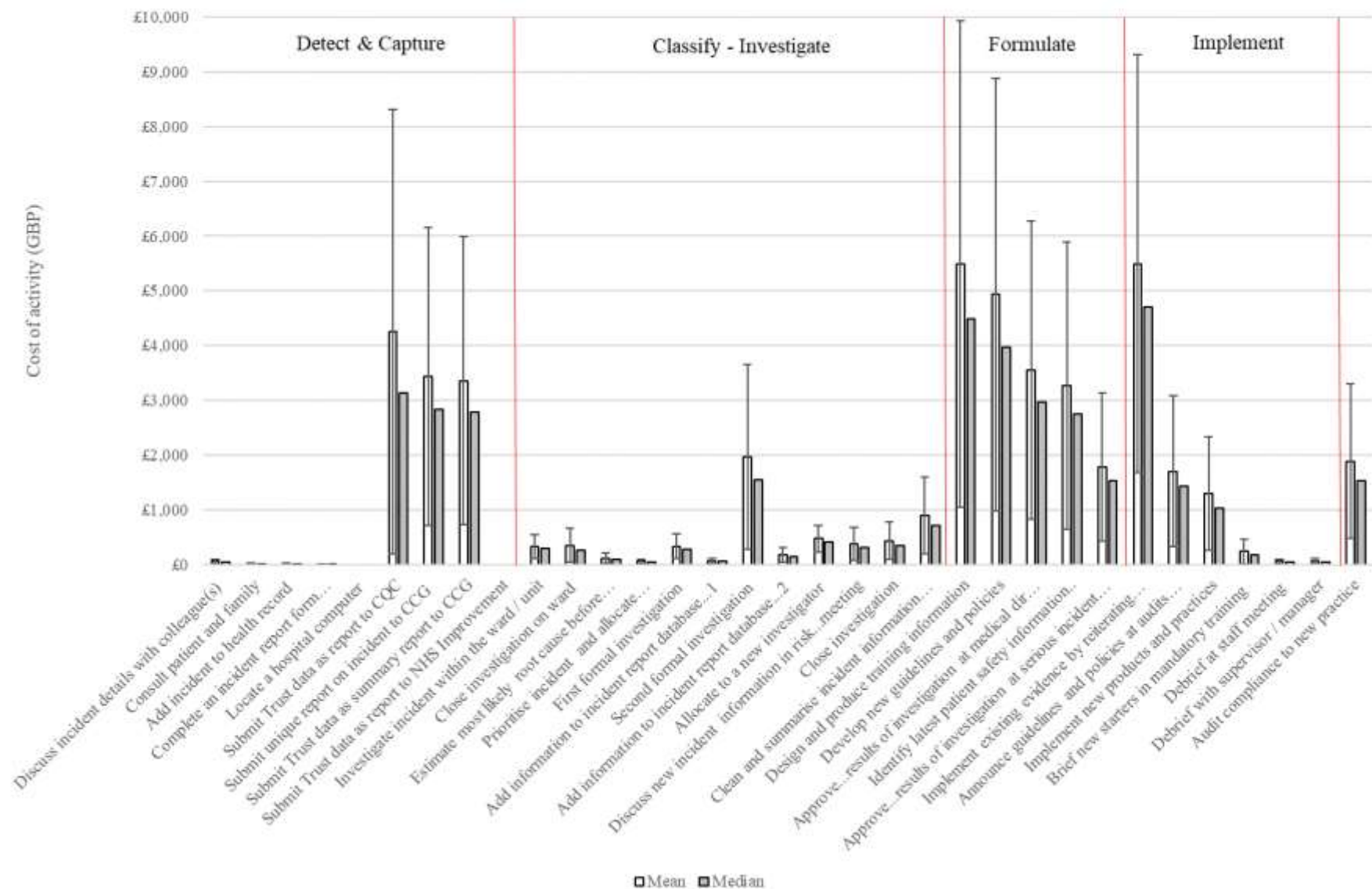


Figure 4.9. Activity-based costing of incident reporting systems using mean and median costs derived using Monte Carlo simulations. Activities are ordered chronologically and aligned to the sequencing structure specified by Benn et al. (2009) to indicate areas where the most resources are consumed. “Detect & Capture” activities account for 52% of all incident reporting activities when the likelihood of “Formulate” activities occurring is reduced.

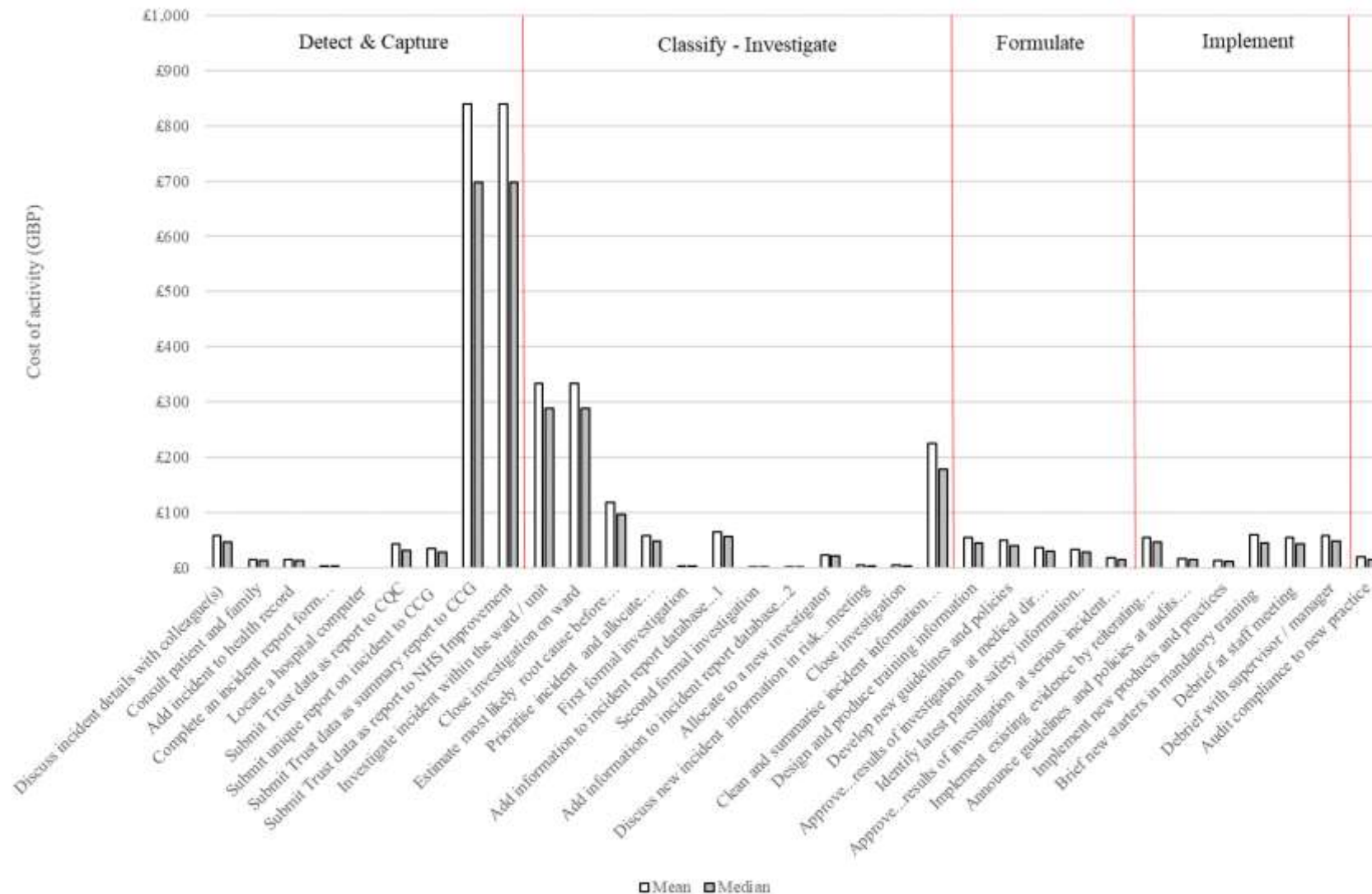


Figure 4.10. Activity-based costing of incident reporting systems using mean and median costs derived using Monte Carlo simulations. Activities are ordered chronologically and aligned to the sequencing structure specified by Benn et al. (2009) to indicate areas where the most resources are consumed. “Formulate” activities account for 41% of all incident reporting activities.

Discussion

The findings from this costing study indicate that the annual economic cost of reporting incidents in the English NHS / NRLS is £949M *per annum*. Managing incident reports for some moderate harms, all severe harms, and deaths is more resource intensive, but occurs less frequently, which explains their relatively modest cost of £8.6M *per annum*. Incorporating all levels of harm reported and managed in the NRLS, these estimates represent 1% of the total annual accounting expenditure of the NHS in England and 90% of the total annual cost of unsafe care occurring in the NHS. Depending on the assumptions used, these estimates could be much higher.

This is a significant finding in that it differs considerably from historical opinion-based estimates that limited their analytical scope to reporting only. As discussed in Chapter one, Renshaw et al. stated that incident reporting was “equivalent to 1,184 UK National Health Service (NHS) employees spending all their time each month completing incident forms”(77). Furthermore, using a peer-reviewed method, the mixed methods analysis by Sinclair et al. provided a contemporary estimate in the UK (80) which was also limited to incident reporting form completion and certain management activities, although the latter were poorly defined. The cost analysis conducted in this study identified a daunting increase in the estimated resource usage associated with national incident reporting systems in England. However, the estimate is the most transparent ever produced and adopts the principles of systems modelling, which is appropriate given the complex constructs involved (248) and the need to address problems with incident reporting systems (201) from a novel perspective.

The centralised costs of the NRLS that were estimated by Carter in 2013(81) do not include the economic activity underpinning data production across the health system. Such costs are increasingly significant given ongoing growth in the number of incident reports submitted by NHS Trusts to the NRLS by frontline healthcare workers. The cost of producing an incident report is a component of the cost of producing feedback reports and, when combined, as this study demonstrates, the cost of the production system is much higher than centralised accounting costs. The economic costing represents a demand on healthcare workers and organisations; in the case of incident reporting, such demands could be traded for, as an example, clinical consultations. This constitutes a resource allocation decision in patient safety that can now be more easily addressed using the evidence produced in this chapter.

Limitations

Time-driven activity-based estimates can be collected in several ways; however, some methods are more valid than others. For instance, the main limitation associated with the time-driven estimates provided in this study is potential respondent bias. The method adopted did not comprise an observation-based approach because the end-to-end process of incident reporting and management at the managerial levels of NHS organisations is unpredictable. This is driven by the randomness associated with where and when harm will occur in the NHS. Unpredictability also arises due to the reactive nature of incident management which, as described in Chapter three, follows a process. Nonetheless, the timing of such processes cannot easily be integrated into a collaborative study design. There are also ethical concerns that arise with respect to researchers interrupting patient safety activities within the NHS. For these reasons, the design relied on participants' recollection of time spent on their regular business activities. This also means that recall bias may be an issue with respect to assessments of the time spent on activities involved in the incident reporting system. The recentness of participants' experience with incident reporting systems was therefore checked for this analysis, although this could also be biased. The direction and magnitude of respondent and recall bias is difficult to estimate given the novelty of this study, yet it must be acknowledged that the estimates informing the cost analysis could have led to a meaningful under or overestimate in the findings.

A second limitation of this study concerns the sample size. After removing observations from participants who did not provide informed consent and/or did not indicate recent experience with incident reporting systems, the usable sample size was lower than that needed to be considered representative of the target population, as stated by Krejcie and Morgan (1970) (257). However, given the exploratory nature of this research, this limitation can be addressed in future research. Moreover, views on sampling in survey-based research vary as some scholars argue that small samples are justified if larger samples are not economically feasible (258) while others contend that sample sizes as small as ten or 20 are acceptable for experimental designs (259). Nevertheless, the descriptive design of this study and the large population size (theoretically, all NHS healthcare workers) warrants a larger sample size in future research on this topic. This will entail overcoming a practical challenge associated with the data collection method, which was that it involved relatively intensive in-person sessions. To scale data collection of this type in future, the lessons learnt from this methodological

approach can be applied to digitised data collection tools. Such methods were too prohibitively expensive to be considered feasible for this research.

Several of the assumptions made in the deterministic and probabilistic cost analysis were arbitrary and this is an important scientific limitation of the study. Specifically, it was not possible to collect data that would inform assumptions related to the hourly costs of operating incident reporting systems in the NHS. This was also the case for assumptions regarding the real-world throughput of incidents into the (specific) activities of the system, and when estimating the extent to which incident information is transferred to some or all the management activities. Despite this limitation, it was essential to use these assumptions to adjust the simulated costs because it is unrealistic to assume fixed costs and fixed incident information trajectories in these models. Therefore, to optimise the modelled costs, these assumptions require further investigation.

The costs estimated in this study are at risk of being under or over counted if individuals are unable to disentangle their estimation of time spent on two or more activities given in the process map. For instance, staff meetings that cover several topics per session, including those unrelated to incident reports and perhaps even unrelated to patient safety, may have been viewed by participants as activities that were wholly related to incident reporting or not related at all. Participants provided discrete responses according to each activity presented to them, but this does not mean all estimates were free from recall bias, or under or over counting. This challenge could be addressed using observation-based methods that are conducted in real-time relative to the activities themselves; however, this method would also suffer from observer bias if participants modified their behaviours (260). Moreover, when using such a method, the onus for defining discrete activities and measuring the time spent on them falls on the researcher rather than the expert healthcare worker, which could exaggerate any bias caused by circumventing direct-expert responses. This limitation is difficult to address in general modelling and simulation as it involves simplifying the process map for incident reporting systems enough to generate time-driven estimates without losing the fidelity needed for evidence to be translational. For this reason, the validation results in Chapter three handle this limitation efficiently as they provide greater confidence in the discrete counting of time spent on the activities costed.

Conclusion

In response to calls for the adoption of study designs that can be translated into practice (261,262), this study demonstrates how health economic analysis can be applied to quality

improvement. This research is the first to report nationwide economic costs associated with incident reporting systems. Previous cost analyses have grossly underestimated these costs by adopting study designs that do not consider the complicated array of activities involved, thereby reducing the scope of evidence that can be included in national resource allocation. The research will be of importance to policymakers because it demonstrates the potential resource impact associated with encouraging incident reporting by healthcare workers. The extent to which these resources are allocated efficiently, which is a normative concept, can only be assessed by measuring the benefits provided by the outputs of incident reporting systems. The measurement and valuation of the resources used in incident reporting systems in the English NHS is a novel contribution to research on information systems in patient safety that will support future efforts to value these systems (8). In addition, the research represents an advancement of methods for understanding the economics of information systems.

Chapter five: Outputs and outcomes from reporting and feedback in England: a case study using interrupted time series analysis

Introduction

The burden of harm remains unacceptably high in Western health systems (8) and, as Chapter two explained, evidence for the economic impact of patient safety interventions is concentrated around six patient safety targets. Incident reporting systems have attracted considerable policy and research attention since the late 1990s. However, the use of epidemiological methods means their effectiveness is poorly characterised, although quantitative evidence on their use as safety measurement tools (33) and potential for improving safety culture (32) has emerged in recent years. The UK pioneered the idea of a national incident reporting and learning system, which is coordinated centrally and is known as the National Reporting and Learning System (NRLS). Given the prominence of these systems in patient safety, a methodological framework for investigating them was presented in preceding chapters. This approach emphasised the need to understand how many resources national and local incident reporting systems consume and what benefits they derive. Both costs and benefits must therefore be estimated to calculate the net health or net monetary cost /benefit of these systems. To inform decision making, these estimates can then be compared to the costs and benefits derived from other health resources.

At a population-level and with respect to the outputs produced by incident reporting systems, there is a lack of evidence on the effectiveness of feedback reports. This chapter adopts an output-outcome focus to estimate the extent to which the feedback loop of incident reporting and management activities is closed when feedback reports are published. Given the positive association between reporting rates and indicators of safety culture, evidence on the effectiveness of incident reporting systems has framed organisational culture as an intermediate outcome of these systems (32). For this reason, previous studies have focused on the rate or volume of incident reporting for research and development purposes (32,68,263) and as a means of increasing incident reporting rates (264–267).

Evidence of impact from incident reporting systems

Studies on the implementation of patient safety alerts using clinical outcome datasets produced from nationwide incident reporting systems have not been able to demonstrate their impact. The methods in published papers are multi-modal with data collected through survey, interview, audit, and observational methods. A recent clinical study by Ramirez et al. aimed to address the dearth of evidence on the effectiveness of incident reporting systems in reducing patient safety incidents (268). The authors found that the implementation of a hospital incident

reporting system was associated with a statistically significant reduction of 63% in patient safety indicators (269). Of the 1983 indicators studied, 82% originated from either surgery, emergency care, intensive care, or general adult care. Evidence on the effectiveness of incident reporting systems has otherwise focused on upstream effects. Lankshear et al. (270) led the development of evidence in the first decade of the NRLS by studying the dissemination of safety alerts using qualitative data collection methods and thematic analysis. They found that 66% of the time, safety alerts were disseminated to ward managers within hours or days of receipt by NHS organisations. They concluded that the dissemination and implementation process is itself not error-free, indicating problems with the output-outcome link. The authors found that activities to reduce the harm addressed by safety alerts were under way before their publication; therefore, the alerts did not provide new information on how to improve care practice(s). This research focused on only 3 patient safety alerts published prior to the study: 1) protecting people suffering from allergies associated with latex; 2) reduction of harm caused by misplaced nasogastric feeding tubes; 3) needle-free intravascular connectors. The limited scope of the study, combined with sample and intervention selection bias, are methodological issues that limit the generalisability of the findings. Nevertheless, this constitutes one of the most informative case studies on the impact of safety alerts and, given the resources required to generate these alerts, the findings indicate that higher marginal gains are available from the outputs of the system.

In an earlier study, the same authors performed a qualitative study of the reactions by NHS Trusts to patient safety alerts aimed at reducing the availability of concentrated potassium chloride in English and Welsh hospitals (271). The sample comprised 20 randomly selected NHS Trusts and 207 clinical areas inspected by the research team, who identified rates of 100% compliance to drug storage policies, 98% compliance to the removal of unauthorised stocks of potassium chloride concentrate, and 90% compliance to documentation-controlled access to the drug in clinical areas. Rates of awareness of these alerts were 78% amongst those in nursing roles and 30% amongst those in junior doctor roles. A similar design was adopted by these authors to investigate the dissemination of medication safety alerts in the NHS using focus groups, interviews, and a survey. Dissemination and implementation efforts were found to be consistent and to address high-priority health service needs, indicating that the alerts were perceived to have improved medication safety in England. However, similar limitations were also evident in this study, which may have additionally suffered from social desirability bias in the focus group (272). This is due to the ethical and moralistic component of patient safety,

particularly given the extensive public coverage of patient safety-related events in mainstream media (1) and a growing litigation culture among NHS patients (273). The lack of experimental evidence on the impact of incident reporting systems on safety outcomes has not dampened advocacy for national or multi-site IT systems that collect voluntarily reported data (263).

Bleeding and patient safety

Patient safety is a broad concept for organisations and individuals to engage with because it encapsulates both clinical and non-clinical activities, all of which are causally linked to the safety of patients under the care of health and social care providers. Technological changes and normative expectations are evolving and rapidly increasing, as evidenced by the exponential growth in information collection and technological development (274). This creates a highly dynamic state of priority setting in which patient safety is an intrinsic and foundational component. Approaches to patient safety therefore transition in and out of the policy agenda at macro, meso, and micro levels. At any one time, researchers and decision makers engage with a set of priorities in patient safety that are universally agreed. The rise in prominence of VTE as a patient safety concern over the last decade clearly demonstrates this evolution in knowledge, perception, and prioritisation (275,276). As Chapter two demonstrates, the identification of VTE as a clinical and economic problem has initiated huge, industry-driven growth in research on target AE.

A conservative estimate of the cost of VTE to the US health system is \$7 to \$10 billion per annum (277). Earlier estimates of the burden range from \$3.4 billion to \$52 billion (2010 dollars) per annum and, of those considered preventable, the direct cost is estimated to be between \$2.1 billion and \$15.4 billion per annum. For the UK, the burden of VTE to the NHS is approximately £640 million per annum (278). VTE prophylaxis and interventional methods have changed considerably over the last 10 to 15 years, benefiting from pharmaceutical R&D resulting in market approval of several novel drugs for anticoagulation and antiplatelet management, often targeting interventional cardiology (279–281). In addition, process-based interventions have been developed as part of publicly sponsored research efforts to derive VTE protocols and “bundle” interventions that clinical teams can adopt based on evidence of their cost-effectiveness (282). As demonstrated in Chapter two, the prominence of VTE and bleeding outcomes as the target adverse event in patient safety literature is evidence of their high-priority status. Poorly managed coagulation that leads to patient harm is, therefore, considered avoidable. Clinical management of patients’ coagulation status involves balancing

the dosage to maintain vascularisation, thus preventing clots from forming and avoiding uncontrollable bleeding. To achieve this, clinicians employ monitoring and interventional technologies that improve coagulation management, using evidence-based methods often derived from large, randomised trials. Despite the interventions available, warfarin-related bleeding is one of the top five adverse drug events in the NHS (283). A complementarity therefore exists between VTE and bleeding in hospitalised patients. The preventability of VTE is entwined with patient safety efforts to reduce its occurrence, thereby implicating bleeding as part of these efforts. This relationship has recently been discussed in peer-reviewed clinical literature and in the context of patient safety (284,285).

There is a dearth of evidence on national bleeding rates associated with inpatient admissions to the NHS and, by extension, the economic burden associated with bleeds of various severity. This is surprising because recommended targets for major bleeding are set at a rate of less than three per cent per annum for all inpatients, signalling thresholds for regular monitoring. Evidence on the economic burden of bleeds in the UK hospital setting is scarce, although estimates of the cost per case of categories of major bleeds have been reported. Campbell et al. investigated Acute Upper Gastrointestinal Bleeds (AUGIB) using a cohort study design and found that in-hospital costs were approximately £2,500 and post-discharge community care costs up to 28-days were approximately £400 (286). These authors also estimated HRQoL using the EQ-5D, which was 0.701 (SE $\pm$ 0.02) as compared to the UK population average of 0.86. These data have limited applicability to cardiovascular patients as the marginal costs and HRQoL were only calculated for AUGIB hospitalisations. Haemorrhagic strokes are considered a major bleed and the costs per annum from these are approximately £17,500 per patient after one year, according to Xu et al. (287), and approximately £22,000 after five years. However, these estimates are for haemorrhagic bleeds that are not a complication of care or a preventable harm in the acute setting; therefore, these may be overestimates. Other UK estimates relating to the burden of stroke are also inappropriate for estimating the cost of bleeds because they conflate ischaemic and haemorrhagic strokes (288). Bleed severity, expressed as a loss of haemoglobin, and the associated hospital costs have not been investigated using a robust design. Therefore, the cost of various types of bleed in the context of patient safety are poorly understood, both globally and in the UK. As such, the best estimate of the cost of bleeds of varying severity is given by Ewen et al. in the US. This article estimates the cost of a major bleed in PCI patients as approximately \$14,000 and for a minor or mild bleed, approximately \$4,000. These estimates have limited generalisability to the UK due to contextual differences

and age-related obsolescence (289), yet in the absence of other estimates, they illustrate the significance of these costs to health systems.

Over the last two decades, cardiac surgery and cardiology have advanced at a rate of change that surpasses other clinical fields. The uptake of minimally invasive methods for treating acute myocardial infarction (angioplasty) has transformed the field and, as a replacement for open-heart surgery, has markedly reduced mortality rates for AMI (290) compared to previous standard of care methods. These methods, along with stenting and, more recently, drug-eluting stents, are technological (product) innovations that have driven recent improvements. Process and policy innovations in the organisation of health services have streamlined the delivery of time-sensitive acute care to AMI patients. NICE guidelines can be considered one such process innovation while the organisation of providers into “hub and spoke” models are policy (structural) innovations. In addition, in 2008 another process innovation, the surgical safety checklist, was introduced which reduced mortality rates in surgery by 50% (14). These examples, which reduce complexity by disregarding educational interventions and medical education, demonstrate the power of “low-tech” solutions in healthcare compared to “high-tech” interventions. Based on the available evidence, cardiology provides an excellent case for information and innovation research because in recent years this field has rapidly developed, implemented, and embedded several innovations. This suggests that of all specialties, cardiovascular care would be especially receptive to innovations, including impactful guidelines such as feedback reports produced from nationwide incident reporting systems. Similarly, it can be argued that the market for innovation in cardiovascular care is both mature and competitive and therefore the low uptake of innovations such as feedback reports in this field is a quality signal for other specialties. Moreover, cardiovascular care is a high priority specialty according to the NHS Long Term Plan (291), as approximately 64,000 lives can be saved each year.

In the age of interventional cardiology, a large amount of resources has been directed towards randomised trials of technologies (292) and techniques that reduce major bleeding in STEMI, NSTEMI, and ACS patients. The movement towards radial rather than femoral access is a recent example of this (293). Thus, there is ample evidence indicating the receptiveness of the field to any type of innovation that reduces major bleeding rates. This receptivity is explained by the disease and economic burden that major bleeds place on health systems (294–298).

Overall, the burden to society from major bleeds in acutely ill cardiovascular patients appears to be high (289), which is a growing concern because the volume of patients treated for heart disease in most Westernised health systems is increasing (299). A global burden of disease study in *The Lancet* presents data on this issue in the United Kingdom and shows that ischemic heart disease is the leading cause of death and morbidity (300). As such, evidence on the economic impact of AMI and ACS interventions is of enduring interest to health systems. In the (relatively likely) event that at-risk patients are admitted for interventional care, major bleeding is a patient safety concern that, by definition, is avoidable. For these reasons, there is an urgent need for research on interventions that potentially improve the management of anticoagulation during inpatient episodes.

Acute Coronary Syndromes and in-hospital bleeding

Ischaemic heart disease is the leading cause of death in the UK (301), which demonstrates that it is a persistent disease and an unmet need in population health improvement. Acute Coronary Syndromes (ACS) (302) have been an ongoing target of technological innovations, including Percutaneous Coronary Intervention (PCI) by femoral and, latterly, radial access sites.

In-hospital bleeding in ACS patients is a patient safety target, as demonstrated by the production of feedback reports on anticoagulation management by the NRLS. More broadly, over the last decade bleeding in hospitalised patients has been a prominent issue in medical research and clinical care, particularly in the context of cardiovascular care (303). A consensus on the definitions of bleeding severity, trends in bleeding rates, and interventions for preventing bleeds have emerged in debates. The reason for this attention is linked to a growth in coagulation management strategies, driven in part by the approval of novel drugs. Severe in-hospital bleeding, such as gastrointestinal bleeding, is neither growing nor falling in incidence according to Patel et al., who analysed US PCI hospitalisations from 2006 to 2012. However, the consequences of a severe bleed are significant; the same authors found a near ten-fold higher risk of mortality following these gastrointestinal bleeds (304). In a more recent US study by Harari et al.'s patients who were readmitted within 30-days of a PCI (approximately 10 per cent of all PCIs) between 2011 and 2014 were twice as likely to experience bleeding and mortality at one-year post-discharge (305).

In the UK, 2,000 major bleeds were identified in a three-year cohort study of 32 hospitals who admitted patients taking oral anticoagulants. The findings indicate a 20 per cent risk of death from major bleeding for this patient population 30-days after the event (306). Similarly, Kwok et al. (2014) found that major bleeds are associated with a 1.5 to 6.7-fold increase in mortality,

depending on the definition of major bleeding applied (307). Several explanations for higher mortality rates from bleeding have been proposed. Lawler et al. synthesised evidence for the association between anaemia and mortality in ACS and found that most studies reported higher rates of bleeding among anaemia patients and, overall, that anaemia was associated with higher mortality (308). Given these associations, more attention has been paid to developing bleed risk prediction scores. In 2019, Urban et al. published the findings of a global expert group who recommended 20 major and minor clinical predictors of bleeding at the time of PCI (309). These guidelines are needed because bleeding is significantly associated with higher morbidity, mortality, and costs (310). However, according to Vora et al., patient and treatment factors explain only around 28 per cent of the variability in hospital bleeding rates, which shows how poorly understood bleeding is (311). This suggests that the debate around the preventability of in-hospital bleeding is not yet settled, which is consistent with the wider debate concerning how preventability is measured in patient safety and, therefore, what outcomes comprise the burden of avoidable harm in a health system (312). Nonetheless, recent reference to bleeding in the context of patient safety (284) suggests its emergence alongside VTE as a preventable harm associated with coagulation management.

Developments in coagulation management

Since 2005, an increasing array of novel drugs, including Low Molecular Weight Heparins (LMWH), bivalirudin, Glycoprotein (GP) IIb/IIIa, and the thienopyridines have become available to clinicians in the UK and USA. Targeting specific factors in the coagulation cascade, the combination of drugs administered has grown in complexity following the publication of findings from randomised trials conducted between 2005 and 2015, including regimens tested with long-standing drugs such as Aspirin (278,313) and Warfarin (145,146,314). A secondary endpoint of most randomised trials investing in these drugs is major bleeding. Minor bleeds have also been studied; however, they are a lower priority in terms of quality improvement and patient safety.

Investigations into new technologies and approaches have improved real-world patient safety using measures of effectiveness rather than efficacy, reflecting the fact that population-level studies are sparse in the literature. The challenge associated with these studies is disentangling the impact of new technologies from other policies, processes, and products in the face of health system reconfigurations, rapid changes in interventional or surgical techniques, and the dissemination of new guidelines (315).

The impact of guidelines on their target outcomes also suffers from a lack of real-world evaluation evidence (95). Theories on the diffusion of information are important in the framing of impact evaluation, which aims to identify the relative (causal) contribution of temporally and spatially related interventions. The lag time to interventions becoming embedded is generally agreed to be 17 years (316); however, the lag between cause and impact of interventions with specific traits is poorly understood (317). For this reason, research using longitudinal data that aims to characterise the real-world diffusion and maturation of interventions and their subsequent outcomes is of immense value to society. Specifically, this type of research can be used to design interventions that diffuse faster and embed sooner, reducing the time taken to improve the quality of care patients receive.

In the absence of evidence and solutions, the prevalence of ACS with comorbidities is likely to increase in a growing elderly population. Polypharmacy and associated medication errors that lead to major bleeding are therefore of increasing concern, particularly as evidence for the pathophysiology of ACS challenges traditional mechanistic modes of ACS management (318). Interventions that disrupt this causal chain are thus needed and the extent to which incident reporting systems should be used (or not) should be considered in the suite of options.

These innovations, paired with the development of pharmacological prophylactics and therapeutics that reduce in-hospital complications, have improved clinical and economic outcomes. Major bleeding as a result of intervening when patients experience an exacerbation of ACS has reduced markedly due to these technologies, yet the contribution of guidelines to practice improvement has not been investigated.

Generating (quasi) experimental evidence on the impact of the NRLS

The tangible units of output from the NRLS are feedback reports. These are like NICE guidelines in that they are produced and disseminated centrally by NHS Improvement. Feedback reports take various forms, which explains the broad terminology used to refer to them, including patient safety alerts, patient safety guidance, patient safety signals, rapid response reports, safer practice notices, toolkits, and quarterly data summaries. Quarterly data summaries of incident reporting to the NRLS are also considered interventions because they potentially provide signals of quality that induce improvement.

Feedback reports aim to improve the quality of care of a segment of at-risk patients in the English and Welsh NHS. As such, these should have a measurable impact on the health system in terms of staff behaviours and patient outcomes. This is methodologically challenging and

requires the construction of logic models that describe expected cause and effect relationships from feedback reports so that conceptual and operational indicators can be derived for empirical study. The components of a research question that need to be operationalised in the design of interventions are captured by PICO (319). Any interventional study should have clearly defined PICO components that can be used to derive an appropriate design. “Black box” interventions are more problematic to study because causality between the introduction of an intervention and observed outcomes is challenging to uncover.

To inform redesign efforts, a piecemeal or bottom-up approach must be integrated into research. The impact of individual reports can be aggregated to estimate the overall benefit of reporting systems, as outlined by Lercel et al. (84). In addition, piecemeal methods support assessments of the impact of typologies of feedback reports; one such typological framework is suggested later by the author. These assessments are needed to effectively reverse engineer the existing system to produce outputs that maximise the marginal benefits of the entire system.

In light of the expense and effort required to construct panel (patient-level) data from HES, for this study, index diagnosis ICD-10 codes of interest were mined from monthly HES publications between 1999 and 2012. The codes of interest were selected from Keltie et al. as these relate most closely to patient safety incident codes (320); these codes are T80-88 and Y40-84, which refer to “misadventures”. Because this was exploratory, all finished consultant episodes and/or admissions for the entire adult population in England were included.

The only misadventure codes that are available online are categorised as T80-88. No further detail is provided about the nature of the diagnosis, such as the clinical area and the essential patient-level information needed to adjust for confounders. Notably, the basic analysis indicates an increase in the use of misadventure codes for the period observed. This is consistent with the concerted effort made by the WHO to include patient safety-related codes in the ICD-10 revision (the previous ICD-9 coding dictionary did not include misadventure codes). However, the increase in the number of incidents does not necessarily reflect an absolute increase in misadventures by clinical providers in England during the period of interest. Datasets that do not contain these reporting errors are essential for patient safety research. To measure the impact of incident reporting systems on patient safety outcomes, valid and reliable observations are needed to design robust quasi-experimental studies.

Quasi-experimental methods are increasingly being used in health services research to overcome the general limitations associated with experimental designs (321). Several methods

can be used to generate robust estimates of effect, but these rely on accurate observational data. The best quasi-experimental designs identify control groups and exploit multiple interruptions in time series data to improve the robustness of causal inferences made about an intervention and its outcomes (322). Equivalent locations can be used as control groups in these designs if appropriate data are available, such as country control groups (323), and investigations of several diseases have taken place in the UK in recent years (324–326).

ITSA population data sources

For population level clinical research, HES is commonly used. This is a routine administrative database that captures all admitted patient care episodes in the English NHS; it covers inpatient, outpatient, maternity, accident and emergency, and adult critical care for every year since 1987. Care is captured by unit of consultation, specifically by the episodes of care provided by a specialist consultant along with details of the type of hospital provider. Patient level data is constructed anonymously by providing a unique identifier for each patient, including the hospital and each episode of care over time. Several consultants may provide care to patients (more for patients with comorbidities) and several hospitals provide treatment for one patient. Episodes may be linked together to produce a panel of data for continuous episodes; these are known as continuous inpatient spells (CIPS), which cover the admission to discharge of each patient. Within each episode of care, the patient's clinical status is described by one primary and up to 19 secondary diagnosis codes (using the ICD-10 coding dictionary) (327), up to 24 procedural or intervention codes, and health resource groups (HRGs). The latter are groupings of clinically equivalent treatments that consume similar levels of resources and are used to determine the amount of reimbursement providers receive for a patient episode (328). The size of the database gives considerable flexibility to researchers seeking a single source of valid data for research purposes.

However, there are caveats to the use of HES that must be considered. First, the entry of hospital codes for primary and secondary diagnoses between providers may be inconsistent and fail to reflect the primary condition for which a patient is treated. The problem of “miscoding” is well documented within particular health systems, such as those in the US (329) and the UK (330), and inconsistency between definitions of primary diagnosis using the ICD-coding system means that international comparisons are fraught with error (331). Second, for those investigating one disease area, any number of ICD codes can be used to measure care quality. For example, Hohl et al. recently reviewed the adverse drug event (ADE) codes used to capture ADEs in international administrative data. They found that a total of 827 ICD-10

codes were used across 41 eligible studies that aimed to identify ADEs from databases. The median number of codes used to search for ADEs was 190 (332). The authors note that only two papers reported the sensitivity of their set of codes to the outcomes of interest in the study (333,334). Third, with specific reference to HES, researchers must be cognisant of the potential to miss relevant outcomes due to the lack of community or primary care data linkage. Clinical sequelae may occur outside the provider settings covered by HES depending on the lag time associated with their manifestation and other practical issues. The Clinical Practice Research Datalink (CPRD) is one such dataset that can be used to capture sequelae that occur outside the acute setting; however, linkage to HES is expensive, time consuming, and results in missing data as CPRD captures a smaller proportion of the population.

Given these methodological issues, the selection of ICD-codes and their validation is a crucial consideration. Evidence on appropriate methods for identifying complications using UK databases provide useful guidance. Four approaches to selecting correct codes are outlined by Keltie et al. (320) as one or a combination of the following: use the index admission (primary diagnosis) only; search for a sequence of admissions for specified clinical codes; adopt a cluster-coding method (335); and conduct a manual clinical review of diagnostic and procedure codes, as described by Cathcart et al. (336). The most appropriate method is that which yields the highest sensitivity to the outcome of interest, as demonstrated by the high sensitivity achieved by Onwere et al. who used the index admission to investigate incidences of blood transfusion associated with C-sections in women with placenta praevia (337). These methods are well specified for health services research using HES; however, their application to patient safety research is more problematic given that the suite of validated patient safety indicators is limited (25).

Linking bleeding in ACS to a study of NRLS feedback reports

In general, there is a dearth of real-world evidence on the impact of coagulation management initiatives other than those involving novel anticoagulants for the prevention of VTE. As demonstrated in the previous section, bleeding is a patient safety concern for which the economic burden and cost-effectiveness of non-pharmaceutical interventions, such as guidelines, has received relatively little attention. Similarly, the impact of patient safety alerts on clinical and economic outcomes is also poorly understood. Among the many alerts that were generated by the NRLS in England, coagulation management guidance was also issued in response to incidents reported in the systems in the preceding months and years of publication.

The safety alerts published by the NRLS are guidelines on heparin and warfarin management and administration for NHS patients, and advice on monitoring and managing patients at risk of VTE and bleeding (338). The impact of these guidelines, which are the product of the activities identified, measured, and valued in Chapter four, has never been quantitatively evaluated using population-level data. Consequently, as is the case for all safety alerts published by the NRLS, there is a large gap in the evidence base on the effectiveness and economic impact of feedback reports and other clinical guidelines aimed at reducing harm from bleeding in the cardiovascular setting.

NRLS feedback reports do not always specify the specialties targeted by the advice; however, given cardiologists' preoccupation with reducing bleeding rates in their patients, as indicated by the proliferation of epidemiological, clinical, and economic research over the last fifteen years, it can be assumed that NRLS guidelines on coagulation management were recognised and implemented by cardiology teams in the English NHS throughout that time.

To assess the before and after-effects of NRLS feedback reports that target bleeding in an ACS population, population-level datasets must be considered. The use of registries for research on comparative effectiveness is of growing importance given the limited practical application of randomised controlled trials (339) and the need to accelerate the production of evidence in relation to cardiovascular disease (340). A salient example of this use of observational datasets is provided by Fröbert et al. (2010), who performed a randomised trial of thrombus aspiration in STEMI patients undergoing percutaneous coronary intervention (341–343). In Sweden, these so-called “mega trials” are considered robust alternatives to randomised trials as there is 96.1% agreement between the data entered into the registries online for all patients and randomised data quality checks (344). In England, an equivalent registry is the Myocardial Infarction National Audit Project (MINAP), which circumvents potential data quality issues associated with routine administrative data, such as HES, and problems specific to identifying patient safety outcomes. MINAP has achieved more than 90% completeness in 20 key data fields (345) and cross-validation evidence in previous studies using MINAP has achieved 96% consistency (346). The completeness, validity, and fidelity of registry datasets can therefore be exploited for research into patient safety, particularly given the heterogeneity of outcomes in this field and the plethora of interventions that are generated at the population level. These examples show that the comparative effectiveness of diverse outputs from incident reporting systems can and should be studied using registry data that would otherwise be overlooked in favour of routine administrative data or costly prospective designs. The design of studies using

these datasets relies on reliably identifiable features of a research question, which are captured by PICO. In this study, the Population of interest included all AMI patients admitted to an NHS hospital as these patients were at risk of major or any bleeding during their inpatient stay; the Interventions were NRLS feedback reports that contain care practice guidance designed to reduce the occurrence of avoidable bleeds (these are avoidable, by definition, because feedback reports on coagulation management were promoted as safety interventions); the Comparator in this case was patients from the Scottish NHS who were not exposed to the NRLS feedback reports in question; the Outcomes for this study were length of stay (in days) and major or any bleeding (rates) as these are closely associated with safer coagulation management.

Aim

This research first aimed to develop and apply methodological approaches for evaluating the output of information from health data systems that intend to improve patient safety. Its second aim was to derive empirical evidence on the effectiveness of NRLS feedback reports to inform the allocation of resources to this system.

Method

A controlled Interrupted Time Series Analysis (ITSA) using segmented regression analysis was designed to estimate the impact of feedback reports produced by the NRLS. Breaks were defined ex ante by reviewing all NRLS feedback reports produced between 2002 and 2012; the full list of feedback reports considered is presented in Appendix E.1. Using this design, the (clinical) effectiveness of outputs from incident reporting systems in England, collectively known as the NRLS, was estimated.

Interventions: feedback reports produced by the NRLS

Outputs from the NRLS were categorised to identify candidate feedback reports that addressed the high priority for patient safety improvement and for which PICO dimensions could be derived (see Appendix E.2.). The Central Alerting System (CAS) (347), which is an online database and portal where all NRLS outputs are published for public viewing, was manually searched for all NRLS feedback reports. Overall, 212 reports published from 2002 to 2012 were identified. The period to June 2012 (inclusive) was used because the NRLS reached a steady state of production up to this date before stopping production for around three years following the closure of the NPSA. The NRLS began producing feedback reports from within NHS England and NHS Improvement in 2015 and, consequently, dissemination through the CAS has been inconsistent in recent years.

Feedback reports were categorised in three ways: the first was the author's own description, which described the clinical area targeted by the alert or guideline; second, using the NRLS categories (348); third, using the 2013/14 "never event" categories defined by the Department of Health (349). Each feedback report was assigned an identifier and the publication date was recorded.

Because the NRLS developed from a start-up programme into routine use, the number of outputs increased each year (Table 5.1). The annual output was highest in 2009 (44 reports) and lowest in 2003, which was the first full year of NRLS operations. From 2009 to 2012, the number of reports declined, which coincided with a reduction in the NPSA's responsibilities prior to its closure in June 2012. The output of each type of report defined by the NRLS is given in Table 5.1. For the purposes of this analysis, reports were classified as alerts or guidelines; the former are high priority interventions that address patient safety incidents with the potential to cause moderate to severe harm to NHS patients; the latter are lower priority guidelines that address low or no harm incidents. As shown in Table 5.1, the majority of NRLS reports produced during this period were guidelines (69%) and the remainder were alerts.

The thematic categorisation provides a list of feedback reports that were grouped according to the clinical setting, including medication-related errors, surgical suite errors, and general healthcare settings. A subset of these categories was created for the exact clinical area or pathology addressed by feedback reports, and a priority level assigned. Reports that specifically address "never events" were categorised separately because of their exceptional status and the fact that never event quality indicators have been developed and, as such, are accessible for analysis in routine administrative databases (25). Overall, medication related reports, surgery related reports, and general healthcare feedback reports were all candidates for before and after analysis. The categories of feedback report were then used to design a feasible before and after study. Multiple interruptions of related interventions were preferred to improve causal claims about interventions captured in a time series. To identify candidate interventions, feedback reports and their respective publication dates were collated, as shown in Table 5.1.

	RRR	PSA	Safer Practice Notice	Guidance	Signal	Toolkit	Annual Output (all types)
2002	0	0	0	1	0	0	2
2003	0	0	0	1	0	0	1
2004	0	1	2	2	0	0	5
2005	0	2	1	1	0	0	4
2006	0	1	2	2	0	0	5
2007	4	5	4	9	0	0	22
2008	11	2	0	10	0	0	23
2009	8	3	2	14	17	0	44
2010	12	1	0	4	18	1	36
2011	3	1	0	0	25	0	29
2012	1	0	0	0	7	0	8
Total		0	0	0	0	0	
Total	39	17	11	44	67	1	179

Table 5.1. NRLS outputs by year and according to output type. As described in Chapter one, for analytical purposes, NRLS outputs are the same type of intervention as guidelines.

Logic model

Logic models are a useful tool for expressing causal linkages between intervention inputs, processes, outputs, and outcomes (45). For complex interventions, as defined by Craig et al. (350), the construction of logic models for feedback reports is a means of handling cause and effect from interventions and of designing robust empirical analyses. Candidate feedback reports for the study of bleeding outcomes in ACS patients were derived with expert advice from a cardiologist and clinical academic researcher.

The development of the conceptual and operational indicators involved reviewing each feedback report that pertained to coagulation management during the period from 2002 to 2013. For each review, where possible the population, intervention details, and outcome targeted by each feedback report was identified. These items were referred to as the conceptual indicators. The conceptual indicators chosen from each feedback report were then compared by the experts to verify their conceptual or clinical consistency, namely that the care practices and outcomes they intended to modify were the same for each publication. The conceptual indicators were translated into operational indicators that were present in the data specification provided by MINAP (note: the specification routinely evolves)(351).

The face validity of the logic models derived for an ITSA of each feedback report was checked by these experts prior to the analysis. Consensus around the study design, including key decisions about the selection of appropriate interruptions and clinical outcomes, was generated informally.

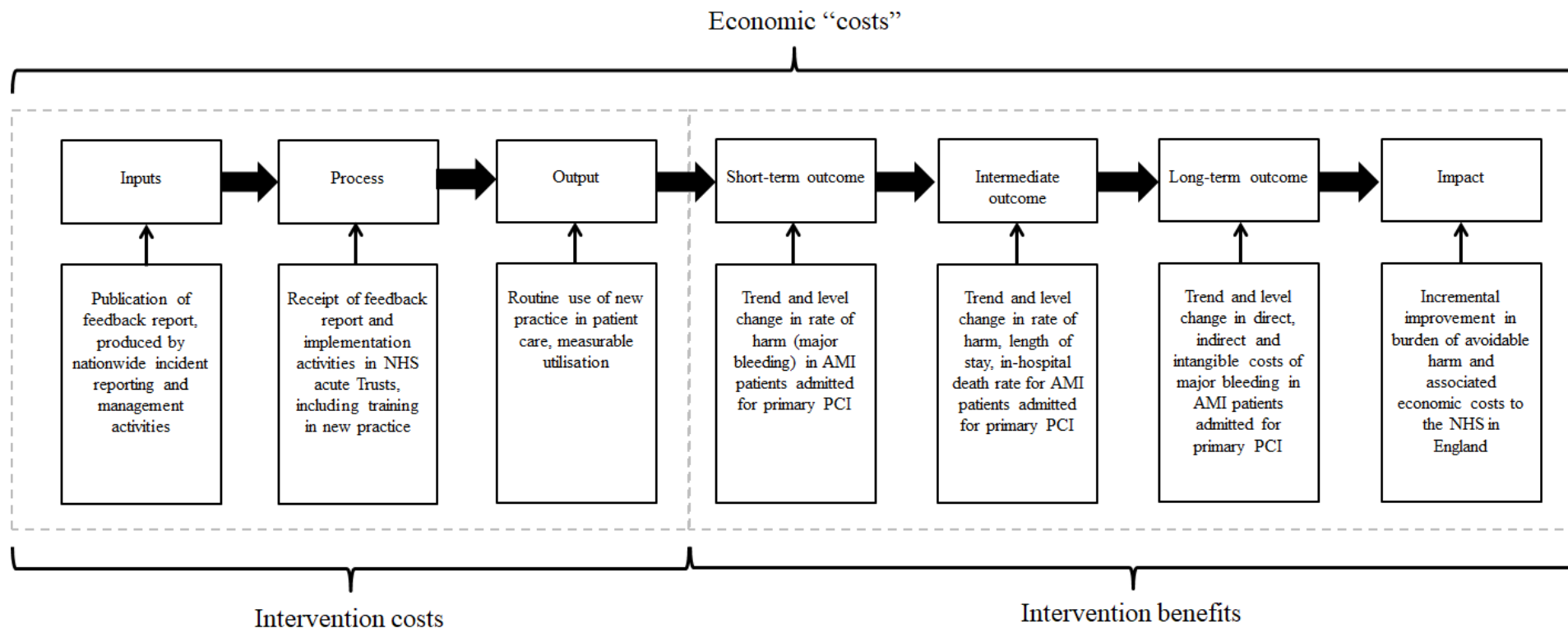


Figure 5.1. Logic model describing the chain of cause and effect(s) expected from National Reporting and Learning System (NRLS) feedback reports (also called patient safety alerts) that target anticoagulation management methods in the English NHS.

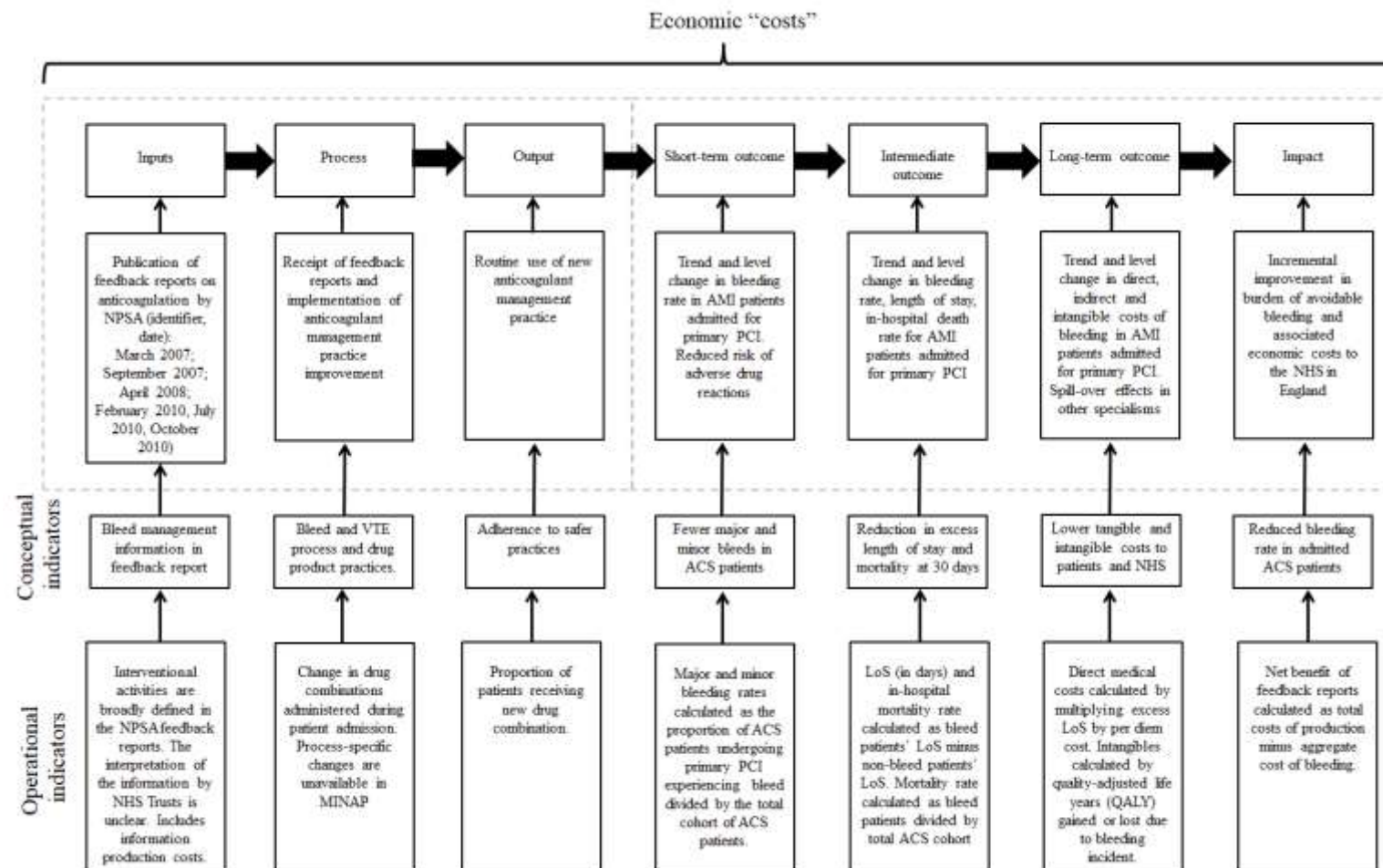


Figure 5.2. Operationalised logic model describing the chain of cause and effect(s) expected from National Reporting and Learning System (NRRS) feedback reports, expanded to include conceptual and operational indicators for measuring the impact of anticoagulation management in the English NHS.

Population

The data for this analysis was derived from MINAP, which is a registry of ACS hospitalisations mandated by the Department of Health and Social Care. Each MINAP entry provides patient demographic and clinical information pertaining to patient care; full details of MINAP data collection and management have been described elsewhere (352). The level of detail provided by the comprehensive list of variables captured in the MINAP registry affords researchers an opportunity to address secular trends and confounders that are otherwise unobserved. In contrast to HES, MINAP provides similar variables on diagnoses and procedures but also includes variables on drugs administered to patients, albeit without volume and dose information. Although MINAP does not record VTE events, it does enable us to operationalise the process indicators derived from the logic model (Figure 5.2) in a clinical setting that is receptive to innovations in anticoagulation management.

The cohort was drawn from 922,147 patients observed between 2003 and 2013. Bleeding complication status was recorded for 835,000 (90.5%) of these patients. The mean age was 69 (SD $\pm$ 14 years) and the gender split for those admitted was 35% female and 65% male. If missing observations for bleeding complication status were encountered, the entire entry was removed (9.5% of all observations). If the bleeding complication variable was entered as “unknown”, this was interpreted as a clinical manifestation of bleeding that was not recorded and was therefore unlikely to have occurred. The definition of the severity of bleed is based on bleeding in the 24 hours following any therapeutic intervention but does not include bleeding complications following repeat angiography or intervention. Severity is defined as: “none”; “intracranial bleed” of any severity and ideally confirmed by scan; “retroperitoneal haemorrhage” of any severity and ideally confirmed by scan; any bleed with a haemoglobin fall greater than 50 g, from any site except intracranial or retroperitoneal; any bleed with a haemoglobin fall greater than 30 g and less than 50 g, from any site except intracranial or retroperitoneal; any bleed with a haemoglobin fall less than 30 g, from any site except intracranial or retroperitoneal; and “unknown”. For comparison with the definitions employed in the peer-reviewed literature, a haemoglobin reduction of 30 g is assumed to be 30 g per litre, which is equivalent to 3 g per decilitre as described in the literature. A major bleed was defined as an intracranial bleed, retroperitoneal bleed, and any bleed with a haemoglobin fall greater than 30 g per litre.

Patients were eligible for the study if they were $\geq$ 18 years of age. Admissions were aggregated at the provider level and readmissions of the same patient were counted as new admissions to

the organisation. This was due to the absence of unique patient identifiers. Patient-level data concerning demographics and cardiovascular risk factors at the time of hospitalisation, administration of anticoagulant during admission, bleeding severity, and length of stay were extracted from the registry; a list of the variables extracted from MINAP is given in Table 5.2.

Extracted variable	Description and coding
Hospital identifier	A unique code for each provider
Date of patient admission	Day, month, and year of a recorded admission
Date of patient discharge	Day, month, and year of a recorded discharge
Gender of patient	Categorical variable (male; female; unknown)
History of a previous AMI	Categorical variable (yes; no; unknown)
Hypertension diagnosis prior to admission	Categorical variable (yes; no; unknown)
Systolic blood pressure on admission	First measurement on admission, continuous variable (mmHg)
Heart rate on admission	First measurement on admission, continuous variable (beats/minute)
Unfractionated heparin	Categorical variable; therapeutic use while in hospital (yes; no; unknown)
Low molecular weight heparin	Categorical variable; therapeutic use while in hospital (yes; no; unknown)
Thienopyridine platelet inhibitor	Categorical variable; therapeutic use while in hospital (yes; no; unknown)
IV GP IIb/IIIa agent	Categorical variable; therapeutic use while in hospital (yes; no; unknown)
Discharge diagnosis	Categorical variable that includes AMI (ST elevation) and ACS (troponin positive) / NSTEMI codes
Bleeding complications (and severity)	Categorical variable (none; intracranial bleed; retroperitoneal haemorrhage; any bleed with Hb fall > 50g; any bleed with Hb fall >30g and <50g; any bleed with Hb fall <30g; unknown)

Table 5.2. Summary of variables extracted from the MINAP database, including the description and coding of each variable in the extract. New variables were generated using those extracted, including: a continuous variable for length of stay calculated using patient admission and discharge dates; a continuous variable for hospital admission volume per year calculated using aggregate admissions based on the hospital identifier(s); a continuous variable for the number of anticoagulants received per patient admission calculated by counting records of unfractionated heparin, LMWH, thienopyridine platelet inhibitor, and IV GP IIb/IIIa agent use. The outcome variables for this study were length of stay, any bleeding during an ACS admission, and major bleeding during an ACS admission. All remaining variables constructed from the MINAP dataset were used as identifiers to group observations for time series analysis and for use as covariates in regression models.

Data cleaning and assumptions

Several assumptions about the MINAP data were made to handle missing data, inconsistent reporting of variables by year, and differences between definitions given in peer-reviewed literature and in the dataset. If missing observations on the “bleeding complication” variable were encountered, the entire entry was removed. If the bleeding complication variable was entered as “unknown”, this was assumed to be “no bleeding” on the basis that a clinical manifestation of bleeding was not observed and was therefore unlikely to have occurred.

Observations that included a length of stay of more than 365 days were removed on the assumption that these reflect incorrect date entries in MINAP. Observations of heart rate and systolic blood pressure that were negative integers or exceeded 220 beats per minutes and 380 mmHg, respectively, were removed. The case volume by NHS site was estimated by counting the number of discharge diagnoses recorded.

Missing data were not imputed into the dataset and were considered missing at random. This assumption is commonly made for ITSA, despite reasonable concerns about this assumption when using observational data in this manner (353). As outlined by Sterne et al.(354), when missing data occur only in an outcome variable that is measured once in each patient record, then the analysis will not be biased, provided all variables associated with the missing outcome are included as covariates (under a missing at random assumption). In this analysis, covariates associated with bleeding were included to reduce bias in the overall interpretation of results.

Comparators

English and Scottish NHS populations

The population of interest was all ACS patients admitted to an NHS hospital. Patient level outcomes were studied from an English perspective because the nationwide incident reporting system defined in previous chapters was developed in and for this region of the UK. Theoretically, all providers should adopt system-level NRLS interventions and, as such, all patients and providers in England are exposed to feedback reports.

A Scottish control group was constructed following a data request to the Information Services Division (ISD) Scotland (ID: IR2019-00192). The Scottish NHS is configured in a broadly similar manner to the English NHS; however, it is governed and regulated autonomously (355). As the “nearest equivalent neighbour” that was not exposed to the safety alerts identified, the Scottish NHS serves as the most appropriate control group for this study. Patient-level information was requested for non-obstetric and non-psychiatric hospitals for the period 2003 to 2013. The indicators for the analysis were all ACS admissions (STEMI and NSTEMI codes

were not incorporated into data recording until 2013), major bleeding (expressed as a percentage), and length of stay (in days). ISD use international standards for coding hospital admissions, therefore equivalent ICD-10 codes were submitted in the request, and these can be found in Table 5.3. Major bleeding codes were selected using the convention established by Jun et al. (356). A convention for measuring minor bleeding using ICD-10 codes has not been established; thus, these codes were not submitted as part of the request. If this convention had been established, the problem of comparing minor bleeding in routine administrative data to that provided in MINAP would have remained as the codes used in the English dataset are based on haemoglobin loss, which is expressed in grams per litre. For these reasons, major bleeding was the outcome chosen for comparison in the multi-group ITSAs.

Data were aggregated at the level of all NHS hospitals in Scotland to calculate the average length of stay, which was defined as the last continuous inpatient stay of a patient with a major bleed. Several 5-digit major bleeding codes given by Jun et al. were not recorded in Scotland, including I9820, K2210, K2212, K2214, K2216, K6380, K3180 and K5520; hence, the 4-digit versions, namely I982, K221, K638, K318, K552, were derived instead.

Data were provided by ISD as a yearly time series to avoid confidentiality and anonymity concerns. In addition, the volume of in-hospital AMI bleeding was considered too low when aggregated by quarter; hence, annual cases of bleeding were provided.

Variable description	ICD-10 codes (Scottish “control” group)	MINAP equivalence (English “intervention” group)
Acute Myocardial Infarction (AMI): included both NSTEMI and STEMI because ISD data did not code these separately until after 2013	I21-I22, fifth digit of “0”, “1”, or “9”	High: both datasets represent the population admitted to an NHS hospital
Major bleeding: constructed using ICD-10 codes that relate to definitions of major bleeding in clinical research. N.B. this does not include all bleeding, i.e., bleeding of any severity	I60, I61, R58, I620, I621, I629, K920, K921, I850, I983, K250, K252, K254, K256, K260, K262, K264, K266, K270, K272, K274, K276, K280, K282, K284, K286, K290, K625, K922, N020, N021, N022, N023, N024, N025, N026, N027, N028, N029, K661, N938, N939, N950, R041, R042, R048, R049, R310, R311, R318, D683, H356, H431, H450, M250, I312, T810, T828, I982, K221, K638, K318, K552	Low: despite conceptual similarity, the recording of major bleeding using routine administrative data in Scotland is more diverse than that given in MINAP. Routine administrative data using ICD-10 coding does not record bleeding severity according to haemoglobin loss (given as g/L in MINAP), which limits the equivalence of this variable. High equivalence exists in the recording of non-traumatic cerebrovascular bleeding, i.e., subarachnoid, and intracranial haemorrhage (I60, I61, I620, I621, I629). High equivalence also exists in the recording of retroperitoneal haemorrhage (R58)
Length of stay (days)	Not applicable	High: both datasets record length of stay for all admissions in a similar format

Table 5.3. Summary of request to the Information Services Directorate (ISD), Scotland, for the period 2003 to 2013. ICD-10 codes were used to extract observations from the Scottish NHS that could be used to construct a control group to study the impact of NRLS feedback reports in the English NHS. Observations from Scotland were aggregated by year and for all NHS hospitals, because an equivalent registry to MINAP does not exist in Scotland, routine administrative data were requested. These use international standards for clinical coding (ICD-10); hence, index diagnoses for AMI were requested to generate the control population of interest to this study. Major bleeding codes were requested based on those used by Jun et al. (2015).(356) and their equivalence to observations in MINAP is described.

Study design

Structural breaks in bleed rates and length of stay were assessed by ITSA using ordinary least squares regression to detect trend and level changes. A single group ITSA was performed using MINAP data by regular month, quarter, and year intervals. This type of analysis relies on counterfactuals derived from pre-intervention trends and projected into the treatment period. This is the main limitation of the design when applied to cardiovascular care because it can be assumed that outcomes in this context are affected by multiple policy, product, and process changes in rapid succession (for example, the introduction of a new drug). This means that the observed effect from an intervention of interest may be confounded by the introduction of an exogenous policy. The presence of a trend in the time series before an intervention is evidence for potential confounding in a single group ITSA.

The single group ITSA takes the following general form:

$$Y_t = \beta_0 + \beta_1 T_t + \beta_2 X_t + \beta_3 X_t T_t + \epsilon_t$$

As described by Linden and Arbour (357), Y_t is the aggregated outcome variable measured at each equally spaced time point t ; T_t is the time since the start of the study; X_t is a dummy variable representing the intervention (preintervention periods 0, otherwise 1); and $X_t T_t$ is an interaction term. β_0 represents the intercept or starting level of the outcome variable. β_1 is the slope or trajectory of the outcome variable until the introduction of the feedback report. β_2 represents the change in the level of the outcome that occurs in the period immediately following the introduction of the intervention (compared with the counterfactual). β_3 represents the difference between preintervention and postintervention slopes of the outcome. Significant p-values in β_2 indicate an immediate treatment effect while those in β_3 indicate a treatment effect over time (358) which is defined by the analyst.

The addition of coefficients that denote the difference in the level and slope between treatment and control prior to and after the intervention (again, as defined by the analyst), represent the interaction between the groups. This takes the following general form:

$$Y_t = \beta_0 + \beta_1 T_t + \beta_2 X_t + \beta_3 X_t T_t + \beta_4 Z + \beta_5 Z T_t + \beta_6 Z X_t + \beta_7 Z X_t T_t + \epsilon_t$$

In this formulation, the addition of coefficients β_4 , β_5 , β_6 , and β_7 capture differences between control and treatment groups, where Z is the dummy variable that denotes cohort assignment (control or treatment). The addition of the control group enables us to assume that omitted

variable bias from policy effects is equal in both groups, facilitating interpretation of pre-intervention and post-intervention effects of feedback reports from the NRLS in England.

The primary endpoints (response variables, Y_t) of interest to this study, as derived for England and Scotland, were length of stay (in days) for ACS admissions (STEMI and NSTEMI), any bleeding during an admission (average rate of any bleeding), and major bleeding during an admission (average rate of major bleeding). The bleeding rates were expressed in the following time units for the single group ITS: month, quarter, and year. For the controlled ITS, bleeding rates were expressed by year.

Models

In total, 33 single- and multiple-group generalised least-squares linear regression models were estimated to test for significant interactions between the date of feedback report publication and changes in the response variables with and without the addition of eight covariates; 22 are reported. The Cumby-Huizinga test for autocorrelation (359) was used to test whether autocorrelation errors followed an AR(1) process at an alpha level of $p < 0.05$. Six lag orders were used in these tests, revealing that the univariate time series for length of stay, major bleeding, and any bleeding at monthly, quarterly, and yearly observations followed at least an AR(1) process (Appendix E.3.). The presence of autocorrelation extended to the multigroup ITSAs.

Of the single ITSAs that were performed, a series of models were generated to explore several ways in which the effect of feedback reports could be manifested. Two main response variables were consistently used: length of stay and bleeding rate (described in more detail below). Using these outcomes, monthly, quarterly, and yearly time series were analysed as a means of altering assumptions about the lags between the introduction of feedback reports and the manifestation of a response in the observed data. In this approach, the pre- and post-intervention segments are shortened (this would be at the year level) or lengthened (at the monthly level). In the absence of evidence informing these lags and the potential influence of the level at which the time series was configured on the coefficients produced in the models, aggregation at these levels was a necessary part of the exploratory analysis. Similarly, because the publication date of feedback reports was date stamped by month and year, interruptions and lags could be explored using the month-level time series. Sequentially, lags of one, two, and three months were used as the interruptions instead of the month of the year when a feedback report was published. Lags were applied evenly for models with multiple interruptions, namely April 2007 became May 2007 for a one-month lag model; for the same model with another interruption

that ordinarily is defined as a publishing date of March 2010, April 2010 became the interruption. This assumes that for every feedback report, the lag period, if present, occurs equally, which simplifies the analysis whilst accounting for potential lags between providers' receipt of information and the organisational change(s) made (if at all). At the year level, several publications of feedback reports would be modelled as a single interruption. This was of interest because some years may be considered higher "dose" years than others, which could be associated with significant trend and level changes in the response variables.

The multi-group ITSAs were also exploratory but were simpler in execution than the series of single-group ITSAs. These models were performed only at the year level because of data availability in Scotland. The years for which feedback reports were published (2007, 2008, 2010) were used as interruptions and, as for the single-group ITSAs, in this scenario multiple feedback reports within one year would be manifested as one interruption in the analysis. Combinations of year interruptions (such as 2007 and 2008, or 2010 only) were explored in the ITSA to see if these led to statistically significant trend and level changes, and in what combination. The bleeding outcomes comprising the time series for Scotland are major bleeding only; however, major bleeding in Scotland was compared to any bleeding in England in some controlled ITSAs. This was reasonable for an exploratory study given the limited equivalence in the recording of bleeding outcomes in the MINAP and ISD datasets.

The generalised family of models were then used to transform original observations based on the pooled autocorrelation estimate ρ , thereby removing the correlation between the errors of each observation period and those of the preceding period. A total of 77 models were developed with response variables specified as either average length of stay for major bleeding, average length of stay for any bleeding, average rate of major bleeding, or average rate of any bleeding (the latter two are expressed as percentages). These variables were chosen based on the consensus built from the logic models (see above). Additionally, length of stay is frequently used as an indicator of resource use in health economics because inpatient days can be valued (crudely) using a per diem cost (360). This indicator is routinely used as a measure of quality improvement and in the evaluation of interventions (361) for which a reduction in length of stay is desirable. The costs associated with statistically significant trend and level changes in length of stay that were robust across several interruptions could therefore be calculated using this indicator. Bleeding rates are clinically linked to the care practice changes described by the feedback reports and are the main clinical outcome of interest. Of note, VTE is also of interest as a response variable, but MINAP does not record these.

Response variables were modelled using stepwise regression methods with and without the following covariates, which were selected based on the theoretical causes of in-hospital bleeding during AMI: average rate of STEMI, average number of admissions in NHS sites, SBP, heart rate, anticoagulant administration (a binary variable), rate of admissions with a previous history of AMI, rate of female admissions, and rate of admissions with pre-existing hypertension. The specifications of each reported model are presented in Table 5.4, while the least informative models are presented in Appendix E.

Table 5.4. Specification of the 22 reported interrupted time series analyses using segmented, generalised linear regression analysis (2003 to 2013). Models with insignificant findings are listed in Appendices E.4 to E.5.					
Model number	Design (single / multiple group)	Response variable	Time series, 2003 – 2013	Interruptions	Covariate specification, statistically significant ($p < 0.05$) covariates reported
1	Single	Average length of stay (in days) in English NHS hospitals	Monthly	March 2007, September 2007, April 2008, February 2010, July 2010, and October 2010	No covariates
2	Single	Average length of stay (in days) in English NHS hospitals	Monthly	March 2007, September 2007, April 2008, February 2010, July 2010, and October 2010	Average number of anticoagulants administered per patient (backward elimination)
3	Single	Average rate of any bleeding (percentage) in English NHS hospitals	Monthly	March 2007, September 2007, April 2008, February 2010, July 2010, and October 2010	No covariates
4	Single	Average rate of any bleeding (percentage) in English NHS hospitals	Monthly	March 2007, September 2007, April 2008, February 2010, July 2010, and October 2010	Average SBP and percentage of hypertension admissions (backward elimination)
5	Single	Average length of stay (in days) in English NHS hospitals	quarterly	Q1 2007, Q3 2007, Q2 2008, Q1 2010, Q3 2010, Q4 2010	No covariates
6	Single	Average length of stay (in days) in English NHS hospitals	quarterly	Q1 2007, Q3 2007, Q2 2008, Q1 2010, Q3 2010, Q4 2010	Average SBP and HR, average number of anticoagulants administered per patient (backward elimination)
7	Single	Average rate of any bleeding (percentage) in English NHS hospitals	quarterly	Q1 2007, Q3 2007, Q2 2008, Q1 2010, Q3 2010, Q4 2010	No covariates

8	Single	Average rate of major bleeding (percentage) in English NHS hospitals	quarterly	Q1 2007, Q3 2007, Q2 2008, Q1 2010, Q3 2010, Q4 2010	No covariates
9	Single	Average length of stay (in days) in English NHS hospitals	Yearly	2010 only	No covariates
10	Single	Average rate of any bleeding (percentage) in English NHS hospitals	Yearly	2010 only	No covariates
11	Single	Average rate of any bleeding (percentage) in English NHS hospitals	Yearly	2010 only	Average percentage of hypertension admissions, average percentage of admissions with previous AMI
12	Single	Average rate of major bleeding (percentage) in English NHS hospitals	Yearly	2010 only	No covariates
13	Single	Average rate of major bleeding (percentage) in English NHS hospitals	Yearly	2010 only	Average percentage of hypertension admissions, average percentage of admissions with previous AMI (forward elimination, backward elimination yielded no significant covariates)
14	Multiple	Average length of stay (in days) in English (intervention) and Scottish (control) NHS hospitals	Yearly	2010 only	No covariates
15	Multiple	Average rate of any bleeding (percentage) in English (intervention) and Scottish (control) NHS hospitals	Yearly	2010 only	No covariates
16	Multiple	Average rate of major bleeding (percentage) in English (intervention) and Scottish (control) NHS hospitals	Yearly	2010 only	No covariates
17	Multiple	Average length of stay (in days) in English (intervention) and Scottish (control) NHS hospitals	Yearly	2008 and 2010	No covariates
18	Multiple	Average rate of any bleeding (percentage) in English (intervention) and Scottish (control) NHS hospitals	Yearly	2008 and 2010	No covariates
19	Multiple	Average rate of major bleeding (percentage) in English (intervention) and Scottish (control) NHS hospitals	Yearly	2008 and 2010	No covariates
20	Multiple	Average length of stay (in days) in English (intervention) and Scottish (control) NHS hospitals	Yearly	2007, 2008, and 2010	No covariates
21	Multiple	Average rate of any bleeding (percentage) in English (intervention) and Scottish (control) NHS hospitals	Yearly	2007, 2008, and 2010	No covariates
22	Multiple	Average rate of major bleeding (percentage) in English (intervention) and Scottish (control) NHS hospitals	Yearly	2007, 2008, and 2010	No covariates
Legend: SBP = Systolic Blood Pressure (mmHg); HR = Heart rate (beats per minute); AMI = Acute Myocardial Infarction					

Hypothesis

Several hypotheses were tested. The null hypothesis was as follows: the introduction of patient safety alerts related to coagulation management in the English NHS had no impact on the rate of bleeding in ACS patients admitted to acute hospitals in England between 2003 and 2013.

Ethical approval

Data used within the study were fully anonymised; therefore, ethical approval was not required under NHS England and NHS Scotland research governance arrangements.

Findings

Descriptive statistics

The average length of stay for AMI was 8.4 days (SD $\pm$ 1.1 day; minimum = 3.4 days; maximum = 10.3 days) between 2003 to 2013. This was associated with an average rate of major bleeding of 0.58% (SD $\pm$ 0.18; minimum = 0%; maximum = 1.1%) and an average rate of any bleeding of 0.94% (SD $\pm$ 0.2; minimum = 0.52%, maximum = 2.1%). The association between length of stay and bleeding severity was a secondary interest in this study and has been explored in previous randomised trials; the mean length of stay by bleeding status is summarised in Table 5.5.

Table 5.5 Mean length of stay by bleeding status for patients in England between 2003 and 2013

Bleeding severity	Obs.	Median	Mean	Std. Dev
None	761,692	5	8.1	11.8
Intracranial bleed	1,587	5	10.9	17.0
Retroperitoneal haemorrhage	1,047	9	13.9	15.7
Any bleed with Hb fall > 50g	1,816	12	17.4	19.1
Any bleed with Hb fall > 30g and < 50g	2,845	12	17.2	17.7
Any bleed with Hb fall < 30g	6,898	9	13.3	4.7
Unknown	30,862	5	9.4	11.1

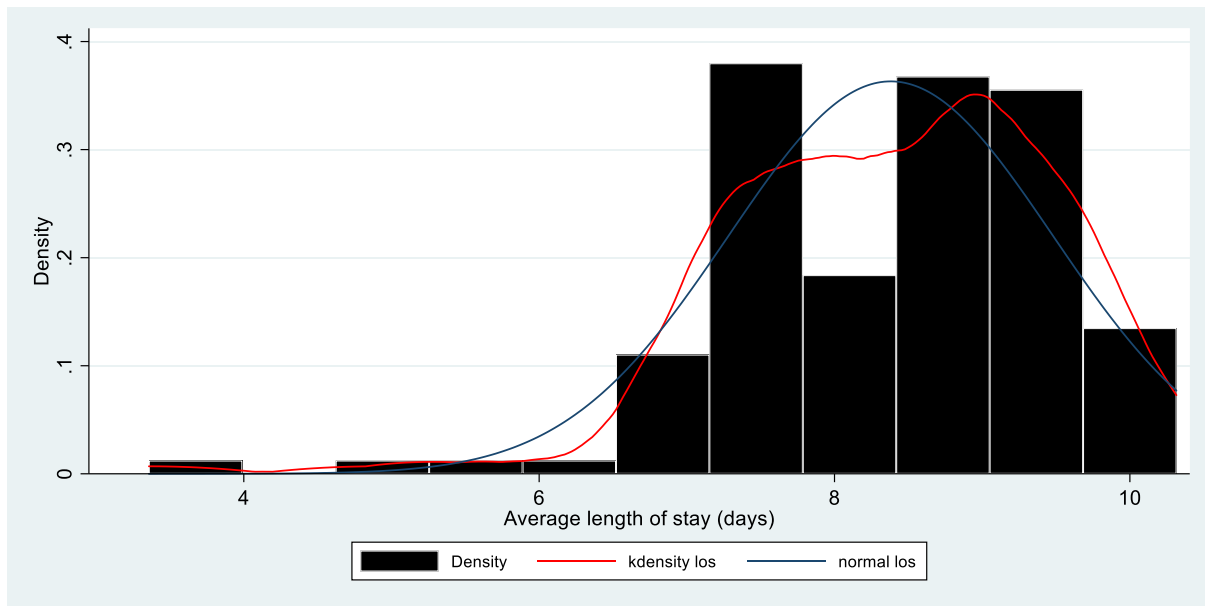


Figure 5.3 Histogram depicting average length of stay of AMI patients in England between 2003 and 2013

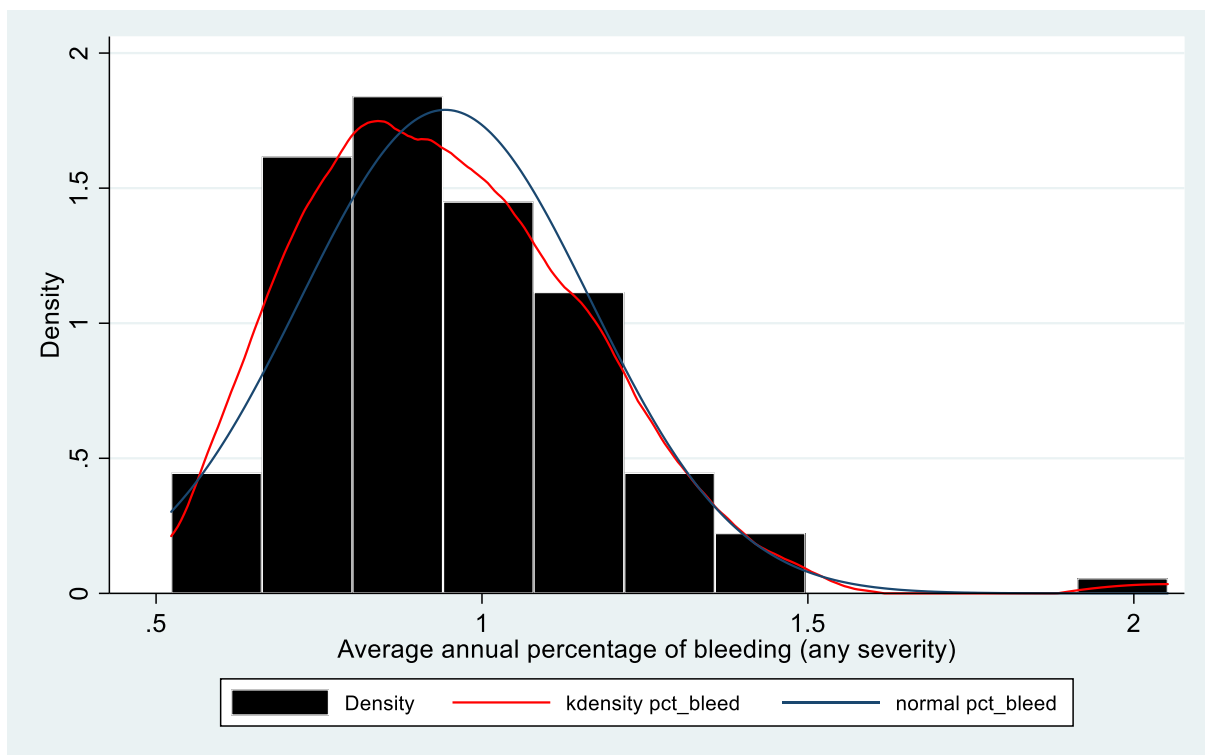


Figure 5.4. Histogram depicting rates of any severity of bleeding in AMI patients in England between 2003 and 2013

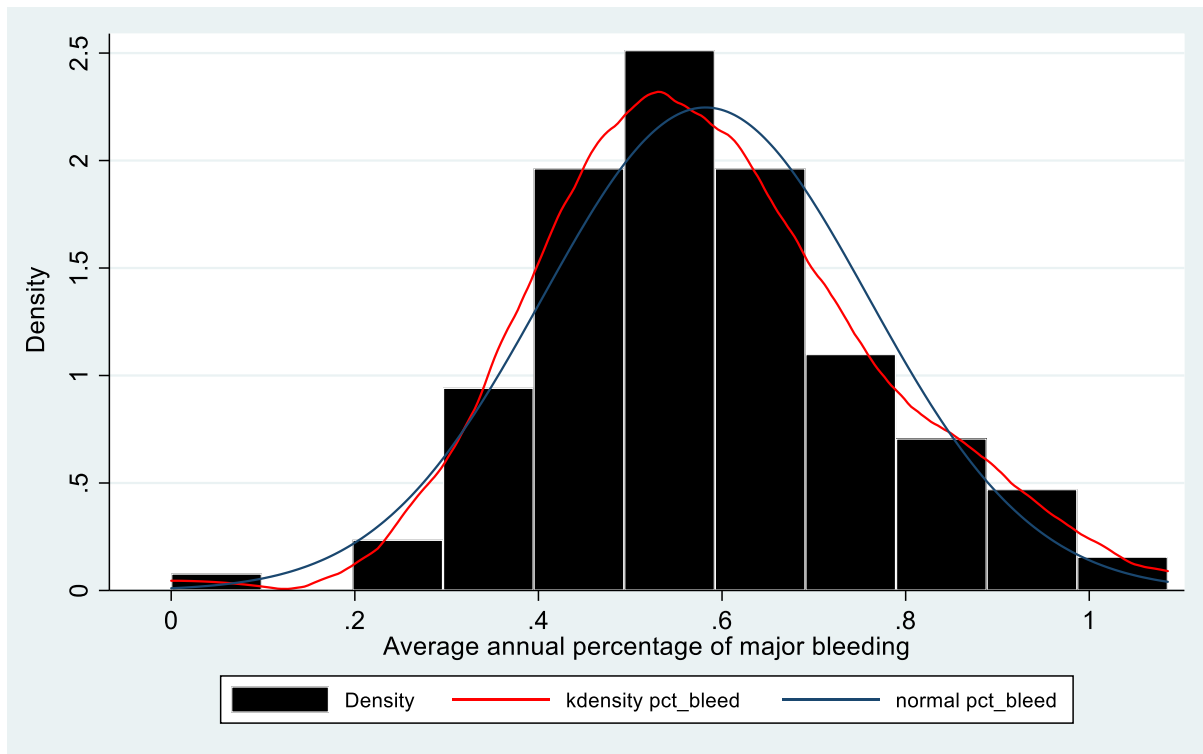


Figure 5.5. Histogram depicting rates of major bleeding in AMI patients in England between 2003 and 2013.

Regression diagnostics, including tests for autocorrelation, are presented in Appendix E.3. In all single and multiple-group models, trends in the response variable demonstrated non-stationarity, which is characteristic of the frequent policy and technological changes that took place in cardiology over the study period. The full list of time series models is presented in Appendix E.

Single group interrupted time series: month level

At the month level, the response variables were analysed with intervention dates specified at the same month of feedback report publication, namely a 0-month lag, and then by introducing +1, +2-, and +3-month lags. In all the models using any bleeding and length of stay as the response variables, one significant interaction was found at March 2007 for any bleeding (percentage). With and without covariates, the coefficients and confidence intervals were 0.11 [0.00070 – 0.22, $p < 0.05$] and 0.11 [0.011 – 0.21, $p < 0.05$], respectively. With and without covariates, the length of stay at month +1 (April 2007) fell by -0.20 [CI = -0.42 – 0.033, $p < 0.1$] and -0.18 [CI = -0.39 – 0.029, $p < 0.1$], respectively.

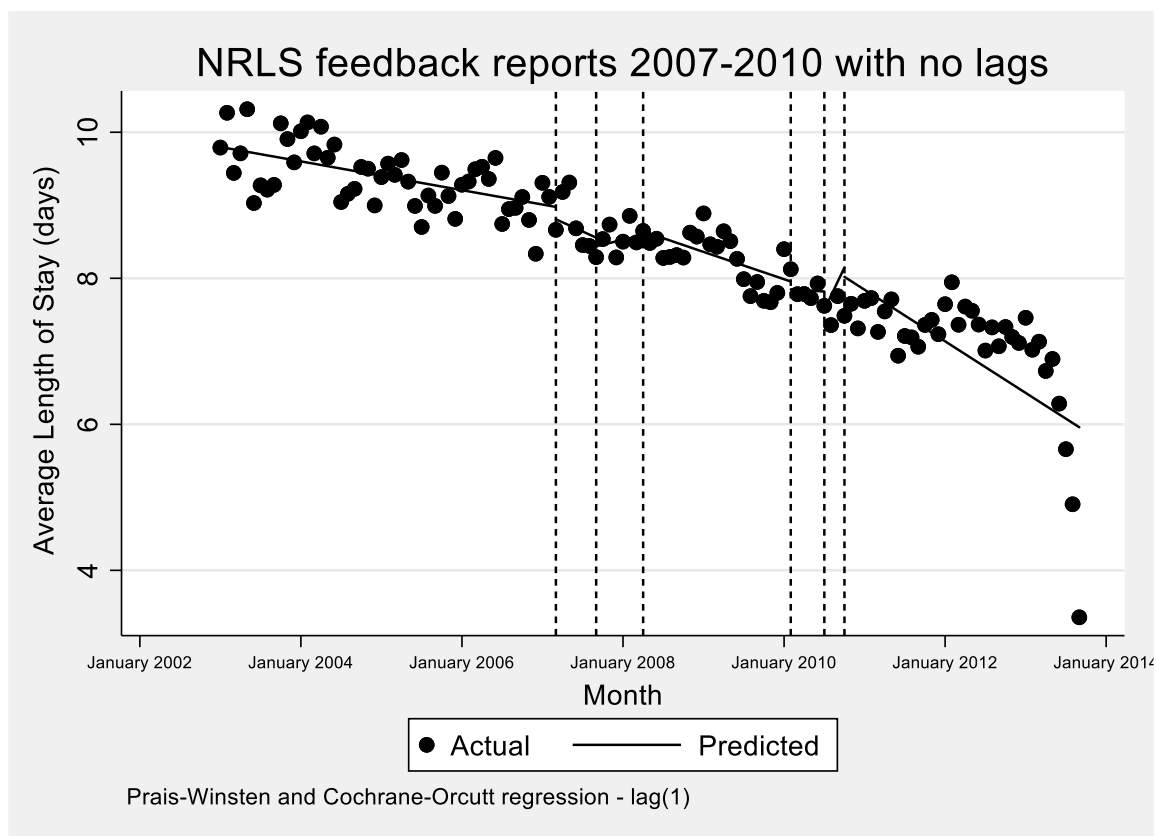


Figure 5.6. Model 1 – single-group interrupted time series analysis of average length of stay in English NHS hospitals from 2003 to 2013 for AMI patients, aggregated by month. Interruptions (dashed lines) are specified at March 2007, September 2007, April 2008, February 2010, July 2010, and October 2010. These interruptions correspond to the NRLS feedback reports presented in Appendix E.2 and are as follows: Patient safety alert: Actions that can make anticoagulant therapy safer (March 2007); Rapid Response Report (RRR): Emergency support in surgical units: dealing with haemorrhage (September 2007); RRR: Risks with Intravenous Heparin Flush Solutions (April 2008); RRR: Reducing harm from omitted and delayed medicines in hospital (February 2010); RRR: Reducing treatment dose errors with low molecular weight heparins (July 2010); Signal: Haemorrhage following removal of femoral catheters (October 2010). A significant ($p < 0.01$) change in the trend was found at March 2007; however, no other interruptions were statistically indicative of an effect of generated by feedback reports. According to an internal communication accompanying the MINAP data extract from the data administrators, the reporting of quality in the final two months of 2013 was inconsistent compared with previous years for reasons that were not disclosed. This may explain the sudden fall in average length of stay at the end of the time series. These observations are therefore assumed to be related to data quality rather than secular trends.

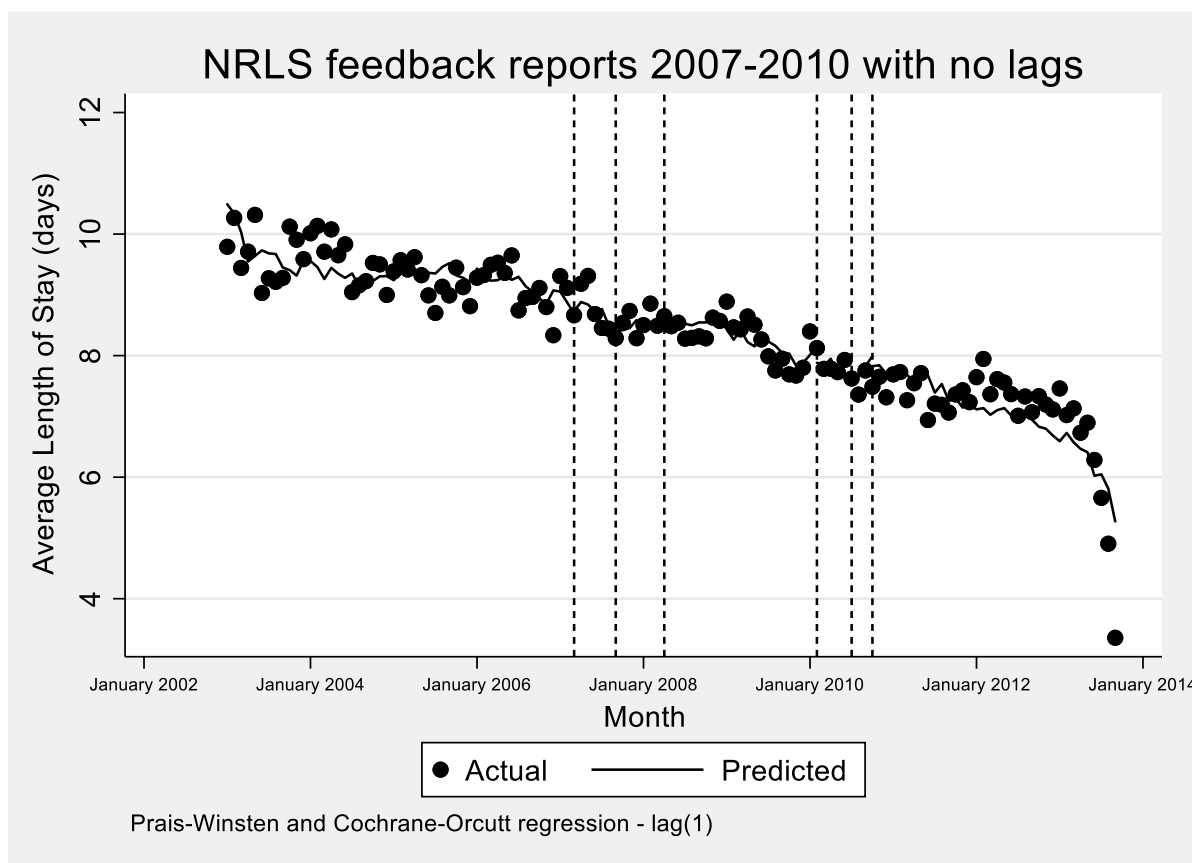


Figure 5.7. Model 2 – single-group interrupted time series analysis of average length of stay in English NHS hospitals from 2003 to 2013 for AMI patients, with statistically significant covariates added by backward elimination, aggregated by month. Interruptions (dashed lines) are specified at March 2007, September 2007, April 2008, February 2010, July 2010, and October 2010. A significant ($p < 0.01$) change in the trend was found at March 2007; however, no other interruptions were statistically indicative of an effect generated by feedback reports. Reporting quality in the final two months of 2013 was inconsistent compared with previous years; therefore, it is this rather than secular trends that explains the sudden fall in average length of stay at the end of the time series.

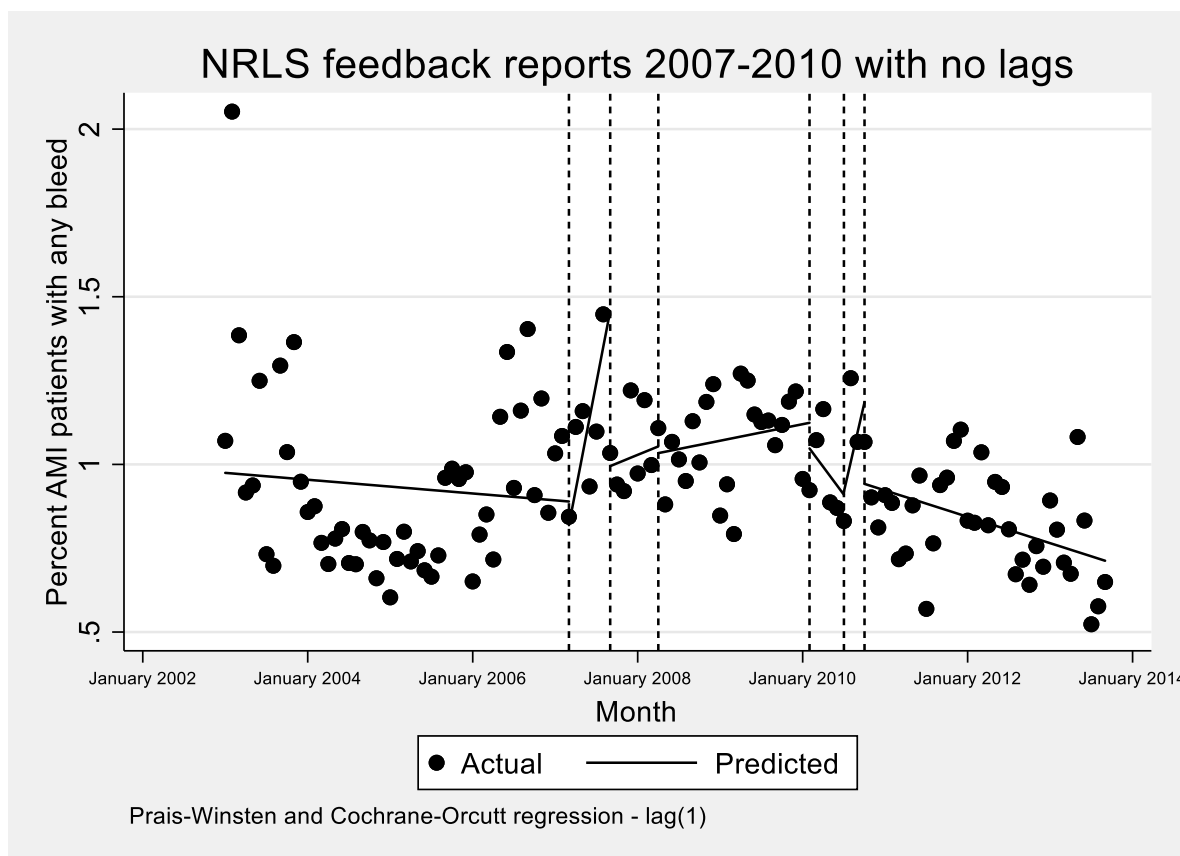


Figure 5.8. Model 3 – single-group interrupted time series analysis of average rate of any bleeding (percentage) in English NHS hospitals from 2003 to 2013 for AMI patients, aggregated by month. Interruptions (dashed lines) are specified at March 2007, September 2007, April 2008, February 2010, July 2010, and October 2010. A significant ($p < 0.01$) change in the trend was found at March 2007; however, no other interruptions were statistically indicative of an effect generated by feedback reports. Reporting quality in the final two months of 2013 was inconsistent compared with previous years; therefore, it is this rather than secular trends that explains the sudden fall in average length of stay at the end of the time series).

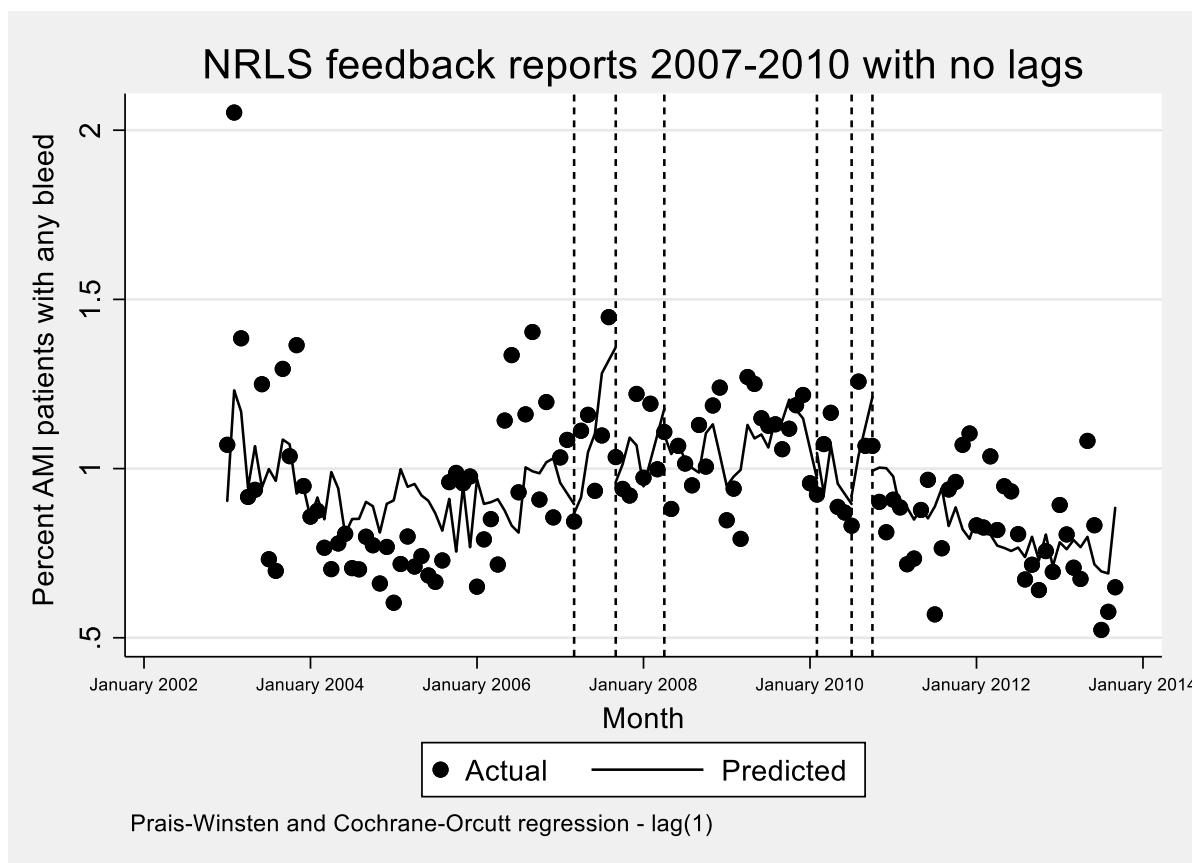


Figure 5.9. Model 4 – single-group interrupted time series analysis of average length of stay in English NHS hospitals from 2003 to 2013 for AMI patients, with statistically significant covariates added by backward elimination, aggregated by month. Interruptions (dashed lines) are specified at March 2007, September 2007, April 2008, February 2010, July 2010, and October 2010. A significant ($p < 0.01$) change in the trend was found at March 2007; however, no other interruptions were statistically indicative of an effect generated by feedback reports. Reporting quality in the final two months of 2013 was inconsistent compared with previous years; therefore, it is this rather than secular trends that explains the sudden fall in average length of stay at the end of the time series.

Table 5.6. Single-group interrupted time series using segmented regressions with generalised linear model of length of stay (LOS) and any bleeding occurring in AMI patients in England between 2003 and 2013 (monthly observations).

Interruptions are specified according to National Reporting and Learning System (NRLS) feedback report publication dates. Monthly time series data are used.

VARIABLES	Model 1: LOS (days)	Model 2: LOS (days)	Model 3: Any bleeding (percentage)	Model 4: Any bleeding (percentage)
Month	-0.016* [-0.030 - -0.0024]	-0.045*** [-0.063 - -0.028]	-0.0017 [-0.0072 - 0.0038]	-0.0048 [-0.012 - 0.0029]
Intervention (March 2007)	-0.17 [-0.93 - 0.59]	-0.21 [-0.91 - 0.50]	-0.071 [-0.43 - 0.29]	-0.10 [-0.44 - 0.23]
Month * Intervention (March 2007)	-0.025 [-0.26 - 0.21]	-0.038 [-0.25 - 0.17]	0.11* [0.00070 - 0.22]	0.11* [0.011 - 0.21]
Intervention (Sept 2007)	-0.12 [-1.08 - 0.85]	-0.16 [-1.08 - 0.76]	-0.46+ [-0.94 - 0.018]	-0.52* [-0.98 - -0.068]
Month * Intervention (Sept 2007)	0.064 [-0.27 - 0.40]	0.11 [-0.19 - 0.41]	-0.098 [-0.25 - 0.050]	-0.073 [-0.21 - 0.063]
Intervention (April 2008)	0.049 [-0.85 - 0.95]	0.031 [-0.81 - 0.87]	-0.020 [-0.45 - 0.41]	-0.14 [-0.54 - 0.25]
Month * Intervention (April 2008)	-0.053 [-0.26 - 0.15]	-0.057 [-0.24 - 0.13]	-0.0043 [-0.096 - 0.087]	-0.028 [-0.11 - 0.057]
Intervention (Jan 2010)	-0.11 [-0.92 - 0.71]	-0.087 [-0.85 - 0.68]	-0.076 [-0.47 - 0.32]	-0.088 [-0.45 - 0.28]
Month * Intervention (Jan 2010)	0.025 [-0.28 - 0.33]	0.077 [-0.20 - 0.36]	-0.032 [-0.17 - 0.11]	-0.015 [-0.15 - 0.11]
Intervention (March 2010)	-0.25 [-1.27 - 0.77]	-0.32 [-1.31 - 0.66]	0.0088 [-0.51 - 0.53]	0.012 [-0.49 - 0.52]
Month * Intervention (March 2010)	0.20 [-0.46 - 0.85]	0.060 [-0.56 - 0.68]	0.12 [-0.20 - 0.43]	0.076 [-0.22 - 0.38]
Intervention (April 2010)	-0.13	-0.024	-0.24	-0.16

Month * Intervention (April 2010)	[-1.28 – 1.03] -0.25 [-0.78 – 0.28]	[-1.14 – 1.09] -0.15 [-0.65 – 0.36]	[-0.84 – 0.35] -0.096 [-0.36 – 0.17]	[-0.73 – 0.41] -0.072 [-0.33 – 0.18]
Average Rate of STEMI				3.86+ [-0.20 – 7.91]
Average Systolic Blood Pressure				0.061*** [0.028 – 0.094]
Per cent admissions w/previous hypertension				0.033** [0.012 – 0.053]
Average #Anticoagulant		11.3*** [6.04 – 16.7]		
Constant	9.80*** [9.39 – 10.2]	2.42 [-1.04 – 5.89]	0.97*** [0.82 – 1.13]	-10.4*** [-16.2 - -4.65]
Observations	129	129	129	129
R-squared	0.760	0.809	0.170	0.288
Adj. R-squared	0.73	0.79	0.076	0.19
Autocorrelation	0.49	0.42	0.34	0.25

in brackets
*** p < 0.001, ** p < 0.01, * p < 0.05, + p < 0.1

For the same model (0-month lag), length of stay fell for each month by -0.016 days [CI = -0.030 - -0.0024, $p < 0.05$] and -0.045 days [CI = -0.063 - -0.028, $p < 0.001$]; however, this was not significantly associated with the introduction of feedback reports. This finding occurred in every monthly time series model generated, with and without covariates, as follows: month +1, -0.019 [CI = -0.032 - -0.0052, $p < 0.01$] and -0.046 [CI = -0.063 - -0.028, $p < 0.001$]; month +2, -0.018 [CI = -0.031 - -0.0046, $p < 0.01$] and -0.046 [CI = -0.064 - -0.028, $p < 0.001$]; month +3, -0.016 [CI = -0.029 - -0.0035, $p < 0.05$] and -0.045 [CI = -0.062 - -0.027, $p < 0.001$]. In models with major bleeding as the response variable, no significant interactions were observed at $p < 0.05$ for any intervention-month interaction. At $p < 0.1$, intervention-month interactions were significant with and without covariates for March 2007 0.063 [CI = -0.0086 – 0.13] and 0.059 [CI = -0.0090 – 0.13], respectively.

Models for major bleeding with covariates were significantly associated with an additional month in the time series for each of the 0, +1, +2 and +3 lag models as follows: -0.0065 [-0.012 - -0.0012, $p < 0.05$], -0.0068 [-0.012 - -0.0015, $p < 0.05$], -0.0063 [-0.012 - -0.00099, $p < 0.05$], and -0.0061 [CI = -0.011 - -0.00079, $p < 0.05$].

Single group interrupted time series: quarter level

Quarterly models revealed no significant associations between the introduction of feedback reports within a quarter and length of stay, any bleeding, or major bleeding, with and without covariates. As shown in Table 5.7, the covariate regression model for LOS provided more explanatory (Adjusted R-squared = 0.88) power than without covariates; however, for bleeds of any severity and major bleeding, the Adjusted R-squared values were 0.22 and 0.43.

Table 5.7. Single-group interrupted time series using segmented regressions with generalised linear model of length of stay (LOS), any bleeding, and major bleeding occurring in AMI patients in England between 2003 and 2013 (quarterly observations).

Interruptions are specified according to National Reporting and Learning System (NRLS) feedback report publication dates. Quarterly time series data are used.

VARIABLES	Model 5: LOS (days)	Model 6: LOS (days)	Model 7: Any bleeding (percentage)	Model 8: Major bleeding (percentage)
Quarter	-0.058* [-0.12 - -0.00011]	-0.20*** [-0.28 - -0.11]	-0.012 [-0.035 - 0.010]	-0.0011 [-0.014 - 0.011]
Intervention (Q1 2007)	0.18 [-0.78 - 1.14]	-0.091 [-0.94 - 0.75]	0.12 [-0.25 - 0.49]	0.019 [-0.23 - 0.27]
Quarter * Intervention (Q1 2007)	0.051 [-1.03 - 1.13]	0.021 [-0.96 - 1.00]	0.12 [-0.30 - 0.53]	0.12 [-0.18 - 0.42]
Intervention (Q3 2007)	-0.66 [-2.45 - 1.12]	-0.15 [-1.76 - 1.45]	0.0096 [-0.67 - 0.69]	-0.096 [-0.61 - 0.42]
Quarter * Intervention (Q3 2007)	0.13 [-1.16 - 1.41]	0.16 [-0.99 - 1.30]	-0.18 [-0.67 - 0.32]	-0.22 [-0.56 - 0.13]
Intervention (Q2 2008)	-0.11 [-1.50 - 1.28]	0.096 [-1.10 - 1.29]	0.052 [-0.48 - 0.58]	0.19 [-0.18 - 0.55]
Quarter * Intervention (Q2 2008)	-0.24 [-0.89 - 0.40]	-0.041 [-0.59 - 0.51]	0.098 [-0.15 - 0.35]	0.089 [-0.073 - 0.25]
Intervention (Q1 2010)	0.37 [-0.72 - 1.46]	0.055 [-0.89 - 1.00]	-0.20 [-0.62 - 0.22]	-0.058 [-0.34 - 0.23]
Quarter * Intervention (Q1 2010)	-0.18 [-1.29 - 0.93]	-0.0052 [-0.98 - 0.97]	-0.034 [-0.46 - 0.39]	-0.027 [-0.33 - 0.28]
Intervention (Q3 2010)	0.14 [-1.65 - 1.93]	-0.019 [-1.62 - 1.58]	0.089 [-0.59 - 0.77]	0.11 [-0.41 - 0.62]
Quarter * Intervention (Q3 2010)	0.14 [-0.94 - 1.22]	-0.031 [-0.98 - 0.92]	-0.014 [-0.43 - 0.40]	0.020 [-0.28 - 0.32]
Intervention (Q4 2010)	0.39	0.048	-0.096	-0.12

Quarter * Intervention (Q4 2010) = o,	[-0.61 – 1.38] -	[-0.81 – 0.91] -	[-0.48 – 0.29] -	[-0.38 – 0.14] -
Average Systolic Blood Pressure		-0.15*		
Average Heart Rate		[-0.29 - -0.013] 0.28*		
Average #Anticoagulant		[0.039 – 0.53] 11.9*		
Constant	9.82*** [9.31 – 10.3]	0.88 [-9.50 – 11.3]	1.03*** [0.82 – 1.23]	0.64*** [0.53 – 0.75]
Observations	43	43	43	43
R-squared	0.873	0.924	0.441	0.595
Adj. R-squared	0.82	0.88	0.22	0.43
Autocorrelation	0.25	0.15	0.26	0.059

in brackets

*** p < 0.001, ** p < 0.01, * p < 0.05, + p < 0.1

Single group interrupted time series: year level

At the year level, the specification of models for years in which the feedback reports were published (2007, 2008, and 2010) produced no significant interactions. The models were respecified to estimate interactions at 2008 and 2010 on the assumption that their effects would only be manifested after the publication of the first two feedback reports, which were published in April and September 2007. None of these yearly time series models provided statistically significant coefficients indicating an effect associated with the publication of feedback reports during these years.

For single interruption models where the intervention was specified at 2010, non-significant ($p < 0.1$) changes to the slopes for length of stay and any bleeding (for models without covariates) were observed. The slope for major bleeding fell significantly ($p < 0.05$) after 2010 and the addition of covariates to this model increased the significance of the interaction ($p < 0.01$). Of all the single group year-level models, the addition of covariates to regression models of any bleeding produced a highly significant interaction ($p < 0.001$). At the year level, a single intervention-year specified at 2010 was significantly associated (-0.083) with a change in any bleeding for AMI patients [CI = -0.11 - -0.057, $p < 0.01$]. A weaker association (-0.069) was observed for a single intervention-year specified at 2010 for major bleeding [CI = -0.14 - -0.0011, $p < 0.05$] without covariates. Using forward elimination to derive a covariate model (Figure 5.14), a significant association (-0.051) between intervention-year 2010 and major bleeding was observed [CI = -0.070 - -0.031, $p < 0.01$].

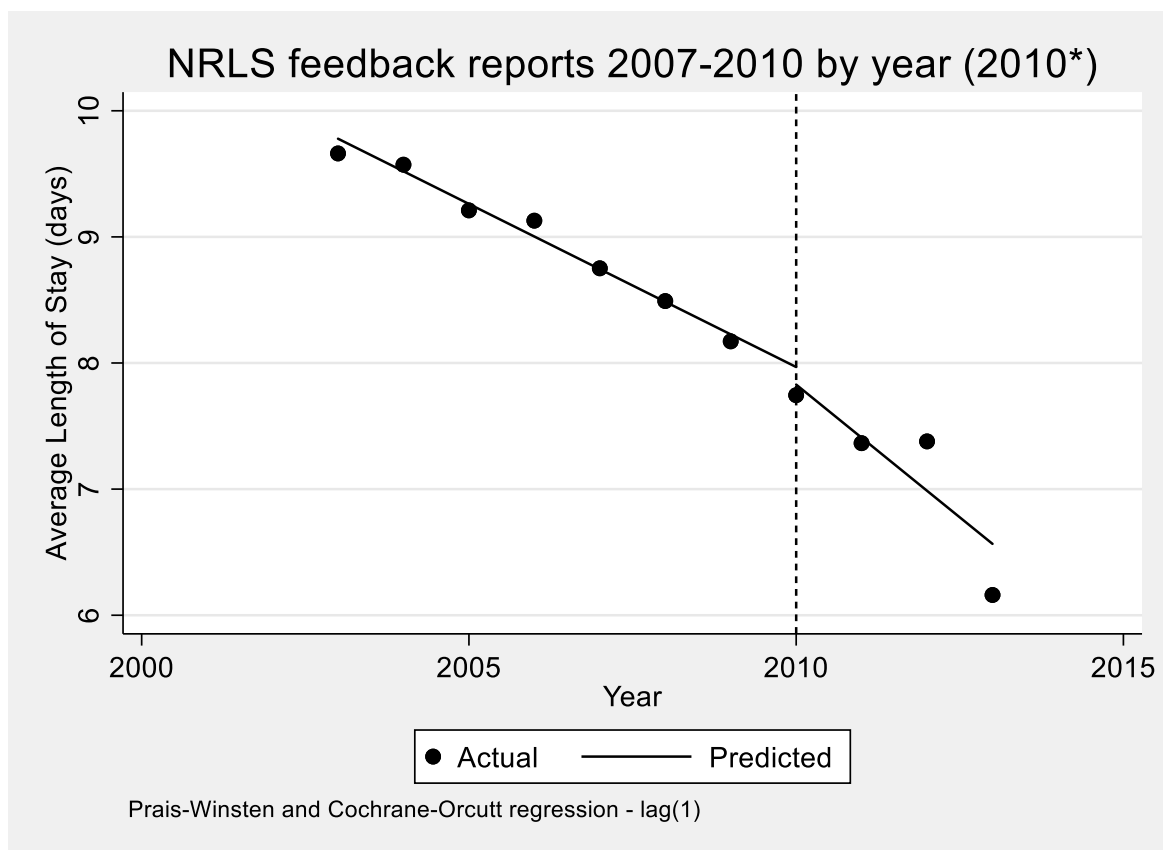


Figure 5.10. Model 9 – single-group interrupted yearly time series analysis of average length of stay from 2003 to 2013 for AMI patients in England. The interruption (dashed line) is specified at 2010. A statistically significant ($p < 0.1$) change in the trend was identified, indicating the presence of an effect before and after 2010.

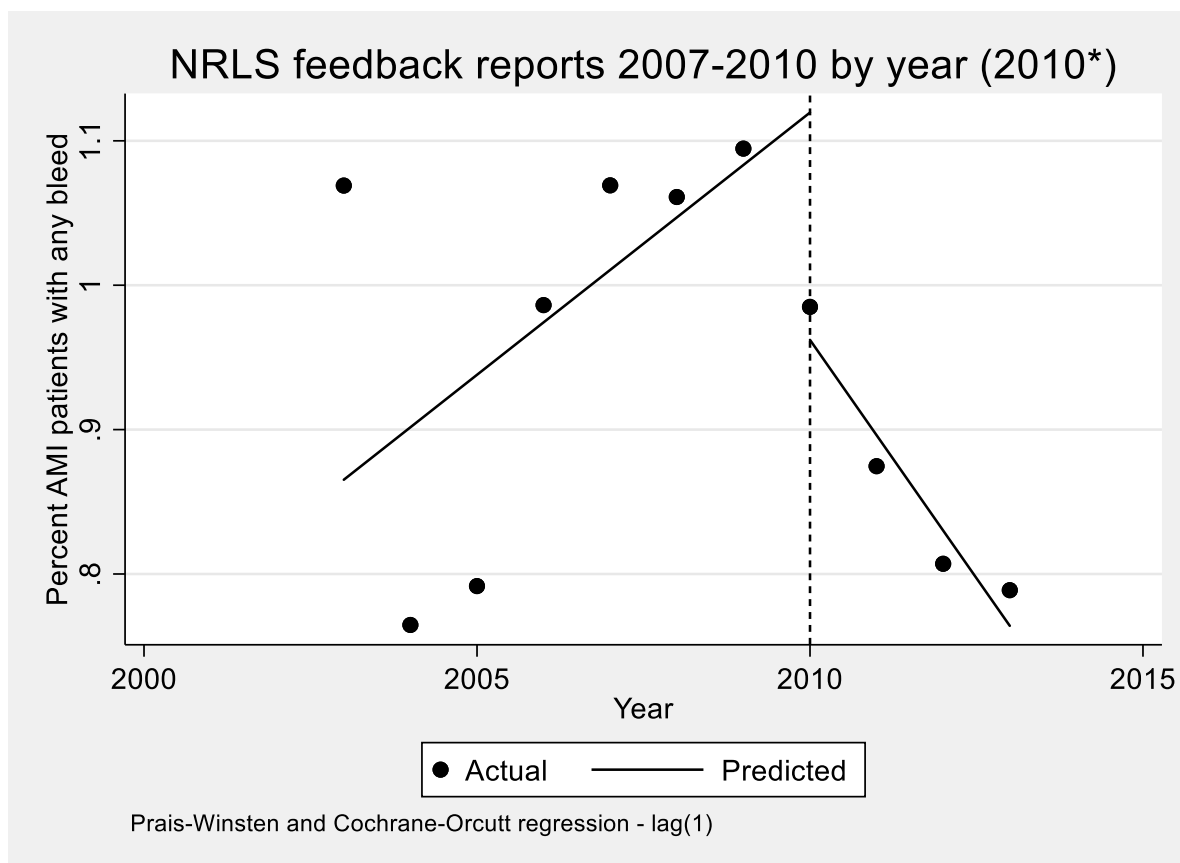


Figure 5.11. Model 10 – single-group interrupted yearly time series analysis of average rate of any bleeding (percentage) from 2003 to 2013 for AMI patients in England, without covariates. The interruption (dashed line) is specified at 2010. A statistically significant ($p < 0.1$) change in the trend was identified, indicating the presence of an effect before and after 2010.

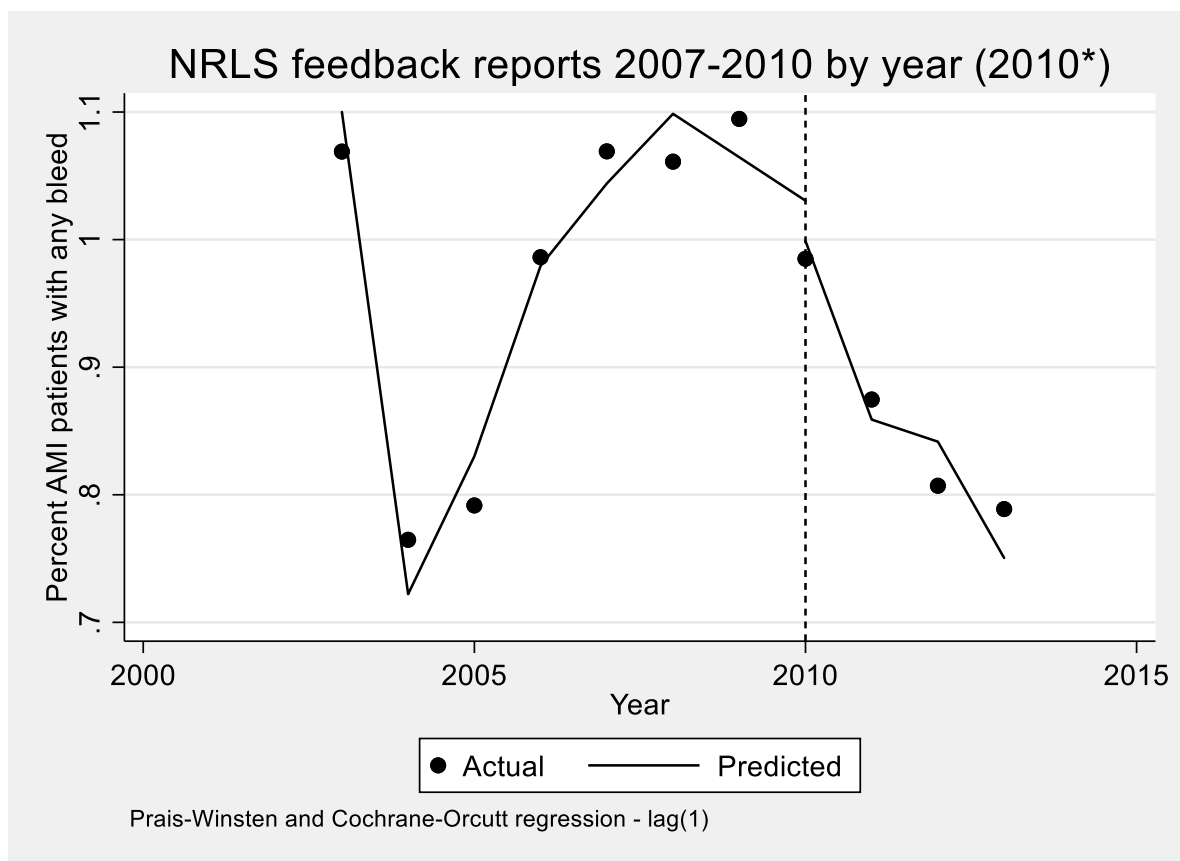


Figure 5.12. Model 11 – single-group interrupted yearly time series analysis of average rate of any bleeding (percentage) from 2003 to 2013 for AMI patients in England, with covariates. The interruption (dashed line) is specified at 2010. A statistically significant ($p < 0.001$) change in the trend was identified, indicating the presence of an effect before and after 2010.

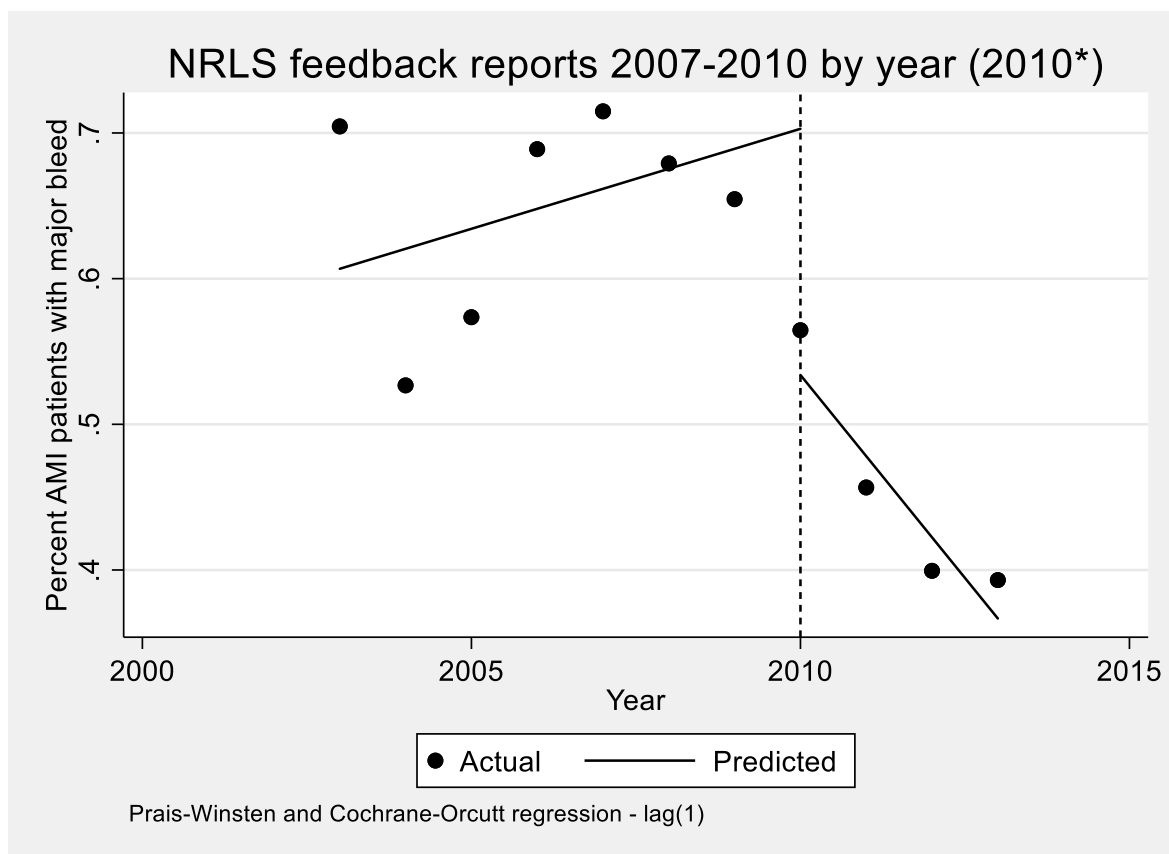


Figure 5.13. Model 12 – single-group interrupted yearly time series analysis of average rate of major bleeding (percentage) from 2003 to 2013 for AMI patients in England, without covariates. The interruption (dashed line) is specified at 2010. A statistically significant ($p < 0.05$) change in the trend was identified, indicating the presence of an effect before and after 2010.

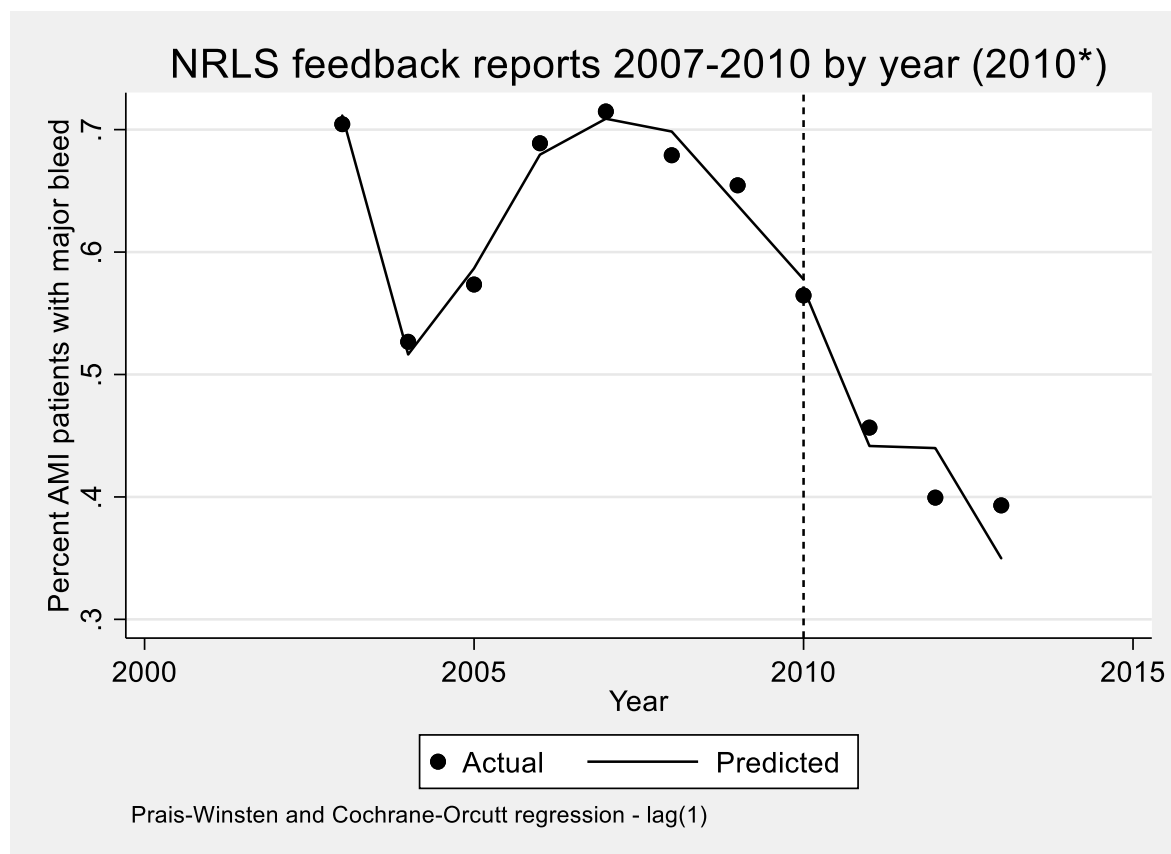


Figure 5.14. Model 13 – single-group interrupted yearly time series analysis of average rate of major bleeding (percentage) in English NHS hospitals from 2003 to 2013 for AMI patients, with covariates added by forward elimination (backward elimination yielded no significant covariates). The interruption in this model (dashed line) is specified at 2010. A significant ($p < 0.01$) change in the trend was identified.

Table 5.8. Single-group interrupted time series using segmented regressions with generalised linear model of length of stay (LOS), any bleeding, and major bleeding occurring in AMI patients in England between 2003 and 2013 (yearly observations).

Interruptions are specified according to National Reporting and Learning System (NRLS) feedback report publication dates. Yearly time series data are used.

VARIABLES	Model 9: LOS (days)	Model 10: Any bleeding (percentage)	Model 11: Any bleeding (percentage)	Model 12: Major bleeding (percentage)	Model 13: Major bleeding (percentage)
Year	-0.26*** [-0.32 - -0.20]	0.036 [-0.011 – 0.083]	-0.030 [-0.072 – 0.011]	0.014 [-0.012 – 0.040]	-0.065** [-0.096 - -0.033]
Intervention (2010)	-0.14 [-0.56 – 0.28]	-0.16 [-0.46 – 0.15]	-0.034 [-0.14 – 0.073]	-0.17+ [-0.34 – 0.0025]	-0.019 [-0.098 – 0.061]
Year * Intervention (2010)	-0.16+ [-0.33 – 0.0062]	-0.10+ [-0.22 – 0.020]	-0.083*** [-0.11 - -0.057]	-0.069* [-0.14 - -0.0011]	-0.051** [-0.070 - -0.031]
Per cent admissions w/previous AMI			-0.052** [-0.085 - -0.020]	0.61*** [0.51 – 0.70]	-0.063** [-0.088 - -0.039]
Per cent admissions w/ hypertension			0.10** [0.061 – 0.14]		0.089*** [0.060 – 0.12]
Constant	9.78*** [9.56 – 10.00]	0.87*** [0.70 – 1.03]	-2.62** [-3.61 - -1.63]		-1.88** [-2.61 - -1.14]
Observations	11	11	11	11	11
R-squared	0.993	0.494	0.997	0.824	0.996
Adj. R-squared	0.99	0.28	0.99	0.75	0.99
Autocorrelation	-0.50	-0.094	-0.74	-0.18	-0.67

in brackets

*** p < 0.001, ** p < 0.01, * p < 0.05, + p < 0.1

Multi-group interrupted time series analysis at year level

Models for major bleeding (percentage) for AMI patients in England and Scotland revealed no significant association with treatment exposure (NRLS feedback reports in England) in 2010, 2008 and 2010, or 2007, 2008 and 2010. Statistically significant differences were found between the dependent variables for the before and after periods of all models. This was confirmed visually.

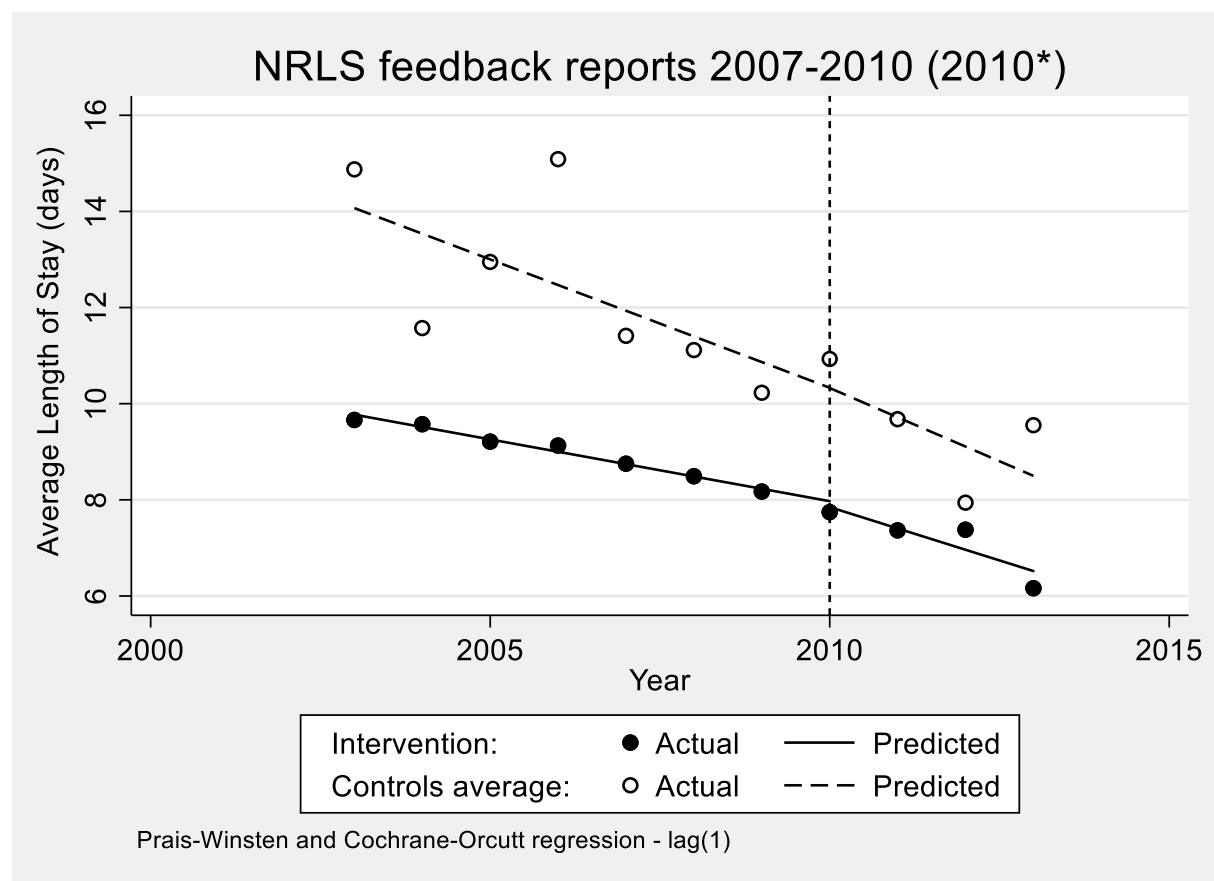


Figure 5.15. Model 14 – multiple-group interrupted time series analysis of average length of stay in English (dashed line) and Scottish (control) NHS hospitals from 2003 to 2013 for AMI patients, aggregated by year. The interruption in this model (dashed line) is specified at 2010 only, which assumes that an effect would only be manifested after the majority of previous feedback reports had been published. No significant change in the trend was identified.

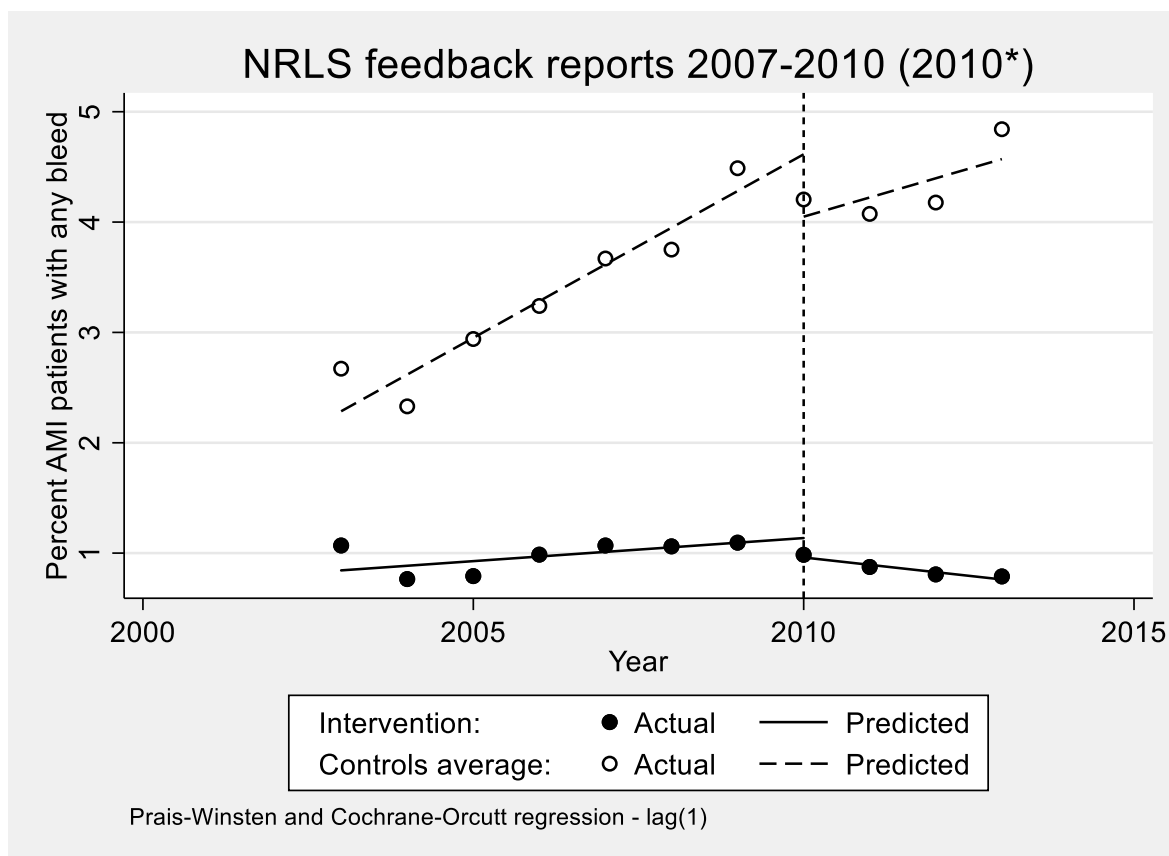


Figure 5.16. Model 15 – multiple-group interrupted time series analysis of average rate of any bleeding (percentage) in English (dashed line) and major bleeding in Scottish (bold line) NHS hospitals from 2003 to 2013 for AMI patients, aggregated by year. The interruption in this model (dashed line) is specified at 2010 only, which assumes that an effect would only be manifested after most previous feedback reports had been published. No significant change in the trend was identified.

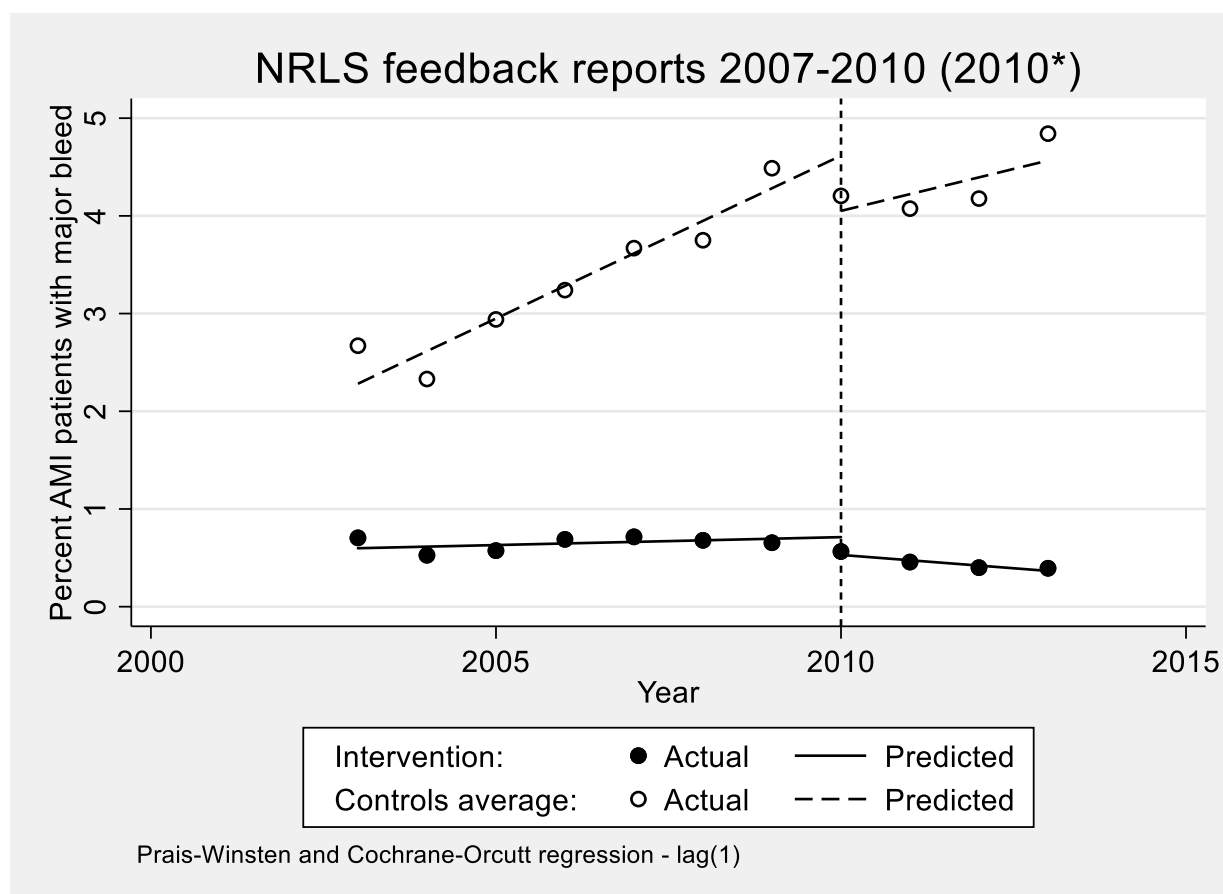


Figure 5.17. Model 16 – multiple-group interrupted time series analysis of average rate of major bleeding (percentage) in English (dashed line) and Scottish (bold line) NHS hospitals from 2003 to 2013 for AMI patients, aggregated by year. The interruption in this model (dashed line) is specified in 2010 only, which assumes that an effect would only be manifested after most of the previous feedback reports had been published. No significant change in the trend was identified. A regression for 2007 and 2008 was omitted due to collinearity between observations.

Table 5.9. Multi-group interrupted time series using segmented regressions with generalised linear model of length of stay (LOS), any bleeding, and major bleeding occurring in AMI patients in England between 2003 and 2013.

Interruption is specified at 2010. Yearly time series data are used.

VARIABLES	Model 14: LOS (days)	Model 15: Any bleeding (percentage)	Model 16: Major bleeding (percentage)
Year	-0.53** [-0.88 - -0.19]	0.33*** [0.27 - 0.40]	0.33*** [0.28 - 0.39]
Treatment	-4.30*** [-6.03 - -2.57]	-1.44*** [-1.76 - -1.13]	-1.68*** [-1.97 - -1.39]
Treatment * Year	0.28 [-0.21 - 0.76]	-0.29*** [-0.38 - -0.20]	-0.32*** [-0.40 - -0.24]
Intervention (2010)	-0.0056 [-2.32 - 2.31]	-0.57* [-0.99 - -0.14]	-0.56** [-0.96 - -0.17]
Intervention * Year	-0.075 [-0.99 - 0.84]	-0.16+ [-0.33 - 0.0093]	-0.16* [-0.32 - -0.0068]
Treatment * Intervention	-0.12 [-3.39 - 3.15]	0.39 [-0.21 - 0.99]	0.38 [-0.17 - 0.94]
Treatment * Intervention * Year (2010)	-0.11 [-1.41 - 1.19]	0.050 [-0.19 - 0.29]	0.091 [-0.13 - 0.31]
Constant	14.1*** [12.8 - 15.3]	2.29*** [2.06 - 2.51]	2.28*** [2.08 - 2.49]
Observations	22	22	22
R-squared	0.907	0.994	0.996
Adj. R-squared	0.86	0.99	0.99
Autocorrelation	-0.29	-0.33	-0.36

in brackets

*** p < 0.001, ** p < 0.01, * p < 0.05, + p < 0.1

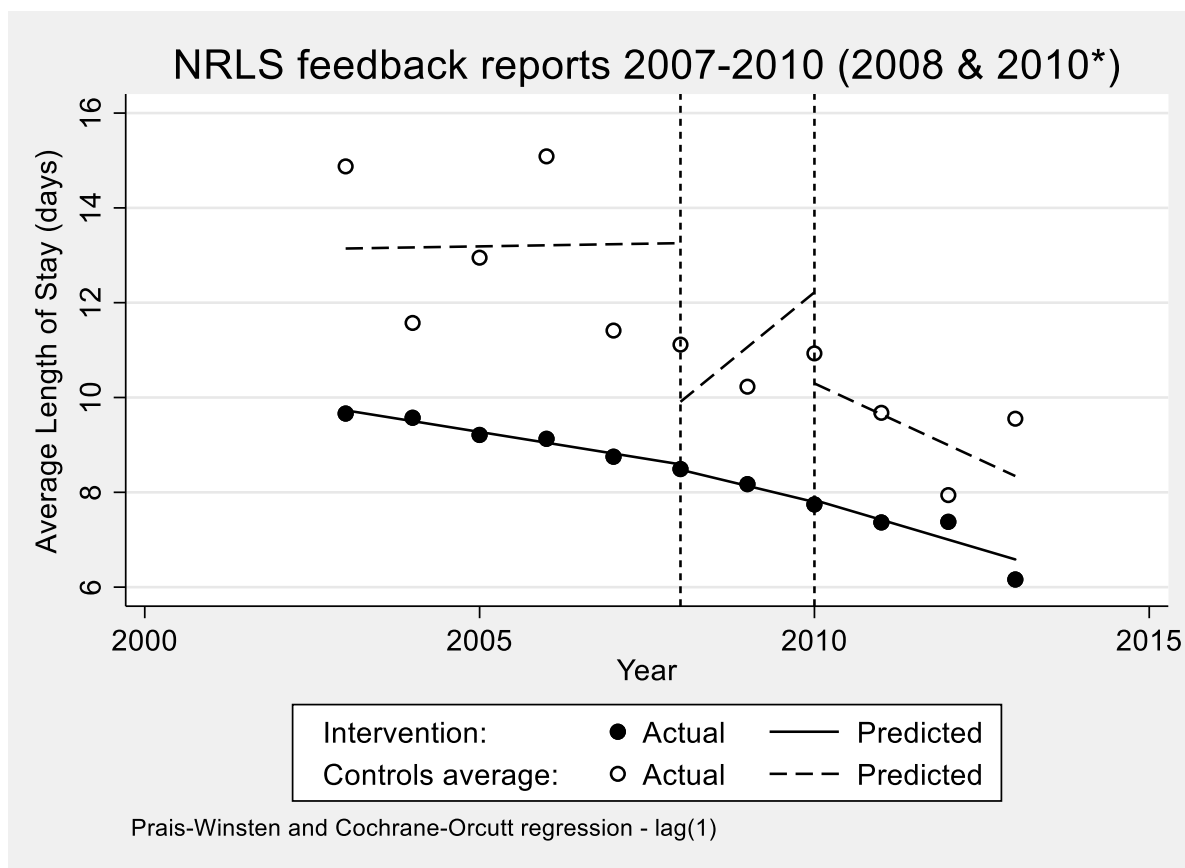


Figure 5.18. Model 17 – multiple-group interrupted time series analysis of average length of stay in English (dashed line) and Scottish (bold line) NHS hospitals from 2003 to 2013 for AMI patients, aggregated by year. The interruptions in this model (dashed lines) are specified at 2008 and 2010. No significant change in the trend was identified.

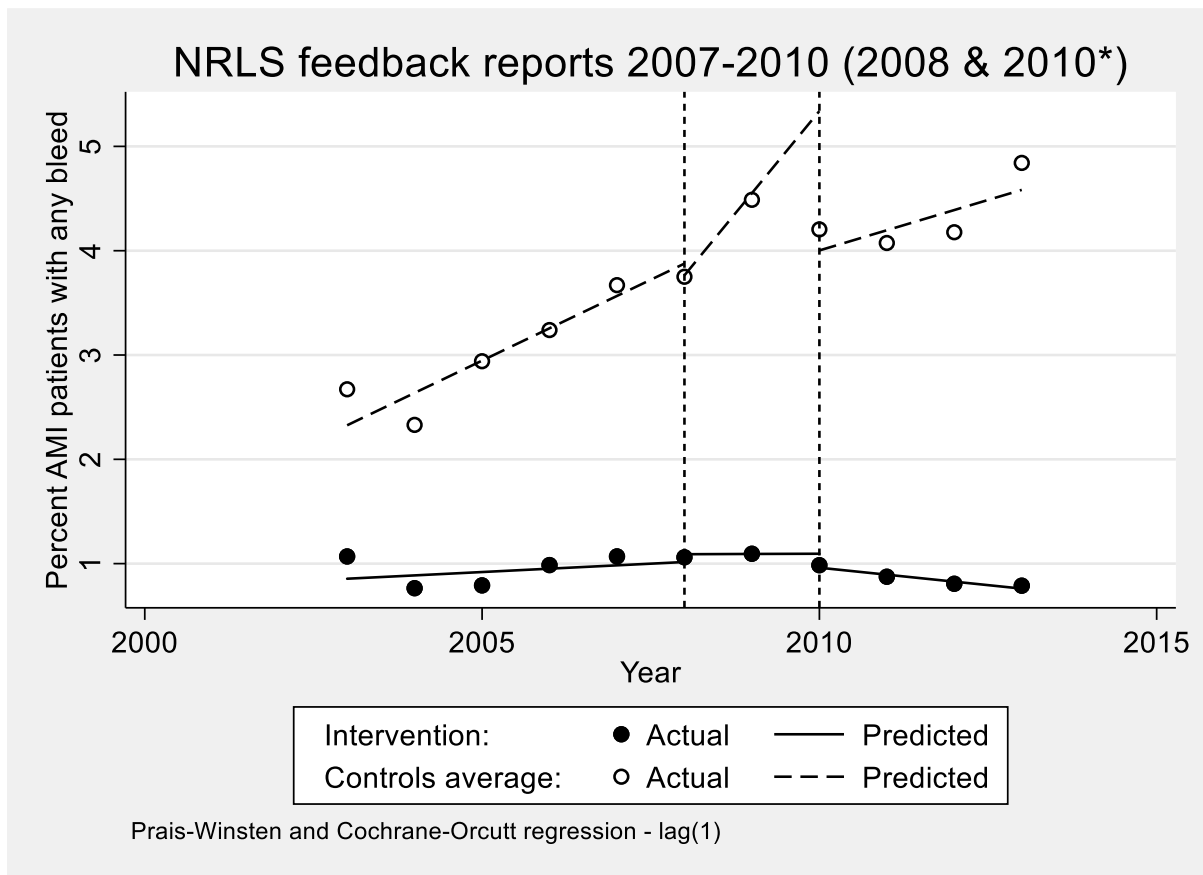


Figure 5.19. Model 18 – multiple-group interrupted time series analysis of average rate of any bleeding (percentage) in English (dashed line) and Scottish (bold line) NHS hospitals from 2003 to 2013 for AMI patients, aggregated by year. The interruptions in this model (dashed lines) are specified at 2008 and 2010. No significant change in the trend was identified.

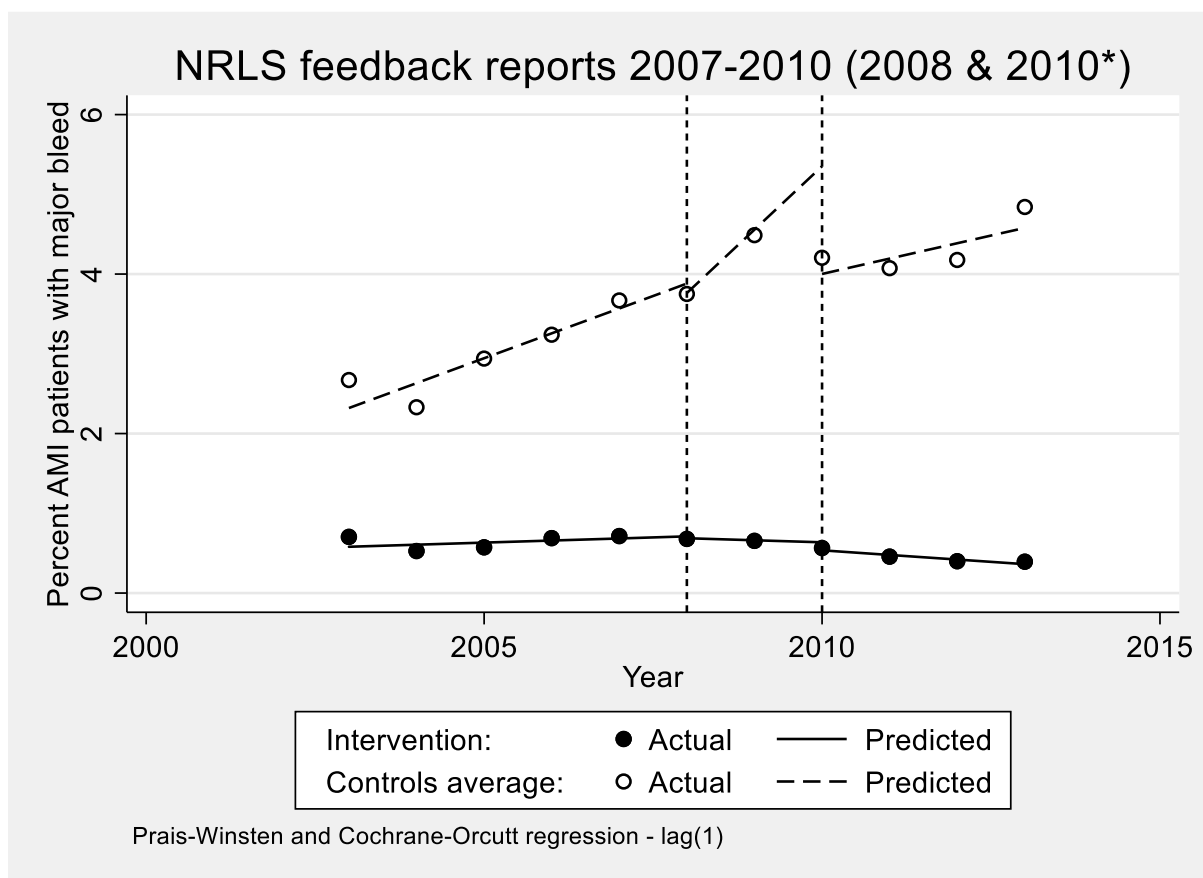


Figure 5.20. Model 19 – multiple-group interrupted time series analysis of average rate of major bleeding in English (dashed line) and Scottish (bold line) NHS hospitals from 2003 to 2013 for AMI patients, aggregated by year. The interruptions in this model (dashed lines) are specified at 2008 and 2010. No significant change in the trend was identified.

Table 5.10. Multi-group interrupted time series using segmented regressions with generalised linear model of length of stay (LOS), any bleeding, and major bleeding occurring in AMI patients in England between 2003 and 2013.

Interruptions are specified at 2008 and 2010. Yearly time series data are used.

VARIABLES	Model 17: LOS (days)	Model 18: Any bleeding (percentage)	Model 19: Major bleeding (percentage)
Year	0.023 [-0.50 – 0.54]	0.31*** [0.19 – 0.43]	0.31*** [0.21 – 0.42]
Treatment	-3.41** [-5.12 - -1.71]	-1.47*** [-1.86 - -1.08]	-1.74*** [-2.09 - -1.39]
Treatment * Year	-0.25 [-0.98 – 0.48]	-0.28** [-0.45 - -0.11]	-0.29** [-0.44 - -0.14]
Intervention (2008)	-3.35* [-6.45 - -0.25]	-0.11 [-0.76 – 0.54]	-0.12 [-0.71 – 0.48]
Intervention * Year	1.13 [-2.47 – 4.73]	0.48 [-0.24 – 1.20]	0.48 [-0.18 – 1.15]
Treatment * Intervention	3.23 [-1.15 – 7.62]	0.19 [-0.73 – 1.11]	0.095 [-0.75 – 0.94]
Treatment * Intervention * Year (2008)	-1.24 [-6.34 – 3.85]	-0.51 [-1.53 – 0.51]	-0.53 [-1.47 – 0.41]
Intervention (2010)	-1.92 [-8.20 – 4.36]	-1.34* [-2.58 - -0.092]	-1.35* [-2.50 - -0.20]
Intervention * Year	-1.81 [-5.36 – 1.75]	-0.59+ [-1.31 – 0.13]	-0.60+ [-1.26 – 0.060]
Treatment * Intervention	1.96 [-6.92 – 10.8]	1.20 [-0.56 – 2.96]	1.25 [-0.38 – 2.87]
Treatment * Intervention * Year (2010)	1.73 [-3.30 – 6.76]	0.52 [-0.49 – 1.54]	0.57 [-0.37 – 1.51]
Constant	13.1*** [11.9 – 14.4]	2.33*** [2.05 – 2.60]	2.32*** [2.07 – 2.57]

Observations	22	22	22
R-squared	0.972	0.996	0.997
Adj. R-squared	0.94	0.99	0.99
Autocorrelation	-0.64	-0.39	-0.43

in brackets

*** $p < 0.001$, ** $p < 0.01$, * $p < 0.05$, + $p < 0.1$

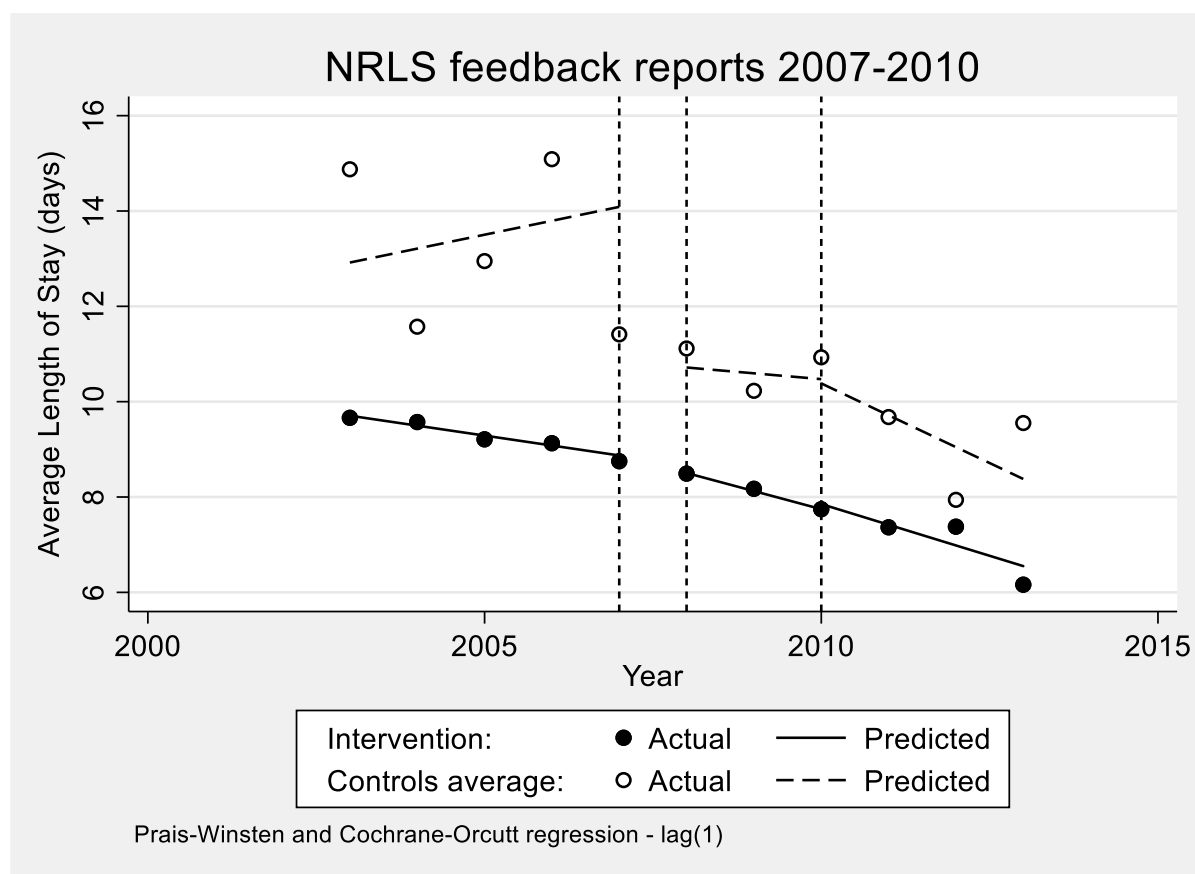


Figure 5.21. Model 20 – multiple-group interrupted time series analysis of average length of stay in English (dashed line) and Scottish (bold line) NHS hospitals from 2003 to 2013 for AMI patients, aggregated by year. The interruptions in this model (dashed lines) are specified at 2007, 2008, and 2010. No significant change in the trend was identified. A regression for 2007 and 2008 was omitted due to collinearity between observations. Reporting quality in 2013 was inconsistent compared with previous years; therefore, it is this rather than secular trends that explains the sudden fall in average length of stay at the end of the time series.

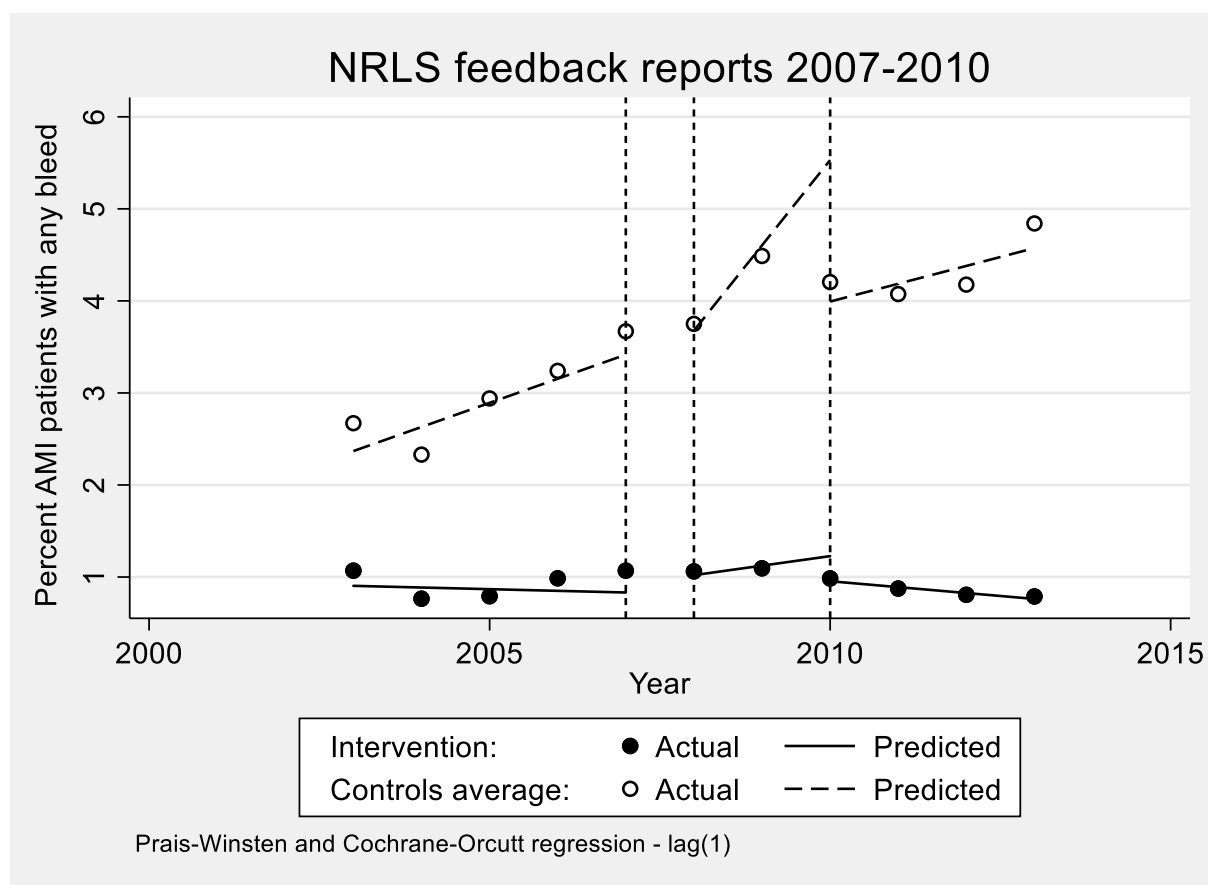


Figure 5.22. Model 21 – multiple-group interrupted time series analysis of average rate of any bleeding (percentage) in English (dashed line) and major bleeding in Scottish (bold line) NHS hospitals from 2003 to 2013 for AMI patients, aggregated by year. The interruptions in this model (dashed lines) are specified at 2007, 2008, and 2010. No significant change in the trend was identified. A regression for 2007 and 2008 was omitted due to collinearity between observations. Reporting quality in 2013 was inconsistent compared with previous years; therefore, it is this rather than secular trends that explains the sudden fall in average length of stay at the end of the time series.

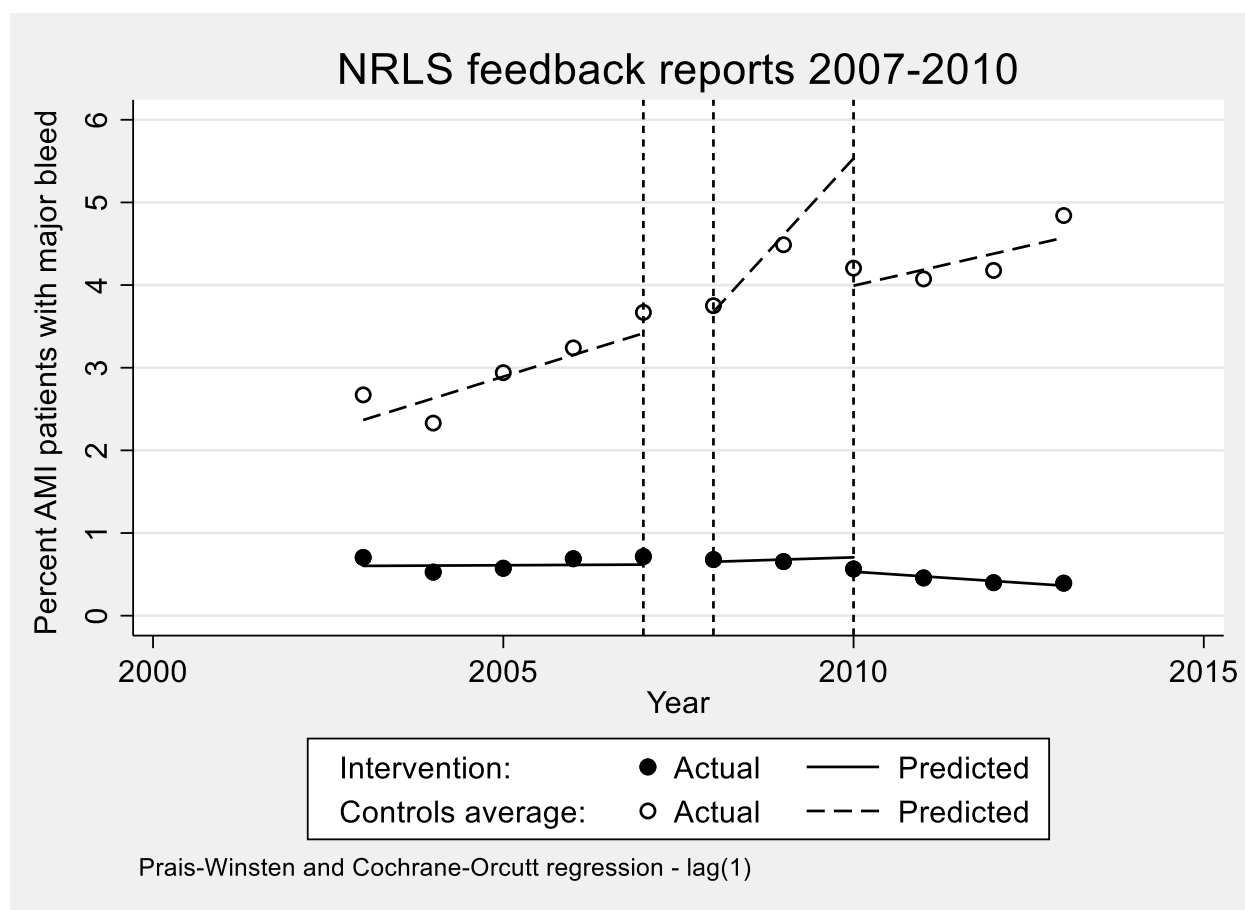


Figure 5.23. Model 22 -multiple-group interrupted time series analysis of average rate of major bleeding (percentage) in English (dashed line) and Scottish (bold line) NHS hospitals from 2003 to 2013 for AMI patients, aggregated by year. The interruptions in this model (dashed lines) are specified at 2007, 2008, and 2010. No significant change in the trend was identified. A regression for 2007 and 2008 was omitted due to collinearity between observations. Reporting quality in 2013 was inconsistent compared with previous years; therefore, it is this rather than secular trends that explains the sudden fall in average length of stay at the end of the time series.

Table 5.11. Multi-group interrupted time series using segmented regressions with generalised linear model of length of stay (LOS), any bleeding, and major bleeding occurring in AMI patients in England between 2003 and 2013.

Interruptions are specified at 2007, 2008, and 2010. Yearly time series data are used.

VARIABLES	(1) Model 20: LOS	(2) Model 21: Any bleeding (percentage)	(2) Model 22: Major bleeding (percentage)
Year	0.29 [-0.65 – 1.23]	0.26** [0.089 – 0.44]	0.26** [0.100 – 0.43]
Treatment	-3.21* [-5.56 - -0.86]	-1.46*** [-1.89 - -1.03]	-1.77*** [-2.17 - -1.36]
Treatment * Year	-0.50 [-1.83 – 0.83]	-0.28* [-0.53 - -0.035]	-0.26* [-0.49 - -0.028]
Intervention (2007)	-2.02 [-6.06 – 2.02]	0.32 [-0.44 – 1.07]	0.32 [-0.39 – 1.03]
Intervention * Year	-0.41 [-4.93 – 4.10]	0.66 [-0.19 – 1.52]	0.67+ [-0.14 – 1.47]
Treatment * Intervention	1.91 [-3.81 – 7.63]	-0.0085 [-1.07 – 1.06]	-0.18 [-1.18 – 0.82]
Treatment * Intervention * Year (2007)	0.24 [-6.15 – 6.63]	-0.54 [-1.75 – 0.67]	-0.64 [-1.78 – 0.50]
Intervention (2008)	-1.23 [-9.28 – 6.82]	-0.98 [-2.51 – 0.54]	-0.99 [-2.43 – 0.45]
Intervention * Year = o,	-	-	-
Treatment * Intervention	1.35 [-10.0 – 12.7]	0.76 [-1.40 – 2.92]	0.86 [-1.18 – 2.90]
Treatment * Intervention * Year (2008) = o,	-	-	-
Intervention (2010)	-0.090 [-7.31 – 7.13]	-1.54* [-2.90 - -0.18]	-1.54* [-2.82 - -0.26]
Intervention * Year	-0.55	-0.73+	-0.74+

Treatment * Intervention	0.20 [-4.76 – 3.67]	1.26 [-1.52 – 0.060]	1.37 [-1.48 – 0.012]
Treatment * Intervention * Year (2010)	0.49 [-10.0 – 10.4]	0.56 [-0.66 – 3.19]	0.65 [-0.45 – 3.18]
Constant	12.9*** [-5.46 – 6.45] [11.3 – 14.6]	2.37*** [-0.56 – 1.69] [2.06 – 2.67]	2.37*** [-0.40 – 1.71] [2.08 – 2.65]
Observations	22	22	22
R-squared	0.960	0.997	0.998
Adj. R-squared	0.90	0.99	0.99
Autocorrelation	-0.48	-0.51	-0.52

in brackets

*** p < 0.001, ** p < 0.01, * p < 0.05, + p < 0.1

Relationship between length of stay and bleeding

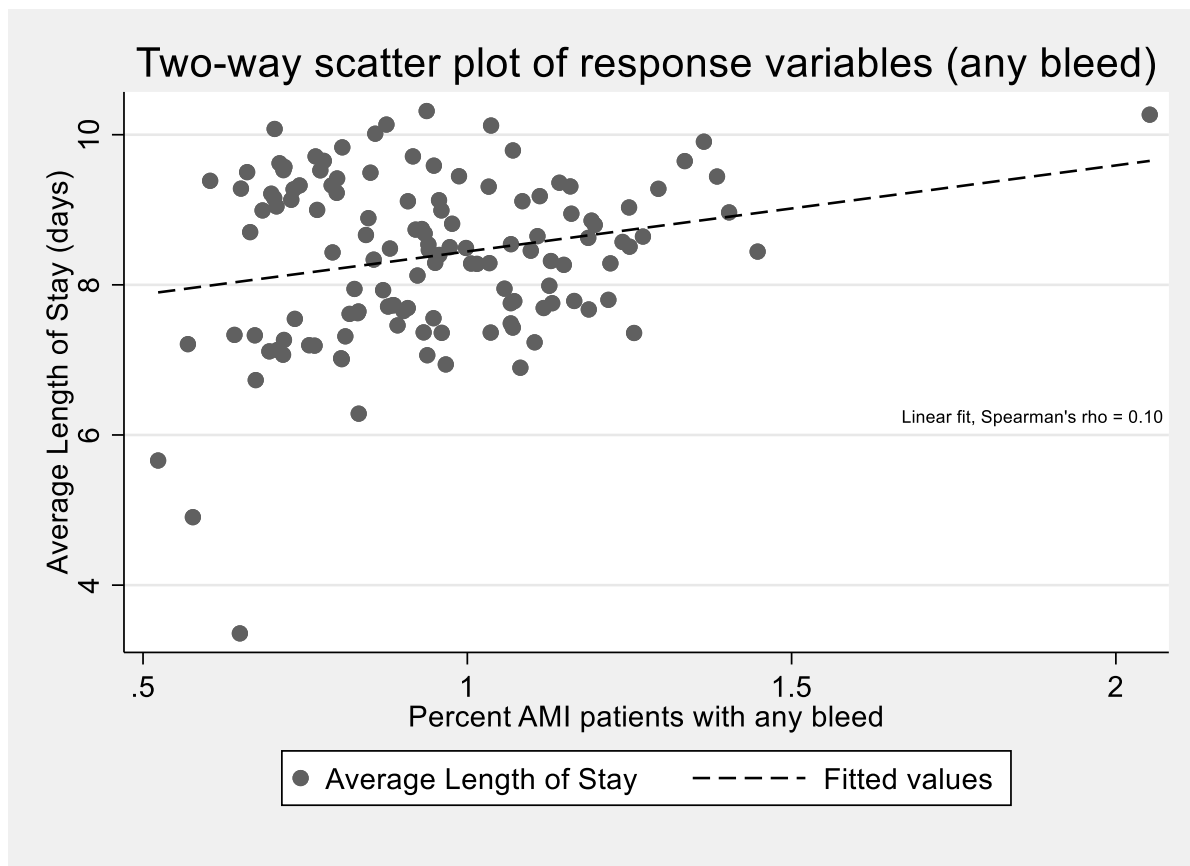


Figure 5.24. Two-way scatter plot with linear fit of average length of stay due to any bleeding for AMI patients in England between 2003 and 2013 (Spearman's Rho = 0.10, Obs. = 129). Test of H_0 : percentage of any bleeding in English hospitals and length of stay are independent: Prob > t = 0.2389, indicating independence between the variables. Average length of stay below 9.5 days is associated with bleeding rates of approximately 1%; average length of stay above approximately 9.5 days is associated with bleeding rates greater than 1.5%.

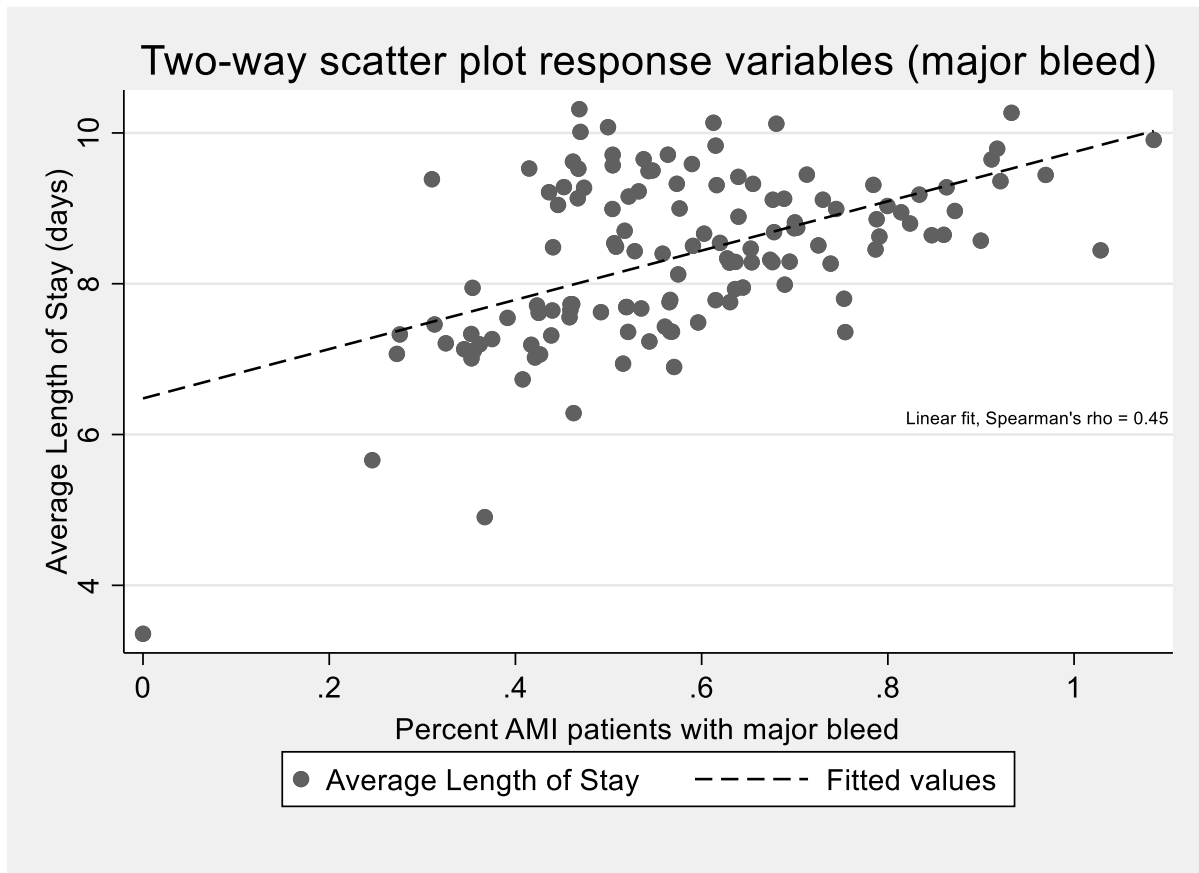


Figure 5.25. Two-way scatter plot with linear fit of average length of stay by major bleeding rate for AMI patients in England between 2003 and 2013 (Spearman's Rho = 0.45, Obs. = 129). Test of H_0 : percentage of major bleeding in English hospitals and length of stay are independent: Prob > t = 0.000, indicating dependence between the variables.

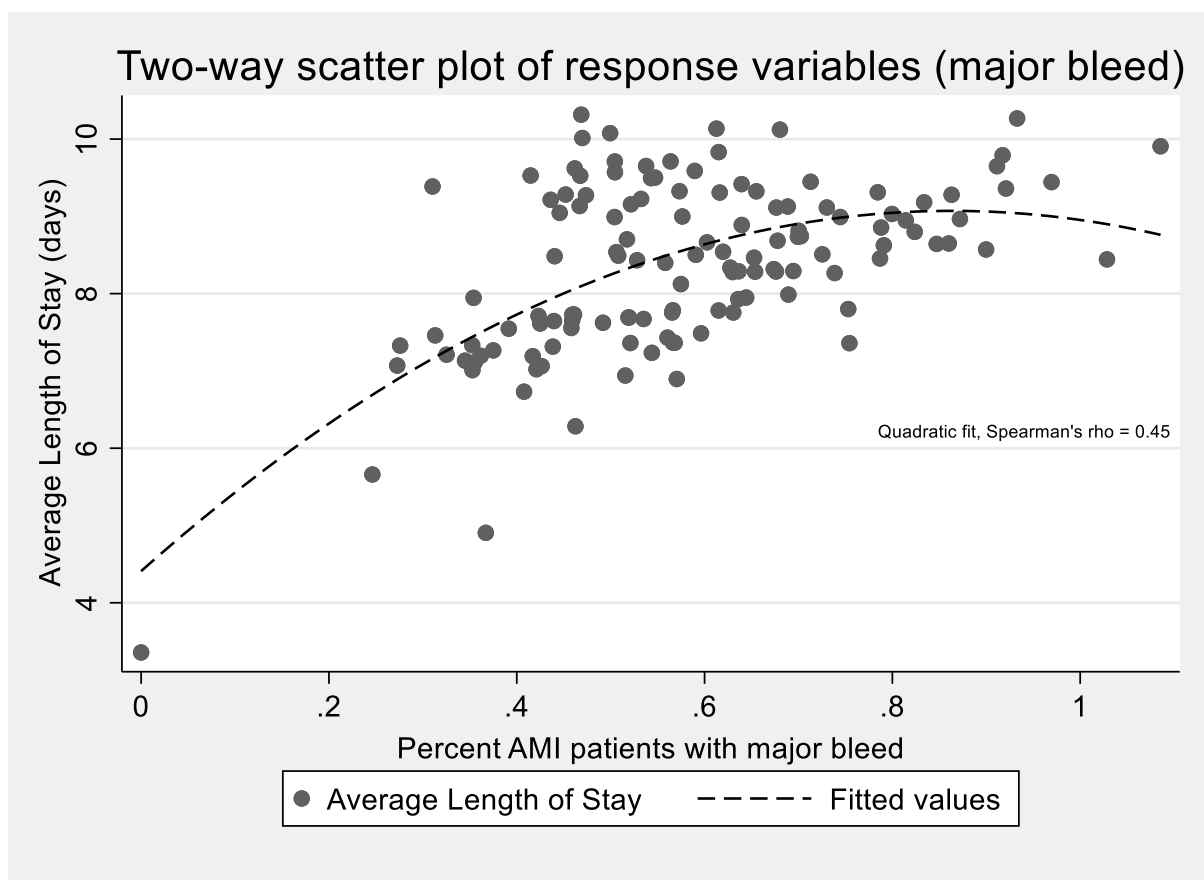


Figure 5.26. Two-way scatter plot with quadratic fit of average length of stay due to major bleeding for AMI patients in England between 2003 and 2013 (Spearman's Rho = 0.45, Obs. = 129). Test of H_0 : percentage of major bleeding in English hospitals and length of stay are independent: Prob > t = 0.000, indicating dependence between the variables.

Discussion

This study reports weak evidence for a causal association between the publication of six NRLS feedback reports and improvement in length of stay and the rate of major or any bleeding in AMI patients admitted to English hospitals between 2003 and 2013. In models 3 and 4 (Table 5.6), a 0.11% increase was found in the percentage of any bleeding for AMI admissions, indicating a detrimental effect of clinical activities taking place before and after March 2007. Five subsequent interruptions were specified in this model and no statistically significant trend and level changes were found. At a yearly level, it was not possible to detect an effect of feedback reports on length of stay or rates of any or major bleeding in AMI patients in England for the periods 2006 to 2007 and 2007 to 2008, which in part as due to collinearity between observations. However, a single group ITSA with an interaction specified at 2010 only was associated with a statistically significant fall in the average percentage of any bleeding (-0.083%, $p < 0.001$) (Table 5.8, model 11) and a fall in major bleeding with (-0.051%, $p < 0.01$) and without (-0.069%, $p < 0.05$) covariates (Table 5.8, models 12 and 13). The introduction of lags to the month-level models was not associated with a change in the overall negative findings; this can be interpreted as weak evidence that implementation of these feedback reports does not occur over a protracted period of three months and that care practice changes are implemented quickly after the publication of these reports. This could be because practitioners can manage drug dosing and administration in hospitals relatively well. Nevertheless, these findings relate more closely to cardiology teams who may be more familiar with coagulation management strategies.

There are several explanations for these observations. Broadly speaking, the early effect of feedback reports, as identified through the interaction with March 2007 in the single group design, may be due to their novelty, which generates higher receptivity among frontline staff. This effect could be viewed as disruptive and therefore initially detrimental to routine practice. The later effect of feedback reports, identified in 2010 for the yearly analysis, may be due to the cumulative dose response of at least three feedback reports on the same topic in 2007 and 2008, followed by a similar report in the first quarter of 2010. However, the evidence for such an effect is weak given that the inclusion of Scottish hospital sites as a control group meant no such yearly effect was identified from NRLS feedback reports. This point is important given that the intervention dates coincide with numerous policy innovations in ACS care in England, which include service reorganisation and care pathway innovations such as the integration of novel thrombolytic and fibrinolytic drugs into NICE guidelines (362). The significant and

continuous fall in length of stay and both any and major bleeding rates year on year are a testament to these developments. The extent to which the effects observed in March 2007 and the aggregated observations for 2010 are explained by other disruptive innovations, such as the introduction of PCI with LMWH alone or in combination with other novel anticoagulant agents, which took place in the latter 2000s, is difficult to estimate without a more detailed design.

The significant interaction found for March 2007 provides more compelling evidence for the effect of NRLS feedback reports because it predates the implementation of national strategies for ACS in England. The diminishing effect of future feedback reports modelled in this study could also be driven by the noise created by the introduction of new national strategies for managing heart attacks (362). The extent to which this is generalisable to other clinical areas can, in theory, be tested if retrospectively analysed data on bleeding rates from non-cardiovascular care specialties are modelled. Although this was beyond the scope of this study, the evidence presented here is the first to highlight the dose-response dynamics of national guidelines produced through incident reporting systems. This has implications for the target, timing, and design of future feedback reports. Specifically, the production of feedback reports on a given topic should consider the presence or absence, current or anticipated, of other high-impact strategies that overlap with the clinical target of the guideline or alert. Because this study is the first of its kind to estimate the clinical effectiveness of NRLS feedback reports at a population-level, there are no alternative study designs with which to compare the findings. Prospectively generated evidence on the effectiveness of incident reporting systems has addressed their effects on inputs and processes of care rather than the end goal of health benefits (67). This approach is likely to have biased the use and development of incident reporting systems in local, regional, and national contexts towards promoting the use of resources to fulfil input and process-based objectives without any consideration of the systemwide impact. This impact requires further investigation across both temporal and spatial dimensions to challenge or verify the findings of this exploratory case study.

The benefit of such evidence could be that users of incident reporting systems become more engaged as beneficiaries of what Benn et al. (36) called active feedback. Health systems are measured in terms of their clinical (or health) effectiveness and, as such, evidence for the clinical impact of incident reporting systems is a quality signal that can enhance learning cycles. The need for population health measures that produce value in learning cycles was recently described by Menear et al. (363) in a novel framework describing value-creating

learning health systems. The inadequacies of incident reporting systems in creating these conditions have been studied qualitatively with respect to the incident reporting practices of healthcare providers. For instance, in a 2005 to 2006 survey of hospitals, Farley et al. (364) found that only around one fifth of all sites distributed summary reports of identified events along with action-oriented strategies to prevent their reoccurrence. In 2008, McRae specified the direction in which incident reporting systems must evolve, stating that:

“At best, an incident report offers a trigger for further investigation and inquiry into a specific event or system issue. Analysing incidents does not itself produce learning.”(201)

However, what this statement and the wider commentary misses is the need to learn about learning. Specifically, it overlooks the need to investigate the impact of incident reporting learning strategies to inform their design and to monitor the long-term consequences of the interventions they may (even relatively infrequently) yield. For this reason, our study should be viewed as a step towards an output rather than an input-centric approach to the design of incident reporting systems.

Limitations

There are several limitations to this study that need to be addressed. These are a consequence of data availability issues and the relatively unspecific nature of the interventions available for study, which limit the strength of the conclusions. First, the interventions were not chosen at random due to the infeasibility of studying the clinical effectiveness of randomly selected feedback reports. Feedback reports from the NRLS between 2002 and 2012 covered a plethora of clinical settings and patient populations and bestowed differing levels of specificity on the intervention(s) recommended and, often by extension, the clinical outcomes being targeted. For quasi-experimental designs, these three key aspects of the feedback reports also limit the accessibility and availability of a population comparator to the English (and Welsh) population. Despite being considered a feasible topic for study, the lack of outcomes on VTE as a time series was a significant but unavoidable omission from the design. Given the clinical significance of VTE in anticoagulation management and patient safety, our inability to observe this outcome before and after feedback reports were introduced obscures the otherwise important outcome related to these interventions.

Second, whilst the Scottish population serves as a theoretically sound control group, the benefits of this cohort to the design is limited. For instance, the potential for spill over effects from English feedback reports into Scottish healthcare practice threatens the main aim of

controlling for confounding variables in the single group ITSA. This concern is compounded by the two- to three-fold difference in the percentage of major bleeding observed in Scottish hospitals compared to English ones. Despite requesting the data from the Information Services Directorate in Scotland using ICD-10 and OPCS codes, which align recorded cases of major bleeding to the clinical definition employed, these differences can be seen as evidence of misspecification of the control group (357). The divergence of the trends observed between the two cohorts provides further evidence of this. Third, compared to the single-group analyses that were performed, the controlled ITSA was limited by the frequency of observations in the time series. Despite a request for monthly observations, these data were unavailable due to concerns over provider and patient anonymity caused by the relatively low absolute counts of major bleeding at monthly and quarter levels. This reduces the statistical precision with which a month-stamped intervention and its effects can be measured. In this study, the higher the aggregation of temporal observations, the lower the precision of measurement.

The direction of bias produced from the aggregate models was difficult to estimate given the lack of contemporaneous evidence with which it could be compared. This was further compounded by a lack of information about the expected effect size from each of the feedback reports, although this was expected given the exploratory nature of the research. This links to the fourth major limitation, which is that it was difficult to infer causality between the interaction effects observed and the publication of feedback reports, which is a feature of the ITSA design (365,366). This problem was handled to an extent by introducing multiple interruptions of the same or similar interventions(s) into the time series. In the absence of a variable indicating the extent to which NRLS feedback reports had been implemented in hospitals, causality between the intervention date specified in the time series and the observed pattern was limited even further. A variable such as rate of adherence to a guideline, similar to that used in the WHO surgical safety checklist (367), could substantiate causal claims regarding the impact of these feedback reports.

Missing data are a concern in most, if not all, health-related studies that involve observational data (354); in this study approximately 10 per cent of the observations in the bleeding (response) variable were missing. The consequences of this for the results of this exploratory study are difficult to estimate without further research and the development of appropriate multiple imputation models. However, it is likely that the findings are biased as a consequence of missing data, given recent evidence published by Bazo-Alvarez et al. (2020) (353). To an extent, the inclusion of all relevant covariates in some of the models reduces the bias caused

by missing observations in the bleeding variable (354), however, this assumes that all relevant covariates were included in these particular models, which cannot be verified. The use of clinical (explanatory) variables that are risk factors for bleeding (anticoagulant administration, systolic blood pressure, heart rate, and hypertension) may not represent all relevant covariates. An absence of evidence on this point therefore limits the extent to which this assumption handles bias from missing data. Therefore, subsequent investigations should address the strength and direction of this bias and, specifically, risk prediction models for major bleeding require stronger explanatory power, as shown by Vora et al. (2016) (311). For this reason, the evolution of knowledge about individual and organisational factors that explain variability in bleeding rates in ACS patients is promising for future research using observational data.

The limitations in the research are thus multifaceted and, as the final point indicates, the execution of this study provides useful insight for future designs. The most robust method for assessing the impact of NRLS feedback reports would be a prospective trial in which patients or hospital sites were randomly exposed to either NRLS feedback or standard of care (as a control). Although a lesser concern for this study, the design of the feedback reports and the extent to which actions are specified could be informed by theories of communication, albeit with precisely specified target populations for the guidance provided, the exact interventions required, and the clinical outcomes that could be audited locally to measure the effect. Prospective process evaluations would be necessary to observe the rate of implementation and adherence to a given set of actions. In this instance, a quasi-experimental design would also be able to infer causality between the introduction of an intervention, albeit retrospectively, and the manifestation of effects. To the extent that the face validation was correct, the logic models derived for our ITSA provided the necessary framework to measure cause and effect from feedback reports. However, operationalisation of the conceptual logic models is the major challenge future designs must address.

Evidence about the clinical and cost-effectiveness of (national) incident reporting systems, such as the NRLS, is limited, which is a problem for system redesign. This study illustrates the difficulties associated with estimating the effectiveness of incident reporting systems at a national level; however, it also demonstrates the potential value of studying the impact of feedback reports using ITSA. The importance of demonstrating the effectiveness of outputs from incident reporting systems has been identified in several qualitative studies (36,364) with respect to the need for active feedback mechanisms. The absence of translational evidence hinders improvements in the design of national outputs from incident reporting systems and

similar health information systems, and limits policymakers' ability to allocate resources efficiently. This study is the most detailed attempt thus far to measure the clinical impact of national incident reporting systems at a population level. The study design follows previously specified methods for identifying treatment effects in the absence of randomised trials (322) and, given the plethora of feedback reports (being) generated from the NRLS, there are opportunities for researchers to conceive similar designs.

Recommendations for future research

Several barriers must be overcome to support the development of comparative effectiveness research on NRLS feedback reports. These are similar to the challenges associated with measuring the impact of guideline implementation efforts. The first challenge lies in building strong study designs that incorporate exposed and intervention-naïve (control) groups. This is especially difficult if control groups are not generated at the time of introduction and a particular ethical challenge in patient safety study designs (18). Currently, it is reasonable to assume that all national patient safety initiatives in England expose all patients, thus precluding the existence of natural control groups. Quasi-experimental designs can manage these methodological difficulties, although prospective randomisation, such as that used by Fröbert et al. (2010) (342) would provide more explanatory power. Second, the dose of an exposure confounds the results if effect sizes are not adjusted accordingly. This leads to potential bias unless variables for dosage are incorporated into effect size estimates. Secondly, these tools need to be used prospectively to avoid recall bias and capture implementation activities in real-time. This requires substantial research resources, as demonstrated in process evaluation studies (56). Research on the implementation of the WHO surgical safety checklist (14) serves as an example of patient safety research where national implementation was measured (368) and estimates of adoption rates were derived (369). It is important to note that Fourcade et al. reported a checklist completion rate of 61% in French cancer centres, despite global promotion of the checklist; in the absence of the same effort for NRLS feedback reports, it is reasonable to assume even lower rates of implementation. Thirdly, the likelihood of observing a dose-response depends on the strength of the basic research informing a guideline (366). In many cases, the basic research may be incomplete, invalid, or unreliable. This is particularly problematic for patient safety alerts, which are generated from frontline healthcare workers for whom data generation may be subject to selection bias. Finally, the likelihood of producing a negative study on the effect of feedback reports is high, which is a disincentive for academic research given the evidence of positive-outcome bias in peer-reviewed journals (370,371). This

could mean that fewer efforts are made to undergo essential investigations. In the case of incident reporting systems, studies on the impact of feedback alerts tend to rely on subjective measures of impact rather than quantitatively driven population-level measures, which may be less contentious. However, the lack of population-level evidence on the impact on clinical outcomes in relation to patient safety is a barrier to redesigning incident reporting systems. By extension, this lack of evidence also limits the ability to configure these systems in a way that produces a perpetual stream of high-value outputs whose ongoing impact is measurable. For the latter, measurement is essential to ensure continual learning although outputs must be designed first to facilitate estimation of their impact in target populations.

Conclusion

Using a single group ITSA, this study provides weak evidence of positive population-level effects from NRLS feedback reports. However, when time-varying confounders using a control series from a Scottish population were accounted for, the weak association was nullified. This suggests that the benefits from this sample of NRLS feedback reports were small or non-existent. Prospective trials comparing benefits from NRLS feedback reports versus controls would provide stronger evidence of their effects. However, these may be costly. Alternative quasi-experimental methods are a viable alternative to measuring the before and after effects of a larger sample of feedback reports. Nevertheless, the accumulation of evidence on the impact of these outputs is needed to improve the strength of evidence on outcomes and the economic benefits these provide.

Chapter six: Concluding remarks

Discussion

Chapter one updates and summarises the economic performance literature related to incident reporting systems. It identified a low-quality study from the United Kingdom which estimated the opportunity costs of incident reporting and a commentary that incorporated the author's opinion of the time spent on incident reporting in England (equivalent to 1,187 full time employees submitting incident reports). In the absence of strong and informative evidence, in Chapter two a broader literature review was undertaken to identify high-quality studies on the economics of patient safety. This review elucidated several recommendations for researchers and policymakers seeking evidence to inform resource allocation for a patient safety policy. Importantly, one high-quality study of a digital intervention for patient safety was identified (158); however, this design was not considered appropriate for investigating incident reporting systems due gaps in the clinical and economic evidence. For these reasons, Chapter three characterised incident reporting systems by proposing a validated process model that captures the national system of incident reporting. The conceptualisation of this model is a milestone because 183 frontline users from the NHS were the participants. Chapter four is equally pivotal and benefitted from the findings in Chapter three as, using TDABC methods, the cost of processing an incident report through reporting and management activities was revealed and estimated as a national annual economic cost. This provides a threshold against which economic benefits from incident reporting systems can be measured in future research. A means of conducting future research on the benefits or effectiveness of incident reporting system (outputs) was explained and a case study investigating the before and after population-level effects of NRLS feedback reports was executed for the first time in Chapter five. The challenges associated with this investigation provide insight into how feedback reports need to be designed and curated to facilitate routine monitoring and evaluation of their effects on patient safety. Without this research, it will be challenging to estimate the long-term average marginal benefits derived from incident reporting systems with a strong causal inference. Infused throughout the thesis are methodological and policy-based recommendations for translational research that will help improve the design of incident reporting systems. The implementation of some of these recommendations should generate findings that lead to an understanding of how these systems can become less inaccurate over time. Put simply, the aim of this thesis was to provide economic insights into incident reporting systems that are less erroneous than previous assumptions. The ongoing lack of evidence on this important topic

provided an opportunity to elucidate major novel findings that serve to reduce the entropy of information.

The underlying question for this research was “are incident reporting systems in the English NHS cost-effective?” The pertinence of this question was explained in previous chapters and, increasingly for health systems, the economic evaluation of digital solutions is becoming routine. In this way, digital products should be evaluated with a rigour akin to that of pharmaceutical products. Economic evaluations that involve a broader suite of products and process-change interventions are being appraised by NICE in the UK (372). However, the application of translational health economic methodologies in information systems has not advanced beyond a conceptual discussion. This discussion could be aligned to the development of generic frameworks for appraising digital products that have been introduced recently (70,373).

NICE appraisals of information systems do not exist. One explanation for this is the lack of resources needed to conduct these evaluations and appraise them formally. As this thesis demonstrates, another reason is the methodological challenge involved in appraising the economic impact of information. Information requires a commoditisation that is difficult to define and express clearly. Moreover, the impact of patient safety information, particularly regarding inputs and processes in incident reporting systems, requires analysts to adopt an extended time horizon. However, lengthier time horizons create additional uncertainty around the impact estimates generated (374). Policy, budgetary, and other competing decision-making cycles mean that the perceived value of these estimates is low. This leads to reactive rather than proactive decision-making, which may not be efficient. The central case for estimating the long-term economic impact from information systems such as the NRLS is that the entropy of information is reduced, significantly improving forecasts of the benefits they provide, which could lead to the adoption of alternatives or re-designs. In addition, evaluation frameworks that are established long in advance can be more quickly augmented for future use and data collection efforts directed towards making rational policy decisions.

The need for the NHS to make proactive evidence-driven choices in relation to its capital investments was demonstrated by Lord Carter’s review on productivity in the NHS (375). This policy report by NHS England demonstrates the potential for value-driven procurement practices to improve, as shown by the high variability in prices paid for similar equipment. Procurement specialists are often responsible for sourcing, purchasing, implementing, and

monitoring the development of information systems and other digital products. Without a conceptual or methodological framework for making these instrumental decisions on behalf of the NHS, procurement specialists are likely to adopt a reactive approach. However, the impact of reactive rather than proactive planning is suboptimal decision making and financial inefficiency, which must be reduced given a funding deficit for the NHS that is projected to last until 2030 (124).

There are no agreed models for assessing the value of incident reporting systems, although several commentators have discussed the resource implications of developing, implementing, and routinely using these systems (69,77,80). A conceptual or theoretical framework for informing resource allocation decisions did not exist before this thesis; therefore, the methods were theoretically driven and informed by a “nearest neighbour” approach. Historically, economic evaluations have adopted decision analytic approaches that model cohorts transitioning between static states rather than individuals dynamically transitioning through a pathway or process (376). A promising method for developing quantitative estimates of the efficiency of incident reporting systems is discrete-event simulation, which is an approach to decision modelling that is more amenable to modelling complex processes and different forms of entity transitioning between events, rather than health or interventional states. For this reason, DES is increasingly being used in economic evaluation. Karnon and Afazali (2014) (376) present four factors that have been used to justify the use of DES in health technology assessments conducted to inform reimbursement decisions. These are (i) heterogeneity exists in the baseline characteristics of the population of interest, (ii) disease progression is a continuous process with few static states, (iii) the rates at which events occur are time-dependent, and (iv) prior events have a bearing on subsequent event rates. When applied to information entities rather than patients, the same factors apply: there is considerable heterogeneity between information management processes and the users of a system; progression of information entities is continuous and, due to the nature of information, highly dynamic; the flow of information entities is time-dependent in that information flows rely to some extent on the input of information upstream; prior treatment of information can, at least in part, affect event rates downstream. In this case, DES affords modellers a means of approximating the real-world flows of resource and capacity constraints, and the costs and benefits expected from alternative health technologies. This modelling approach would have enhanced the thesis; however, the lack of a robust body of evidence on the effectiveness of feedback reports produced by incident reporting systems precluded this.

Additionally, more research is needed to determine the structural differences in the way incident reporting and management is performed across NHS institutions; variance in levels of agreement with the processes presented in Chapter three signals meaningful differences in the way institutions perform the same core task; these are undoubtedly manifested in the economic cost estimates given in Chapter four. Further research into these differences could identify best practice, defined, perhaps, as the most technically efficient process for incident reporting and management in the NHS. As mentioned, the model conceptualisation approach presented in Chapter three was methodologically challenging and, with more resources, the research could be improved by recruiting an even larger sample. The statistical reasoning for this was given in the chapter; however, the other central reason for this is that a systemwide model would benefit from more user input into any re-design effort, ideally using methods with greater sampling reach. An electronic version of the questionnaires presented in both Chapters three and four was tested to increase recruitment for these studies; nevertheless, the level of sophistication required to avoid measurement error was prohibitively expensive. As such, the approach used in the thesis should be viewed as proof of the methodological concept, which could be scaled up based on lessons learned about how to measure these parameters (more) accurately. Given the efficiency implications for the NHS, resourcing this research is justified because the potential to reduce measurement error is (now) apparent.

This thesis conceptualised elements of health systems that shape patient safety and economic outcomes. Although the orientation of the research has been towards health economics, ideas and methods from systems engineering have been infused throughout because methods from economic science must evolve to bridge the gap into translation. With this overarching aim, structural elements informing the economics of patient safety and incident reporting systems, viewed as a system within a system, can be estimated. The research placed an emphasis on developing and validating the inputs and processes that comprise incident reporting systems in England. The guiding principle for this was taken from W. Edwards Deming, one of the originators of quality improvement, who advised that processes must first be understood before any type of system can be improved. Based on the inputs and processes designated for any given system, the performance of these components can then be measured. In economic evaluation, these steps are known as model conceptualisation, which is an essential step that occurs before costs and consequences can be estimated (198). Economic outcomes were estimated in this research and, for the first time, so too was the national annual economic cost of incident reporting systems. The marginal cost of an incident report has been estimated with

greater transparency, the use of larger sample sizes than in previous studies (77,80), and appropriate structural assumptions that formalise the sociotechnical and systemic features of incident reporting systems. The marginal benefit of these systems was estimated using a piecemeal approach that was recommended for estimating the return on investment of such systems in the aviation sector. In isolation, the negative findings suggest that the marginal benefit from incident reporting systems is undetectable or non-existent; however, there are several limitations to this estimation that were discussed in detail. There are enormous gaps that need to be filled in order to better understand the true economic impact of incident reporting systems and this is reflected in the difficulty experienced by experts in estimating their value (8). As a foundation for future research, this thesis strived to provide a systems thinking end-to-end approach. The research should be viewed as providing the first few tethers necessary to cross a vast ravine; from those tethers, a structurally sound bridge can be built.

Opportunity costs of incident reporting systems in England

The opportunity costs of incident reporting systems in England were estimated in this thesis and when using agreed methods for valuing health (QALYs), trade-offs can be approximated. Better estimates and an expanded analysis of costs (and benefits) are needed to support decisions; hence, initial estimates are cautious and based on certain assumptions. Nevertheless, the value of an initial estimation will be high given that no previous estimates exist.

The first assumption is that the effects of incident reporting systems are not positive, as demonstrated in Chapter five. This may not be the case given the limitations reported for this study; there are known unknowns about the effect of feedback reports in the English NHS, particularly given the volume and diversity of reports produced. As such, the assumption of a zero effect on population-level outcomes from the NRLS may be favourably or unfavourably biased, amounting to a type two error, namely assuming a zero effect is a favourable bias if the true effect size is negative.

The second assumption is that the costs of developing, implementing, and routinely using incident reporting systems are captured adequately by the cost analysis performed in Chapter four. As reported in the limitations, these do not include the development and implementation costs of introducing the NRLS. These costs can be annuitised into the annual cost estimate; however, they are historical and relatively small, and therefore of less concern to policymakers. The cost analysis also does not include the contemporary operational costs of the NRLS at NHS Improvement; although these were specified in the process maps used in Chapter four for completeness and transparency, actual estimates were not possible.

Third, willingness-to-pay thresholds for health interventions in England are implied in the decisions made by NICE. These thresholds are expressed as a cost per QALY, which may be £13,000 (377) or as high as £50,000 for end-of-life care therapies (378). The general accepted threshold is between £20,000 and £30,000 per QALY(379). Using these thresholds, the annual opportunity cost (excluding benefits) from incident reporting systems in England can be calculated by dividing the annual costs derived from the deterministic assumptions in Chapter four (£956M) by each threshold. These calculations are presented in Table 6.1.

Table 6.1. National Institute for Health and Care Excellence (NICE) implied thresholds for health technology adoption and opportunity costs expressed as Quality-Adjusted Life Years (QALYs) foregone

Health technology	Threshold (cost per QALY)	QALYs
Standard	£12,936	73,902
Standard	£20,000	47,800
Standard	£30,000	31,867
End-of-life care	£50,000	19,120
Very rare diseases	£300,000	3,187

The annual economic cost of incident reporting systems was assumed to be £956M and the equivalent QALYs were calculated at each threshold.

The QALYs calculated in Table 6.1 can be interpreted as the number of QALYs incident reporting systems must generate to avoid a net loss from their operation in the English NHS. The willingness-to-pay for incident reporting systems has never been studied, which links to a wider question regarding the acceptability of categorising digital health technologies as standard technologies. Assuming they are standard health technologies, the most likely QALY threshold that must be achieved each year is between 31,867 and 73,902; in other words, between 31,867 and 73,902 years of life in perfect health must be accrued each year. These values can be expressed as incremental QALY gains required, if the same QALYs lost from avoidable adverse events can be saved using alternative interventions for the same cost or price. If the same number of QALYs can be saved for less than the incremental cost of incident reporting systems (£956M per annum), then this approach will dominate the NRLS strategy. To place these values in context, other clinical examples are needed; for instance, Baguelin et al. (2010) modelled QALY gains for an H1N1 vaccination programme during an epidemic with a lifetime horizon of costs and benefits, and estimated that a total of between 1,579 and 5,546 QALYs could be gained (380).

The value of safety interventions can be measured in several ways, as explained earlier in this thesis. Non-health benefits are an important component of patient safety that extend beyond what QALYs can capture directly using traditional analytic approaches. Recent advances in thinking about patient safety show an expanded role for safety interventions and policies in health systems. Gandhi et al. (381) describe how patient safety can galvanise efforts to integrate health services, which is a central objective of health reforms given evidence that it leads to higher quality care in dimensions such as patient satisfaction, patient-perceived quality of care, and access to services (382). This extends to measuring the impact of safety interventions on health workers, whose safety is entwined with patient safety (383). Health workers may benefit from using incident reporting systems and similar safety interventions because they provide a means of handling toxic working cultures (384) and improving clinician wellbeing. Specifically, health worker burnout (385) is a core concern that can be addressed with patient safety policies, such as incident reporting, by improving the organisational culture (264). The implication of this expanded approach is that there is a plethora of indicators needed to determine value, such as those that capture non-health benefits from safety interventions; in health economics, the related term is “indirect” benefits, such as improved productivity. For priority setting, QALYs and DALYs are frequently used indicators of direct health benefits in Europe and are preferred measures for valuing safety interventions, according to the European Commission (125). Theoretically, these can also be used to capture non-health gains that are manifested as health gains; for example, better health worker wellbeing could lead to better productivity, improved patient access, lower costs, and less avoidable harm, which leads to more QALYs as compared to a “do nothing” approach. Whilst conceptually simple to outline, it remains a challenge to accurately model these trajectories in the manner required by policy makers who make system-level decisions in a cost-utility paradigm. For this central reason, non-health benefits should be captured in a holistic framework for evaluating safety interventions.

Given the ongoing challenge of scarce resources in the English NHS, these estimations require formal investigation by academics and policymakers. Utilising the methodological approaches described in the framework presented in this thesis, these large gaps in understanding can be addressed. Importantly, direct, indirect, and intangible costs and benefits from incident reporting systems should be measured within the economic costing to ensure the distributional effects of these systems are captured. This reflects the final area of this thesis for which more research is essential. The trade-offs made by using incident reporting systems in health systems

should be quantified; however, to estimate these, the effect sizes of the increasing number of feedback reports or patient safety alerts that are produced must be estimated. Ideally, the thesis would have produced a complete economic evaluation using a quantitative synthesis of effect sizes that were derived from high quality studies, such as (statistically homogenous) randomised trials or non-randomised observational studies. These studies are yet to be produced, although there are hundreds, if not thousands, of patient safety alerts that have been produced around the World that could be evaluated using these approaches. In doing so, the features of feedback reports that produce effects of varying magnitudes would be revealed. These features, such as contextual and content-related factors, could be replicated as part of the continual redesign of incident reporting systems and related patient safety interventions. These factors remain unknown, as does the effect size attributable to incident reporting systems, and the latter is a major limitation that was, unfortunately, beyond the scope of this thesis. Nevertheless, this aspect should be addressed in future research.

Table 6.2. Summary of the thesis themes, findings, and importance of each chapter				
Chapter	Problem	Findings	Importance of the chapter to policy makers	Importance to the economics of incident reporting systems
Two	Searches on the economics of incident reporting systems could miss important methodological guidance from broader literature on the economics of patient safety.	One high-quality economic evaluation of a digital intervention for patient safety was identified. The features of this evaluation differ substantially from the decision problem for incident reporting systems. Most high-quality studies on the economics of patient safety target VTE.	This chapter provides a suite of impactful recommendations for policy makers to consider in investment decisions. Only high-quality clinical and economic evaluations were included, which strengthens confidence in the recommendations, updating previous reviews from 2012.	The absence of a methodological approach that could address the central question in this thesis indicates that a conceptual model is novel and of high value.
Three	In the absence of methodological guidance specific to the economics of patient safety information systems, a conceptual model is needed. Data from incident reporting software vendors is difficult to access and a conceptual model may be biased by the activity fields collected for commercial purposes.	A validated process map of incident reporting and management was constructed from a sample of 183 NHS staff (known as users). This represents the production line of data collection and analysis, from which costs can be estimated.	Expansion of the use of process mapping in health services research has been advocated in the literature. The approach given in this chapter is highly novel because it is rare that a conceptual model of an economic decision problem is validated with a large sample of users. This approach contributes to the development of translational health economics, which should facilitate the production of value in the health system by involving key stakeholders in strengthening health systems.	The process map provides the structural assumptions needed to develop a decision-analytic model that could be applied to an economic evaluation of incident reporting systems. A decision-analytic model is not specified in this thesis, but several approaches are suggested, including the use of discrete-event models and related microsimulation methods. Costs and benefits can be estimated using these validated structural assumptions; more detailed structural models, based on NHS settings, should be developed.

Four	A conceptual model does not provide a quantification of resource use on its own. A dataset of costs associated with incident reporting systems does not exist; hence, such a dataset has not been designed.	Using deterministic assumptions, the economic cost of incident reporting systems in the English NHS is £956 million per annum. This is not an accounting cost but represents the value of time spent by NHS staff operating this system.	The economic cost of incident reporting systems can be used to augment policy efforts to improve their design for the goal of reducing harm to patients. These methods can be applied to other health information systems. Waste (defined as technical inefficiency) can be avoided, and the system redesigned with a better understanding of the (potential) impact of these changes on the labour force. The optimal reporting volume and typological mix can be informed by this cost analysis.	The marginal and average cost of incident reporting systems has never been estimated using a validated model and Time-Driven Activity-Based Costing methods. This is an essential ingredient of an economic evaluation, alongside the clinical or health effectiveness of the entire intervention versus an alternative strategy for improving patient safety.
Five	The effectiveness of incident reporting systems requires a conceptual framework from which these complex interventions can be evaluated. Experimental methods have not been used to estimate an effect size that is attributable to the outputs from incident reporting systems.	Feedback reports or patient safety alerts can be identified retrospectively and logic models for expected cause and effect can be derived. The multi-group interrupted time series analysis is more robust than the single group ITSA. When controlling for secular trends using a Scottish control group, an effect caused by NRLS feedback reports could not be detected for these clinical outcomes.	Systematic appraisals of the outputs from incident reporting systems are needed. Evidence gaps can be addressed using experimental methods, although the findings may be negative for several reasons that include methodological limitations or “true” ineffectiveness. Policy makers can use this chapter as a model for future research; the same approach can be applied to other health information systems.	In the absence of a detectable effect size using a large dataset, the clinical effectiveness of incident reporting systems at the population-level is unclear. The findings in this chapter are an estimate of the direction of effect, yet the magnitude of any positive effect remains unknown. A positive effect using high-quality experimental evidence is usually a prerequisite for economic evaluations of interventions (as opposed a “do-nothing” strategy or standard of care).

Closing comments

This thesis adds substantial value to an underserved topic in health policy. Policy making in patient safety requires economic evidence on a more regular basis to keep pace with the rapid evolution of the discipline by medical leaders. Chapter two provides a valuable set of recommendations that can support the recent integration of patient safety into the policy objectives of G20 countries. Chapter three fills a gap in understanding of the processes involved in incident reporting systems by fully aligning the nature of digital processes to the meaning of a system, which is more expansive. After nearly two decades of incident reporting system development, known unknowns about the processes involved have been addressed. As shown in Chapter four, the process map, which can be considered a conceptual model of incident reporting systems, can be applied in various research settings. This thesis focuses on the economic evaluation of incident reporting systems, which is why a TDABC study was performed. The deterministic estimate of the economic cost involved in the operation of this system in England, year-on-year, is large when compared to a “do-nothing” strategy; whilst this is unsurprising, the estimate is novel and provides a benchmark for policy makers to reflect and build on in future efforts. Moreover, this estimate can be viewed as a marginal cost for which marginal benefits must also be estimated, in the same way that all novel, patented drug entities and devices are appraised prior to their adoption on the frontline. Other than the methodological constraints that currently exist, there is no reason why policy makers should not adopt the same decision methods for established or novel digital solutions. On the contrary, the sooner policy makers adopt these methods into decision making, the sooner rational decisions can be made; this is of growing importance given the continued expansion of the digital health market. Chapter five demonstrates the methodological constraints facing researchers whose aim is to estimate the effect of digitally derived interventions on population health. Disease-specific registries that integrate patient-safety outcomes into their architecture are needed to increase the potential for researchers to evaluate disease-specific outputs from national incident reporting systems. The integration of patient safety indicators and codes into routine administrative datasets will aid in this effort. However, the evolution of definitions as to what constitutes harm, twinned with the expansion of feedback reports on more diverse clinical outcomes, means that researchers may not be able to investigate cause and effect with incident reporting systems as precisely as needed to rapidly advance our understanding of what works. Prospective randomised trials of feedback reports would address these long-standing methodological problems, and the limitations inherent to quasi-experimental methods, expeditiously providing the most certainty with respect to effect size estimates. A randomised

trial of a feedback report published by the NRLS would be a landmark for estimating an effect size attributable to these systems. Ethical concerns about withholding patient safety information in this scenario must be presented with an understanding that after nearly two decades of resource use, and without a robustly demonstrated clinical effect using population-level data, more valuable resources may be denied to patients elsewhere. This is a perennial problem for health system leaders and there are no easy answers. Nevertheless, this thesis provides novel findings that advance the argument for ongoing research on the economics of patient safety and incident reporting systems.

References

1. Francis R. Report of the Mid Staffordshire NHS Foundation Trust Public Inquiry. London; 2013.
2. Marshall M, Øvretveit J. Can we save money by improving quality? *BMJ Qual Saf*. 2011;20(4):293–6.
3. Donaldson L. An organisation with a memory. *Clin Med (Northfield Il)*. 2002 Sep;2(5):452–7.
4. Frontier Economics. Exploring the costs of unsafe care in the NHS [Internet]. Frontier Economics, London. 2014. Available from: <http://www.frontier-economics.com/documents/2014/10/exploring-the-costs-of-unsafe-care-in-the-nhs-frontier-report-2-2-2-2.pdf>
5. Robertson R, Wenzel L, Thompson J, Charles A. Understanding NHS financial pressures: How are they affecting patient care? The King's Fund. 2017.
6. Roberts A, Marshall L, Charlesworth A. A decade of austerity? Summary [Internet]. 2012. Available from: <https://www.nuffieldtrust.org.uk/files/2017-01/decade-of-austerity-full-web-final.pdf>
7. Walshe K, Shortell SM. When things go wrong: How health care organizations deal with major failures - Important opportunities for improvement will be missed if we fail to investigate and learn from the “airplane crashes” of health care. *Health Aff*. 2004;23(3):103–11.
8. Slawomirski L, Auraaen A, Klazinga NS. The economics of patient safety [Internet]. 2017. Available from: <https://www.oecd.org/els/health-systems/The-economics-of-patient-safety-March-2017.pdf>
9. Donabedian A. The seven pillars of quality. *Arch Pathol Lab Med*. 1990;114(11):1115–8.
10. Donabedian A. Evaluating the quality of medical care. *Milbank Q*. 2005;83:691–729.
11. Ayanian JZ, Markel H. Donabedian's lasting framework for health care quality. *N Engl J Med*. 2016;375(3):205–7.
12. Darzi A. High Quality Care For All [Internet]. 2008. Available from:

https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/228836/7432.pdf

13. Sutherland K, Leatherman S. Regulation and quality improvement A review of the evidence [Internet]. Quest for Quality and Improved Performance. 2006. Available from:
https://www.health.org.uk/sites/default/files/RegulationQualityImprovement_ReviewEvidence_full.pdf
14. Haynes AB, Weiser TG, Berry WR, Lipsitz SR, Breizat AHS, Dellinger EP, et al. A surgical safety checklist to reduce morbidity and mortality in a global population. *N Engl J Med*. 2009;360(5):491–9.
15. Schmidt S, Hendricks V, Griebenow R, Riedel R. Demographic change and its impact on the health-care budget for heart failure inpatients in Germany during 1995–2025. *Herz*. 2013;38(8):862–7.
16. Halaweish I, Alam HB. Changing demographics of the American population. *Surg Clin*. 2015;95(1):1–10.
17. Institute of Medicine (US) Committee on Quality of Health Care in America. Crossing the quality chasm: a new health system for the 21st century. National Academies Press (US); 2001.
18. Meltzer D. Economic analysis in patient safety: A neglected necessity. *BMJ Qual Saf*. 2012;21(6):443–5.
19. Hussey PS, Wertheimer S, Mehrotra A. The Association Between Health Care Quality and Cost A Systematic Review. *Ann Intern Med*. 2013 Jan;158(1):27–34.
20. Better MI, Anderson GF. Spending on Medical Care. 2014;299(20):2444–5.
21. Kane RC. Comparative Effectiveness and Health Care Spending. *N Engl J Med*. 2010 May;362(19):1845–6.
22. Shojania KG, Duncan BW, McDonald KM, Wachter RM, Markowitz AJ. Making health care safer: a critical analysis of patient safety practices. *Evid Rep Technol Assess (Summ)*. 2001;(43):i–x, 1–668.
23. Hauck KD, Wang S, Vincent C, Smith PC. Healthy Life-Years Lost and Excess Bed-

- Days Due to 6 Patient Safety Incidents. *Med Care*. 2017;55(2):125–30.
24. Hauck K, Wang S, Smith P. The costs to patients and health services of safety incidents : Evidence from English hospitals. 2014;1–72.
 25. Bottle A, Aylin P. Application of AHRQ patient safety indicators to English hospital data. *Qual Saf Heal Care*. 2009;18(4):303–8.
 26. Zhan C, Miller MR. Administrative data based patient safety research: A critical review. *Qual Saf Heal Care*. 2003;12(SUPPL. 2):58–63.
 27. Romano PS, Chan BK, Schembri ME, Rainwater JA. Can administrative data be used to compare postoperative complication rates across hospitals? *Med Care* [Internet]. 2002 Oct;40(10):856–67. Available from: <http://www.ncbi.nlm.nih.gov/pubmed/12395020>
 28. Zhan C. Excess Length of Stay, Charges, and Mortality Attributable to Medical Injuries During Hospitalization. *JAMA* [Internet]. 2003 Oct;290(14):1868. Available from: <http://jama.jamanetwork.com/article.aspx?doi=10.1001/jama.290.14.1868>
 29. Appleby J, Harrison T, Hawkins L, Dixon A. How can payment systems help to deliver better care ? [Internet]. The King’s Fund. 2012. Available from: http://www.kingsfund.org.uk/sites/files/kf/field/field_publication_file/payment-by-results-the-kings-fund-nov-2012.pdf
 30. Department of Health. Payment by Results Consultation: 2005;(August 2003). Available from: http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_4065324.pdf
 31. Waring J, Rowley E, Dingwall R, Palmer C, Murcott T. Narrative review of the UK Patient Safety Research Portfolio. 2010;15(January):26–32.
 32. Hutchinson A, Young TA, Cooper KL, McIntosh A, Karnon JD, Scobie S, et al. Trends in healthcare incident reporting and relationship to safety and quality data in acute hospitals: results from the National Reporting and Learning System. *Qual Saf Health Care* [Internet]. 2009 Feb;18(1):5–10. Available from: <http://www.ncbi.nlm.nih.gov/pubmed/19204125>
 33. Howell A-M, Burns EM, Bouras G, Donaldson LJ, Athanasiou T, Darzi A. Can Patient

- Safety Incident Reports Be Used to Compare Hospital Safety? Results from a Quantitative Analysis of the English National Reporting and Learning System Data. *PLoS One*. 2015;10(12):e0144107.
34. Williams SK, Osborn SS. The development of the National Reporting and Learning System in England and Wales, 2001-2005. *Med J Aust* [Internet]. 2006;184(S10):S65-8. Available from: <http://www.ncbi.nlm.nih.gov/pubmed/16719740>
 35. Friedman CP, Allee NJ, Delaney BC, Flynn AJ, Silverstein JC, Sullivan K, et al. The science of Learning Health Systems: Foundations for a new journal. *Learn Heal Syst*. 2017 Jan;1(1):e10020.
 36. Benn J, Koutantji M, Wallace L, Spurgeon P, Rejman M, Healey A, et al. Feedback from incident reporting: information and action to improve patient safety. *Qual Saf Heal Care* [Internet]. 2009 Feb;18(1):11–21. Available from: <http://qualitysafety.bmj.com/lookup/doi/10.1136/qshc.2007.024166>
 37. Roberts KH. New challenges in organizational research: high reliability organizations. *Ind Cris Q* [Internet]. 1989 Jun 1;3(2):111–25. Available from: <https://doi.org/10.1177/108602668900300202>
 38. Kaplan HS, Fastman BR. System Improvement. 2003;68–73.
 39. Anderson JE, Kodate N, Walters R, Dodds A. Can incident reporting improve safety? Healthcare practitioners' views of the effectiveness of incident reporting. *Int J Qual Heal Care*. 2013;25(2):141–50.
 40. Morse JW, Linder FE, Silver GA, Bogue DJ, Stavenhagen R, Paddock WC. Demography, Feedback, and Decision-Making for Economic and Social Development. *Milbank Mem Fund Q* [Internet]. 1964 Apr;42(2):301. Available from: <https://www.jstor.org/stable/3348669?origin=crossref>
 41. Stansfield TC, Longenecker CO. The effects of goal setting and feedback on manufacturing productivity: a field experiment. *Int J Product Perform Manag* [Internet]. 2006 Apr;55(3/4):346–58. Available from: <https://www.emerald.com/insight/content/doi/10.1108/17410400610653273/full/html>
 42. Kim JS, Hamner WC. Effect of performance feedback and goal setting on productivity and satisfaction in an organizational setting. *J Appl Psychol*. 1976;61(1):48–57.

43. Hays MJ, Kornell N, Bjork RA. The costs and benefits of providing feedback during learning. *Psychon Bull Rev*. 2010;17(6):797–801.
44. Noble DJ, Panesar SS, Pronovost PJ. A Public Health Approach to Patient Safety Reporting Systems Is Urgently Needed. *J Patient Saf* [Internet]. 2011;7(2). Available from: https://journals.lww.com/journalpatientsafety/Fulltext/2011/06000/A_Public_Health_Approach_to_Patient_Safety.11.aspx
45. Millar A, Simeone RS, Carnevale JT. Logic models: a systems tool for performance management. *Eval Program Plann* [Internet]. 2001 Feb;24(1):73–81. Available from: <https://linkinghub.elsevier.com/retrieve/pii/S0149718900000483>
46. Carter AW, Mossialos E, Darzi A. A national incident reporting and learning system in England and Wales, but at what cost? *Expert Rev Pharmacoeconomics Outcomes Res*. 2015;15(3):365–8.
47. Trochim WM, Cabrera DA, Milstein B, Gallagher RS, Leischow SJ. Practical challenges of systems thinking and modeling in public health. *Am J Public Health*. 2006;96(3):538–46.
48. Rudmik L, Drummond M. Health economic evaluation: important principles and methodology. *Laryngoscope* [Internet]. 2013 Jun;123(6):1341–7. Available from: <http://www.ncbi.nlm.nih.gov/pubmed/23483522>
49. Pemberton Levy H. Why and How to Value Your Information as an Asset [Internet]. 2015. Available from: <https://www.gartner.com/smarterwithgartner/why-and-how-to-value-your-information-as-an-asset/>
50. Price CP, Wolstenholme J, McGinley P, St John A. Translational health economics: The key to accountable adoption of in vitro diagnostic technologies. *Heal Serv Manag Res* [Internet]. 2018;31(1):43–50. Available from: <http://www.ncbi.nlm.nih.gov/pubmed/29084478>
51. Nilsen P. Making sense of implementation theories, models and frameworks. *Implement Sci* [Internet]. 2015;10(1):53. Available from: <https://doi.org/10.1186/s13012-015-0242-0>
52. Meyers DC, Durlak JA, Wandersman A. The quality implementation framework: a

- synthesis of critical steps in the implementation process. *Am J Community Psychol*. 2012 Dec;50(3–4):462–80.
53. Greenhalgh T, Robert G, Macfarlane F, Bate P, Kyriakidou O. Diffusion of innovations in service organizations: Systematic review and recommendations. *Milbank Q*. 2004;82(4):581–629.
 54. Eccles MP, Mittman BS. Welcome to implementation science. *Implement Sci*. 2006;1(1):1–3.
 55. Moore GF, Audrey S, Barker M, Bond L, Bonell C, Hardeman W, et al. Process evaluation of complex interventions: Medical Research Council guidance. *BMJ* [Internet]. 2015;350. Available from: <https://www.bmj.com/content/350/bmj.h1258>
 56. Oakley A, Strange V, Bonell C, Allen E, Stephenson J. Process evaluation in randomised controlled trials of complex interventions. *BMJ* [Internet]. 2006;332(7538):413–6. Available from: <https://www.bmj.com/content/332/7538/413>
 57. Jun GT, Ward J, Morris Z, Clarkson J. Health care process modelling: which method when? *Int J Qual Heal Care* [Internet]. 2009;21(3):214–24. Available from: <https://doi.org/10.1093/intqhc/mzp016>
 58. Keen S. A monetary Minsky model of the Great Moderation and the Great Recession. *J Econ Behav Organ* [Internet]. 2013;86:221–35. Available from: <http://dx.doi.org/10.1016/j.jebo.2011.01.010>
 59. Jamison DT, Summers LH, Alleyne G, Arrow KJ, Berkley S, Binagwaho A, et al. Global health 2035: a world converging within a generation. *Lancet* [Internet]. 2013 Dec 7;382(9908):1898–955. Available from: [https://doi.org/10.1016/S0140-6736\(13\)62105-4](https://doi.org/10.1016/S0140-6736(13)62105-4)
 60. Schumpeter J. *History of Economic Analysis*. New York: Oxford University Press; 1954.
 61. Archive HPM, Minsky HP. Bard Digital Commons The Financial Instability Hypothesis: A Restatement Recommended Citation. 1978; Available from: http://digitalcommons.bard.edu/hm_archive/180
 62. Godley W. Money and credit in a Keynesian model of income determination. *Cambridge J Econ* [Internet]. 1999 Jul;23(4):393–411. Available from:

<https://academic.oup.com/cje/article-lookup/doi/10.1093/cje/23.4.393>

63. Godley W, Lavoie M. Fiscal policy in a stock-flow consistent (SFC) model. *J Post Keynes Econ.* 2007;30(1):79–100.
64. Godley W, Zezza G. Debt and lending: A cri de coeur [Internet]. *Economics Policy Note Archive.* 2006. Available from: <https://ideas.repec.org/p/lev/levypn/06-4.html>
65. Nakajima K, Kurata Y, Takeda H. A web-based incident reporting system and multidisciplinary collaborative projects for patient safety in a Japanese hospital. *Qual Saf Health Care* [Internet]. 2005 Apr;14(2):123–9. Available from: <http://www.ncbi.nlm.nih.gov/pubmed/15805458>
66. Keistinen T, Kinnunen M. Increased patient safety with an Internet-based reporting system. *World Hosp Heal Serv.* 2008;44(2):37–9.
67. Stavropoulou C, Doherty C, Tosey P. How Effective Are Incident-Reporting Systems for Improving Patient Safety? A Systematic Literature Review. *Milbank Q* [Internet]. 2015 Dec;93(4):826–66. Available from: <http://www.ncbi.nlm.nih.gov/pubmed/26626987>
68. Sari ABA, Sheldon TA, Cracknell A, Turnbull A. Sensitivity of routine system for reporting patient safety incidents in an NHS hospital: Retrospective patient case note review. *Br Med J.* 2007;334(7584):79–81.
69. Pham JC, Girard T, Pronovost PJ. What to do with healthcare Incident Reporting Systems. *J Public health Res.* 2013;2(3):27.
70. National Institute of Health and Clinical Excellence (NICE). Consultation Paper: Value Based Assessment of Health Technologies. 2014;1–28.
71. WHO. Everybody's business--strengthening health systems to improve health outcomes: WHO's framework for action. World Health Organization; 2007.
72. Morozov E. To save everything, click here: the folly of technological solutionism. New York, USA: PublicAffairs; 2013.
73. Shannon CE. A Mathematical Theory of Communication. *Bell Syst Tech J* [Internet]. 1948 Jul;27(3):379–423. Available from: <http://ieeexplore.ieee.org/lpdocs/epic03/wrapper.htm?arnumber=6773024>

74. Atherton T. Description and Outcomes of the Doctorquality Incident Reporting System Used at Baylor Medical Center at Grapevine. *Baylor Univ Med Cent Proc*. 2002;15(2):203–8.
75. Boyle TA, Scobie AC, MacKinnon NJ, Mahaffey T. Quality-related event learning in community pharmacies: Manual versus computerized reporting processes. *J Am Pharm Assoc [Internet]*. 2012;52(4):498–506. Available from: <http://dx.doi.org/10.1331/JAPhA.2012.11004>
76. Goldsmith P, Moon J, Anderson P, Kirkup S, Williams S, Gray M. Do clinical incidents, complaints and medicolegal claims overlap? *Int J Health Care Qual Assur [Internet]*. 2015;28(8):864–71. Available from: <http://www.ncbi.nlm.nih.gov/pubmed/26440488>
77. Renshaw M, Vaughan C, Ottewill M, Ireland A, Carmody J. Clinical incident reporting: wrong time, wrong place. *Int J Health Care Qual Assur [Internet]*. 2008;21(4):380–4. Available from: <http://www.ncbi.nlm.nih.gov/pubmed/18785464>
78. Savage SW, Schneider PJ, Pedersen CA. Utility of an online medication-error-reporting system. *Am J Health Syst Pharm [Internet]*. 2005 Nov;62(21):2265–70. Available from: <http://www.ncbi.nlm.nih.gov/pubmed/16239417>
79. Shah A, Mohamed-Ahmed O, Peirsegaale P, McClymont C, Knight M. Incident reviews in UK maternity units: A systematic appraisal of the quality of local guidelines. *BMC Pregnancy Childbirth*. 2015;15(1):1–6.
80. Sinclair A, Guérin A, Robin C, Dey P. Investigating the cost and efficiency of incident reporting in a specialist paediatric NHS hospital and impact on patient safety. *Eur J Hosp Pharm*. 2017;24(2):91–5.
81. Carter AW. A Pilot Study: In the Era of Patient Safety, what’s the Resource Use Associated with the UK National Reporting and Learning System (NRLS) and what Potential Economic Benefits to Society does it produce? London School of Economics & Political Science, UK; 2013.
82. O’Rourke B, Oortwijn W, Schuller T. The new definition of health technology assessment: A milestone in international collaboration. *Int J Technol Assess Health Care [Internet]*. 2020/05/13. 2020;36(3):187–90. Available from:

<https://www.cambridge.org/core/article/new-definition-of-health-technology-assessment-a-milestone-in-international-collaboration/8A3BA65D279F3FDAA83ADB3D08CF8C17>

83. Geldsetzer P, Fawzi W. Quasi-experimental study designs series-paper 2: complementary approaches to advancing global health knowledge. *J Clin Epidemiol*. 2017 Sep;89:12–6.
84. Lercel D, Steckel R, Mondello S, Carr E, Patankar M. Aviation Safety Management Systems Return on Investment Study. *Cent Aviat Saf Res*. 2011;(February):1–26.
85. Lamont T, Barber N, de Pury J, Fulop N, Garfield-Birkbeck S, Lilford R, et al. New approaches to evaluating complex health and care systems. *BMJ* [Internet]. 2016 Feb;i154. Available from: <http://www.bmj.com/lookup/doi/10.1136/bmj.i154>
86. Lu C-T, Young J, Schreckengast S, Chen H. Safety Culture: The Perception of Taiwan's Aviation Leaders. *Int J Appl Aviat Stud*. 2003;3(2):243–58.
87. Wreathall J, Nemeth C. Assessing risk: the role of probabilistic risk assessment (PRA) in patient safety improvement. *BMJ Qual Saf* [Internet]. 2004;13(3):206–12. Available from: <https://qualitysafety.bmj.com/content/13/3/206>
88. Vale L, Thomas R, MacLennan G, Grimshaw J. Systematic Review of Economic Evaluations and Cost Analyses of Guideline Implementation Strategies. *Eur J Heal Econ*. 2007 Jun;8(2):111–21.
89. Hoomans T, Evers SMAA, Ament AJHA, Hübber MWA, van der Weijden T, Grimshaw JM, et al. The Methodological Quality of Economic Evaluations of Guideline Implementation into Clinical Practice: A Systematic Review of Empiric Studies. *Value Heal* [Internet]. 2007;10(4):305–16. Available from: <http://www.sciencedirect.com/science/article/pii/S109830151060616X>
90. Drummond MF, Jefferson TO. Guidelines for authors and peer reviewers of economic. *Br Med J*. 1996;313(August):275–83.
91. Severens J. Value for money of changing healthcare services? Economic evaluation of quality improvement. *Qual Saf Heal Care*. 2003;12(5):366–71.
92. Shiell A, Hawe P, Gold L. Complex interventions or complex systems? Implications for health economic evaluation. *BMJ* [Internet]. 2008;336(7656):1281–3. Available

from: <https://www.bmj.com/content/336/7656/1281>

93. Thomas R, Grimshaw J, McClinton S, McIntosh E, Mollison J. An evaluation of a guideline-based open-access urological investigation service (URGE). Final project report to Chief Scientist Office of Scottish Office Home and Health Department. HSRU. 1998;
94. Gurwitz JH, Noonan JP, Soumerai SB. Reducing the use of H₂-receptor antagonists in the long-term-care setting. *J Am Geriatr Soc* [Internet]. 1992 Apr;40(4):359–64. Available from: <http://www.ncbi.nlm.nih.gov/pubmed/1348256>
95. Grimshaw JM, Thomas RE, MacLennan G, Fraser C, Ramsay CR, Vale L, et al. Effectiveness and efficiency of guideline dissemination and implementation strategies. *Health Technol Assess*. 2004 Feb;8(6):iii–iv, 1–72.
96. Mason J, Wood J, Freemantle N. Designing Evaluations of Interventions to Change Professional Practice. *J Health Serv Res Policy* [Internet]. 1999 Apr;4(2):106–11. Available from: <http://journals.sagepub.com/doi/10.1177/135581969900400209>
97. McIntosh E, Donaldson C, Ryan M. Recent advances in the methods of cost-benefit analysis in healthcare. Matching the art to the science. *Pharmacoeconomics* [Internet]. 1999 Apr;15(4):357–67. Available from: <http://www.ncbi.nlm.nih.gov/pubmed/10537954>
98. Sculpher M. Evaluating the cost-effectiveness of interventions designed to increase the utilization of evidence-based guidelines. *Fam Pract*. 2000;17(SUPPL. 1):26–31.
99. Drummond M. Clinical Guidelines: A NICE Way to Introduce Cost-Effectiveness Considerations? *Value Heal* [Internet]. 2016;19(5):525–30. Available from: <http://dx.doi.org/10.1016/j.jval.2016.04.020>
100. Arrow KJ. Uncertainty and the welfare economics of medical care. 1963. *Bull World Health Organ* [Internet]. 2004/03/16. 2004 Feb;82(2):141–9. Available from: <https://pubmed.ncbi.nlm.nih.gov/15042238>
101. Fuchs VR. The future of health economics. *J Health Econ*. 2000 Mar;19(2):141–57.
102. Black John, Hashimzade Nigar MG. *Oxford Dictionary of Economics*. Fourth. Oxford, UK: Oxford University Press; 2012.

103. Brazier J, Ratcliffe J, Salomon JA, Tsuchiya A. Measuring and Valuing Health Benefits for Economic Evaluation. Second. Oxford, UK: Oxford University Press; 2017.
104. WHO. Constitution of the World Health Organization. In: World Health Organization: Basic documents. 45th ed. Geneva, Switzerland; 2005.
105. Jha AK, Larizgoitia I, Audera-Lopez C, Prasopa-Plaizier N, Waters H, Bates DW. The global burden of unsafe medical care: analytic modelling of observational studies. *BMJ Qual Saf* [Internet]. 2013 Oct;22(10):809–15. Available from: <http://qualitysafety.bmj.com/lookup/doi/10.1136/bmjqs-2012-001748>
106. Brennan TA, Leape LL, Laird NM, Hebert L, Localio AR, Lawthers AG, et al. Incidence of adverse events and negligence in hospitalized patients. Results of the Harvard Medical Practice Study I. *N Engl J Med*. 1991 Feb;324(6):370–6.
107. Wilson RM, Runciman WB, Gibberd RW, Harrison BT, Newby L, Hamilton JD. The Quality in Australian Health Care Study. *Med J Aust*. 1995 Nov;163(9):458–71.
108. Rafter N, Hickey A, Conroy RM, Condell S, O'Connor P, Vaughan D, et al. The Irish National Adverse Events Study (INAES): the frequency and nature of adverse events in Irish hospitals – a retrospective record review study. *BMJ Qual Saf* [Internet]. 2017;26(2):111–9. Available from: <https://qualitysafety.bmj.com/content/26/2/111>
109. Vincent C, Neale G, Woloshynowych M. Adverse events in British hospitals: Preliminary retrospective record review. *Br Med J*. 2001;322(7285):517–9.
110. Guyatt GH, Sackett DL, Sinclair JC, Hayward R, Cook DJ, Cook RJ. Users' guides to the medical literature. IX. A method for grading health care recommendations. Evidence-Based Medicine Working Group. *JAMA*. 1995 Dec;274(22):1800–4.
111. Etchells E, Mittmann N, Koo M, Baker M, Krahn M, Shojania K, et al. The economics of patient safety in acute care: Technical report [Internet]. 2012. 67 p. Available from: <http://www.patientsafetyinstitute.ca>
112. de Rezende BA, Or Z, Com-Ruelle L, Michel P. Economic evaluation in patient safety: a literature review of methods. *BMJ Qual Saf* [Internet]. 2012 Jun;21(6):457–65. Available from: <http://www.ncbi.nlm.nih.gov/pubmed/22396602>

113. Mittmann N, Koo M, Daneman N, McDonald A, Baker M, Matlow A, et al. The economic burden of patient safety targets in acute care: a systematic review. *Drug Healthc Patient Saf* [Internet]. 2012/10/05. 2012;4:141–65. Available from: <https://pubmed.ncbi.nlm.nih.gov/23097615>
114. Karnon J, Campbell F, Czoski-Murray C. Model-based cost-effectiveness analysis of interventions aimed at preventing medication error at hospital admission (medicines reconciliation). *J Eval Clin Pract* [Internet]. 2009 Apr;15(2):299–306. Available from: <http://doi.wiley.com/10.1111/j.1365-2753.2008.01000.x>
115. Maenthaisong R, Chaiyakunapruk N, Thamlikitkul V. Cost-effectiveness analysis of chlorhexidine gluconate compared with povidone-iodine solution for catheter-site care in Siriraj Hospital, Thailand. *J Med Assoc Thai* [Internet]. 2006 Nov;89 Suppl 5:S94--101. Available from: <http://www.ncbi.nlm.nih.gov/pubmed/17718250>
116. Waters HR, Korn R, Colantuoni E, Berenholtz SM, Goeschel CA, Needham DM, et al. The Business Case for Quality. *Am J Med Qual* [Internet]. 2011 Sep;26(5):333–9. Available from: <http://journals.sagepub.com/doi/10.1177/1062860611410685>
117. Regenbogen SE, Greenberg CC, Resch SC, Kollengode A, Cima RR, Zinner MJ, et al. Prevention of retained surgical sponges: a decision-analytic model predicting relative cost-effectiveness. *Surgery*. 2009 May;145(5):527–35.
118. Shermock KM, Horn E, Lipsett PA, Pronovost PJ, Dorman T. Number needed to treat and cost of recombinant human erythropoietin to avoid one transfusion-related adverse event in critically ill patients. *Crit Care Med*. 2005;33(3):497–503.
119. Brown CA, Lilford RJ. Should the UK government's deep cleaning of hospitals programme have been evaluated? *J Infect Prev*. 2009;10(4):143–7.
120. Karnon J, McIntosh A, Dean J, Bath P, Hutchinson A, Oakley J, et al. Modelling the expected net benefits of interventions to reduce the burden of medication errors. *J Health Serv Res Policy*. 2008;13(2):85–91.
121. Calugar A, Ortega-Sánchez IR, Tiwari T, Oakes L, Jahre JA, Murphy T V. Nosocomial pertussis: costs of an outbreak and benefits of vaccinating health care workers. *Clin Infect Dis*. 2006;42(7):981–8.
122. Van Rijen MML, Kluytmans J. Costs and benefits of the MRSA Search and Destroy

- policy in a Dutch hospital. *Eur J Clin Microbiol Infect Dis*. 2009;28(10):1245–52.
123. Wang SJ, Middleton B, Prosser LA, Bardon CG, Spurr CD, Carchidi PJ, et al. A cost-benefit analysis of electronic medical records in primary care. *Am J Med*. 2003;114(5):397–403.
 124. Darzi A, Quilter-Pinner H, Kibasi T. The Lord Darzi Review of Health and Care Interim Report, Institute for Public Policy Research [Internet]. 2018. Available from: <https://www.ippr.org/publications/darzi-review-interim-report>
 125. Zsifkovits J, Zuba M GW et al. Costs of unsafe care and cost effectiveness of patient safety programmes. European Commission Report, Brussels; 2016.
 126. Etchells E, Koo M, Daneman N, McDonald A, Baker M, Matlow A, et al. Comparative economic analyses of patient safety improvement strategies in acute care: a systematic review. *BMJ Qual Saf*. 2012 Jun;21(6):448–56.
 127. Carter AW, Mandavia R, Mayer E, Marti J, Mossialos E, Darzi A. Systematic review of economic analyses in patient safety: A protocol designed to measure development in the scope and quality of evidence. *BMJ Open*. 2017;7(8):1–6.
 128. Higgins J, S G. Cochrane Handbook for Systematic Reviews of Interventions Version 5.1.0. The Cochrane Collaboration. 2011.
 129. Moher D, Liberati A, Tetzlaff J, Altman DG, PRISMA Group. Preferred reporting items for systematic reviews and meta-analyses: the PRISMA statement. *PLoS Med* [Internet]. 2009 Jul;6(7):e1000097. Available from: <http://www.ncbi.nlm.nih.gov/pubmed/19621072>
 130. Neyt M, Chalon PX. Search MEDLINE for economic evaluations: tips to translate an OVID strategy into a PubMed one. *Pharmacoeconomics* [Internet]. 2013 Dec;31(12):1087–90. Available from: <http://www.ncbi.nlm.nih.gov/pubmed/24202991>
 131. Bramer WM, Giustini D, De Jonge GB, Holland L, Bekhuis T. De-duplication of database search results for systematic reviews in EndNote. *J Med Libr Assoc*. 2016;104(3):240–3.
 132. AHRQ. Agency for Healthcare Research and Quality. Patient Safety Indicators Technical Specifications. [Internet]. [cited 2019 Oct 25]. Available from: https://www.qualityindicators.ahrq.gov/Modules/PSI_TechSpec_ICD10_v2019.aspx

133. Chapel J. Economic evaluation: alternatives to roi to show societal benefits [Internet]. 2016 [cited 2019 Oct 25]. Available from:
https://www.cdc.gov/dhds/pubs/docs/cb_march2016.pdf
134. Ball C, Sackett D, Phillips B. Oxford Centre for Evidence-based Medicine – Levels of Evidence (March 2009 [Internet]. 2009 [cited 2020 Aug 16]. Available from:
<https://www.cebm.net/2009/06/oxford-centre-evidence-based-medicine-levels-evidence-march-2009>
135. Higgins JPT, Altman DG, Gøtzsche PC, Jüni P, Moher D, Oxman AD, et al. The Cochrane Collaboration’s tool for assessing risk of bias in randomised trials. *BMJ*. 2011;343(7829):1–9.
136. Eldridge S, Campbell M, Campbell M, Drahota A, Giraudeau B, Higgins J, et al. New cochrane risk of bias tool for cluster randomised tools. *Trials*. 2017;18(4).
137. Newell D. Intention-to-Treat Analysis: Implications for Quantitative and Qualitative Research. *Int J Epidemiol* [Internet]. 1992;21(5):837–41. Available from:
<https://academic.oup.com/ije/article-lookup/doi/10.1093/ije/21.5.837>
138. Drummond MF, Jefferson TO. Guidelines for authors and peer reviewers of economic submissions to the *BMJ*. *BMJ* [Internet]. 1996 Aug;313(7052):275–83. Available from: <http://www.bmj.com/cgi/doi/10.1136/bmj.313.7052.275>
139. Husereau D, Drummond M, Petrou S, Carswell C, Moher D, Greenberg D, et al. Consolidated Health Economic Evaluation Reporting Standards (CHEERS) statement. *BMJ Br Med J* [Internet]. 2013 Mar 25;346:f1049. Available from:
<http://www.bmj.com/content/346/bmj.f1049.abstract>
140. Cohen J. A coefficient of agreement for nominal scales. *Educ Psychol Meas* [Internet]. 1960;20(1):37–46. Available from: <http://epm.sagepub.com>
141. Landis JR, Koch GG. The measurement of observer agreement for categorical data. *Biometrics* [Internet]. 1977 Mar;33(1):159–74. Available from:
<http://www.ncbi.nlm.nih.gov/pubmed/843571>
142. Riley RD, Higgins JPT, Deeks JJ. Interpretation of random effects meta-analyses. *BMJ* [Internet]. 2011 Feb;342:d549. Available from:
<http://www.ncbi.nlm.nih.gov/pubmed/21310794>

143. Kilonzo MM, Vale LD, Cook JA, Milne AC, Stephen AI, Avenell A. A cost-utility analysis of multivitamin and multiminerall supplements in men and women aged 65 years and over. *Clin Nutr* [Internet]. 2007 Jun;26(3):364–70. Available from: <https://linkinghub.elsevier.com/retrieve/pii/S0261561406001981>
144. Amin A, Jing Y, Trocio J, Lin J, Lingohr-Smith M, Graham J. Evaluation of medical costs associated with use of new oral anticoagulants compared with standard therapy among venous thromboembolism patients. *J Med Econ* [Internet]. 2014 Nov;17(11):763–70. Available from: <http://www.tandfonline.com/doi/full/10.3111/13696998.2014.950670>
145. Agnelli G, Buller HR, Cohen A, Curto M, Gallus AS, Johnson M, et al. Oral apixaban for the treatment of acute venous thromboembolism. *N Engl J Med*. 2013;369(9):799–808.
146. Bauersachs, R., Berkowitz, S. D., Brenner, B. et al. Oral Rivaroxaban for Symptomatic Venous Thromboembolism. *N Engl J Med* [Internet]. 2010 Dec;363(26):2499–510. Available from: <http://www.nejm.org/doi/abs/10.1056/NEJMoa1007903>
147. Bailey AL. Oral rivaroxaban for the treatment of symptomatic pulmonary embolism. *Cardiol Rev*. 2012;28(3):1287–97.
148. Edoxaban versus Warfarin for the Treatment of Symptomatic Venous Thromboembolism. *N Engl J Med* [Internet]. 2013 Oct;369(15):1406–15. Available from: <http://www.nejm.org/doi/10.1056/NEJMoa1306638>
149. Schulman S, Kearon C, Kakkar AK, Mismetti P, Schellong S, Eriksson H, et al. Dabigatran versus Warfarin in the Treatment of Acute Venous Thromboembolism. *N Engl J Med* [Internet]. 2009 Dec;361(24):2342–52. Available from: <http://www.nejm.org/doi/abs/10.1056/NEJMoa0906598>
150. Schulman S, Kakkar AK, Goldhaber SZ, Schellong S, Eriksson H, Mismetti P, et al. Treatment of acute venous thromboembolism with dabigatran or warfarin and pooled analysis. *Circulation*. 2014;129(7):764–72.
151. Amin A, Jing Y, Trocio J, Lin J, Lingohr-Smith M, Graham J. Evaluation of medical costs avoided when new oral anticoagulants are used for extended treatment of venous

- thromboembolism based on clinical trial results. *J Thromb Thrombolysis* [Internet]. 2015 Aug;40(2):131–8. Available from: <http://link.springer.com/10.1007/s11239-014-1158-2>
152. Browne C, Lanitis T, Hamilton M, Li X, Horbyluk R, Mardekian J, et al. Impact of apixaban vs low molecular weight heparin/vitamin k antagonist on hospital resource use in patients with venous thromboembolism. *J Med Econ* [Internet]. 2017 Jan;20(1):98–106. Available from: <https://www.tandfonline.com/doi/full/10.1080/13696998.2016.1258365>
 153. Carrier M, Lazo-Langner A, Shivakumar S, Tagalakakis V, Zarychanski R, Solymoss S, et al. Screening for occult cancer in unprovoked venous thromboembolism. *N Engl J Med*. 2015;373(8):697–704.
 154. de Jong LA, Dvortsin E, Janssen KJ, Postma MJ. Cost-effectiveness Analysis for Apixaban in the Acute Treatment and Prevention of Venous Thromboembolism in the Netherlands. *Clin Ther* [Internet]. 2017 Feb;39(2):288--302.e4. Available from: <https://linkinghub.elsevier.com/retrieve/pii/S0149291816309250>
 155. Roos D, Dijksman LM, Oudemans-Van Straaten HM, De Wit LT, Gouma DJ, Gerhards MF. Randomized clinical trial of perioperative selective decontamination of the digestive tract versus placebo in elective gastrointestinal surgery. *Br J Surg*. 2011;98(10):1365–72.
 156. Elías I, Oyagüez I, Alvarez-Sala LA, García-Bragado F, Navarro A, González P, et al. Cost-effectiveness analysis of apixaban compared to low-molecularweight heparins and vitamin k antagonists for treatment and secondary prevention of venous thromboembolism. *Farm Hosp* [Internet]. 2016;40(3):187–208. Available from: <http://www.ncbi.nlm.nih.gov/pubmed/27145388>
 157. Agnelli G, Buller HR, Cohen A, Curto M, Gallus AS, Johnson M, et al. Apixaban for extended treatment of venous thromboembolism. *N Engl J Med*. 2013;368(8):699–708.
 158. Elliott RA, Putman KD, Franklin M, Annemans L, Verhaeghe N, Eden M, et al. Cost Effectiveness of a Pharmacist-Led Information Technology Intervention for Reducing Rates of Clinically Important Errors in Medicines Management in General Practices (PINCER). *Pharmacoeconomics* [Internet]. 2014 Jun;32(6):573–90. Available from: <http://link.springer.com/10.1007/s40273-014-0148-8>

159. Avery AJ, Rodgers S, Cantrill JA, Armstrong S, Cresswell K, Eden M, et al. A pharmacist-led information technology intervention for medication errors (PINCER): a multicentre, cluster randomised, controlled trial and cost-effectiveness analysis. *Lancet* [Internet]. 2012 Apr;379(9823):1310–9. Available from: <https://linkinghub.elsevier.com/retrieve/pii/S0140673611618175>
160. Fowler RA, Mittmann N, Geerts W, Heels-Ansdell D, Gould MK, Guyatt G, et al. Cost-effectiveness of Dalteparin vs Unfractionated heparin for the prevention of venous Thromboembolism in Critically Ill patients. *JAMA - J Am Med Assoc*. 2014;312(20):2135–45.
161. PROTECT Investigators for the Canadian Critical Care Trials Group and the Australian and New Zealand Intensive Care Society Clinical Trials Group, Cook D, Meade M, Guyatt G, Walter S, Heels-Ansdell D, et al. Dalteparin versus unfractionated heparin in critically ill patients. *N Engl J Med* [Internet]. 2011 Apr;364(14):1305–14. Available from: <http://www.ncbi.nlm.nih.gov/pubmed/21417952>
162. Haines TP, Hill A-M, Hill KD, Brauer SG, Hoffmann T, Etherton-Beer C, et al. Cost effectiveness of patient education for the prevention of falls in hospital: economic evaluation from a randomized controlled trial. *BMC Med* [Internet]. 2013 Dec;11(1):135. Available from: <http://bmcmmedicine.biomedcentral.com/articles/10.1186/1741-7015-11-135>
163. Haines TP, Hill A-M, Hill KD, McPhail S, Oliver D, Brauer S, et al. Patient Education to Prevent Falls Among Older Hospital Inpatients. *Arch Intern Med* [Internet]. 2011 Mar;171(6). Available from: <http://archinte.jamanetwork.com/article.aspx?doi=10.1001/archinternmed.2010.444>
164. Avenell A, Campbell MK, Cook JA, Hannaford PC, Kilonzo MM, McNeill G, et al. Effect of multivitamin and multimineral supplements on morbidity from infections in older people (MAVIS trial): pragmatic, randomised, double blind, placebo controlled trial. *BMJ* [Internet]. 2005 Aug;331(7512):324–9. Available from: <http://www.bmj.com/lookup/doi/10.1136/bmj.331.7512.324>
165. Pineo G, Lin J, Stern L, Subrahmanian T, Annemans L. Economic Impact of Enoxaparin After Acute Ischemic Stroke Based on PREVAIL. *Clin Appl Thromb*

- [Internet]. 2011 Apr;17(2):150–7. Available from:
<http://journals.sagepub.com/doi/10.1177/1076029610389026>
166. Sherman DG, Albers GW, Bladin C, Fieschi C, Gabbai AA, Kase CS, et al. The efficacy and safety of enoxaparin versus unfractionated heparin for the prevention of venous thromboembolism after acute ischaemic stroke (PREVAIL Study): an open-label randomised comparison. *Lancet* [Internet]. 2007 Apr;369(9570):1347–55. Available from: <https://linkinghub.elsevier.com/retrieve/pii/S0140673607606333>
 167. Pineo G, Lin J, Stern L, Subrahmanian T, Annemans L. Economic impact of enoxaparin versus unfractionated heparin for venous thromboembolism prophylaxis in patients with acute ischemic stroke: A hospital perspective of the PREVAIL trial. *J Hosp Med* [Internet]. 2012 Mar;7(3):176–82. Available from: <http://www.journalofhospitalmedicine.com/jhospmed/article/127527/economic-impact-enoxaparin-stroke>
 168. Preblich R, Kwong WJ, White RH, Goldhaber SZ. Cost-effectiveness of edoxaban for the treatment of venous thromboembolism based on the Hokusai-VTE study. *Hosp Pract* [Internet]. 2015 Dec;43(5):249–57. Available from: <http://www.tandfonline.com/doi/full/10.1080/21548331.2015.1099412>
 169. Revankar N, Patterson J, Kadambi A, Raymond V, BSc WE-H. A Canadian Study of the Cost-Effectiveness of Apixaban Compared With Enoxaparin for Post-Surgical Venous Thromboembolism Prevention. *Postgrad Med* [Internet]. 2013 Jul;125(4):141–53. Available from: <http://www.tandfonline.com/doi/full/10.3810/pgm.2013.07.2686>
 170. Lassen MR, Gallus A, Raskob GE, Pineo G, Chen D, Ramirez LM. Apixaban versus Enoxaparin for Thromboprophylaxis after Hip Replacement. *N Engl J Med* [Internet]. 2010 Dec;363(26):2487–98. Available from: <http://www.nejm.org/doi/abs/10.1056/NEJMoa1006885>
 171. Lassen MR, Raskob GE, Gallus A, Pineo G, Chen D, Hornick P. Apixaban versus enoxaparin for thromboprophylaxis after knee replacement (ADVANCE-2): a randomised double-blind trial. *Lancet* [Internet]. 2010 Mar;375(9717):807–15. Available from: <https://linkinghub.elsevier.com/retrieve/pii/S0140673609621255>
 172. Lassen MR, Raskob GE, Gallus A, Pineo G, Chen D, Portman RJ. Apixaban or Enoxaparin for Thromboprophylaxis after Knee Replacement. *N Engl J Med*

- [Internet]. 2009 Aug;361(6):594–604. Available from:
<http://www.nejm.org/doi/abs/10.1056/NEJMoa0810773>
173. Whitty JA, McInnes E, Bucknall T, Webster J, Gillespie BM, Banks M, et al. The cost-effectiveness of a patient centred pressure ulcer prevention care bundle: Findings from the INTACT cluster randomised trial. *Int J Nurs Stud* [Internet]. 2017 Oct;75:35–42. Available from: <https://linkinghub.elsevier.com/retrieve/pii/S0020748917301396>
 174. Chaboyer W, Bucknall T, Webster J, McInnes E, Gillespie BM, Banks M, et al. The effect of a patient centred care bundle intervention on pressure ulcer incidence (INTACT): A cluster randomised trial. *Int J Nurs Stud* [Internet]. 2016 Dec;64:63–71. Available from: <https://linkinghub.elsevier.com/retrieve/pii/S0020748916301705>
 175. Mahan CE, Holdsworth MT, Welch SM, Borrego M, Spyropoulos AC. Deep-vein thrombosis: a United States cost model for a preventable and costly adverse event. *Thromb Haemost*. 2011 Sep;106(3):405–15.
 176. Scott 2nd RD, Solomon SL, McGowan Jr JE. Applying economic principles to health care. *Emerg Infect Dis* [Internet]. 2001;7(2):282–5. Available from: <https://pubmed.ncbi.nlm.nih.gov/11294724>
 177. Dijkman LM, Roos D, Gerhards MF, Tijssen JGP, Gouma DJ, Dijkgraaf MGW. Cost-Effectiveness of Perioperative Selective Decontamination of the Digestive Tract versus Placebo in Elective Gastrointestinal Surgery. *Dig Surg* [Internet]. 2012;29(5):384–90. Available from: <https://www.karger.com/Article/FullText/343095>
 178. Ferrando A, Pagano E, Scaglione L, Petrinco M, Gregori D, Ciccone G. A decision-tree model to estimate the impact on cost-effectiveness of a venous thromboembolism prophylaxis guideline. *Qual Saf Health Care* [Internet]. 2009 Aug;18(4):309–13. Available from: <http://www.ncbi.nlm.nih.gov/pubmed/19651937>
 179. Grünbauer A. Databases for systematic literature searches [Internet]. *clinfo.eu*. 2016 [cited 2021 Jul 28]. Available from: <https://www.clinfo.eu/databases-literature-searches/>
 180. Wieseler B, Kerekes MF, Vervoelgyi V, McGauran N, Kaiser T. Impact of document type on reporting quality of clinical drug trials: a comparison of registry reports, clinical study reports, and journal publications. *BMJ*. 2012 Jan;344:d8141.

181. Mhaskar R, Djulbegovic B, Magazin A, Soares HP, Kumar A. Published methodological quality of randomized controlled trials does not reflect the actual quality assessed in protocols. *J Clin Epidemiol* [Internet]. 2012/03/16. 2012 Jun;65(6):602–9. Available from: <https://pubmed.ncbi.nlm.nih.gov/22424985>
182. Soares HP, Daniels S, Kumar A, Clarke M, Scott C, Swann S, et al. Bad reporting does not mean bad methods for randomised trials: observational study of randomised controlled trials performed by the Radiation Therapy Oncology Group. *BMJ*. 2004 Jan;328(7430):22–4.
183. Mathews SC, McShea MJ, Hanley CL, Ravitz A, Labrique AB, Cohen AB. Digital health: a path to validation. *npj Digit Med* [Internet]. 2019;2(1):1–9. Available from: <http://dx.doi.org/10.1038/s41746-019-0111-3>
184. Kaplan RS, Anderson SR. Time-driven activity-based costing: A simpler and more powerful path to higher profits. Boston, MA: Harvard Business Review Press; 2007.
185. Kaplan RS, Porter ME. How to solve the cost crisis in health care. *Harv Bus Rev* [Internet]. 2011 Sep;89(9):46--52, 54, 56--61 passim. Available from: <http://www.ncbi.nlm.nih.gov/pubmed/21939127>
186. Holbrook A, Bowen JM, Patel H, O'Brien C, You JJ, Tahavori R, et al. Process mapping evaluation of medication reconciliation in academic teaching hospitals: a critical step in quality improvement. *BMJ Open* [Internet]. 2016;6(12):e013663. Available from: <http://www.ncbi.nlm.nih.gov/pubmed/28039294>
187. Eaton J. Political Economy: A Marxist Textbook. 1963. 29 p.
188. Mikalef P, Krogstie J, Pappas IO, Pavlou P. Exploring the relationship between big data analytics capability and competitive performance: The mediating roles of dynamic and operational capabilities. *Inf Manag* [Internet]. 2020;57(2):103169. Available from: <https://doi.org/10.1016/j.im.2019.05.004>
189. Benjamin J. B. Information as an Economic Good: A Réévaluation of Theoretical Approaches. *Mediat Information, Commun*. 2019;(January 1989):379–94.
190. Hall K. The economic nature of information. *Inf Soc*. 1981;1(2):143–66.
191. Arrow K. Economic Welfare and the Allocation of Resources for Invention. In: Rowley CK (eds) *Readings in Industrial Economics* [Internet]. Palgrave, London.;

1972. p. 609–26. Available from: https://doi.org/10.1007/978-1-349-15486-9_13
192. Torres N V, Santos G. The (mathematical) modeling process in biosciences. *Front Genet*. 2015;6(DEC):1–9.
 193. Nowak M, Pfaff H, Karbach U. Does Value Stream Mapping affect the structure, process, and outcome quality in care facilities? A systematic review. *Syst Rev* [Internet]. 2017 Aug 24;6(1):170. Available from: <https://pubmed.ncbi.nlm.nih.gov/28838320>
 194. George ML, Rowlands D, Price M, Maxey J. *The Lean Six Sigma Pocket Toolbook*. McGraw Hill; 2005. 33–54 p.
 195. Fillingham D. Can lean save lives? *Leadersh Health Serv (Bradf Engl)* [Internet]. 2007;20(4):231–41. Available from: <http://www.ncbi.nlm.nih.gov/pubmed/20698096>
 196. Antonacci G, Reed JE, Lennox L, Barlow J. The use of process mapping in healthcare quality improvement projects. *Heal Serv Manag Res* [Internet]. 2018;31(2):74–84. Available from: <http://www.ncbi.nlm.nih.gov/pubmed/29707978>
 197. Trebble TM, Hansi N, Hydes T, Smith MA, Baker M. Process mapping the patient journey: an introduction. *BMJ* [Internet]. 2010 Aug;341(aug13 1):c4078--c4078. Available from: <http://www.bmj.com/cgi/doi/10.1136/bmj.c4078>
 198. Roberts M, Russell LB, Paltiel AD, Chambers M, McEwan P, Krahm M, et al. Conceptualizing a model: a report of the ISPOR-SMDM Modeling Good Research Practices Task Force--2. *Value Health* [Internet]. 2012;15(6):804–11. Available from: <https://pubmed.ncbi.nlm.nih.gov/22999129>
 199. Eddy DM, Hollingworth W, Caro JJ, Tsevat J, McDonald KM, Wong JB, et al. Model transparency and validation: a report of the ISPOR-SMDM Modeling Good Research Practices Task Force-7. *Med Decis Making* [Internet]. 32(5):733–43. Available from: <http://www.ncbi.nlm.nih.gov/pubmed/22990088>
 200. Voit EO. Optimization in integrated biochemical systems. *Biotechnol Bioeng* [Internet]. 1992 Aug;40(5):572–82. Available from: <http://doi.wiley.com/10.1002/bit.260400504>
 201. Macrae C. The problem with incident reporting. *BMJ Qual Saf*. 2016;25(2):71–5.

202. Dovey SM, Wallis KA. Incident reporting in primary care: epidemiology or culture change? Vol. 20, BMJ quality & safety. England; 2011. p. 1001–3.
203. Holmström A-R, Laaksonen R, Airaksinen M. How to make medication error reporting systems work – Factors associated with their successful development and implementation. Health Policy (New York) [Internet]. 2015;119(8):1046–54. Available from: <http://www.sciencedirect.com/science/article/pii/S016885101500069X>
204. Porter M, Lee T. The strategy that will fix health care. Harv Bus Rev. 2013;
205. Richmond B. The “thinking” in systems thinking: Seven essential skills. 2010.
206. Howell A-M, Burns EM, Hull L, Mayer E, Sevdalis N, Darzi A. International recommendations for national patient safety incident reporting systems: an expert Delphi consensus-building process. BMJ Qual Saf [Internet]. 2017;26(2):150–63. Available from: <https://qualitysafety.bmj.com/content/26/2/150>
207. Dixon-Woods M, McNicol S, Martin G. Ten challenges in improving quality in healthcare: lessons from the Health Foundation’s programme evaluations and relevant literature. BMJ Qual & Saf [Internet]. 2012 Oct 1;21(10):876 LP – 884. Available from: <http://qualitysafety.bmj.com/content/21/10/876.abstract>
208. de Silva D. Evidence scan: What’s getting in the way? Barriers to improvement in the NHS. London, UK; 2015.
209. Pitt M, Monks T, Crowe S, Vasilakis C. Systems modelling and simulation in health service design, delivery and decision making. BMJ Qual & Saf [Internet]. 2016 Jan 1;25(1):38 LP – 45. Available from: <http://qualitysafety.bmj.com/content/25/1/38.abstract>
210. Rus I, Neu H, Münch J. A Systematic Methodology for Developing Discrete Event Simulation Models of Software Development Processes. 2014;(ProSim). Available from: <http://arxiv.org/abs/1403.3559>
211. Caro JJ. Psst, have i got a model for you... Med Decis Mak. 2015;35(2):139–41.
212. Sorra JS, Dyer N. Multilevel psychometric properties of the AHRQ hospital survey on patient safety culture. BMC Health Serv Res [Internet]. 2010;10(1):199. Available from: <https://doi.org/10.1186/1472-6963-10-199>

213. Kaplan B, Maxwell JA. Qualitative Research Methods for Evaluating Computer Information Systems. In: Anderson JG, Aydin CE (eds) *Evaluating the Organizational Impact of Healthcare Information Systems Health Informatics* [Internet]. New York; 2005. p. 30–55. Available from: https://doi.org/10.1007/0-387-30329-4_2
214. Pope C, Ziebland S, Mays N. Qualitative research in health care. Analysing qualitative data. *BMJ* [Internet]. 2000 Jan;320(7227):114–6. Available from: <http://www.ncbi.nlm.nih.gov/pubmed/10625273>
215. Accounts Commission. The map to success - using process mapping to improve performance. *Audit Scotl* [Internet]. 2000;(May):1–28. Available from: <http://www.audit-scotland.gov.uk/>
216. NHS. Process mapping, analysis and redesign. [Internet]. London: Department of Health; 2005. Available from: http://www.institute.nhs.uk/building_capability/building_improvement_capability/references.html#sthash.PAay2YJM.dpuf
217. Bouamrane MM, McGee-Lennon M, Brewster S, Mair F. Using process-mapping to design integrated health information management systems. In: *Proceedings - IEEE Symposium on Computer-Based Medical Systems*. 2011.
218. Bouamrane MM, Mair FS. A study of clinical and information management processes in the surgical pre-assessment clinic. *BMC Med Inform Decis Mak*. 2014;14(1).
219. Strauss A, Corbin JM. *Basics of qualitative research: Grounded theory procedures and techniques*. Sage Publications; 1990.
220. Maithel S, Sierra R, Korndorffer J, Neumann P, Dawson S, Callery M, et al. Construct and face validity of MIST-VR, Endotower, and CELTS. *Surg Endosc Other Interv Tech* [Internet]. 2006;20(1):104–12. Available from: <https://doi.org/10.1007/s00464-005-0054-4>
221. Dulan G, Rege R V, Hogg DC, Gilberg-Fisher KK, Tesfay ST, Scott DJ. Content and face validity of a comprehensive robotic skills training program for general surgery, urology, and gynecology. *Am J Surg* [Internet]. 2012;203(4):535–9. Available from: <http://www.sciencedirect.com/science/article/pii/S0002961012000086>
222. Baka A, Figgou L, Triga V. “Neither agree, nor disagree”: A critical analysis of the

- middle answer category in Voting Advice Applications. *Int J Electron Gov.* 2012;5(3–4):244–63.
223. Lozano LM, García-Cueto E, Muñiz J. Effect of the Number of Response Categories on the Reliability and Validity of Rating Scales. *Methodology* [Internet]. 2008 Jan;4(2):73–9. Available from: <https://econtent.hogrefe.com/doi/10.1027/1614-2241.4.2.73>
 224. Norman G. Likert scales, levels of measurement and the “laws” of statistics. *Adv Heal Sci Educ.* 2010;15(5):625–32.
 225. Gwet KL. Testing the difference of correlated agreement coefficients for statistical significance. *Educ Psychol Meas.* 2016;76(4):609–37.
 226. Klein D. Implementing a general framework for assessing interrater agreement in Stata. *Stata J* [Internet]. 2018;18(4):871–901. Available from: <http://www.stata-journal.com/article.html?article=st0544>
 227. Hu LT, Bentler PM. Cutoff criteria for fit indexes in covariance structure analysis: Conventional criteria versus new alternatives. *Struct Equ Model.* 1999;6(1):1–55.
 228. Caro JJ, Briggs AH, Siebert U, Kuntz KM. Modeling Good Research Practices; Overview: A Report of the ISPOR-SMDM Modeling Good Research Practices Task Force-1. *Value Heal* [Internet]. 2012 Sep 1;15(6):796–803. Available from: <https://doi.org/10.1016/j.jval.2012.06.012>
 229. Siebert U, Alagoz O, Bayoumi AM, Jahn B, Owens DK, Cohen DJ, et al. State-Transition Modeling: A Report of the ISPOR-SMDM Modeling Good Research Practices Task Force-3. *Value Heal* [Internet]. 2012 Sep 1;15(6):812–20. Available from: <https://doi.org/10.1016/j.jval.2012.06.014>
 230. Karnon J, Stahl J, Brennan A, Caro JJ, Mar J, Möller J. Modeling using Discrete Event Simulation: A Report of the ISPOR-SMDM Modeling Good Research Practices Task Force-4. *Value Heal* [Internet]. 2012 Sep 1;15(6):821–7. Available from: <https://doi.org/10.1016/j.jval.2012.04.013>
 231. Pitman R, Fisman D, Zaric GS, Postma M, Kretzschmar M, Edmunds J, et al. Dynamic transmission modeling: a report of the ISPOR-SMDM Modeling Good Research Practices Task Force--5. *Value Heal J Int Soc Pharmacoeconomics Outcomes Res.*

- 2012;15(6):828–34.
232. Briggs AH, Weinstein MC, Fenwick EAL, Karnon J, Sculpher MJ, Paltiel AD. Model parameter estimation and uncertainty analysis: a report of the ISPOR-SMDM Modeling Good Research Practices Task Force Working Group-6. *Med Decis Mak.* 2012;32(5):722–32.
 233. Vemer P, Krabbe PFM, Feenstra TL, Van Voorn GAK, Ramos C, Al MJ. Improving Model Validation in Health Technology Assessment: Comments on Guidelines of the ISPOR-SMDM Modeling Good Research Practices Task Force. *Value Heal [Internet]*. 2013 Sep 1;16(6):1106–7. Available from: <https://doi.org/10.1016/j.jval.2013.06.015>
 234. Roza M, Voogd J, Sebalj D. The Generic Methodology for Verification and Validation to support acceptance of models, simulations and data. *J Def Model Simul.* 2013;10(4):347–65.
 235. Peters BA, Smith JS, Medeiros DJ, Rohrer MW. ACCOUNTING FOR PARAMETER UNCERTAINTY IN SIMULATION INPUT MODELING. In: *Proceedings of the 2001 Winter Simulation Conference*. Citeseer; 2001. p. 354.
 236. Smith PC, Yip W. The economics of health system design. *Oxford Rev Econ Policy [Internet]*. 2016 Feb;32(1):21–40. Available from: <https://academic.oup.com/oxrep/article-lookup/doi/10.1093/oxrep/grv018>
 237. Morgan JS, Howick S, Belton V. A toolkit of designs for mixing Discrete Event Simulation and System Dynamics. *Eur J Oper Res [Internet]*. 2017;257(3):907–18. Available from: <http://dx.doi.org/10.1016/j.ejor.2016.08.016>
 238. Raffo D, Vandeville J. Combining Process Feedback with Discrete Event Simulation Models to Support Software Project Management. In: Madhavji NH, Fernández-Ramil JC, Perry DE; *Software Evolution and Feedback [Internet]*. Chichester, UK: John Wiley & Sons, Ltd; 2006. p. 427–41. Available from: <http://doi.wiley.com/10.1002/0470871822.ch21>
 239. Hilbert M, López P. The World ' s Technological Capacity. *Science* (80-). 2011;332(April):60–5.
 240. Cottle M, Hoover W. Transforming Health Care Through Big Data. 2013;1–24.
 241. IHTT. Transforming Health Care through Big Data Strategies for leveraging big data

- in the health care industry. [Internet]. 2013. Available from:
<https://iht2bigdata2013.questionpro.com>
242. WHO. Toolkit on monitoring health systems strengthening [Internet]. Health Information Systems. 2008. Available from:
https://www.who.int/healthinfo/statistics/toolkit_hss/EN_PDF_Toolkit_HSS_InformationSystems.pdf
 243. Royston G. Meeting global health challenges through operational research and management science. *Bull World Health Organ* [Internet]. 2011;89(9):683–8. Available from: <http://www.who.int/bulletin/volumes/89/9/11-086066.pdf>
 244. Gruen RL, Elliott JH, Nolan ML, Lawton PD, Parkhill A, McLaren CJ, et al. Sustainability science: an integrated approach for health-programme planning. *Lancet* (London, England) [Internet]. 2008 Nov;372(9649):1579–89. Available from: <http://www.ncbi.nlm.nih.gov/pubmed/18984192>
 245. Syme S, Balfour J. Social determinants of disease. 14th ed. Public Health and Preventive Medicine. Stamford, Conn: Appleton & Lange; 1998. 795 p.
 246. Stokols D, Pelletier KR, Fielding JE. The ecology of work and health: research and policy directions for the promotion of employee health. *Health Educ Q* [Internet]. 1996 May;23(2):137–58. Available from: <http://www.ncbi.nlm.nih.gov/pubmed/8744869>
 247. Kannampallil TG, Schauer GF, Cohen T, Patel VL. Considering complexity in healthcare systems. *J Biomed Inform* [Internet]. 2011;44(6):943–7. Available from: <http://dx.doi.org/10.1016/j.jbi.2011.06.006>
 248. Greenhalgh T, Papoutsis C. Studying complexity in health services research: desperately seeking an overdue paradigm shift. *BMC Med* [Internet]. 2018;16(1):95. Available from: <http://www.ncbi.nlm.nih.gov/pubmed/29921272>
 249. Mogyrosy Z, Smith PC. The main methodological issues in costing health care services - a literature review. 2005. Report No.: 007cherp.
 250. Benning A, Ghaleb M, Suokas A, Dixon-Woods M, Dawson J, Barber N, et al. Large scale organisational intervention to improve patient safety in four UK hospitals: mixed method evaluation. *BMJ* [Internet]. 2011 Feb 3;342:d195. Available from: <http://www.bmj.com/content/342/bmj.d195.abstract>

251. Office for National Statistics. UK labour market : July 2018. Stat Bull. 2018;(July):61.
252. Curtis L, Burns A. Unit Costs of Health and Social Care [Internet]. Personal Social Services Research Unit, University of Kent, Canterbury.; 2018. Available from: 10.22024/UniKent/01.02.79286
253. NHS Digital. NHS Digital, Workforce [Internet]. Workforce statistics. [cited 2020 Jun 6]. Available from: <https://digital.nhs.uk/data-and-information/areas-of-interest/workforce>
254. Romeyke T, Stummer H. Clinical pathways as instruments for risk and cost management in hospitals - a discussion paper. Glob J Health Sci [Internet]. 2012 Feb 29;4(2):50–9. Available from: <https://pubmed.ncbi.nlm.nih.gov/22980151>
255. Nixon RM, Wonderling D, Grieve RD. Non-parametric methods for cost-effectiveness analysis: the central limit theorem and the bootstrap compared. Health Econ [Internet]. 2010 Mar;19(3):316–33. Available from: <http://www.ncbi.nlm.nih.gov/pubmed/19378353>
256. Thompson SG, Barber JA. How should cost data in pragmatic randomised trials be analysed? BMJ [Internet]. 2000 Apr;320(7243):1197–200. Available from: <http://www.ncbi.nlm.nih.gov/pubmed/10784550>
257. Krejcie R V, Morgan DW. Determining sample size for research activities. Educ Psychol Meas. 1970;30(3):607–10.
258. Isaac S, Michael WB. Handbook in research and evaluation: A collection of principles, methods, and strategies useful in the planning, design, and evaluation of studies in education and the behavioral sciences. EdITS publishers; 1995.
259. Roscoe JT. Fundamental research statistics for the behavioral sciences. 2nd ed. New York, USA: Holt, Rinehart and Winston; 1975.
260. Dhar S, Tansek R, Toftey EA, Dziekan BA, Chevalier TC, Bohlinger CG, et al. Observer bias in hand hygiene compliance reporting. Infect Control Hosp Epidemiol. 2010;31(8):869–70.
261. Berwick DM, Nolan TW, Whittington J. The triple aim: care, health, and cost. Health Aff. 2008;27(3):759–69.

262. Whittington JW, Nolan K, Lewis N, Torres T. Pursuing the Triple Aim: The First 7 Years. *Milbank Q* [Internet]. 2015 Jun;93(2):263–300. Available from: <https://pubmed.ncbi.nlm.nih.gov/26044630>
263. Shaw R, Drever F, Hughes H, Osborn S, Williams S. Adverse events and near miss reporting in the NHS. *Qual Saf Heal Care*. 2005;14(4):279–83.
264. Flott K, Nelson D, Moorcroft T, Mayer EK, Gage W, Redhead J, et al. Enhancing safety culture through improved incident reporting: a case study in translational research. *Health Aff*. 2018;37(11):1797–804.
265. Lawton R, Parker D. Barriers to incident reporting in a healthcare system. *BMJ Qual Saf*. 2002;11(1):15–8.
266. Hotton E, Jordan L, Peden C. Improving incident reporting among junior doctors. *BMJ Open Qual*. 2014;3(1):u202381-w2481.
267. Evans SM, Smith BJ, Esterman A, Runciman WB, Maddern G, Stead K, et al. Evaluation of an intervention aimed at improving voluntary incident reporting in hospitals. *BMJ Qual Saf*. 2007;16(3):169–75.
268. Shojania KG. The frustrating case of incident-reporting systems. *BMJ Qual Saf*. 2008;17(6):400–2.
269. Ramírez E, Martín A, Villán Y, Lorente M, Ojeda J, Moro M, et al. Effectiveness and limitations of an incident-reporting system analyzed by local clinical safety leaders in a tertiary hospital: Prospective evaluation through real-time observations of patient safety incidents. *Medicine (Baltimore)* [Internet]. 2018 Sep;97(38):e12509–e12509. Available from: <https://pubmed.ncbi.nlm.nih.gov/30235764>
270. Lankshear A, Lowson K, Harden J, Lowson P, Saxby RC. Making patients safer: nurses' responses to patient safety alerts. *J Adv Nurs*. 2008 Sep;63(6):567–75.
271. Lankshear AJ, Sheldon TA, Lowson K V, Watt IS, Wright J. Evaluation of the implementation of the alert issued by the UK National Patient Safety Agency on the storage and handling of potassium chloride concentrate solution. *Qual Saf Heal Care*. 2005;14(3):196–201.
272. Grimm P. Social Desirability Bias. In: *Wiley International Encyclopedia of Marketing* [Internet]. Chichester, UK: John Wiley & Sons, Ltd; 2010. Available from:

<http://doi.wiley.com/10.1002/9781444316568.wiem02057>

273. Birks Y, Aspinall F, Bloor K. Understanding the drivers of litigation in health services [Internet]. 2018. Available from:
<https://www.york.ac.uk/media/healthsciences/images/research/prepare/UnderstandingDriversOfLitigationInHealthServices.pdf>
274. Roser M, Ritchie H. Technological Progress [Internet]. Published online at OurWorldInData.org. 2013 [cited 2020 Aug 20]. Available from:
<https://ourworldindata.org/technological-progress>
275. Ginsberg JS. Management of Venous Thromboembolism. Wood AJJ, editor. *N Engl J Med* [Internet]. 1996 Dec;335(24):1816–29. Available from:
<http://www.nejm.org/doi/10.1056/NEJM199612123352407>
276. Beckman MG, Hooper WC, Critchley SE, Ortel TL. Venous Thromboembolism. *Am J Prev Med* [Internet]. 2010 Apr;38(4):S495--S501. Available from:
<https://linkinghub.elsevier.com/retrieve/pii/S0749379709009465>
277. Grosse SD, Nelson RE, Nyarko KA, Richardson LC, Raskob GE. The economic burden of incident venous thromboembolism in the United States: A review of estimated attributable healthcare costs. *Thromb Res* [Internet]. 2016 Jan;137(3):3–10. Available from: <https://linkinghub.elsevier.com/retrieve/pii/S0049384815302097>
278. Sterne JA, Botalia PN, Bryden PA, Davies PA, López-López JA, Okoli GN, et al. Oral anticoagulants for primary prevention, treatment and secondary prevention of venous thromboembolic disease, and for prevention of stroke in atrial fibrillation: systematic review, network meta-analysis and cost-effectiveness analysis. *Health Technol Assess*. 2017;21(9):1–386.
279. Zeymer U, Rao S V, Montalescot G. Anticoagulation in coronary intervention. *Eur Heart J* [Internet]. 2016 Dec;37(45):3376–85. Available from:
<http://www.ncbi.nlm.nih.gov/pubmed/26946415>
280. Capodanno D. Risk Stratification for Percutaneous Coronary Intervention. *Interv Cardiol Clin* [Internet]. 2016;5(2):249–57. Available from:
<http://www.ncbi.nlm.nih.gov/pubmed/28582208>
281. Dauerman HL. Anticoagulation Strategies for Primary Percutaneous Coronary

Intervention: Current Controversies and Recommendations. *Circ Cardiovasc Interv.* 2015;8(5):1–12.

282. Mahan CE, Hussein MA, Amin AN, Spyropoulos AC. Venous thromboembolism pharmacy intervention management program with an active, multifaceted approach reduces preventable venous thromboembolism and increases appropriate prophylaxis. *Clin Appl Thromb Hemost* [Internet]. 18(1):45–58. Available from: <http://www.ncbi.nlm.nih.gov/pubmed/21949041>
283. Pirmohamed M, James S, Meakin S, Green C. Adverse drug reactions as cause of admission to hospital: Authors' reply. *Bmj.* 2004;329(7463):460.
284. Dreijer AR, Kruip MJHA, Diepstraten J, Polinder S, Brouwer R, Mol PGM, et al. Effect of antithrombotic stewardship on the efficacy and safety of antithrombotic therapy during and after hospitalization. *PLoS One.* 2020;15(6):e0235048.
285. Dreijer AR, Diepstraten J, Brouwer R, Croles FN, Kragten E, Leebeek FWG, et al. Risk of bleeding in hospitalized patients on anticoagulant therapy: Prevalence and potential risk factors. *Eur J Intern Med.* 2019 Apr;62:17–23.
286. Campbell HE, Stokes EA, Bargo D, Logan RF, Mora A, Hodge R, et al. Costs and quality of life associated with acute upper gastrointestinal bleeding in the UK: cohort analysis of patients in a cluster randomised trial. *BMJ Open* [Internet]. 2015 Apr 1;5(4):e007230. Available from: <http://bmjopen.bmj.com/content/5/4/e007230.abstract>
287. Xu X-M, Vestesson E, Paley L, Desikan A, Wonderling D, Hoffman A, et al. The economic burden of stroke care in England, Wales and Northern Ireland: Using a national stroke register to estimate and report patient-level health economic outcomes in stroke. *Eur Stroke J* [Internet]. 2017 Nov 30;3(1):82–91. Available from: <https://doi.org/10.1177/2396987317746516>
288. Patel A, Berdunov V, Quayyum Z, King D, Knapp M, Wittenberg R. Estimated societal costs of stroke in the UK based on a discrete event simulation. *Age Ageing* [Internet]. 2020 Feb 27;49(2):270–6. Available from: <https://doi.org/10.1093/ageing/afz162>
289. Ewen EF, Zhao L, Kolm P, Jurkovitz C, Fidan D, White HD, et al. Determining the in-hospital cost of bleeding in patients undergoing percutaneous coronary intervention. *J*

- Interv Cardiol. 2009 Jun;22(3):266–73.
290. Perrier S, Kindo M, Gerelli S, Mazzucotelli J-P. Coronary artery bypass grafting or percutaneous revascularization in acute myocardial infarction?: Table 1: Interact Cardiovasc Thorac Surg [Internet]. 2013 Dec;17(6):1015–9. Available from: <https://academic.oup.com/icvts/article-lookup/doi/10.1093/icvts/ivt381>
 291. NHS. The NHS long term plan [Internet]. 2019. Available from: <http://www.longtermplan.nhs.uk>
 292. Bangalore S, Toklu B, Kotwal A, Volodarskiy A, Sharma S, Kirtane AJ, et al. Anticoagulant therapy during primary percutaneous coronary intervention for acute myocardial infarction: a meta-analysis of randomized trials in the era of stents and P2Y12 inhibitors. BMJ [Internet]. 2014 Nov;349(nov11 4):g6419--g6419. Available from: <http://www.bmj.com/cgi/doi/10.1136/bmj.g6419>
 293. Campelo-Parada F, Carrié D, Bartorelli AL, Namiki A, Hovasse T, Kimura T, et al. Radial Versus Femoral Approach for Percutaneous Coronary Intervention: MACE Outcomes at Long-Term Follow-up. J Invasive Cardiol [Internet]. 2018;30(7):262–8. Available from: <http://www.ncbi.nlm.nih.gov/pubmed/29958176>
 294. Budaj A, Eikelboom JW, Mehta SR, Afzal R, Chrolavicius S, Bassand J-P, et al. Improving clinical outcomes by reducing bleeding in patients with non-ST-elevation acute coronary syndromes. Eur Heart J. 2009;30(6):655–61.
 295. Stone GW, Witzenbichler B, Guagliumi G, Peruga JZ, Brodie BR, Dudek D, et al. Bivalirudin during primary PCI in acute myocardial infarction. N Engl J Med. 2008;358(21):2218–30.
 296. Yusuf S, Mehta SR, Chrolavicius S, Afzal R, Pogue J, Granger CB. Fifth Organization to Assess Strategies in Acute Ischemic Syndromes Investigators. Comparison of fondaparinux and enoxaparin in acute coronary syndromes. N Engl J Med. 2006;354(14):1464–76.
 297. Rao S V, Kaul PR, Liao L, Armstrong PW, Ohman EM, Granger CB, et al. Association between bleeding, blood transfusion, and costs among patients with non-ST-segment elevation acute coronary syndromes. Am Heart J. 2008;155(2):369–74.
 298. Steg PG, Huber K, Andreotti F, Arnesen H, Atar D, Badimon L, et al. Bleeding in

- acute coronary syndromes and percutaneous coronary interventions: position paper by the Working Group on Thrombosis of the European Society of Cardiology. *Eur Heart J*. 2011;32(15):1854–64.
299. Joseph P, Leong D, McKee M, Anand SS, Schwalm J-D, Teo K, et al. Reducing the Global Burden of Cardiovascular Disease, Part 1: The Epidemiology and Risk Factors. *Circ Res*. 2017 Sep;121(6):677–94.
 300. Steel N, Ford JA, Newton JN, Davis ACJ, Vos T, Naghavi M, et al. Changes in health in the countries of the UK and 150 English Local Authority areas 1990–2016: a systematic analysis for the Global Burden of Disease Study 2016. *Lancet* [Internet]. 2018 Nov;392(10158):1647–61. Available from: <https://linkinghub.elsevier.com/retrieve/pii/S0140673618322074>
 301. Newton JN, Briggs ADM, Murray CJL, Dicker D, Foreman KJ, Wang H, et al. Changes in health in England, with analysis by English regions and areas of deprivation, 1990–2013: a systematic analysis for the Global Burden of Disease Study 2013. *Lancet*. 2015;386(10010):2257–74.
 302. Timmis A. Acute coronary syndromes. *Bmj*. 2015;351:h5153.
 303. Ndrepepa G, Kastrati A. Bleeding complications in patients undergoing percutaneous coronary interventions: current status and perspective. *Coron Artery Dis*. 2014 May;25(3):247–57.
 304. Patel NJ, Pau D, Nalluri N, Bhatt P, Thakkar B, Kanotra R, et al. Temporal Trends, Predictors, and Outcomes of In-Hospital Gastrointestinal Bleeding Associated With Percutaneous Coronary Intervention. *Am J Cardiol*. 2016 Oct;118(8):1150–7.
 305. Hariri E, Hansra B, Barringhaus KG, Mohamud D, Smith CS, Akhter MW, et al. Trends, Predictors, and Outcomes Associated With 30-Day Hospital Readmissions After Percutaneous Coronary Intervention in a High-Volume Center Predominantly Using Radial Vascular Access. *Cardiovasc Revascularization Med* [Internet]. 2020;21(12):1525–31. Available from: <https://www.sciencedirect.com/science/article/pii/S155383892030289X>
 306. Green L, Tan J, Morris JK, Alikhan R, Curry N, Everington T, et al. A three-year prospective study of the presentation and clinical outcomes of major bleeding

- episodes associated with oral anticoagulant use in the UK (ORANGE study). *Haematologica*. 2018 Apr;103(4):738–45.
307. Kwok CS, Rao S V, Myint PK, Keavney B, Nolan J, Ludman PF, et al. Major bleeding after percutaneous coronary intervention and risk of subsequent mortality: a systematic review and meta-analysis. *Open Hear* [Internet]. 2014;1(1):e000021. Available from: <http://www.ncbi.nlm.nih.gov/pubmed/25332786>
 308. Lawler PR, Filion KB, Dourian T, Atallah R, Garfinkle M, Eisenberg MJ. Anemia and mortality in acute coronary syndromes: a systematic review and meta-analysis. *Am Heart J*. 2013;165(2):143–53.
 309. Urban P, Mehran R, Collieran R, Angiolillo DJ, Byrne RA, Capodanno D, et al. Defining High Bleeding Risk in Patients Undergoing Percutaneous Coronary Intervention. *Circulation* [Internet]. 2019 Jul 16;140(3):240–61. Available from: <https://doi.org/10.1161/CIRCULATIONAHA.119.040167>
 310. V. RS, David D, Sumeet S, S. WW, S. BR, C. MJ, et al. Association Between Periprocedural Bleeding and Long-Term Outcomes Following Percutaneous Coronary Intervention in Older Patients. *JACC Cardiovasc Interv* [Internet]. 2012 Sep 1;5(9):958–65. Available from: <https://doi.org/10.1016/j.jcin.2012.05.010>
 311. Vora AN, Peterson ED, McCoy LA, Garratt KN, Kutcher MA, Marso SP, et al. The Impact of Bleeding Avoidance Strategies on Hospital-Level Variation in Bleeding Rates Following Percutaneous Coronary Intervention: Insights From the National Cardiovascular Data Registry CathPCI Registry. *JACC Cardiovasc Interv* [Internet]. 2016;9(8):771–9. Available from: <https://www.sciencedirect.com/science/article/pii/S193687981600162X>
 312. de Vries EN, Ramrattan MA, Smorenburg SM, Gouma DJ, Boermeester MA. The incidence and nature of in-hospital adverse events: a systematic review. *Qual Saf Health Care*. 2008 Jun;17(3):216–23.
 313. Colwell CW, Froimson MI, Mont MA, Ritter MA, Trousdale RT, Buehler KC, et al. Thrombosis Prevention After Total Hip Arthroplasty. *J Bone Jt Surgery-American* Vol. 2010;92(3):527–35.
 314. Tonnessen BH, Money SR. Low-Molecular-Weight Heparin Versus Coumarin for the

- Prevention of Recurrent Venous Thromboembolism in Patients With Cancer. *Perspect Vasc Surg Endovasc Ther*. 2004;16(2):144–6.
315. Sorenson C, Drummond, Bhuiyan-Khan. Medical technology as a key driver of rising health expenditure: disentangling the relationship. *Clin Outcomes Res* [Internet]. 2013 May;223. Available from: <http://www.dovepress.com/medical-technology-as-a-key-driver-of-rising-health-expenditure-disent-peer-reviewed-article-CEOR>
 316. Morris ZS, Wooding S, Grant J. The answer is 17 years, what is the question: understanding time lags in translational research. *J R Soc Med* [Internet]. 2011 Dec;104(12):510–20. Available from: <http://journals.sagepub.com/doi/10.1258/jrsm.2011.110180>
 317. Higgins KL. Chapter 1 - Lines or Circles: The Basics of Systems Thinking. In: KL Higgins; *Financial Whirlpools* [Internet]. San Diego, USA: Elsevier; 2013. p. 3–26. Available from: <https://linkinghub.elsevier.com/retrieve/pii/B9780124059054000014>
 318. Crea F, Libby P. Acute coronary syndromes: the way forward from mechanisms to precision treatment. *Circulation*. 2017;136(12):1155–66.
 319. Higgins JPT, S G. *Cochrane Handbook for Systematic Reviews of Interventions* Version 5.1.0 [Internet]. The Cochrane Collaboration. 2011. Available from: www.handbook.cochrane.org
 320. Keltie K, Cole H, Arber M, Patrick H, Powell J, Campbell B, et al. Identifying complications of interventional procedures from UK routine healthcare databases: a systematic search for methods using clinical codes. *BMC Med Res Methodol*. 2014 Jan;14:126.
 321. Bärnighausen T. Quasi-experiments in public health and health systems research. *Eur J Public Health* [Internet]. 2017 Nov;27(suppl_3). Available from: <https://academic.oup.com/eurpub/article/doi/10.1093/eurpub/ckx187.817/4556778>
 322. Kontopantelis E, Doran T, Springate DA, Buchan I, Reeves D. Regression based quasi-experimental approach when randomisation is not an option: interrupted time series analysis. *BMJ* [Internet]. 2015 Jun;350:h2750. Available from: <http://www.ncbi.nlm.nih.gov/pubmed/26058820>
 323. Lopez Bernal J, Cummins S, Gasparrini A. The use of controls in interrupted time

- series studies of public health interventions. *Int J Epidemiol* [Internet]. 2018 Dec 1;47(6):2082–93. Available from: <https://doi.org/10.1093/ije/dyy135>
324. O'Donnell A, Anderson P, Jané-Llopis E, Manthey J, Kaner E, Rehm J. Immediate impact of minimum unit pricing on alcohol purchases in Scotland: controlled interrupted time series analysis for 2015-18. *BMJ* [Internet]. 2019 Sep 25;366:15274. Available from: <http://www.bmj.com/content/366/bmj.15274.abstract>
 325. Metcalfe D, Zogg CK, Judge A, Perry DC, Gabbe B, Willett K, et al. Pay for performance and hip fracture outcomes. *Bone Joint J* [Internet]. 2019 Jul 31;101-B(8):1015–23. Available from: <https://doi.org/10.1302/0301-620X.101B8.BJJ-2019-0173.R1>
 326. Lopez Bernal JA, Lu CY, Gasparrini A, Cummins S, Wharham JF, Soumerai SB. Association between the 2012 Health and Social Care Act and specialist visits and hospitalisations in England: A controlled interrupted time series analysis. *PLOS Med* [Internet]. 2017 Nov 14;14(11):e1002427. Available from: <https://doi.org/10.1371/journal.pmed.1002427>
 327. The WHO. International Statistical Classification of Diseases and Related Health Problems [Internet]. 2010. Available from: https://www.who.int/classifications/icd/ICD10Volume2_en_2010.pdf?ua=1
 328. NHS. Reference costs 2017-18 [Internet]. 2020. Available from: <https://improvement.nhs.uk/resources/reference-costs/>
 329. Fisher ES, Whaley FS, Krushat WM, Malenka DJ, Fleming C, Baron J a., et al. The accuracy of Medicare's hospital claims data: Progress has been made, but problems remain. *Am J Public Health*. 1992;82:243–8.
 330. Burns EM, Rigby E, Mamidanna R, Bottle A, Aylin P, Ziprin P, et al. Systematic review of discharge coding accuracy. *J Public Health (Bangkok)*. 2011 Jul;
 331. Quan H, Moskal L, Forster AJ, Brien S, Walker R, Romano PS, et al. International variation in the definition of “main condition” in ICD-coded health data. *Int J Qual Health Care*. 2014 Oct;26(5):511–5.
 332. Hohl CM, Karpov A, Reddekopp L, Stausberg J. ICD-10 codes used to identify adverse drug events in administrative data: a systematic review. *J Am Med Inform*

- Assoc. 2014;21:547–57.
333. Hohl CM, Kuramoto L, Yu E, Rogula B, Stausberg J, Sobolev B. Evaluating adverse drug event reporting in administrative data from emergency departments: a validation study. *BMC Health Serv Res.* 2013;13:473.
 334. Wu C, Bell CM, Wodchis WP. Incidence and economic burden of adverse drug reactions among elderly patients in Ontario emergency departments: a retrospective study. *Drug Saf [Internet].* 2012 Sep 1;35(9):769–81. Available from: <https://pubmed.ncbi.nlm.nih.gov/22823502>
 335. Clark J, Smith R. Dr Foster case notes. *BMJ Br Med J.* 2004;328:362.
 336. Cathcart P, Nuttall M, Van Der Meulen J, Emberton M, Van Der Meulen SE, Emberton SE, et al. Trends in paediatric circumcision and its complications in England between 1997 and 2003. *Br J Surg.* 2006;93(7):885–90.
 337. Onwere C, Gurol-Urganci I, Cromwell D a., Mahmood T a., Templeton A, Van Der Meulen JH. Maternal morbidity associated with placenta praevia among women who had elective caesarean section. *Eur J Obstet Gynecol Reprod Biol.* 2011;159:62–6.
 338. Lankshear A, Harden J, Lowson K. A baseline study of anticoagulant management in UK hospitals. *Qual Saf Health Care [Internet].* 2010 Aug;19(4):295–7. Available from: <http://www.ncbi.nlm.nih.gov/pubmed/20679136>
 339. Lauer MS, D’Agostino Sr RB. The randomized registry trial--the next disruptive technology in clinical research? *N Engl J Med.* 2013;369(17):1579.
 340. Antman EM, Harrington RA. Transforming clinical trials in cardiovascular disease: mission critical for health and economic well-being. *Jama.* 2012;308(17):1743–4.
 341. Frøbert O, Calais F, James SK, Lagerqvist B. ST-elevation myocardial infarction, thrombus aspiration, and different invasive strategies. A TASTE trial substudy. *J Am Hear Assoc Cardiovasc Cerebrovasc Dis.* 2015;4(6).
 342. Frøbert O, Lagerqvist B, Olivecrona GK, Omerovic E, Gudnason T, Maeng M, et al. Thrombus aspiration during ST-segment elevation myocardial infarction. *N Engl J Med.* 2013;369:1587–97.
 343. Olivecrona GK, Lagerqvist B, Frøbert O, Gudnason T, Maeng M, Råmunddal T, et al.

- Impact of thrombus aspiration during ST-Elevation Myocardial Infarction: a six month composite endpoint and risk of stroke analyses of the TASTE trial. *BMC Cardiovasc Disord.* 2016;16(1):62.
344. Wachtell K, Lagerqvist B, Olivecrona GK, James SK, Fröbert O. Novel Trial Designs: Lessons Learned from Thrombus Aspiration During ST-Segment Elevation Myocardial Infarction in Scandinavia (TASTE) Trial. *Curr Cardiol Rep* [Internet]. 2016;18(1):11. Available from: <https://doi.org/10.1007/s11886-015-0677-6>
 345. Herrett E, Smeeth L, Walker L, Weston C. The Myocardial Ischaemia National Audit Project (MINAP). *Heart* [Internet]. 2010 Aug 1;96(16):1264 LP – 1267. Available from: <http://heart.bmj.com/content/96/16/1264.abstract>
 346. Zaman MJ, Stirling S, Shepstone L, Ryding A, Flather M, Bachmann M, et al. The association between older age and receipt of care and outcomes in patients with acute coronary syndromes: a cohort study of the Myocardial Ischaemia National Audit Project (MINAP). *Eur Heart J* [Internet]. 2014 Jun 14;35(23):1551–8. Available from: <https://doi.org/10.1093/eurheartj/ehu039>
 347. Medicines & Healthcare products Regulatory Agency. Central Alerting System (CAS) [Internet]. 2014 [cited 2020 Aug 23]. Available from: <https://www.cas.mhra.gov.uk/Home.aspx>
 348. NRLS reporting categories. No Title. 2014;
 349. NHS. Never events list 2018 [Internet]. 2018. Available from: https://improvement.nhs.uk/documents/2266/Never_Events_list_2018_FINAL_v5.pdf
 350. Craig P, Dieppe P, Macintyre S, Michie S, Nazareth I, Petticrew M. Developing and evaluating complex interventions: the new Medical Research Council guidance. *BMJ* [Internet]. 2008 Sep;a1655. Available from: <http://www.bmj.com/lookup/doi/10.1136/bmj.a1655>
 351. NICOR. Myocardial Ischaemia / MINAP (Heart Attack audit) [Internet]. 2018 [cited 2021 Jul 28]. Available from: <https://www.nicor.org.uk/national-cardiac-audit-programme/myocardial-ischaemia-minap-heart-attack-audit/>
 352. Wilkinson C, Weston C, Timmis A, Quinn T, Keys A, Gale CP. The Myocardial Ischaemia National Audit Project (MINAP). *Eur Hear J - Qual Care Clin Outcomes*

- [Internet]. 2020 Jan 1;6(1):19–22. Available from:
<https://doi.org/10.1093/ehjqcco/qcz052>
353. Bazo-Alvarez JC, Morris TP, Pham TM, Carpenter JR, Petersen I. Handling Missing Values in Interrupted Time Series Analysis of Longitudinal Individual-Level Data. *Clin Epidemiol* [Internet]. 2020 Oct 8;12:1045–57. Available from:
<https://pubmed.ncbi.nlm.nih.gov/33116899>
 354. Sterne JAC, White IR, Carlin JB, Spratt M, Royston P, Kenward MG, et al. Multiple imputation for missing data in epidemiological and clinical research: potential and pitfalls. *BMJ* [Internet]. 2009 Jun 29;338:b2393–b2393. Available from:
<https://pubmed.ncbi.nlm.nih.gov/19564179>
 355. Cylus J, Richardson E, Findley L, Longley M, O'Neill C, Steel D. United Kingdom: Health System Review. *Health Syst Transit*. 2015;17(5):1–126.
 356. Jun M, James MT, Manns BJ, Quinn RR, Ravani P, Tonelli M, et al. The association between kidney function and major bleeding in older adults with atrial fibrillation starting warfarin treatment: Population based observational study. *BMJ*. 2015;350.
 357. Linden A. Conducting interrupted time-series analysis for single- and multiple-group comparisons. *Stata J*. 2015;15(2):480–500.
 358. Linden A, Adams JL. Applying a propensity score-based weighting model to interrupted time series data: improving causal inference in programme evaluation. *J Eval Clin Pract* [Internet]. 2011 Dec;17(6):1231–8. Available from:
<http://www.ncbi.nlm.nih.gov/pubmed/20973870>
 359. Baum C, Schaffer M. IVACTEST: Stata module to perform Cumby-Huizinga test for autocorrelation after IV/OLS estimation. 2007 May. (Staistical Software Components). Report No.: S456841.
 360. Drummond M, Sculpher M, Claxton K, Stoddart G, Torrance G. *Methods for the economic evaluation of health care programmes*. Fourth edi. Oxford: Oxford University Press; 2015.
 361. Rahman N, Ng SH-X, Ramachandran S, Wang DD, Sridharan S, Tan CS, et al. Drivers of hospital expenditure and length of stay in an academic medical centre: a retrospective cross-sectional study. *BMC Health Serv Res*. 2019 Jul;19(1):442.

362. National Institute for Health and Care Excellence (NICE). National Institute for Health and Care Excellence: Quality standard topic - Acute coronary syndromes (including myocardial infarction). Stand Indic [Internet]. 2014;(August):1–16. Available from: <https://www.nice.org.uk/guidance/qs68/documents/acute-coronary-syndromes-including-myocardial-infarction-briefing-paper2>
363. Menear M, Blanchette MA, Demers-Payette O, Roy D. A framework for value-creating learning health systems. *Heal Res Policy Syst*. 2019;17(1):1–13.
364. Farley DO, Haviland A, Champagne S, Jain AK, Battles JB, Munier WB, et al. Adverse-event-reporting practices by US hospitals: results of a national survey. *Qual Saf Health Care* [Internet]. 2008 Dec;17(6):416–23. Available from: <http://www.ncbi.nlm.nih.gov/pubmed/19064656>
365. Mohr L. *Impact Analysis for Program Evaluation*. California: Thousand Oaks; 1995.
366. Shadish W, Cook T, Campbell D. *Experimental and Quasi-Experimental Designs for Generalized Causal Inference*. New York: Houghton Mifflin; 2002.
367. Schwendimann R, Blatter C, Lüthy M, Mohr G, Girard T, Batzer S, et al. Adherence to the WHO surgical safety checklist: an observational study in a Swiss academic center. *Patient Saf Surg* [Internet]. 2019 Dec;13(1):14. Available from: <https://pssjournal.biomedcentral.com/articles/10.1186/s13037-019-0194-4>
368. Russ SJ, Sevdalis N, Moorthy K, Mayer EK, Rout S, Caris J, et al. A Qualitative Evaluation of the Barriers and Facilitators Toward Implementation of the WHO Surgical Safety Checklist Across Hospitals in England: Lessons From the “Surgical Checklist Implementation Project.” *Ann Surg* [Internet]. 2015;261(1). Available from: https://journals.lww.com/annalsofsurgery/Fulltext/2015/01000/A_Qualitative_Evaluati_on_of_the_Barriers_and.14.aspx
369. Fourcade A, Blache J-L, Grenier C, Bourgain J-L, Minvielle E. Barriers to staff adoption of a surgical safety checklist. *BMJ Qual & Saf* [Internet]. 2012 Mar 1;21(3):191 LP – 197. Available from: <http://qualitysafety.bmj.com/content/21/3/191.abstract>
370. Callaham ML, Wears RL, Weber EJ, Barton C, Young G. Positive-Outcome Bias and Other Limitations in the Outcome of Research Abstracts Submitted to a Scientific

- Meeting. JAMA [Internet]. 1998 Jul 15;280(3):254–7. Available from: <https://doi.org/10.1001/jama.280.3.254>
371. Emerson GB, Warne WJ, Wolf FM, Heckman JD, Brand RA, Leopold SS. Testing for the presence of positive-outcome bias in peer review: a randomized controlled trial. *Arch Intern Med*. 2010;170(21):1934–9.
 372. Claxton K, Martin S, Soares M, Rice N, Spackman E, Hinde S, et al. Methods for the estimation of the National Institute for Health and Care Excellence cost-effectiveness threshold. *Health Technol Assess*. 2015 Feb;19(14):1–503, v–vi.
 373. Paulden M. Recent amendments to NICE’s value-based assessment of health technologies: implicitly inequitable? *Expert Rev Pharmacoecon Outcomes Res* [Internet]. 2017;17(3):239–42. Available from: <http://www.ncbi.nlm.nih.gov/pubmed/28490259>
 374. Cohen DJ, Reynolds MR. Interpreting the results of cost-effectiveness studies. *J Am Coll Cardiol* [Internet]. 2008 Dec;52(25):2119–26. Available from: <http://www.ncbi.nlm.nih.gov/pubmed/19095128>
 375. Carter P. Operational productivity and performance in English NHS acute hospitals: Unwarranted variations [Internet]. London, UK; 2016. Available from: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/499229/Operational_productivity_A.pdf
 376. Karnon J, Haji Ali Afzali H. When to use discrete event simulation (DES) for the economic evaluation of health technologies? A review and critique of the costs and benefits of DES. *Pharmacoeconomics* [Internet]. 2014 Jun;32(6):547–58. Available from: <http://www.ncbi.nlm.nih.gov/pubmed/24627341>
 377. Claxton K, Martin S, Soares M, Rice N, Spackman E, Hinde S, et al. Methods for the estimation of the National Institute for Health and Care Excellence cost-effectiveness threshold. *Health Technol Assess* [Internet]. 2015 Feb;19(14):1–503, v–vi. Available from: <http://www.ncbi.nlm.nih.gov/pubmed/25692211>
 378. Bovenberg J, Penton H, Buyukkaramikli N. 10 Years of End-of-Life Criteria in the United Kingdom. *Value Heal* [Internet]. 2021;24(5):691–8. Available from: <https://www.sciencedirect.com/science/article/pii/S1098301521000371>

379. National Institute for Health and Care Excellence (NICE). Guide to the Methods of Technological Appraisal. London, UK; 2008.
380. Baguelin M, Hoek AJ Van, Jit M, Flasche S, White PJ, Edmunds WJ. Vaccination against pandemic influenza A/H1N1v in England: A real-time economic evaluation. *Vaccine* [Internet]. 2010 Mar;28(12):2370–84. Available from: <https://linkinghub.elsevier.com/retrieve/pii/S0264410X10000320>
381. Gandhi TK, Kaplan GS, Leape L, Berwick DM, Edgman-Levitan S, Edmondson A, et al. Transforming concepts in patient safety: a progress report. *BMJ Qual Saf*. 2018 Dec;27(12):1019–26.
382. Baxter S, Johnson M, Chambers D, Sutton A, Goyder E, Booth A. The effects of integrated care: a systematic review of UK and international evidence. *BMC Health Serv Res*. 2018 May;18(1):350.
383. Shaw A, Flott K, Fontana G, Durkin M, Darzi A. No patient safety without health worker safety. *Lancet* [Internet]. 2020 Nov 14;396(10262):1541–3. Available from: [https://doi.org/10.1016/S0140-6736\(20\)31949-8](https://doi.org/10.1016/S0140-6736(20)31949-8)
384. Leape LL, Shore MF, Dienstag JL, Mayer RJ, Edgman-Levitan S, Meyer GS, et al. Perspective: a culture of respect, part 2: creating a culture of respect. *Acad Med*. 2012 Jul;87(7):853–8.
385. Shin A, Gandhi T, Shoshana H. Make the clinician burnout epidemic a national priority. *Health Affairs (blog)*. 2016.

Appendix A

This appendix provides supplementary information and data relevant to Chapter one.

A.1 Summary of search themes (1 to 3) and terms used to inform the incident reporting system literature review in Chapter one.

THEME 1	THEME 2	THEME 3
(National adj Reporting adj3 Learning adj System) OR NRLS OR (Incident adj report\$3 adj system) OR (risk adj report\$3 adj system\$1 OR risk-manag\$5 adj system) OR (incident adj manag\$5 system\$1 OR incident adj system\$1) OR (Datix adj system\$1) OR (Datix adj incident adj report\$3 adj system\$1) OR (Datix OR adverse adj event adj report\$3 adj system\$1) OR (adverse adj event adj system) OR (error adj report\$3 adj system\$1) OR (harm adj report\$3 adj system) OR (never adj event report\$3 adj system) OR (incident adj report\$3) OR (datix adj report\$3) OR (national adj incident adj report\$3) OR (error adj report\$3) OR (harm adj report\$3) OR (never adj event adj report\$3) OR (risk adj manage\$4 adj report\$3) OR (risk report\$3) OR (event adj report\$3)	(implement\$5) OR (compliance\$2) OR (adherence\$2) OR (concordance\$2) OR (uptake) OR (active adj3 (implement45)) OR (passive adj3 (implement45)) OR (deliver\$1)	(feedback) OR (guidance) OR (guideline\$1) OR (patient adj safety adj alert) OR (alert) OR (rapid adj response adj report) OR (signal) OR (safer adj practice adj notice) OR (practice adj guideline) OR (clinical adj protocol) OR (nurs\$3 adj protocol) NOT (feedback adj loop) NOT (loop)

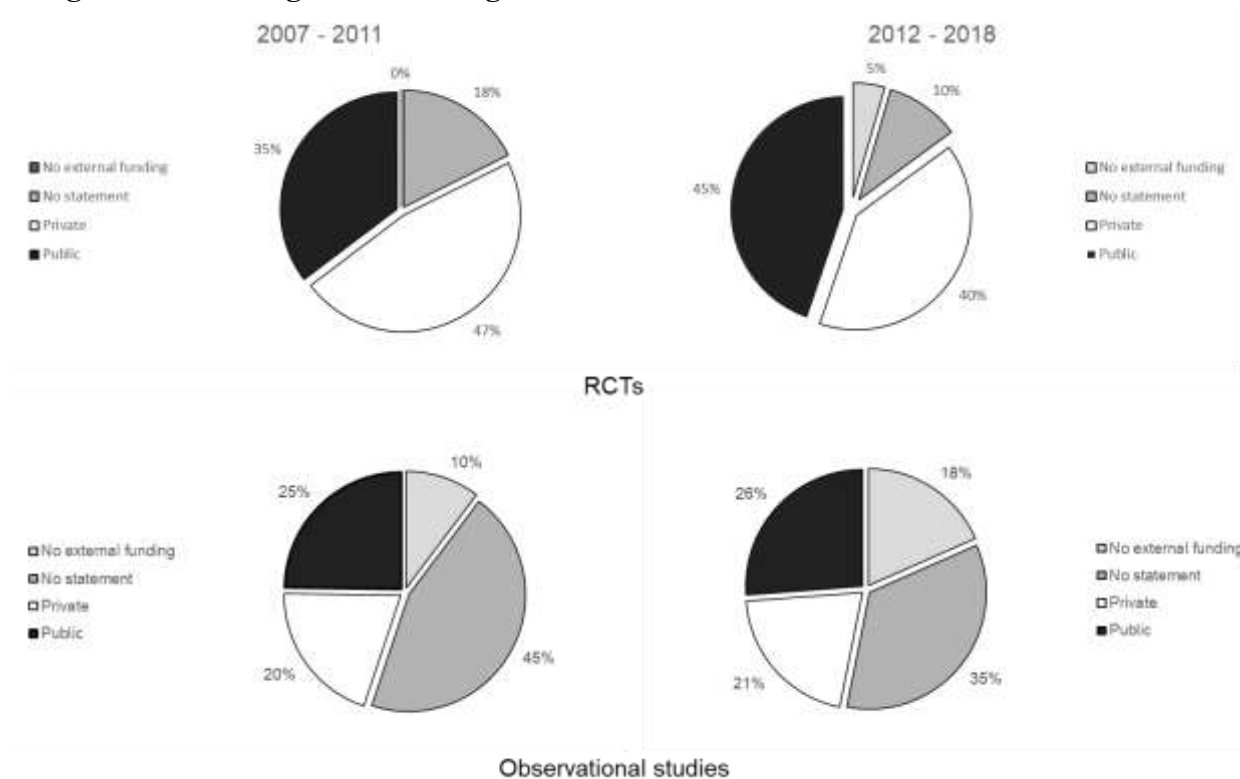
A.2 Summary of search themes (4 to 6) and terms used to inform the incident reporting system literature review in Chapter one.

THEME 4	THEME 5	THEME 6
(health\$5 adj provider) OR (clinician) OR (nurse) OR (doctor) OR (physician) OR (surgeon) OR (physiotherapy\$4) OR (healthcare personnel) OR (ward) OR (hospital) OR (hospital adj ward) OR (healthcare facility) OR (health services) OR (hospital subdivisions and components) OR (hospital organi#ation) OR (health system\$1)	(economic adj1 aspect) OR cost\$3 OR (health-care-cost\$3) OR (cost adj1 (analy\$3 OR evaluation)) OR (cost-effectiv\$4) OR (cost-benefit analy\$3) OR (cost-effectiv\$4 analy\$3) OR (cost-utilit\$2 analy\$3) OR (cost-utilit\$2) OR (cost-benefit) OR (efficien\$2) OR (technical efficien\$2) OR (allocative efficien\$2) OR (financ\$3 adj1 analy\$3) OR (financ\$3 adj1 evaluation) OR (productivity) OR (organi#ational adj1 efficien\$2) OR (economic adj1 evaluation) OR (economic adj endpoint)	(treatment outcome\$1) OR (patient outcome\$1) OR (healthcare quality) OR (disease management) OR (activity adj analy\$3) OR (hospital adj activity) OR (clinical indicator\$1) OR (guid\$5 outcome\$1) OR (outcome\$1) OR (saf\$3 adj outcome) OR (saf\$3 adj indicator\$1) OR (saf\$3 adj measure\$4) OR (adverse adj event\$1 adj rate) OR (error adj rate) OR (rate adj2 harm) OR (never adj event adj rate) OR (error) OR (iatrogenic adj harm) OR (patient adj safety adj incident)

Appendix B

This appendix provides supplementary information and data relevant to Chapter two.

B.1. Supplementary findings on the funding sources of eligible articles



Funding sources for RCTs from 2007 to 2011 (top left) and 2012 to 2018 (top right) and for observational studies from 2007 to 2011 (bottom left) and 2012 to 2018 (bottom right). These account for 9% and 88%, respectively, of the study designs used to produce evidence on the economics of patient safety since 2007. As a proportion, public funding overtook private funding of RCTs between 2012 and 2018 and fewer observational studies are now funded publicly. The highest growth in a single AE was for VTE, which was driven by private funding of clinical-level RCTs. This observation is limited by the proportion of articles that do not provide a funding source statement.

B.2. Extract of data frame describing eligible studies

authors	year	title	country	journal	economic analysis type	intervention setting	intervention type (OECD definition)	funding	target adverse event
Abel, G. A.; Chen, K.; Taback, N.; Hassett, M. J.; Schrag, D.; Aceves-Avila, F. J.; Benites-Godinez, V.; Ramos-Remus, C. Adkroyd-Stolarz, S.; Guernsey, J. R.; Mackinnon, N. J.; Kov	2013	Impact of oncology-related direct-to-consumer advertising: association with appropriate and inappropriate prescriptions	United States	Cancer	roi	community - home	System-level public engagement and health literacy initiatives	Public	med error
	2011	Cost of medication errors in rheumatic patients in Mexico	Mexico	Clinical Rheumatology	eb	n/a	Medication management / reconciliation	No statement	med error
	2009	Adverse events in older patients admitted to acute care: a preliminary cost description	Canada	Healthcare Management Forum	eb	n/a	National interventions based on specific safety themes	Private	multiple
A'Court, J.; Yassa, R.; Charalambous, C. P.	2017	Litigation related to casting in Orthopaedics-An analysis of claims against the National Health Service in England	United Kingdom	Injury	legal costs	urgery - orthopaedi	Clinical care standards	No statement	multiple
Adams, J.; Kaplow, R.; Dominy, J.; Stroud, B.	2015	Beyond a Band-Aid Approach: An Internal Agency Solution to Nurse Staffing	United States	Nursing Economics	roi	hospital - general	Human resources interventions	No statement	multiple
Adams, M. A.; Elmunzer, B. J.; Scheiman, J. M.	2014	Effect of a health system's medical error disclosure program on gastroenterology-related claims rates and costs	United States	American Journal of Gastroenterology	roi	hospital - general	Mandatory reporting of specified adverse events	NEF	diagnostic error
Adelani, M. A.; Keeney, J. A.; Nunley, R. M.; Ciohisay, J. C.;	2013	Readmission following total knee arthroplasty: venous thromboembolism as a "never event" is a counterproductive misnomer	United States	Journal of Arthroplasty	eb	n/a	VTE prevention protocols	No statement	vte
Admon, A. J.; Seymour, C. W.; Gershengorn, H. B.; Wunsd	2014	Hospital-level variation in ICU admission and critical care procedures for patients hospitalized for pulmonary embolism	United States	Chest	eb	n/a	VTE prevention protocols	Public	vte
A-Elgayoum, Salwa M. E.; El-Feki, Abd El-Karim Ahmed; M	2009	Malaria overdiagnosis and burden of malaria misdiagnosis in the suburbs of central Sudan: special emphasis on artemisinin-based combination therapy era	Sudan	Diagnostic microbiology and infectious disease	eb	n/a	Infection detection, reporting and surveillance systems	Public	diagnostic error
Agarwal, S.; Clark, D., 3rd; Sud, K.; Jaber, W. A.; Cho, L.; Me	2015	Gender Disparities in Outcomes and Resource Utilization for Acute Pulmonary Embolism Hospitalizations in the United States	United States	American Journal of Cardiology	eb	n/a	VTE prevention protocols	NEF	vte
Agarwal, S.; Menon, V.; Jaber, W. A.	2015	Residential zip code influences outcomes following hospitalization for acute pulmonary embolism in the United States	United States	Vascular Medicine	eb	n/a	VTE prevention protocols	NEF	vte
Agboola, S.; Golas, S.; Fischer, N.; Nikolova-Simons, M.; O	2017	Healthcare utilization in older patients using personal emergency response systems: an analysis of electronic health records and medical alert data : Brief Description: A Longitudinal Retrospective Analyses of healthcare utilization rates in older patients using Personal Emergency Response Systems from 2011 to 2015	United States	BMC Health Services Research	roi	community	Digital technology solutions for safety	No statement	multiple
Agee, C.; Coulter, L.; Hudson, J.	2015	Effects of pharmacy resident led education on resident physician prescribing habits associated with stress ulcer prophylaxis in non-intensive care unit patients	United States	American Journal of Health-System Pharmacy	roi	hospital - ward	Professional education and training	Private	med error
Aguiar, Karina da Silva; Santos, Jamile Machado Dos; Caml	2018	Patient safety and the value of pharmaceutical intervention in a cancer hospital	Brazil	Einstein (Sao Paulo, Brazil)	roi	hospital - general	Medication management / reconciliation	No statement	med error
Ahmad, A.; Weston, P. J.; Ahmad, M.; Sharma, D.; Purewa	2015	A cost-benefit analysis of twice-daily consultant ward rounds and clinical input on investigation and pharmacy costs in a major teaching hospital in the UK	United Kingdom	BMJ Open	ee	hospital - ward	Human resources interventions	NEF	multiple
Ahsan, S. Y.; Saberwal, B.; Lambiase, P. D.; Koo, C. Y.; Lee,	2014	A simple infection-control protocol to reduce serious cardiac device infections	United Kingdom	Europace	roi	surgery - cardiac	Clinical care standards	Public	hai
Akazawa, M.; Imai, H.; Igarashi, A.; Tsutani, K.	2010	Potentially inappropriate medication use in elderly Japanese patients	Japan	American Journal of Geriatric Pharmacotherapy	eb	n/a	Medication management / reconciliation	Public	med error
Akronroye, A. T.; Baskin, M. N.; Sammaliev, M.; Stack, A. M.	2010	Impact of a bronchiolitis guideline on ED resource use and cost: a segmented time-series analysis	United States	Pediatrics	roi	ED	Clinical care standards	Private	multiple
Akiyama, M.; Kondo, T.	2007	Risk management and measuring productivity with POAS—point of act system	United States	Studies in Health Technology & Informatics	roi	hospital - general	Clinical governance systems and frameworks related to safety	No statement	multiple
Albert, S. M.; Raviotta, J.; Lin, C. J.; Edelstein, O.; Smith, K.	2016	Cost-effectiveness of a statewide falls prevention program in Pennsylvania: Healthy Steps for Older Adults	United States	American Journal of Managed Care	ee	community	Fall prevention programme	Public	fall
Aldridge, V. E.; Park, H. K.; Bounthavong, M.; Morreale, A.	2009	Implementing a comprehensive, 24-hour emergency department pharmacy program	United States	American Journal of Health-System Pharmacy	roi	ED	Medication management / reconciliation	No statement	med error
Alekna, V.; Stukas, R.; Tamulaityte-Morozoviene, I.; Surki	2015	Self-reported consequences and healthcare costs of falls among elderly women	Lithuania	Medicina (Kaunas, Lithuania)	eb	n/a	Fall prevention programme	No statement	fall
Alkhaffaf, B.; Decadt, B.	2010	15 years of litigation following laparoscopic cholecystectomy in England	England	Annals of Surgery	legal costs	rgery - general surge	Clinical care standards	No statement	multiple
Alkhaffaf, B.; Decadt, B.	2010	Litigation following groin hernia repair in England	England	Hernia	legal costs	rgery - general surge	Clinical care standards	No statement	multiple
Allen, B.	2013	Effects of a comprehensive nutritional program on pressure ulcer healing, length of hospital stay, and charges to patients	United States	Clinical Nursing Research	ee	hospital - ward	Patient hydration and nutrition standards	NEF	pu
Allen, L.; McGarragh, B.; Barrett, D.; Stenson, B.; Turpin, P. ;	2012	Air-fluidized therapy in patients with suspected deep tissue injury: a case series	United States	Journal of Wound, Ostomy, & Continence Nursing	roi	hospital - ward	Pressure injury (ulcer) prevention protocols	Private	pu
Al-Omar, H. A.; Al-Sultan, M. S.; Abu-Auda, H. S.	2013	Prescribing of potentially inappropriate medications among the elderly population in an ambulatory care setting in a Saudi military hospital: trend and cost	Saudi Arabia	Geriatrics & gerontology international	eb	n/a	Medication management / reconciliation	NEF	med error
Al-Qurayshi, Zaid H.; Hauch, Adam T.; Slakey, Douglas P.; I	2015	Retained foreign bodies: risk and outcomes at the national level	United States	Journal of the American College of Surgeons	eb	n/a	National interventions based on specific safety themes	NEF	never event
Al-Tawfiq, J. A.; Abed, M. S.	2010	Decreasing ventilator-associated pneumonia in adult intensive care units using the Institute for Healthcare Improvement bundle	Saudi Arabia	American Journal of Infection Control	roi	critical care	Ventilator-associated pneumonia minimisation protocols	Public	vap
Al-Temimi, M. B.; Berglin, M. A.; Kim, E. G.; Tessier, D. J.; J	2017	Endostapler versus Hem-O-Lok clip to secure the appendiceal stump and mesoappendix during laparoscopic appendectomy	United States	American Journal of Surgery	cost analysis	rgery - general surge	Clinical care standards	NEF	multiple
Amin, A.; Bruno, A.; Trocio, J.; Lin, J.; Lingohr-Smith, M.	2015	Incremental Health Care Burden of Bleeding Among Patients with Venous Thromboembolism in the United States	United States	Journal of Managed Care & Specialty Pharmacy	eb	n/a	VTE prevention protocols	Private	vte
Amin, A.; Hussein, M.; Battleman, D.; Lin, J.; Stemkowski,	2010	Appropriate VTE prophylaxis is associated with lower direct medical costs	United States	Hospital practice (1995) Hospital practice	roi	hospital - ward	VTE prevention protocols	Private	vte
Amin, A.; Jing, Y.; Trocio, J.; Lin, J.; Lingohr-Smith, M.; Gra	2014	Evaluation of medical costs associated with use of new oral anticoagulants compared with standard therapy among venous thromboembolism patients	United States	Journal of Medical Economics	ee	acute medical	VTE prevention protocols	Private	vte
Amin, A.; Jing, Y.; Trocio, J.; Lin, J.; Lingohr-Smith, M.; Gra	2015	Evaluation of medical costs avoided when new oral anticoagulants are used for extended treatment of venous thromboembolism based on clinical trial results	United States	Journal of Thrombosis & Thrombolysis	ee	acute medical	VTE prevention protocols	Private	vte
Amin, A. N.; Lin, J.; Lenhart, G.; Schulman, K. L.	2009	Clinical and economic outcomes in patients at risk of venous thromboembolism receiving appropriate enoxaparin or unfractionated heparin prophylaxis	United States	Thrombosis & Haemostasis	ee	hospital - ward	VTE prevention protocols	Private	vte
Amin, A. N.; Lin, J.; Johnson, B. H.; Schulman, K. L.	2010	Clinical and economic outcomes with appropriate or partial prophylaxis	United States	Thrombosis Research	roi	hospital - ward	VTE prevention protocols	Private	vte
Anderegg, S. V.; Wilkinson, S. T.; Couldry, R. J.; Grauer, D.	2014	Effects of a hospitalwide pharmacy practice model change on readmission and return to emergency department rates	United States	American Journal of Health-System Pharmacy	roi	ED	Medication management / reconciliation	No statement	med error
Anderson, D. J.; Miller, B. A.; Chen, L. F.; Adcock, L. H.; Coc	2011	The network approach for prevention of healthcare-associated infections: long-term effect of participation in the Duke Infection Control Outreach Network	United States	Infection Control & Hospital Epidemiology	roi	hospital - general	National interventions based on specific safety themes	Private	hai
Andrade, C. C.; Almeida, C. F.; Pereira, W. E.; Alemao, M. I	2016	Costs of topical treatment of pressure ulcer patients	Brazil	Revista Da Escola de Enfermagem Da Usp	cost analysis	hospital - ward	Pressure injury (ulcer) prevention protocols	NEF	pu
Anezaki, H.; Hashimoto, H.	2017	Process value of care safety: women's willingness to pay for perinatal services	Japan	International Journal for Quality in Health Care	other	maternity services	National interventions based on specific safety themes	Public	multiple

B.3. Data summary for meta-analysis of randomised trials with full economic evaluations on the economics of patient safety

Author	Year	Outcome	Comparators	AE_tr eatme nt	N_tre atme nt	noAE_t reatme nt	AE_c ontrol	N_co ntrol	noAE _contr ol
Agnelli et al. (AMPLIFY-1)	2013	vte	Apixaban vs enoxaparin + warfarin	59	2690	2631	71	2635	2564
Agnelli et al. (AMPLIFY-EXT, 2.5mg)	2013	vte	Apixaban 2.5mg vs placebo	14	840	826	73	829	756

Agnelli et al. (AMPLIFY-EXT, 5mg)	2013	vte	Apixaban 5mg vs placebo	14	813	799	73	829	756
Bauersachs et al. (EINSTEIN-DVT)	2012	vte	Rivaroxaban vs enoxaparin + warfarin	36	1731	1695	51	1718	1667
Bauersachs et al. (EINSTEIN-EXT)	2012	vte	Rivaroxaban vs enoxaparin + warfarin	8	602	594	42	594	552
Büller et al. (EINSTEIN-PE)	2012	vte	Rivaroxaban vs enoxaparin + warfarin	50	2419	2369	44	2413	2369
Carrier et al. (SOME)	2015	vte (diagnostic error)	Limited screening vs limited screening + CT	4	14	10	5	19	14
Cook et al. (PROTECT)	2011	vte	Dalteparin vs unfractionated heparin	96	1873	1777	109	1973	1864
Elliott et al. (PINCER, ACEi)	2014	medication error	Simple feedback vs Pincer	436	5329	4893	255	4851	4596
Elliott et al. (PINCER, beta-blocker)	2014	medication error	Simple feedback vs Pincer	658	2222 4	21566	499	2031 2	19813
Elliott et al. (PINCER, NSAID)	2014	medication error	Simple feedback vs Pincer	86	2014	1928	51	1852	1801
Haines et al. (educational material)	2011	in-hospital fall	Multimedia patient education programme (tools only) vs usual care	96	424	328	81	381	300
Haines et al. (follow-up against education)	2011	in-hospital fall	Multimedia patient education programme with follow-up vs materials only	70	401	331	96	424	328
Haines et al. (follow-up)	2011	in-hospital fall	Multimedia patient education program with follow-up vs usual care	70	401	331	81	381	300
Lassen et al. (ADVANCE -1, knee)	2009	vte	Apixaban vs enoxaparin	104	1157	1053	100	1130	1030
Lassen et al. (ADVANCE -2, knee)	2010	vte	Apixaban vs enoxaparin	147	976	829	243	997	754
Lassen et al. (ADVANCE-3, hip)	2010	vte	Apixaban vs enoxaparin	27	1949	1922	74	1917	1843
Preblich et al. (HOKUSAI-VTE)	2015	vte	Edoxaban vs warfarin	130	4118	3988	146	4122	3976
Roos et al.	2013	hospital-acquired infection (hai)	Selective decontamination of digestive tract vs placebo	28	143	115	67	146	79
Schulman et al. (RECOVER)	2009	vte	Dabigatran vs warfarin	30	1274	1244	27	1265	1238
Schulman et al. (RECOVER-2)	2014	vte	Dabigatran vs warfarin	30	1279	1249	28	1289	1261
Schulman et al. (RESONATE, active comparator)	2013	vte	Dabigatran vs placebo	3	681	678	37	662	625
Schulman et al. (RESONATE, placebo-controlled)	2013	vte	Dabigatran vs warfarin	26	1430	1404	18	1426	1408
Sherman et al. (PREVAIL)	2007	vte	Enoxaparin vs unfractionated heparin	68	666	598	121	669	548
Whitty et al. (INTACT)	2017	pressure ulcer	Care bundle vs standard care	49	799	750	84	799	715

Appendix C

This appendix provides supplementary information and data relevant to Chapter three.

C.1. Questionnaire used for stage two data collection in Chapter three

Questionnaire Protocol

Developing and validating a process map for incident reporting systems in the NHS

Lead researcher: Alexander Carter

Email: a.w.carter@imperial.ac.uk

IRAS Project ID: 153350

This pack contains three sections; consent to participate, the questionnaire guide, and a supporting schematic. Consent to participate will be obtained before data collection.

Consent to Participate

(Refer to the adjoining information sheet*)

Study title: Developing and validating a process map for incident reporting systems in the NHS (IRAS: 153350)

Study aim: To generate evidence that will support the development of incident reporting systems to improve their effectiveness.

Project: This study has been running since 2014 and involves the collection of data to understand how incident reporting systems operate in the NHS. In particular, there is a lack of data quantifying the human and administrative burden involved in incident reporting systems. This study is needed for two reasons: 1) to identify the various NHS personnel and associated tasks involved in operating incident reporting and feedback and learning systems, and 2) to determine the resource usage involved in their operation.

Confidentiality: Your participation is voluntary and the information you provide, should you wish to do so, will be used for the purpose of refining the content of the assessment tool. Please signal to the researcher any confidential information you do not want to appear in published form and/or where you wish the source to be made anonymous, please do not hesitate to request this. Should you request anonymity, all identifiable data gathered from this project will remain stored with and accessible only to the researchers listed.

Authorisation to Proceed:

I..... (Print name) Date:

In line with the GDPR guidelines that came into force on May 25th 2018, I hereby agree to:

Item	Initial (each you agree to)
Participate in this research	
Be quoted in publications	
Be identified in publications	
Have my anonymised information used in future research	
Be contacted about this research in the future	

Participant Signature:.....

Anonymity / Note any special requests:

*EPS research participant information sheet part 2. (Previously 'Part 2_NHS Information Sheet for Participants_version 1 (HRA amendment)')

Questionnaire (IRAS project ID: 153350)

PART 1: Demographic information

1. What is your job title and relevant clinical area (cardiology, oncology, general practice, etc.)?

2. How long have you been working in your current role?

3. Which age bracket do you fit into? Please circle

18 – 25

26 – 35

36 – 59

60+

4. How would you rate the standard of patient safety in your NHS trust? Please circle using the scale below where 10 is a national leader and 1 is a poor national performer.

1 2 3 4 5 6 7 8 9 10

5. Have you been involved in managing, investigating, and/or reviewing incidents after they are reported? If 'YES', please describe the role or roles you have held

YES

☒ NO

☐

.....
.....

6. When was the last time you were involved in the reporting/management/investigation of an incident? Please give the date and/or tick one of the boxes below

Date:

Less than 6 months ago

☐

More than 6 months ago

☐

7. Approximately how many hours of regular formal training in patient safety do you receive each year? Please circle:

30 minutes

☐

1 hour

2 hours

More

☐

than 2 hours

☐

If you answered 'More than 2 hours,' please estimate the number of hours of formal training you receive.....

8. What type of training is this?

Statutory Mandatory

☐

General patient safety training

☐

Datix software training

☐

Other:.....

PART 2: Introducing the process map

Participants are shown the process map and the researcher provides a thorough explanation of the events in the process and the transitions between them. Participants are invited to ask clarification questions.

PART 3: Questionnaire completion

At this stage, participants are provided with a copy of the questionnaire and process map and asked to rate the accuracy of the events and transitions. Perceived accuracy is assessed on a 4-point Likert scale:

entirely disagree = 1

disagree = 2

agree = 3

entirely agree = 4

C.2. Stage one activities identified and consolidated after three-stage review

Interview	Activity				
	Review one		Review two		Final code
1	P1	Discussion with ward manager and senior nurse	P1	Pre-report deliberation and discussion of incident details and severity	P1
	P2A	Data entry	P2	Completion of Datix incident reporting form	P2
	P3	Discussion with consultant	P3	Post-report deliberation and discussion of incident details and actions	P3
	P4	Discussion with patient	P4	Discuss incident with patient and/or relatives	P4
2	P1	Locate a computer not in use	P5	Locate a computer on which to enter an incident report	P5
	P2A	Data entry	P2	Completion of Datix incident reporting form	P2
	P3	Discuss incident with junior	P1	Pre-report deliberation and discussion of incident details and severity	P1
3	P1	Allocate reports entered into Datix (P2A)	P6	Allocate submitted Datix incident reports to investigators	P6
	P2	Liaise with individual reporters	P7	Post-report deliberation and discussion of incident details and actions with reporter	P3
	P3	Ward manager meetings to discuss incidents and administration of Datix	P8	Post-report deliberation and discussion of incident details and actions with ward manager	P3
	P4	Local risk manager meetings to discuss incidents and administration of Datix and patient safety	P9	Local meeting: risk managers' discussion of incident details and actions	P7
	P5	Meeting with medical risk leader	P10	Post-report deliberation and discussion of incident details and actions with medical risk leader	P3
	P6	Guidance or policy or feedback review and/or development	P11	Review or development of guidelines, policies, and feedback	P8
	P7	Production of patient safety information materials	P12	Production of patient safety information materials	P9
	P8	Relaunch guidelines to frontline	P13	Implement and monitor existing or new guidelines or policies	P10
	P9	Following up incident reports and reporters	P47	Datix incident report management: update supporting information	P11
4	P1	Discussion with senior colleagues	P1	Pre-report deliberation and discussion of incident details and severity	P1
	P2	Data entry	P2	Completion of Datix incident reporting form	P2
	P3	Guidance or policy or feedback review and/or development	P11	Review or development of guidelines, policies, and feedback	P8
	P4	Meeting with colleagues	P3	Post-report deliberation and discussion of incident details and actions	P3
	P5	Discussion with patient	P4	Discuss incident with patient and/or relatives	P4
5	P1	Data entry	P2	Completion of Datix incident reporting form	P2
	P2	Discussion with colleagues about data entry	P1	Pre-report deliberation and discussion of incident details and severity	P1
	P3	Investigation of incidents reported by staff	P14	First formal investigation of Datix incident report	P12
	P4	Risk management meeting	P9	Local meeting: risk managers discussion of incident details and actions	P7
	P5	Second investigation of serious incident designation	P15	Second formal investigation of Datix incident report (for serious incident)	P13
	P6	Guidance or policy or feedback review and /or development	P11	Review or development of guidelines, policies, and feedback	P8
	P7	Production of patient safety information materials	P12	Production of patient safety information materials	P9
	P8	Incident report training for juniors	P16	Informal Datix incident reporting training	P14

6	P1	Data entry	P2	Completion of Datix incident reporting form	P2
	P2	Meeting with Local Negotiating Committee	P17	Local meeting: Local Negotiating Committee discussion of patient safety	P15
	P3	Meeting of Joint Staff Committee	P18	Local meeting: Joint Staff Committee discussion of patient safety	P16
	P4	Medical union meeting	P19	Local meeting: medical union meeting discussion of patient safety	P17
7	P1	Meeting with colleagues - audit meeting	P20	Local meeting: audit meeting discussion of patient safety	P18
	P2	Data entry	P2	Completion of Datix incident reporting form	P2
	P3	MHRA guidance review and surveillance	P11	Review or development of guidelines, policies, and feedback	P8
8	P1	NRLS data preparation for reporting	P21	Data preparation for performance reporting to NRLS	P19
	P2	Liaise with risk managers and chief investigators	P22	Management and oversight of incident investigations by risk managers and chief investigators	P20
	P3	Corporate patient safety alert meeting	P23	Corporate inclusion in review or development of guidelines, policies, and feedback	P8
	P4	Medical directors meeting	P24	Corporate meeting: Serious incident panel review 2 (corporate)	P21
	P5	NRLS report production	P25	Production of Trust performance data report for NRLS	P22
9	P1	Corporate welcome	P26	Trust training: Statutory Mandatory Training on patient safety	P23
	P2	Risk manager/chief investigator training	P27	Datix investigator training	P24
	P3	Junior doctor training	P28	Trust training: junior doctor general patient safety training	P25
	P4	Clinical risk management training	P29	Trust training: Clinical risk management	P25
	P5	Paediatric teaching	P30	Trust training: Specialty specific training in patient safety	P25
	P6	Datix software updates and training (once every 7 years)	P31	Datix training update	P26
	P7	Data entry	P2	Completion of Datix incident reporting form	P2
	P8	Trust reporting data analysis	P32	Allocate moderate, serious, and extreme harm Datix reports to serious incident panel review	P27
	P9	Medical directors meeting	P24	Corporate meeting: Serious incident panel review 2	P21
	P10	Division clinical review of serious incidents (ID 5, P5)	P15	Second formal investigation of Datix incident report	P13
	P11	Allocate reports entered into Datix (P2A)	P33	Maintain, upgrade, or downgrade severity of incident reported	P27
	P12	Report to commissioners	P34	Prepare report of serious incidents reported for local NHS commissioner	P28
	P13	Level one concise investigation	P35	Third formal investigation of Datix incident report (level one concise investigation)	P29
	P14	Datix configuration	P36	Datix optimisation by technician	P30
	P15	Investigation of incidents reported by staff, quality assurance by corporate team	P22	Management and oversight of incident investigations by risk managers and chief investigator	P20
	P16	Panel meeting, review of investigations	P37	Division meeting: Serious incident panel review 1	P31
	P17	Close review of incident and disseminate findings using Datix	P38	Close investigation and disseminate findings using Datix	P32
	P18	Production of patient safety information materials	P12	Production of patient safety information materials	P9
	P19	Send incident reporting data to NRLS	P21	Data preparation for performance reporting to NRLS	P19
	P20	Sourcing national learning from national alerts	P39	Surveillance of patient safety alerts and learning materials	P33

10	P1	Clinician scenario specific training	P30	Trust training: Specialty specific training in patient safety	P25
	P2	Implementation of safety alerts module	P40	Management of Datix module updates	P30
	P3	Training in how to capture CAS alerts and configure the security individuals need to use to capture alerts	P41	Trust training: local surveillance of patient safety alerts and learning materials	P25
	P4	Training on risk analysis	P29	Trust training: Clinical risk management	P25
	P5	Writing policies	P11	Review or development of policies	P8
	P6	Writing guidelines	P11	Review or development of guidelines	P8
	P7	Writing SOPs	P11	Review or development of standard operating procedures (SOPs)	P8
	P8	Track implementation of policy end-to-end	P44	Management and oversight of guideline, policy, and feedback implementation	P10
11	P1	Discussion with charge nurse	P1	Pre-report deliberation and discussion of incident details and severity	P1
	P2	Data entry	P2	Completion of Datix incident reporting form	P2
	P3	MDT meeting (Wrexham Trust, now obsolete)			
12	P1	Safety and complaints investigation	P3	Management and oversight of Datix incident report investigations	P20
	P2	Implementing guidance, policy, and SOPs	P13	Implementing existing or new guidelines or policies	P10
	P3	Review email report on incidents	P33	Maintain, upgrade, or downgrade severity of incident reported	P27
	P4	Review reported severity of incidents and (possibly) regrade		Include in P33	P27
	P5	Liaise with division governance team	P3	Post-report discussion and deliberation of incident details and severity	P3
	P6	Root cause analysis (minor investigation)	P1	Pre-report deliberation and discussion of incident details and severity	P1
	P7	Data entry into Datix (RCA detail)	P2	Completion of Datix incident reporting form	P2
	P8	Root cause analysis (moderate to serious)	P14	First formal investigation of Datix incident report	P12
	P9	Panel meeting, review of investigations	P37	Division meeting: Serious incident panel review 1	P31
	P10	Discussion with incident reporter	P3	Post-report discussion and deliberation of incident details and severity	P3
	P11	Data entry (incident report)	P2	Completion of Datix incident reporting form	P2
	P12	Review internal alerts	P11	Review or development of guidelines, policies, and feedback	P8
	P13	Performance management of staff in patient safety	P45	Local performance management for patient safety	P34
	P14	Discussion of incidents during handover	P3	Post-report discussion and deliberation of incident details and severity	P3
	P15	Senior staff meeting with incident discussion	P3	Post-report discussion and deliberation of incident details and severity	P35
	P16	General staff meeting with incident discussion	P3	Post-report discussion and deliberation of incident details and severity	P35
13	P1	Receive medical notes from coders	P46	Receive patient case notes from clinical coders	P36
	P2	Data entry - submit incident report from coders	P2	Completion of Datix incident reporting form	P2
	P3	Assign consultant to investigate incident	P6	Allocate submitted Datix incident reports to investigators	P6
	P4	Support consultants' investigation	P14	First formal investigation of Datix incident report	P12
	P5	Validate names on investigation report	P46	Datix incident report management: validate investigator names	P11
	P6	Update Datix with paper investigation notes	P47	Datix incident report management: update supporting information	P11
	P6b	Decide whether to submit incident to NRLS	P48	Datix incident report management: validate incident for NRLS reporting	P11
	P7	Discuss feedback with colleague	P11	Review or development of guidelines, policies, and feedback	P8
	P8	Production of patient safety information materials	P12	Production of patient safety information materials	P9
	P9	Attend quality and safety meeting	P49	Local meeting: quality and safety discussion of patient safety	P18

	P10	Attend critical review meeting	P50	Local meeting: critical review discussion of incident details and actions (moderate to serious incidents)	P18
	P11	Attend local risk management meeting	P9	Local meeting: risk managers' discussion of incident details and actions	P7
	P12	Attend risk and audit team meeting	P20	Local meeting: audit meeting discussion of patient safety	P18
	P13	Attend Division Health and Safety meeting	P51	Division meeting: Health and Safety meeting discussion of patient safety	P18
	P14	Attend local Datix meeting	P9	Local meeting: risk managers' discussion of incident details and actions	P7
14	P1	Clinical risk management training (delivery)	P29	Local training: Clinical risk management	P25
	P2	Data entry (from clinical coder flagged incidents)	P2	Completion of Datix incident reporting form	P2
	P3	Incident severity validation and re-coding	P33	Maintain, upgrade, or downgrade severity of incident reported	P27
	P4	Forward to consultant for incident review	P14	First formal investigation of Datix incident report	P12
	P5	MDT meeting	P50	Local meeting: critical review discussion of incident details and actions (moderate to serious incidents)	P18
	P6	Validate serious or moderate investigation and send to division governance leader	P51	Validate moderate to serious incident investigation and send to division governance leader	P11
	P7	CCG regrading of incident severity	P52	Commissioner regrading of incident severity	P27
	P8	Complete serious incident template for CCG investigation	P53	Complete serious incident investigation commissioner template	P37
	P9	Validate Datix incident reports for NRLS reporting	P48	Datix incident report management: validate incident for NRLS reporting	P11
	P10	Review CAS alerts delivered by corporate governance team	P11	Review or development of guidelines, policies, and feedback	P8
	P11	Implementation and audit of learning	P13	Implement and monitor existing or new guidelines or policies	P10
	P12	Prepare risk management meeting minutes	P12	Production of patient safety information materials	P9
	P13	Production of risk newsletter	P12	Production of patient safety information materials	P9
	P14	Post graduate forum (MDT meeting)	P55	Local training: incident report review	P25
	P15	Attend critical review meeting	P50	Local meeting: critical review discussion of incident details and actions (moderate to serious incidents)	P18
	P16	Review birth register for risk/incidents	P56	Retrospective incident surveillance	P36
15	P1	Data entry	P2	Completion of Datix incident reporting form	P2
	P2	Discuss with ward manager	P3	Post-report deliberation and discussion of incident details and actions	P3

C.3. Supplementary findings from stage one in Chapter three

During interviews, five participants estimated their time spent on at least one of eight discrete events, all of which are summarised in Table 3.3.

‘Completion of Datix incident reporting form’ represents a previously measured construct. This means estimates from this study can be used for comparison or triangulation and, to an extent, to check the internal and external validity of the study.

Discrete event identified	Time, mean (SD), mins	N
Pre-report deliberation and discussion of incident details and severity	7.5 ($\pm$ 3.5)	2
Discuss incident with patient and/or relatives	5	1
Locate a computer on which to enter an incident report	5	1
Completion of Datix incident reporting form	11.3 ($\pm$ 6.4)	3
Post-report deliberation and discussion of incident details and actions	170 ($\pm$ 226.3)	2
Allocate submitted Datix incident reports to investigators	20	1
Datix incident report management: update supporting information	120	1
Local meeting: risk managers’ discussion of incident details and actions	240	1
Review or development of guidelines, policies, and feedback	15	1

Table C.3. Time-driven activity-based estimates of time spent on certain incident reporting system activities (given in minutes).

C.4. Frequency tables for demographic information

	Count	Percent
Age group (in years)		
18-25	13	7.70%
26-35	48	28.60%
36-59	98	58.30%
60+	9	5.40%
Total	168	100.00%
Presence of incident reporting system experience		
No	49	29.20%
Yes	119	70.80%
Total	168	100.00%
Last use of incident reporting system		
Less than 6 months	124	82.10%
More than 6 months	27	17.90%
Total	151	100.00%
Last involvement in incident reporting system		
Less than 6 months	115	88.50%
More than 6 months	15	11.50%
Total	130	100.00%
Type of patient safety training received		
Statutory mandatory	58	37.90%
General patient safety	11	7.20%
Datix software	5	3.30%
Other	62	40.50%
Multiple entries	17	11.10%
Total	153	100.00%
Annotated question		
No	142	84.50%
Yes	26	15.50%
Total	168	100.00%
Discuss incident with patient and/or relative(s)		
Entirely disagree	3	2.00%
Disagree	14	9.50%
Agree	65	43.90%
Entirely agree	66	44.60%
Total	148	100.00%

Pre-report discussion of incident details and severity		
Entirely disagree	11	7.70%
Disagree	20	14.00%
Agree	69	48.30%
Entirely agree	43	30.10%
Total	143	100.00%
Locate a computer on which to enter an incident report		
Entirely disagree	5	3.30%
Disagree	8	5.30%
Agree	56	36.80%
Entirely agree	83	54.60%
Total	152	100.00%
Complete an incident report online		
Entirely disagree	6	3.90%
Disagree	4	2.60%
Agree	53	34.60%
Entirely agree	90	58.80%
Total	153	100.00%
Post-report discussion of incident and next steps		
Entirely disagree	8	5.60%
Disagree	25	17.60%
Agree	67	47.20%
Entirely agree	42	29.60%
Total	142	100.00%
Ward-level investigation		
Entirely disagree	2	1.50%
Disagree	15	11.50%
Agree	58	44.30%
Entirely agree	56	42.70%
Total	131	100.00%
Ward meeting: patient safety		
Entirely disagree	14	10.10%
Disagree	29	21.00%
Agree	55	39.90%
Entirely agree	40	29.00%
Total	138	100.00%
Local performance management of individuals		
Entirely disagree	6	4.50%

Disagree	40	30.30%
Agree	54	40.90%
Entirely agree	32	24.20%
Total	132	100.00%
Review medical records		
Entirely disagree	4	2.90%
Disagree	13	9.30%
Agree	53	37.90%
Entirely agree	70	50.00%
Total	140	100.00%
Incident investigation triage		
Entirely disagree	5	3.80%
Disagree	18	13.60%
Agree	61	46.20%
Entirely agree	48	36.40%
Total	132	100.00%
Allocate submitted incident reports to investigators		
Entirely disagree	2	1.50%
Disagree	11	8.30%
Agree	54	40.60%
Entirely agree	66	49.60%
Total	133	100.00%
Incident report database management		
Entirely disagree	2	1.60%
Disagree	8	6.50%
Agree	61	49.60%
Entirely agree	52	42.30%
Total	123	100.00%
First formal investigation of incident report		
Entirely disagree	2	1.60%
Disagree	11	8.60%
Agree	66	51.60%
Entirely agree	49	38.30%
Total	128	100.00%
Local meeting: risk managers' discussion of incident details and actions		
Disagree	9	7.10%
Agree	72	57.10%
Entirely agree	45	35.70%

Total	126	100.00%
Second formal investigation of incident report (serious incident)		
Entirely disagree	2	1.70%
Disagree	19	16.10%
Agree	54	45.80%
Entirely agree	43	36.40%
Total	118	100.00%
Local meeting (2): risk managers' discussion of incident details and actions		
Entirely disagree	2	1.70%
Disagree	20	17.10%
Agree	57	48.70%
Entirely agree	38	32.50%
Total	117	100.00%
Local meeting: audit or MDT or M&M		
Entirely disagree	3	2.50%
Disagree	9	7.60%
Agree	66	55.50%
Entirely agree	41	34.50%
Total	119	100.00%
Production of patient safety information materials		
Entirely disagree	4	4.40%
Disagree	17	18.70%
Agree	47	51.60%
Entirely agree	23	25.30%
Total	91	100.00%
Review or development of guidelines, policies, and feedback		
Entirely disagree	2	2.00%
Disagree	15	14.70%
Agree	47	46.10%
Entirely agree	38	37.30%
Total	102	100.00%
Third formal investigation (level one concise investigation)		
Entirely disagree	8	7.60%
Disagree	20	19.00%
Agree	46	43.80%
Entirely agree	31	29.50%
Total	105	100.00%

Incident investigation management		
Entirely disagree	2	1.90%
Disagree	14	13.10%
Agree	49	45.80%
Entirely agree	42	39.30%
Total	107	100.00%
Division meeting: serious incident panel review one		
Entirely disagree	1	1.00%
Disagree	8	7.60%
Agree	56	53.30%
Entirely agree	40	38.10%
Total	105	100.00%
Corporate meeting: serious incident panel review two		
Disagree	9	9.00%
Agree	49	49.00%
Entirely agree	42	42.00%
Total	100	100.00%
Closure of investigation		
Entirely disagree	2	2.00%
Disagree	5	5.00%
Agree	46	45.50%
Entirely agree	48	47.50%
Total	101	100.00%
Production of incident investigation report for commissioner		
Entirely disagree	3	3.00%
Disagree	7	7.00%
Agree	51	51.00%
Entirely agree	39	39.00%
Total	100	100.00%
Surveillance of latest patient safety information		
Entirely disagree	4	4.20%
Disagree	10	10.50%
Agree	52	54.70%
Entirely agree	29	30.50%
Total	95	100.00%
Implementation of existing or new guidelines or policies		
Entirely disagree	3	2.80%
Disagree	8	7.50%

Agree	59	55.10%
Entirely agree	37	34.60%
Total	107	100.00%
Data preparation for performance reporting to NRLS		
Entirely disagree	3	3.40%
Disagree	5	5.70%
Agree	43	49.40%
Entirely agree	36	41.40%
Total	87	100.00%
Production of organisation performance report for NRLS		
Entirely disagree	2	2.40%
Disagree	9	10.80%
Agree	40	48.20%
Entirely agree	32	38.60%
Total	83	100.00%
Production of organisation performance report for commissioner		
Entirely disagree	2	2.40%
Disagree	8	9.80%
Agree	39	47.60%
Entirely agree	33	40.20%
Total	82	100.00%
Connect: 'Allocate submitted incident reports to investigators' with 'Ward-level investigation'		
Entirely disagree	2	2.80%
Disagree	5	6.90%
Agree	43	59.70%
Entirely agree	22	30.60%
Total	72	100.00%
Connect: 'Local meeting: risk managers' discussion of incident details and actions' with 'Incident report database management' (after first formal investigation)		
Entirely disagree	3	3.60%
Disagree	8	9.60%
Agree	46	55.40%
Entirely agree	26	31.30%
Total	83	100.00%
Connect: 'Local meeting: risk managers' discussion of incident details and actions' with 'Incident report database management' (after second formal investigation)		
Entirely disagree	2	2.70%
Disagree	12	16.40%
Agree	31	42.50%

Entirely agree	28	38.40%
Total	73	100.00%
Connect: 'Local meeting: audit or MDT [meeting] or M&M [meeting]' with 'Local performance management of individuals'		
Disagree	12	16.20%
Agree	43	58.10%
Entirely agree	19	25.70%
Total	74	100.00%
Connect: 'Production of patient safety information materials' with 'Ward meeting: patient safety'		
Entirely disagree	4	5.50%
Disagree	11	15.10%
Agree	41	56.20%
Entirely agree	17	23.30%
Total	73	100.00%
Connect: 'Production of patient safety information materials' with 'Local meeting: audit or MDT or M&M'		
Entirely disagree	3	4.10%
Disagree	19	25.70%
Agree	32	43.20%
Entirely agree	20	27.00%
Total	74	100.00%
Connect: 'Review or development of guidelines, policies, and feedback' with 'Production of patient safety information materials'		
Entirely disagree	3	3.50%
Disagree	20	23.30%
Agree	37	43.00%
Entirely agree	26	30.20%
Total	86	100.00%
Connect: 'Closure of investigation' with 'Local meeting: audit or MDT or M&M'		
Disagree	5	7.50%
Agree	40	59.70%
Entirely agree	22	32.80%
Total	67	100.00%
Connect: 'Surveillance of latest patient safety information' with 'Production of patient safety information materials'		
Entirely disagree	4	5.20%
Disagree	12	15.60%
Agree	43	55.80%
Entirely agree	18	23.40%
Total	77	100.00%

C.5. Cross tables exploring statistical differences between groups by age

	Age group (in years)				
	18-25	26-35	36-59	60+	Total
	No. Obs	No. Obs	No. Obs	No. Obs	No. Obs
Discuss incident with patient and/or relative(s)					
Entirely disagree	0	0	3	0	3
Disagree	0	3	9	2	14
Agree	6	17	38	4	65
Entirely agree	6	23	35	2	66
Total	12	43	85	8	148
Pearson chi2(9) = 7.9172 Pr = 0.543					
Pre-report discussion of incident details and severity					
Entirely disagree	0	2	9	0	11
Disagree	1	9	10	0	20
Agree	5	21	39	4	69
Entirely agree	6	11	24	2	43
Total	12	43	82	6	143
Pearson chi2 (9) = 8.2874 Pr = 0.505					
Locate a computer on which to enter an incident report					
Entirely disagree	1	3	1	0	5
Disagree	0	0	7	1	8
Agree	2	18	33	3	56
Entirely agree	9	23	48	3	83
Total	12	44	89	7	152
Pearson chi2 (9) = 12.0037 Pr = 0.213					
Complete an incident report online					
Entirely disagree	0	5	1	0	6
Disagree	1	0	3	0	4
Agree	2	16	30	5	53
Entirely agree	9	23	55	3	90
Total	12	44	89	8	153
Pearson chi2 (9) = 16.4093 Pr = 0.059					
Post-report discussion of incident and next steps					
Entirely disagree	0	2	6	0	8
Disagree	4	8	12	1	25
Agree	3	20	39	5	67

Entirely agree	1	13	27	1	42
Total	8	43	84	7	142
Pearson chi2 (9) = 9.2015 Pr = 0.419					
Ward-level investigation					
Entirely disagree	0	1	1	0	2
Disagree	2	5	8	0	15
Agree	3	15	34	6	58
Entirely agree	2	16	36	2	56
Total	7	37	79	8	131
Pearson chi2 (9) = 6.4865 Pr = 0.690					
Ward meeting: patient safety					
Entirely disagree	0	6	8	0	14
Disagree	1	8	17	3	29
Agree	5	13	34	3	55
Entirely agree	1	15	22	2	40
Total	7	42	81	8	138
Pearson chi2 (9) = 7.5035 Pr = 0.585					
Local performance management of individuals					
Entirely disagree	0	2	3	1	6
Disagree	5	9	23	3	40
Agree	0	20	33	1	54
Entirely agree	1	9	20	2	32
Total	6	40	79	7	132
Pearson chi2 (9) = 13.3957 Pr = 0.146					
Review medical records					
Entirely disagree	0	1	3	0	4
Disagree	1	2	9	1	13
Agree	6	16	31	0	53
Entirely agree	5	19	40	6	70
Total	12	38	83	7	140
Pearson chi2 (9) = 7.1062 Pr = 0.626					
Incident investigation triage					
Entirely disagree	0	1	4	0	5
Disagree	1	5	12	0	18

Agree	6	13	37	5	61
Entirely agree	0	17	28	3	48
Total	7	36	81	8	132
Pearson chi2 (9) = 9.5356 Pr = 0.389					
Allocate submitted incident reports to investigators					
Entirely disagree	0	1	1	0	2
Disagree	1	2	7	1	11
Agree	5	13	31	5	54
Entirely agree	2	19	43	2	66
Total	8	35	82	8	133
Pearson chi2 (9) = 5.7306 Pr = 0.767					
Incident report database management					
Entirely disagree	0	1	1	0	2
Disagree	2	2	3	1	8
Agree	2	14	39	6	61
Entirely agree	2	15	35	0	52
Total	6	32	78	7	123
Pearson chi2 (9) = 14.5942 Pr = 0.103					
First formal investigation of incident report					
Entirely disagree	0	0	2	0	2
Disagree	1	3	7	0	11
Agree	6	19	34	7	66
Entirely agree	0	11	38	0	49
Total	7	33	81	7	128
Pearson chi2 (9) = 15.6266 Pr = 0.075					
Local meeting: risk managers' discussion of incident details and actions					
Disagree	0	3	6	0	9
Agree	6	18	42	6	72
Entirely agree	0	12	32	1	45
Total	6	33	80	7	126
Pearson chi2 (6) = 7.8457 Pr = 0.250					
Second formal investigation of incident report (serious incident)					
Entirely disagree	0	0	2	0	2
Disagree	2	6	9	2	19

Agree	3	15	32	4	54
Entirely agree	1	11	31	0	43
Total	6	32	74	6	118
Pearson chi2 (9) = 8.4337 Pr = 0.491					
Local meeting (2): risk managers' discussion of incident details and actions					
Entirely disagree	0	0	2	0	2
Disagree	2	6	11	1	20
Agree	3	15	36	3	57
Entirely agree	2	9	26	1	38
Total	7	30	75	5	117
Pearson chi2 (9) = 2.7288 Pr = 0.974					
Local meeting: audit or MDT or M&M					
Entirely disagree	0	0	3	0	3
Disagree	0	2	7	0	9
Agree	5	19	39	3	66
Entirely agree	1	10	27	3	41
Total	6	31	76	6	119
Pearson chi2 (9) = 5.2670 Pr = 0.810					
Production of patient safety information materials					
Entirely disagree	0	2	2	0	4
Disagree	2	7	8	0	17
Agree	4	12	29	2	47
Entirely agree	0	6	16	1	23
Total	6	27	55	3	91
Pearson chi2 (9) = 6.2238 Pr = 0.717					
Review or development of guidelines, policies, and feedback					
Entirely disagree	0	0	2	0	2
Disagree	1	6	7	1	15
Agree	0	13	32	2	47
Entirely agree	1	10	26	1	38
Total	2	29	67	4	102
Pearson chi2 (9) = 5.8968 Pr = 0.750					
Third formal investigation (level one concise investigation)					
Entirely disagree	0	0	6	2	8

Disagree	1	10	9	0	20
Agree	1	12	31	2	46
Entirely agree	1	5	24	1	31
Total	3	27	70	5	105
Pearson chi2 (9) = 18.4309 Pr = 0.030					
Incident investigation management					
Entirely disagree	0	0	2	0	2
Disagree	1	5	7	1	14
Agree	0	12	33	4	49
Entirely agree	2	10	29	1	42
Total	3	27	71	6	107
Pearson chi2 (9) = 6.5833 Pr = 0.680					
Division meeting: serious incident panel review one					
Entirely disagree	0	0	1	0	1
Disagree	1	4	2	1	8
Agree	1	13	39	3	56
Entirely agree	1	11	27	1	40
Total	3	28	69	5	105
Pearson chi2 (9) = 8.9085 Pr = 0.446					
Corporate meeting: serious incident panel review two					
Disagree	1	2	6	0	9
Agree	0	14	32	3	49
Entirely agree	2	9	29	2	42
Total	3	25	67	5	100
Pearson chi2 (6) = 4.9960 Pr = 0.544					
Closure of investigation					
Entirely disagree	0	0	2	0	2
Disagree	1	1	3	0	5
Agree	1	14	28	3	46
Entirely agree	1	12	33	2	48
Total	3	27	66	5	101
Pearson chi2 (9) = 7.3269 Pr = 0.603					
Production of incident investigation report for commissioner					
Entirely disagree	0	2	1	0	3

Disagree	1	1	4	1	7
Agree	2	18	28	3	51
Entirely agree	0	7	31	1	39
Total	3	28	64	5	100
Pearson chi2 (9) = 13.3375 Pr = 0.148					
Surveillance of latest patient safety information					
Entirely disagree	0	2	2	0	4
Disagree	1	4	4	1	10
Agree	1	11	35	5	52
Entirely agree	1	10	18	0	29
Total	3	27	59	6	95
Pearson chi2 (9) = 8.6392 Pr = 0.471					
Implementation of existing or new guidelines or policies					
Entirely disagree	0	1	2	0	3
Disagree	1	2	4	1	8
Agree	2	16	38	3	59
Entirely agree	0	11	25	1	37
Total	3	30	69	5	107
Pearson chi2 (9) = 5.8232 Pr = 0.757					
Data preparation for performance reporting to NRLS					
Entirely disagree	0	1	2	0	3
Disagree	1	3	0	1	5
Agree	0	13	27	3	43
Entirely agree	2	7	26	1	36
Total	3	24	55	5	87
Pearson chi2 (9) = 15.1713 Pr = 0.086					
Production of organisation performance report for NRLS					
Entirely disagree	0	0	2	0	2
Disagree	1	5	1	2	9
Agree	0	13	25	2	40
Entirely agree	2	5	24	1	32
Total	3	23	52	5	83
Pearson chi2 (9) = 18.2195 Pr = 0.033					
Production of organisation performance report for commissioner					

Entirely disagree	0	0	2	0	2
Disagree	1	5	0	2	8
Agree	2	10	25	2	39
Entirely agree	0	8	24	1	33
Total	3	23	51	5	82
Pearson chi2 (9) = 18.8429 Pr = 0.027					
Connect: 'Allocate submitted incident reports to investigators' with 'Ward-level investigation'					
Entirely disagree	0	2	0	0	2
Disagree	0	2	2	1	5
Agree	2	12	25	4	43
Entirely agree	1	7	14	0	22
Total	3	23	41	5	72
Pearson chi2 (9) = 8.3573 Pr = 0.499					
Connect: 'Local meeting: risk managers' discussion of incident details and actions' with 'Incident report database management' (after first formal investigation)					
Entirely disagree	0	1	2	0	3
Disagree	2	2	4	0	8
Agree	0	14	28	4	46
Entirely agree	1	7	18	0	26
Total	3	24	52	4	83
Pearson chi2 (9) = 15.6650 Pr = 0.074					
Connect: 'Local meeting: risk managers' discussion of incident details and actions' with 'Incident report database management' (after second formal investigation)					
Entirely disagree	0	1	1	0	2
Disagree	1	3	8	0	12
Agree	1	12	14	4	31
Entirely agree	1	5	22	0	28
Total	3	21	45	4	73
Pearson chi2 (9) = 11.4584 Pr = 0.246					
Connect: 'Local meeting: audit or MDT [meeting] or M&M [meeting]' with 'Local performance management of individuals'					
Disagree	2	3	7	0	12
Agree	0	15	26	2	43
Entirely agree	0	4	15	0	19
Total	2	22	48	2	74
Pearson chi2 (6) = 13.5190 Pr = 0.035					

Connect: 'Production of patient safety information materials' with 'Ward meeting: patient safety'					
Entirely disagree	0	1	2	1	4
Disagree	0	5	6	0	11
Agree	2	13	25	1	41
Entirely agree	0	4	13	0	17
Total	2	23	46	2	73
Pearson chi2 (9) = 11.4013 Pr = 0.249					
Connect: 'Production of patient safety information materials' with 'Local meeting: audit or MDT or M&M'					
Entirely disagree	0	1	2	0	3
Disagree	0	8	11	0	19
Agree	1	11	18	2	32
Entirely agree	1	4	15	0	20
Total	2	24	46	2	74
Pearson chi2 (9) = 5.9462 Pr = 0.745					
Connect: 'Review or development of guidelines, policies, and feedback' with 'Production of patient safety information materials'					
Entirely disagree	0	2	1	0	3
Disagree	1	8	10	1	20
Agree	2	9	25	1	37
Entirely agree	0	8	18	0	26
Total	3	27	54	2	86
Pearson chi2 (9) = 6.3394 Pr = 0.706					
Connect: 'Closure of investigation' with 'Local meeting: audit or MDT or M&M'					
Disagree	1	1	3	0	5
Agree	0	11	27	2	40
Entirely agree	1	5	16	0	22
Total	2	17	46	2	67
Pearson chi2 (6) = 7.8771 Pr = 0.247					
Connect: 'Surveillance of latest patient safety information' with 'Production of patient safety information materials'					
Entirely disagree	0	3	0	1	4
Disagree	0	6	5	1	12
Agree	2	11	28	2	43
Entirely agree	0	5	13	0	18
Total	2	25	46	4	77
Pearson chi2 (9) = 13.6267 Pr = 0.136					

C.6. Cross tables exploring statistical differences between groups by incident reporting system experience

	Presence of incident reporting system experience		
	No	Yes	Total
	No. Obs	No. Obs	No. Obs
Discuss incident with patient and/or relative(s)			
Entirely disagree	1	2	3
Disagree	0	14	14
Agree	21	44	65
Entirely agree	22	44	66
Total	44	104	148
Pearson chi2 (3) = 6.5588 Pr = 0.087			
Pre-report discussion of incident details and severity			
Entirely disagree	2	9	11
Disagree	3	17	20
Agree	29	40	69
Entirely agree	10	33	43
Total	44	99	143
Pearson chi2 (3) = 8.3991 Pr = 0.038			
Locate a computer on which to enter an incident report			
Entirely disagree	1	4	5
Disagree	1	7	8
Agree	18	38	56
Entirely agree	25	58	83
Total	45	107	152
Pearson chi2 (3) = 1.5281 Pr = 0.676			
Complete an incident report online			
Entirely disagree	2	4	6
Disagree	1	3	4
Agree	19	34	53
Entirely agree	23	67	90
Total	45	108	153
Pearson chi2 (3) = 1.7844 Pr = 0.618			
Post-report discussion of incident and next steps			

Entirely disagree	3	5	8
Disagree	11	14	25
Agree	18	49	67
Entirely agree	9	33	42
Total	41	101	142
Pearson chi2 (3) = 4.3404 Pr = 0.227			
Ward-level investigation			
Entirely disagree	1	1	2
Disagree	8	7	15
Agree	13	45	58
Entirely agree	9	47	56
Total	31	100	131
Pearson chi2 (3) = 9.9147 Pr = 0.019			
Ward meeting: patient safety			
Entirely disagree	6	8	14
Disagree	4	25	29
Agree	15	40	55
Entirely agree	14	26	40
Total	39	99	138
Pearson chi2 (3) = 5.3878 Pr = 0.146			
Local performance management of individuals			
Entirely disagree	2	4	6
Disagree	11	29	40
Agree	13	41	54
Entirely agree	10	22	32
Total	36	96	132
Pearson chi2 (3) = 0.6459 Pr = 0.886			
Review medical records			
Entirely disagree	1	3	4
Disagree	2	11	13
Agree	14	39	53
Entirely agree	18	52	70
Total	35	105	140
Pearson chi2 (3) = 0.7167 Pr = 0.869			

Incident investigation triage			
Entirely disagree	1	4	5
Disagree	3	15	18
Agree	15	46	61
Entirely agree	12	36	48
Total	31	101	132
Pearson chi2 (3) = 0.6023 Pr = 0.896			
Allocate submitted incident reports to investigators			
Entirely disagree	0	2	2
Disagree	2	9	11
Agree	16	38	54
Entirely agree	11	55	66
Total	29	104	133
Pearson chi2 (3) = 3.6035 Pr = 0.308			
Incident report database management			
Entirely disagree	2	0	2
Disagree	2	6	8
Agree	13	48	61
Entirely agree	10	42	52
Total	27	96	123
Pearson chi2 (3) = 7.3937 Pr = 0.060			
First formal investigation of incident report			
Entirely disagree	2	0	2
Disagree	3	8	11
Agree	15	51	66
Entirely agree	8	41	49
Total	28	100	128
Pearson chi2 (3) = 8.2411 Pr = 0.041			
Local meeting: risk managers' discussion of incident details and actions			
Disagree	2	7	9
Agree	18	54	72
Entirely agree	6	39	45
Total	26	100	126
Pearson chi2 (2) = 2.3165 Pr = 0.314			

Second formal investigation of incident report (serious incident)			
Entirely disagree	1	1	2
Disagree	3	16	19
Agree	14	40	54
Entirely agree	7	36	43
Total	25	93	118
Pearson chi2 (3) = 2.6724 Pr = 0.445			
Local meeting: risk managers' discussion of incident details and actions			
Entirely disagree	1	1	2
Disagree	6	14	20
Agree	14	43	57
Entirely agree	5	33	38
Total	26	91	117
Pearson chi2 (3) = 3.5797 Pr = 0.311			
Local meeting: audit or MDT or M&M			
Entirely disagree	0	3	3
Disagree	4	5	9
Agree	13	53	66
Entirely agree	7	34	41
Total	24	95	119
Pearson chi2 (3) = 4.3053 Pr = 0.230			
Production of patient safety information materials			
Entirely disagree	1	3	4
Disagree	2	15	17
Agree	7	40	47
Entirely agree	6	17	23
Total	16	75	91
Pearson chi2 (3) = 1.9314 Pr = 0.587			
Review or development of guidelines, policies, and feedback			
Entirely disagree	0	2	2
Disagree	2	13	15
Agree	4	43	47
Entirely agree	10	28	38
Total	16	86	102
Pearson chi2 (3) = 5.5110 Pr = 0.138			

Third formal investigation (level one concise investigation)			
Entirely disagree	1	7	8
Disagree	5	15	20
Agree	8	38	46
Entirely agree	4	27	31
Total	18	87	105
Pearson chi2 (3) = 1.3849 Pr = 0.709			
Incident investigation management			
Entirely disagree	0	2	2
Disagree	2	12	14
Agree	10	39	49
Entirely agree	6	36	42
Total	18	89	107
Pearson chi2 (3) = 1.1123 Pr = 0.774			
Division meeting: serious incident panel review one			
Entirely disagree	0	1	1
Disagree	2	6	8
Agree	6	50	56
Entirely agree	8	32	40
Total	16	89	105
Pearson chi2 (3) = 2.3596 Pr = 0.501			
Corporate meeting: serious incident panel review two			
Disagree	2	7	9
Agree	8	41	49
Entirely agree	6	36	42
Total	16	84	100
Pearson chi2 (2) = 0.3550 Pr = 0.837			
Closure of investigation			
Entirely disagree	0	2	2
Disagree	2	3	5
Agree	4	42	46
Entirely agree	10	38	48
Total	16	85	101
Pearson chi2 (3) = 5.2243 Pr = 0.156			

Production of incident investigation report for commissioner			
Entirely disagree	1	2	3
Disagree	1	6	7
Agree	11	40	51
Entirely agree	3	36	39
Total	16	84	100
Pearson chi2 (3) = 3.8654 Pr = 0.276			
Surveillance of latest patient safety information			
Entirely disagree	1	3	4
Disagree	1	9	10
Agree	8	44	52
Entirely agree	7	22	29
Total	17	78	95
Pearson chi2 (3) = 1.5540 Pr = 0.670			
Implementation of existing or new guidelines or policies			
Entirely disagree	1	2	3
Disagree	1	7	8
Agree	9	50	59
Entirely agree	7	30	37
Total	18	89	107
Pearson chi2 (3) = 0.9112 Pr = 0.823			
Data preparation for performance reporting to NRLS			
Entirely disagree	1	2	3
Disagree	2	3	5
Agree	8	35	43
Entirely agree	5	31	36
Total	16	71	87
Pearson chi2 (3) = 2.4894 Pr = 0.477			
Production of organisation performance report for NRLS			
Entirely disagree	0	2	2
Disagree	4	5	9
Agree	9	31	40
Entirely agree	3	29	32
Total	16	67	83

Pearson chi2 (3) = 6.4243 Pr = 0.093			
Production of organisation performance report for commissioner			
Entirely disagree	0	2	2
Disagree	3	5	8
Agree	8	31	39
Entirely agree	5	28	33
Total	16	66	82
Pearson chi2 (3) = 2.5575 Pr = 0.465			
Connect: 'Allocate submitted incident reports to investigators' with 'Ward-level investigation'			
Entirely disagree	2	0	2
Disagree	1	4	5
Agree	7	36	43
Entirely agree	4	18	22
Total	14	58	72
Pearson chi2 (3) = 8.5842 Pr = 0.035			
Connect: 'Local meeting: risk managers' discussion of incident details and actions' with 'Incident report database management' (after first formal investigation)			
Entirely disagree	0	3	3
Disagree	2	6	8
Agree	10	36	46
Entirely agree	3	23	26
Total	15	68	83
Pearson chi2 (3) = 2.0885 Pr = 0.554			
Connect: 'Local meeting: risk managers' discussion of incident details and actions' with 'Incident report database management' (after second formal investigation)			
Entirely disagree	0	2	2
Disagree	1	11	12
Agree	6	25	31
Entirely agree	4	24	28
Total	11	62	73
Pearson chi2 (3) = 1.2386 Pr = 0.744			
Connect: 'Local meeting: audit or MDT [meeting] or M&M [meeting]' with 'Local performance management of individuals'			
Disagree	5	7	12
Agree	7	36	43
Entirely agree	2	17	19

Total	14	60	74
Pearson chi2 (2) = 5.1158 Pr = 0.077			
Connect: 'Production of patient safety information materials' with 'Ward meeting: patient safety'			
Entirely disagree	0	4	4
Disagree	1	10	11
Agree	7	34	41
Entirely agree	4	13	17
Total	12	61	73
Pearson chi2 (3) = 1.8535 Pr = 0.603			
Connect: 'Production of patient safety information materials' with 'Local meeting: audit or MDT or M&M'			
Entirely disagree	0	3	3
Disagree	5	14	19
Agree	5	27	32
Entirely agree	5	15	20
Total	15	59	74
Pearson chi2 (3) = 1.8965 Pr = 0.594			
Connect: 'Review or development of guidelines, policies and feedback' with 'Production of patient safety information materials'			
Entirely disagree	1	2	3
Disagree	2	18	20
Agree	4	33	37
Entirely agree	5	21	26
Total	12	74	86
Pearson chi 2(3) = 2.1062 Pr = 0.551			
Connect: 'Closure of investigation' with 'Local meeting: audit or MDT or M&M'			
Disagree	1	4	5
Agree	5	35	40
Entirely agree	4	18	22
Total	10	57	67
Pearson chi2 (2) = 0.4704 Pr = 0.790			
Connect: 'Surveillance of latest patient safety information' with 'Production of patient safety information materials'			
Entirely disagree	1	3	4
Disagree	2	10	12

Agree	6	37	43
Entirely agree	4	14	18
Total	13	64	77
Pearson chi2 (3) = 0.8169 Pr = 0.845			

C.7. Cross tables exploring statistical differences between groups by last use of incident reporting system

	Last IRS use		
	Less than 6 months	More than 6 months	Total
	No. Obs	No. Obs	No. Obs
Discuss incident with patient and/or relative(s)			
Entirely disagree	2	0	2
Disagree	13	1	14
Agree	45	12	57
Entirely agree	52	10	62
Total	112	23	135
Pearson chi2 (3) = 2.0668 Pr = 0.559			
Pre-report discussion of incident details and severity			
Entirely disagree	10	0	10
Disagree	16	3	19
Agree	48	13	61
Entirely agree	35	6	41
Total	109	22	131
Pearson chi2 (3) = 3.0598 Pr = 0.382			
Locate a computer on which to enter an incident report			
Entirely disagree	4	1	5
Disagree	5	2	7
Agree	44	7	51
Entirely agree	63	13	76
Total	116	23	139
Pearson chi2 (3) = 1.0873 Pr = 0.780			
Complete an incident report online			
Entirely disagree	4	2	6
Disagree	4	0	4
Agree	38	8	46
Entirely agree	70	14	84
Total	116	24	140

Pearson chi2 (3) = 1.9503 Pr = 0.583			
Post-report discussion of incident and next steps			
Entirely disagree	7	0	7
Disagree	19	3	22
Agree	46	15	61
Entirely agree	35	4	39
Total	107	22	129
Pearson chi2 (3) = 5.3439 Pr = 0.148			
Ward-level investigation			
Entirely disagree	2	0	2
Disagree	10	2	12
Agree	43	9	52
Entirely agree	45	10	55
Total	100	21	121
Pearson chi2 (3) = 0.4502 Pr = 0.930			
Ward meeting: patient safety			
Entirely disagree	11	1	12
Disagree	26	3	29
Agree	44	6	50
Entirely agree	23	12	35
Total	104	22	126
Pearson chi2 (3) = 9.6220 Pr = 0.022			
Local performance management of individuals			
Entirely disagree	4	1	5
Disagree	33	4	37
Agree	40	10	50
Entirely agree	23	5	28
Total	100	20	120
Pearson chi2 (3) = 1.3821 Pr = 0.710			
Review medical records			
Entirely disagree	4	0	4
Disagree	8	3	11
Agree	42	6	48
Entirely agree	54	12	66

Total	108	21	129
Pearson chi2 (3) = 2.4315 Pr = 0.488			
Incident investigation triage			
Entirely disagree	3	1	4
Disagree	14	3	17
Agree	46	8	54
Entirely agree	36	11	47
Total	99	23	122
Pearson chi2 (3) = 1.3269 Pr = 0.723			
Allocate submitted incident reports to investigators			
Entirely disagree	2	0	2
Disagree	7	2	9
Agree	37	10	47
Entirely agree	55	10	65
Total	101	22	123
Pearson chi2 (3) = 1.1957 Pr = 0.754			
Incident report database management			
Disagree	5	1	6
Agree	44	12	56
Entirely agree	42	9	51
Total	91	22	113
Pearson chi2 (2) = 0.2752 Pr = 0.871			
First formal investigation of incident report			
Entirely disagree	0	1	1
Disagree	8	2	10
Agree	49	11	60
Entirely agree	39	8	47
Total	96	22	118
Pearson chi2 (3) = 4.4612 Pr = 0.216			
Local meeting: risk managers' discussion of incident details and actions			
Disagree	7	1	8
Agree	52	12	64
Entirely agree	36	8	44
Total	95	21	116

Pearson chi2 (2) = 0.1877 Pr = 0.910			
Second formal investigation of incident report (serious incident)			
Entirely disagree	1	0	1
Disagree	14	3	17
Agree	38	11	49
Entirely agree	36	5	41
Total	89	19	108
Pearson chi2 (3) = 1.8345 Pr = 0.607			
Local meeting (2): risk managers' discussion of incident details and actions			
Entirely disagree	1	0	1
Disagree	15	3	18
Agree	42	10	52
Entirely agree	31	5	36
Total	89	18	107
Pearson chi2 (3) = 0.6395 Pr = 0.887			
Local meeting: audit or MDT or M&M			
Entirely disagree	3	0	3
Disagree	6	2	8
Agree	55	8	63
Entirely agree	31	8	39
Total	95	18	113
Pearson chi2 (3) = 2.1628 Pr = 0.539			
Production of patient safety information materials			
Entirely disagree	3	1	4
Disagree	17	0	17
Agree	38	6	44
Entirely agree	17	5	22
Total	75	12	87
Pearson chi2 (3) = 4.6202 Pr = 0.202			
Review or development of guidelines, policies, and feedback			
Entirely disagree	2	0	2
Disagree	12	3	15
Agree	42	3	45
Entirely agree	27	9	36

Total	83	15	98
Pearson chi2 (3) = 5.8170 Pr = 0.121			
Third formal investigation (level one concise investigation)			
Entirely disagree	6	2	8
Disagree	15	5	20
Agree	37	6	43
Entirely agree	27	3	30
Total	85	16	101
Pearson chi2 (3) = 2.6444 Pr = 0.450			
Incident investigation management			
Entirely disagree	2	0	2
Disagree	12	2	14
Agree	37	9	46
Entirely agree	36	5	41
Total	87	16	103
Pearson chi2 (3) = 1.3025 Pr = 0.729			
Division meeting: serious incident panel review one			
Entirely disagree	1	0	1
Disagree	5	3	8
Agree	49	4	53
Entirely agree	33	6	39
Total	88	13	101
Pearson chi2 (3) = 6.0341 Pr = 0.110			
Corporate meeting: serious incident panel review two			
Disagree	7	2	9
Agree	42	4	46
Entirely agree	34	7	41
Total	83	13	96
Pearson chi2 (2) = 1.9387 Pr = 0.379			
Closure of investigation			
Entirely disagree	2	0	2
Disagree	3	1	4
Agree	40	5	45
Entirely agree	38	8	46

Total	83	14	97
Pearson chi2 (3) = 1.4271 Pr = 0.699			
Production of incident investigation report for commissioner			
Entirely disagree	2	1	3
Disagree	6	1	7
Agree	40	8	48
Entirely agree	34	4	38
Total	82	14	96
Pearson chi2 (3) = 1.5165 Pr = 0.678			
Surveillance of latest patient safety information			
Entirely disagree	3	1	4
Disagree	9	1	10
Agree	43	6	49
Entirely agree	22	6	28
Total	77	14	91
Pearson chi2 (3) = 1.6636 Pr = 0.645			
Implementation of existing or new guidelines or policies			
Entirely disagree	2	1	3
Disagree	6	2	8
Agree	49	7	56
Entirely agree	30	6	36
Total	87	16	103
Pearson chi2 (3) = 1.6988 Pr = 0.637			
Data preparation for performance reporting to NRLS			
Entirely disagree	2	0	2
Disagree	3	2	5
Agree	34	7	41
Entirely agree	32	3	35
Total	71	12	83
Pearson chi2 (3) = 4.1829 Pr = 0.242			
Production of organisation performance report for NRLS			
Entirely disagree	2	0	2
Disagree	5	3	8
Agree	31	7	38

Entirely agree	29	2	31
Total	67	12	79
Pearson chi2 (3) = 5.5946 Pr = 0.133			
Production of organisation performance report for commissioner			
Entirely disagree	2	0	2
Disagree	4	3	7
Agree	32	5	37
Entirely agree	28	4	32
Total	66	12	78
Pearson chi2 (3) = 4.7261 Pr = 0.193			
Connect: 'Allocate submitted incident reports to investigators' with 'Ward-level investigation'			
Entirely disagree	1	0	1
Disagree	4	1	5
Agree	34	8	42
Entirely agree	18	3	21
Total	57	12	69
Pearson chi2 (3) = 0.4554 Pr = 0.929			
Connect: 'Local meeting: risk manager discussion of incident details and actions' with 'Incident report database management' (after first formal investigation)			
Entirely disagree	3	0	3
Disagree	8	0	8
Agree	32	12	44
Entirely agree	23	2	25
Total	66	14	80
Pearson chi2 (3) = 6.8068 Pr = 0.078			
Connect: 'Local meeting: risk manager discussion of incident details and actions' with 'Incident report database management' (after second formal investigation)			
Entirely disagree	2	0	2
Disagree	11	1	12
Agree	23	8	31
Entirely agree	24	2	26
Total	60	11	71
Pearson chi2 (3) = 4.5634 Pr = 0.207			
Connect: 'Local meeting: audit or MDT [meeting] or M&M [meeting]' with 'Local performance management of individuals'			

Disagree	11	1	12
Agree	35	7	42
Entirely agree	17	1	18
Total	63	9	72
Pearson chi2 (2) = 1.6508 Pr = 0.438			
Connect: 'Production of patient safety information materials' with 'Ward meeting: patient safety'			
Entirely disagree	3	1	4
Disagree	9	2	11
Agree	36	3	39
Entirely agree	14	2	16
Total	62	8	70
Pearson chi2 (3) = 1.7794 Pr = 0.619			
Connect: 'Production of patient safety information materials' with 'Local meeting: audit or MDT or M&M'			
Entirely disagree	3	0	3
Disagree	16	2	18
Agree	26	5	31
Entirely agree	16	3	19
Total	61	10	71
Pearson chi2 (3) = 0.7760 Pr = 0.855			
Connect: 'Review or development of guidelines, policies and feedback' with 'Production of patient safety information materials'			
Entirely disagree	2	1	3
Disagree	19	1	20
Agree	31	4	35
Entirely agree	21	4	25
Total	73	10	83
Pearson chi2 (3) = 2.6014 Pr = 0.457			
Connect: 'Closure of investigation' with 'Local meeting: audit or MDT or M&M'			
Disagree	3	2	5
Agree	33	6	39
Entirely agree	19	2	21
Total	55	10	65
Pearson chi2 (2) = 2.8814 Pr = 0.237			
Connect: 'Surveillance of latest patient safety information' with 'Production of patient			

safety information materials'			
Entirely disagree	2	2	4
Disagree	9	3	12
Agree	38	4	42
Entirely agree	14	2	16
Total	63	11	74
Pearson chi2 (3) = 5.8934 Pr = 0.117			

C.8. Cross tables exploring statistical differences between groups by last involvement in incident reporting system

	Last IRS use		
	Less than 6 months	More than 6 months	Total
	No. Obs	No. Obs	No. Obs
Discuss incident with patient and/or relative(s)			
Entirely disagree	2	0	2
Disagree	13	1	14
Agree	45	12	57
Entirely agree	52	10	62
Total	112	23	135
Pearson chi2 (3) = 2.0668 Pr = 0.559			
Pre-report discussion of incident details and severity			
Entirely disagree	10	0	10
Disagree	16	3	19
Agree	48	13	61
Entirely agree	35	6	41
Total	109	22	131
Pearson chi2 (3) = 3.0598 Pr = 0.382			
Locate a computer on which to enter an incident report			
Entirely disagree	4	1	5
Disagree	5	2	7
Agree	44	7	51
Entirely agree	63	13	76
Total	116	23	139
Pearson chi2 (3) = 1.0873 Pr = 0.780			
Complete an incident report online			
Entirely disagree	4	2	6
Disagree	4	0	4

Agree	38	8	46
Entirely agree	70	14	84
Total	116	24	140
Pearson chi2 (3) = 1.9503 Pr = 0.583			
Post-report discussion of incident and next steps			
Entirely disagree	7	0	7
Disagree	19	3	22
Agree	46	15	61
Entirely agree	35	4	39
Total	107	22	129
Pearson chi2 (3) = 5.3439 Pr = 0.148			
Ward-level investigation			
Entirely disagree	2	0	2
Disagree	10	2	12
Agree	43	9	52
Entirely agree	45	10	55
Total	100	21	121
Pearson chi2 (3) = 0.4502 Pr = 0.930			
Ward meeting: patient safety			
Entirely disagree	11	1	12
Disagree	26	3	29
Agree	44	6	50
Entirely agree	23	12	35
Total	104	22	126
Pearson chi2 (3) = 9.6220 Pr = 0.022			
Local performance management of individuals			
Entirely disagree	4	1	5
Disagree	33	4	37
Agree	40	10	50
Entirely agree	23	5	28
Total	100	20	120
Pearson chi2 (3) = 1.3821 Pr = 0.710			
Review medical records			
Entirely disagree	4	0	4

Disagree	8	3	11
Agree	42	6	48
Entirely agree	54	12	66
Total	108	21	129
Pearson chi2 (3) = 2.4315 Pr = 0.488			
Incident investigation triage			
Entirely disagree	3	1	4
Disagree	14	3	17
Agree	46	8	54
Entirely agree	36	11	47
Total	99	23	122
Pearson chi2 (3) = 1.3269 Pr = 0.723			
Allocate submitted incident reports to investigators			
Entirely disagree	2	0	2
Disagree	7	2	9
Agree	37	10	47
Entirely agree	55	10	65
Total	101	22	123
Pearson chi2 (3) = 1.1957 Pr = 0.754			
Incident report database management			
Disagree	5	1	6
Agree	44	12	56
Entirely agree	42	9	51
Total	91	22	113
Pearson chi2 (2) = 0.2752 Pr = 0.871			
First formal investigation of incident report			
Entirely disagree	0	1	1
Disagree	8	2	10
Agree	49	11	60
Entirely agree	39	8	47
Total	96	22	118
Pearson chi2 (3) = 4.4612 Pr = 0.216			
Local meeting: risk managers' discussion of incident details and actions			
Disagree	7	1	8

Agree	52	12	64
Entirely agree	36	8	44
Total	95	21	116
Pearson chi2 (2) = 0.1877 Pr = 0.910			
Second formal investigation of incident report (serious incident)			
Entirely disagree	1	0	1
Disagree	14	3	17
Agree	38	11	49
Entirely agree	36	5	41
Total	89	19	108
Pearson chi2 (3) = 1.8345 Pr = 0.607			
Local meeting (2): risk managers' discussion of incident details and actions			
Entirely disagree	1	0	1
Disagree	15	3	18
Agree	42	10	52
Entirely agree	31	5	36
Total	89	18	107
Pearson chi2 (3) = 0.6395 Pr = 0.887			
Local meeting: audit or MDT or M&M			
Entirely disagree	3	0	3
Disagree	6	2	8
Agree	55	8	63
Entirely agree	31	8	39
Total	95	18	113
Pearson chi2 (3) = 2.1628 Pr = 0.539			
Production of patient safety information materials			
Entirely disagree	3	1	4
Disagree	17	0	17
Agree	38	6	44
Entirely agree	17	5	22
Total	75	12	87
Pearson chi2 (3) = 4.6202 Pr = 0.202			
Review or development of guidelines, policies, and feedback			
Entirely disagree	2	0	2

Disagree	12	3	15
Agree	42	3	45
Entirely agree	27	9	36
Total	83	15	98
Pearson chi2 (3) = 5.8170 Pr = 0.121			
Third formal investigation (level one concise investigation)			
Entirely disagree	6	2	8
Disagree	15	5	20
Agree	37	6	43
Entirely agree	27	3	30
Total	85	16	101
Pearson chi2 (3) = 2.6444 Pr = 0.450			
Incident investigation management			
Entirely disagree	2	0	2
Disagree	12	2	14
Agree	37	9	46
Entirely agree	36	5	41
Total	87	16	103
Pearson chi2 (3) = 1.3025 Pr = 0.729			
Division meeting: serious incident panel review one			
Entirely disagree	1	0	1
Disagree	5	3	8
Agree	49	4	53
Entirely agree	33	6	39
Total	88	13	101
Pearson chi2 (3) = 6.0341 Pr = 0.110			
Corporate meeting: serious incident panel review two			
Disagree	7	2	9
Agree	42	4	46
Entirely agree	34	7	41
Total	83	13	96
Pearson chi2 (2) = 1.9387 Pr = 0.379			
Closure of investigation			
Entirely disagree	2	0	2

Disagree	3	1	4
Agree	40	5	45
Entirely agree	38	8	46
Total	83	14	97
Pearson chi2 (3) = 1.4271 Pr = 0.699			
Production of incident investigation report for commissioner			
Entirely disagree	2	1	3
Disagree	6	1	7
Agree	40	8	48
Entirely agree	34	4	38
Total	82	14	96
Pearson chi2 (3) = 1.5165 Pr = 0.678			
Surveillance of latest patient safety information			
Entirely disagree	3	1	4
Disagree	9	1	10
Agree	43	6	49
Entirely agree	22	6	28
Total	77	14	91
Pearson chi2 (3) = 1.6636 Pr = 0.645			
Implementation of existing or new guidelines or policies			
Entirely disagree	2	1	3
Disagree	6	2	8
Agree	49	7	56
Entirely agree	30	6	36
Total	87	16	103
Pearson chi2 (3) = 1.6988 Pr = 0.637			
Data preparation for performance reporting to NRLS			
Entirely disagree	2	0	2
Disagree	3	2	5
Agree	34	7	41
Entirely agree	32	3	35
Total	71	12	83
Pearson chi2 (3) = 4.1829 Pr = 0.242			
Production of organisation performance report for NRLS			

Entirely disagree	2	0	2
Disagree	5	3	8
Agree	31	7	38
Entirely agree	29	2	31
Total	67	12	79
Pearson chi2 (3) = 5.5946 Pr = 0.133			
Production of organisation performance report for commissioner			
Entirely disagree	2	0	2
Disagree	4	3	7
Agree	32	5	37
Entirely agree	28	4	32
Total	66	12	78
Pearson chi2 (3) = 4.7261 Pr = 0.193			
Connect: 'Allocate submitted incident reports to investigators' with 'Ward-level investigation'			
Entirely disagree	1	0	1
Disagree	4	1	5
Agree	34	8	42
Entirely agree	18	3	21
Total	57	12	69
Pearson chi2 (3) = 0.4554 Pr = 0.929			
Connect: 'Local meeting: risk managers' discussion of incident details and actions' with 'Incident report database management' (after first formal investigation)			
Entirely disagree	3	0	3
Disagree	8	0	8
Agree	32	12	44
Entirely agree	23	2	25
Total	66	14	80
Pearson chi2 (3) = 6.8068 Pr = 0.078			
Connect: 'Local meeting: risk managers' discussion of incident details and actions' with 'Incident report database management' (after second formal investigation)			
Entirely disagree	2	0	2
Disagree	11	1	12
Agree	23	8	31
Entirely agree	24	2	26
Total	60	11	71
Pearson chi2 (3) = 4.5634 Pr = 0.207			

Connect: 'Local meeting: audit or MDT [meeting] or M&M [meeting];' with 'Local performance management of individuals'			
Disagree	11	1	12
Agree	35	7	42
Entirely agree	17	1	18
Total	63	9	72
Pearson chi2 (2) = 1.6508 Pr = 0.438			
Connect: 'Production of patient safety information materials' with 'Ward meeting: patient safety'			
Entirely disagree	3	1	4
Disagree	9	2	11
Agree	36	3	39
Entirely agree	14	2	16
Total	62	8	70
Pearson chi2 (3) = 1.7794 Pr = 0.619			
Connect: 'Production of patient safety information materials' with 'Local meeting: audit or MDT or M&M'			
Entirely disagree	3	0	3
Disagree	16	2	18
Agree	26	5	31
Entirely agree	16	3	19
Total	61	10	71
Pearson chi2 (3) = 0.7760 Pr = 0.855			
Connect: 'Review or development of guidelines, policies and feedback' with 'Production of patient safety information materials'			
Entirely disagree	2	1	3
Disagree	19	1	20
Agree	31	4	35
Entirely agree	21	4	25
Total	73	10	83
Pearson chi2 (3) = 2.6014 Pr = 0.457			
Connect: 'Closure of investigation' with 'Local meeting: audit or MDT or M&M'			
Disagree	3	2	5
Agree	33	6	39
Entirely agree	19	2	21
Total	55	10	65

Pearson chi2 (2) = 2.8814 Pr = 0.237			
Connect: 'Surveillance of latest patient safety information' with 'Production of patient safety information materials'			
Entirely disagree	2	2	4
Disagree	9	3	12
Agree	38	4	42
Entirely agree	14	2	16
Total	63	11	74
Pearson chi2 (3) = 5.8934 Pr = 0.117			
	Last IRS involvement		
	Less than 6 months	More than 6 months	Total
	No. Obs	No. Obs	No. Obs
Discuss incident with patient and/or relative(s)			
Entirely disagree	2	0	2
Disagree	13	1	14
Agree	43	5	48
Entirely agree	45	5	50
Total	103	11	114
Pearson chi2 (3) = 0.3540 Pr = 0.950			
Pre-report discussion of incident details and severity			
Entirely disagree	10	0	10
Disagree	16	1	17
Agree	41	6	47
Entirely agree	33	3	36
Total	100	10	110
Pearson chi2 (3) = 2.0048 Pr = 0.571			
Locate a computer on which to enter an incident report			
Entirely disagree	4	1	5
Disagree	5	2	7
Agree	40	1	41
Entirely agree	58	7	65
Total	107	11	118
Pearson chi2 (3) = 6.2018 Pr = 0.102			
Complete an incident report online			
Entirely disagree	3	1	4
Disagree	4	0	4

Agree	35	3	38
Entirely agree	65	8	73
Total	107	12	119
Pearson chi2 (3) = 1.6926 Pr = 0.639			
Post-report discussion of incident and next steps			
Entirely disagree	6	0	6
Disagree	16	1	17
Agree	44	7	51
Entirely agree	34	3	37
Total	100	11	111
Pearson chi2 (3) = 1.9351 Pr = 0.586			
Ward-level investigation			
Entirely disagree	2	0	2
Disagree	8	0	8
Agree	41	7	48
Entirely agree	44	4	48
Total	95	11	106
Pearson chi2 (3) = 2.2865 Pr = 0.515			
Ward meeting: patient safety			
Entirely disagree	11	0	11
Disagree	24	2	26
Agree	40	3	43
Entirely agree	23	7	30
Total	98	12	110
Pearson chi2 (3) = 7.0726 Pr = 0.070			
Local performance management of individuals			
Entirely disagree	4	1	5
Disagree	29	2	31
Agree	39	4	43
Entirely agree	23	2	25
Total	95	9	104
Pearson chi2 (3) = 1.0409 Pr = 0.791			
Review medical records			
Entirely disagree	3	0	3

Disagree	8	3	11
Agree	39	3	42
Entirely agree	51	4	55
Total	101	10	111
Pearson chi2 (3) = 5.1538 Pr = 0.161			
Incident investigation triage			
Entirely disagree	3	1	4
Disagree	14	2	16
Agree	42	6	48
Entirely agree	35	3	38
Total	94	12	106
Pearson chi2 (3) = 1.2785 Pr = 0.734			
Allocate submitted incident reports to investigators			
Entirely disagree	2	0	2
Disagree	7	2	9
Agree	33	7	40
Entirely agree	54	2	56
Total	96	11	107
Pearson chi2 (3) = 6.6139 Pr = 0.085			
Incident report database management			
Disagree	5	1	6
Agree	42	7	49
Entirely agree	41	3	44
Total	88	11	99
Pearson chi2 (2) = 1.5085 Pr = 0.470			
First formal investigation of incident report			
Disagree	8	0	8
Agree	45	8	53
Entirely agree	39	3	42
Total	92	11	103
Pearson chi2 (2) = 2.5901 Pr = 0.274			
Local meeting: risk managers' discussion of incident details and actions			
Disagree	7	0	7
Agree	49	7	56

Entirely agree	36	4	40
Total	92	11	103
Pearson chi2 (2) = 1.0509 Pr = 0.591			
Second formal investigation of incident report (serious incident)			
Entirely disagree	1	0	1
Disagree	14	3	17
Agree	35	6	41
Entirely agree	36	1	37
Total	86	10	96
Pearson chi2 (3) = 4.2096 Pr = 0.240			
Local meeting (2): risk managers' discussion of incident details and actions			
Entirely disagree	1	0	1
Disagree	13	2	15
Agree	40	4	44
Entirely agree	31	3	34
Total	85	9	94
Pearson chi2 (3) = 0.3847 Pr = 0.943			
Local meeting: audit or MDT or M&M			
Entirely disagree	3	0	3
Disagree	5	0	5
Agree	51	5	56
Entirely agree	31	5	36
Total	90	10	100
Pearson chi2 (3) = 1.5653 Pr = 0.667			
Production of patient safety information materials			
Entirely disagree	3	0	3
Disagree	15	0	15
Agree	36	4	40
Entirely agree	16	3	19
Total	70	7	77
Pearson chi2 (3) = 2.8716 Pr = 0.412			
Review or development of guidelines, policies, and feedback			
Entirely disagree	2	0	2
Disagree	12	1	13

Agree	41	2	43
Entirely agree	26	5	31
Total	81	8	89
Pearson chi2 (3) = 3.1451 Pr = 0.370			
Third formal investigation (level one concise investigation)			
Entirely disagree	6	1	7
Disagree	15	1	16
Agree	35	3	38
Entirely agree	26	3	29
Total	82	8	90
Pearson chi2 (3) = 0.5116 Pr = 0.916			
Incident investigation management			
Entirely disagree	2	0	2
Disagree	11	1	12
Agree	36	5	41
Entirely agree	35	2	37
Total	84	8	92
Pearson chi2 (3) = 1.3294 Pr = 0.722			
Division meeting: serious incident panel review one			
Entirely disagree	1	0	1
Disagree	5	2	7
Agree	47	3	50
Entirely agree	32	2	34
Total	85	7	92
Pearson chi2 (3) = 4.7863 Pr = 0.188			
Corporate meeting: serious incident panel review two			
Disagree	7	1	8
Agree	40	2	42
Entirely agree	33	4	37
Total	80	7	87
Pearson chi2 (2) = 1.2090 Pr = 0.546			
Closure of investigation			
Entirely disagree	2	0	2
Disagree	3	0	3

Agree	39	3	42
Entirely agree	36	5	41
Total	80	8	88
Pearson chi2 (3) = 1.1709 Pr = 0.760			
Production of incident investigation report for commissioner			
Entirely disagree	2	0	2
Disagree	6	1	7
Agree	37	4	41
Entirely agree	34	3	37
Total	79	8	87
Pearson chi2 (3) = 0.4876 Pr = 0.922			
Surveillance of latest patient safety information			
Entirely disagree	3	0	3
Disagree	9	0	9
Agree	41	3	44
Entirely agree	21	4	25
Total	74	7	81
Pearson chi2 (3) = 3.0349 Pr = 0.386			
Implementation of existing or new guidelines or policies			
Entirely disagree	2	0	2
Disagree	6	1	7
Agree	47	3	50
Entirely agree	29	4	33
Total	84	8	92
Pearson chi2 (3) = 1.4113 Pr = 0.703			
Data preparation for performance reporting to NRLS			
Entirely disagree	2	0	2
Disagree	3	1	4
Agree	32	3	35
Entirely agree	31	2	33
Total	68	6	74
Pearson chi2 (3) = 1.9041 Pr = 0.593			
Production of organisation performance report for NRLS			
Entirely disagree	2	0	2

Disagree	5	1	6
Agree	29	3	32
Entirely agree	28	2	30
Total	64	6	70
Pearson chi2 (3) = 0.8545 Pr = 0.836			
Production of organisation performance report for commissioner			
Entirely disagree	2	0	2
Disagree	4	2	6
Agree	29	2	31
Entirely agree	28	2	30
Total	63	6	69
Pearson chi2 (3) = 5.1300 Pr = 0.163			
Connect: 'Allocate submitted incident reports to investigators' with 'Ward-level investigation'			
Entirely disagree	1	0	1
Disagree	3	1	4
Agree	33	5	38
Entirely agree	17	1	18
Total	54	7	61
Pearson chi2 (3) = 1.5767 Pr = 0.665			
Connect: 'Local meeting: risk managers' discussion of incident details and actions' with 'Incident report database management' (after first formal investigation)			
Entirely disagree	3	0	3
Disagree	6	0	6
Agree	31	7	38
Entirely agree	23	0	23
Total	63	7	70
Pearson chi2 (3) = 6.5497 Pr = 0.088			
Connect: 'Local meeting: risk managers' discussion of incident details and actions' with 'Incident report database management' (after second formal investigation)			
Entirely disagree	2	0	2
Disagree	11	1	12
Agree	21	5	26
Entirely agree	24	0	24
Total	58	6	64
Pearson chi2 (3) = 5.6776 Pr = 0.128			

Connect: 'Local meeting: audit or MDT [meeting] or M&M [meeting]' with 'Local performance management of individuals'			
Disagree	9	0	9
Agree	33	5	38
Entirely agree	17	0	17
Total	59	5	64
Pearson chi2 (2) = 3.7110 Pr = 0.156			
Connect: 'Production of patient safety information materials' with 'Ward meeting: patient safety'			
Entirely disagree	3	1	4
Disagree	9	1	10
Agree	33	1	34
Entirely agree	14	1	15
Total	59	4	63
Pearson chi2 (3) = 3.2309 Pr = 0.357			
Connect: 'Production of patient safety information materials' with 'Local meeting: audit or MDT or M&M'			
Entirely disagree	3	0	3
Disagree	16	1	17
Agree	24	3	27
Entirely agree	15	1	16
Total	58	5	63
Pearson chi2 (3) = 0.7915 Pr = 0.852			
Connect: 'Review or development of guidelines, policies, and feedback' with 'Production of patient safety information materials'			
Entirely disagree	2	0	2
Disagree	18	0	18
Agree	30	3	33
Entirely agree	20	2	22
Total	70	5	75
Pearson chi2 (3) = 1.9481 Pr = 0.583			
Connect: 'Closure of investigation' with 'Local meeting: audit or MDT or M&M'			
Disagree	3	1	4
Agree	32	3	35
Entirely agree	18	2	20
Total	53	6	59
Pearson chi2 (2) = 1.0615 Pr = 0.588			

Connect: 'Surveillance of latest patient safety information' with 'Production of patient safety information materials'			
Entirely disagree	2	1	3
Disagree	9	1	10
Agree	36	1	37
Entirely agree	13	2	15
Total	60	5	65
Pearson chi2 (3) = 4.8223 Pr = 0.185			

C.9. Cross tables exploring statistical differences between groups by type of patient safety training received

	Type training received					
	Statutory mandatory	General patient safety	Datix software	Other	Multiple entries	Total
	No. Obs	No. Obs	No. Obs	No. Obs	No. Obs	No. Obs
Discuss incident with patient and/or relative(s)						
Entirely disagree	1	0	0	0	1	2
Disagree	4	0	1	2	5	12
Agree	24	7	2	26	5	64
Entirely agree	24	3	2	26	2	57
Total	53	10	5	54	13	135
Pearson chi2 (12) = 25.1348 Pr = 0.014						
Pre-report discussion of incident details and severity						
Entirely disagree	3	1	0	4	2	10
Disagree	8	2	0	6	2	18
Agree	25	7	4	22	8	66
Entirely agree	15	0	0	19	2	36
Total	51	10	4	51	14	130
Pearson chi2 (12) = 12.3904 Pr = 0.415						
Locate a computer on which to enter an incident report						
Entirely disagree	2	2	0	1	0	5
Disagree	2	0	1	1	3	7
Agree	15	4	1	25	7	52
Entirely agree	36	4	3	27	5	75

Total	55	10	5	54	15	139
Pearson chi2 (12) = 25.8530 Pr = 0.011						
Complete an incident report online						
Entirely disagree	1	3	0	2	0	6
Disagree	1	0	0	1	1	3
Agree	16	3	2	22	6	49
Entirely agree	37	4	3	29	8	81
Total	55	10	5	54	15	139
Pearson chi2 (12) = 21.6328 Pr = 0.042						
Post-report discussion of incident and next steps						
Entirely disagree	4	0	0	2	1	7
Disagree	9	3	0	10	2	24
Agree	19	6	3	25	10	63
Entirely agree	19	1	2	13	1	36
Total	51	10	5	50	14	130
Pearson chi2 (12) = 12.0540 Pr = 0.441						
Ward-level investigation						
Entirely disagree	1	0	0	1	0	2
Disagree	5	2	0	7	1	15
Agree	17	3	1	21	9	51
Entirely agree	20	5	3	18	4	50
Total	43	10	4	47	14	118
Pearson chi2 (12) = 6.5480 Pr = 0.886						
Ward meeting: patient safety						
Entirely disagree	4	1	0	6	3	14
Disagree	11	3	1	9	1	25
Agree	21	2	2	20	6	51
Entirely agree	13	4	0	16	4	37
Total	49	10	3	51	14	127
Pearson chi2 (12) = 7.4901 Pr = 0.824						

Local performance management of individuals						
Entirely disagree	2	0	1	2	1	6
Disagree	12	5	1	16	3	37
Agree	18	5	1	21	6	51
Entirely agree	13	0	1	12	1	27
Total	45	10	4	51	11	121
Pearson chi2 (12) = 10.6975 Pr = 0.555						
Review medical records						
Entirely disagree	0	1	0	2	1	4
Disagree	4	2	1	3	1	11
Agree	16	4	3	19	8	50
Entirely agree	25	3	1	27	5	61
Total	45	10	5	51	15	126
Pearson chi2 (12) = 10.8735 Pr = 0.540						
Incident investigation triage						
Entirely disagree	2	1	0	2	0	5
Disagree	7	2	0	6	1	16
Agree	18	5	0	22	9	54
Entirely agree	15	2	5	17	3	42
Total	42	10	5	47	13	117
Pearson chi2 (12) = 14.1470 Pr = 0.291						
Allocate submitted incident reports to investigators						
Entirely disagree	0	1	0	1	0	2
Disagree	1	1	0	6	2	10
Agree	15	4	2	17	9	47
Entirely agree	25	4	3	24	3	59
Total	41	10	5	48	14	118
Pearson chi2 (12) = 14.8373 Pr = 0.250						
Incident report database management						
Entirely disagree	1	0	0	1	0	2

Disagree	2	2	0	3	0	7
Agree	16	5	1	22	11	55
Entirely agree	18	2	4	21	3	48
Total	37	9	5	47	14	112
Pearson chi2 (12) = 13.6629 Pr = 0.323						
First formal investigation of incident report						
Entirely disagree	1	0	0	1	0	2
Disagree	4	1	0	3	3	11
Agree	19	7	1	24	7	58
Entirely agree	15	2	4	19	4	44
Total	39	10	5	47	14	115
Pearson chi2 (12) = 9.0090 Pr = 0.702						
Local meeting: risk managers' discussion of incident details and actions						
Disagree	3	2	0	3	1	9
Agree	20	6	3	27	8	64
Entirely agree	16	2	1	18	4	41
Total	39	10	4	48	13	114
Pearson chi2 (8) = 4.0998 Pr = 0.848						
Second formal investigation of incident report (serious incident)						
Entirely disagree	1	0	0	1	0	2
Disagree	6	1	0	7	3	17
Agree	16	6	1	18	7	48
Entirely agree	12	2	3	19	3	39
Total	35	9	4	45	13	106
Pearson chi2 (12) = 6.8575 Pr = 0.867						
Local meeting (2): risk managers' discussion of incident details and actions						
Entirely disagree	2	0	0	0	0	2
Disagree	8	1	1	8	2	20
Agree	17	2	3	19	9	50
Entirely agree	9	5	1	16	1	32
Total	36	8	5	43	12	104

Pearson chi2 (12) = 12.9076 Pr = 0.376						
Local meeting: audit or MDT or M&M						
Entirely disagree	3	0	0	0	0	3
Disagree	4	1	1	3	0	9
Agree	18	6	2	24	9	59
Entirely agree	10	3	1	20	2	36
Total	35	10	4	47	11	107
Pearson chi2 (12) = 13.0414 Pr = 0.366						
Production of patient safety information materials						
Entirely disagree	1	0	0	1	2	4
Disagree	5	2	1	4	3	15
Agree	14	4	1	19	2	40
Entirely agree	7	2	0	11	1	21
Total	27	8	2	35	8	80
Pearson chi2 (12) = 13.6336 Pr = 0.325						
Review or development of guidelines, policies, and feedback						
Entirely disagree	1	0	0	0	0	1
Disagree	2	1	1	9	2	15
Agree	16	4	2	14	6	42
Entirely agree	12	2	0	18	2	34
Total	31	7	3	41	10	92
Pearson chi2 (12) = 10.2049 Pr = 0.598						
Third formal investigation (level one concise investigation)						
Entirely disagree	2	0	0	3	1	6
Disagree	6	2	1	8	0	17
Agree	14	3	2	18	5	42
Entirely agree	9	1	1	14	5	30
Total	31	6	4	43	11	95
Pearson chi2 (12) = 5.0903 Pr = 0.955						

Incident investigation management						
Entirely disagree	1	0	0	0	1	2
Disagree	5	1	1	5	0	12
Agree	13	4	1	22	5	45
Entirely agree	13	1	2	18	5	39
Total	32	6	4	45	11	98
Pearson chi2 (12) = 8.5375 Pr = 0.742						
Division meeting: serious incident panel review one						
Entirely disagree	0	0	0	0	1	1
Disagree	3	1	0	2	0	6
Agree	13	3	3	23	8	50
Entirely agree	15	2	1	17	2	37
Total	31	6	4	42	11	94
Pearson chi2 (12) = 14.2867 Pr = 0.283						
Corporate meeting: serious incident panel review two						
Disagree	5	0	1	1	1	8
Agree	10	4	2	24	5	45
Entirely agree	14	2	0	16	4	36
Total	29	6	3	41	10	89
Pearson chi2 (8) = 10.8924 Pr = 0.208						
Closure of investigation						
Entirely disagree	1	0	0	1	0	2
Disagree	1	0	0	3	0	4
Agree	10	4	2	21	5	42
Entirely agree	17	3	1	17	5	43
Total	29	7	3	42	10	91
Pearson chi2 (12) = 5.1599 Pr = 0.952						
Production of incident investigation report for commissioner						
Entirely disagree	1	0	0	1	1	3
Disagree	3	0	0	2	1	6
Agree	14	4	1	22	4	45

Entirely agree	10	2	3	16	5	36
Total	28	6	4	41	11	90
Pearson chi2 (12) = 6.0429 Pr = 0.914						
Surveillance of latest patient safety information						
Entirely disagree	1	0	0	2	1	4
Disagree	1	1	0	5	2	9
Agree	14	4	2	20	4	44
Entirely agree	10	1	1	14	3	29
Total	26	6	3	41	10	86
Pearson chi2 (12) = 5.1660 Pr = 0.952						
Implementation of existing or new guidelines or policies						
Entirely disagree	1	0	0	2	0	3
Disagree	1	1	1	4	1	8
Agree	19	3	1	23	7	53
Entirely agree	10	2	2	16	3	33
Total	31	6	4	45	11	97
Pearson chi2 (12) = 5.4646 Pr = 0.941						
Data preparation for performance reporting to NRLS						
Entirely disagree	1	0	0	1	0	2
Disagree	2	0	0	3	0	5
Agree	11	5	1	16	6	39
Entirely agree	12	1	2	16	3	34
Total	26	6	3	36	9	80
Pearson chi2 (12) = 6.3263 Pr = 0.899						
Production of organisation performance report for NRLS						
Entirely disagree	1	0	0	0	0	1
Disagree	2	1	0	4	1	8
Agree	11	4	1	18	4	38
Entirely agree	11	1	1	14	3	30
Total	25	6	2	36	8	77

Pearson chi2 (12) = 4.2139 Pr = 0.979						
Production of organisation performance report for commissioner						
Entirely disagree	1	0	0	0	0	1
Disagree	2	1	0	4	0	7
Agree	11	4	1	16	5	37
Entirely agree	11	1	1	15	3	31
Total	25	6	2	35	8	76
Pearson chi2 (12) = 5.4576 Pr = 0.941						
Connect: 'Allocate submitted incident reports to investigators' with 'Ward-level investigation'						
Entirely disagree	0	0	0	2	0	2
Disagree	0	2	0	1	1	4
Agree	10	3	1	22	4	40
Entirely agree	10	1	1	6	2	20
Total	20	6	2	31	7	66
Pearson chi2 (12) = 17.6482 Pr = 0.127						
Connect: 'Local meeting: risk managers' discussion of incident details and actions' with 'Incident report database management' (after first formal investigation)						
Entirely disagree	1	0	1	0	1	3
Disagree	4	1	0	2	1	8
Agree	8	5	3	20	1	37
Entirely agree	12	0	0	11	2	25
Total	25	6	4	33	5	73
Pearson chi2 (12) = 21.0972 Pr = 0.049						
Connect: 'Local meeting: risk managers' discussion of incident details and actions' with 'Incident report database management' (after second formal investigation)						
Entirely disagree	1	0	0	0	1	2
Disagree	5	0	0	4	2	11
Agree	6	5	2	12	1	26
Entirely agree	10	1	1	12	1	25
Total	22	6	3	28	5	64
Pearson chi2 (12) = 15.7575 Pr = 0.203						

Connect: 'Local meeting: audit or MDT [meeting] or M&M [meeting]' with 'Local performance management of individuals'						
Disagree	2	1	0	7	1	11
Agree	18	3	2	11	4	38
Entirely agree	6	1	0	9	0	16
Total	26	5	2	27	5	65
Pearson chi2 (8) = 8.5768 Pr = 0.379						
Connect: 'Production of patient safety information materials' with 'Ward meeting: patient safety'						
Entirely disagree	1	0	1	0	2	4
Disagree	1	2	1	4	2	10
Agree	14	3	0	17	3	37
Entirely agree	7	1	1	5	2	16
Total	23	6	3	26	9	67
Pearson chi2 (12) = 17.8368 Pr = 0.121						
Connect: 'Production of patient safety information materials' with 'Local meeting: audit or MDT or M&M'						
Entirely disagree	1	0	0	0	2	3
Disagree	3	1	1	8	4	17
Agree	13	4	1	9	1	28
Entirely agree	7	3	0	8	0	18
Total	24	8	2	25	7	66
Pearson chi2 (12) = 21.6459 Pr = 0.042						
Connect: 'Review or development of guidelines, policies, and feedback' with 'Production of patient safety information materials'						
Entirely disagree	1	0	0	1	1	3
Disagree	3	3	0	8	3	17
Agree	13	3	3	11	4	34
Entirely agree	8	2	0	11	2	23
Total	25	8	3	31	10	77
Pearson chi2 (12) = 9.3403 Pr = 0.674						
Connect: 'Closure of investigation' with 'Local meeting: audit or MDT or M&M'						
Disagree	1	1	0	3	0	5
Agree	8	5	2	13	6	34

Entirely agree	10	1	1	7	1	20
Total	19	7	3	23	7	59
Pearson chi2 (8) = 7.5929 Pr = 0.474						
Connect: 'Surveillance of latest patient safety information' with 'Production of patient safety information materials'						
Entirely disagree	0	0	1	2	1	4
Disagree	1	2	0	6	2	11
Agree	14	3	1	16	3	37
Entirely agree	9	0	1	6	1	17
Total	24	5	3	30	7	69
Pearson chi2 (12) = 15.9267 Pr = 0.195						

C.10. Cross tables exploring statistical differences between groups by annotated process map

	Annotated question		
	No	Yes	Total
	No. Obs	No. Obs	No. Obs
Discuss incident with patient and/or relative(s)			
Entirely disagree	1	2	3
Disagree	10	4	14
Agree	57	8	65
Entirely agree	55	11	66
Total	123	25	148
Pearson chi2 (3) = 7.6302 Pr = 0.054			
Pre-report discussion of incident details and severity			
Entirely disagree	10	1	11
Disagree	15	5	20
Agree	58	11	69
Entirely agree	36	7	43
Total	119	24	143
Pearson chi2 (3) = 1.4756 Pr = 0.688			
Locate a computer on which to enter an incident report			
Entirely disagree	4	1	5
Disagree	7	1	8
Agree	47	9	56
Entirely agree	69	14	83

Total	127	25	152
Pearson chi2 (3) = 0.1530 Pr = 0.985			
Complete an incident report online			
Entirely disagree	3	3	6
Disagree	3	1	4
Agree	44	9	53
Entirely agree	78	12	90
Total	128	25	153
Pearson chi2 (3) = 5.8035 Pr = 0.122			
Post-report discussion of incident and next steps			
Entirely disagree	8	0	8
Disagree	21	4	25
Agree	54	13	67
Entirely agree	35	7	42
Total	118	24	142
Pearson chi2 (3) = 1.9418 Pr = 0.585			
Ward-level investigation			
Entirely disagree	2	0	2
Disagree	11	4	15
Agree	48	10	58
Entirely agree	47	9	56
Total	108	23	131
Pearson chi2 (3) = 1.3753 Pr = 0.711			
Ward meeting: patient safety			
Entirely disagree	13	1	14
Disagree	23	6	29
Agree	46	9	55
Entirely agree	32	8	40
Total	114	24	138
Pearson chi2 (3) = 1.4730 Pr = 0.689			
Local performance management of individuals			
Entirely disagree	6	0	6
Disagree	31	9	40
Agree	45	9	54

Entirely agree	28	4	32
Total	110	22	132
Pearson chi2 (3) = 2.5800 Pr = 0.461			
Review medical records			
Entirely disagree	3	1	4
Disagree	12	1	13
Agree	45	8	53
Entirely agree	55	15	70
Total	115	25	140
Pearson chi2 (3) = 1.9393 Pr = 0.585			
Incident investigation triage			
Entirely disagree	5	0	5
Disagree	15	3	18
Agree	51	10	61
Entirely agree	38	10	48
Total	109	23	132
Pearson chi2 (3) = 1.4950 Pr = 0.683			
Allocate submitted incident reports to investigators			
Entirely disagree	2	0	2
Disagree	8	3	11
Agree	46	8	54
Entirely agree	53	13	66
Total	109	24	133
Pearson chi2 (3) = 1.5765 Pr = 0.665			
Incident report database management			
Entirely disagree	2	0	2
Disagree	7	1	8
Agree	51	10	61
Entirely agree	43	9	52
Total	103	20	123
Pearson chi2 (3) = 0.5141 Pr = 0.916			
First formal investigation of incident report			
Entirely disagree	2	0	2
Disagree	7	4	11

Agree	58	8	66
Entirely agree	41	8	49
Total	108	20	128
Pearson chi2 (3) = 4.5918 Pr = 0.204			
Local meeting: risk managers' discussion of incident details and actions			
Disagree	8	1	9
Agree	58	14	72
Entirely agree	38	7	45
Total	104	22	126
Pearson chi2 (2) = 0.5617 Pr = 0.755			
Second formal investigation of incident report (serious incident)			
Entirely disagree	2	0	2
Disagree	18	1	19
Agree	44	10	54
Entirely agree	33	10	43
Total	97	21	118
Pearson chi2 (3) = 3.3684 Pr = 0.338			
Local meeting (2): risk managers' discussion of incident details and actions			
Entirely disagree	2	0	2
Disagree	15	5	20
Agree	48	9	57
Entirely agree	32	6	38
Total	97	20	117
Pearson chi2 (3) = 1.4085 Pr = 0.704			
Local meeting: audit or MDT or M&M			
Entirely disagree	2	1	3
Disagree	8	1	9
Agree	57	9	66
Entirely agree	32	9	41
Total	99	20	119
Pearson chi2 (3) = 2.0454 Pr = 0.563			
Production of patient safety information materials			
Entirely disagree	2	2	4
Disagree	12	5	17

Agree	42	5	47
Entirely agree	18	5	23
Total	74	17	91
Pearson chi2 (3) = 6.0142 Pr = 0.111			
Review or development of guidelines, policies, and feedback			
Entirely disagree	2	0	2
Disagree	8	7	15
Agree	39	8	47
Entirely agree	32	6	38
Total	81	21	102
Pearson chi2 (3) = 7.6590 Pr = 0.054			
Third formal investigation (level one concise investigation)			
Entirely disagree	8	0	8
Disagree	18	2	20
Agree	39	7	46
Entirely agree	21	10	31
Total	86	19	105
Pearson chi2 (3) = 7.1044 Pr = 0.069			
Incident investigation management			
Entirely disagree	1	1	2
Disagree	11	3	14
Agree	43	6	49
Entirely agree	33	9	42
Total	88	19	107
Pearson chi2 (3) = 2.9601 Pr = 0.398			
Division meeting: serious incident panel review one			
Entirely disagree	1	0	1
Disagree	7	1	8
Agree	48	8	56
Entirely agree	30	10	40
Total	86	19	105
Pearson chi2 (3) = 2.2250 Pr = 0.527			
Corporate meeting: serious incident panel review two			
Disagree	7	2	9

Agree	42	7	49
Entirely agree	32	10	42
Total	81	19	100
Pearson chi2 (2) = 1.3996 Pr = 0.497			
Closure of investigation			
Entirely disagree	2	0	2
Disagree	5	0	5
Agree	40	6	46
Entirely agree	35	13	48
Total	82	19	101
Pearson chi2 (3) = 4.7743 Pr = 0.189			
Production of incident investigation report for commissioner			
Entirely disagree	2	1	3
Disagree	6	1	7
Agree	42	9	51
Entirely agree	28	11	39
Total	78	22	100
Pearson chi2 (3) = 1.9055 Pr = 0.592			
Surveillance of latest patient safety information			
Entirely disagree	2	2	4
Disagree	8	2	10
Agree	42	10	52
Entirely agree	23	6	29
Total	75	20	95
Pearson chi2 (3) = 2.1295 Pr = 0.546			
Implementation of existing or new guidelines or policies			
Entirely disagree	0	3	3
Disagree	7	1	8
Agree	49	10	59
Entirely agree	30	7	37
Total	86	21	107
Pearson chi2 (3) = 12.8230 Pr = 0.005			
Data preparation for performance reporting to NRLS			
Entirely disagree	2	1	3

Disagree	4	1	5
Agree	35	8	43
Entirely agree	30	6	36
Total	71	16	87
Pearson chi2 (3) = 0.5275 Pr = 0.913			
Production of organisation performance report for NRLS			
Entirely disagree	1	1	2
Disagree	7	2	9
Agree	33	7	40
Entirely agree	25	7	32
Total	66	17	83
Pearson chi2 (3) = 1.3432 Pr = 0.719			
Production of organisation performance report for commissioner			
Entirely disagree	1	1	2
Disagree	7	1	8
Agree	33	6	39
Entirely agree	25	8	33
Total	66	16	82
Pearson chi2 (3) = 2.3274 Pr = 0.507			
Connect: 'Allocate submitted incident reports to investigators' with 'Ward-level investigation'			
Entirely disagree	2	0	2
Disagree	3	2	5
Agree	34	9	43
Entirely agree	16	6	22
Total	55	17	72
Pearson chi2 (3) = 1.6977 Pr = 0.637			
Connect: 'Local meeting: risk managers' discussion of incident details and actions' with 'Incident report database management' (after first formal investigation)			
Entirely disagree	3	0	3
Disagree	5	3	8
Agree	36	10	46
Entirely agree	22	4	26
Total	66	17	83
Pearson chi2 (3) = 2.6547 Pr = 0.448			

Connect: 'Local meeting: risk managers' discussion of incident details and actions' with 'Incident report database management' (after second formal investigation)			
Entirely disagree	2	0	2
Disagree	10	2	12
Agree	25	6	31
Entirely agree	22	6	28
Total	59	14	73
Pearson chi2 (3) = 0.6155 Pr = 0.893			
Connect: 'Local meeting: audit or MDT [meeting] or M&M [meeting]' with 'Local performance management of individuals'			
Disagree	10	2	12
Agree	33	10	43
Entirely agree	16	3	19
Total	59	15	74
Pearson chi2 (2) = 0.5696 Pr = 0.752			
Connect: 'Production of patient safety information materials' with 'Ward meeting: patient safety'			
Entirely disagree	3	1	4
Disagree	8	3	11
Agree	34	7	41
Entirely agree	15	2	17
Total	60	13	73
Pearson chi2 (3) = 1.2539 Pr = 0.740			
Connect: 'Production of patient safety information materials' with 'Local meeting: audit or MDT or M&M'			
Entirely disagree	2	1	3
Disagree	15	4	19
Agree	25	7	32
Entirely agree	19	1	20
Total	61	13	74
Pearson chi2 (3) = 3.2656 Pr = 0.352			
Connect: 'Review or development of guidelines, policies, and feedback' with 'Production of patient safety information materials'			
Entirely disagree	2	1	3
Disagree	12	8	20
Agree	31	6	37
Entirely agree	22	4	26
Total	67	19	86

Pearson chi2 (3) = 5.3684 Pr = 0.147			
Connect: 'Closure of investigation' with 'Local meeting: audit or MDT or M&M'			
Disagree	3	2	5
Agree	36	4	40
Entirely agree	16	6	22
Total	55	12	67
Pearson chi2 (2) = 4.6734 Pr = 0.097			
Connect: 'Surveillance of latest patient safety information' with 'Production of patient safety information materials'			
Entirely disagree	3	1	4
Disagree	8	4	12
Agree	37	6	43
Entirely agree	15	3	18
Total	63	14	77
Pearson chi2 (3) = 2.5214 Pr = 0.471			

C.11. Linear regression models for associations between demographic variables (predictors) and levels of agreement (response variable) by activity

Linear Regression with Robust Standard Errors: consenting participants (part 1)												
VARIABLES	(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)	(12)
	Discuss incident with patient and/or relative(s)	Pre-report discussion of incident details and severity	Locate a computer on which to enter an incident report	Complete an incident report online	Post-report discussion of incident and next steps	Ward-level investigation	Ward meeting: patient safety	Local performance management of individuals	Review medical records	Incident investigation triage	Allocate submitted incident reports to investigators	Incident report database management
clin_exp	-0.013 (0.015)	0.004 (0.018)	0.018 (0.012)	0.010 (0.012)	-0.012 (0.017)	0.002 (0.015)	0.010 (0.018)	-0.003 (0.018)	0.015 (0.013)	0.015 (0.018)	0.015 (0.010)	-0.015 (0.012)
safetyrat	0.125** (0.050)	0.106* (0.060)	0.045 (0.053)	0.072 (0.055)	0.047 (0.059)	0.066 (0.059)	0.018 (0.069)	-0.000 (0.065)	0.025 (0.048)	0.063 (0.054)	0.106** (0.041)	-0.066 (0.040)
anntraining	-0.018 (0.062)	0.064 (0.087)	-0.141** (0.067)	-0.031 (0.065)	0.034 (0.076)	-0.043 (0.076)	-0.017 (0.099)	-0.053 (0.086)	-0.062 (0.084)	0.058 (0.073)	-0.154** (0.064)	0.036 (0.058)
1.age	-0.264 (0.186)	-0.784*** (0.267)	0.051 (0.351)	-0.130 (0.288)	0.217 (0.415)	-0.344 (0.392)	-0.172 (0.315)	0.333 (0.521)	-0.146 (0.383)	0.307 (0.310)	0.115 (0.342)	-0.100 (0.261)
2.age	-0.271 (0.202)	-0.863*** (0.291)	0.038 (0.361)	-0.066 (0.280)	0.323 (0.375)	-0.453 (0.377)	-0.362 (0.310)	0.363 (0.543)	-0.195 (0.404)	0.071 (0.315)	-0.098 (0.346)	-0.106 (0.257)
3.age	-0.538 (0.373)	-0.998** (0.388)	-0.378 (0.500)	-0.290 (0.372)	0.293 (0.513)	-0.908* (0.482)	-0.754 (0.502)	-0.777 (0.641)	-0.187 (0.646)	0.170 (0.466)	-0.303 (0.413)	-0.692** (0.318)
1.irsexp	-0.192 (0.169)	0.122 (0.286)	-0.075 (0.262)	0.192 (0.243)	0.247 (0.257)	0.652** (0.293)	0.380 (0.314)	0.185 (0.270)	0.021 (0.296)	-0.400 (0.282)	-0.071 (0.229)	-0.144 (0.184)
1.lastirsuse	-0.097 (0.186)	0.299 (0.256)	0.038 (0.272)	0.130 (0.250)	0.099 (0.251)	0.414 (0.276)	0.843*** (0.319)	0.481* (0.271)	0.435 (0.294)	-0.146 (0.332)	-0.047 (0.243)	0.086 (0.159)
1.training	-0.007 (0.207)	-0.521 (0.344)	-0.715 (0.469)	-0.872* (0.507)	-0.355 (0.304)	0.110 (0.267)	-0.157 (0.389)	-0.557** (0.239)	-0.755** (0.358)	-0.465 (0.360)	-0.732** (0.363)	-0.731*** (0.244)
2.training	-0.083 (0.336)	0.226 (0.279)	-0.196 (0.377)	-0.055 (0.319)	0.089 (0.323)	0.354 (0.296)	-0.427 (0.623)	-0.841*** (0.306)	-0.619 (0.461)	0.964*** (0.200)	0.028 (0.202)	0.258 (0.165)
3.training	0.142 (0.134)	0.175 (0.210)	-0.033 (0.166)	-0.100 (0.164)	-0.289 (0.204)	-0.139 (0.188)	0.104 (0.233)	-0.072 (0.208)	-0.117 (0.174)	-0.054 (0.205)	-0.228 (0.159)	-0.102 (0.148)
4.training	-0.573** (0.278)	-0.169 (0.308)	-0.350 (0.256)	-0.067 (0.216)	-0.510* (0.280)	-0.133 (0.230)	-0.158 (0.385)	-0.389 (0.327)	-0.376 (0.280)	0.120 (0.243)	-0.356 (0.240)	-0.309* (0.179)
1.annotated	-0.197 (0.175)	0.141 (0.234)	0.030 (0.202)	-0.373 (0.226)	0.052 (0.190)	-0.105 (0.220)	0.124 (0.249)	-0.050 (0.205)	0.264 (0.197)	0.151 (0.222)	0.043 (0.200)	-0.021 (0.172)
Constant	2.967***	2.681***	3.332***	3.027***	2.389***	2.787***	2.531***	2.509***	3.398***	2.704***	3.103***	4.257***

	(0.390)	(0.457)	(0.617)	(0.486)	(0.565)	(0.485)	(0.515)	(0.654)	(0.416)	(0.496)	(0.447)	(0.369)
Observations	112	110	116	116	109	101	106	102	107	100	101	96
R-squared	0.312	0.143	0.125	0.169	0.069	0.133	0.089	0.147	0.115	0.142	0.200	0.195
AdjR-squared	0.221	0.0272	0.0134	0.0626	-0.0582	0.00305	-0.0394	0.0207	-0.00909	0.0129	0.0804	0.0678

Robust standard errors in parentheses

*** p < 0.01, ** p < 0.05, * p < 0.1

	Linear Regression with Robust Standard Errors: consenting participants (part 2)																	
	(13)	(14)	(15)	(16)	(17)	(18)	(19)	(20)	(21)	(22)	(23)	(24)	(25)	(26)	(27)	(28)	(29)	(30)
VARIABLES	First formal investigation of incident report	Local meeting: risk manager s' discussion of incident details and actions	Second formal investigation of incident report (serious incident)	Local meeting (2): risk manager s' discussion of incident details and actions	Local meeting: audit or MDT or M&M	Production of patient safety information materials	Review or development of guidelines, policies, and feedback	Third formal investigation (level one concise investigation)	Incident investigation on management	Division meeting: serious incident panel review one	Corporate meeting: serious incident panel review two	Closure of investigation	Production of incident investigation report for commissioner	Surveillance of latest patient safety information	Implementation of existing or new guidelines or policies	Data preparation for performance reporting to NRLS	Production of organisational performance report for NRLS	Production of organisational performance report for commissioner
clin_exp	0.023*	-0.008	0.019	-0.000	-0.017	0.045**	0.004	-0.006	-0.010	0.008	0.009	0.012	0.020	-0.018	-0.026	0.001	0.006	0.006
	(0.013)	(0.012)	(0.016)	(0.017)	(0.024)	(0.018)	(0.016)	(0.021)	(0.018)	(0.015)	(0.015)	(0.017)	(0.017)	(0.022)	(0.016)	(0.014)	(0.016)	(0.015)
safetyrat	0.072	0.079	0.053	0.080	-0.012	0.133	0.030	0.094	0.069	0.057	0.076	0.034	0.146**	-0.002	0.043	0.066	0.054	0.107
	(0.051)	(0.053)	(0.057)	(0.055)	(0.058)	(0.091)	(0.065)	(0.078)	(0.049)	(0.057)	(0.067)	(0.058)	(0.064)	(0.066)	(0.064)	(0.067)	(0.069)	(0.073)
annttraining	-0.002	-0.027	0.019	-0.049	0.017	0.224**	0.088	0.219**	0.107	0.105	0.025	-0.061	-0.004	0.228**	0.170**	0.049	0.051	0.078
	(0.068)	(0.063)	(0.091)	(0.082)	(0.074)	(0.089)	(0.086)	(0.093)	(0.086)	(0.080)	(0.079)	(0.080)	(0.080)	(0.107)	(0.081)	(0.068)	(0.073)	(0.074)
1.age	0.179	0.223	-0.053	-0.146	-0.078	0.205	-0.080	-0.255	-0.108	0.226	-0.186	0.316	0.260	0.231	0.875**	-0.137	-0.159	0.506
	(0.182)	(0.206)	(0.459)	(0.457)	(0.216)	(0.372)	(0.834)	(0.536)	(0.594)	(0.449)	(0.662)	(0.493)	(0.396)	(0.679)	(0.369)	(0.605)	(0.647)	(0.369)
2.age	0.151	0.236	0.089	-0.166	-0.143	0.471	0.220	-0.029	-0.010	0.437	-0.178	0.383	0.551	0.443	0.981**	0.155	0.018	0.720*
	(0.175)	(0.192)	(0.458)	(0.473)	(0.252)	(0.399)	(0.827)	(0.541)	(0.622)	(0.449)	(0.681)	(0.517)	(0.416)	(0.707)	(0.385)	(0.641)	(0.676)	(0.388)
3.age	-0.347	-0.091	-0.740	-0.657	0.111	0.697	0.075	-0.129	0.394	0.464	0.162	0.475	0.137	0.150	0.716	-0.272	-0.325	0.362
	(0.287)	(0.275)	(0.527)	(0.552)	(0.431)	(0.566)	(0.939)	(0.860)	(0.748)	(0.573)	(0.732)	(0.545)	(0.672)	(0.852)	(0.676)	(0.863)	(0.934)	(0.664)
1.irsexp	0.155	0.232	-0.224	0.373	0.218	-0.278	-0.806***	-0.029	-0.235	-0.364	0.194	-0.280	0.096	-0.414	-0.622**	-0.280	-0.033	-0.245
	(0.242)	(0.203)	(0.264)	(0.344)	(0.220)	(0.332)	(0.281)	(0.438)	(0.346)	(0.293)	(0.345)	(0.262)	(0.317)	(0.389)	(0.271)	(0.296)	(0.344)	(0.296)
1.lastirsuse	-0.039	0.211	0.032	0.061	0.231	0.080	-0.205	-0.355	-0.145	-0.171	0.204	0.043	-0.147	-0.182	-0.738**	-0.453	-0.487	-0.327
	(0.244)	(0.192)	(0.195)	(0.342)	(0.237)	(0.337)	(0.327)	(0.402)	(0.311)	(0.330)	(0.335)	(0.238)	(0.347)	(0.430)	(0.327)	(0.306)	(0.334)	(0.321)
1.training	-0.180	-0.539**	-0.223	0.500	0.014	0.037	-0.168	-0.356	-0.396	-0.395	-0.049	-0.222	0.079	-0.485**	-0.399	-0.263	-0.376*	-0.505**
	(0.255)	(0.251)	(0.251)	(0.314)	(0.228)	(0.273)	(0.210)	(0.219)	(0.243)	(0.314)	(0.240)	(0.244)	(0.303)	(0.230)	(0.330)	(0.211)	(0.210)	(0.243)
2.training	0.688***	0.158	0.876***	0.534*	-0.128	-0.602	-0.581	0.084	-0.069	0.165	-0.842***	-0.397	0.901***	-0.074	0.128	0.817***	0.670	0.775*
	(0.186)	(0.276)	(0.229)	(0.275)	(0.460)	(0.402)	(0.495)	(0.488)	(0.568)	(0.408)	(0.312)	(0.261)	(0.271)	(0.328)	(0.383)	(0.275)	(0.407)	(0.438)

3.training	0.112	-0.041	0.002	0.232	0.293	0.068	-0.051	-0.134	0.114	-0.027	0.097	-0.143	0.160	-0.232	-0.130	0.101	0.054	0.078
	(0.165)	(0.159)	(0.209)	(0.204)	(0.194)	(0.232)	(0.197)	(0.235)	(0.200)	(0.174)	(0.196)	(0.186)	(0.185)	(0.228)	(0.164)	(0.209)	(0.207)	(0.214)
4.training	-0.173	-0.063	-0.119	0.088	0.171	-0.661*	-0.119	0.145	0.141	-0.420	0.029	0.100	0.009	-0.416	-0.045	0.033	-0.025	0.084
	(0.252)	(0.223)	(0.272)	(0.253)	(0.253)	(0.354)	(0.292)	(0.378)	(0.355)	(0.290)	(0.278)	(0.278)	(0.318)	(0.337)	(0.263)	(0.280)	(0.318)	(0.305)
1.annotated	-0.083	0.040	0.288	0.005	0.007	-0.131	-0.445*	0.514**	-0.191	0.164	0.168	0.345*	0.133	-0.259	-0.454	0.058	-0.008	0.199
	(0.226)	(0.159)	(0.209)	(0.238)	(0.202)	(0.249)	(0.237)	(0.257)	(0.272)	(0.175)	(0.213)	(0.200)	(0.210)	(0.278)	(0.290)	(0.208)	(0.229)	(0.216)
Constant	2.352***	2.428***	2.782***	2.270***	3.073** *	1.318	3.515***	2.084**	2.808***	2.687** *	2.575***	3.059***	1.472**	3.073***	2.595***	2.935***	2.871***	1.915***
	(0.418)	(0.443)	(0.592)	(0.624)	(0.500)	(0.868)	(0.982)	(0.847)	(0.636)	(0.613)	(0.816)	(0.661)	(0.628)	(0.777)	(0.594)	(0.709)	(0.767)	(0.626)
Observations	99	98	90	89	97	71	82	87	87	84	80	81	82	77	86	74	70	69
R-squared	0.132	0.117	0.117	0.100	0.085	0.399	0.174	0.196	0.092	0.150	0.106	0.111	0.204	0.161	0.223	0.140	0.154	0.196
AdjR-squared	-0.00100	-0.0198	-0.0345	-0.0560	-0.0588	0.262	0.0160	0.0528	-0.0700	-0.00784	-0.0701	-0.0615	0.0513	-0.0120	0.0822	-0.0458	-0.0425	0.00540

Robust standard errors in parentheses

*** p < 0.01, ** p < 0.05, * p < 0.1

Linear Regression with Robust Standard Errors: consenting participants (part 3)									
	(31)	(32)	(33)	(34)	(35)	(36)	(37)	(38)	(39)
VARIABLES	Connect: 'Allocate submitted incident reports to investigators' with 'Ward-level investigation'	Connect: 'Local meeting: risk managers' discussion of incident details and actions' with 'Incident report database management' (after first formal investigation)	Connect: 'Local meeting (2): risk managers' discussion of incident details and actions' with 'Incident report database management' (after second formal investigation)	Connect: 'Local meeting: audit or MDT [meeting] or M&M [meeting]' with 'Local performance management of individuals'	Connect: 'Production of patient safety information materials' with 'Ward meeting: patient safety'	Connect: 'Production of patient safety information materials' with 'Local meeting: audit or MDT or M&M'	Connect: 'Review or development of guidelines, policies and feedback' with 'Production of patient safety information materials'	Connect: 'Closure of investigation' with 'Local meeting: audit or MDT or M&M'	Connect: 'Surveillance of latest patient safety information' with 'Production of patient safety information materials'
clin_exp	-0.001	-0.020	-0.018	-0.008	0.025	0.026	0.014	0.015	-0.002
	(0.015)	(0.021)	(0.026)	(0.019)	(0.021)	(0.022)	(0.019)	(0.017)	(0.016)
safetyrat	0.146**	0.089	0.107	0.009	0.008	0.145	0.069	0.012	0.050
	(0.067)	(0.072)	(0.107)	(0.058)	(0.071)	(0.091)	(0.071)	(0.059)	(0.056)
anntraining	0.028	0.120	0.043	0.065	0.163*	0.007	0.241**	0.079	0.061
	(0.088)	(0.094)	(0.116)	(0.097)	(0.094)	(0.107)	(0.109)	(0.086)	(0.094)
1.age	-0.256	0.279	-0.215	0.836***	0.138	-0.766	0.477	0.438	0.264
	(0.439)	(0.679)	(0.679)	(0.275)	(0.363)	(0.562)	(0.419)	(0.791)	(0.411)
2.age	-0.040	0.652	0.371	0.963***	0.399	-0.433	0.759*	0.486	0.841**
	(0.407)	(0.680)	(0.689)	(0.342)	(0.444)	(0.570)	(0.444)	(0.790)	(0.396)
3.age	-0.198	0.667	-0.087	0.566	-0.935	0.217	0.346	0.500	0.026
	(0.430)	(0.790)	(0.798)	(0.494)	(0.717)	(0.756)	(0.714)	(0.936)	(0.746)

1.irsexp	0.306	0.427*	0.053	0.434	-0.580*	0.083	-0.534	-0.140	-0.479
	(0.297)	(0.249)	(0.280)	(0.266)	(0.314)	(0.368)	(0.417)	(0.385)	(0.545)
1.lastirsuse	0.421	0.706***	0.272	0.226	-0.083	0.188	-0.261	-0.224	-0.524
	(0.286)	(0.262)	(0.281)	(0.253)	(0.313)	(0.335)	(0.409)	(0.359)	(0.664)
1.training	-0.740***	-0.473*	0.112	-0.135	-0.097	0.210	-0.242	-0.302	-0.484*
	(0.274)	(0.256)	(0.353)	(0.466)	(0.322)	(0.273)	(0.292)	(0.241)	(0.280)
2.training	-0.514	-1.188**	0.162	-0.192	-1.153***	-0.837**	0.156	-0.438*	-0.174
	(0.441)	(0.514)	(0.462)	(0.231)	(0.400)	(0.381)	(0.341)	(0.236)	(0.657)
3.training	-0.478**	-0.064	-0.009	-0.211	-0.173	-0.073	-0.168	-0.438**	-0.506**
	(0.198)	(0.226)	(0.282)	(0.205)	(0.236)	(0.235)	(0.278)	(0.212)	(0.218)
4.training	-0.392	-0.456	-0.699	-0.565**	-0.565	-1.044***	-0.369	-0.386*	-0.771**
	(0.350)	(0.591)	(0.574)	(0.265)	(0.382)	(0.335)	(0.339)	(0.210)	(0.337)
1.annotated	0.154	-0.099	0.152	-0.069	-0.454	-0.142	-0.437	0.244	-0.229
	(0.234)	(0.262)	(0.381)	(0.249)	(0.274)	(0.266)	(0.282)	(0.278)	(0.272)
Constant	2.183***	1.601**	2.133**	1.808***	2.968***	2.341***	2.081***	2.852***	2.773***
	(0.673)	(0.793)	(0.954)	(0.458)	(0.672)	(0.848)	(0.633)	(0.910)	(0.541)
Observations	58	66	57	61	60	59	70	54	64
R-squared	0.288	0.235	0.152	0.199	0.373	0.396	0.236	0.166	0.329
AdjR-squared	0.0772	0.0433	-0.105	-0.0225	0.195	0.222	0.0587	-0.105	0.154

Robust standard errors in parentheses

*** p < 0.01, ** p < 0.05, * p < 0.1

C.12. Linear regression models for associations between demographic variables (predictors) and levels of agreement (response variable) by echelon

Linear Regression with Robust Standard Errors: Consent Only						
	(1)	(2)	(3)	(4)	(5)	(6)
VARIABLES	Average score, echelon 2	Average score, echelon 3	Average score, echelon 4	Average score, echelon 5	Average score (connectors), echelon 3	Average score (connectors), echelon 4
clin_exp	0.002	0.004	0.004	0.001	-0.000	0.012
	(0.010)	(0.009)	(0.012)	(0.014)	(0.015)	(0.015)
safetyrat	0.068**	0.040	0.055	0.064	0.123*	0.057
	(0.034)	(0.028)	(0.039)	(0.067)	(0.063)	(0.047)
anntraining	-0.035	0.014	0.139**	0.058	0.079	0.089
	(0.041)	(0.037)	(0.059)	(0.066)	(0.077)	(0.079)
1.age	-0.276	-0.243	0.116	0.091	-0.026	0.124
	(0.219)	(0.217)	(0.480)	(0.525)	(0.391)	(0.405)
2.age	-0.311	-0.197	0.156	0.301	0.451	0.604

	(0.210)	(0.219)	(0.491)	(0.552)	(0.408)	(0.408)
3.age	-0.684**	-0.456*	0.068	-0.084	0.269	-0.164
	(0.266)	(0.275)	(0.614)	(0.800)	(0.477)	(0.617)
1.irsexp	0.156	-0.091	0.055	-0.184	0.343	-0.172
	(0.170)	(0.139)	(0.259)	(0.288)	(0.247)	(0.361)
1.lastirsuse	0.241	0.075	-0.135	-0.425	0.469*	-0.198
	(0.148)	(0.116)	(0.247)	(0.302)	(0.251)	(0.398)
1.training	-0.405***	-0.283*	-0.064	-0.382**	-0.120	-0.193
	(0.151)	(0.169)	(0.241)	(0.172)	(0.250)	(0.260)
2.training	0.006	0.241	0.061	0.786***	-0.476*	0.002
	(0.217)	(0.221)	(0.246)	(0.273)	(0.251)	(0.533)
3.training	-0.038	0.027	-0.073	0.064	-0.094	-0.524***
	(0.109)	(0.093)	(0.126)	(0.193)	(0.179)	(0.182)
4.training	-0.292**	-0.145	-0.259	-0.000	-0.541**	-0.757***
	(0.136)	(0.110)	(0.258)	(0.271)	(0.241)	(0.278)
1.annotated	-0.041	-0.001	0.157	0.067	-0.012	0.145
	(0.119)	(0.108)	(0.163)	(0.208)	(0.192)	(0.237)
Constant	2.922***	3.180***	2.400***	2.666***	1.429**	2.516***
	(0.321)	(0.302)	(0.549)	(0.666)	(0.611)	(0.506)
Observations	116	113	94	75	95	71
R-squared	0.174	0.127	0.130	0.149	0.245	0.325
AdjR-squared	0.0692	0.0124	-0.0115	-0.0320	0.124	0.171

Robust standard errors in parentheses

*** p < 0.01, ** p < 0.05, * p < 0.1

C.13. Spearman's rank correlations between demographic variables and levels of agreement by activity

Variables	(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)	(12)	(13)	(14)	(15)	(16)	(17)	(18)	(19)	(20)	(21)	(22)	(23)	(24)	(25)	(26)	(27)	(28)	(29)	(30)	(31)	(32)	(33)
(1) Clinical exp.	1.00																																
(2) Safety rating	-0.32	1.00																															
(3) Annual training	0.17	0.05	1.00																														
(4)	-0.38	0.16	0.06	1.00																													
(5)	0.01	0.17	-0.07	0.11	1.00																												
(6)	0.01	-0.06	-0.20	0.09	0.18	1.00																											
(7)	0.11	0.00	-0.02	-0.16	0.24	0.62	1.00																										
(8)	0.15	0.04	-0.14	-0.02	0.14	0.09	0.22	1.00																									
(9)	0.01	0.17	-0.02	-0.09	0.02	0.13	0.31	0.53	1.00																								
(10)	0.03	-0.11	-0.09	0.09	0.32	0.46	0.40	0.17	0.21	1.00																							
(11)	0.03	0.18	-0.07	0.17	0.08	0.28	0.10	0.28	0.22	0.15	1.00																						
(12)	0.11	-0.14	0.01	0.06	0.18	0.44	0.36	0.21	0.21	0.48	0.43	1.00																					
(13)	0.15	-0.04	-0.00	-0.04	0.22	0.39	0.35	0.21	0.28	0.29	0.10	0.28	1.00																				
(14)	0.06	0.03	-0.24	0.02	0.31	0.52	0.49	0.11	0.19	0.68	0.17	0.38	0.57	1.00																			
(15)	0.20	-0.17	0.03	-0.01	0.33	0.49	0.39	0.08	0.37	0.65	0.16	0.37	0.46	0.63	1.00																		
(16)	0.23	0.08	0.08	-0.05	0.32	0.29	0.34	0.35	0.54	0.38	0.17	0.14	0.24	0.37	0.53	1.00																	
(17)	0.05	0.08	-0.03	0.02	0.17	0.24	0.21	0.37	0.66	0.56	0.30	0.36	0.37	0.47	0.50	0.67	1.00																
(18)	0.10	-0.08	-0.17	-0.11	0.08	0.21	-0.01	0.27	0.37	0.22	0.46	0.30	0.15	0.27	0.31	0.50	0.55	1.00															
(19)	0.05	-0.00	-0.20	-0.13	0.02	0.09	0.18	0.35	0.54	0.25	0.45	0.34	-0.05	0.19	0.18	0.40	0.59	0.71	1.00														
(20)	-0.01	-0.21	-0.19	-0.13	-0.02	0.48	0.25	0.28	0.32	0.11	0.27	0.42	0.18	0.18	0.21	0.19	0.30	0.40	0.34	1.00													
(21)	0.08	0.29	0.33	0.33	0.27	-0.01	0.10	0.29	0.22	0.03	0.17	0.20	0.40	0.04	0.18	0.35	0.23	0.01	-0.07	-0.10	1.00												
(22)	-0.03	0.29	0.04	0.06	0.08	0.16	0.17	0.50	0.55	0.19	0.44	0.29	0.23	0.11	0.30	0.39	0.45	0.35	0.35	0.07	0.57	1.00											
(23)	0.05	0.30	0.09	-0.19	0.36	0.04	0.06	0.24	0.30	0.06	0.13	0.03	0.12	0.00	0.20	0.31	0.33	0.29	0.26	0.10	0.16	0.23	1.00										
(24)	-0.02	0.35	0.09	-0.16	0.25	0.16	0.10	0.30	0.46	0.07	0.11	0.14	0.33	0.19	0.30	0.43	0.44	0.28	0.33	0.26	0.38	0.42	0.62	1.00									
(25)	0.20	0.21	0.03	-0.13	0.10	0.21	0.22	0.32	0.65	0.22	0.27	0.24	0.21	0.32	0.32	0.59	0.60	0.47	0.57	0.24	0.31	0.51	0.44	0.57	1.00								
(26)	0.02	0.30	-0.13	0.12	0.22	0.27	0.24	0.33	0.47	0.19	0.30	0.25	0.22	0.34	0.24	0.51	0.42	0.31	0.45	0.38	0.36	0.48	0.31	0.53	0.64	1.00							
(27)	0.12	0.04	-0.23	-0.06	0.07	0.24	0.11	0.40	0.37	0.34	0.20	0.34	0.28	0.36	0.37	0.33	0.50	0.23	0.26	0.21	0.27	0.51	0.28	0.43	0.37	0.39	1.00						
(28)	0.27	0.15	-0.15	-0.04	0.15	0.09	0.27	0.40	0.31	0.21	0.17	0.19	0.07	0.07	0.08	0.32	0.29	0.27	0.31	0.02	0.26	0.33	0.45	0.15	0.46	0.43	0.20	1.00					
(29)	0.09	0.15	0.11	0.12	0.17	0.22	0.23	0.54	0.49	0.30	0.23	0.35	0.31	0.19	0.36	0.50	0.51	0.23	0.19	0.13	0.59	0.71	0.39	0.51	0.51	0.48	0.66	0.35	1.00				
(30)	-0.05	0.42	0.19	0.14	0.21	0.00	0.20	0.40	0.35	0.09	0.22	0.24	0.22	0.10	0.24	0.42	0.27	0.03	0.06	-0.09	0.71	0.72	0.26	0.40	0.35	0.41	0.41	0.28	0.68	0.45	1.00		
(31)	0.28	-0.05	0.12	0.17	0.21	-0.01	0.20	0.20	0.30	0.29	0.01	0.15	0.15	0.17	0.35	0.26	0.21	0.02	0.09	-0.21	0.36	0.21	0.34	0.11	0.32	0.20	0.12	0.50	0.45	0.34	1.00		
(32)	0.26	-0.09	0.10	0.15	0.11	0.07	0.19	0.19	0.29	0.19	0.12	0.15	0.15	0.07	0.29	0.28	0.17	0.01	0.09	-0.14	0.28	0.13	0.33	0.12	0.28	0.20	0.08	0.45	0.43	0.24	0.92	1.00	
(33)	0.20	-0.01	0.15	0.22	0.12	0.13	0.17	0.24	0.40	0.24	0.14	0.22	0.31	0.17	0.32	0.32	0.33	0.17	0.17	-0.03	0.41	0.26	0.38	0.23	0.41	0.29	0.12	0.45	0.55	0.35	0.90	0.88	1.00

Two-way table of responses given by frontline NHS staff on the validity of incident reporting system activities presented on a process map developed in an earlier study (see Chapter three, “Stage one”). Scores were entered on a scale from 1 to 4, where 1 meant “strongly disagree”, 2 meant “disagree”, 3 meant “agree”, and 4 meant “strongly agree”. Correlation coefficients are given in bold type if they exceed 0.5 or -0.5, which indicates positive or negative agreement, respectively (that is, at least moderately strong). The corresponding activity for each item number is given in Appendix C.14 (below).

C.14. Legend describing the item numbers (in brackets) given in Appendix C.13 that correspond to the specific incident reporting system activities studied.

Item number	Activity
(4) Echelon one	Discuss incident with patient and/or relative(s)
(5) Echelon two	Pre-report discussion of incident details and severity
(6) Echelon two	Locate a computer on which to enter an incident report
(7) Echelon two	Complete an incident report online
(8) Echelon two	Post-report discussion of incident and next steps
(9) Echelon two	Ward-level investigation
(10) Echelon two	Ward meeting: patient safety
(11) Echelon two	Local performance management of individuals
(12) Echelon three	Review medical records
(13) Echelon three	Incident investigation triage
(14) Echelon three	Allocate submitted incident reports to investigators
(15) Echelon three	Incident report database management
(16) Echelon three	First formal investigation of incident report
(17) Echelon three	Local meeting: risk managers' discussion of incident details and actions
(18) Echelon three	Second formal investigation of incident report (serious incident)
(19) Echelon three	Local meeting (2): risk managers' discussion of incident details and actions
(20) Echelon three	Local meeting: audit or MDT or M&M
(21) Echelon three	Production of patient safety information materials
(22) Echelon three	Review or development of guidelines, policies, and feedback
(23) Echelon four	Third formal investigation (level one concise investigation)
(24) Echelon four	Incident investigation management
(25) Echelon four	Division meeting: serious incident panel review one
(26) Echelon four	Corporate meeting: serious incident panel review two
(27) Echelon four	Closure of investigation
(28) Echelon four	Closure of investigation
(29) Echelon four	Production of incident investigation report for commissioner
(30) Echelon four	Implementation of existing or new guidelines or policies
(31) Echelon five	Data preparation for performance reporting to NRLS
(32) Echelon five	Production of organisation performance report for NRLS
(33) Echelon five	Production of organisation performance report for commissioner

Appendix D

This appendix provides supplementary information and data relevant to Chapter four.

D.1. Assumptions about the frequency of incident reporting system activities using Chapter three findings.

Stage 3 activities (strong evidence)	Associated activities	Associated activities	Associated activities	Probability
Consultpatientandfamilyl				0.83
Discussincidentdetaillow				0.75
Locatehospitalcomputerl				0.86
Completeincidentreportlow				0.87
Debriefwithsuplow				0.75
Investigateincidentinwardlow				0.82
Debriefatstaffmeetingl				0.72
Addincidenttohealthrec low				0.84
Prioritiseincidentlow				0.79
Allocatetoanewinvest1 low	Addinformation1low			0.85
Addinformation2low				0.83
Firstformalinvestigatio nl				0.82
Estimate most likely root low				0.82
Secondformalinvestiga tionl				0.79
Allocatetoanewinvest2 low	Addinformation3low			0.78
Discussnewincidentlow				0.80
DesignandproduceNH SIlow	DesignandproduceTr ustlow			0.74
DevelopnewguideNHS Ilow	DevelopnewguideTr ustlow			0.80
ApproveandactionSIpa nallow				0.82
Approveandactionmed dirlow				0.83
Closeformalinvestigati onl				0.85
Submitunique repCCGI low				0.82
Identifylatestpatientsaf low				0.78
Implementnewprodlo w	Announceguidelinesl ow	Implementexistin glow	Auditcomplianc elow	0.80

Cleanandsummlow				0.82
SubmitTrustdataNHSII ow				0.81
SubmitTrustdataCCGI ow				0.81

D.2. NHS England staff composition data (2020) informing hourly wage estimates

Level	Staff Group 2	Feb-20		Proportion	Band	Lower	Upper	Mean	Weighted mean	Std. Err	Alpha	Beta
000a_Nursing Associate	024_Nursing support staff	1,130	1,130	0.002	4	12.2	14.1	13.1	0.0	13.1	1.0	13.1
000a_Nursing Associate Total		1,130	1,130	0.002	4	12.2	14.1	13.1	0.0	13.1	1.0	13.1
000b_Trainee Nursing Associate	024_Nursing support staff	4,430	4,430	0.009	3	10.7	12.3	11.5	0.1	11.5	1.0	11.5
000b_Trainee Nursing Associate Total		4,430	4,430	0.009	3	10.7	12.3	11.5	0.1	11.5	1.0	11.5
001_Nurse Consultant	006_Nurses - adult	701	701	0.001	8a-c	25.6	43.0	34.3	0.1	34.3	1.0	34.3
	007_Nurses - children's	61	61	0.000	8a-c	25.6	43.0	34.3	0.0	34.3	1.0	34.3
	010_Nurses - mental health	187	187	0.000	8a-c	25.6	43.0	34.3	0.0	34.3	1.0	34.3
001_Nurse Consultant Total		949	949	0.002	8a-c	25.6	43.0	34.3	0.1	34.3	1.0	34.3
002_Manager	018_Allied health professions	2,653	2,653	0.006	8a-c	25.6	43.0	34.3	0.2	34.3	1.0	34.3
002_Manager Total		2,653	2,653	0.006	8a-c	25.6	43.0	34.3	0.2	34.3	1.0	34.3
002_Modern Matron	006_Nurses - adult	3,394	3,394	0.007	8a	25.6	30.1	27.9	0.2	27.9	1.0	27.9
	007_Nurses - children's	301	301	0.001	8a	25.6	30.1	27.9	0.0	27.9	1.0	27.9
	010_Nurses - mental health	449	449	0.001	8a	25.6	30.1	27.9	0.0	27.9	1.0	27.9
002_Modern Matron Total		4,144	4,144	0.009	8a	25.6	30.1	27.9	0.2	27.9	1.0	27.9
002_Nursing Assistant / Auxiliary	024_Nursing support staff	47,044	47,044	0.100	4	12.2	14.1	13.1	1.3	13.1	1.0	13.1
002_Nursing Assistant / Auxiliary Total		47,044	47,044	0.100	4	12.2	14.1	13.1	1.3	13.1	1.0	13.1
004_Healthcare Assistant	029_Healthcare assistants & support workers	3	3	0.000	2 or 3	10.5	12.3	11.4	0.0	11.4	1.0	11.4
004_Healthcare Assistant Total		3	3	0.000	2 or 3	10.5	12.3	11.4	0.0	11.4	1.0	11.4
004_Nurse Manager	006_Nurses - adult	5,521	5,521	0.012	8a-c	25.6	43.0	34.3	0.4	34.3	1.0	34.3
	007_Nurses - children's	488	488	0.001	8a-c	25.6	43.0	34.3	0.0	34.3	1.0	34.3
	010_Nurses - mental health	2,743	2,743	0.006	8a-c	25.6	43.0	34.3	0.2	34.3	1.0	34.3
004_Nurse Manager Total		8,752	8,752	0.019	8a-c	25.6	43.0	34.3	0.6	34.3	1.0	34.3
004_Nursing Assistant Practitioner	024_Nursing support staff	6,144	6,144	0.013	4	12.2	14.1	13.1	0.2	13.1	1.0	13.1

004_Nursing Assistant Practitioner Total		6,144	6,144	0.013	4	12.2	14.1	13.1	0.2	13.1	1.0	13.1
005_Healthcare Assistant	024_Nursing support staff	69,899	69,899	0.149	2 or 3	10.5	12.3	11.4	1.7	11.4	1.0	11.4
	046_Healthcare assistants & support workers	93	93	0.000	2 or 3	10.5	12.3	11.4	0.0	11.4	1.0	11.4
005_Healthcare Assistant Total		69,992	69,992	0.149	2 or 3	10.5	12.3	11.4	1.7	11.4	1.0	11.4
005_Midwives	014_Midwives	22,223	22,223	0.047	6	16.9	22.1	19.5	0.9	19.5	1.0	19.5
005_Midwives Total		22,223	22,223	0.047	6	16.9	22.1	19.5	0.9	19.5	1.0	19.5
010_Other 1st Level Nurse	006_Nurses - adult	180,204	180,204	0.385	5	13.9	17.9	15.9	6.1	15.9	1.0	15.9
	007_Nurses - children's	9,649	9,649	0.021	5	13.9	17.9	15.9	0.3	15.9	1.0	15.9
	010_Nurses - mental health	31,064	31,064	0.066	5	13.9	17.9	15.9	1.1	15.9	1.0	15.9
010_Other 1st Level Nurse Total		220,918	220,918	0.472	5	13.9	17.9	15.9	7.5	15.9	1.0	15.9
011_Other 2nd Level Nurse	006_Nurses - adult	1,568	1,568	0.003	6	16.9	22.1	19.5	0.1	19.5	1.0	19.5
	007_Nurses - children's	50	50	0.000	6	16.9	22.1	19.5	0.0	19.5	1.0	19.5
	010_Nurses - mental health	409	409	0.001	6	16.9	22.1	19.5	0.0	19.5	1.0	19.5
011_Other 2nd Level Nurse Total		2,028	2,028	0.004	6	16.9	22.1	19.5	0.1	19.5	1.0	19.5
Weighted sum		390410		0.83					12.985			

D.3. Weighted average calculation of proportions of health workers who are doctors

Seniority	Proportion	Lower wage (£)	Upper wage (£)
Foundation or Core	0.05	16.38	18.96
Registrar	0.10	22.44	28.43
Consultant	0.02	52.15	63.37
Weighted average	0.17		

D.4. Probabilistic assumptions for doctors' salaries as a proportion of all health workers

	No.	Proportion	mean	se	alpha	beta
Associate Specialist	7999	0.02	25.44	25.44	1.00	25.44
Consultant	9952	0.02	57.76	57.76	1.00	57.76
Core Training	8245	0.02	17.67	17.67	1.00	17.67
Foundation Doctor Yr1	6341	0.01	17.67	17.67	1.00	17.67
Foundation Doctor Yr2	7660	0.02	17.67	17.67	1.00	17.67
Hospital Practitioner / Clinical Assistant	6950	0.01	25.44	25.44	1.00	25.44
Other and Local HCHS Doctor Grades	6304	0.01	25.44	25.44	1.00	25.44
Specialty Doctor	8739	0.02	25.44	25.44	1.00	25.44
Specialty Registrar	9736	0.02	25.44	25.44	1.00	25.44
Staff Grade	6192	0.01	25.44	25.44	1.00	25.44
Weighted average		0.17				

D.5. Summary of NRLS incident report throughput by severity (2018 to 2019)

Summary, one-year throughput		
<=moderate	>=severe	Sum total
1,576,091	4,982	1,581,073

Summary per NHS acute trust, one-year throughput		
Mean	6,039	19
St.Dev	3,317	14
Std.Err	13	0.05
Min	1,266	0.00
Max	21,976	95

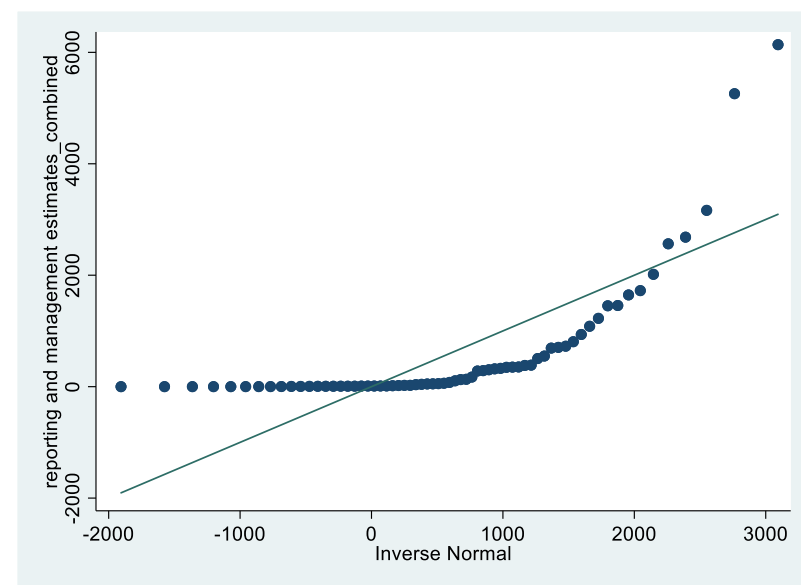
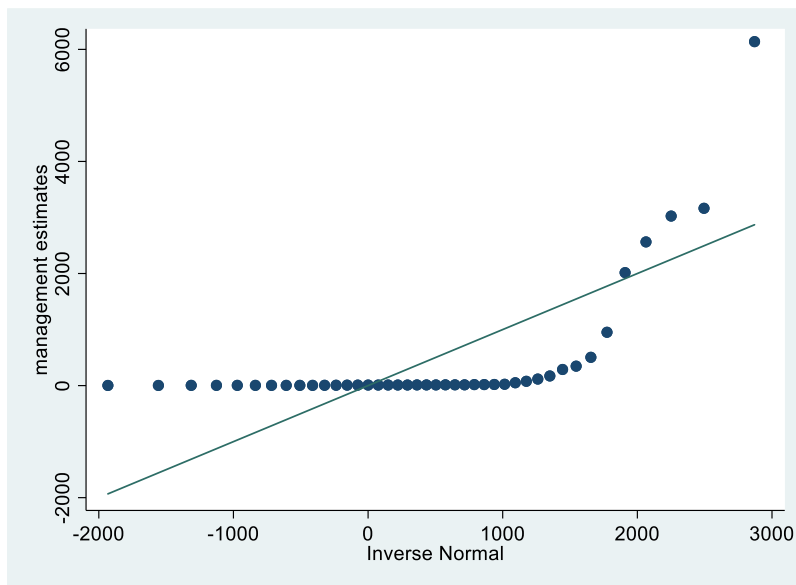
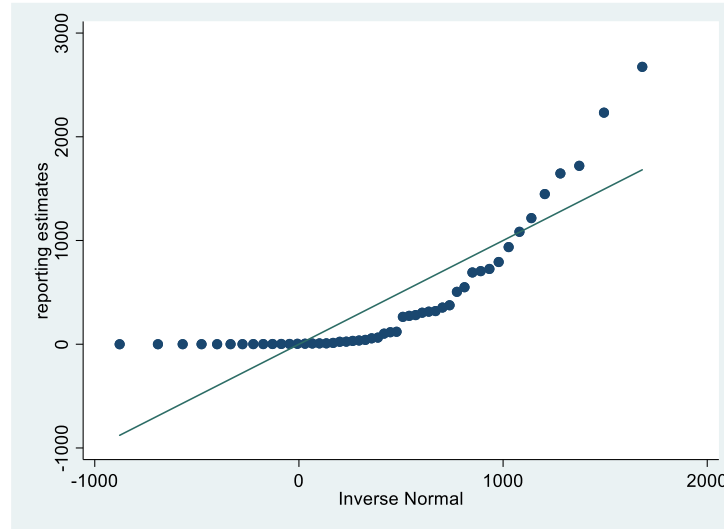
D.6. Assumptions about the occurrence of activities and likelihood of costs incurred by stage of safety reporting system

Stage	Activity	Weight	Assumption
Detect & Capture	Submit Trust data as report to CQC	0.01	Approximately 1% of all incidents in England are moderate harm, severe harm, or death. These incidents are assumed to be the only types that enter departmental,

			divisional, and organisational management echelons.
Detect & Capture	Submit unique report on incident to CCG	0.01	As above.
Detect & Capture	Submit Trust data as summary report to CCG	0.25	In any single year, quarterly reports on incidents are sent by NHS organisations to various NHS institutions. These reports include all incident types, and it is assumed that for all incidents this activity must happen 25%of the time.
Detect & Capture	Submit Trust data as report to NHS Improvement	0.25	As above
Detect & Capture	Discuss incident details with colleague(s)	1	For every incident that is reported, this step is certain to occur.
Detect & Capture	Consult patient and family	1	For every incident that is reported, this step is certain to occur.
Detect & Capture	Add incident to health record	1	For every incident that is reported, this step is certain to occur.
Detect & Capture	Complete an incident report form using software provided	1	For every incident that is reported, this step is certain to occur.
Detect & Capture	Locate a hospital computer	1	For every incident that is reported, this step is certain to occur.
Classify - Investigate	Second formal investigation	0.01	Approximately 1%of all incidents in England are moderate harm, severe harm, or death. These incidents are assumed to be the only types that enter departmental, divisional, and organisational management echelons.
Classify - Investigate	Clean and summarise incident information, add to Trust repository	0.25	
Classify - Investigate	Allocate to a new investigator	0.05	
Classify - Investigate	Close investigation	0.01	Approximately 1%of all incidents in England are moderate harm, severe harm, or death. These incidents are assumed to be the only types that enter departmental, divisional, and organisational management echelons.
Classify - Investigate	Discuss new incident information in risk management meeting	0.01	As above.
Classify - Investigate	First formal investigation	0.01	As above.
Classify - Investigate	Add information to incident report database and notify investigators (2), repeated activity	0.01	As above.
Classify - Investigate	Estimate most likely root cause before formal investigation	1	For every incident that is reported, this step is certain to occur.

Classify - Investigate	Add information to incident report database and notify investigators (1), first occurrence of a repeated activity	1	For every incident that is reported, this step is certain to occur.
Classify - Investigate	Prioritise incident and allocate to investigator	1	For every incident that is reported, this step is certain to occur.
Classify - Investigate	Close investigation on ward	1	For every incident that is reported, this step is certain to occur.
Classify - Investigate	Investigate incident within the ward/unit	1	For every incident that is reported, this step is certain to occur.
Formulate	Design and produce training information	0.01	Approximately 1% of all incidents in England are moderate harm, severe harm, or death. These incidents are assumed to be the only types that enter departmental, divisional, and organisational management echelons.
Formulate	Develop new guidelines and policies	0.01	As above.
Formulate	Approve and action results of investigation at medical director's office	0.01	As above.
Formulate	Identify latest patient safety information and evidence	0.01	As above.
Formulate	Approve and action results of investigation at serious incident review panel	0.01	As above.
Implement	Implement existing evidence by reiterating guidelines or policies	0.01	As above.
Implement	Announce guidelines and policies at audits, MDT, M&M, RM, or Q&S meeting	0.01	As above.
Implement	Implement new products and practices	0.01	As above.
Implement	Brief new starters in mandatory training	0.25	Every fourth incident that occurs on the ward-level is discussed with newly recruited healthcare workers.
Implement	Debrief at staff meeting	1	For every incident that is reported, this step is certain to occur.
Implement	Debrief with supervisor / manager	1	For every incident that is reported, this step is certain to occur.
Monitor	Audit compliance to new practice	0.01	Approximately 1% of all incidents in England are moderate harm, severe harm, or death. These incidents are assumed to be the only types that enter departmental, divisional, and organisational management echelons. Frontline compliance with new practices and processes is checked for all actions that result from these incidents.

D.7. Qnorm plots for reporting (top row), management (lower left), and overall costs (lower right)



Questionnaire

Measuring resource usage for incident reporting systems in the NHS

Lead researcher: Alexander Carter

Email: a.w.carter@imperial.ac.uk

IRAS Project ID: 247294

Version 1.3

This pack contains: consent to participate, participants' questionnaire, and a supporting schematic.
Consent will be obtained before data collection.

Consent to Participate

(Refer to the adjoining information sheet*)

Study title: Measuring resource usage for incident reporting systems in the NHS (IRAS: 247294)

Study aim: Generate evidence that will improve the efficiency and effectiveness of incident reporting systems.

Project: This study has been running since 2014 and involves the collection of data to understand how incident reporting systems operate in the NHS. There is a lack of data quantifying the human and administrative burden involved in incident reporting systems. This study is needed for two reasons: 1) to identify the various NHS personnel and associated tasks involved in operating incident reporting and feedback and learning systems, and 2) to determine the resource usage involved in their operation.

Confidentiality: Your participation is voluntary and the information you provide, should you wish to do so, will be used for research and quality improvement in the NHS. Your responses will be anonymised, and all potentially identifiable data gathered from this project will be stored with and accessible only by the researchers listed.

Authorisation to proceed:

Print name and add date of consent (sign separately, below table)

I..... Date:

In line with the GDPR guidelines that came into force on May 25th, 2018, I hereby agree to:

Item	Initial each item that you agree to and leave blank those to which you do not consent
Be anonymously quoted in publications	
Have my anonymised data used in publications	
Have my anonymised data used in future research	
Be contacted about this research in the future	

Participant signature (giving consent to participate):

Have you consented to take part in this study before today? **Yes / No** (delete as appropriate)

Specific anonymity requests:

* Imperial College London study on incident reporting systems information sheet version 6

Incident Reporting Systems Survey

Instructions

This questionnaire asks for information about your professional background and your experience of patient safety and incident reporting and management. It will take about 15 to 25 minutes to complete.

If you do not wish to answer a question, or if a question does not apply to you, you may leave your answer blank. If the option is given, select 'Not applicable' ('N/A').

- ***Incident reporting systems*** are a set of reporting, investigation, feedback, and learning activities that take place in response to patient safety-related incidents.
- An ***"incident"*** is defined as any event which has given rise to potential or actual harm or injury, to patient dissatisfaction, or to damage/loss of property.
- ***"Patient safety"*** is defined as the avoidance and prevention of patient injuries or adverse events resulting from the processes of healthcare delivery.

SECTION A: Background Information

In this survey, think of your "ward/department" as the work area, department, or clinical area of the hospital where you spend most of your work time or provide most of your clinical services.

1. What is your primary work area or unit in this hospital? Select ONE answer.

☐ a. Many different hospital wards/No specific unit	☐ h. Psychiatry/mental health	☐ n. Other, please specify:
☐ b. Medicine (non-surgical)	☐ i. Rehabilitation	
☐ c. Surgery	☐ j. Pharmacy	
☐ d. Obstetrics	☐ k. Laboratory	
☐ e. Paediatrics	☐ l. Radiology	
☐ f. Emergency department	☐ m. Anaesthetics	
☐ g. Intensive care unit (any type)		

2. What is your staff position in this hospital? Select ONE answer that best describes your staff position.

☐ a. Registered Nurse	☐ g. Dietician
☐ b. Healthcare assistant	☐ h. Ward manager / Matron
☐ c. Doctor - consultant	☐ i. Risk manager
☐ d. Doctor – Registrar/SAS	☐ j. Physio, Occupational, or Speech Therapist
☐ e. Doctor – core/foundation trainee	☐ k. Administration/Management
☐ f. Pharmacist	☐ l. Other, please specify:

3. Which NHS pay band and level are you in? TICK the relevant band. If this has changed in the last 18 months, place a CROSS in the band you were previously in.

- ☐ a. Band 1
☐ b. Band 2
☐ c. Band 3
☐ d. Band 4
☐ e. Band 5
☐ f. Band 6
☐ g. Band 7

- ☐ h. Band 8a
☐ i. Band 8b
☐ j. Band 8c
☐ k. Band 8d
☐ l. Band 9
☐ m. Not applicable

Level (years of experience)

4. How long have you worked in your current specialty or profession?

- ☐ a. Less than 1 year
☐ b. 1 to 5 years
☐ c. 6 to 10 years
☐ d. 11 to 15 years
☐ e. 16 to 20 years
☐ f. 21 years or more

5. Which of the options below best describes the NHS Trust you currently work in?

- ☐ a. Foundation
☐ b. Mental health Trust
☐ c. Acute Trust
☐ d. Community health Trust

6. In your staff position, do you typically have direct interaction or contact with patients?

- ☐ a. YES, I typically have direct interaction or contact with patients.
☐ b. NO, I typically do NOT have direct interaction or contact with patients.

SECTION B: Your Ward/Department

Please indicate your agreement or disagreement with the following statements about your work area/unit.

Think about your hospital ward/department...	Strongly Disagree ▼	Disagree ▼	Neither ▼	Agree ▼	Strongly Agree ▼
1. We are actively doing things to improve patient safety	☐ ₁	☐ ₂	☐ ₃	☐ ₄	☐ ₅
2. Mistakes have led to positive changes here	☐ ₁	☐ ₂	☐ ₃	☐ ₄	☐ ₅
3. It is just by chance that more serious mistakes don't happen around here	☐ ₁	☐ ₂	☐ ₃	☐ ₄	☐ ₅
4. When an incident is reported, it feels like the <i>person</i> is being written up, not the problem	☐ ₁	☐ ₂	☐ ₃	☐ ₄	☐ ₅

SECTION B: Your Ward/Department (continued)

	Strongly Disagree ▼	Disagree ▼	Neither ▼	Agree ▼	Strongly Agree ▼
5. After we make changes to improve patient safety, we evaluate their effectiveness	☐ ₁	☐ ₂	☐ ₃	☐ ₄	☐ ₅

6. Patient safety is never sacrificed to get more work done	☐ ₁	☐ ₂	☐ ₃	☐ ₄	☐ ₅
7. We have patient safety problems in this unit	☐ ₁	☐ ₂	☐ ₃	☐ ₄	☐ ₅
8. Our procedures and systems are good at preventing errors from happening	☐ ₁	☐ ₂	☐ ₃	☐ ₄	☐ ₅

SECTION C: Communications

How often do the following things happen in your ward/department?

Think about your hospital ward/department...	Never ▼	Rarely ▼	Some- times ▼	Most of the time ▼	Always ▼
1. We are given feedback about changes put into place based on incident reports.....	☐ ₁	☐ ₂	☐ ₃	☐ ₄	☐ ₅
2. Staff will freely speak up if they see something that may negatively affect patient care.....	☐ ₁	☐ ₂	☐ ₃	☐ ₄	☐ ₅
3. We are informed about errors that happen in this ward/department	☐ ₁	☐ ₂	☐ ₃	☐ ₄	☐ ₅
4. Staff feel free to question the decisions or actions of those with more authority	☐ ₁	☐ ₂	☐ ₃	☐ ₄	☐ ₅
5. In this unit, we discuss ways to prevent errors from happening again ...	☐ ₁	☐ ₂	☐ ₃	☐ ₄	☐ ₅
6. Staff are afraid to ask questions when something does not seem right .	☐ ₁	☐ ₂	☐ ₃	☐ ₄	☐ ₅

SECTION D: Frequency of Incidents Reported

In your hospital work area/unit, when the following mistakes happen, *how often are they reported?*

	Never ▼	Rarely ▼	Some- times ▼	Most of the time ▼	Always ▼
1. When a mistake is made, but is <u>caught and corrected before affecting the patient</u> , how often is this reported?	☐ ₁	☐ ₂	☐ ₃	☐ ₄	☐ ₅
2. When a mistake is made, but has <u>no potential to harm the patient</u> , how often is this reported?	☐ ₁	☐ ₂	☐ ₃	☐ ₄	☐ ₅
3. When a mistake is made that <u>could harm the patient</u> , but does not, how often is this reported?	☐ ₁	☐ ₂	☐ ₃	☐ ₄	☐ ₅

SECTION E: Patient Safety Grade

Please give your work area/unit in this hospital an overall grade on patient safety.

☐	☐	☐	☐	☐
A	B	C	D	E
Excellent	Very Good	Acceptable	Poor	Failing

SECTION F: Number of Incidents Reported

1. In the past 12 months, how many incident reports relating to *low harm, no harm, or near miss* incidents have you filled out and submitted?

☐ a. No incident reports	☐ d. 6 to 10 incident reports
☐ b. 1 to 2 incident reports	☐ e. 11 to 20 incident reports

- ☐ c. 3 to 5 incident reports ☐ f. 21 incident reports or more

2. **In the past 12 months**, how many incident reports relating to **moderate harm, severe harm, or never events** incidents have you filled out and submitted?

- ☐ a. No incident reports ☐ d. 6 to 10 incident reports
☐ b. 1 to 2 incident reports ☐ e. 11 to 20 incident reports
☐ c. 3 to 5 incident reports ☐ f. 21 incident reports or more

3. **In the past 12 months**, which incident reporting software have you used to report or manage incidents?
Select all that apply.

- ☐ a. Datix ☐ d. NRLS e-form
☐ b. SIRMS ☐ e. Safeguard
☐ c. Care Report ☐ f. Other, please specify

SECTION G: Incident reporting and management experience

***"Reporting"** is defined as the process up to and including the entry of an incident report into incident reporting software.*

***"Management"** is defined as the activities performed by the individuals and teams responsible for formally responding to incidents reported. This includes investigating incidents and providing feedback to relevant staff and departments in your Trust.*

9. Using the definitions above, which of the following activities are you most familiar with? If equally familiar, select both.

- ☐ a. Reporting
☐ b. Management

10. When was the last time you were involved in **reporting or managing** an incident? Select ONE answer.

- ☐ a. Less than 6 months ago ☐ c. More than 12 months ago
☐ b. More than 6 months ago, but less than 12 months ☐ d. I don't know

3. What position in clinical governance do you have in this hospital? Select ONE answer that best describes your position.

☐ a. Lead investigator	☐ h. Quality (& Safety) manager
☐ b. Risk and / or governance manager	☐ i. Datix manager
☐ c. Investigator – supporting lead	☐ j. SIRMS manager
☐ d. Clinical governance lead – division	☐ k. Service manager
☐ e. Clinical governance lead – NHS Trust	☐ l. Not applicable
☐ f. Clinical educator	☐ m. Other, please specify below:
☐ g. Audit manager	

SECTION H: Estimating resource usage for specific steps in NHS incident reporting systems

Instructions

In this section, you will be introduced to a schematic that will be explained by the researcher. This is a *detailed* description of the activities and delays that occur in the reporting and management of incidents.

In this part of the survey, think of the *general* sequence of events for ONE incident flowing through the activities and delays in the schematic. Estimate the time you spend on each event. To improve your recall, start by thinking about the last incident you were involved in and then draw on your previous experiences with incident reporting systems.

- If you replied 'Reporting' to question 1, section G then **estimate the time spent on reporting incidents using Table 1 and the 'Reporting' schematic. [Go to page 8.](#)**
- If you (also) replied 'Management' to question 1, section G then estimate the time spent on management activities using **Table 2**. Both schematics are linked, as shown by 'link points', but we have separated them to make the exercise simpler. **[Go to the 'Management' supplement'.](#)**

Using the schematic and how to give your responses

1. Familiarise yourself with the process map: start from the 'Serious incident occurs' node in the top left corner and follow the activities and delays given.
2. At each activity or delay, estimate the time taken when processing ONE incident. Give your answers in the tables provided.
3. If one activity starts and stops several times before it is completed, then do not add the time between the activity stopping and restarting into your estimates. Note this additional delay on the schematics provided.
4. Decimal places can be used in your responses. Round your answers to the nearest quarter or half (0.25 for one-quarter, 0.5 for one-half, 0.75 for three-quarters)
5. A delay is the time between one activity finishing and another one starting. In the schematic, delays are denoted as red circles that are labelled as D1, D2, D3, etc.

To account for a range of estimates, lower and upper values should be given. In our analysis, we will assume that low harm, no harm, or near miss incidents correspond to lower estimates. We will also assume that moderate harms, severe harms, and never events correspond to upper estimates.

Referring to the schematic on incident **REPORTING** provided, enter your estimates for the events that correspond to **Table 1**. Give your response in minutes, hours, or work days and delete the time units that do not apply. Consider 1 work day to be 8 hours.

Table 1					
	Activity or Delay	Choose ONE unit of time per row (delete as appropriate)	Lower estimate per incident	Upper estimate per incident	N/A
	START from 'Incident occurs'				
1	DELAY (D1)	Minute(s) / Hour(s) / Day(s)			☐
2	Consult patient and family	Minute(s) / Hour(s) / Day(s)			☐
3	Manage clinical impact of harm	Minute(s) / Hour(s) / Day(s)			☐
4	DELAY (D2)	Minute(s) / Hour(s) / Day(s)			☐
5	Add incident information to health record	Minute(s) / Hour(s) / Day(s)			☐
6	Discuss incident details with colleague(s) (e.g., severity of harm or potential root causes)	Minute(s) / Hour(s) / Day(s)			☐
7	Locate a hospital computer	Minute(s) / Hour(s) / Day(s)			☐
8	Complete an incident report form using Trust software provided	Minute(s) / Hour(s) / Day(s)			☐
9	DELAY (D3)	Minute(s) / Hour(s) / Day(s)			☐
10	Debrief with supervisor/manager (e.g., discuss individual learning)	Minute(s) / Hour(s) / Day(s)			☐
11	DELAY (D4)	Minute(s) / Hour(s) / Day(s)			☐

12	Investigate incident within the ward/unit	Minute(s) / Hour(s) / Day(s)			☐
13	Close investigation (e.g., by staff meeting)	Minute(s) / Hour(s) / Day(s)			☐
14	Brief new starters in mandatory training	Minute(s) / Hour(s) / Day(s)			☐
15	DELAY (D5)	Minute(s) / Hour(s) / Day(s)			☐
16	Debrief at staff meeting (e.g., briefing, huddle, or governance meeting)	Minute(s) / Hour(s) / Day(s)			☐
17	Implement new products and processes into practice	Minute(s) / Hour(s) / Day(s)			☐
18	DELAY (D6)	Minute(s) / Hour(s) / Day(s)			☐
19	Audit compliance with new practice	Minute(s) / Hour(s) / Day(s)			☐
	Management activities that occur outside the ward/unit				
20	Announce guidelines and policies at audit or MDT or M&M or risk management or quality and safety meeting	Minute(s) / Hour(s) / Day(s)			☐
	End				

SECTION I: Additional questions about this research

1. Did you take part in our previous research studies on the incident reporting process (in 2015) and/or validating and developing a process map for NHS incident reporting systems (in 2018)?

- ☐ a. Yes, I took part in both
 ☐ d. Yes, I took part in 2018 only
☐ b. Yes, I took part in 2015 only
 ☐ e. No, I did not take part in either study

Please indicate your agreement or disagreement with the following statements about this research.

	Strongly Disagree ▼	Disagree ▼	Neither ▼	Agree ▼	Strongly Agree ▼
2. The schematic provided models the flow of events in incident reporting systems	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

Think about all the ways you hear about risks to patient safety...

	Strongly Disagree ▼	Disagree ▼	Neither ▼	Agree ▼	Strongly Agree ▼
3. Incident reporting systems are an effective way for me to regularly <i>learn</i> about risks to the safety of patients I care for.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

4. Incident reporting systems are an effective way for me to regularly <i>improve</i> the care I give patients.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

5. Incident reporting systems are a valuable use of the time I spend on them (e.g., reporting or managing incidents)	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

Provide details of any important resources used in incident reporting systems that are not captured in this questionnaire, such as equipment. If you have additional thoughts about the incident reporting process, please annotate the schematics provided on the next page.

THANK YOU FOR COMPLETING THIS SURVEY.

Questionnaire

Measuring resource usage for incident reporting systems in the NHS

Management supplement

Lead researcher: Alexander Carter

Email: a.w.carter@imperial.ac.uk

IRAS Project ID: 247294

Version 1.3

This pack contains: participants' questionnaire and a supporting schematic.

Using the schematic and how to give your responses

6. Familiarise yourself with the process map: start from the 'Serious incident occurs' node in the top left corner and follow the activities and delays given.
7. For each activity or delay, estimate the time taken when processing ONE incident. Give your answers in the tables provided.
8. If one activity starts and stops several times before it is completed, then do not add the time between the activity stopping and restarting into your estimates. Note this additional delay on the schematics provided.
9. Decimal places can be used in your responses. Round your answers to the nearest quarter or half (0.25 for one-quarter, 0.5 for one-half, 0.75 for three-quarters)
10. A delay is the time between one activity finishing and another one starting. In the schematic, delays are denoted as red circles that are labelled as D1, D2, D3, etc.

To account for a range of estimates, **lower and upper values should be given**. In our analysis, we will assume that low harm, no harm, or near miss incidents correspond to lower estimates. We will also assume that moderate harms, severe harms, and never events correspond to upper estimates.

Referring to the schematic on incident **MANAGEMENT** provided, enter your estimates for the events that correspond to **Table 2** below. Give your response in minutes, hours, or work days and delete the time units that do not apply. Consider 1 work day to be 8 hours.

Table 2					
	Activity or Delay	Choose ONE unit of time per row (delete as appropriate)	Lower estimate <i>per incident</i>	Upper estimate <i>per incident</i>	N/A
	START from 'Complete incident report form...'				
1	DELAY (D7)	Minute(s) / Hour(s) / Day(s)			☐
2	Estimate most likely root cause before formal investigation	Minute(s) / Hour(s) / Day(s)			☐
3	Prioritise incident and allocate to investigator	Minute(s) / Hour(s) / Day(s)			☐
4	Add information to incident report database and notify investigator(s)	Minute(s) / Hour(s) / Day(s)			☐
5	DELAY (D8)	Minute(s) / Hour(s) / Day(s)			☐

6	First formal investigation	Minute(s) / Hour(s) / Day(s)			☐
7	Add information to incident report database and notify investigator(s)	Minute(s) / Hour(s) / Day(s)			☐
8	Allocate to a new investigator	Minute(s) / Hour(s) / Day(s)			☐
9	Second formal investigation	Minute(s) / Hour(s) / Day(s)			☐
10	Discuss new incident information in risk management meeting	Minute(s) / Hour(s) / Day(s)			☐
11	Close investigation (e.g., by staff/investigation team meeting)	Minute(s) / Hour(s) / Day(s)			☐
12	DELAY (D9)	Minute(s) / Hour(s) / Day(s)			☐
13	Approve and action results of investigation at serious incident review panel	Minute(s) / Hour(s) / Day(s)			☐
14	DELAY (D10)	Minute(s) / Hour(s) / Day(s)			☐
15	Approve and action results of investigation at medical director's office	Minute(s) / Hour(s) / Day(s)			☐
16	Submit unique report on incident to CCG	Minute(s) / Hour(s) / Day(s)			☐

17	Clean and summarise incident information, add to Trust repository	Minute(s) / Hour(s) / Day(s)			☐
18	Submit Trust data as report to CQC	Minute(s) / Hour(s) / Day(s)			☐
19	Submit Trust data as summary report to CCG	Minute(s) / Hour(s) / Day(s)			☐
20	Submit Trust data as report to NHS Improvement	Minute(s) / Hour(s) / Day(s)			☐
21	Identify latest patient safety information and evidence	Minute(s) / Hour(s) / Day(s)			☐
22	Develop new guidelines and policies	Minute(s) / Hour(s) / Day(s)			☐
23	DELAY (D11)	Minute(s) / Hour(s) / Day(s)			☐
24	Implement existing evidence by reiterating guidelines or policies	Minute(s) / Hour(s) / Day(s)			☐
25	Design and produce training information	Minute(s) / Hour(s) / Day(s)			☐
26	DELAY (D12)	Minute(s) / Hour(s) / Day(s)			☐
27	DELAY (D13) between submitting data to NHS Improvement and receiving Patient Safety Alerts	Minute(s) / Hour(s) / Day(s)			☐
Link to reporting activities map					

SECTION I: Additional questions about this research

2. Did you take part in our previous research studies on the incident reporting process (in 2015) and/or validating and developing a process map for NHS incident reporting systems (in 2018)?

- ☐ a. Yes, I took part in both ☐ d. Yes, I took part in 2018 only
☐ b. Yes, I took part in 2015 only ☐ e. No, I did not take part in either study

Please indicate your agreement or disagreement with the following statements about this research.

	Strongly Disagree ▼	Disagree ▼	Neither ▼	Agree ▼	Strongly Agree ▼
2. The schematic provided models the flow of events in incident reporting systems	☐ ₁	☐ ₂	☐ ₃	☐ ₄	☐ ₅
Think about all the ways you hear about risks to patient safety...					
	Strongly Disagree ▼	Disagree ▼	Neither ▼	Agree ▼	Strongly Agree ▼
3. Incident reporting systems are an effective way for me to regularly <i>learn</i> about risks to the safety of patients I care for.....	☐ ₁	☐ ₂	☐ ₃	☐ ₄	☐ ₅
4. Incident reporting systems are an effective way for me to regularly <i>improve</i> the care I give patients.....	☐ ₁	☐ ₂	☐ ₃	☐ ₄	☐ ₅
5. Incident reporting systems are a valuable use of the time I spend on them (e.g., reporting or managing incidents)	☐ ₁	☐ ₂	☐ ₃	☐ ₄	☐ ₅

SECTION I: Additional questions about this research (continued)

Provide details of any important resources used in incident reporting systems that are not captured in this questionnaire, such as equipment. If you have additional thoughts about the incident reporting process, please annotate the schematics provided on the next page.

THANK YOU FOR COMPLETING THIS SURVEY.

D.9 Frequency tables of demographic responses provided by consenting participants

unit		Freq.	Percent	Cum.
-----+-----				
many		6	8.82	8.82
med		4	5.88	14.71
surg		15	22.06	36.76
obs		1	1.47	38.24
paeds		1	1.47	39.71
icu		3	4.41	44.12
pharm		2	2.94	47.06
radiol		1	1.47	48.53
anaes		5	7.35	55.88
other		30	44.12	100.00
-----+-----				
Total		68	100.00	

hospcareer_				
t (years)		Freq.	Percent	Cum.
-----+-----				
<1		6	22.22	22.22
1-5		11	40.74	62.96
6-10		4	14.81	77.78
11-15		2	7.41	85.19
16-20		2	7.41	92.59
>21		2	7.41	100.00
-----+-----				
Total		27	100.00	

position		Freq.	Percent	Cum.
-----+-----				
RN		7	9.72	9.72
cons		8	11.11	20.83

reg		13	18.06	38.89
corefound		2	2.78	41.67
pharm		2	2.78	44.44
dietic		1	1.39	45.83
matron		3	4.17	50.00
RM		2	2.78	52.78
AHP		10	13.89	66.67
admin		10	13.89	80.56
other		14	19.44	100.00
-----+-----				
Total		72	100.00	

payscale				
(band)		Freq.	Percent	Cum.
-----+-----				
4		2	4.00	4.00
5		3	6.00	10.00
6		5	10.00	20.00
7		15	30.00	50.00
8a		15	30.00	80.00
8b		8	16.00	96.00
8d		2	4.00	100.00
-----+-----				
Total		50	100.00	

specialty_t		Freq.	Percent	Cum.
-----+-----				
<1		7	9.46	9.46
1-5		19	25.68	35.14
6-10		11	14.86	50.00
11-15		10	13.51	63.51
16-20		12	16.22	79.73
>21		15	20.27	100.00
-----+-----				
Total		74	100.00	

trust_type	Freq.	Percent	Cum.
-----+-----			
foundation	19	27.14	27.14
acute	50	71.43	98.57
independent	1	1.43	100.00
-----+-----			
Total	70	100.00	

D.10. Summary of Kruskal-Wallis and median tests of between group differences in time estimates

Reporting time estimates

Kruskal-Wallis equality-of-populations rank test for healthcare worker position or role (position)

+-----+			
position	Obs	Rank Sum	
-----+-----+-----			
RN	4	77.00	
cons	6	221.00	
reg	12	173.00	
corefound	2	51.00	
pharm	1	6.00	
-----+-----+-----			
RM	1	48.00	
AHP	8	201.00	
admin	5	117.00	
other	10	331.00	
+-----+			

chi-squared = 18.985 with 8 d.f.
probability = 0.0149

Median test

Greater										
than the position										
median	RN	cons	reg	corefound	pharm	RM	AHP	admin	other	Total
-----+-----										
no	2	1	11	1	1	0	5	2	2	25
yes	2	5	1	1	0	1	3	3	8	24
-----+-----										
Total	4	6	12	2	1	1	8	5	10	49

Pearson chi2(8) = 17.2868 Pr = 0.027

Fisher's exact = 0.006

Kruskal-Wallis equality-of-populations rank test for between group differences for career time in specialty (specialty_t)

+-----+			
	specialty	Obs	Rank Sum
-----+-----+-----			
	<1	3	105.00
	1-5	13	250.00
	6-10	9	171.00
	11-15	9	290.00
	16-20	9	258.00
-----+-----+-----			
	>21	7	201.00
+-----+			

chi-squared = 8.147 with 5 d.f.

probability = 0.1483

Median test

Greater								
than the		specialty_t						
median	<1	1-5	6-10	11-15	16-20	>21		Total
-----+-----+-----								
no	0	9	7	3	3	3		25
yes	3	4	2	6	6	4		25
-----+-----+-----								
Total	3	13	9	9	9	7		50
Pearson chi2(5) = 9.8437 Pr = 0.080								
Fisher's exact = 0.085								

Kruskal-Wallis equality-of-populations rank test for responses to "When a mistake is made that could harm the patient, but does not, how often is this reported?"

+-----+			
	repvol3	Obs	Rank Sum
-----+-----+-----			
	never	1	11.00
	rarely	3	59.00
	sometimes	10	142.00
	most of the time	20	575.00
	always	12	294.00
+-----+			

chi-squared = 9.039 with 4 d.f.
probability = 0.0601

Median test

Greater |

than the | repvol3

median | never rarely sometimes most of t always | Total

-----+-----+-----

no | 1 2 8 6 6 | 23

yes | 0 1 2 14 6 | 23

-----+-----+-----

Total | 1 3 10 20 12 | 46

Pearson chi2(4) = 8.1333 Pr = 0.087

Fisher's exact = 0.053

Management time estimates

Kruskal-Wallis equality-of-populations rank test for between group differences in response to "We are informed about errors that happen in this ward/department" (comms3)

+-----+			
	comms3	Obs	Rank Sum
-----+-----+-----			
	rarely	1	15.50
	sometimes	9	126.50
	most of the time	21	451.00
	always	9	227.00
+-----+			

chi-squared = 4.533 with 3 d.f.
probability = 0.2094

Median test

Greater									
than the comms3									
median rarely sometimes most of t always Total									
-----+-----+-----									
no	1	8	11	2		22			
yes	0	1	10	7		18			
-----+-----+-----									
Total	1	9	21	9		40			

Pearson chi2(3) = 8.9594 Pr = 0.030

Fisher's exact = 0.020

Kruskal-Wallis equality-of-populations rank test for between group responses to "Staff feel free to question the decisions or actions of those with more authority" (comms4)

+-----+			
	comms4	Obs	Rank Sum
-----+-----+-----			
	rarely	3	96.00
	sometimes	14	225.50
	most of the time	18	363.00
	always	5	135.50
+-----+			

chi-squared = 6.488 with 3 d.f.
probability = 0.0901

Median test

Greater					
than the comms4					
median	rarely	sometimes	most of t	always	Total
-----+-----+-----					
no	1	11	9	1	22
yes	2	3	9	4	18
-----+-----+-----					
Total	3	14	18	5	40
Pearson chi2(3) = 6.3684 Pr = 0.095					
Fisher's exact = 0.082					

Kruskal-Wallis equality-of-populations rank test for between group differences in responses to "Staff are afraid to ask questions when something does not seem right" (comms6)

+-----+			
	comms6	Obs	Rank Sum
-----+-----+-----			
	never	4	108.00
	rarely	26	586.00
	sometimes	9	102.00
	most of the time	1	24.00
+-----+			

chi-squared = 7.650 with 3 d.f.
probability = 0.0538

Median test

Greater											
than the		comms6									
median	never	rarely	sometimes	most of t		Total					
-----+-----+-----											
no	2	12	8	0		22					
yes	2	14	1	1		18					
-----+-----+-----											
Total	4	26	9	1		40					
Pearson chi2(3) = 6.2609 Pr = 0.100											
Fisher's exact = 0.065											

Kruskal-Wallis equality-of-populations rank test for perceived organisation safety rating (safetyrat)

+-----+			
safetyrat	Obs	Rank Sum	
-----+-----+-----			
excellent	4	111.50	
very good	29	590.50	
acceptable	5	72.00	
poor	1	6.00	
+-----+			

chi-squared = 4.651 with 3 d.f.
probability = 0.1992

Median test

Greater |

than the | safetyrat

median	excellent	very good	acceptabl	poor	Total

```
no | 1 14 5 1 | 21
```

```
yes |    3    15    0    0 |    18
```

Total		4	29	5	1		39

Pearson $\chi^2(3) = 6.8442$ Pr = 0.077

Fisher's exact = 0.050

Reporting and Management time combined

Kruskal-Wallis equality-of-populations rank test for healthcare worker position or role (position)

+-----+			
position	Obs	Rank Sum	
-----+-----+-----			
RN	6	186.00	
cons	7	338.00	
reg	12	208.00	
corefound	2	63.00	
pharm	2	69.00	
-----+-----+-----			
matron	3	50.00	
RM	2	126.00	
AHP	10	342.00	
admin	10	329.00	
other	12	500.00	
+-----+			

chi-squared = 22.018 with 9 d.f.
probability = 0.0088

Median test

Greater											
than the	position										
median	RN	cons	reg	core	found	pharm	matron	RM	AHP	admin	other Total
-----+-----+-----											
no	3	1	11	1	1	3	0	5	5	3	33
yes	3	6	1	1	1	0	2	5	5	9	33
-----+-----+-----											
Total	6	7	12	2	2	3	2	10	10	12	66

Pearson chi2(9) = 19.9048 Pr = 0.019

Fisher's exact = 0.006

Kruskal-Wallis equality-of-populations rank test for between group differences for career time in specialty (specialty_t)

+-----+			
	specialty	Obs	Rank Sum
-----+-----+-----			
	<1	7	291.00
	1-5	18	417.50
	6-10	10	246.00
	11-15	9	388.00
	16-20	11	436.00
-----+-----+-----			
	>21	12	499.50
+-----+			

chi-squared = 13.646 with 5 d.f.

probability = 0.0180

Median test

Greater |

```

than the | specialty_t

```

```
median |  <1  1-5  6-10  11-15  16-20  >21 | Total
```

-----+-----+									
no		2	13	8	3	4	4		34
yes		5	5	2	6	7	8		33
-----+-----+									
Total		7	18	10	9	11	12		67

Pearson $\chi^2(5) = 11.5804$ Pr = 0.041

Fisher's exact = 0.043

Kruskal-Wallis equality-of-populations rank test "When a mistake is made that could harm the patient, but does not, how often is this reported?"

+-----+			
	repvol3	Obs	Rank Sum
-----+-----+-----			
	never	1	15.00
	rarely	3	76.00
	sometimes	11	199.00
	most of the time	30	1054.00
	always	15	486.00
+-----+			

chi-squared = 8.893 with 4 d.f.
probability = 0.0638

Median test

Greater										
than the repvol3										
median	never	rarely	sometimes	most of t	always	Total				
-----+-----+-----										
no	1	2	9	11	7	30				
yes	0	1	2	19	8	30				
-----+-----+-----										
Total	1	3	11	30	15	60				
Pearson chi2(4) = 7.9879 Pr = 0.092										
Fisher's exact = 0.057										

Kruskal-Wallis equality-of-populations rank test for perceived organisation safety rating (safetyrat)

+-----+			
safetyrat	Obs	Rank Sum	
-----+-----+-----			
excellent	8	356.00	
very good	37	1128.00	
acceptable	12	326.00	
poor	4	81.00	
+-----+			

chi-squared = 6.683 with 3 d.f.
probability = 0.0827

Median test

Greater					
than the		safetyrat			
median	excellent	very good	acceptabl	poor	Total
-----+-----+-----					
no	1	19	8	3	31
yes	7	18	4	1	30
-----+-----+-----					
Total	8	37	12	4	61

Pearson chi2(3) = 6.8458 Pr = 0.077

Fisher's exact = 0.076

Appendix E

This appendix provides supplementary information and data relevant to Chapter five.

E.1. Table of NRLS feedback reports published between 2002 and 2012

	Report Type	Date	Reference #	Clinical Area	NRLS Categorisation	Never Event Category	
1	PSA	Feb-04	PSA02	General	Infrastr (stff/fac/env)	General h/c	Crash call number standardisation
2	Guidance	Oct-02		General	Infrastr (stff/fac/env)	General h/c	Engaging clinicians
3	Guidance	Jan-03		General	Infrastr (stff/fac/env)	General h/c	Design for patient safety report
4	Guidance	Jan-04		General	Cnsnt&Comms	General h/c	Patient safety issues with learning disability patients
5	Safer practice notice	May-04		General	Med Dev	General h/c	Improving infusion device safety: NPSA toolkit
6	Safer practice notice	May-04		Drug	Med	Medication Event	Safer practice with Repevax and Revaxis vaccines
7	Guidance	Jul-04		General	Cnsnt&Comms	General h/c	Seven steps to patient safety: full reference
8	PSA	Mar-05	PSA06	Surgery	Ttmnt	Surgical	Right place surgery
9	PSA	Aug-05		Neonatal	Pt Acc	General h/c	Misplaced nasogastric tubes in neonates
10	Guidance	Aug-05		General	Cnsnt&Comms	General h/c	Medical error
11	Safer practice notice	Nov-05		General	Docs (records/ID)	General h/c	Safer patient identification
12	Guidance	Jan-06		General	Cnsnt&Comms	General h/c	Manchester patient safety framework
13	PSA	Jun-06	PSA13	Drug	Med	Medication Event	Misdosing oral methotrexate
14	Safer practice notice	Nov-06		General	Ttmnt	General h/c	Right patient, right blood: core competencies

15	Safer practice notice	Nov-06		General	Ttmnt	General h/c	Right patient, right blood: advice for safer transfusions
16	Guidance	Nov-06		General	Impl care & mntr	General h/c	Risk assessment programme
17	Safer practice notice	Jan-07		General	Infrastr (stff/fac/env)	General h/c	Colour coding hospital cleaning materials and equipment
18	Guidance	Jan-07		General	Cnsnt&Comms	General h/c	Patient safety bulletin
19	Guidance	Jan-07		General	Infrastr (stff/fac/env)	General h/c	Design for PS: dispensing environment
20	Guidance	Jan-07		General	Infrastr (stff/fac/env)	General h/c	Design for PS: graphic design of medication
21	Guidance	Jan-07		General	Infrastr (stff/fac/env)	General h/c	Design for PS: graphic design of dispensed medicines
22	Guidance	Jan-07		Emergency care	Cnsnt&Comms	General h/c	Future ambulances
23	Safer practice notice	Feb-07		General	Slf Hm	General h/c	Bedrails safer practice notice
24	Safer practice notice	Feb-07		General	Impl care & mntr	General h/c	Early identification of failure to act on radiological imaging reports
25	PSA	Mar-07	PSA18	Drug	Med	Medication Event	Anticoagulant management
26	PSA	Mar-07	PSA21	Anaesthesia	Med	Medication Event	Misadministration of epidural injection
27	PSA	Mar-07	PSA19	Drug	Med	Medication Event	Safer measurement and administration of medicines
28	PSA	Mar-07	PSA22	Drug	Med	General h/c	Fluid induced hyponatraemia
29	Guidance	Mar-07		General	Impl care & mntr	General h/c	Healthcare risk assessment made easy

30	Guidance	Apr-07		General	Infrastr (stff/fac/env)	General h/c	National specifications for cleanliness in the NHS
31	RRR	Jun-07	RRR01	Drug	Med	Medication Event	Oncology - chemotherapy product confusion
32	Safer practice notice	Jul-07		General	Docs (rec0rds/ID)	General h/c	Standardising wristbands improves safety
33	Guidance	Jul-07		General	Impl care & mntr	General h/c	Ensuring safer practice for adults with learning disabilities
34	RRR	Sep-07	RRR02	Drug	Med	Medication Event	Non-lipid/lipid formulations of antifungal dosing
35	RRR	Sep-07	RRR03	Surgery	Ttmnt	General h/c	Appropriate setting to prevent haemorrhage
36	RRR	Nov-07	RRR04	General	Med Dev	General h/c	Fire hazard with bandaging
37	Guidance	Nov-07		General	Impl care & mntr	General h/c	Recognising deterioration in hospitalised patients
38	PSA	Dec-07	PSG001	Drug	Med	Medication Event	Medication reconciliation
39	RRR	Jan-08	RRR001	Drug	Med	Medication Event	Oncology - misdosed drug
40	Guidance	Jan-08		General	Impl care & mntr	General h/c	Risk matrix for risk managers
41	Guidance	Mar-08		Mental Health/Community	Impl care & mntr	Mental Health	SAEs in mental health
42	RRR	Apr-08	RRR002	Drug / General	Med	Medication Event	Heparin concentration errors
43	Guidance	Apr-08		General	Impl care & mntr	General h/c	Towards safer radiotherapy
44	RRR	May-08	RRR003	General	Ttmnt	General h/c	Chest drain insertion
45	Guidance	May-08		General	Infrastr (stff/fac/env)	General h/c	Design for patient safety
46	Guidance	May-08		General	Cnsnt&Comms	General h/c	Compendium of patient safety in practice

47	Guidance	Jun-08		General	Cnsnt&Comms	General h/c	Five actions to improve patient safety reporting
48	RRR	Jul-08	RRR006	General	Impl care & mntr	General h/c	Arterial line infusion and sampling
49	RRR	Jul-08	RRR05	Drug	Med	Medication Event	Misdosed opioid
50	RRR	Aug-08	RRR004	Drug	Med	Medication Event	Misdosed Vinca Alkaloids
51	PSA	Aug-08	PSG002	General	Impl care & mntr	General h/c	Ventilated patient management
52	RRR	Sep-08	RRR007	General	Ttmnt	General h/c	Haemodialysis/risk from hydrogen peroxide treated water
53	PSA	Sep-08	PSA04	General	Infectn	General h/c	Hand hygiene
54	RRR	Oct-08	RRR008	Drug	Med	Medication Event	Hib vaccination
55	Guidance	Oct-08		Nutrition	Impl care & mntr	General h/c	Water: the forgotten nutrient
56	Guidance	Oct-08		General	Infrastr (stff/fac/env)	General h/c	Significant event audit
57	RRR	Nov-08	RRR009	Surgery	Ttmnt	Surgical	Neurosurgery - wrong site surgery
58	RRR	Nov-08	RRR010	Mental Health/Community	Pt Acc	General h/c	Resuscitating mental health and learning disability patients
59	Guidance	Nov-08		General	Cnsnt&Comms	General h/c	Seven steps to patient safety in mental health
60	RRR	Dec-08	RRR011	Drug	Med	Medication Event	Overdosing midazolam
61	Guidance	Dec-08		General	Cnsnt&Comms	General h/c	Team self-review
62	PSA	Jan-09	PSA002	Surgery	Ttmnt	Surgical	WHO SSC
63	Guidance	Jan-09		Nutrition	Cnsnt&Comms	General h/c	Nutrition factsheet

64	RRR	Feb-09	RRR012	General	Med	Medication Event	Oral bowel cleansing solutions
65	Guidance	Feb-09		General	Cnsnt&Comms	General h/c	Seven steps to patient safety for primary care
66	Guidance	Feb-09		General	Infectn	General h/c	National specifications for cleanliness in the NHS
67	Guidance	Feb-09		General	Impl care & mntr	General h/c	Acting on serious risks to patients
68	Guidance	Feb-09		General	Cnsnt&Comms	General h/c	Never events framework 2009-10
69	RRR	Mar-09	RRR001	Surgery	Ttmnt	Surgical	Orthopaedics/hip fracture
70	RRR	Apr-09	RRR02	General	Impl care & mntr	General h/c	Urology - wrong sized catheter in males
71	Safer practice notice	Apr-09		General	Ttmnt	General h/c	Throat Packs
72	RRR	May-09	RRR003	Mental Health/Community	Pt Abuse	General h/c	Child protection
73	RRR	Jun-09	RRR004	General	Ttmnt	General h/c	Ophthalmology/Glaucoma
74	Safer practice notice	Jun-09		General	Docs (recrds/ID)	General h/c	Risk of not using the NHS number for identification
75	Guidance	Jun-09		General	Cnsnt&Comms	General h/c	Questions are the answer! 7 questions for board members
76	Guidance	Jun-09		General	Cnsnt&Comms	General h/c	Seven steps to patient safety in general practice
77	RRR	Jul-09	RRR005	Urology	Ttmnt	Surgical	Perforation of bowel
78	RRR	Sep-09	RRR006	General	Impl care & mntr	General h/c	Oxygen management
79	Signal	Sep-09		General	Slf Hm	Mental Health	Wardrobes used as ligature points

80	Signal	Sep-09		General	Impl care & mntr	General h/c	Extravasation injury in neonates
81	Signal	Sep-09		Anaesthesia	Med	Medication Event	Total IV anaesthesia
82	Signal	Sep-09		General	Impl care & mntr	General h/c	Poor quality organs for transplant
83	Signal	Sep-09		General	Ttmnt	General h/c	Delayed diagnosis of testicular torsion
84	Signal	Sep-09		General	Ttmnt	General h/c	Managing sickle cell crises
85	Signal	Sep-09		General	Med	General h/c	Vaccine storage
86	Signal	Sep-09		General	Impl care & mntr	General h/c	Delayed diagnosis of spinal fracture
87	Signal	Sep-09		General	Impl care & mntr	General h/c	Bleed after liver biopsy
88	PSA	Nov-09	PSA003	General	Cnsnt&Comms	General h/c	Being open in communication
89	Signal	Nov-09		General	Impl care & mntr	General h/c	Nasogastric tube feeding under restraint
90	Signal	Nov-09		General	Impl care & mntr	General h/c	Recognising compartment syndrome
91	Signal	Nov-09		General	Infrastr (stff/fac/env)	General h/c	Distance to travel for key on-call staff
92	Signal	Nov-09		Obstetrics	Ttmnt	Maternity	Missed diagnosis and treatment delay in ectopic pregnancy
93	Signal	Nov-09		General	Impl care & mntr	General h/c	Pressure ulcer under plaster casts
94	Signal	Nov-09		Anaesthesia	Med	Medication Event	Residual anaesthetic drugs in cannulae
95	Signal	Nov-09		General	Cnsnt&Comms	General h/c	Confidentiality issues for patients harming others
96	Signal	Nov-09		Community care	Med	General h/c	Pain relief in terminal care in the community

97	Guidance	Nov-09		General	Med	Medication Event	Anaesthetic e-form
98	Guidance	Nov-09		General	Ttmnt	Surgical	Wrong side biopsy
99	Guidance	Nov-09		General	Cnsnt&Comms	General h/c	Being Open Framework
100	Guidance	Nov-09		General	Cnsnt&Comms	General h/c	Being open: communicating incidents with patients
101	Guidance	Nov-09		General	Infrastr (stff/fac/env)	General h/c	Analysing significant event audits in general practice
102	RRR	Dec-09	RRR007	Surgery	Ttmnt	Surgical	Tourniquet removal in extremities surgery
103	PSA	Dec-09	PSA005	Drug	Med	Medication Event	Misdosing lithium
104	Guidance	Dec-09		Infection	Infectn	General h/c	Matching Michigan: data collection tools for central venous catheter bloodstream infections
105	Guidance	Dec-09		General	Med	Medication Event	Safer lithium therapy
106	RRR	Jan-10	RRR008	Drug / General	Med	General h/c	Vaccine cold storage
107	Guidance	Jan-10		General	Cnsnt&Comms	General h/c	Safety and simulation: learning from a national review
108	RRR	Feb-10	RRR009	Drug / General	Med	Medication Event	Medication management/delayed or omitted doses (anti-infective and anticoagulants)
109	PSA	Feb-10	PSA001	Drug	Med	Medication Event	Misdosing IV gentamicin in neonates
110	Signal	Feb-10		Antenatal	Ttmnt	General h/c	Neonatal resuscitation
111	Signal	Feb-10		General	Pt Acc	General h/c	Contact injuries from wheelchairs in hospitals
112	Signal	Feb-10		General	Docs (recrds/ID)	General h/c	Transferring neurosurgery patient images
113	Signal	Feb-10		Drug	Med	Medication Event	Wrong strength phenol

114	Signal	Feb-10		General	Acc/Admi/Trans/Dis	General h/c	Mental health patients in transit
115	Signal	Feb-10		Surgery	Med	Medication Event	Injectable medicines in theatre
116	Signal	Feb-10		General	Impl care & mntr	General h/c	Extravasation of neonates revisited
117	Signal	Feb-10		Mental Health/Community	Pt Acc	General h/c	ECT patient safety issues
118	Guidance	Feb-10		General	Infrastr (stff/fac/env)	General h/c	Design for patient safety
119	Toolkit	Feb-10		General	Cnsnt&Comms	General h/c	Nasogastric tube audit
120	RRR	Mar-10	RRR010	Surgery	Impl care & mntr	Surgical	Post-operative management of gastrostomy
121	Guidance	Mar-10		General	Infrastr (stff/fac/env)	General h/c	Pembury: summary report
122	Guidance	Mar-10		General	Cnsnt&Comms	General h/c	Framework for reporting and learning from SAEs
123	RRR	Apr-10	RRR011	Surgery	Impl care & mntr	Surgical	Pre-operative pregnancy checks
124	RRR	May-10	RRR012	Obstetrics	Ttmnt	Surgical	Retained foreign objects
125	RRR	Jun-10	RRR013	General	Med	Medication Event	Insulin administration
126	RRR	Jul-10	RRR014	Drug	Med	Medication Event	Misdosing LMWH
127	RRR	Aug-10	RRR015	Antenatal	Med	General h/c	IV fluid management
128	RRR	Sep-10	RRR016	Surgery	Ttmnt	Surgical	General laparoscopic surgery
129	RRR	Oct-10	RRR017	General	Ttmnt	General h/c	Emergency transfusion/avoiding delays
130	Signal	Oct-10		Drug	Med	Medication Event	IV paracetamol dosing errors in children

131	Signal	Oct-10		Drug	Med	Medication Event	Anticoagulant patients and head injury
132	Signal	Oct-10		General	Ttmnt	General h/c	Delay in diagnosis and treatment of spinal cord compression
133	Signal	Oct-10		General	Impl care & mntr	General h/c	Bleed after femoral catheter removal
134	Signal	Oct-10		Anaesthesia	Impl care & mntr	Medication Event	Wrong site nerve block
135	Signal	Oct-10		General	Impl care & mntr	General h/c	Non-invasive ventilation
136	Signal	Oct-10		Infection	Infectn	General h/c	Low temperature sign of sepsis in new-borns
137	Signal	Oct-10		General	Ttmnt	General h/c	Harm to bariatric patients from treatment delay
138	Signal	Oct-10		Drug	Med	Medication Event	Detecting harm after paracetamol overdose
139	Signal	Oct-10		General	Impl care & mntr	General h/c	Accurate patient weight
140	RRR	Nov-10	RRR018	Drug / General	Med	Medication Event	Misdosing/loading dosing
141	RRR	Dec-10	RRR019	Palliative Care	Med Dev	General h/c	Syringe driver and pump use
142	RRR	Jan-11	RRR001	General	Ttmnt	General h/c	Fall aftercare
143	Signal	Feb-11		General	Infrastr (stff/fac/env)	General h/c	Safe use of ultra low beds
144	Signal	Feb-11		General	Cnsnt&Comms	General h/c	Harm to patient nil by mouth
145	Signal	Feb-11		General	Med Dev	General h/c	Harm from compression bandages
146	Signal	Feb-11		Orthopaedics	Impl care & mntr	General h/c	Missed diagnosis of paediatric fractures
147	Signal	Feb-11		General	Med Dev	General h/c	Airway suction equipment

148	Signal	Feb-11		General	Pt Acc	General h/c	Risk of harm from child entanglement in lines
149	Signal	Feb-11		General	Impl care & mntr	General h/c	Bleeds from AV fistula
150	Signal	Feb-11		General	Cnsnt&Comms	General h/c	Patients' resuscitation status
151	Signal	Feb-11		Drug	Med	Medication Event	Sedation errors during emergency treatment in inappropriate setting
152	PSA	Mar-11	PSA003	General	Med	Medication Event	Diabetic management
153	Signal	Mar-11		General	Slf Hm	Mental Health	Plastic bags and self-harm
154	Signal	Mar-11		Drug	Med	Medication Event	IV morphine administration on neonatal units
155	Signal	Mar-11		Orthopaedics	Ttmnt	General h/c	Rib fracture patients
156	Signal	Mar-11		Antenatal	Ttmnt	General h/c	Imperforate anus in new-borns
157	Signal	Mar-11		General	Ttmnt	General h/c	Detecting and treating acute limb ischaemia
158	Signal	Mar-11		Cardiology	Ttmnt	General h/c	Prosthetic valve endocarditis
159	Signal	Mar-11		Antenatal	Impl care & mntr	General h/c	Plasma sodium monitoring in babies
160	Signal	Mar-11		General	Impl care & mntr	General h/c	Multiple use of single use injectable medicines
161	Signal	Sep-11		General	Impl care & mntr	General h/c	Ingestion of Vernagel
162	Signal	Sep-11		General	Ttmnt	General h/c	Harm from acupuncture
163	Signal	Sep-11		General	Impl care & mntr	General h/c	Retained guidewire following central venous access
164	Signal	Sep-11		General	Impl care & mntr	General h/c	Air embolism when removing central lines

165	Signal	Sep-11		Surgery	Impl care & mntr	Surgical	Tracking removal of intentionally retained swabs
166	Signal	Sep-11		Orthopaedics	Impl care & mntr	Surgical	Risk of bowel obstruction post orthopaedic surgery
167	Signal	Sep-11		Autoimmune	Ttmnt	General h/c	Systemic Lupus Erythematosus management
168	Signal	Sep-11		Drug	Med	Medication Event	Prevention of harm with alfacalcidol preparations
169	RRR	Oct-11	RRR002	Antenatal	Impl care & mntr	General h/c	MCADD baby management
170	RRR	Nov-11	RRR003	Anaesthesia	Med Dev	General h/c	Spinal, epidural, regional administration connectors
171	Signal	Feb-12		General	Ttmnt	General h/c	Prompt treatment for necrotising fasciitis
172	Signal	Feb-12		Drug	Med	Medication Event	Buccal Midazolam harm prevention
173	Signal	Feb-12		General	Impl care & mntr	General h/c	Risk of skin-prep related fire in OT
174	Signal	Feb-12		General	Impl care & mntr	General h/c	Diagnosing death after CPR
175	Signal	Feb-12		Surgery	Ttmnt	Surgical	Risk of harm following gastric bypass
176	Signal	Feb-12		Neurology	Impl care & mntr	Medication Event	CPM syndrome after rapid sodium correction
177	Signal	Feb-12		General	Impl care & mntr	General h/c	Gastrostomy issues
178	RRR	Mar-12	RRR001	General	Impl care & mntr	General h/c	Nasogastric tube flushing
179	Alert	Jul-02	NRLS-1051	Drug	Impl care & mntr	Medication Event	Potassium solutions: errors during IV infusions

E.2. NRLS feedback reports selected for before and after study of effects


National Patient Safety Agency

Patient safety alert

18



Alert

28 March 2007

Immediate action	☐
Action	☒
Update	☐
Information request	☐

Ref: NPSA/2007/18

Actions that can make anticoagulant therapy safer

Anticoagulants are one of the classes of medicines most frequently identified as causing preventable harm and admission to hospital.¹⁻³ Managing the risks associated with anticoagulants can reduce the chance of patients being harmed in the future.

This patient safety alert has been developed in collaboration with the British Society for Haematology (BSH) and a broad range of other clinical organisations and individual clinicians, patients and patient groups.

Action for the NHS and the independent sector

The National Patient Safety Agency (NPSA) is recommending that NHS and independent sector organisations in England and Wales take the following steps:

- 1 Ensure all staff caring for patients on anticoagulant therapy have the necessary work competences. Any gaps in competence must be addressed through training to ensure that all staff may undertake their duties safely.
- 2 Review and, where necessary, update written procedures and clinical protocols for anticoagulant services to ensure they reflect safe practice, and that staff are trained in these procedures.
- 3 Audit anticoagulant services using BSH/NPSA safety indicators as part of the annual medicines management audit programme. The audit results should inform local actions to improve the safe use of anticoagulants, and should be communicated to clinical governance, and drugs and therapeutics committees (or equivalent). This information should be used by commissioners and external organisations as part of the commissioning and performance management process.
- 4 Ensure that patients prescribed anticoagulants receive appropriate verbal and written information at the start of therapy, at hospital discharge, on the first anticoagulant clinic appointment, and when necessary throughout the course of their treatment. The BSH and the NPSA have updated the patient-held information (yellow) booklet.
- 5 Promote safe practice with prescribers and pharmacists to check that patients' blood clotting (International Normalised Ratio, INR) is being monitored regularly and that the INR level is safe before issuing or dispensing repeat prescriptions for oral anticoagulants.

For response by:

- All NHS and independent sector organisations in England and Wales

For action by:

- The chief pharmacist/pharmaceutical advisor should lead the response to this alert, supported by the chief executive, medical director, nursing director and clinical governance lead/risk manager

We recommend you also inform:

- Medical staff
- Nursing staff
- Pharmacy staff
- General practitioners
- Community pharmacists
- Dental surgeons
- Patient advice and liaison service staff in England
- Community health councils in Wales
- Medical laboratory scientists

The NPSA has informed:

- Chief executives of acute trusts, primary care organisations, ambulance trusts, mental health trusts and local health boards in England and Wales
- Chief executives/regional directors and clinical governance leads of strategic health authorities (England) and regional offices (Wales)
- Healthcare Commission
- Healthcare Inspectorate Wales
- Commission for Social Care Inspection

- Medicines and Healthcare products Regulatory Agency
- Welsh Health Supplies
- Royal colleges and societies
- NHS Direct
- Relevant patient organisations and community health councils in Wales
- Independent Healthcare Forum
- Business Services Centre (Wales)
- Independent Healthcare Advisory Services

Patient safety alert 18

Actions that can make anticoagulant therapy safer

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- 6 Promote safe practice for prescribers co-prescribing one or more clinically significant interacting medicines for patients already on oral anticoagulants; to make arrangements for additional INR blood tests, and to inform the anticoagulant service that an interacting medicine has been prescribed. Ensure that those dispensing clinically significant interacting medicines for these patients check that these additional safety precautions have been taken.
- 7 Ensure that dental practitioners manage patients on anticoagulants according to evidence-based therapeutic guidelines. In most cases, dental treatment should proceed as normal and oral anticoagulant treatment should not be stopped or the dosage decreased inappropriately.
- 8 Amend local policies to standardise the range of anticoagulant products used, incorporating characteristics identified by patients as promoting safer use.
- 9 Promote the use of written safe practice procedures for the administration of anticoagulants in social care settings. It is safe practice for all dose changes to be confirmed in writing by the prescriber. A risk assessment should be undertaken on the use of Monitored Dosage Systems for anticoagulants for individual patients. The general use of Monitored Dosage Systems for anticoagulants should be minimised as dosage changes using these systems are more difficult.

Action deadlines for the Safety Alert Broadcast System (SABS)

Deadline (action underway): 2 July 2007

Action plan to be agreed and actions started

Deadline (action complete): 31 March 2008

All actions to be completed

Further information about SABS can be found at:

www.info.doh.gov.uk/sar2/cmopatie.nsf

Further information on the action points

- 1 **Ensure all staff caring for patients on anticoagulant therapy have the necessary work competences. Any gaps in competence must be addressed through training to ensure that all staff may undertake their duties safely.**

Healthcare organisations must ensure that staff who prescribe, adjust the dosage, dispense, prepare, administer, monitor and discharge patients on anticoagulant therapy have received adequate training to ensure they have the necessary work competences to undertake their duties safely. Particular attention should be given to ensuring that systems are in place for foundation year doctors to receive training and to attain the necessary work competences.

There is evidence that providing nurses, pharmacists and biomedical scientists with these competences, in addition to medical staff, can help deliver inpatient and ambulatory care more safely.¹

The NPSA has commissioned e-learning modules on initiating and maintaining anticoagulant therapy which can help practitioners assess their current level of competence and provide training covering knowledge and understanding to promote safe practice. The e-learning modules are available at www.npsa.nhs.uk/health/alerts

A competence is an expectation of work performance. The process of preparing competences has been established by Skills for Health (www.skillsforhealth.org.uk). Work competences are intended to be multi-disciplinary and outline safe practice for all staff undertaking these responsibilities, including medical staff.

Rapid Response Report 3

From reporting to learning

10 September 2007

Emergency support in surgical units: Dealing with haemorrhage

Please circulate this advice to all relevant staff

As a result of the death of a patient the National Patient Safety Agency (NPSA) is advising that surgery should not be commissioned or delivered in facilities which lack the systems and equipment to manage emergencies safely.

In a recent incident a patient died following routine laparoscopic surgery exacerbated by no blood being available, a lack of critical resuscitation devices such as central venous catheters and an absence of surgical equipment such as abdominal packs and vascular sutures. Poor communication, lack of surgical assistance in the facility and a lack of basic communication devices further worsened the situation. In the concerned case there was no telephone available in the operating theatre.

Routine elective surgery including laparoscopic surgery has serious but well recognised risks such as severe haemorrhage. All units need to have in place robust co-ordinated systems and equipment which can respond immediately to these emergencies. These systems need regular review, testing and updating and must ensure adequate supply of blood, resuscitation equipment and the necessary surgical equipment in case of the occurrence of a recognised complication such as haemorrhage.

For IMMEDIATE ACTION by the NHS and the independent sector, the deadline date for ACTION COMPLETE is 30 November 2007:

Managers of surgery should advise surgeons, nursing staff, operating department practitioners and other healthcare professionals of the issues and ensure:

1. A co-ordinated system for the urgent supply of blood products is established and maintained. Blood must be available quickly for all operative procedures. This will include the ability to communicate directly and immediately with the transfusion laboratory and for blood products to be transported between the laboratory and the unit without delay.
2. All units have access to emergency equipment that may be required in the event of haemorrhage, such as the appropriate sutures and packs. This emergency surgical and resuscitation equipment will need to reflect the range of surgery undertaken in the unit and the degree of geographical isolation from other healthcare services. A formal check should be carried out before every procedure.
3. A formal backup system for surgeons and anaesthetists is essential so that consultants have a system for summoning help in emergency situations.

NPSA action

The NPSA has informed: All Acute Sector and Primary Care NHS Organisations, Treatment Centres, NHS Surgical Units, Day Care Centres, Independent Sector Hospitals, Independent Healthcare Advisory Services and the Royal Colleges.

Further NPSA action

We will continue to monitor any incident reports involving haemorrhage following routine elective surgery which are reported to the NRLS. For further information, contact Dr Kevin Cleary, Medical Director (NPSA), on 020 7927 9527 or email rr@npsa.nhs.uk

DH Gateway Number: 8759

Rapid Response Report

NPSA/2008/RRR002

From reporting to learning

24 April 2008

Risks with Intravenous Heparin Flush Solutions

For IMMEDIATE ACTION by the NHS and the independent sector, the deadline date for ACTION COMPLETE is 24 July 2008. This guidance is applicable to all healthcare professionals prescribing, dispensing or administering intravenous flush solutions to NHS patients. All relevant healthcare professionals and organisations should be made aware of this guidance, including independent contractors and out of hours providers. Actions should be co-ordinated by the Chief Pharmacist or Pharmaceutical Advisor.

Issue

Intravenous heparin flushes are widely used in healthcare to keep both peripheral and central lines open. Risks with heparin flushes are not well recognised by practitioners and risks are increased if they are not formally prescribed or subject to a patient group direction. Other problems include confusion with other 'look-alike' products, selecting wrong medicine when placed in an unlabelled syringe and errors in calculating and making up dilutions.

Patient Safety Incidents

An independent report has recently been published reviewing the circumstances of four patient safety incidents where an anaesthetist mis-selected sodium heparin 25,000 units in 5 ml (Monoparin) instead of sodium heparin 50 units in 5 ml (Hepsal) and administered the more concentrated solution in unlabelled syringes to four children. Thankfully the four children only experienced some temporary bleeding and otherwise are not reported to have suffered longer term harm. However, the potential for serious harm was recognised by the hospital trust. The independent report provides important learning for safer practice. The report can be found at:

www.who.int/patientsafety/information_centre/reports/en/

The NPSA has reviewed patient safety incident reports concerning mis-selection of sodium heparin products and has received 28 incident reports between January 2005 and December 2007. In addition there were also 8 reports where other medicines including diamorphine, lidocaine and magnesium were mis-selected for heparin flush solution products.

Evidence on heparin flushes recently reviewed by UK Medicines Information (UKMi) indicates no advantage over normal saline for maintaining peripheral intravenous catheters (www.druginfozone.nhs.uk/Record%20Viewing/viewRecord.aspx?id=591809). This is also noted in the British National Formulary. For more complex devices, such as central venous or arterial catheters, the evidence is less clear. More specific policies may be required locally depending on the individual devices in use.

Action

- Organisations should review local policies to minimise the use of heparin flush solutions in all devices, including complex central venous or arterial catheters. This should take into account the evidence reviewed by UK Medicines Information (UKMi) which confirms that heparin flushes should not normally be used to flush peripheral intravenous catheters.
- All flush solutions should only be administered following a prescription or patient group direction.
- Local policy and procedures should be reviewed to ensure risk with heparin flush solutions is minimised.
- Healthcare organisations should ensure that all relevant staff are made aware of this guidance and revised policy.

Previous related NPSA recommendations concerning injectable medicines

- The NPSA has previously recommended that the use of concentrated sodium heparin products should be minimised, and wards and departments should normally only stock sodium heparin products of 1,000 units / ml or less. (NPSA Alert 18 – March 2007).
- The NPSA has previously recommended that healthcare organisations should review their multidisciplinary policies and procedures for the preparation and administration of injectable medicines (NPSA Alert 20 – March 2007). These should include the following safe practice guidance:
 - All syringes, including flushes and infusions, must be labelled immediately after preparation by the person who prepared them. The only exception to this is in situations where preparation and bolus (push) administration is one uninterrupted process and the unlabelled product does not leave the hands of the person who prepared it. Only one unlabelled medicine must be handled at one time.
 - For high risk injectable products, such as concentrated heparin, consider the use of double checking systems such as an independent check by another practitioner.
 - Implement a 'purchasing for safety' policy to promote procurement of injectable medicines with inherent safety features.

Further Information

Support information on this Rapid Response Report is available at www.npsa.nhs.uk/patientsafety/ or David Cousin, Head of Safe Medication Practice, c/o rrr@npsa.nhs.uk Telephone: 020 7927 9356

Gateway reference: 9828

Rapid Response Report

NPSA/2010/RRR009

From reporting to learning

24 February 2010

Reducing harm from omitted and delayed medicines in hospital

Issue

Medicine doses are often omitted or delayed in hospital for a variety of reasons. Whilst these events may not seem serious, for some critical medicines or conditions, such as patients with sepsis or those with pulmonary embolisms, delays or omissions can cause serious harm or death. Patients going into hospital with chronic conditions are particularly at risk. For example, patients with Parkinson's disease who do not receive their medicines on time may recover slowly or lose function, such as ability to walk. This has been highlighted by the Parkinson's Disease Society's 'Get it on time' campaign, which has produced resources for both patients and staff to help raise awareness and enable patients to get their medication on time.

The Productive Ward initiative from the National Health Service Institute for Innovation and Improvement (NHS Ili) provides information on minimising interruptions and streamlining the medicines ward round and National Patient Safety Agency (NPSA)/National Institute for Health and Clinical Excellence (NICE) guidance on medicines reconciliation supports the reduction in omitted doses. These are useful resources, but further work is needed in the NHS to address this as an important patient safety issue.

Patient safety incidents

Between September 2006 and June 2009, the NPSA received reports of 27 deaths, 68 severe harms and 21,383 other patient safety incidents relating to omitted or delayed medicines. Of the 95 most serious incidents, 31 involved anti-infectives (antibiotic and antifungals), and 23 involved anticoagulants. Wider evidence suggests that the true rate of harm may be much higher, as events such as these are often not reported.

Work on reducing risks with omitted and delayed critical medicines is needed over a long period. The NPSA is recommending a staged approach, with initial actions now focused on specific critical medicines and longer term work with stakeholders over the next two years to sustain improvements over time.

For IMMEDIATE ACTION by all organisations in the NHS and independent sector who admit patients for in-patient treatment. Deadline for ACTION COMPLETE is 24 February 2011.

An executive director, nominated by the chief executive, working with the chief pharmacist and relevant medical/nursing staff should:

1. identify a list of critical medicines where timeliness of administration is crucial. This list should include anti-infectives, anticoagulants, insulin, resuscitation medicines and medicines for Parkinson's disease, and other medicines identified locally;
2. ensure medicine management procedures include guidance on the importance of prescribing, supplying and administering critical medicines, timeliness issues and what to do when a medicine has been omitted or delayed;
3. review and, where necessary, make changes to systems for the supply of critical medicines within and out-of-hours to minimise risks;
4. review incident reports regularly and carry out an annual audit of omitted and delayed critical medicines. Ensure that system improvements to reduce harm from omitted and delayed medicines are made. This information should be included in the organisation's annual medication safety report;
5. make all staff aware (by wide distribution of this RRR) that omission or delay of critical medicines, for inpatients or on discharge from hospital, are patient safety incidents and should be reported.

Further information

Supporting information including detailed evidence of harm and compliance checklists are available at www.nrls.npsa.nhs.uk/alerts. Further queries should be directed to the NPSA medication safety team at mr@npsa.nhs.uk; telephone 020 7927 9890.

The NPSA has informed: NHS organisations, independent sector, commissioners, regulators and relevant professional bodies in England and Wales.

Gateway ref: 13614

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Rapid Response Report

NPSA/2010/RRR014

From reporting to learning

30 July 2010

Reducing treatment dose errors with low molecular weight heparins

Issue

Prescribed doses of low molecular weight heparins (LMWHs) for the treatment of a thromboembolic event are dependent on the weight of the patient and renal function. Underdosing has an increased risk of a further thromboembolic event, while overdosing can increase the risk of bleeding. Dosing errors with LMWHs can occur if the prescribed treatment dose is not calculated using the patient's current weight. Reports to the National Reporting and Learning System (NRLS) indicate that some patients are not weighed prior to dosing, that body weight is estimated or recorded inaccurately, or that doses based on a patient's weight are miscalculated. Additionally, there are numerous reports where the prescribed, dispensed or administered dose and frequency of LMWH were outside accepted guidelines for the required clinical indication and other predisposing conditions such as renal failure. Limited patient information (i.e. weight, dosage, indication and intended duration of treatment) communicated at transfers of care has also led to reports of harm.

Evidence of harm

Between January 2005 and September 2009, the NPSA received 2,716 patient safety incident reports relating to dosing errors concerning LMWHs. These include one incident reported to have led to death and three reports of severe harm. A review of NHS Litigation Authority claims identified one further death.

Reducing the risk of harm

The recommendations in this Rapid Response Report (RRR) relate to all healthcare sectors and specialties where the prescribing, administration, monitoring and dispensing of treatment doses of LMWHs occur. The use of treatment doses in the community is becoming more commonplace making this relevant to a range of staff and settings.

For IMMEDIATE ACTION by all organisations in the NHS and independent sector. Deadline for ACTION COMPLETE is 28 January 2011.

An executive director, nominated by the chief executive, working with the chief pharmacist and relevant medical/nursing staff should ensure that:

1. A patient's weight is used as the basis for calculating the required treatment dose of LMWH. The weight must be accurately recorded in kilograms (kg) in the inpatient medication chart (when in use) and clinical record. Patients should be weighed at the start of therapy and, where applicable, during treatment.
2. Renal function is considered when prescribing treatment doses of LMWHs. The renal function test should not delay initiation of the first dose but every effort must be made to base subsequent dosing on these results.
3. Dose calculation tools are available for a range of body weights, specific clinical indications and LMWH products, and that consideration is given to rationalising the range of LMWH products used in the organisation.
4. Essential information such as dose, weight, renal function, indication and duration of treatment is communicated at transfers of care (e.g. by discharge letters) and used to ensure that future doses are safe.
5. Dosing checks based on patient information are made by healthcare professionals who review, dispense or administer LMWHs when this information is readily available to them.
6. System improvements should be demonstrated through the collection and review of data, such as incident reports, clinical pharmacy interventions, audit or other relevant outcome measures.

Further information

Supporting information, including evidence of harm and a compliance checklist, is available at www.nrls.npsa.nhs.uk/alerts. Further queries should be directed to the NPSA medication safety team at mr@npsa.nhs.uk; telephone 020 7927 9890.

The NPSA has informed: NHS organisations, independent sector, commissioners, regulators and professional bodies.

Gateway ref: 14444

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Haemorrhage following removal of femoral catheters | Signal

Reference number 1293

Issue date 29 October 2010

Type Signal

This **Signal** is about the risk of haemorrhage following the removal of femoral catheters from adult patients.

An extract from an incident reads:

"Pressure applied for 10min after removing femoral catheter, then dressed and 10min rest . No bleeding so left with husband. In bathroom bled approx 1 pint ."

Femoral catheters are a reliable route of access to the cardiovascular system. They are inserted in aseptic conditions, often in the operating theatre or intensive care unit, by specifically trained individuals. Removing the catheter should be a carefully planned, aseptic procedure associated with minimal blood loss. When the procedure is not performed in a controlled manner with adequate monitoring, excessive bleeding may result.

A trigger incident, where a patient died following elective femoral catheter removal in the evening, prompted a search of the National Reporting and Learning System (NRLS). There were 45 incidents reported related to femoral catheter haemorrhage of which two resulted in death and 15 in moderate harm. A range of themes emerged such as insufficient pressure on the site following catheter removal, catheter removal prior to transfer without informing the receiving team, catheters thought to be venous were in fact arterial and no outward signs of bleeding thus delaying diagnosis (one of these was a death). Other confounding factors were sometimes cited as contributing to the outcome such as heparin infusions, coexisting thrombosis, and catheter removal while on ECMO (Extracorporeal membrane oxygenation) treatment. There were 15 cases of inadvertent removal, often by the patient themselves.

The reports suggest inconsistencies with preparation for catheter removal and aftercare, particularly in relation to recommended duration of pressure, observation and rest. Methods to secure the catheters would also appear to be variable.

Units that use these devices should have access to local guidelines for safe removal and aftercare of femoral catheters (arterial and venous). The procedure should be planned and occur in areas where assistance is readily available and a contingency for excessive bleeding on catheter removal should be in place.

Please contact us with any information about your initiatives to reduce risks in these areas.

Signals are notifications of key risks emerging from review of serious incidents reported to the NRLS and shared by the NPSA.

E.3. Autocorrelation tests

Itsa, los

Cumby-Huizinga test for autocorrelation (Breusch-Godfrey)

H0: variable is MA process up to order q

HA: serial correlation present at specified lags >q

H0: q=0 (serially uncorrelated) | H0: q=specified lag-1

HA: s.c. present at range specified | HA: s.c. present at lag specified

-----+-----
lags | chi2 df p-val | lag | chi2 df p-val

-----+-----+-----
1 - 1 | 39.431 1 0.0000 | 1 | 39.431 1 0.0000

1 - 2 | 41.889 2 0.0000 | 2 | 12.178 1 0.0005

1 - 3 | 43.867 3 0.0000 | 3 | 6.904 1 0.0086

1 - 4 | 46.910 4 0.0000 | 4 | 0.007 1 0.9346

1 - 5 | 47.122 5 0.0000 | 5 | 0.154 1 0.6951

1 - 6 | 48.947 6 0.0000 | 6 | 3.139 1 0.0764

Test allows predetermined regressors/instruments

Test requires conditional homoskedasticity

Itsa, pct_bleed

Cumby-Huizinga test for autocorrelation (Breusch-Godfrey)

H0: variable is MA process up to order q

HA: serial correlation present at specified lags >q

H0: q=0 (serially uncorrelated) | H0: q=specified lag-1

HA: s.c. present at range specified | HA: s.c. present at lag specified
-----+-----

lags	chi2	df	p-val	lag	chi2	df	p-val
1 - 1	4.128	1	0.0422	1	4.128	1	0.0422
1 - 2	5.659	2	0.0590	2	2.372	1	0.1236
1 - 3	5.980	3	0.1126	3	0.942	1	0.3317
1 - 4	8.664	4	0.0701	4	1.207	1	0.2720
1 - 5	8.899	5	0.1132	5	0.073	1	0.7863
1 - 6	9.073	6	0.1695	6	0.083	1	0.7727

Test allows predetermined regressors/instruments

Test requires conditional homoskedasticity

Itsa, los quarterly

Cumby-Huizinga test for autocorrelation (Breusch-Godfrey)

H0: variable is MA process up to order q

HA: serial correlation present at specified lags >q

H0: q=0 (serially uncorrelated)	H0: q=specified lag-1
HA: s.c. present at range specified	HA: s.c. present at lag specified

lags	chi2	df	p-val	lag	chi2	df	p-val
1 - 1	4.451	1	0.0349	1	4.451	1	0.0349
1 - 2	11.615	2	0.0030	2	5.393	1	0.0202
1 - 3	11.657	3	0.0087	3	3.277	1	0.0703
1 - 4	11.798	4	0.0189	4	0.083	1	0.7737
1 - 5	25.455	5	0.0001	5	3.667	1	0.0555
1 - 6	28.255	6	0.0001	6	11.913	1	0.0006

Test allows predetermined regressors/instruments

Test requires conditional homoskedasticity

Itsa, pct_bleed, quarterly

Cumby-Huizinga test for autocorrelation (Breusch-Godfrey)

H0: variable is MA process up to order q

HA: serial correlation present at specified lags >q

H0: q=0 (serially uncorrelated) | H0: q=specified lag-1

HA: s.c. present at range specified | HA: s.c. present at lag specified

lags	chi2	df	p-val	lag	chi2	df	p-val

1 - 1	0.122	1	0.7264	1	0.122	1	0.7264

1 - 2	1.097	2	0.5779	2	1.001	1	0.3171

1 - 3	2.315	3	0.5096	3	1.022	1	0.3121

1 - 4	2.577	4	0.6309	4	0.175	1	0.6753

1 - 5	4.870	5	0.4320	5	1.976	1	0.1598

1 - 6	8.103	6	0.2307	6	3.362	1	0.0667

Test allows predetermined regressors/instruments

Test requires conditional homoskedasticity

Itsa, los, year level

Cumby-Huizinga test for autocorrelation (Breusch-Godfrey)

H0: variable is MA process up to order q

HA: serial correlation present at specified lags >q

H0: q=0 (serially uncorrelated) | H0: q=specified lag-1

HA: s.c. present at range specified | HA: s.c. present at lag specified

-----+-----							
lags	chi2	df	p-val	lag	chi2	df	p-val
-----+-----+-----+-----							
1 - 1	6.518	1	0.0107	1	6.518	1	0.0107
1 - 2	7.098	2	0.0288	2	0.642	1	0.4229
1 - 3	8.620	3	0.0348	3	0.171	1	0.6795
1 - 4	8.620	4	0.0713	4	0.022	1*	0.8808
1 - 5	10.738	5	0.0568	5	0.000	1*	0.9824
1 - 6	10.996	6	0.0885	6	3.056	1*	0.0804

Test allows predetermined regressors/instruments

Test requires conditional homoskedasticity

* Eigenvalues adjusted to make matrix positive semidefinite

Itsa, pct_bleed year level

Cumby-Huizinga test for autocorrelation (Breusch-Godfrey)

H0: variable is MA process up to order q

HA: serial correlation present at specified lags >q

-----+-----							
H0: q=0 (serially uncorrelated)				H0: q=specified lag-1			
HA: s.c. present at range specified				HA: s.c. present at lag specified			

-----+-----							
lags	chi2	df	p-val	lag	chi2	df	p-val
-----+-----+-----+-----							
1 - 1	0.178	1	0.6732	1	0.178	1	0.6732
1 - 2	3.264	2	0.1956	2	2.753	1	0.0971
1 - 3	3.912	3	0.2711	3	0.014	1*	0.9060
1 - 4	5.392	4	0.2494	4	0.299	1*	0.5848
1 - 5	9.097	5	0.1053	5	0.002	1	0.9670

1 - 6 | 9.224 6 0.1614 | 6 | 0.448 1 0.5031

Test allows predetermined regressors/instruments

Test requires conditional homoskedasticity

* Eigenvalues adjusted to make matrix positive semidefinite

Multi group

Itsa, los, year level

Cumby-Huizinga test for autocorrelation

H0: variable is MA process up to order q

HA: serial correlation present at specified lags >q

H0: q=0 (serially uncorrelated) H0: q=specified lag 1

HA: s.c. present at range specified HA: s.c. present at lag specified

lags	chi2	df	p-val	lags	chi2	df	p-val

1 - 1	4.613	1	0.0317	1 - 1	4.613	1	0.0317

1 - 2	21.318	2	0.0000	1 - 2	5.070	1	0.0243

1 - 3	22.000	3	0.0001	1 - 3	0.844	1	0.3583

1 - 4	22.000	4	0.0002	1 - 4	1.120	1	0.2899

1 - 5	22.000	5	0.0005	1 - 5	0.229	1	0.6320

1 - 6	22.000	6	0.0012	1 - 6	3.546	1	0.0597

Test allows predetermined regressors/instruments

Test requires conditional homoskedasticity

Itsa, pct_bleed, year level

Cumby-Huizinga test for autocorrelation

H0: variable is MA process up to order q

HA: serial correlation present at specified lags >q

H0: q=0 (serially uncorrelated) | H0: q=specified lag-1

HA: s.c. present at range specified | HA: s.c. present at lag specified

lags	chi2	df	p-val	lag	chi2	df	p-val

1 - 1	4.994	1	0.0254	1	4.994	1	0.0254

1 - 2	21.244	2	0.0000	2	3.003	1	0.0831

1 - 3	22.000	3	0.0001	3	0.849	1	0.3569

1 - 4	22.000	4	0.0002	4	3.494	1	0.0616

1 - 5	22.000	5	0.0005	5	0.549	1	0.4589

1 - 6	22.000	6	0.0012	6	5.330	1	0.0210

Test allows predetermined regressors/instruments

Test requires conditional homoskedasticity

Liberal bleed

Itsa, los, single group, month level

Cumby-Huizinga test for autocorrelation (Breusch-Godfrey)

H0: variable is MA process up to order q

HA: serial correlation present at specified lags >q

H0: q=0 (serially uncorrelated) | H0: q=specified lag-1

HA: s.c. present at range specified | HA: s.c. present at lag specified

lags	chi2	df	p-val	lag	chi2	df	p-val

1 - 1	39.431	1	0.0000	1	39.431	1	0.0000

1 - 2		41.889	2	0.0000		2		12.178	1	0.0005
1 - 3		43.867	3	0.0000		3		6.904	1	0.0086
1 - 4		46.910	4	0.0000		4		0.007	1	0.9346
1 - 5		47.122	5	0.0000		5		0.154	1	0.6951
1 - 6		48.947	6	0.0000		6		3.139	1	0.0764

Test allows predetermined regressors/instruments

Test requires conditional homoskedasticity

Itsa, pct_bleed, month level

Cumby-Huizinga test for autocorrelation (Breusch-Godfrey)

H0: variable is MA process up to order q

HA: serial correlation present at specified lags >q

H0: q=0 (serially uncorrelated) | H0: q=specified lag-1

HA: s.c. present at range specified | HA: s.c. present at lag specified

-----+-----

lags		chi2	df	p-val		lag		chi2	df	p-val

-----+-----+-----

1 - 1		13.612	1	0.0002		1		13.612	1	0.0002
1 - 2		13.736	2	0.0010		2		1.826	1	0.1766
1 - 3		16.197	3	0.0010		3		3.553	1	0.0594
1 - 4		16.472	4	0.0024		4		2.119	1	0.1455
1 - 5		16.560	5	0.0054		5		0.238	1	0.6258
1 - 6		17.021	6	0.0092		6		0.766	1	0.3814

Test allows predetermined regressors/instruments

Test requires conditional homoskedasticity

Itsa, los, quarter level

Cumby-Huizinga test for autocorrelation (Breusch-Godfrey)

H0: variable is MA process up to order q

HA: serial correlation present at specified lags >q

H0: q=0 (serially uncorrelated) | H0: q=specified lag-1

HA: s.c. present at range specified | HA: s.c. present at lag specified

lags	chi2	df	p-val	lag	chi2	df	p-val

1 - 1	4.451	1	0.0349	1	4.451	1	0.0349

1 - 2	11.615	2	0.0030	2	5.393	1	0.0202

1 - 3	11.657	3	0.0087	3	3.277	1	0.0703

1 - 4	11.798	4	0.0189	4	0.083	1	0.7737

1 - 5	25.455	5	0.0001	5	3.667	1	0.0555

1 - 6	28.255	6	0.0001	6	11.913	1	0.0006

Test allows predetermined regressors/instruments

Test requires conditional homoskedasticity

Itsa, pct_bleed quarter level

Cumby-Huizinga test for autocorrelation (Breusch-Godfrey)

H0: variable is MA process up to order q

HA: serial correlation present at specified lags >q

H0: q=0 (serially uncorrelated) | H0: q=specified lag-1

HA: s.c. present at range specified | HA: s.c. present at lag specified

lags	chi2	df	p-val	lag	chi2	df	p-val
1 - 1	2.416	1	0.1201	1	2.416	1	0.1201
1 - 2	3.182	2	0.2038	2	1.400	1	0.2368
1 - 3	4.180	3	0.2426	3	1.458	1	0.2273
1 - 4	5.266	4	0.2610	4	0.318	1	0.5725
1 - 5	7.532	5	0.1840	5	3.245	1	0.0717
1 - 6	10.929	6	0.0906	6	5.293	1	0.0214

Test allows predetermined regressors/instruments

Test requires conditional homoskedasticity

itsa, los, year level

Cumby-Huizinga test for autocorrelation (Breusch-Godfrey)

H0: variable is MA process up to order q

HA: serial correlation present at specified lags >q

H0: q=0 (serially uncorrelated) H0: q=specified lag 1

HA: s.c. present at range specified HA: s.c. present at lag specified

lags	chi2	df	p-val	lag	chi2	df	p-val

1 - 1	6.518	1	0.0107	1	6.518	1	0.0107

1 - 2	7.098	2	0.0288	2	0.642	1	0.4229

1 - 3	8.620	3	0.0348	3	0.171	1	0.6795

1 - 4	8.620	4	0.0713	4	0.022	1*	0.8808

1 - 5	10.738	5	0.0568	5	0.000	1*	0.9824

1 - 6	10.996	6	0.0885	6	3.056	1*	0.0804

Test allows predetermined regressors/instruments

Test requires conditional homoskedasticity

* Eigenvalues adjusted to make matrix positive semidefinite

Itsa, pct_bleed, year level

Cumby-Huizinga test for autocorrelation (Breusch-Godfrey)

H0: variable is MA process up to order q

HA: serial correlation present at specified lags >q

H0: q=0 (serially uncorrelated) | H0: q=specified lag-1

HA: s.c. present at range specified | HA: s.c. present at lag specified

lags	chi2	df	p-val	lag	chi2	df	p-val

1 - 1	0.052	1	0.8197	1	0.052	1	0.8197

1 - 2	2.441	2	0.2951	2	2.280	1	0.1311

1 - 3	3.136	3	0.3711	3	0.072	1	0.7891

1 - 4	5.885	4	0.2079	4	0.037	1*	0.8483

1 - 5	9.452	5	0.0923	5	0.019	1	0.8898

1 - 6	9.545	6	0.1452	6	0.052	1*	0.8198

Test allows predetermined regressors/instruments

Test requires conditional homoskedasticity

* Eigenvalues adjusted to make matrix positive semidefinite

Ista, multi group, los

Cumby-Huizinga test for autocorrelation

H0: variable is MA process up to order q

HA: serial correlation present at specified lags >q

H0: q=0 (serially uncorrelated) | H0: q=specified lag-1

HA: s.c. present at range specified | HA: s.c. present at lag specified

-----+-----							
lags	chi2	df	p-val	lag	chi2	df	p-val
-----+-----+-----+-----							
1 - 1	4.613	1	0.0317	1	4.613	1	0.0317
1 - 2	21.318	2	0.0000	2	5.070	1	0.0243
1 - 3	22.000	3	0.0001	3	0.844	1	0.3583
1 - 4	22.000	4	0.0002	4	1.120	1	0.2899
1 - 5	22.000	5	0.0005	5	0.229	1	0.6320
1 - 6	22.000	6	0.0012	6	3.546	1	0.0597

Test allows predetermined regressors/instruments

Test requires conditional homoskedasticity

Itsa, pct_bleed, multigroup

Cumby-Huizinga test for autocorrelation

H0: variable is MA process up to order q

HA: serial correlation present at specified lags >q

-----+-----										
H0: q=0 (serially uncorrelated)				H0: q=specified lag-1						
HA: s.c. present at range specified				HA: s.c. present at lag specified						
-----+-----										
lags		chi2	df	p-val		lag		chi2	df	p-val
-----+-----+-----+-----										
1 - 1		4.819	1	0.0281		1		4.819	1	0.0281
1 - 2		21.290	2	0.0000		2		3.396	1	0.0653
1 - 3		22.000	3	0.0001		3		0.848	1	0.3571
1 - 4		22.000	4	0.0002		4		2.060	1	0.1512

1 - 5 | 22.000 5 0.0005 | 5 | 0.272 1 0.6019

1 - 6 | 22.000 6 0.0012 | 6 | 4.132 1 0.0421

Test allows predetermined regressors/instruments

Test requires conditional homoskedasticity

E.4. Models using quarterly time series observations.

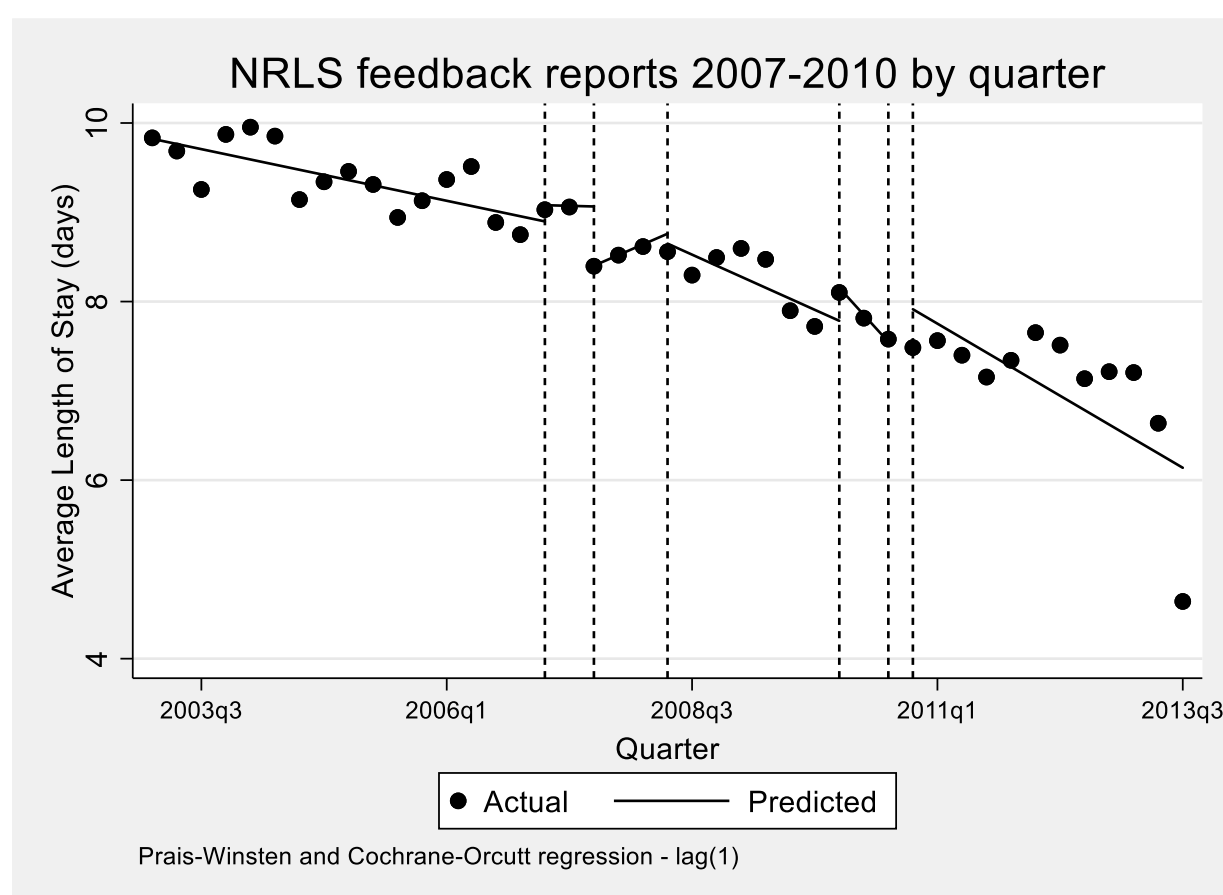


Figure E.4.1. Single group interrupted time series analysis of average length of stay in English NHS hospitals from 2003 to 2013 for AMI patients in England, aggregated by quarter. Interruptions (dashed lines) are specified at 2007q1, 2007q3, 2008q2, 2010q1, 2010q3, and 2010q4.

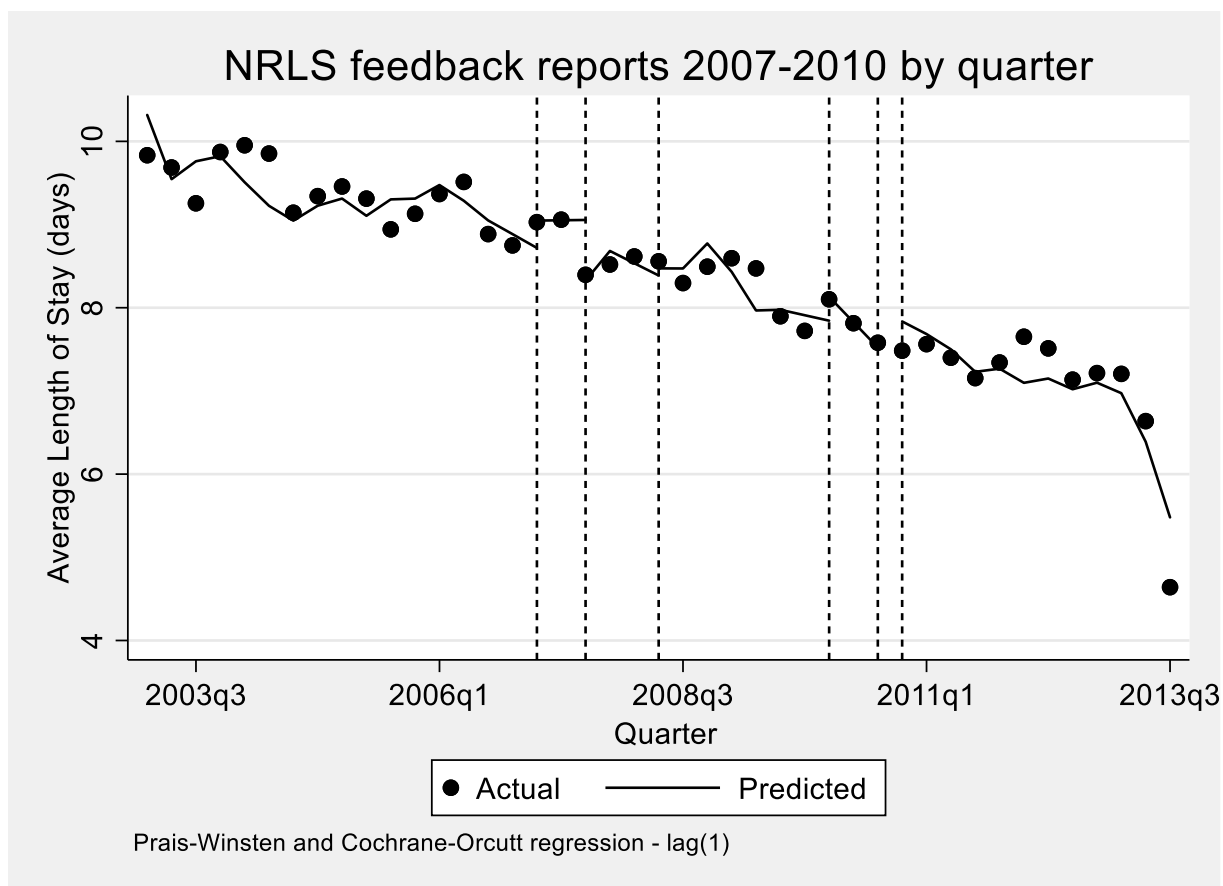


Figure E.4.2. Single group interrupted time series analysis of average length of stay in English NHS hospitals from 2003 to 2013 for AMI patients in England, aggregated by quarter, with covariates. Interruptions (dashed lines) are specified at 2007q1, 2007q3, 2008q2, 2010q1, 2010q3, and 2010q4.

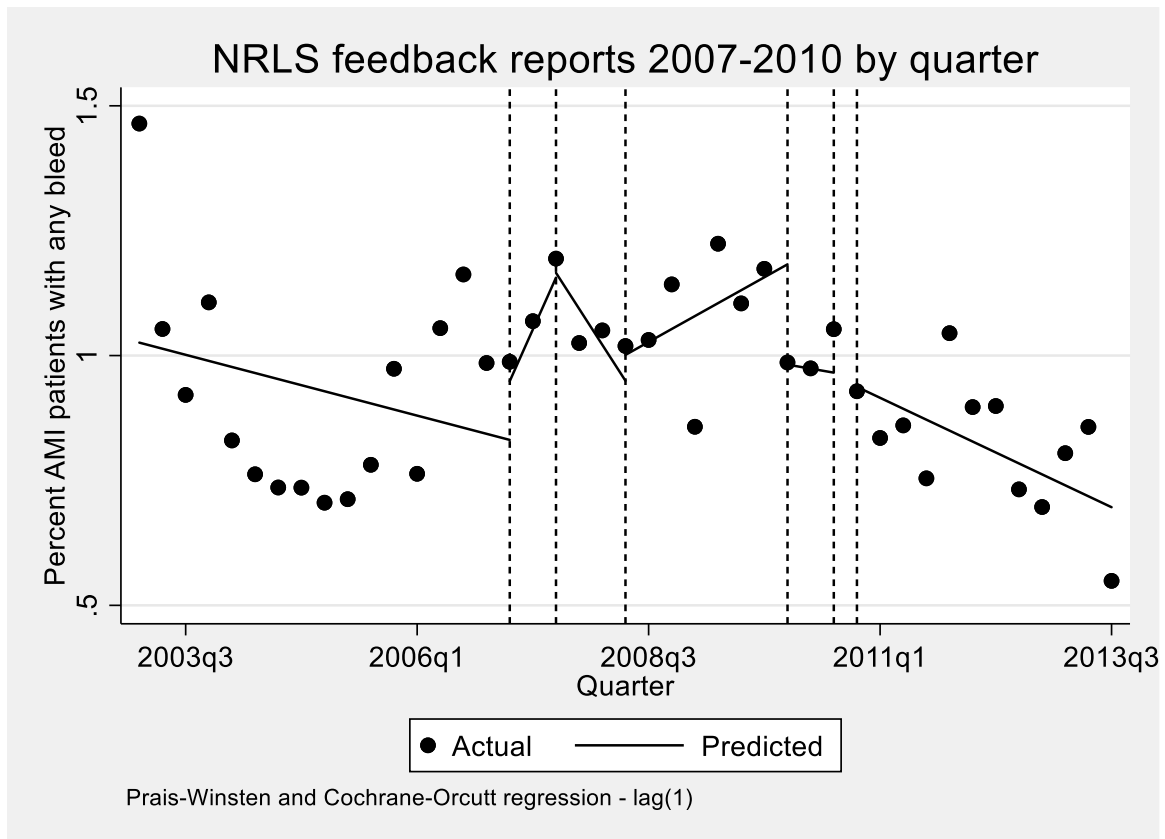


Figure E.4.3. Single group interrupted time series analysis of average percentage of any bleeding stay in English hospitals from 2003 to 2013 for AMI patients, aggregated by quarter. Interruptions (dashed lines) are specified at 2007q1, 2007q3, 2008q2, 2010q1, 2010q3, and 2010q4.

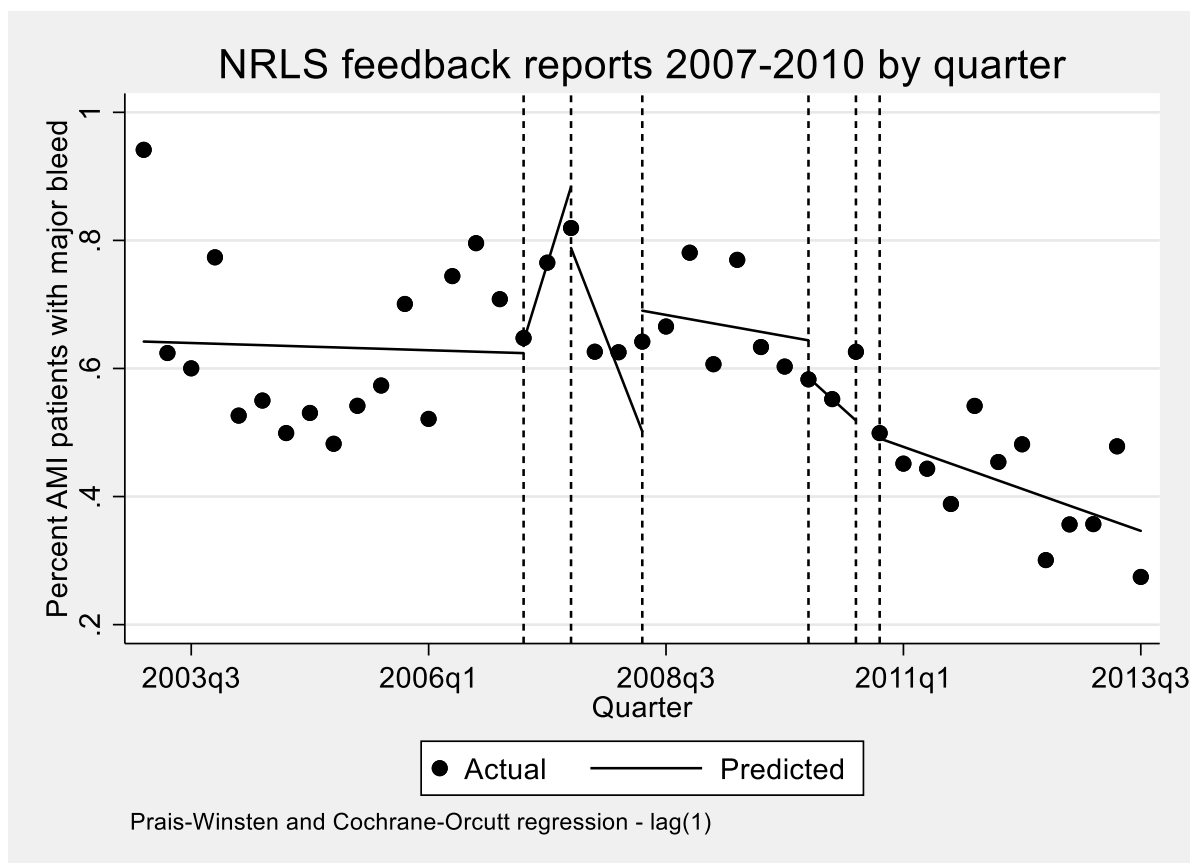


Figure E.4.4. Single group interrupted time series analysis of average percentage of major bleeding in English NHS hospitals from 2003 to 2013 for AMI patients, aggregated by year. Interruptions (dashed lines) are specified at 2007q1, 2007q3, 2008q2, 2010q1, 2010q3, and 2010q4.

E.5. Models using yearly time series observations

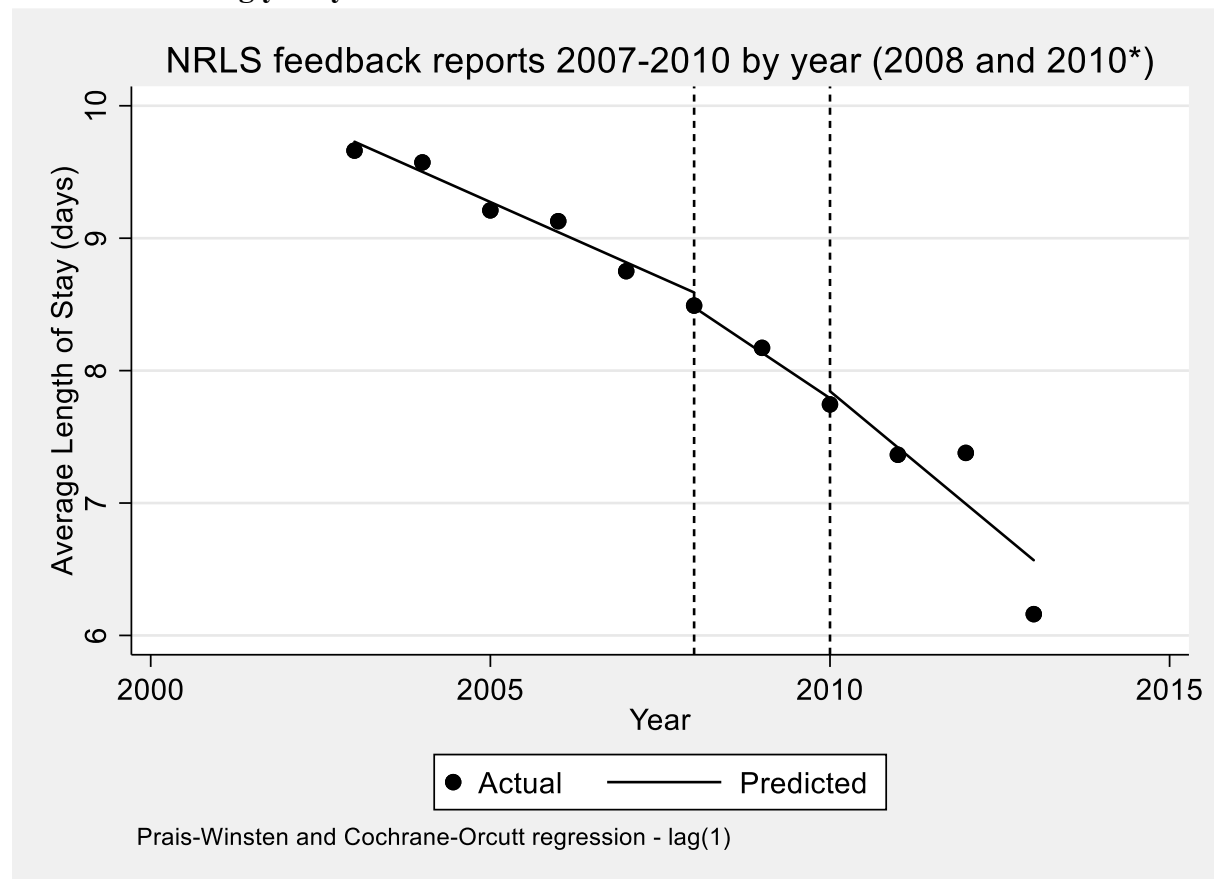


Figure E.4.5. Single group interrupted time series analysis of average length of stay in English NHS hospitals from 2003 to 2013 for AMI patients, with covariates added by forward elimination (backward elimination yielded no significant covariates), aggregated by year. Interruptions in this model (dashed lines) are specified at 2008 and 2010.

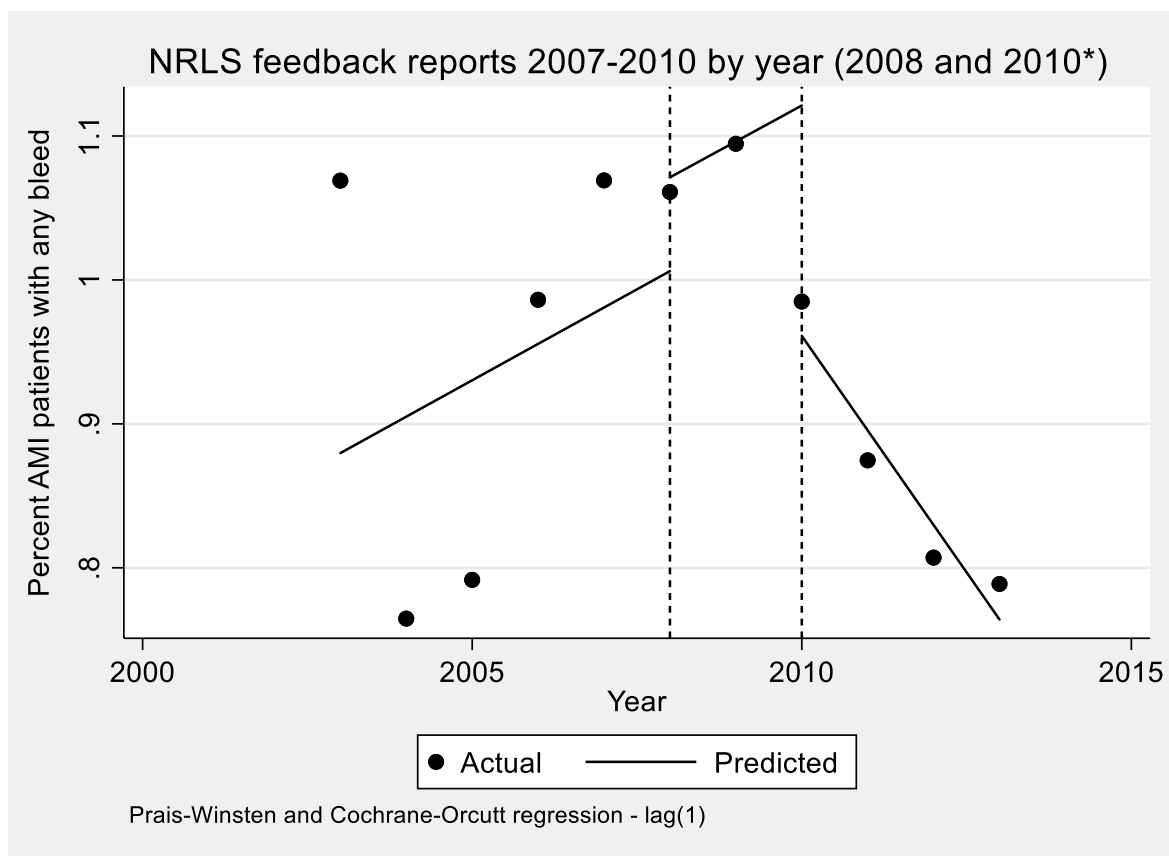


Figure E.4.6. Single group interrupted time series analysis of average percentage of any bleeding in English NHS hospitals from 2003 to 2013 for AMI patients, aggregated by year. Interruptions in this model (dashed line) are specified at 2008 and 2010.

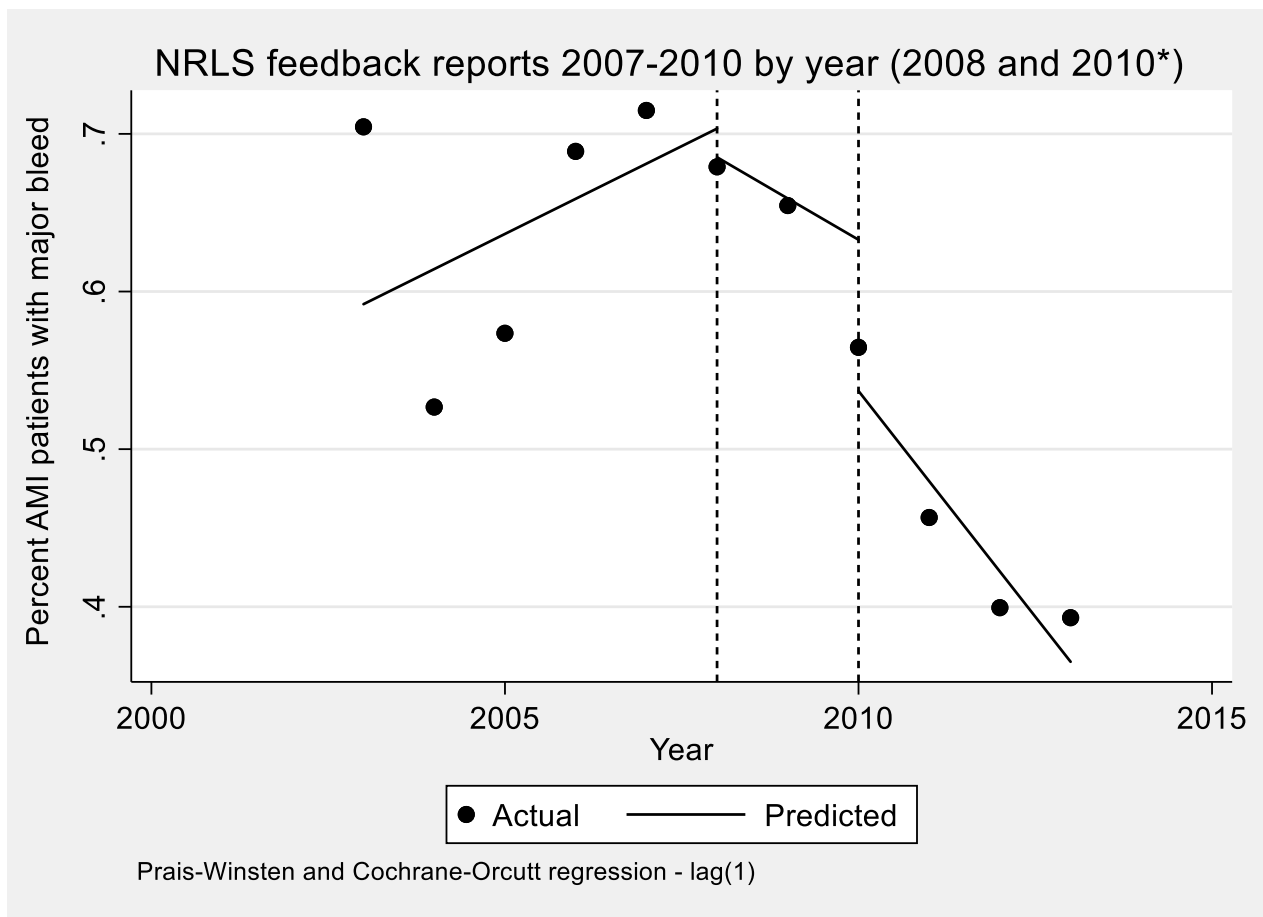


Figure E.4.7. Single group interrupted time series analysis of average percentage of any bleeding in English NHS hospitals from 2003 to 2013 for AMI patients, aggregated by year. Interruptions in this model (dashed line) are specified at 2008 and 2010.

VARIABLES	(1) Model E.4.5: 2008 + 2010: LOS	(2) Model E.4.6: Any bleeding (percentage)	(3) Model E.4.7: Major bleeding (percentage)
Year	-0.23** [-0.36 - -0.098]	0.025 [-0.075 - 0.13]	0.022 [-0.033 - 0.077]
Intervention (2008)	-0.11 [-0.87 - 0.65]	0.065 [-0.42 - 0.56]	-0.018 [-0.30 - 0.26]
Year * Intervention (2008)	-0.12 [-0.99 - 0.75]	-0.00032 [-0.51 - 0.50]	-0.048 [-0.35 - 0.25]
Intervention (2010)	0.053 [-1.46 - 1.57]	-0.16 [-1.01 - 0.69]	-0.096 [-0.60 - 0.41]
Year * Intervention (2010)	-0.082 [-0.94 - 0.78]	-0.091 [-0.60 - 0.42]	-0.031 [-0.33 - 0.27]
Constant	9.73*** [9.43 - 10.0]	0.88*** [0.64 - 1.12]	0.59*** [0.46 - 0.72]
Observations	11	11	11
R-squared	0.996	0.516	0.843
Adj. R-squared	0.99	0.032	0.69
Autocorrelation	-0.56	-0.12	-0.22

in brackets
 *** p < 0.001, ** p < 0.01, * p < 0.05, + p < 0.1

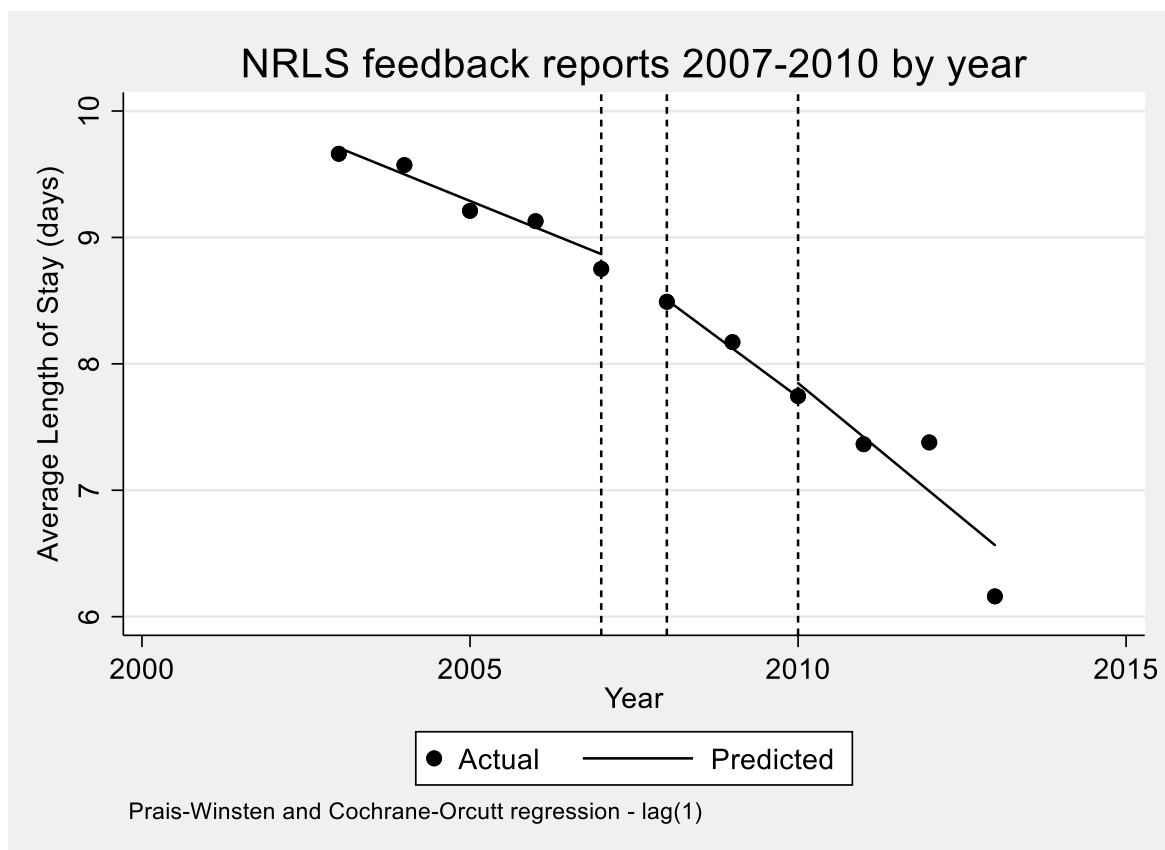


Figure E.4.8. Single group interrupted time series analysis of average length of stay in English NHS hospitals from 2003 to 2013 for AMI patients, aggregated by year, without covariates. The interruptions in this model (dashed lines) are specified at 2007, 2008, and 2010. A regression between 2007 and 2008 was omitted due to collinearity between these observations.

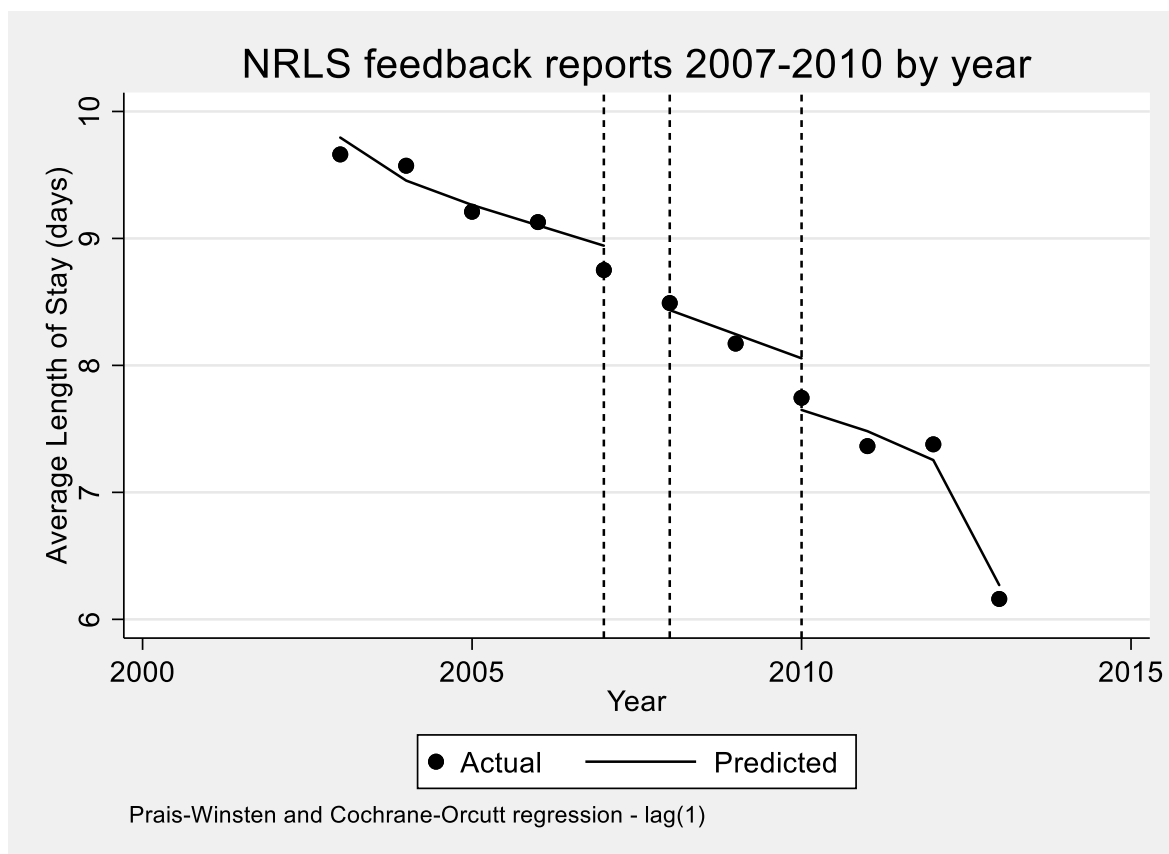


Figure E.4.9. Single group interrupted time series analysis of average length of stay in English NHS hospitals from 2003 to 2013 for AMI patients, aggregated by year, with covariates. The interruptions in this model (dashed lines) are specified at 2007, 2008, and 2010. A regression between 2007 and 2008 was omitted due to collinearity between these observations.

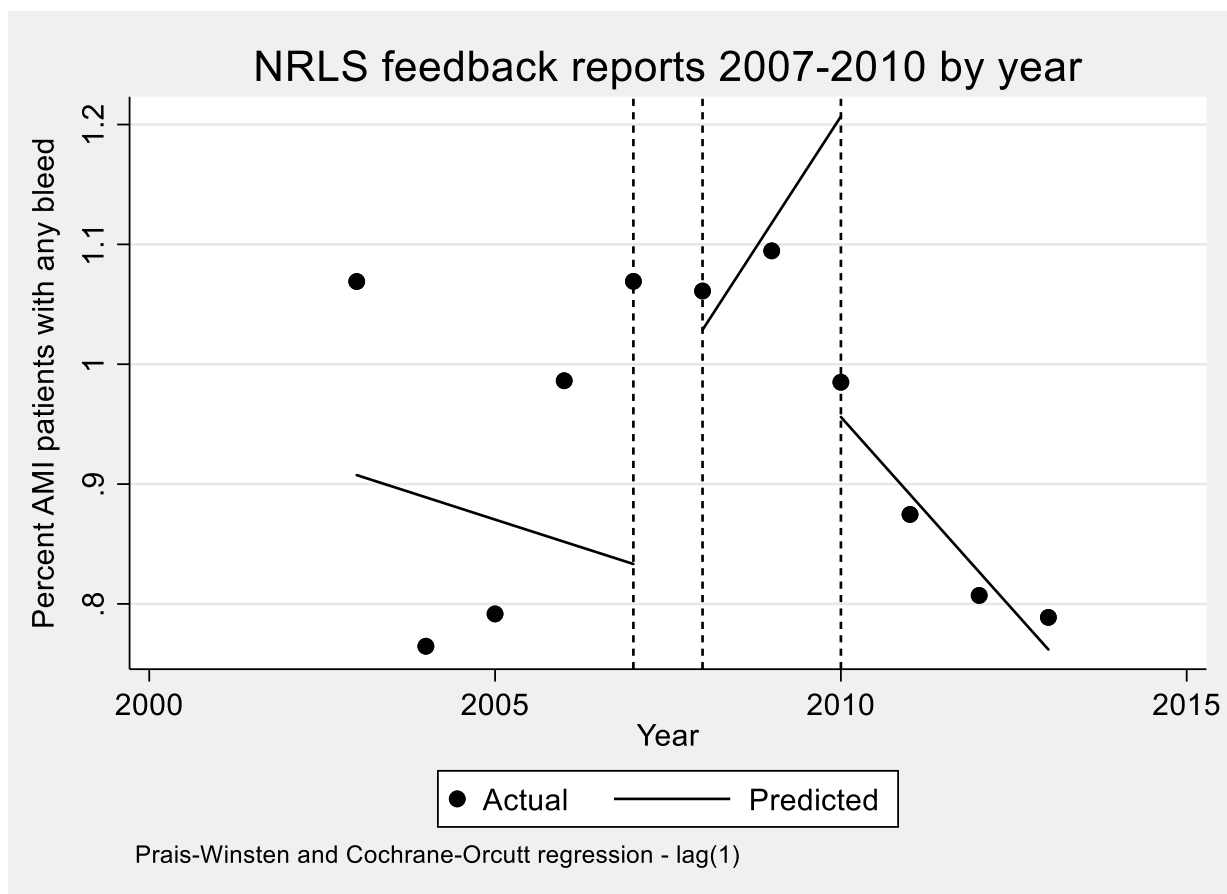


Figure E.4.10. Single group interrupted time series analysis of average percentage of any bleeding in English NHS hospitals from 2003 to 2013 for AMI patients, aggregated by year. The interruptions in this model (dashed lines) are specified at 2007, 2008, and 2010. No significant change in the trend was identified. A regression between 2007 and 2008 was omitted due to collinearity between observations.

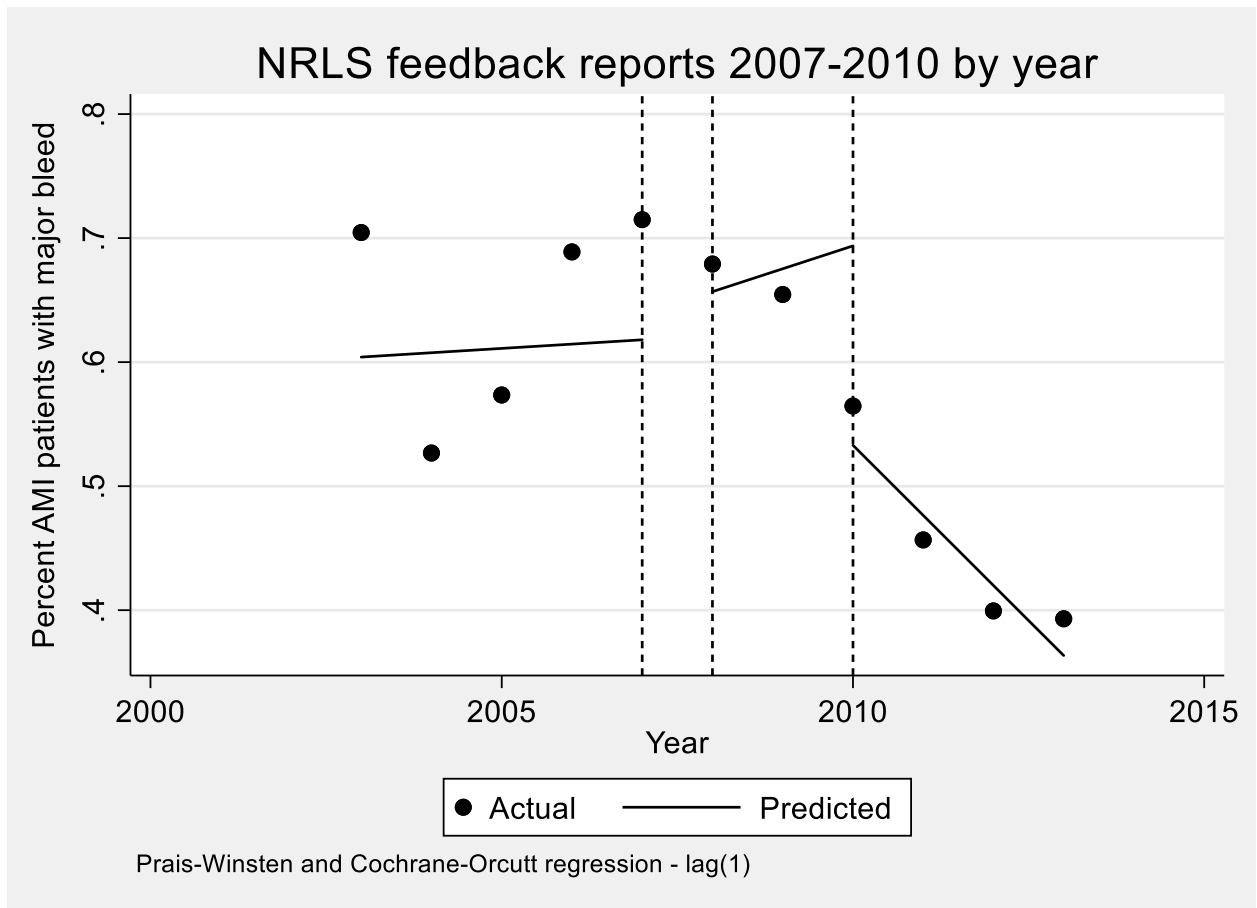


Figure E.4.11. Single group interrupted time series analysis of average percentage of any bleeding in English NHS hospitals from 2003 to 2013 for AMI patients, aggregated by year. The interruptions in this model (dashed lines) are specified at 2007, 2008, and 2010. No significant change in the trend was identified. A regression between 2007 and 2008 was omitted due to collinearity between observations.

VARIABLES	(1) Model E.4.8: LOS	(2) Model E.4.9: LOS	(3) Model E.4.10: Any bleeding (percentage)	(4) Model E.4.11: Major bleeding (percentage)
Year	-0.21+ [-0.45 - 0.025]	-0.16* [-0.24 - -0.070]	-0.019 [-0.15 - 0.11]	0.0035 [-0.074 - 0.081]
Intervention (2007)	-0.10 [-1.14 - 0.94]	-0.20 [-0.58 - 0.17]	0.30 [-0.25 - 0.84]	0.13 [-0.20 - 0.47]
Year * Intervention (2007)	-0.17 [-1.37 - 1.02]	-0.11 [-0.57 - 0.34]	0.11 [-0.50 - 0.71]	0.015 [-0.36 - 0.39]
Intervention (2008)	0.12 [-2.02 - 2.27]	-0.16 [-0.99 - 0.68]	-0.19 [-1.26 - 0.88]	-0.11 [-0.78 - 0.55]
Year * Intervention (2008) = o,	-	-	-	-
Intervention (2010)	0.11 [-1.79 - 2.01]	-0.48 [-1.26 - 0.30]	-0.25 [-1.22 - 0.71]	-0.16 [-0.76 - 0.43]
Year * Intervention (2010)	-0.043 [-1.15 - 1.06]	0.0053 [-0.40 - 0.42]	-0.15 [-0.72 - 0.41]	-0.075 [-0.42 - 0.27]
Average #Total Admission		0.0029* [0.0012 - 0.0046]		
Constant	9.71*** [9.30 - 10.1]	8.35*** [7.53 - 9.17]	0.91*** [0.68 - 1.13]	0.60*** [0.47 - 0.74]
Observations	11	11	11	11
R-squared	0.996	1.000	0.867	0.929
Adj. R-squared	0.99	1	0.67	0.82
Autocorrelation	-0.55	-0.81	-0.45	-0.47

in brackets

*** p < 0.001, ** p < 0.01, * p < 0.05, + p < 0.1

The economics of patient safety and incident reporting systems: translational evidence

By Alexander W. Carter