

Understanding the influence of health information technology on quality and safety in secondary care

**A thesis presented for the degree of
Doctor of Philosophy (PhD)**

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Declaration of Originality

I declare that the work in this thesis is my own. Any contributions by my colleagues are acknowledged appropriately.

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Thesis Abstract

The rapid evolution of health information technology (IT) and drive towards a fully digital healthcare system is a laudable and compelling aspiration that has the undoubted potential to improve the effectiveness, efficiency and experience of care. Whilst health IT has the promise to solve many of the challenges facing healthcare there is a paucity of high-quality evidence to thoroughly evaluate its successes and failures, nor fully identify the very real and often unexpected risks and challenges that come hand-in-hand with potential opportunities and benefits. This thesis therefore seeks to systematically investigate the influence of health IT on the three core facets of healthcare quality in secondary care - effectiveness, safety and experience.

An introduction to the current landscape and strategies for the evaluation of health IT is presented to provide context. Following this a number of linked studies undertake to evaluate the current impact of health IT on quality in secondary care. Examinations of the impact of organisational digital maturity on clinical outcomes, stakeholder experience and regulatory judgements of quality are presented. These are followed by an evaluation of nationally reported patient safety incidents related to health IT, and finally a chapter that seeks to define an emerging threat to patient safety - cybersecurity and digital resilience - and identify linked research, practice and policy priorities. The final part of the thesis focuses on a single technology - mobile computing - and undertakes a detailed examination of its current impact on communication and teamwork through a systematic review, followed by an exploration of multi-professional perspectives on moving towards a 'mobile-first' culture of work within the hospital setting. The thesis concludes by highlighting outstanding challenges and identifying future implications for research, day-to-day practice and health policy.

The next decade will see fundamental change in all aspects of healthcare driven by new digital technologies. This exciting future must however be viewed with cautious scepticism, an acknowledgement that new technology in isolation cannot bridge the quality and cost-effectiveness chasm, and awareness that technology may also be a new source of potential

harm which must be understood, measured and mitigated. There is a requirement for all new technology to be unequivocally backed by high-quality robust evidence and regulated and evaluated in a pragmatic yet comprehensive manner.

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Chapter 1 - Introduction

This chapter sets the context for the thesis by providing a backdrop against which the work is conducted. It outlines the current state of play and existing evidence for the influence of health IT on quality and safety, provides a concise history of IT within the health sector and also describes current approaches for evaluating various aspects of health IT and new technologies.

“... up to the present time psychological data and research techniques have played an insignificant role in the field... particularly in the field of aviation has the importance of human requirements in equipment design come to be recognised. There probably is no other engineering field in which the penalties for failure to suit the equipment to human requirements are so great. With present equipment, flying is so difficult that many individuals cannot learn to pilot an aircraft safely, and even with careful selection and extensive training of pilots, human errors account for a major proportion of aircraft accidents. The point has been reached where addition of new instruments and devices... on the cockpit instrument panel actually tends to decrease the over-all effectiveness of the pilot by increasing the complexity of a task that already is near the threshold of human ability. As aircraft become more complex and attain higher speeds, the necessity for designing the machine to suit the inherent characteristics of the human operators becomes increasingly apparent”¹.

It is more than 60 years since aviation understood the challenges and potential risks of combining technology, humans and safety critical actions; if the pilot became the clinician, and the cockpit became the hospital then health information technology (IT) and healthcare has a lot of ground to make up and is trailing in its understanding of the opportunities and risks that will present themselves as we enter the digital age of health. Modern healthcare is a complex system of loosely-coupled human, organisational and technical components that is poorly understood. Individual clinicians must juggle multiple complex tasks whilst sifting and utilising uncertain and changing evidence on a continuous basis under unrelenting time

pressures²; yet understanding and improving this system is fundamental to the delivery of safe, effective and cost-efficient healthcare.

“... the current paradigm of medical care depends heavily on the autonomous and highly trained doctor to collect and process information necessary to care for each patient. This paradigm is challenged by the increasing requirements for knowledge by both patients and doctors; by the need to evaluate populations of patients inside and outside one’s practice; by consistently unmet quality of care expectations; by the costliness of redundant, fragmented, and suboptimal care; and by a seemingly insurmountable demand for chronic disease care.

Medical care refinements within the old paradigm may not solve these challenges, suggesting a shift to a new paradigm is needed. A new paradigm could be considerably more reliant on health information technology because that offers the best option for addressing our challenges and creating a foundation for future medical progress, although this process will be disruptive”³

1.1 - Can health IT improve the quality and safety of healthcare, or does it lead to harm?

Health IT has been lauded as one of the core building blocks for safer healthcare and encompasses a broad range of digital systems that support the delivery of care⁴. Potential advantages over traditional paper-based hospital systems include the ability to facilitate simultaneous and remote access, improvements in the legibility of records, better communication and teamwork, provision of evidenced-based dynamic decision support tools, enhancements to data security and patient confidentiality, the better use of data and support for complex analytics, higher quality tracking and capturing of adverse events, the support of medication safety and the provision of a greater range of tailored interfaces and outputs that can meet the needs of all stakeholders^{5,6}. Furthermore, the digitisation of health has the potential to significantly improve patient safety and reduce adverse events by reducing medical error, improving the quality and availability of information, supporting better decision making and communication, and fostering improvements in workflow and culture⁶⁻

¹³. Health IT has the undoubted potential to transform care delivery and improve patient outcomes; ultimately becoming the standard, all-encompassing method for delivering care across all healthcare settings.

Whilst the development and implementation of new technologies can facilitate improvements in the safety and efficiency of care delivery there is also increasing evidence of potential harm; usability issues, disruptions to established clinical processes and unsafe work-arounds to circumvent technology-related constraints leading to “e-iatrogenesis” – patient harm caused by the application of new digital technologies to the delivery of their care through human error, technical design flaws or organisational failures^{14,15}. With the number of licensed electronic health records companies having increased 20-fold in the past decade, there is now an increasing realisation that the unique safety risks posed by new technologies, and the potential for e-iatrogenic harm must be considered carefully alongside the potential benefits¹⁶.

Whilst there has been significant and rapid growth in the use of health IT there is a surprisingly limited evidence base for its benefit with “...no articles found reviewing the benefits or drawbacks of health information systems accruing to patients which should be of concern to adopters, payers and jurisdictions”¹⁷. Indeed, as recently as 2011 health IT was listed in the top ten technology-related hazards in healthcare by the Emergency Care Research Institute¹⁸. Increasingly there are examples of new technology fostering error and harm rather than reducing their likelihood, and weakening rather than strengthening the complex systems of people, technology and process that underpin the effective and safe delivery of care¹⁹. A key function of integrated electronic hospital systems is the provision of computerised ordering systems which aim to improve safety and reduce costs²⁰. Whilst there is evidence pointing to the positive impacts of this technology, including fewer adverse events and some limited financial savings²¹, there are also potentially a number of unintended adverse consequences associated with its adoption; more or new work for clinicians, increased resource and finance costs, workflow issues, never ending system demands, paper persistence, changes in communication patterns and practices, altered

emotions, new kinds of errors, changes in the power structure and blind overdependence on technology^{21–24}. In addition to direct unintended adverse outcomes organisations must also be cognisant to the risks of health IT leading to secondary adverse outcomes due to reduced human vigilance – the ‘computer is always right’ problem. An example of such is the Therac-25 system failure in which six patients suffered significant radiation overdoses, and several deaths as experienced operators trusted messages being displayed by a computer and disregarded clinical signs and their own clinical acumen due to blind faith in the technology²⁵. Cases such as this must be avoided and so in addition to robust processes of quality assurance and monitoring, organisations must also hand-in-hand develop a positive culture of safety to guard against errors, maintain quality and reduce patient harm.

The number of evaluative studies aiming to understand health IT is increasing, and whilst the majority do demonstrate positive effects, around a quarter of all studies demonstrate either no impact, or a negative impact on performance or outcomes⁸. Specific examples of potential, or actual adverse events and harm resulting from new health IT developments have included: medication errors due to failures in patient identification²⁶, drug dosing errors²⁷ and increased rates of adverse drug reactions²⁸ resulting from failures in electronic prescribing systems; reduced efficiency and increased utilisation of resources amongst junior doctors²⁹, coupled with the imposition of additional tasks and workload on already busy clinicians; the disruption of traditional patterns of work and secondary negative impacts upon established routines and practices with the introduction of an electronic health records systems³⁰; reduced statin prescribing in patients with hypercholesterolemia in the community following the introduction of a new electronic health record³¹; an unexpected increase in mortality in children dependent on time-sensitive interventions following the introduction of a new clinical information system in a Paediatric Intensive Care Unit³²; the death of two patients due to incorrect data entry on radiology information systems³³; complete failures in complex integrated digital hospital records and care systems preventing the delivery of safe care in a hospital in the US³⁴, and the loss of safety-critical applications to over 80 UK hospitals for a period of 4 days following failures in critical infrastructure and contingency systems³⁵. Identifying, analysing and preventing adverse safety events caused by e-

iatrogenesis is vital, and also a challenge. Avoidable episodes of harm, be they never events or near-misses are commonly multi-faceted, and may involve not only hardware and software, but also user behaviours and interactions, organisational characteristics, and broader processes, rules and regulations that interact in a complex and poorly understood fashion^{36,37}.

1.2 - Putting health IT in context: why IT consistently under achieves and fails to deliver and the productivity paradox

“Most of our systems are much more complicated than can be considered healthy and are too messy and chaotic to be used in comfort and confidence. The average customer of the computing industry has been served so poorly that he expects his system to crash all the time, and we witness a massive worldwide distribution of bug-ridden software for which we should be deeply ashamed”³⁸

Given the paucity of evidence unknown range of risks the digital delivery of care must be viewed within a wider technology context and not just through the narrow confines of more traditional approaches to evaluating healthcare interventions. A number of industries and sectors have tried, and frequently failed at the large-scale implementation of computerised systems, often publicly and entirely; the FoxMeyer ERP program, Canada’s gun registration system and FBI virtual case files^{39,40} in the US, or the BBC digital archiving project⁴¹ and Universal Credit system⁴² in the UK are well cited examples. This “*productivity paradox*” was identified as early as 1993 through lessons learnt from the computerisation of a wide cross-section of industries from financial services to retail⁴³; the predicted transformation in quality, reliability and efficiency instead manifested as disrupted workflows, disgruntled staff and widespread confusion; “*you can see the computer age everywhere but in the productivity statistics⁴⁴*.” It is important to appreciate that digitising large complex organisations is a process of adaptive change that involves not just the simple technical steps of putting in place new hardware and systems, but fostering substantial, complex and nuanced changes

in people and behaviours. Failures across all sectors, industries and walks of life therefore share many common overarching characteristics⁴⁵:

- Failure to appreciate and plan the complexity and costs of computerisation
- Failure to gain buy-in and support ongoing engagement of end-users
- Failure to change the skill mix of end-users or bring in new skills
- Failure to appreciate changes to the work, the nature of the work, the tasks to be done and who does them
- Failure to appreciate the situation and getting the speed of implementation wrong

1.3 - The implementation of health IT: a history of failure and a promising future

The process for effectively evaluating new technologies has been established for decades, however, there is a relative paucity of evidence in relation to health IT and an overall lack of awareness about the processes involved in successful adoption and implementation⁴⁶. The implementation of new IT in the hospital setting has been problematic and lags behind other sectors with privacy concerns, spiraling costs and time delays contributing to the problem⁴⁷. Multiple context- and innovation-specific barriers have been identified to the early adoption of new technologies including financial, legal, social and ethical factors, together with low digital literacy in clinicians, a shortage of evidence for their cost-effectiveness and poor interoperability^{48,49}. A recent systematic review has found a growing emphasis on problems related to health IT workability and how innovations affect organisational structures and goals, as well as highlighting the importance of adequate resources, financial and administrative support, stakeholder engagement and the effect of technology on roles and responsibilities within the hospital as vital factors influencing success and failure⁵⁰. Adequate funding and resourcing are also vital to success with 12 studies reporting this to be a major barrier¹³ with common contributing factors including initial start-up costs, ongoing recurring financial costs and punitive costs as a result of the loss of productivity⁵¹. Furthermore, only half of nurses report the introduction of new technology as being a positive experience with recognition that professionals do not automatically use new technology as intended by developers due to perceived dysfunction, initial bad impressions, lack of motivation and

inadequate training and coaching⁵². It is not just clinical staff who find new technology challenging however. Attempts to implement patient accessible electronic health records have met with very low levels of uptake and a perception that they are neither useful nor easy to use. This may suggest that they are either a flawed concept from the outset, irreparably damaged by poor product design, prone to failure through inappropriate implementation or a victim of the right solution delivered at the wrong time with patients just not ready for such an accessible and personalised health record⁵³. Nonetheless some US accountable care organisations have reported that they manage to have around one-third of their patients utilising these systems resulting in up to 10% fewer medical appointments and a significant reduction in the utilisation of other resources by offering non-traditional patient-centred ways of care delivery despite relatively low levels of IT literacy⁵⁴.

Whilst the implementation of new technology has frequently been piecemeal, prone to failure and under-delivery and associated with negative coverage, the continual influx of innovative technology is a predictable and inevitable characteristic of modern healthcare delivery and is at the forefront of most health policy agendas; successful implementation strategies are therefore fundamental. Much has been written about the theory of successful implementation, and some core themes have been identified that are associated with success including expectation management, time and training requirements for the implementation and adoption of new systems, the emergence of a champion or problem solver and the readiness of health care providers to accept new digital health systems⁵⁵. Other authors have also identified alternative elements required for the successful deployment of new technology including positive decision making, the importance of visible beneficial impacts, the perception of adding value, user friendliness, an easily surmountable learning curve and the presence of a strong educational foundation and support system⁴⁶.

Whilst many individual factors which contribute to the successful implementation of new health IT systems have been hypothesised, Cresswell provides a concise summary of the factors for successful implementation through the identification of 10 key considerations across the technology lifecycle based on experiences from the US and UK⁵⁶:

- Clarify what problem the technology is designed to tackle - pre-existing processes must be thoroughly mapped with agreement on the specific problem to be addressed by a specific functionality being reached
- Build consensus - professional, managerial and administrative consensus around the strategic vision and buy-in from all stakeholders must be obtained
- Consider your options - once the problem has been identified, time and resource must be committed to considering all options, both off-the-shelf and customized
- Choose systems that meet clinical needs and are affordable - a new system must fulfil a range of requirements across many domains, and should be both fit for the organisational purpose and clinical practice
- Plan appropriately - effective planning and preparation is essential to tailor implementation strategies to the organisational circumstances, avoid scope-creep and prevent the inadvertent introduction of new threats to patient safety
- Don't forget the infrastructure - if infrastructure is not afforded sufficient attention then the software will fail or ferment negative user attitudes at an early stage
- Train staff - training should be tailored to the individual roles of users and be as hands-on as possible; training should account for 40% of an implementation budget
- Continuously evaluate progress - evaluation is commonly an after-thought; real-time, longitudinal data collection and evaluation strategies are required to feed-back into continuous iterative implementation and development
- Maintain the system - maintenance is often under-estimated in relation to recurring costs, and also those costs associated with developments resulting from subsequent organisational change
- Stay the course - the benefits of major transformative ventures are notoriously difficult to measure and may take some time to materialise. It is important to manage expectation as this often exceeds what is achievable in the shorter term

The adoption of health IT is somewhat more mature in the US compared to the UK with \$19 billion having been committed to promote the adoption of electronic health records and associated functionality under the Health Information Technology for Economic and Clinical

Health (HITECH) Act of 2009 and Meaningful Use Act of 2010. This created a strategic plan for a nationwide interoperable health information system under the auspices of the Office of the National Coordinator of Health Information Technology (ONCHIT), whilst also providing financial incentives to doctors and hospitals who adopt electronic health records and penalising those who do not. This reflects a shared consensus that electronic systems are essential to improve healthcare outcomes, coupled with a promise that every American should have benefited from electronic health records by 2014⁵⁷. These lofty ambitions have been largely achieved in spite of obstacles to information exchange and interoperability in the US where regulations make it illegal to create a universal patient identifier.

The NHS meanwhile has been on a digital journey for many decades - with much achieved in some areas, little progress in others and the recent winding down of the £12.4 billion centralised National Programme for IT in the NHS (NPfIT) - resulting in a complex, hard to understand and fragmented picture of digital healthcare provision across the country. The original plan to revolutionise IT in the NHS began in 2003 with an aim to create a single, centrally-mandated electronic care record for patients by connecting 30,000 GP practices with 300 hospitals together with allowing open secure access by all health care professionals. More than a decade later only a handful of hospitals could be classed as paperless, patient records stored on the NHS spine are of debatable accuracy and value, the patient portal has been abandoned, vast amounts of communication still occurs via Royal Mail, fax or patients themselves and only 3% of organisations have met the original NPfIT completion criteria⁵⁸. Furthermore *“the focus was placed upon technology and not service change, and minimal attention was given to the adaptive elements of massive IT installations. There was no comprehensive strategy to engage clinicians or NHS executives to ensure they understood the reasons why NPfIT was being developed or implemented.”*⁴⁵ Despite the failure of the NPfIT local organisations have made some measurable progress in implementing new technologies and safety-critical applications. Despite 37 NHS Trusts possessing Patient Administration Systems (PAS) that are more than 20 years old, and a further 46 that are more than 10 years old - reflecting their importance and a general failure of the NPfIT to deliver strategic systems - by 2014 100% of NHS acute providers had digital

Patient Administration Systems (PAS), Radiology Information Systems (RIS) and Picture Archiving and Communication Systems (PACS). Meanwhile, 89% of providers had implemented electronic ordering systems, 81% electronic bed management, 53% electronic clinical notes, 37% e-observations, 33% advanced e-prescribing and only 30% clinical workflow engines/integrated care pathways ⁵⁹.

To take the development, implementation and evaluation of new technologies forward it is therefore important to not repeat the mistakes of the past and default to the “waterfall” model of large contracts, centralised dictats and complex politically shaped contractual relationships which exclude users. Instead a genuine bottom-up, or middle-out approach should be adopted to promote agility, transcend the realpolitik of the fragmented cash-strapped NHS and fully realise paperless hospitals, remote access to records and the high levels of inter-operability between community, primary and secondary care that the service requires to deliver optimal patient care whilst developing a true understanding of the costs, risks and benefits of new health IT^{60–62}. With this in mind in February 2016, the National Health Service (NHS) launched a review of health IT across the NHS led by Professor Bob Wachter - “Making IT work: harnessing the power of health IT to improve care in England” - with an aim to *“look at how NHS trusts have used IT systems, the successes and failures and what has been learned.”* The aim of the report was to inform how an estimated £5 billion would be spent over the following years to meet the ambition for a paper free health and care system by 2020. A key aim was to identify factors impacting the successful adoption of electronic health systems in the NHS and provide a set of recommendations which draw upon on the key challenges, priorities and opportunities across both high-level digital implementation and clinical engagement. It identifies a requirement to develop an understanding of the experiences of clinicians and managers in planning, implementing and adopting digital systems, scoping current capacities and capabilities of NHS Trusts in understanding and commissioning digital health systems, and highlighting the potential impact of digital systems on clinical workflows and the relationships between patients and their clinicians^{63,64}. Published in mid-2016⁴⁵ it highlighted that *“in order for the NHS to continue to provide a high level of healthcare at an affordable cost, it simple must modernise*

and transform. This transformation will involve enormous changes in culture, structure, governance, workforce, and training. But none of the changes are likely to be as sweeping, as important, or as challenging as creating a fully digitised NHS." The extensive and deep diving report highlighted a number of key principles which should be taken forward in all new health IT and technology focused developments:

- Digitize for the correct reasons - better health, better healthcare and lower cost
- It is better to get it right than to do it quickly - staged improvements may take years
- Return on investment from health IT is not just financial - cost savings may take 10 years to emerge due to the productivity paradigm of IT
- When it comes to centralisation the NHS should learn, but not over-learn the lesson of NPfIT - centralisation sometimes makes sense and there must be a balance between local/regional control and engagement versus centralisation
- Interoperability should be built in from the start - national standards must be developed and enforced
- While privacy is very important, so too is data sharing - privacy and confidentiality concerns can hinder data sharing that is important for patient care and research, and a balance must be struck
- Health IT systems must embrace user-centred design - systems must be designed with the input and needs of end-users central to their development from the outset
- Going live with a health IT system is the beginning, not the end - systems need to evolve and mature and there must be a degree of tolerance for short term slow-downs and unanticipated consequences following the implementation of new systems
- A successful digital strategy must be multi-faceted, and required workforce development - the deficit in leaders and a workforce trained in both clinical care and informatics must be remedied, together with the provision of adequate education and training
- Health IT entails both technical and adaptive change - implementing IT is one of the most complex and adaptive changes in the history of healthcare. Success in the NHS will require sustained engagement

1.4 - Evaluating the development, implementation and safe use of health IT: a sociotechnical system approach

Sociotechnical systems are those in which workplaces are underpinned by complex interactions between people and technology, where “...*the social and the technical are indivisibly combined*”⁶⁵. As a result, the causal attributions of health IT related risks and adverse events are difficult to identify as they generally involve interactions of both technical and non-technical factors which are notoriously difficult to separate. Indeed, when looking at healthcare IT “*getting it right requires a new approach, one that may appear paradoxical yet is ultimately obvious: digitising effectively is not simply about the technology, it is mostly about the people*”⁴⁵. Digitally enabled healthcare is a complex and adaptive system with non-linear emergent and dynamic behaviours. As such, assessing and evaluating the design, development and implementation of health IT is challenging, with a requirement to address the complex relationships between hardware, software, information content and human factors. A successful framework for evaluating health IT must therefore be a comprehensive model which integrates specific technological (software, hardware) and measurement (methods to collect data, organisational surveillance) dimensions, together with wider sociotechnical dimensions such as people, workflow, communication, organisational policies, and external rules and regulations³⁷.

A number of related sociotechnical models have been proposed to support the effective design, implementation and evaluation of health IT, all of which contain the same key technical, environment and social components. Henriksen et al⁶⁶ described five domains: individual provider characteristics (e.g. knowledge, skills, experience), the nature and complexity of the task (e.g. patient load, competing task load), the physical environment where the task takes place (e.g. distractions, layout, lighting, noise), the human-system interface (e.g. equipment location, controls and displays, software) and organisational and management characteristics (e.g. organisational climate, group norms, morale, communication, staffing, organisational structures, resource availability, commitment to quality). Vincent et al⁶⁷ proposed a hierarchy of factors that affect risk and safety and their subsequent influence on clinical practice which includes patient characteristics, task factors,

staff factors, team factors, work environment and organisational/management factors.

Carayon et al⁶⁸ developed the Systems Engineering Initiative for Patient Safety that identifies three key domains: the characteristics of providers together with their resources and organisational setting, the interpersonal and technical aspects of care and changes in the patients' health status or behaviours. Finally, Harrison et al³⁶ developed the Interactive Sociotechnical Analysis Framework that utilises a broad-brush approach to combine the complex inter-relationships between technology, clinicians and workflows with a focus on the importance of examining the actual use of technology rather than the planned use, the impact on technical and physical settings, users' renegotiation and reinterpretation of features, and also the interaction and interdependence among social and technical systems.

Whilst these models provide the key elements required - technical, environment and social – they do not break down the technology aspect into individual specific components such as the interplay of hardware and software, or the user interface and usability which are necessary for the identification of specific failures and latterly solutions. Nor do they account for the specific monitoring and governance procedures and structures that are required for the successful implementation and evaluation of new health IT systems. To overcome these limitations Sittig et al proposed a multi-dimensional sociotechnical model of evaluation based upon eight interacting and inter-dependent dimensions that account for the key factors that influence the success or failure of health IT³⁷:

1. Hardware and software computing infrastructure - the hardware and software required to run an application; for most part the user is not aware of the infrastructure that exists until it fails
2. Clinical content - the data-information-knowledge continuum e.g. structured and unstructured textual or numerical data and images, demographic information
3. Human-computer interface - the aspects of the system that users can see, touch or hear; it must match the user's clinical workflow through usability and functionality
4. People - all those involved in every aspect of the design, development, implementation and use of the technology together with their knowledge and skills

5. Workflow and communication - people work collectively and collaboratively which requires two-way communication and workflow patterns that match the technology
6. Organisational policies, procedures and culture – these affect all other dimensions and must align with the technology and vice versa
7. External rules, regulations and pressures - the external forces which facilitate or constrain the development, implementation, evaluation or use of health IT such as limitations placed by external factors such as Data Protection Act⁶⁹ in the UK
8. System measurement and monitoring - the effects of technology must be measured and monitored on a regular basis with the availability, correct use, effectiveness and unintended consequences captured

This sociotechnical approach to evaluating health IT has been used to exam a number of technologies in a variety of settings including the development and implementation of clinical decision support systems⁷⁰, automatic notification and alert systems⁷¹ and also methods for enhanced communication and automatic notification of abnormal test results within the primary care setting⁷². Despite this structured and comprehensive approach to evaluation health IT related patient safety has yet to find its place in the mainstream of patient safety measurement and reporting; the basic-science of measuring health IT related harm and patient safety in remains in its infancy.

1.5 - Evaluating the development, implementation and safe use of health IT: current user experiences

The sociotechnical approach to understanding the risks associated with the design and implementation health IT may also be used to help understand and assess user experiences and perceptions of new technology. Half of health professionals have been confronted with the introduction of new IT in the last three years, and only half of these rate the introduction as a positive experience⁵² despite the fact that a majority of users have positive attitudes towards the use of new digital technology and are highly amenable to their implementation⁷³.

Users perception of technology is crucial. Success or failure may be objective with real shortcomings in the technology, or subjective with problems merely in the eyes of the user; either way perception and subjective user assessments are key to successful design and implementation. Clinicians report broad and varying levels of digital satisfaction, with overall levels reported to be high in around a quarter of papers, medium in half of all papers and low in the remaining quarter¹³. Clinicians who engage more readily and are exposed to longer and more sophisticated digital technology generally report more positive opinions about it⁷⁴, and the vast majority of clinicians report a positive attitude and expectation of the potential for health IT to improve the quality of care⁷⁵. Low levels of satisfaction and negative attitudes towards new technologies meanwhile are seen when doctors feel removed from the system, are fearful of uncertainties, when the system does not meet clinical needs or leads to negative impacts on workflow and with template-based electronic documentation that is purely aimed at improving efficiency and not care quality⁷⁶⁻⁷⁸. When specifically looking at user perception of risk, half of users report a severe perceived risk associated with the unavailability of technology, failures to locate the most recent patient information and failures related to design and usability especially in high risk areas such as emergency and critical care departments⁷⁹. The perception of risk and consequence is greater in those hospitals with high levels of digital maturity which is likely to represent the high levels of digital dependency in these institutions and subsequent concerns about the consequences of prolonged downtime, even if this is a seldom occurrence⁸⁰.

Interestingly, whilst early satisfaction with new technology is often high and associated with positive perceptions of support and usefulness over the first year or so following implementation, satisfaction tends to be lower with time reinforcing the importance of maximising early positive impressions of training, support and performance to engender high user satisfaction⁸¹. Education and training in itself cannot solve the problem of dysfunctional flawed technology nor facilitate successful implementation of new technology in the short term in isolation. Nonetheless, participation in focused training is associated with higher self-reported skills and digital literacy which promotes a reduced perception of risk⁷⁹. Indeed, not only does focused education consistently improve proficiency of use and satisfaction, it also

provides wider benefits through improving clinicians broader knowledge of informatics and technology in general⁸².

In addition to considering individual user experiences it is important to identify and understand the growing gap between reported end user satisfaction and that of IT professionals. Over half of all surveys demonstrate a growing disparity between IT professionals and clinicians in their satisfaction with health IT, with specific focus on areas such as quality, ease of use, delivery, on time implementation and whether the product works as promoted and is worth the money and resources invested⁸³. Furthermore, around half of clinicians using digital systems report their own suggestions for improvements in their usability⁸⁴, with functions most commonly reported as requiring improvement including slow system response times, poor integration with existing systems and infrastructure, communication between clinical areas, complex navigation processes and poor support for decision making due to overuse of checkboxes and copy and paste practices^{13,85}. In order to address these problems health IT must be sensitive to the non-monetary costs of non-adaptive and rigid technologies that are unable to evolve with the changing patterns of care and clinical workflows. Clinician satisfaction is a legitimate and sensitive barometer for the ongoing assessment of a technology's efficacy and validity and should take precedence over the satisfaction of IT professionals who often have different objectives and priorities as the institutional decision makers and buyers of technology. Further evidence for the best approach to convince clinicians of the need for health IT is required, and they in turn need to commit to approaching the digital agenda with an open and supportive mind-set, and with a willingness to actively engage in the process and take clinical ownership. The involvement of clinicians in every step of the process, from technology selection to acquisition, implementation, optimisation and ongoing evaluation is crucial for enabling the successful digitisation of the healthcare economy⁸³.

1.6 - Evaluating the development, implementation and safe use of health IT: governance and regulation

The transformation of the healthcare from one reliant on paper to one that is fully digitized may raise troubling issues regarding safety, privacy and ethics; there is a need for a robust and accountable regulatory process and buy-in from all stakeholders including healthcare professionals and patients to ensure it is done to the highest possible standards.

Privacy and confidentiality concerns are prominent for all stakeholder. Not only do they hinder clinicians' acceptance and adoption of new technologies⁸⁶ but are also a significant concern for patients. Most patients want control over the information which is recorded and stored, and only a minority support unfettered comprehensive access to all and any clinician⁸⁷. Pregnancy, contraceptive choices, sexual health and mental health being considered the most sensitive, private and potentially stigmatising data that patients are most likely to want to keep to themselves⁸⁸. Furthermore, the vast majority of patients are unaware and poorly informed about the nature, speed and scale of the digitisation of health and the potential impact upon data sharing, confidentiality and privacy⁸⁹. In addition to the privacy and confidentiality concerns, the digitisation of health may also have considerable implications on medical malpractice and liability; easier access to information, the undermining of professional judgement due to information overload, changes in the recording of results and assessments and the use of decision support systems are all examples of developments which may act to change professional responsibilities, redefine standards of care and modify currently upheld legal norms, precedents and obligations⁹⁰.

In order to design and run a suitable regulatory regime in addition to considering the responsibilities of patients and clinicians it is important to understand the responsibilities and liabilities of technology companies. Interestingly, the legal process of 'learned intermediaries' means that even when a digital product is implicated in an adverse safety event the contractual and legal responsibility, and therefore liability rests with the user, even if they are following the correct instructions for use. Developers and vendors of digital products are not responsible for errors as the users, from a legal perspective, are thought able to identify and correct any errors or faults generated by the product even if they have been concealed from

users in the full knowledge of the vendor. Many clinicians may be worryingly unaware of this 'hold harmless' clause⁹¹.

Although it is well established that health IT may introduce new types of error and have a negative impact on patient safety comprehensive data on harm is somewhat lacking. Historically health IT has not been subject to formal processes of regulation in comparison to diagnostic, prognostic, monitoring and treatment software that are subject to medical device regulation and certification. The majority of IT software and hardware used in healthcare is therefore not subject to comprehensive regulation and explicit safety assurance structures and processes⁹². In response to this clear need for greater oversight of health IT the Safety Assurance Factors for HER Resilience (SAFER) Guides was developed to provide recommended practices to help organisations optimise the safe use of health IT and empower stakeholders to have meaningful conversations in order to enhance functionality and drive improvements in quality⁹³. The implementation of technology and organisational digital maturity is highly heterogeneous and as such it is difficult to establish common priorities for safety. To account for this variation in digital maturity a three-stage framework for the development of digital health technology patient safety goals (e-PSG's) has been proposed to allow for nationwide tracking and benchmarking of safety performance: the first phase aiming to address and mitigate safety concerns unique and specific to the technology (e.g. malfunctioning hardware or software), the second phase seeking to address issues created by the failure to use the technology appropriately or the misuse of the technology (e.g. alert override) and the final phase focusing on the use of technology to monitor health care processes and outcomes to detect, manage and learn from potential safety events in real-time before they can harm patients⁹⁴. In addition to these proposed tools and frameworks a further 'red-flag' based approach to the risk management of health IT has been suggested as a means of allowing institutions to identify potential safety concerns through routine surveillance for commonly occurring problems such as incorrect patient identification, extended unavailability, failure to heed a computer-generated alerts, system-to-system interface errors, failure to identify, find or use the most recent patient data, incorrect item selection from a list and the presence of open or incomplete orders⁹⁵.

Advancing better measurements of health IT related harm and developing alternative approaches to data collection in order to capture the full spectrum of risks is therefore key, both at an organisational and regulatory level. Voluntary reporting only detects a small proportion of problems and often neglects latent errors and near misses that could point to important safety issues that are often associated with poor, but not obviously catastrophic system flaws that may be inadvertently attributed to inadequate user training or commitment⁹⁶. Formal processes to identify, monitor and address IT engineered errors should therefore accompany the drive for a digital healthcare system. The need for transparency and effective error reporting has already been emphasised as of key importance in some countries, most notably in the US with the publication of the roadmap for the Federal Health IT Safety Centre lays out four key regulatory goals: firstly facilitation of a nationwide post-marketing surveillance system to monitor safety events, secondly development of methods and structures to support the investigation of major safety events, thirdly creation of the infrastructure and methods to facilitate random inspections and assessments of organisations and finally to be an advocate for health IT safety within government and the wider sector; regulatory goals which are applicable in all nations and settings⁹⁷.

1.7 - Evaluating the development, implementation and safe use of health IT: intra-operability and implications for industry

The health IT market is rapidly expanding with many varied and potentially lucrative opportunities for technology companies. However, the cost and resource required for the development of complex technologies, coupled with a relative lack of minimum inter-operability standards and key data standardisation⁹⁸ means small disruptive technology start-ups have been excluded from the field; health IT to date has largely been the preserve of large commercial organisations with reimbursement and profits rewarded through back-end functions and a focus on successful billing, rather than supporting day-to-day clinical practice⁹⁹. Even in a capitated or prospective payment environment the investment required

is hard to justify and may be prohibitive for even large organisations given the powerful short-term cost pressures, let alone small disruptive start-ups which may want to enter the fray with alternative options. The opening up of the market and development of common standards for openness and interoperability however will generate new opportunities for both established providers and disruptive entrants. In order to seize these new opportunities technology companies must tackle economic inefficiencies in order to generate tangible customer returns on investment, focus on building networks and collaborations so that improvements made by one user can enhance value for current and future users, and help develop software-enabled models of care hand-in-hand with clinicians to make it easier to deliver high-quality cost-effective care. Moreover, as new innovations and technology become embedded in the healthcare economy disruption cycles will be shortened and there will be increased competition on value and quality. In addition to ensuring access to the market and continued innovation systems developers and technology companies must be clear and honest about the limitations of their technology and systems; focusing on realistic expectations, good systems design and early involvement of clinicians. Technology companies and professionals must examine their motives and drivers, identify and fix errors in a visible and transparent manner and be more sensitive to the needs clinicians in order to close this satisfaction gap and deliver the shared goal of better, more efficient and higher quality healthcare.

1.8 - Evaluating the development, implementation and safe use of health IT: healthcare quality and IT

The quality of healthcare may be defined by a number of attributes. Donabedian¹⁰⁰ described seven pillars of healthcare quality which must be taken into account when assessing and assuring quality:

1. Efficacy - the ability of care, at its best, to improve quality
2. Effectiveness - the degree to which attainable health improvements are realized
3. Efficiency - the ability to obtain the greatest health improvement at the lowest cost
4. Optimality - the most advantageous balancing of costs and benefits

5. Acceptability - conformity to patient preferences regarding accessibility, the patient-practitioner relation, the amenities, the effects of care and the costs of care
6. Legitimacy - conformity to social preferences concerning all of the above
7. Equity - fairness in the distribution of care and its effects on health

More recently Darzi¹⁰¹ identified that healthcare quality must be understood from the perspective of the patient - who pay regard to both outcomes and experience - and as such healthcare quality should consist of three key aspects:

1. Patient Safety - firstly, do no harm
2. Patient Experience - ensuring care is delivered with compassion, dignity and respect, and understanding patient satisfaction with their own experiences
3. Effectiveness of Care - evaluating the success of treatments through both clinical measures and patient reported outcomes

Given these established methods for understanding healthcare quality it is therefore logical to evaluate the influence of health IT on quality and safety in secondary care through these perspectives.

1.9 - Conclusions

Health IT has a fundamental role to play in improving patient safety and will undoubtedly transform the quality of care delivered to patients. Much focus has been placed on recognizing the benefits of such technology, in addition to understanding how it can be implemented successfully. Importantly however, whilst limited high-quality evidence is available, there is an increasing realisation that the potential gains and opportunities come hand-in-hand with substantial and often unexpected risks to patients. In addition to a limited and narrow understanding of the true impact of health IT, multiple context and technology specific barriers mean that healthcare remains many years behind other sectors in its adoption of new technologies and overall digital maturity. The story of IT innovation in health to date is largely one of lofty ambition, under-delivery and failed expectation. In order to fully realise the true potential of health IT it is therefore imperative to gain a fuller understanding

of its current impact, and ensure that the potential and actual risks are carefully considered alongside the benefits. All stakeholders must work tirelessly on the basis of robust evidence to deliver meaningful and clinically relevant products that place supporting the delivery of care at the fore, and which help fulfil the shared goal of better, more efficient and higher quality healthcare for all.

1.10 - Conceptual framework and thesis aim

In order to develop a more digitally mature healthcare system, maximise the benefits of novel digital technology and mitigate against new risks it is crucial to better understand how health IT influences the three principal facets of care quality. The aim of this thesis was therefore to systematically investigate the influence of health IT on the three core facets of healthcare quality in secondary care - effectiveness, safety and experience. In order provide an ordered and logical approach to tackling this challenge, and support a hypothesis driven approach to the design, conduct and presentation of each discrete study included, an underlying conceptual framework for the thesis was constructed as seen in *Figure 1.1* below.

Health Information Technology in Secondary Care		
Effectiveness	Safety	Experience
Chapter 2 - Clinical Outcomes and Stakeholder Experience		
Chapter 3 - Communication & Teamwork		
Chapter 4 - Mobile Culture of Work		
Chapter 5 - Regulatory Findings		
	Chapter 6 - Patient Safety Incidents	
Chapter 7 - Cybersecurity & Digital Resilience		

Figure 1.1 - Conceptual framework for investigating the impact of the health IT on quality in secondary care

Chapter 2 - An examination of the relationship between organisational digital maturity, clinical outcomes and stakeholder experience in secondary care in England

This chapter examines the relationship between organisational digital maturity, selected clinical outcomes and stakeholder experience in secondary care in England. Understanding the impact of health IT on clinical outcomes is important to provide an evidence base to direct innovation and investment, and also to support the development of effective and meaningful measures of digital maturity. Meanwhile, the experiences of receiving and delivering care are also important and useful markers of quality in their own right. Indeed, poor experiences of health IT are commonly cited as a barrier to innovation and a source of frustration for patients and staff. Firstly, the NHS Clinical Digital Maturity Index (CDMI) is evaluated to see whether it is a meaningful assessment of digital maturity and whether it may be used as a measure of high-functioning organisations. This is followed by an examination of the impact of digital maturity on selected clinical outcomes and stakeholder experience. The statistical models aim to address the complex relationships in play by controlling for other factors known to influence clinical outcomes and stakeholder experience at a hospital level.

2.1 - Introduction

Reducing variation in care quality and improving patient safety continues to be a significant challenge for all healthcare systems. Up to one in ten patients admitted to hospital are affected by an adverse event, up to half of these are thought to be potentially avoidable¹⁰², and there remains significant variance in the quality, safety and effectiveness of care delivered^{103,104}. There is growing evidence that new technology can help meet these challenges¹⁰⁵, and as a result healthcare is increasingly dependent upon IT to support the delivery of high-quality, efficient and safe care. Electronic systems may have a number of potential benefits over traditional paper-based systems, and can help support patient safety,

reduce adverse events, improve clinical outcomes, lessen error, strengthen the quality and availability of information, support better decision making and communication, and foster improvements in workflow and culture^{6–13}.

There is a paucity of evidence that robustly evaluates the impact of health IT on meaningful patient outcomes at a health system level. The majority of evaluations tend to focus on the narrow, direct operational or process led benefits of specific products and technologies, many predate recent advances in health IT technology or are focused on single institutions, and only a handful evaluate the impact of multi-functional commercially developed systems^{8,106–108}. Despite this, there is a growing body of evidence to suggest that hospitals with more mature electronic notes, order entry and clinical decision support have fewer complications, lower mortality rates and reduced costs¹⁰⁹. For example, one US study of 167,233 patients suggested that increases in the use of health IT are associated with a 15% reduction in the odds of a fatal admission, a 16% reduction in the adjusted odds of complications and up to a \$538 reduction in per patient costs¹¹⁰. A further US study looking at 45,235 patients has suggested that patients with cardiovascular disease, pneumonia or those requiring surgery during admission who are exposed to a fully electronic health record (eHR) have a 17-30% lower odds of experiencing an in-hospital adverse event⁹.

Digital maturity and the better use of health IT may well be associated with markers of care quality, but there is also increasing evidence for its negative impact on experience. The use of health IT has been shown to increase the proportion of time spent on administrative tasks¹⁰ resulting in junior doctors spending just 1.7 hours with patients in a typical day, whilst spending 5.2 hours using computers¹¹¹. Furthermore, the use of electronic systems has also been shown to reduce the amount of direct communication between patients and staff¹¹², and also lead to information overload, frequent interruptions to work, a change in the content of professional work and higher risk of professional burnout^{109,113}. These sobering reminders of the potential pitfalls of health IT means that whilst most health professionals have been confronted with the introduction of new technology in the last three years, only half of them rate the introduction as a positive experience⁵² despite the fact that the majority had a positive attitude towards the use of new technology prior to its implementation⁷³. In addition

to this there is increasing evidence to suggest that there is growing disparity in the satisfaction with health IT between IT professionals and clinical end-users, suggesting that decisions regarding health IT are increasingly based on the needs of administrators and IT professionals rather than clinical end-users. This gap results in a lack of clinically optimised electronic systems that have severe usability issues, lack appropriate features to support common clinical tasks and poorly support the documentation and retrieval of patient data¹¹⁴. These realities mean that health IT commonly hinders the routine work of healthcare professionals, has no significant impact on clinician job satisfaction⁷⁴ and often fails to realise its true potential to benefit staff and patients⁸³.

Health IT not only influences the experience of staff but also that of patients, and increasingly there is a recognition of the positive impact of patient experience on outcomes and organisational performance. Despite the growing importance of patient-centeredness, there is a relative paucity of evidence examining the relationship between health IT and patient experience despite the great potential for health IT to engage hospitalised patients in their care¹¹⁵. One study from the US has identified the positive association between the use of electronic health records and just three hypothesised measures of patient experience: whether staff gave the patient information on what to do for recovery at home, whether the patient would rate the hospital highly and whether the patient would recommend the hospital to others¹¹⁶. A further review also found that the use of electronic health records by clinicians found neutral or positive effects on patient experience¹¹⁷, and another suggested that the advanced use of electronic systems does not lead to a reduction in patient experience¹¹⁸.

The first step to understanding the impact of health IT on outcomes and experience is to identify a robust and useful method for assessing the relative digital maturity of an organisation. Digital maturity is the extent to which an organisation's health IT may be seen as an enabler of high-quality healthcare through supporting improvements to both service delivery and patient experience. Digital maturity encompasses not only technology, resource and capability, but also the digital literacy, ability and motivation of staff and patients to use new technologies. The inter-operability of different systems, and their ability to work in conjunction to maximise the potential benefits of health IT are also fundamental to support

their ability to transform the healthcare sector^{107,119}. Established frameworks for evaluating digital maturity in healthcare typically focus on the narrow, direct operational benefits delivered by a new technology or product, rather than assessing the more complex and nuanced impact upon all stakeholders across the whole system^{120,121}. In order to use digital maturity assessments in a meaningful way, there is a need therefore to interrogate the current method used to benchmark organisations in England - the NHS CDMI Tool¹²² - and establish whether or not they are useful and fit for purpose.

Much of the published literature looking at the impact of health IT on safety and outcomes is focused on the US healthcare system. Due to the influence of centrally mandated incentives to improve the adoption and meaningful use of health IT provided in the \$30 billion HITECH Act^{123–125} drawing meaningful comparisons to other healthcare systems is extremely challenging. Meanwhile stakeholder experience is a complex and multifactorial element of healthcare and the judgement as to whether or not the digital maturity of an organisation can influence these broader measures of care is unclear. Whilst the better use of health IT is unlikely to directly impact experience in isolation, many of the benefits it can deliver are likely to improve the day-to-day experiences of secondary care for all stakeholders.

The present study therefore sought to examine the NHS CDMI Tool as a means for assessing digital maturity, and to determine whether or not the digital maturity of acute hospitals in England is associated with clinical outcomes and stakeholder experience.

2.2 - Hypothesis, aim and objectives

2.2.1 - Hypothesis

The effective use of new health IT has the potential to transform the quality of care delivered to patients. There is however a current paucity of evidence about the impact of organisational digital maturity on clinical outcomes and stakeholder experience in secondary care. By examining the current tools for assessing digital maturity, and then providing a best

estimate of its impact on meaningful patient outcomes and stakeholder experience it will be possible to inform the future development and evaluation of health IT, support the better day-to-day use of technology and provide data for evidence-based decisions on the future of health IT provision in the NHS in England.

2.2.2 - Aim

The principal aim of this study is to establish the relationship between organisational digital maturity, clinical outcomes and stakeholder experience in secondary care in England.

2.2.3 - Objectives

In order to fulfil the stated aim, this study will seek to fulfill the following objectives:

1. To establish the relationship between organisational digital maturity and selected clinical outcomes in secondary care in England
2. To establish the relationship between organisational digital maturity and selected measure of stakeholder experience in secondary care in England
3. To establish whether the NHS Clinical Digital Maturity Index is meaningful assessment of digital maturity and whether it may be used as a measure of high-functioning organisations

2.3 - Methods

2.3.1 - Study population

Data was collected from all 136 non-specialist NHS Trusts in England that provide acute care. All data included in the analysis covered the 12-month period from January 2015-January 2016 to coincide with the data collection and reporting period for the linked Clinical Digital Maturity Index (CDMI) scores for each organisation that were captured in January 2016. Data collected included five specified outcome variables and a further 16 covariables

pertaining to staffing, infrastructure and workload. This data covered 17,686,479 A&E attendances, 5,606,092 emergency admissions and 7,499,904 planned admissions with a mean length of stay for all admissions was 4 days, and mean patient age 53yrs. Data for the 2016 Adult Inpatient and NHS Staff Satisfaction Surveys scores was also collated from 126/136 NHR Trusts which accounted for 16,692,399 A&E admissions, 14,266,229 inpatient episodes and 683,059 whole-time equivalent (WTE) staff members. Summary descriptive statistics for all collected data is seen in *Table 2.1*. The quality and completeness of the data was good with missing data accounting for <0.2% of all data items included.

2.3.2 - The NHS Clinical Digital Maturity Index (CDMI)

In 2013 NHS England launched the Clinical Digital Maturity Index (CDMI) - a benchmarking tool that enables NHS organisations to individually rate their own technical capabilities, and facilitate a better understanding of how investing in new technology can improve patient safety and outcomes, reduce bureaucracy, deliver efficiency gains, and facilitate the drive towards a paperless NHS¹²². These ambitions not only align with the strategic direction of the NHS, which focuses heavily on the adoption of digital technology, but also facilitates the continuing aspiration to effectively integrate health and social care; a challenge that will necessarily rely heavily on data sharing and inter-connectivity of systems¹²⁶. Through a self-assessment framework, the tool identifies an organisation's digital maturity across three main themes; allows them to benchmark their performance against their peers and identifies key areas for development and improvement. Three principal themes are assessed - readiness, capabilities and infrastructure - and these are further divided into 13 sections that are scored via 133 individual questions¹²⁷:

- Readiness - covering strategic alignment, leadership, resourcing, governance and information governance. Provides an assessment of an organisation's ability to plan, deliver and optimise the digital systems it needs to be "paper-free"
- Capabilities - covering records, assessments and plans, transfers of care, orders and results management, medicines management and optimisation, remote and assistive care, asset and resource optimisation and standards. Provides an assessment of the

digital capabilities that are available to an organisation and the extent to which they are being optimised across the organisation as a whole

- Infrastructure - covering areas such as Wi-Fi, mobile devices single sign-on and business continuity. The extent to which an organisation's essential underpinning infrastructure is in place to support the delivery of their required capabilities

A summary diagram of the CDMI Tool is seen in *Appendix A*. The CDMI tool was chosen as it is the only standardised measure of digital maturity available for all NHS providers in England. Although the tool provides important benchmarking information to help organisations highlight and identify areas for improvement, it is yet to be formally examined against outcomes, experience or other relevant measures.

2.3.2.1 - Description of CDMI data and Principal Component Analysis (PCA)

Standard descriptive statistics were employed to evaluate the CDMI scores from all 241 NHS Provider organisations in England. Scores for the 136 acute care providers of interest were then extracted and used for subsequent analyses. Geographical variation in CDMI was evaluated through the creation of an atlas of variation in which mean CDMI scores for each Lower Layer Super Output Area (LSOA)¹²⁸ - a standardised measure for small area statistics - were mapped to the number of A&E attendances from that area in the 12-month period from January 2014 – January 2015. The association between CDMI score and Global Digital Exemplar (GDE) status was confirmed through a univariate regression analysis.

The CDMI Tool utilises scores from 133 questions across 13 sections to generate total scores across three domains, in addition to an overall aggregate score. In order to validate this hierarchy, characterise the variance in scores across each of the sections and domains, and perform variable reduction to inform which scoring level to use in the subsequent multivariate analysis, a principal component analysis (PCA) was performed.

A PCA was run on scores from the 13 distinct sections of the CDMI score for the 136 Trusts included in the analysis. Inspection of the correlation matrix showed all variables had at least

one correlation coefficient >0.3 as seen in *Table 2.2*. The overall Kaiser-Meyer-Olkin (KMO) measure was 0.907 or 'marvellous'¹²⁹, and Bartlett's Test of Sphericity was statistically significant ($p<0.0005$) indicating the data was likely factorisable.

PCA revealed that two components had eigenvalues >1 which explained 44.53% and 13.59% of the total variance respectively. Visual inspection of the scree plot confirmed that these two components should be retained as per the Kaiser criterion.¹³⁰ Eigenvalues and scree plot are seen in *Figure 2.2*. Furthermore, a two-component solution meets the interpretability criterion, and as such two components were retained. The two-component solution explained 58.12% of the total variance. An orthogonal rotation was employed to aid with interpretability and is seen in *Figure 2.3*. The rotated solution exhibits a simple structure, and interpretation of the data is certainly consistent with the attributes of the CDMI Tool; namely that the 13 sections effectively map to the three hierarchal domains of readiness, capability and infrastructure. In light of this confirmatory analysis, it was deemed that the tool was appropriate to be used with only the three core domains and total aggregate CDMI score were used in subsequent analyses. Component loadings and communalities of the rotated solution are seen in *Table 2.3*.

2.3.2.2 - Evaluation of CDMI data

The PCA analysis confirmed the validity of evaluating three distinct domains – readiness, capabilities and infrastructure – together with overall aggregate CDMI score. Whilst the total CDMI score for an organisation is helpful to understand the aggregate influence of digital maturity on clinically relevant outcomes, it is arguably of more interest to identify which distinct component, if any, is most related to clinical outcomes. To these ends digital maturity scores were handled in aggregate, and also via analysis of each individual domain, whilst simultaneously controlling for the remainder. Normality of the data was checked, and no transformations were used. Categorisation of the CDM score – median split, tertiles and quartiles - was evaluated, but this did not assist in the interpretation of the results and therefore all variables were treated as continuous throughout the analysis.

2.3.3 - Organisational covariates and outcome data

In order to satisfy the stated aims and objectives it is important to consider relevant factors that may exert influence, whilst also minimising the potential impact of collinearity and multiple testing error within the data studied. An initial exploratory analysis of the data was undertaken to evaluate the optimal handling of the outcome variables and the key variable of interest; namely organisational digital maturity. Following this exploratory analysis, plausible covariates – related to infrastructure, staffing and workload - that are likely to influence the outcome variables were individually assessed to inform the final multivariate analysis. This process was conducted in order to provide the best estimate of the relationship between digital maturity and relevant organisational outcomes.

2.3.3.1 - Organisational covariates

In order to best as possible control for confounders and provide the best estimate of the relationship between digital maturity and clinical outcomes 16 covariates pertaining to staffing, infrastructure and workload that were readily available, and identified as potentially influencing clinical outcomes were evaluated for inclusion. There is a firm body of evidence that staffing levels, be that total staff numbers, variation in staffing levels, skills mix and access to senior clinical input all have a significant impact on clinical outcomes^{131,132,141,133–140}. In addition to the impact of staffing levels, hospital characteristics such as bed numbers, academic or teaching hospital status and maturity of infrastructure and technology have also be shown to directly influence patient outcomes^{103,139,141–146}. Finally, the impact of workload, volume and bed occupancy across a range of health conditions and setting has also been shown to have a large impact on clinically relevant outcomes^{137,142,154,143,147–153}. A pragmatic selection of covariates to examine was made based on the published literature and the ready availability and robustness of data, whilst ensuring the risk of collinearity and multiple sampling bias was minimised. Selected staffing, workload and hospital infrastructure data was collated from relevant publicly available datasets generated by NHS Digital¹⁵⁵, academic hospital status was defined as membership of the Association of UK University Hospitals¹⁵⁶

and Global Digital Exemplar (GDE) status as awarded by the Department of Health and NHS England¹⁵⁷:

1. *Staffing* - total number of staff (all staff groups), total number of clinical staff (professionally registered), clinical/non-clinical staffing ratio, doctor/nurse staffing ratio, consultant/junior doctor staffing ratio, manager/clinical staffing ratio, doctor/bed number ratio, nurse/bed number ratio
2. *Infrastructure/Size* - total number of general and adult inpatient beds, total number of adult critical care beds (ITU) beds, academic hospital status, Global Digital Exemplar (GDE) status
3. *Workload* - number of A&E attendances, number of inpatient admissions, mean general and adult inpatient bed occupancy, mean adult critical care bed occupancy

In order to provide the best estimate for the relationship between organisational digital maturity and stakeholder experience thirteen of these organisational covariates were selected via a pragmatic approach based upon published evidence and ready availability of data for the model. In addition to these structural factors, hospital performance and clinical outcomes are also likely to influence stakeholder experience and so three of clinically important outcome measures used in this study were also included in the final model:

1. *Staffing* - total number of all (all staff groups); clinical/non-clinical staff ratio; doctor/nurse ratio; consultant/junior doctor ratio; doctor/bed ratio; and nurse/bed ratio
2. *Infrastructure/Size* - total number of general and adult inpatient beds; total number of adult critical care (ITU) beds; and academic hospital status
3. *Workload* - total number A&E attendances; total number of inpatient admissions; mean general and adult bed occupancy; mean adult critical care bed occupancy
4. *Clinical outcomes* - Summary Hospital Level Mortality Index (SHMI), Percentage of harm-free patient care episodes (HFC) and Relative risk of long length of stay (LLOS)

Summary descriptive statistics of all data is presented in *Table 2.1*.

2.3.3.2 - Measures of clinical outcomes

The data analysed included five outcome variables which arise from routinely collected hospital administrative data that relate to organisational performance, and which are commonly used to assess the performance of healthcare organisations. All outcome measures used are based on hospital episode statistics (HES) data, and are publicly available from NHS Digital¹⁵⁵ and the Dr Foster Unit¹⁵⁸ at Imperial College London.

1. *Summary Hospital Level Mortality Index (SHMI)* - a transparent and reproducible measure of deaths in hospital, or within 30 days of discharge that risk-adjusts for admission diagnosis, age, gender, type of admission and patient co-morbidities. It has been reported by all NHS Trusts providing acute care since October 2011 and accounts for 81% of variability in mortality with a C-statistic of 0.911^{159,160}
2. *Relative risk of readmission (READ)* - calculated by evaluating the number of emergency readmissions within 28-days of discharge from hospital. Whilst readmission rates are a complex and potentially problematic quality metric, they are widely used to assess hospital performance^{161,162}
3. *Relative risk of long length of stay (LLOS)* - calculated by assessing the number of hospital episodes associated with a risk-adjusted length of stay that exceeds the upper quartile for all patients nationally with that episode type.¹⁶³ LLOS has been shown to be a potentially useful adjunct to assist with the evaluation of shortcomings in the quality and safety of care delivered in hospital¹⁶⁴
4. *Percentage of harm-free patient care episodes (HFC)* - assessed via the NHS Safety Thermometer Tool which provides a point-of-care survey instrument to measure the provision of harm-free care across each day of a hospital admission. The tool assesses four commonly occurring harms: pressure ulcers, falls, catheter associated urinary tract infections (CAUTI's) and venous thromboembolism (VTE). The stated goal is to deliver harm free care to 95% of admitted patients¹⁶⁵
5. *Percentage of patient episodes featuring complications of care (COC)* - evaluated via Patient Safety Indicator (PSI) 90 that forms part of the Agency for Healthcare Research and Quality (AHRQ) risk-adjusted Quality Indicators¹⁶⁶. PSI-90 provides a

composite measure of hospital-level quality based on the occurrence of potentially preventable safety events: pressure ulcer; iatrogenic pneumothorax; in-hospital fall with hip fracture; peri-operative haemorrhage haematoma, pulmonary embolism or deep venous thrombosis; post-operative acute kidney injury, respiratory failure, sepsis or wound dehiscence; unrecognised abdominopelvic accidental puncture¹⁶⁷

Summary descriptive statistics of all outcome data is presented in *Table 2.1*.

2.3.3.3 - Measures of stakeholder experience

Two standardised measures of stakeholder experience were chosen to provide comparable results across all the organisations included. Alternative measures such as the NHS Friends and Family Test and results from local staff surveys were considered, but these either did not provide equal depth and richness of data, or were not readily available for all organisations and thus would have limited the quality and breadth of the study.

The National Adult Inpatient Survey is an annual study conducted by the Care Quality Commission (CQC) in England to understand the experiences of adults receiving hospital care, how these experiences change over time, and how they may be used to identify outlier organisations and improve quality¹⁶⁸. The 2016 survey studied 77,850 patients aged 16 and over who stayed at least one night in hospital with a response rate of 44% across all eligible NHS organisations. The survey includes 76 questions across five core domains with all responses returned on either Likert scales, or as yes/no responses with overall percentage scores reported. Raw scores are weighted for organisation-specific patient demographics in order to standardise the results to a common average case mix and remove potential confounding and variation due to differences in demography¹⁶⁹. For the purposes of this analysis average scores for each of the five key domains were utilised, together with the overall patient experience score for each organisation.

The NHS Staff Survey was first run in 2003 and aims to examine what organisations can do to deliver better patient care, create better working conditions and improve staff well-

being¹⁷⁰. It identifies 32 key areas and all responses are returned either on a 5-point Likert scale, or as a yes/no response with subsequent overall percentage scores reported. All data is weighted by occupational group in order to standardise the results and account for the well documented variation in reporting by different staff groups¹⁷¹. For the purposes of this analysis only results from eight of the key findings deemed likely to be influenced by digital maturity, together with the overall engagement score were used in order to minimise the risk of multiple sampling error.

Summary descriptive statistics of all experience data is presented in *Table 2.1*.

2.3.4 - Examining the relationship between organisational digital maturity, clinical outcomes and stakeholder experience

Standard descriptive statistics were employed to explore all collated data. All covariates were assessed for normality and no further transformations were deemed to be required with all data being treated as parametric for the purposes of analysis. Where covariates represented proportions, the frequency distribution of data was such that normality was preserved and no transformations to account for this were required. All outcome covariates were also normally distributed and were treated as continuous variables in subsequent regression models. The distribution of stakeholder experience scores was also checked, and once again no transformation was required with all data being treated as ordinal for the purposes of analysis. The normality of the CDMI data was also checked and no transformations were used. Categorisation of the CDMI score – median split, tertiles and quartiles - was evaluated, but this did not assist in the interpretation of the results and therefore all data was treated as continuous for the purposes of this analysis.

Each of the covariates was initially assessed by means of scatter plots and subsequent univariate regression against each of stated outcomes and CDMI scores with significance at $p < 0.05$. The GDE status of an organisation, as expected, was shown to be closely related to the CDMI score so as to be effectively collinear; it did not therefore provide any meaningful

contribution to the model, and so was excluded from subsequent analyses. Only those covariates with a significant relationship to the selected outcome variable, or a significant relationship with one or more of the CDMI variables was retained for multivariate analysis.

As each of the outcome variables chosen assess a different, but often overlapping aspect of clinical quality the relationship between each measure, and each domain of the CDMI scores was assessed through univariate regression analysis. COC and READ were not significantly associated to CDMI scores and so were not considered for further analysis. HFC was related to all CDMI domains and so was retained for analysis. LLOS was related to all domains except for infrastructure and so was also retained for subsequent analysis. SHMI was only significantly related to the capability domain but was retained due to its prevalence as a primary outcome measure for assessing organisational quality. Therefore, LLOS, HFC and SHMI were retained for subsequent multivariate analysis.

Multivariate modelling via a kitchen sink approach with all covariates selected *a priori*, and a backward stepwise selection approach with all significant covariates carried over from the univariate stage were performed. For the backward stepwise selection model an α -to-enter (*pe*) of 0.05 and α -to-remove (*pr*) of 0.1 was selected; the model was invariant whether the *pr* parameter was 0.2 or 0.1¹⁷². Models were run to independently assess the influence of aggregate CDMI score and scores across each of the three individual CDMI domains.

2.4 - Results

2.4.1 - An exploration of CDMI scores

Full CDMI scores were available for all 136 acute NHS Trusts included in the analysis and the quality and completeness of the data was excellent with 0% missing data. The mean aggregate total CDMI score was 796.02 (324 – 1253, SD 171.156), and the scores were deemed to be normally distributed following assessment of Q-Q plots and a Shapiro-Wilk Test $p>0.05$. There was also significant variation seen across the three distinct domains of

CDMI with a mean infrastructure score of 67.69 (20 – 100, SD 16.214), mean capability score of 353.25 (115 – 671, SD 114.812) and mean readiness score of 375.08 (177 – 495, SD 68.076). Scores from all three domains were also deemed to be normally distributed following assessment of Q-Q plots and Shapiro-Wilk Tests of $p > 0.05$. Geographical variation in CDMI was evaluated through the creation of an atlas of variation demonstrating the mean aggregate total CDMI scores for each Lower Layer Super Output Area (LSOA) by number of A&E attendances for 2014-15 which is seen in *Figure 2.1*.

16/136 (11.77%) of organisations were Global Digital Exemplars (GDE). A univariate regression analysis was performed to assess the association between GDE status and CDMI scores. As expected, GDE status of an organisation was shown to be significantly related to the CDMI score. Total CDMI score was shown to significantly predict GDE status, $F(1,134) = 35.61$, $p = < 0.0005$, with an adjusted $R^2 = 0.2040$. The GDE status of an organisation led to additional significant increase in total aggregate CDMI score of 242.51 (95% CI 162.13 – 322.89). Readiness scores were also shown to significantly predict GDE status, $F(1,134) = 12.77$, $p = < 0.0005$, with an adjusted $R^2 = 0.0801$ and GDE status leading to an additional significant increase in total readiness score of 62.1 (95% CI 27.73 – 96.47). A similar relationship was also seen with capability scores, $F(1,134) = 36.66$, $p = < 0.0005$, with an adjusted $R^2 = 0.2089\%$ and GDE status leading to an additional significant increase in total capability score of 164.55 (95% CI 110.79 – 218.30); and also with infrastructure scores, $F(1,134) = 14.90$, $p = < 0.0005$, with an adjusted $R^2 = 0.0934$ and GDE status conferring a significant gain of 15.86 (95% CI 7.73 – 23.99) in infrastructure score. As GDE status and CDMI score was effectively collinear GDE status did not provide any meaningful contribution to the proposed multivariate model, and so was subsequently excluded from future analyses. Of interest, GDE status was also shown to be significantly related to the outcome variables SHMI ($B = -0.064725$, $p = 0.007$) and LLOS ($B = 1.036393$, $p = 0.049$) at a univariate level.

2.4.2 - Examining the relationship between CDMI score and clinical outcomes

2.4.2.1 - Exploration and evaluation of outcome variables

Outcome data was obtained for all 136 NHS Trusts included in the analysis. The quality and completeness of the data was good, with <1% of data missing. Standard descriptive statistics for the outcome variables was performed and is summarised in *Table 2.1*:

Summary Hospital Level Mortality Index (SHMI) mean 1.00 (0.669 – 1.173, SD 0.09, IQR 0.119), relative risk of readmission (READ) mean 99.54 (83.54 – 111.15, SD 5.58, IQR 7.60), relative risk of long length of stay (LLOS) mean 98.59 (72.23 – 119.89, SD 10.23, IQR 15.74), % of harm-free patient care episodes (HFC) mean 93.80 (88.00 – 98.00, SD 1.961, IQR 2.00) and % of patient episodes featuring complications of care (COC) mean 3.11 (1.54 – 5.80, SD 0.75, IQR 0.82). All outcome variables were deemed to be normally distributed following assessment of Q-Q plots and Shapiro-Wilk Tests of $p > 0.05$.

A univariate linear regression was run to understand the relationship ($p < 0.05$) between each aspect of the CDMI score and the selected outcomes and inform which to select for the final multivariate analysis; the summary regression matrix is seen in *Table 2.4*. Different outcome variables were related to different domains of the CDMI score. READ and COC were not significantly related to any domain of the CDMI score and so were not considered for further analysis. All models had good fit of data with $p < 0.05$. SHMI was significantly related to the capability domain; $F(1,134) = 5.17$, $p = 0.025$, with an adjusted $R^2 = 0.0300$ and $B = -0.0001513$ (95% CI -0.0002829 – -0.0000197). LLOS was significantly related to the total aggregate CDMI score, readiness score and capability score; $F(1,134) = 9.59$, $p = 0.002$, with an adjusted $R^2 = 0.0598$ and $B = 0.155801$ (95% CI 0.0056274 – 0.0255328); $F(1,134) = 7.76$, $p = 0.006$, with an adjusted $R^2 = 0.0547$ and $B = 0.0354604$ (95% CI 0.0102763 – 0.0606445) and $F(1,134) = 7.12$, $p = 0.009$, with an adjusted $R^2 = 0.0434$ and $B = 0.201933$ (95% CI 0.0052273 – 0.0351593) respectively. HFC was significantly related to the total aggregate CDMI score, readiness score, capability score and infrastructure score: $F(1,134) = 12.38$ $p=0.001$, with an adjusted $R^2 = 7.78\%$ and $B = 0.0033696$ (95% CI 0.0014758 – 0.0052635); $F(1,134) = 9.94$ $p=0.00285$, with an adjusted $R^2 = 6.90\%$ and $B = 0.0076534$ (95% CI 0.0028515 – 0.0124552); $F(1,134) = 9.13$ $p=0.003$, with an adjusted $R^2 = 5.68\%$ and $B = 0.043619$ (95% CI 0.0015066 – 0.0072171) and $F(1,134) = 4.42$ $p=0.037$,

with an adjusted $R^2 = 2.47\%$ and $B = 0.218572$ (95% CI 0.0012978 – 0.0424166) respectively. LLOS and HFC are significantly related to two and three of the CDMI domains respectively and so were retained for the subsequent multivariate analysis. Whilst SHMI was only significantly related to the capability domain of CDMI it was also retained for the subsequent multivariate analysis due to its prevalence as a primary outcome variable in care quality analysis.

2.4.2.2 - Exploration and evaluation of covariates

Covariate data was obtained from all 136 NHS Trusts included in the analysis and is summarised in *Table 2.1*. The quality and completeness of the data was acceptable with 4.4% of data missing. Standard descriptive statistics for each of the 15 covariates retained for the final analysis was performed, and as expected there was significant variation, particularly with regards staffing numbers and skills-mix across the organisations: total number of staff (all staff groups) mean 5188.73 (1517.00 – 13,536.00, SD 2561.61, IQR 3295.00), total number of clinical staff (professionally registered) mean 2912.20 (805.00 – 8488.00, SD 1572.16, IQR 1795.00), clinical/non-clinical staffing ratio mean 0.99 (0.68 – 1.56, SD 0.15, IQR 0.20), doctor/nurse staffing ratio mean 0.40 (0.14 – 0.56, SD 0.07, IQR 0.09), consultant/junior staffing ratio mean 0.77 (0.54 – 1.22, SD 0.17, IQR 0.14), manager/clinical staffing ratio mean 0.04 (0.01 – 0.09, SD 0.01, IQR 0.02), doctor/bed number ratio mean 0.85 (0.51 – 2.36, SD 0.269, IQR 0.24), nurse/bed number ratio mean 2.13 (1.37 – 6.34, SD 0.68, IQR 0.54), total number of general and adult inpatient beds mean 701.60 (193.00 – 1623.00, SD 302.436, IQR 438.00), total number of adult critical care beds (ITU) beds mean 26.81 (5.00 – 108.00, SD 24.49, IQR 21.00), number of A&E attendances mean 129,080.59 (44,727– 416,419, SD 66,454.92, IQR 68,013), number of inpatient admissions mean 110,056.42 (25,331 – 255,895, SD 48,951.36, IQR 61,637.00), mean general and adult inpatient bed occupancy 88.96 (69 – 98, SD 4.91, IQR 5.30) and mean adult critical care bed occupancy 82.15 (50 – 100, SD 9.78, IQR 13.00). 31/136 hospital (22.79%) of organisations had academic hospital status.

Each covariate was assessed initially by scatter plots, and then by univariate regression analysis against each of the stated outcome variables, and against each domain of the CDMI score in order to inform which covariates to include in the final multivariate regression analysis model; only those with a significant relationship to the outcome variables, or one or more domain of the CDMI score being retained. The summary regression matrix identifying those covariates with a significant relationship ($p < 0.05$) to either one or more of the CDMI domains, or more or more of the outcome variables is seen in *Table 2.4*.

A&E attendance was significantly associated with SHMI ($B = -3.09^{-7}$, $p = 0.008$), HFC ($B = 6.36^{-6}$, $p = 0.013$), aggregate CDMI score ($B = 0.0005458$, $p = 0.014$) and capability score ($B = 0.0003794$, $p = 0.011$). Number of admissions were significantly associated with SHMI ($B = -3.53^{-7}$, $p = 0.027$), HFC ($B = 7.36^{-6}$, $p = 0.036$), aggregate CDMI score ($B = 0.0009942$, $p = 0.001$), readiness score ($B = 0.0003277$, $p = 0.006$), capability score ($B = 0.0006089$, $p = 0.002$) and infrastructure score ($B = 0.0000576$, $p = 0.045$). Total staff numbers were significantly related to SHMI ($B = -8.91^{-6}$, $p = 0.002$), LLOS ($B = 0.0013918$, $p < 0.0005$), HFC ($B = 0.000163$, $p = 0.011$), aggregate CDMI score ($B = 0.03656$, $p < 0.0005$), readiness score ($B = 0.0068479$, $p = 0.002$) and capability score ($B = 0.0145655$, $p < 0.0005$). Total clinical staff numbers were related to SHMI ($B = -0.0000173$, $p < 0.0005$), LLOS ($B = 0.0024027$, $p < 0.0005$), HFC ($B = 0.0002974$, $p = 0.005$), aggregate CDMI score ($B = 0.03656$, $p < 0.0005$), readiness score ($B = 0.010551$, $p = 0.004$) and capability score ($B = 0.0247527$, $p < 0.0005$). Dr/Nurse ratio was significantly associated with SHMI ($B = -0.334332$, $p = 0.001$). Clinical/Non-clinical staff ratio was significantly associated with SHMI ($B = -0.2180829$, $p < 0.0005$), LLOS ($B = 5.91386$, $p = 0.014$), HFC ($B = 2.405923$, $p = 0.037$) and the capability score ($B = 156.3026$, $p = 0.019$). Cons/Jr doctor ratio was only significantly related to LLOS ($B = -20.3853$, $p = 0.002$). The total number of general and acute beds was significantly related to LLOS ($B = 0.0229891$, $p = 0.001$), HFC ($B = 0.0012596$, $p = 0.017$), aggregate CDMI score ($B = 0.157739$, $p < 0.0005$), readiness score ($B = 0.472616$, $p = 0.009$), capability score ($B = 0.995344$, $p = 0.001$) and infrastructure score ($B = 0.010943$, $p = 0.011$). The total number of adult ITU beds was significantly related to SHMI ($B = -0.0010909$, $p < 0.0005$), LLOS ($B = 0.1604666$, $p < 0.0005$), aggregate CDMI score ($B = 2.251494$, $p < 0.0005$), readiness score ($B = 0.6809739$, $p = 0.004$) and capability score ($B = 1.47019$, $p < 0.0005$). Average ITU

bed occupancy was only related to the aggregate CDMI score ($B=406.4855$, $p=0.007$) and capability score ($B=316.8003$, $p=0.002$). Average general and acute bed occupancy was just significantly related to the readiness score ($B=-258.277$, $p=0.023$). Dr/Bed number ratio was significantly related to SHMI ($B=0.0321738$, $p=0.003$), HFC ($B=-6941698$, $p=0.003$), aggregate CDMI score ($B=-103.3575$, $p<0.0005$), readiness score ($B=-38.06428$, $p<0.0005$), capability score ($B=-56.2904$, $p<0.0005$) and infrastructure score ($B=-9.002864$, $p<0.0005$). Nurse/Bed ratio was significantly associated with SHMI ($B=0.151941$, $p=0.002$), HFC ($B=-0.2649029$, $p=0.013$), aggregate CDMI score ($B=-44.24357$, $p<0.0005$), readiness score ($B=-15.50511$, $p<0.0005$), capability score ($B=-24.8383$, $p<0.0005$) and infrastructure score ($B=-3.900166$, $p<0.0005$). Finally, academic status of the hospital was significantly related to SHMI ($B=-0.0602981$, $p=0.001$), LLOS ($B=9.578028$, $p<0.0005$), HFC ($B=0.8289878$, $p=0.038$), aggregate CDMI score ($B=123.9159$, $p<0.0005$), readiness score ($B=35.85577$, $p=0.009$), capability score ($B=80.46394$, $p<0.0005$) and infrastructure score ($B=7.596154$, $p=0.02$).

2.4.2.3 - Multivariate regression analysis: predicting outcomes from digital maturity

Multivariate regression analysis was run to predict each of the retained outcomes (SHMI, HFC and LLOS) from individual CDMI domain scores and the 15 specified covariates. The total aggregate CDMI score was not included in the principal analysis due to collinearity with each of the CDMI domains as would be expected, and therefore was evaluated in isolation. Three models were utilised: firstly, a kitchen sink approach with all 15 covariates retained; secondly, a model in which only those covariates that were significantly related to the outcome measure at the univariate analysis were retained; and finally, a backward stepwise selection model with a $pr(0.1)$ and $pe(0.05)$ that started with all significant covariates and each of CDMI domain scores locked. All models had a good fit of the data with $p = <0.05$.

The multivariate regression analysis for SHMI revealed Model 1 - the kitchen sink model - to have $F(18,117) = 3.59$, $p<0.0005$ and an adjusted $R^2 = 0.3560$. Only Dr/Nurse ratio ($B = -0.2353947$, $p=0.046$), Cons/Jnr ratio ($B = -0.1457694$, $p=0.018$) and the number of general and adult beds ($B = 0.0001266$, $p=0.042$) were shown to significantly add to the prediction.

Model 2 - the significant covariate model - meanwhile demonstrated $F(14,121) = 3.48$, $p=0.0001$ and an adjusted $R^2 = 0.2048$. None of the covariates included in the model added significantly to the prediction. Model 3 – the backward stepwise selection model – was shown to have $F(8,127) = 6.16$, $p<0.0005$ and an adjusted $R^2 = 0.2341$. Staff numbers ($B = 0.0000445$, $p=0.014$), Dr/Nurse ratio ($B = -0.0001029$, $p=0.001$), total number of general and adult beds ($B=0.0001247$, $p=0.004$) and Dr/Bed ratio ($B = 0.03999898$, $p=0.001$) were shown to be the covariates that significantly add to the prediction. The summary regression matrix for each model, together with all covariates and regression coefficients can be found in *Table 2.5a*.

For HFC Model 1 had $F(18,117) = 1.82$, $p=0.0301$ and an adjusted $R^2 = 0.0989$ with none of the covariates adding significantly to the model. Model 2 showed $F(13,122) = 2.36$, $p=0.0077$ and an adjusted $R^2 = 0.1155$ with only the total number of clinical staff being a significant contributor to the model ($B = 0.0031668$, $p=0.045$). Finally, for Model 3 $F(6,129) = 4.08$, $p=0.0009$ and an adjusted $R^2 = 0.1204$. The number of staff ($B=-0.0009478$, $p=0.024$) and total number of clinical staff ($B = 0.0021023$, $p=0.006$) were the only significant covariates that contributed to the model. The summary regression matrix for each model, together with all covariates and regression coefficients can be found in *Table 2.5b*.

Model 1 of the multiple regression for LLOS demonstrated $F(18,117) = 5.14$, $p = <0.0005$ and an adjusted $R^2 = 0.3554$. Only the number of inpatient admissions ($B = -0.0002401$, $p<0.0005$), Cons/Jr doctor ratio ($B = 14.70755$, $p=0.014$) and number of general and adult beds ($B = 0.0229891$, $p=0.001$) were statistically significant covariates to the prediction. Model 2 gave an $F(11,124) = 7.63$, $p = <0.0005$ and an adjusted $R^2 = 0.3508$, with Cons/Jr doctor ratio ($B = -22.62757$, $p<0.0005$), number of general and adult beds ($B = 0.208051$, $p=0.001$) and academic status ($B = 5.578075$, $p=0.045$) being significant to the prediction. Finally, Model 3 demonstrated $F(8,127) = 10.66$, $p = <0.0005$ and an adjusted $R^2 = 0.3641$. The total number of inpatient admissions ($B = -0.0002406$, $p<0.0005$), number of staff ($B = 0.002271$, $p=0.001$), Cons/Jr doctor ratio ($B = -21.91996$, $p<0.0005$), number of general and inpatient beds ($B = 0.0206147$, $p=0.001$) and academic status ($B = 5.629142$, $p=0.018$)

were statistically significant to the prediction. The summary regression matrix for each model, together with all covariates and regression coefficients can be found in *Table 2.5c*.

For the final evaluation a backward stepwise multivariate regression analysis with a $pr(0.1)$ and $pe(0.05)$ was run to predict each outcome from the overall total aggregate CDMI score and 15 specified covariates. The summary regression matrix with all covariates and regression coefficients can be found in *Table 2.6*. All models had a good fit of the data with $p = <0.005$. For SHMI $F(8,127) = 7.57$, $p = <0.0005$ and an adjusted $R^2 = 0.2803$ with the total number of staff ($B = 0.0000635$, $p=0.001$), total number of clinical staff ($B = -0.000138$, $p=<0.0005$), Dr/Nurse ratio ($B = -2.337211$, $p=0.021$), Cons/Jr ratio ($B = -0.1409635$, $p=0.014$), the number of general and adult beds ($B = 0.0001277$, $p=0.002$) and Dr/Bed ratio ($B = 0.403429$, $p=0.001$) contributing significantly to the model. For HFC $F(4,131) = 5.75$, $p = 0.0003$ and an adjusted $R^2 = 0.123$ with the aggregate CDMI score ($B = 0.0029215$, $p=0.004$), total number of staff ($B = -0.0008611$, $p=0.035$) and total number of clinical staff ($B = 0.0019482$, $p=0.009$) significantly contributing to the model. Finally, for LLOS $F(16,119) = 5.59$, $p = <0.0005$ and an adjusted $R^2 = 0.3523$ with a number of covariates significantly contributing to the model: total number of admission ($B = -0.0002338$, $p=<0.0005$), total number of staff ($B = 0.0021523$, $p=<0.0005$), total number of clinical staff ($B = 0.0021523$, $p=0.001$), Cons/Jr ratio ($B = -21.02906$, $p=<0.0005$), number of general and adult beds ($B = 0.0203946$, $p= 0.001$) and academic status of the organisations ($B = 5.674449$, $p=0.016$).

It must be highlighted that none of the individual CDMI domain scores added a statistically significant contribution to any of the models across all outcomes. Interestingly however, when evaluating aggregate CDMI scores there was a weak, but significant relationship to HFC ($B = 0.0029215$, $p=0.005$). Measures of staffing such as Dr/Bed ratio, and measures of organisational size such as number of inpatient and adult beds, and total number of staff consistently played a significant part in predicting clinical outcomes across all models.

2.4.2.4 - Multivariate regression analysis: predicting digital maturity from organisational factors

A two-model multivariate approach was adopted to evaluate predictors of CDMI score based upon the previous models; Model 1 utilised the approach in which all covariates that were significant at the univariate level were retained, whilst Model 2 adopted a backward stepwise selection approach with a $pr(0.1)$ and $pe(0.05)$ starting with all significant covariates. Total aggregate CDMI score, and scores for each of the three domains were evaluated. The summary regression matrix for the univariate analysis is seen in *Table 2.4*, and a summary matrix for each of the two multivariate regression models can be seen in *Table 2.7* with all covariates and regression coefficients. All models had a good fit of the data with $p = <0.0005$ throughout.

Total aggregate CDMI score revealed $F(10,125) = 4.71$, $p = <0.0005$ and an adjusted $R^2 = 0.2739$, and $F(3,132) = 14.18$, $p = <0.0005$ and an adjusted $R^2 = 0.2265$ for Model 1 and Model 2 respectively. None of the selected covariates added significantly to Model 1 except for Dr/Bed ratio ($B = -167.1842$, $p=0.019$), whilst the total number of staff ($B = 0.0112734$, $p=0.041$) and Dr/Bed ratio ($B = -83.97831$, $p=<0.0005$) added significantly to the prediction of Model 2. For the readiness domain Model 1 showed $F(9,126) = 4.20$, $p = 0.0001$ and an adjusted $R^2 = 0.1759$, and Model 2 $F(3,132) = 10.69$, $p = <0.0005$ and an adjusted $R^2 = 0.1772$. None of the covariates significantly contributed to either model except for Dr/Bed ratio which significantly contributed to both Model 1 ($B = -71.25716$, $p=0.013$) and Model 2 ($B = -31.008$, $p=<0.0005$). For the capability domain Model 1 had $F(11,124) = 3.57$, $p = 0.0002$ and an adjusted $R^2 = 0.2403$ with only mean ITU bed occupancy rates contributing significantly to the model ($B = 219.9076$, $p=0.025$). Model 2 showed $F(4,131) = 9.31$, $p = <0.0005$ and an adjusted $R^2 = 0.1975$ with three covariates significantly contributing to the model: total number of staff ($B = 0.0176932$, $p=0.01$), mean ITU bed occupancy ($B = 219.3528$, $p=0.021$) and Dr/Bed ratio ($B = -48.26106$, $p=0.001$). For the infrastructure domain Model 1 revealed $F(5,130) = 5.55$, $p = 0.0001$ and an adjusted $R^2 = 0.1441$ with just Dr/Bed ratio ($B = -9.34858$, $p=<0.0005$) significantly adding to the prediction.

2.4.3 - Examining the relationship between organisational digital maturity and stakeholder experience

2.4.3.1 - Organisational digital maturity and patient experience

Outcome data for the six selected scores (AW, SHQCC, BIMC, BR, CCFP, OPES) from the 2016 National Inpatient Survey¹⁶⁸ was obtained for all 126 NHS Trusts included in the analysis. Standard descriptive statistics were employed and are summarised in *Table 2.1*.

A univariate regression analysis was run to understand the high-level relationship between organisational digital maturity and patient experience; the summary regression matrix is seen in *Table 2.8*. Broadly the quality of the models was poor with none returning results at $p < 0.05$, and the best adjusted R^2 being returned at 0.0321.

Independent multivariate regression analyses were then run to identify the relationship between each of the six patient satisfaction domains (AW, SHQCC, BIMC, BR, CCFP and OPES) and both aggregate total CDMI score, each of the three CDMI domain scores (readiness, capability and infrastructure) and the 16 specified covariates; the summary regression analysis matrices for these are seen in *Table 2.9a* and *Table 2.9b*. Overall the quality of all models and fit of the data was reasonably good throughout.

In assessing the relationship with total aggregate CDMI score the AW domain revealed $F(17,108) = 3.12$, $p = 0.002$ and adjusted $R^2 = 0.2238$; SHQCC domain $F(17,108) = 2.27$, $p = 0.0058$ and adjusted $R^2 = 0.176$; BIMC domain $F(17,108) = 1.83$, $p = 0.0326$ and adjusted $R^2 = 0.1016$; BR domain $F(17,108) = 4.56$, $p < 0.0005$ and adjusted $R^2 = 0.3263$; CCFP domain $F(17,108) = 3.19$, $p = 0.0001$ and adjusted $R^2 = 0.2299$ and OPES domain $F(17,108) = 3.14$, $p = 0.0002$ and adjusted $R^2 = 0.2253$. Aggregate CDMI score was not significantly related to any of the six patient experience domains. Interestingly, the only consistent predictor of patient experience was consultant/junior doctor ratio which showed a significant relationship in five out of six domains: SHQCC $B = 8.526127$ ($p = 0.001$), BIMC $B = 6.849499$ ($p = 0.003$), BR $B = 5.090798$ ($p = 0.01$), CCFP $B = 3.840146$ ($p = 0.009$) and OPES $B = 5.595879$ ($p = 0.001$).

In assessing the relationship with each of the three domains of CDMI the quality of the models and fit of the data was also reasonable good with the AW domain $F(19,106) = 2.75$, $p=0.0005$ and adjusted $R^2 = 0.0.2099$; SHQCC domain $F(19,106) = 2.18$, $p=0.0065$ and adjusted $R^2 = 0.1525$; BIMC domain $F(19,106) = 1.70$, $p=0.0467$ and adjusted $R^2 = 0.0965$; BR domain $F(19,106) = 4.09$, $p<0.0005$ and adjusted $R^2 = 0.3194$; CCFP domain $F(19,106) = 2.81$, $p=0.0004$ and adjusted $R^2 = 0.0.2154$ and OPES domain $F(19,106) = 2.83$, $p=0.0004$ and adjusted $R^2 = 0.2179$. There were no significant relationships seen between any of the three CDMI domain scores and the six domains of patient experience. As expected, once again the only consistent predictor of patient experience in these models was consultant/junior doctor ratio which again displayed a significant relationship in the same five out of six patient experience domains: SHQCC $B = 8.166779$ ($p=0.001$), BIMC $B = 6.584711$ ($p=0.005$), BR $B = 4.954229$ ($p=0.001$), CCFP $B = 3.834389$ ($p=0.010$) and OPES $B = 5.437218$ ($p=0.002$).

2.4.3.1 - Organisational digital maturity and staff experience

Outcome data for the nine selected scores (KF1, KF2, KF7, KF9, KF14, KF30, KF31, KF32 and overall staff engagement) from the 2016 NHS Staff Survey¹⁷⁰ was obtained for all 126 NHS Trusts included in the analysis. Standard descriptive statistics were employed and are summarised in *Table 2.1*.

A univariate regression analysis was run to understand the high-level relationship between organisational digital maturity and staff experience; the summary regression matrix is seen in *Table 2.10*. Once again, although an improvement on that seen with the evaluation of patient experience, broadly the quality of the models was poor with the majority of models not significant at $p<0.05$, and the best adjusted R^2 being returned at 0.0385.

Total aggregate CDMI scores were only significantly related to KF1 (staff recommendation as a place to work or receive treatment) $F(1,124) = 4.97$, $p=0.0277$ with an adjusted $R^2 = 0.0307$ and $B = 0.0001919$ (95% CI 0.0000214 – 0.0003624). Scores in the readiness domain were significantly related to KF14 (staff satisfaction with resourcing and support)

$F(3,122) = 2.33, p=0.0776$ with an adjusted $R^2 = 0.0309$ and $B = 0.0003782$ (95% CI 0.0000387 – 0.0007177); KF30 (fairness and effectiveness of procedures for reporting errors, near misses and incidents) $F(3,122) = 1.72, p=0.1659$ with an adjusted $R^2 = 0.0170$ and $B = 0.003171$ (95% CI 0.0000271 – 0.0006071); KF31 (staff confidence and security in reporting unsafe clinical practice) $F(3,122) = 2.20, p=0.0914$ with an adjusted $R^2 = 0.0280$ and $B = 0.0003401$ (95% CI 0.0000377 – 0.0006425) and KF32 (effective use of patient/service user feedback) $F(3,122) = 1.36, p=0.2578$ with an adjusted $R^2 = 0.0086$ and $B = 0.0003719$ (95% CI 7.48⁻⁶ – 0.0007364). Of note, OPES (overall patient experiences) was also near to significance with its relationship to readiness domain scores with $B = 0.0003168$ ($p=0.053$).

Independent multivariate regression analyses were run to identify the relationship between each of the nine staff satisfaction domains (KF1, KF2, KF7, KF9, KF14, KF30, KF31, KF32 AND OES) and both aggregate total CDMI score, each of the three CDMI domain scores (readiness, capability and infrastructure) and the 16 specified covariates; the summary regression analysis matrices for these are seen in *Table 2.11a* and *Table 2.11b*. The overall the quality of all models and fit of the data was reasonably good throughout.

Total aggregate CDMI score was not significantly related to any of the nine domains of staff satisfaction. The only consistent predictor of staff experience in the models evaluated was harm free care (HFC) which was significantly related in 7 out of the 9 domains: KF1 $F(17,108) = 3.51, p<0.0005$ with an adjusted $R^2 = 0.3558$ and $B = 0.23853$ (95% CI 0.0079021 – 0.0398044); KF7 $F(17,108) = 2.96, p=0.0003$ with an adjusted $R^2 = 0.02105$ and $B = 0.0054002$ (95% CI 0.0021891 – 0.0086112); KF9 $F(17,108) = 2.68, p=0.011$ with an adjusted $R^2 = 0.1862$ and $B = 0.0103957$ (95% CI 0.0039006 – 0.0168908); KF30 $F(17,108) = 2.52, p=0.021$ with an adjusted $R^2 = 0.1709$ and $B = 0.127299$ (95% CI 0.0046313 – 0.208284); KF31 $F(17,108) = 2.45, p=0.0028$ with an adjusted $R^2 = 0.2784$ and $B = 0.0095829$ (95% CI 0.0010603 – 0.181056); KF32 $F(17,108) = 1.56, p=0.0887$ with an adjusted $R^2 = 0.0705$ and $B = 0.011755$ (95% CI 0.0010253 – 0.224847) and OES $F(17,108) = 3.13, p=0.0002$ with an adjusted $R^2 = 0.3298$ and $B = 0.126261$ (95% CI 0.0039608 – 0.212913).

When assessing the relationship between each specific CDMI domain and staff experience once again HFC was the most consistent predictor with significance across all 9 domains: KF1 $F(19,106) = 3.39$, $p < 0.0005$ with an adjusted $R^2 = 0.2663$ and $B = 0.239667$ (95% CI 0.0080416 – 0.398917); KF2 $F(19,106) = 1.50$, $p < 0.1016$ with an adjusted $R^2 = 0.0701$ and $B = 0.129015$ (95% CI 0.002831 – 0.022972); KF7 $F(19,106) = 2.68$, $p = 0.0007$ with an adjusted $R^2 = 0.02039$ and $B = 0.0053864$ (95% CI 0.0021413 – 0.0086315); KF9 $F(19,106) = 2.67$, $p = 0.0008$ with an adjusted $R^2 = 0.2022$ and $B = 0.0105859$ (95% CI 0.004114 – 0.0170578); KF14 $F(19,106) = 1.53$, $p = 0.0910$ with an adjusted $R^2 = 0.0741$ and $B = 0.0149672$ (95% CI 0.0048134 – 0.251209); KF30 $F(19,106) = 2.48$, $p = 0.0018$ with an adjusted $R^2 = 0.3076$ and $B = 0.0127529$ (95% CI 0.0046648 – 0.0015544); KF31 $F(19,106) = 2.38$, $p = 0.0028$ with an adjusted $R^2 = 0.1732$ and $B = 0.0095032$ (95% CI 0.0009687 – 0.180376); KF32 $F(19,106) = 1.89$, $p = 0.0220$ with an adjusted $R^2 = 0.1193$ and $B = 0.0118779$ (95% CI 0.0013671 – 0.0223887) and OES $F(19,106) = 3.10$, $p = 0.001$ with an adjusted $R^2 = 0.2422$ and $B = 0.127602$ (95% CI 0.0041404).

Interestingly, readiness domain scores were significantly related to 4 out of the 9 domains with a significant at $p < 0.05$. However, given that is arguably easy to confuse statistical significance with substantive or theoretical importance, the choice of significance must be interpreted appropriately¹⁷³. If therefore a significance of $p < 0.1$ is selected then 7 out of the 9 staff satisfaction domains are significantly related to scores in the readiness domain: KF1 $F(19,106) = 3.39$, $p < 0.0005$ with an adjusted $R^2 = 0.2663$ and $B = 0.0006139$ (95% CI 0.0000284 – 0.0011993, $p = 0.040$); KF9 $F(19,106) = 2.67$, $p = 0.0008$ with an adjusted $R^2 = 0.2022$ and $B = 0.0002357$ (95% CI -2.23^{-6} – 0.0004736, $p = 0.052$); KF14 $F(19,106) = 1.53$, $p = 0.0910$ with an adjusted $R^2 = 0.0741$ and $B = 0.000357$ (95% CI -0.0000163 – 0.0007303, $p = 0.061$); KF30 $F(19,106) = 2.48$, $p = 0.0018$ with an adjusted $R^2 = 0.3076$ and $B = 0.0002607$ (95% CI -0.0000367 – 0.000558, $p = 0.085$); KF31 $F(19,106) = 2.38$, $p = 0.0028$ with an adjusted $R^2 = 0.1732$ and $B = 0.0003199$ (95% CI 6.12^{-6} – 0.0006336, $p = 0.046$); KF32 $F(19,106) = 1.89$, $p = 0.0220$ with an adjusted $R^2 = 0.1193$ and $B = 0.0005051$ (95% CI 0.0001187 – 0.0008915, $p = 0.011$) and OES $F(19,106) = 3.10$, $p = 0.001$ with an adjusted $R^2 = 0.2422$ and $B = 0.0003573$ (95% CI 0.0000404 – 0.0006742, $p = 0.027$).

It is also important to note that KF14 (staff satisfaction with resourcing and support) and KF2 (staff satisfaction with the quality and care they are able to deliver) are the two domains that plausibly are the most likely to be related to digital maturity as health IT is integral to care delivery and the support that underpins it; neither however were significant at $p < 0.05$ in any of the models evaluated.

2.5 - Discussion

2.5.1 - Summary of key findings

The drive for a fully digital healthcare system in England is gaining momentum as clinicians, patients and policymakers alike seek solutions to the challenges of variation in care, increasing patient demand, limited fiscal resources and how to support access to new analytical techniques and technologies. The effective use of health IT can undoubtedly provide solutions to these challenges, and deliver improvements in the quality of care delivered to patients. However, in order for health IT to realise its potential there is a pressing need to develop robust and useful methods of assessing organisational digital maturity, and also address gaps in the understanding of the impact of digital maturity on clinical outcomes and stakeholder experience at a health systems level.

Using nationally representative data we found that the CDMI Tool is a useful measure of organisational digital maturity, and furthermore likely acts as a surrogate marker for high-performing hospitals. Organisational digital maturity was associated with a higher proportion of patients receiving harm free care and improved staff experience. Although other organisational factors also have a significant role to play there is a consistent theme; well-led organisations have better health IT, improved clinical outcomes and more satisfied staff. The relationship between organisational digital maturity, clinical outcomes and stakeholder experience is complex and considers a wide variety of inter-related and linked variables with

multi-directional cause and effect. Whilst challenging to directly assert causation, the relationships identified in this evaluation are both plausible and highly likely to be present.

The NHS CDMI Tool is a self-assessment framework that evaluates an organisation's digital maturity, allows them to benchmark their performance against their peers and identify key areas for development and improvement¹²². Disappointingly there remains widespread variation in organisational digital maturity across England with a mean total CDMI score of 796.02 (324 - 1253, SD 171.56), despite the drive for a fully electronic NHS being more than a decade old⁶⁰. The CDMI tool attempts to account for the important wider aspects of digital maturity such as leadership and digital literacy which are typically lacking from commonly used technology focused measures¹⁰⁷, but nonetheless it still has not been correlated against independent and meaningful measures of process or outcomes. The validity of a test is arguably a single construct with multiple aspects^{174,175}, and according to this theory the findings presented in this study suggest that the CDMI Tool, despite some limitations, is likely to be useful measurement of organisational digital maturity and is the best measure currently available to healthcare organisations in England. As expected, total CDMI score is significantly related to GDE status with exemplar organisations reporting an additional total CDMI score of 242.51 (95% CI 162.13 – 322.89, $p < 0.0005$) and also academic status ($B = 123.9159$, 95% CI 58.57 – 189.26, $p < 0.0005$) which supports the construct and criterion validity of the test. Further supporting this is the significant relationship seen between digital maturity and Care Quality Commission (CQC) inspection outcomes as described elsewhere in this body of work. The principal component analysis neatly identifies the three key domains of the CDMI tool which further supports the construct validity of the tool by showing its discriminant validity. The content validity of the CDMI Tool has been previously established and accepted following its adoption by NHS Digital as a national benchmarking tool in England.

There is a relative paucity of evidence evaluating the relationship between digital maturity and clinical outcomes at an organisational level. This study has shown that at a univariate level the relative risk of readmission and complications of care are not related to organisational digital maturity. Adjusted mortality is related to capability scores, whilst long

length of stay is related to capability, readiness and aggregate CDMI scores, and harm free care is related to capability, readiness and infrastructure scores as well as the aggregate CDMI score. Whilst some significant relationships are present at a univariate level, when other organisational factors are considered these relationships disappear; there is no relationship between any of the three CDMI domains - capability, readiness and infrastructure - and any meaningful clinical outcome measure. When looking at aggregate CDMI scores however the significant relationship with harm free care ($B = 0.0029215$, 95% CI $0.00095 - 0.00489$, $p=0.004$) persists; digitally mature hospitals deliver a higher proportion of harm free care to their patients.

The most consistent predictor of staff experience in this study was harm free care (HFC) which was significantly related to all 9 domains of staff satisfaction evaluated. Aspects of organisational digital maturity do also appear to be related to staff experience with a consistent association to scores in the readiness domain of the CDMI score seen. At a univariate level 4 out of the 9 staff satisfaction domains were significantly related at a significance of $p<0.05$. Meanwhile, at the multivariate level 4 out of 9 domains of staff satisfaction were significantly related at a significance of $p<0.05$, which increased to 7 out of 9 domains at a significance of $p<0.1$.

The readiness score of the CDMI index represents an organisations ability to plan, deliver and optimise the digital systems it needs to deliver paper-free care by assessing strategic alignment, leadership, resourcing, governance and information governance; it is in effect a marker of effective leadership and resource, and it is likely that good leadership and effective health IT come hand-in-hand. It is also highly likely that well-led organisations have robust policies and procedures in place to reduce the harmful events and deliver the safer care. The consistent relationship seen in this study between safety, experience and organisational readiness is significant. Well-led organisations are likely to have more satisfied, engaged and empowered staff¹⁷⁶, and both the readiness aspects of digital maturity and the safety of care delivered are likely to be surrogates for good leadership. Whilst digital maturity inevitably does play a small role in influencing clinical outcomes and experience, other institutional variables such as staffing, patient volume and academic

status play a much more significant role and likely have a far greater influence on clinical outcomes. Digital maturity scores appear to act as a surrogate for other institutional factors with high performing well-led organisations likely to have better IT.

This study has provided a unique and valuable insight into the influence of organisational digital maturity on clinical outcomes and stakeholder experience at a hospital level. It suggests that whilst there are more significant factors that influence outcomes - such as staffing levels, staff skills mix and volume of work - digital maturity still has an important role in supporting the delivery of harm free care to patients and improving the working lives of staff. This study not only characterises the current influence of digital maturity on outcomes and experience in secondary care but has also provided firm evidence to support the use of the NHS CDMI Tool to improve health IT and shape future policy and practice.

2.5.2 - Placing the findings of this study in the wider context: explaining the influence of organisational digital maturity on outcomes

Determinants of clinical outcomes at an organisational level are numerous and complex and consider a wide range of inter-related and linked variables with multi-directional cause and effect. As shown in this analysis and others many organisational factors influence both digital maturity, organisational performance and clinical outcomes¹³⁹.

This study has indicated that organisational digital maturity may have some part to play in influencing selected clinical outcomes. Out of the five outcome measures evaluated - LLOS, COC, HFC, READ and SHMI - digital maturity was shown to only have a significant impact on harm free care. Nonetheless, the strength and fit of the models would suggest that although other variables clearly have a greater role to play, digital maturity is still relevant. The relationship between harm free care - the absence of either a pressure ulcer, fall, CAUTI or VTE during a hospital episode - and organisational digital maturity may be due to a number of factors. It is likely that effective and well-led organisations that have robust policies and procedures in place to reduce harmful events and deliver safe care will also

have a mature and developed approach to health IT. Additionally there is clear evidence that the use of electronic systems and other digital innovations can significantly improve compliance with prophylaxis¹⁷⁷ and reduce the incidence of VTE events¹⁷⁸, reduce the duration of unneeded catheterisation¹⁷⁹ and subsequent incidence of CAUTI¹⁸⁰, improve the prediction and identification of pressure ulcers^{181,182} and support better risk assessments and reductions in the incidence of inpatient falls^{183,184}. Arguably HFC and COC are overlapping domains which share common components; it is therefore of interest that whilst there is a clear association between HFC and digital maturity this is not the case for COC. A likely explanation for this is that firstly HFC comprises just four aspects of safe care, whilst COC is a composite measure of ten hospital related events some of which may be directly attributable to specific clinical errors. Additionally, the capture of COC relies upon administrative data (with all the criticisms that have been highlighted elsewhere in this chapter), whilst HFC relies on bedside data collection in a simple yes/no format through the NHS Safety Thermometer which means the data is likely to be more robust and accurate.

Patients with common conditions who are treated at major academic teaching hospitals have significantly lower mortality rates¹⁴⁶ and lower rates of failure to rescue incidents¹³⁹. These findings are also seen with those patients treated at high volume institutions^{139,147,152}. These large academic hospitals, typically located in urban areas, are also more likely to digitally mature and have better health IT than small, non-academic rural institutions that may lack the resource, knowledge and skill to embark on large, expensive and complex IT projects which can drive better performance and quality improvement^{103,123,185}. These findings are supported by the significant relationship between aggregate CDMI score and academic status ($B = 123.9159$, 95% CI 58.57 – 189.26, $p < 0.0005$) that was shown in this study, together with the significant relationships between measures of hospital size and volume - such as number of admissions, bed numbers and staffing - and both outcomes and digital maturity throughout all univariate and multivariate models analysed. Throughout all models analysed staffing was the only variable which consistently played a significant role in influencing outcomes. If the goal is better outcomes for patients then investment in staff is crucial and health IT must not be seen as a shortcut.

Even when controlling for other factors such as workload, institutional volume, digital maturity and academic status staffing remains the predominant variable; well-staffed hospitals have better outcomes. Whilst this relationship is somewhat more nuanced and complex it does fit with previously published evidence^{133,134,136}. Of note, in this analysis measures of bed occupancy - be that general or ITU bed occupancy - were not found to be significantly related to clinical outcomes at a multivariate level despite this being identified in previous studies^{148,149}. Interestingly higher Dr/Bed ratio ($B = 0.04034$, 95% CI $-0.2523 - -0.2960$, $p=0.001$) and increased Consultant/Junior doctor ratio ($B = -0.14096$, 95% CI $-0.2523 - -0.2960$, $p=0.014$) were both significantly associated with a poorer SHMI in the final model with is contrary to previous findings¹⁴². This may be due to the plausible, and confounding relationship that may exist between the increasing number and seniority of doctors per patient, and the complexity and therefore risk of the care and clinical processes being delivered in certain institutions despite contradictory evidence for this being present elsewhere in the literature^{131,140}. It may also be confounded by the potential influence of irregular staffing through the increased use of bank and agency staff in some institutions. This will act to skew the underlying staffing data, and may also negatively impact clinical outcomes, care quality and efficiency^{186–189}; neither of which can be quantified or assessed in this analysis.

2.5.3 - Placing the findings of this study in the wider context: explaining the influence of organisational digital maturity on stakeholder experience

Determinants of stakeholder experience at an organisational level are numerous and complex and involve a wide range of factors¹⁷⁶. As shown in this analysis and others, many organisational, stakeholder and external factors influence satisfaction, and determining causality and identifying key themes is therefore challenging.

The importance of staff well-being and engagement has not always been a priority for the NHS¹⁹⁰. It has now however been accepted that focusing on staff well-being is vital to delivering sustainable high-quality services, and this has led to substantial commitments to

invest in staff and make the NHS a model employer^{191,192}. Furthermore, the importance of staff engagement and motivation in improving the quality of care and patient experience, and supporting the delivery of the four elements of the quality, innovation, productivity and prevention (QIPP) programme in the NHS have also been clearly recognised^{190,193}. The relationship between staff engagement, job satisfaction and performance is hotly debated and is the subject of an extensive and varied array of academic literature and published data¹⁷⁶. There is evidence to suggest that there is an association between employee engagement and better organisational performance both in terms of business (e.g. productivity, innovation, customer measures) and people (e.g. staff absence/turnover and well-being) indicators^{194,195}, and whilst there does seem to be true correlation between job satisfaction and performance the data remains controversial and open to interpretation¹⁹⁶. Whilst there is a relative paucity of evidence assessing the impact of staff engagement in the health service, a positive culture of engagement has been shown to predict organisational performance more so than any other variable, and the use of high performance work practices and better staff engagement has been linked with improvements in a range of operational, staffing and performance metrics^{197–199}. Arguably, effective staff management and improved engagement results in better care, happier patients and reduced mortality²⁰⁰.

Patient experience metrics are also gaining increasing traction across healthcare systems. Information on the patient experience can be used in a variety of ways to improve care, including to identify specific areas for improvement, support institutional benchmarking, aid with strategic decision making and to directly influence the delivery of care itself^{201–203}. Different measures of patient experience are widely used across a range of healthcare systems²⁰⁴ including the Friends and Family Test²⁰⁵ and National Adult Inpatient Survey¹⁶⁹ in the UK, the Hospital Consumer Assessment of Healthcare Providers and Systems²⁰⁶ in the US and the Patient Experience Questionnaire²⁰⁷ in Australia. Across all systems the experience of patients receiving care in hospitals varies significantly between providers with many factors including race, socio-deprivation and hospital characteristics linked to experience scores²⁰⁸. Interestingly it has been suggested that there is a care paradox in experience, with vulnerable patients in greatest need of hospital care generally the least satisfied with the care they receive²⁰⁹. Nonetheless, patient and staff views on safety culture

and experiences of care have been shown to offer unique perspectives and contribute independently to the delivery safe care, accounting for 49% of the variance in safety outcomes²¹⁰. These findings are consistent with those found in this study, with the only consistent predictor of patient experience being those covariates related to staffing levels and increases in senior staff numbers as consistently described in other healthcare systems²¹¹.

Organisational culture and leadership are vital for the delivery of positive stakeholder experience and engagement. The culture and leadership of an organisation are crucial to its performance, and the promotion of a positive culture can directly influence work behaviours, attitudes and satisfaction²¹². Good leadership behaviours, positive relationships between staff and leadership, and a strong organisational culture are significantly associated with job satisfaction and experience^{213,214}. Indeed, positive assessments of hospital leadership are strongly associated with burnout and job satisfaction of doctors and other healthcare professionals²¹⁵. Good clinical leadership does not only benefit the experience of staff and patients, but may also have a positive impact on the management of financial resources, the social performance of providers and crucially the quality of care offered to patients²¹⁶. Furthermore current evidence suggests that positive relational leadership styles lead to better patient experience, lower mortality and a reduction in medication errors²¹⁷, and specific programmes to improve multi-professional teamwork and leadership can positively influence a range of clinical outcomes²¹⁸.

As highlighted in this study there is an empirical relationship between staff experience and elements of organisational digital maturity, which is likely due to the influence of good leadership rather than a direct causal effect in itself. The readiness domain of CDMI pertains to organisational culture and leadership, and the association between culture and leadership, staff satisfaction and clinical outcomes has already been described. Importantly there is clear evidence that leadership and culture may also directly impact digital maturity and the effective use of health IT. Indeed, effective clinical leadership and the development of an organisational vision that comprises a long-term commitment to the deployment of health IT can help cultivate digital literacy, establish mutual partnerships with IT

professionals and deliver successful and IT projects²¹⁹. Importantly digital maturity does not detrimentally impair patient experience¹¹⁸, and despite some racial, ethnic and literacy barriers patients are generally positive regarding the potential benefits and use of electronic health records systems²²⁰. Indeed, it has been identified that the use of electronic systems can improve physician-patient communication and increase patient experience²²¹ with the majority of studies finding either a neutral or positive impact on patient experience¹¹⁷. Furthermore, whilst the majority of patients feel that paper-based systems have no negative impact upon them, once concerns regarding security and confidentiality have been adequately addressed they would prefer their healthcare provider to use electronic systems²²². This supports our findings that whilst digital maturity may not be positively related to patient experience, importantly, the drive for a paperless healthcare system in England has not impaired the experience of patients receiving care. This finding is important given recent public controversies surrounding the expansion of electronic systems, the move towards healthcare based on artificial intelligence and proposals for the widespread sharing of electronic patient data^{223–226}.

2.5.4 - Strengths and limitations of this study

This study has suggested that organisational digital maturity plays a significant, albeit limited role in influencing clinical outcomes and stakeholder experience, and that other organisational factors likely have a far greater impact. These results however must be interpreted and qualified within the inevitable strengths and limitations of the study.

A core strength of this study is the large, nationally representative data that has been used. It is a pragmatic and evidence-based examination of 17,686,479 A&E attendances, 5,606,092 emergency admissions, 7,499,904 planned admissions and 683,059 members of staff over a 12-month period across 136 individual NHS acute care providers in England. Furthermore, the quality and completeness of the data was good with missing data accounting for just <0.2% of all items included. This represents a much larger and more representative population than other similar published studies^{9,12,116–118}. Furthermore, this

study is the first to look at the impact of digital maturity on clinical outcomes in the English NHS and the first to examine the impact of organisational digital maturity on stakeholder experience.

This study has a number of limitations which must be accounted for. Many of these stem from the use of routinely collected data and the pragmatic, but evidence-based approach to analysis. Determinants of clinical outcomes and measures of experience at a hospital or system level are numerous and complex and consider a wide range of inter-related variables. It is therefore challenging to establish causal inference and account for all potential confounders that may be present.

The use of routinely collected administrative data allows for completeness and consistency of data across a wide number of organisations and provides a range of covariates which can be used to improve the significance and fit of the statistical models chosen and reduce the likelihood of error. Hospital administrative data may offer valuable insights into potential safety problems, and can be used to track progress and provide quality benchmarks across a number of levels of care²²⁷. Previous studies have demonstrated that routinely collected hospital administrative data, including HES Data, can be used to effectively to compare relevant clinical outcomes across hospitals²²⁸ with high levels of coding accuracy²²⁹. There have however also been criticisms of the quality, accuracy and completeness of such data with gaps in its ability to rule out the presence of comorbidities²³⁰, poor identification and registration of post-operative complications²³¹ and poor clinical engagement in the coding and use of HES data being reported²³². It is likely that these criticisms, and any variance in the data, will be accounted for by the size of the dataset but nonetheless it still may act to influence the findings returned from this study.

In addition to criticisms of the use of routine administrative data, there has also been some controversy over whether clinical indicators used for quality improvement, such as hospital mortality ratios, provide a meaningful and robust method for comparing hospital performance. Are they *“incredibly useful if used as a smoke alarm - everyone from Francis to Keogh says it’s idiotic to ignore them”*? Or conversely do they merely provide an over-

simplistic and misleading view of hospital performance when *“hospital is where 50% of people end up dying - so it is counterintuitive to use [mortality ratios] as an indicator of poor quality, when it is actually one of hospital’s functions^{227,233}?”* There is a risk that such comparative measures of organisational quality and performance may be over-interpreted and result in inconsistent sanctions or unjustified rewards for providers, and diversion from genuine improvement towards superficial improvement or the adoption of gaming behaviours and unjustified clinical decision making in order to manipulate the system^{234,235}. Indeed, it has been suggested that the very idea that hospitals with higher risk-adjusted mortality deliver a poorer standard of care is neither consistent nor reliable^{236,237}. Further criticisms of the data have been proposed including the “case-mix adjustment fallacy” in which errors are made in attributing differences in risk adjusted mortality to differences in quality of care²³⁴, or the “constant risk fallacy” in which risk adjustment can counterintuitively act to exaggerate the very bias it is intending to reduce²³⁸. Whilst these criticisms are frequently made and the meaningful use of such comparative statistics questioned, they remain the most widely used and understood means of comparing quality and driving improvement. In order to address some of the concerns highlighted we have used valid and reliable indicators that have been designed and implemented with rigour, apply appropriate risk-adjustment and which provide evidence-based and widely accepted measures of quality^{166,239}.

Experience surveys, be they staff or patient facing, be also be open to criticism for their underlying design and methodology. A key weakness of these tools is the impact of response rates on reported findings. Hospitals with a higher response rate tend to report more positive experience scores. This can only be partially explained by case-mix, and is also likely to be influenced by efficient hospital administration and higher overall quality²⁴⁰. Meanwhile, low response rates have been shown to negatively affect results with non-respondents more likely to have a less favourable perception of the care they have received^{241,242}, and further criticisms have been made of the case-mix adjustment that is used in the survey instruments evaluated in this study²⁴³. Nonetheless the tools used in this evaluation are widely accepted and used across the NHS for a range of academic, clinical and service delivery purposes with robust evidence for their usefulness and validity.

As previously identified the first step to understanding the impact of health IT on patient outcomes is to identify a robust method for assessing the relative digital maturity of an organisation. In order to do this, it is important to build an effective evaluation framework that captures the full range of factors that influence the success or failure of health IT systems. It is recognised that a multi-dimensional approach is required to capture the holistic influence of resources and ability, system usage and interoperability, and overall impact at each stage of the care pathway. It is crucial to remember that patients, not IT managers, need to be the epicentre of a digitally connected community, primary and secondary care system¹⁰⁷. There are numerous proposed methods for assessing digital maturity. Many have a very narrow focus on organisational or performance measures such as system usage²⁴⁴, financial savings or value for money judgements²⁴⁵ and interoperability across settings and care sectors²⁴⁶. Some have adopted a 'smallball' approach based on the evaluation of discrete aspects of a project across a technically-led phased implementation²⁴⁷, whilst only a limited number have attempted to use a comprehensive framework for assessment which includes the identification of any unintended consequences or harm²⁴⁸. The findings of this study would suggest that the CDMI measure is a good tool, and almost certainly the best currently available. There is however a possibility that it fails to pick up key aspects of digital maturity that have a greater impact on outcomes and instead acts as proxy for other attributes of high-performing organisations; the failure to find a strong relationship between digital maturity and outcomes may actually due to gaps in the CDMI measure rather than the absence of a relationship. Arguably, utilising more targeted assessments such as specific usability questionnaires focusing on the compatibility of health IT systems with clinical tasks, the support for information exchange, communication and collaboration in clinical work and interoperability and reliability may have exposed more detailed and concentrated findings on the direct impact of health IT systems on staff^{114,249}.

As with all studies the approach taken to statistical modelling may also be criticised. A large number of covariates will directly influence clinical outcomes as discussed. However, the decision on which to include when creating a good statistical model must be balanced against concerns regarding multiple testing and the subsequent risk of error due to

multiplicity or collinearity. A pragmatic, but evidence-based approach to covariate selection and regression modelling was therefore adopted; the selection of covariates was based on evidence, and an initial univariate analysis of their relationships was performed to inform final model selection. Additionally, stepwise models have been criticised for potentially failing to include all variables that have an actual influence on the outcome, and also including variables that may not have any significant influence.²⁵⁰ Furthermore, they may also suffer from a multiple testing problem in the absence of error-level adjustment that can lead to an increased risk of Type 1 error and subsequent false positives results being delivered.^{251,252} Finally, the use of a stepwise model for variable selection may be affected by the presence of collinearity, and given the complex inter-dependencies within the covariates selected this is certainly a risk. These weaknesses were mitigated by excluding those covariates that were found to not be collinear, but nonetheless there still may be inaccuracies within the final model. Despite these criticisms and the complexity of the relationships at play, the overall significance of the regression models was reasonable however, with a good fit throughout suggesting that the methodology chosen was appropriate and that the findings returned are valid; digital maturity does have a role to play in influencing clinical outcomes, but other covariates have a far greater impact. All models showed significance at $p < 0.05$, the $Adj R^2$ for all models was also acceptable with a range of 0.0701 – 0.3641 and the majority of models returning a value > 0.25 . Meanwhile, the F -statistic for all models was also acceptable with a range of 1.50 – 5.57 and the majority of models returning a value of > 5 .

2.6 - Conclusion

Using nationally representative data from 136 hospitals in England this study has shown that better organisational digital maturity is associated with a higher proportion of patients receiving harm free care and improved staff experience.

Whilst it has a significant role to play, other organisational factors such as measures of staffing and volume play a greater and more significant role in influencing clinical outcomes. When accounting for other relevant factors digital maturity does not significantly influence

mortality, length of stay, readmission rate or number of complications of care. The effective use of health IT and greater digital maturity can undoubtedly lead to improvements in care quality, however to maximise its potential we must develop a deeper understanding about how it impacts care delivery in holistic real-world settings, the influence it exerts on all stakeholders across the care pathway, and how it acts to support and enable other drivers of quality and safety.

Although the better use of health IT is unlikely to impact experience in isolation, many of the benefits it can deliver may improve the day-to-day experiences of patients and staff alike. Equally, it is plausible that whilst good health IT may not improve staff experience, poor health IT with dysfunctional and poorly designed systems that act as a barrier to clinical work may have a direct negative impact; good health IT supports and facilitates effective and safe care and becomes part of the norm, unnoticed and remaining in the background. In order to maximise its potential, it is important to further understand the impact of a paperless healthcare system on patients, and also further identify the key aspects of health IT to prioritise and get right in order to deliver a better working environment for staff.

A key element of delivering better clinical outcomes, improving safety and enhancing the experience of staff is supporting effective communication and teamwork. Mobile technology is ubiquitous and has the potential to deliver many benefits to clinicians and patients. However, its current role in healthcare is limited, and impact on care quality poorly understood. The next chapter therefore aims to elucidate the current effect of mobile technology on communication and teamwork within secondary care.

Table 2.1 - Summary descriptive statistics for the 2016 Clinical Digital Maturity Index (CDMI) cores, selected organisational covariates and outcomes

		Descriptive Statistics			
		Mean	Range	Std. Dev	95% CI
2016 CDMI Score	Readiness (/500)	375.90	177 - 495	67.367	363.97 - 387.82
	Capability (/800)	353.57	115 - 671	116.309	332.98 - 374.16
	Infrastructure (/100)	67.80	20 - 100	16.412	64.89 - 70.71
	Total (/1400)	797.26	324 - 1253	174.15	766.43 - 828.09
Covariates	A&E Attendances	132,789.78	44,727 - 416,419	67,642.24	120,814.92 - 144,764.63
	Inpatient Admissions	113,246.11	30,494 - 255,895	48,989.54	104,573.43 - 121,918.88
	Total Staff (all groups)	5,424.93	1,850 - 14,209	2,676.66	4,951.08 - 5,898.79
	Total Clinical Staff	2,957.22	805 - 8,488	1,600.240	2,685.89 - 3,228.65
	Clinical/Non-Clinical Ratio	0.993	0.716 - 1.562	0.140	0.969 - 1.018
	Dr/Nurse Ratio	0.404	0.140 - 0.564	0.074	0.391 - 0.417
	Cons/Jnr Ratio	0.776	0.545 - 1.554	0.133	0.753 - 0.800
	Manager/Clinical Ratio	0.041	0.013 - 0.092	0.0144	0.038 - 0.044
	Total General Beds	778.50	226 - 1,835	324.759	721.01 - 835.99
	Total ITU Beds	29.01	5 - 108	24.407	24.51 - 33.51
	General Bed Occupancy	0.888	0.692 - 0.985	0.051	0.879 - 0.896
	ITU Bed Occupancy	0.824	0.500 - 1.000	0.100	0.807 - 0.842
	Doctor/Bed Ratio	1.009	0.193 - 3.544	0.716	0.883 - 1.136
	Nurse/Bed Ratio	2.468	0.467 - 8.159	1.604	2.184 - 2.752
	Academic Status	32/136 (23.5%)			
	Global Digital Exemplar Status	16/136 (11.8%)			
Clinical Outcomes	SHMI	1.00	0.669 - 1.173	0.092	0.989 - 1.021
	HFC	93.811	87.778 - 98.775	1.929	93.470 - 94.153
	LLOS	98.853	72.230 - 119.890	10.474	96.999 - 100.707
	COC	3.106	1.540 - 5.800	0.750	2.997 - 3.234
	READ	99.542	83.540 - 11.150	5.583	98.542 - 100.496
2016 National Inpatient Survey	AW (/100)	83.815	76.50 - 89.80	3.062	83.273 - 84.357
	SHQCC (/100)	65.348	57.30 - 73.60	3.219	64.778 - 65.918
	BIMC (/100)	68.242	59.90 - 75.50	2.902	67.728 - 68.756
	BR (/100)	84.849	78.20 - 91.70	2.183	84.462 - 85.235
	CCFP (/100)	80.496	76.10 - 86.90	1.990	80.144 - 80.848
	Overall Experience Score (/100)	76.551	70.60 - 83.00	2.337	76.138 - 76.529
2016 NHS Staff Survey	KF1 (/5)	3.751	3.317 - 4.201	0.173	3.721 - 3.782
	KF2 (/5)	3.948	3.647 - 4.276	0.097	3.931 - 3.966
	KF7 (%)	0.705	0.633 - 0.793	0.338	0.699 - 0.711
	KF9 (/5)	3.733	3.555 - 3.925	0.675	3.721 - 3.745
	KF14 (/5)	3.320	3.094 - 3.668	0.983	3.302 - 3.337
	KF30 (/5)	3.718	3.485 - 3.928	0.083	3.704 - 3.733
	KF31 (/5)	3.661	3.411 - 3.881	0.087	3.645 - 3.676
	KF32 (/5)	3.700	3.411 - 3.981	0.104	3.681 - 3.718
	Overall Engagement Score (/5)	3.803	3.572 - 4.030	0.092	3.786 - 3.819

Key:

Outcomes:

SHMI – summary hospital-level mortality indicator
HFC – proportion of patients receiving harm free care
LLOS – relative risk of long length of stay
COC - complications of care
READ - relative risk of readmission

2016 National Inpatient Survey:

AW – domain average for access and waiting
SHQCC – domain average for safe, high-quality and co-ordinated care
BIMC – domain average for better information and more choice
BR – domain average for building closer relationships
CCFP – domain average for clean, friendly and comfortable place to be
OPES – domain average for overall patient experience score

2016 NHS Staff Survey:

KF1 – staff recommendation as a place to work or receive treatment
KF2 – staff satisfaction with the quality of work and care they are able to deliver
KF7 – percentage of staff able to contribute towards improvements at work
KF9 – effective team working
KF14 – staff satisfaction with resourcing and support
KF30 – fairness and effectiveness of procedures for reporting errors, near misses and incidents
KF31 – staff confidence and security in reporting unsafe clinical practice
KF32 – effective use of patient/service user feedback

Figure 2.1 - Atlas of variation showing mean aggregate Clinical Digital Maturity Index (CDMI) score for each Lower Layer Super Output Area (LSOA) in England according to number of A&E attendances (2014-15)

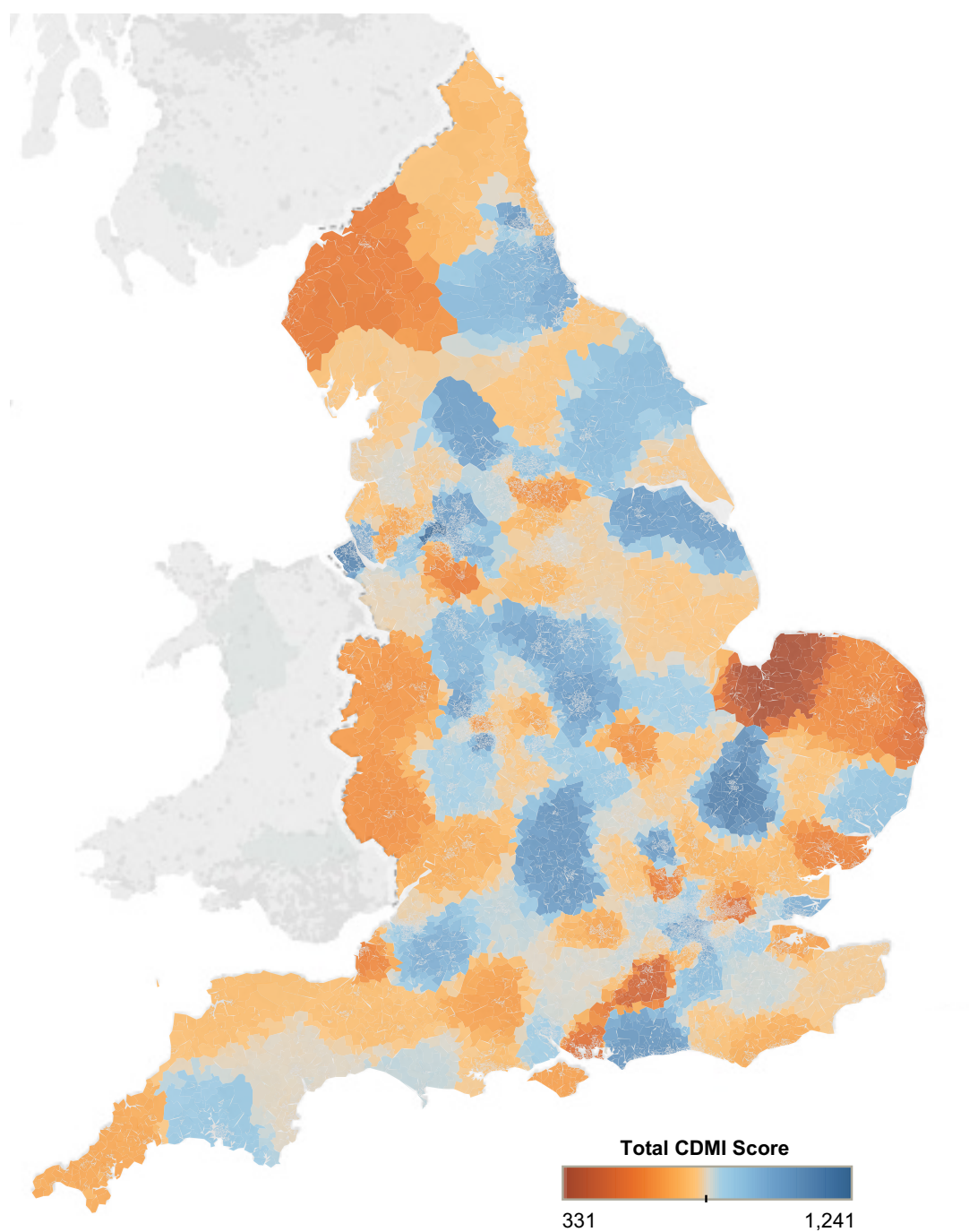


Table 2.2 - Principal component analysis (PCA) correlation matrix for the 2016 CDMI scores from 136 acute NHS Trusts in England

	Strategic Alignment	Leadership	Resourcing	Governance	Information Governance	Asset and Resource Optimisation	Decision Support	Medicines Management and Optimisation	Orders and Results Management	Records	Remote and Assistive Care	Transfers of Care	Standards	Infrastructure
Strategic Alignment	-	0.637	0.625	0.662	0.378	0.317	0.349	0.239	0.403	0.375	0.165	0.299	0.324	0.518
Leadership	0.637	-	0.592	0.619	0.346	0.319	0.240	0.179	0.369	0.298	0.128	0.350	0.333	0.504
Resourcing	0.625	0.592	-	0.745	0.486	0.386	0.331	0.205	0.469	0.405	0.189	0.385	0.393	0.582
Governance	0.662	0.619	0.745	-	0.527	0.301	0.254	0.173	0.339	0.300	0.164	0.283	0.295	0.554
Information Governance	0.378	0.346	0.486	0.527	-	0.293	0.269	0.263	0.280	0.270	0.109	0.282	0.246	0.406
Asset and Resource Optimisation	0.317	0.319	0.386	0.301	0.293	-	0.599	0.347	0.436	0.496	0.329	0.495	0.343	0.417
Decision Support	0.349	0.240	0.331	0.254	0.269	0.599	-	0.536	0.523	0.723	0.312	0.627	0.476	0.401
Medicines Management and Optimisation	0.239	0.179	0.205	0.173	0.263	0.347	0.536	-	0.434	0.527	0.223	0.443	0.439	0.416
Orders and Results Management	0.403	0.369	0.469	0.339	0.280	0.436	0.524	0.434	-	0.645	0.222	0.552	0.453	0.548
Records	0.375	0.298	0.405	0.300	0.270	0.496	0.723	0.527	0.645	-	0.344	0.674	0.450	0.518
Remote and Assistive Care	0.165	0.128	0.189	0.164	0.109	0.329	0.312	0.223	0.222	0.344	-	0.294	0.160	0.348
Transfers of Care	0.299	0.350	0.385	0.283	0.282	0.495	0.627	0.443	0.552	0.674	0.294	-	0.362	0.503
Standards	0.324	0.333	0.393	0.295	0.246	0.343	0.476	0.439	0.453	0.450	0.160	0.362	-	0.421
Infrastructure	0.518	0.504	0.582	0.554	0.406	0.417	0.401	0.416	0.548	0.518	0.348	0.503	0.421	-

Figure 2.2 - Summary of eigenvalues and scree plot of the principal component analysis (PCA) for the 2016 CDMI scores from 136 acute NHS Trusts in England

Component	Initial Eigenvalues		
	Total	% of Variance	Cumulative %
1	6.234	44.530	44.530
2	1.902	13.588	58.118
3	0.920	6.572	64.689
4	0.754	5.385	70.075
5	0.707	5.048	75.122
6	0.621	4.438	79.560
7	0.538	3.845	83.405
8	0.465	3.323	86.728
9	0.445	3.175	89.903
10	0.381	2.718	92.621
11	0.328	2.341	94.962
12	0.264	1.887	96.850
13	0.230	1.643	98.493
14	0.211	1.507	100.000

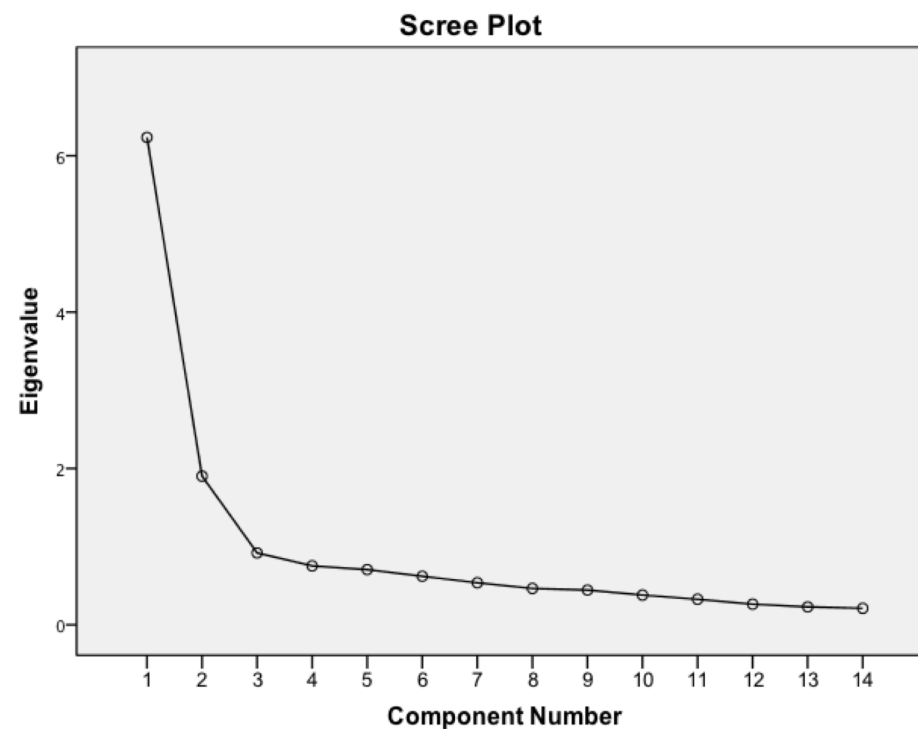


Figure 2.3 - A varimax orthogonal rotation plot of the principal component analysis (PCA) for the 2016 CDMI scores from 136 acute NHS Trusts in England

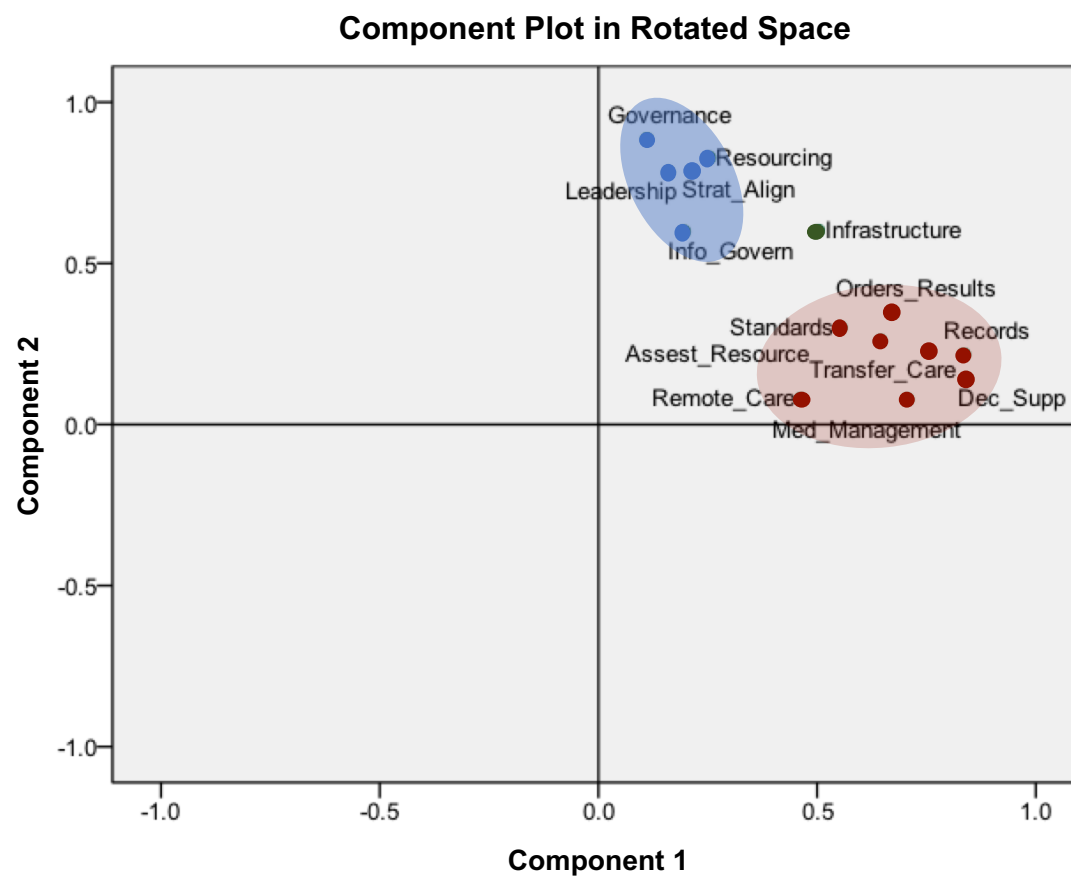


Table 2.3 - Component loadings and communalities of the rotated solution of the principal component analysis (PCA) for the 2016 CDMI scores from 136 acute NHS Trusts in England

<i>Rotated structure matrix for PCA with varimax rotation of a two-component model</i>			
Items	Rotated component coefficients		
	Component 1	Component 2	Communalities
Decision Support	0.841		0.666
Records	0.836		0.639
Transfers of Care	0.756		0.749
Medicines Management and Optimisation	0.706		0.797
Orders and Results Management	0.673	0.347	0.397
Asset and Resource Optimisation	0.645		0.484
Standards	0.553	0.301	0.727
Remote and Assistive Care	0.462		0.505
Governance		0.886	0.573
Resourcing		0.828	0.746
Strategic Alignment		0.787	0.220
Leadership		0.783	0.623
Infrastructure	0.502	0.602	0.397
Information Governance		0.599	0.615

NB - All coefficients <0.3 suppressed

Table 2.4 - Univariate regression analysis matrix showing the relationships between Clinical Digital Maturity Index (CDMI) Score, outcome variables and specified covariates (n=136, significance at p<0.05)

			Independent Variables				
			Outcome Variables (B, p, 95% CI)				
			SHMI	READ	LLOS	HFC	COC
Dependent Variables	CDMI Scores	Aggregate CDMI Score	-0.0000742, p=0.102 (-0.0001632 - 0.0000149)	0.0024879, p=0.383 (-0.0031329 - 0.0081087)	0.0155801, p=0.002 (0.0056274 - 0.0255328)	0.0033696, p=0.001 (0.0014758 - 0.0052635)	0.0005833, p=0.121 (-0.000156 - 0.0013227)
		Readiness Score	-0.0000254, p=0.824 (-0.0002516 - 0.0002007)	0.0029013, p=0.686 (-0.0112621 - 0.0170647)	0.0354604, p=0.006 (0.0102763 - 0.0606445)	0.0076534, p=0.00285 (0.0028515 - 0.0124552)	0.0007601, p=0.423 (-0.0011111 - 0.0026313)
		Capability Score	-0.0001513, p=0.025 (-0.0002829 - -0.0000197)	0.0038806, p=0.361 (-0.0044963 - 0.0122576)	0.0201933, p=0.0.009 (0.0052273 - 0.0351593)	0.0043619, p=0.003 (0.0015066 - 0.0072171)	0.0008948, p=0.111 (-0.0002068 - 0.0019964)
		Infrastructure Score	-0.000227, p=0.637 (-0.001176 - 0.00722)	0.0315014, p=0.295 (-0.0277588 - 0.0907617)	0.0984811, p=0.0.072 (-0.0089666 - 0.2059287)	0.0218572, p=0.037 (0.0012978 - 0.0424166)	0.0067342, p=0.090 (-0.0010569 - 0.0145252)
	Covariates	A&E Attendance	-3.09 ⁻⁷ , p=0.008 (-5.36 ⁻⁷ - -8.22 ⁻⁸)	-1.00 ⁻⁶ , p=0.892 (-0.0000156 - 0.0000136)	0.0000231, p=0.085 (-3.25 ⁻⁶ - 0.0000495)	6.36 ⁻⁶ , p=0.013 (1.35 ⁻⁶ - 0.0000114)	1.64 ⁻⁷ , p=0.867 (-1.77 ⁻⁶ - 2.10 ⁻⁶)
		Admissions	-3.53 ⁻⁷ , p=0.027 (-6.64 ⁻⁷ - -4.10 ⁻⁸)	5.22 ⁻⁶ , p=0.604 (0.0000146 - 0.0000251)	0.0000354, p=0.053 (-4.35 ⁻⁷ - 0.0000712)	7.36 ⁻⁶ , p=0.036 (4.96 ⁻⁷ - 0.0000142)	9.36 ⁻⁷ , p=0.482 (-1.69 ⁻⁶ - 3.56 ⁻⁶)
		Total Staff	-8.91 ⁻⁶ , p=0.002 (-0.0000146 - -3.27 ⁻⁶)	-0.000049, p=0.792 (0.0004148 - 0.0003168)	0.0013918, p=<0.0005 (0.0007667 - 0.002017)	0.000163, p=0.011 (0.0000376 - 0.0002885)	0.0000713, p=0.003 (0.0000244 - 0.0001182)
		Total Clinical Staff	-0.0000173, p=<0.0005 (-0.0000264 - -8.09 ⁻⁶)	-0.0001313, p=0.667 (-0.0007338 - 0.0004712)	0.0024027, p=<0.0005 (0.0013801 - 0.0034253)	0.0002974, p=0.005 (0.0000919 - 0.000503)	0.001178, p=0.003 (0.000406 - 0.000195)
		Dr/Nurse Ratio	-0.334332, p=0.001 (-0.5376372 - -0.1310271)	-7.684432, p=0.250 (-20.84892 - 5.480057)	7.67461, p=0.538 (-5.066697 - 42.86107)	0.9752037, p=0.678 (-3.667653 - 5.61806)	2.295652, p=0.009 (0.5891436 - 4.00216)
		Clinical/Non-Clinical Ratio	-0.2180829, p=<0.0005 (-0.3156949 - -0.1204708)	-1.37356, p=0.679 (-7.914914 - 5.167794)	5.91386, p=0.014 (3.010963 - 26.40413)	2.405923, p=0.037 (0.1444056 - 4.667441)	0.1121838, p=0.798 (-0.753939 - 0.9782966)
		Cons/Jnr Ratio	0.0134597, p=0.817 (-0.1013511 - 0.1282706)	2.893469, p=0.427 (-4.283604 - 10.07054)	-20.3853, p=0.002 (-35.11527 - -9.971288)	-2.064643, p=0.105 (-4.566203 - 0.4369177)	0.214953, p=0.656 (-0.7364965 - 1.166403)
		Manager/Clinical Ratio	-0.549033, p=0.31 (-1.614409 - 0.516343)	-34.7965, p=0.304 (-101.5338 - 31.94079)	7.109297, p=0.895 (-136.6396 - 108.233)	3.101841, p=0.795 (-20.42082 - 26.6245)	4.702077, p=0.294 (-4.129318 - 13.53347)
		General Beds	-0.0000444, p=0.066 (-0.0000916 - 2.91 ⁻⁶)	0.0012392, p=0.414 (-0.0017525 - 0.00422309)	0.0229891, p=0.001 (0.003491 - 0.140374)	0.0012596, p=0.017 (0.0002286 - 0.0022906)	0.0002884, p=0.15 (-0.0001054 - 0.0006823)
		ITU Beds	-0.0010909, p=<0.0005 (-0.0016822 - -0.0004995)	-0.150444, p=0.444 (-0.0538051 - 0.0237163)	0.1604666, p=<0.0005 (0.0949745 - 0.2259588)	0.013016, p=0.058 (-0.0004428 - 0.0264748)	0.0091411, p=<0.0005 (0.0042427 - 0.0140395)
		ITU Bed Occupancy	-0.1397301, p=0.079 (-0.2956875 - 0.162273)	-1.931775, p=0.700 (-11.81045 - 7.946899)	5.43295, p=0.552 (-12.60874 - 23.47464)	2.573182, p=0.142 (-0.8698438 - 6.016208)	1.515089, p=0.021 (0.2327551 - 2.797423)
		General Bed Occupancy	-0.2028078, p=0.18 (-0.0948731 - 0.5004887)	-6.721321, p=0.479 (-25.46111 - 12.01847)	20.05866, p=0.198 (-8.305373 - 59.76003)	-1.552292, p=0.642 (-8.140063 - 5.035479)	1.369354, p=0.276 (-1.104528 - 3.843236)
		Dr/Bed Ratio	0.0321738, p=0.003 (0.0112487 - 0.0530989)	-0.6822582, p=0.319 (-2.032627 - 0.6681102)	-1.402548, p=0.263 (-3.868208 - 1.063113)	-0.6941698, p=0.003 (-1.155122 - -0.233218)	-0.546871, p=0.547 (-0.2338336 - 0.1244593)
		Nurse/Bed Ratio	0.0151941, p=0.002 (0.0058554 - 0.245327)	-0.1709417, p=0.578 (0.7774672 - 0.4355837)	-2.299799, p=0.216 (-2.033345 - 0.1632269)	-0.2649029, p=0.013 (-0.4732815 - -0.0565242)	-0.0264339, p=0.516 (-0.1066754 - 0.0538076)
		Academic Status	-0.0602981, p=0.001 (-0.0949715 - -0.0256247)	-0.9780522, p=0.394 (-3.237948 - 1.281843)	9.578028, p=<0.0005 (5.773303 - 13.38275)	0.8289878, p=0.038 (0.0459312 - 1.1612044)	0.5918509, p=<0.0005 (0.309492 - 0.8742099)
		GDE Status	-0.064725, p=0.007 (-0.1110452 - -0.0184048)	1.505792, p=0.318 (-1.466508 - 4.478092)	4.408666, p=0.109 (-0.9919107 - 9.809243)	1.036393, p=0.049 (0.0037946 - 2.068991)	0.358875, p=0.071 (-0.0311989 - 0.748949)

			Independent Variables			
			CDMI Scores (B, p, 95% CI)			
			Aggregate CDMI Score	Readiness Score	Capability score	Infrastructure Score
Dependent Variables	CDMI Scores	Aggregate CDMI Score	-	-	-	-
		Readiness Score	-	-	-	-
		Capability Score	-	-	-	-
		Infrastructure Score	-	-	-	-
	Covariates	A&E Attendance	0.0005458, p=0.014 (0.0001133 - 0.0009782)	0.0001597, p=0.071 (-0.0000141 - 0.0003335)	0.0003794, p=0.011 (0.0000898 - 0.000669)	6.66 ⁻⁰⁶ , p= 0.754 (-0.0000352 - 0.0000486)
		Admissions	0.0009942, p=0.001 (0.000416 - 0.0015725)	0.0003277, p=0.006 (0.0000946 - 0.0005608)	0.0006089, p=0.002 (0.0002182 - 0.0009996)	0.0000576, p=0.045 (1.35 ⁻⁰⁶ - 0.0001138)
		Total Staff	0.0222315, p=<0.0005 (0.0118101 - 0.32653)	0.0068479, p=0.002 (0.0025941 - 0.0111017)	0.0145655, p=<0.0005 (0.0075534 - 0.0215776)	0.0008181, p=0.123 (-0.0002233 - 0.0018595)
		Total Clinical Staff	0.03656, p=<0.0005 (0.193863 - 0.537338)	0.010551, p=0.004 (0.0035095 - 0.0175924)	0.0247527, p=<0.0005 (0.132468 - 0.362587)	0.0012563, p=0.15 (-0.0004615 - 0.0029741)
		Dr/Nurse Ratio	267.1074, p=0.187 (-131.2956 - 665.5104)	21.18798, p=0.793 (-138.2692 - 180.6451)	220.5587, p=0.104 (-45.78657 - 486.904)	25.36068, p=0.186 (-12.37893 - 63.1003)
		Clinical/Non-Clinical Ratio	156.0553, p=0.119 (-40.54736 - 352.6581)	-2.171525, p=0.793 (-81.08383 - 76.74078)	156.3026, p=0.019 (25.920332 - 286.6849)	1.924263, p=0.84 (-16.86754 - 20.71607)
		Cons/Jnr Ratio	-0.4543243, p=0.997 (-218.514 - 217.6054)	15.72793, p=0.72 (-70.96212 - 102.418)	-29.64449, p=0.689 (-175.8321 - 116.5431)	13.46224, p=0.197 (-7.066112 - 33.99059)
		Manager/Clinical Ratio	-295.2195, p=0.774 (-2325.478 - 1735.039)	48.33753, p=0.906 (-759.3901 - 856.0652)	-393.0792, p=0.569 (-1753.748 - 967.5897)	49.52212, p=0.611 (-142.6776 - 241.7218)
		General Beds	0.157739, p=<0.0005 (0.0709168 - 0.2445612)	0.0472616, p=0.009 (0.0120164 - 0.0825068)	0.0995344, p=0.001 (0.0409715 - 0.1580972)	0.010943, p=0.011 (0.0025366 - 0.193494)
		ITU Beds	2.251494, p=<0.0005 (1.138652 - 3.364336)	0.6809739, p=0.004 (0.2273325 - 1.134615)	1.470191, p=<0.0005 (0.7213576 - 2.219024)	0.100329, p=0.074 (-0.0098863 - 0.2105443)
		ITU Bed Occupancy	406.4855, p=0.007 (115.047 - 697.924)	62.475, p=0.3 (-56.20952 - 181.1595)	316.8003, p=0.002 (123.2541 - 510.3465)	27.21015, p=0.057 (-0.7875624 - 55.20787)
		General Bed Occupancy	-495.8152, p=0.084 (-1058.562 - 66.93161)	-258.277, p=0.023 (-480.2841 - -36.26988)	-190.6537, p=0.323 (-571.0073 - 189.6999)	-46.88445, p=0.084 (-100.1956 - 6.426748)
		Dr/Bed Ratio	-103.3575, p=<0.0005 (-140.4517 - -66.26341)	-38.06428, p=<0.0005 (-53.05485 - -23.07371)	-56.2904, p=<0.0005 (-82.1165 - -30.4643)	-9.002864, p=<0.0005 (-12.5778 - -5.427932)
		Nurse/Bed Ratio	-44.24357, p=<0.0005 (-61.02527 - -27.46187)	-15.50511, p=<0.0005 (-22.3297 - -8.680521)	-24.8383, p=<0.0005 (-36.43264 - -13.24396)	-3.900166, p=<0.0005 (-5.511373 - -2.288958)
		Academic Status	123.9159, p=<0.0005 (58.57363 - 189.2581)	35.85577, p=0.009 (9.231871 - 62.47967)	80.46394, p=<0.0005 (36.48749 - 124.4404)	7.596154, p=0.02 (1.220212 - 13.9721)
		GDE Status	242.5083, p=<0.0005 (162.1292 - 322.8875)	62.1, p=<0.005 (27.73261 - 96.46739)	164.5458, p=<0.0005 (110.7931 - 218.2986)	15.8625, p=<0.005 (7.736068 - 23.98893)

Table 2.5a - Multivariate regression analysis matrix for Summary Hospital Level Mortality Index (SHMI). Model 1 represents a kitchen sink approach with all covariates included, Model 2 includes only covariates that were significant at a univariate level and Model 3 utilises a backward stepwise regression model (0.1, 0.05) starting with all retained covariates (n=136, significance at $p < 0.05$)

Summary Hospital Level Mortality Index (SHMI)						
Covariate	Multivariate Regression Analysis					
	Model 1 – Kitchen Sink		Model 2 – Significant Covariates		Model 3 – Backward Stepwise	
	Coefficient B (95% CI)	Sig (p)	Coefficient B (95% CI)	Sig (p)	Coefficient B (95% CI)	Sig (p)
Readiness Score	0.0001945 (-0.0000837 - 0.0004727)	0.169	0.0002 (-0.0000847 - 0.0004846)	0.167	0.0001937 (-0.0000788 - 0.0004661)	0.162
Capability Score	-0.0000384 (-0.0002037 - 0.000127)	0.647	-0.0000368 (-0.0002055 - 0.0001318)	0.666	-0.0000504 (0.000213 - 0.0001121)	0.54
Infrastructure Score	0.0002304 (-0.0011163 - 0.0015772)	0.735	0.0000981 (-0.0014772 - 0.001281)	0.888	0.0000243 (-0.0012777 - 0.0013264)	0.971
A&E Attendance	1.85 ⁻⁷ (-5.43 ⁻⁷ - 1.73 ⁻⁷)	0.308	-1.78 ⁻⁷ (-5.43 ⁻⁷ - 1.86 ⁻⁷)	0.334	-	-
Admissions	2.23 ⁻⁷ (-6.64 ⁻⁷ - 1.11 ⁻⁷)	0.619	2.80 ⁻⁷ (-6.17 ⁻⁷ - 1.18 ⁻⁶)	0.537	-	-
Total Staff	0.0000446 (-0.000317 - 0.000121)	0.249	0.0000367 (-0.000224 - 0.0000434)	0.342	0.0000445 (9.09 ⁻⁶ - 0.0000799)	0.014
Total Clinical Staff	0.0001062 (-0.0000317 - 0.000121)	0.119	-0.0000903 (-0.000224 - 0.0000434)	0.184	-0.0001029 (-0.0001624 - -0.0000433)	0.001
Dr/Nurse Ratio	-0.2353947 (-0.4661907 - -0.0045987)	0.046	-0.188906 (-4.49304 - 0.0371183)	0.101	-0.184481 (-0.3856914 - 0.0167295)	0.072
Clinical/Non-Clinical Ratio	-0.0421438 (-0.2706812 - 0.1863936)	0.716	-0.0104142 (-0.2340737 - 0.2132453)	0.927	-	-
Cons/Jnr Ratio	-0.1457694 (-0.2657054 - 0.0258334)	0.018	-	-	-	-
Manager/Clinical Ratio	-0.897783 (-1.894044 - 0.984782)	0.077	-	-	-	-
General Beds	0.0001266 (4.80 ⁻⁶ - 0.0002483)	0.042	-	-	0.0001247 (0.0000413 - 0.0002082)	0.004
ITU Beds	0.0001067 (-0.0012135 - 0.0014269)	0.873	0.000063 (-0.0012824 - 0.0014084)	0.926	-	-
ITU Bed Occupancy	-0.0478115 (-0.1988202 - 0.1031972)	0.532	-	-	-	-
General Bed Occupancy	0.1245757 (-0.1628771 - 0.41285)	0.392	-	-	-	-
Dr/Bed Ratio	0.0359629 (-0.0389983 - 0.1109236)	0.344	0.337018 (-0.0430381 - 0.1104418)	0.386	0.0399898 (0.0164397 - 0.0635399)	0.001
Nurse/Bed Ratio	0.0030655 (-0.0312324 - 0.0373634)	0.86	0.0031531 (-0.0320781 - 0.0383844)	0.86	-	-
Academic Status	0.0003752 (-0.542897 - 0.0550401)	0.989	-0.0083266 (-0.0645455 - 0.0478923)	0.77	-	-
GDE Status	-	-	-	-	-	-

Table 2.5b - Multivariate regression analysis matrix for Harm Free Care (HFC). Model 1 represents a kitchen sink approach with all covariates included, Model 2 includes only covariates that were significant at a univariate level and Model 3 utilises a backward stepwise regression model (0.1, 0.05) starting with all retained covariates (n=136, significance at p<0.05)

Harm Free Care (HFC)						
Covariate	Multivariate Regression Analysis					
	Model 1 – Kitchen Sink		Model 2 – Significant Covariates		Model 3 – Backward Stepwise	
	Coefficient B (95% CI)	Sig (p)	Coefficient B (95% CI)	Sig (p)	Coefficient B (95% CI)	Sig (p)
Readiness Score	0.0043436 (-0.0023956 - 0.0110828)	0.204	0.0047934 (-0.0017864 - 0.0113731)	0.152	0.0064495 (0.0002011 - 0.012698)	0.043
Capability Score	0.0011701 (-0.0028361 - 0.0051762)	0.564	0.0013672 (-0.0035442 - 0.0052786)	0.49	0.0016917 (-0.0020838 - 0.0054671)	0.377
Infrastructure Score	-0.000675 (-0.0333016 - 0.0319516)	0.967	-0.0014912 (-0.0333165 - 0.0303341)	0.926	-0.0015507 (-0.0306782 - 0.0275769)	0.916
A&E Attendance	2.83 ⁻⁶ (-5.85 ⁻⁶ - 0.0000115)	0.52	3.75 ⁻⁶ (-4.86 ⁻⁶ - 0.0000122)	0.38	-	-
Admissions	-5.75 ⁻⁶ (-0.0000272 - 0.0000157)	0.597	-8.14 ⁻⁶ (-0.0000282 - 0.0000119)	0.423	-	-
Total Staff	0.001522 (-0.0033721 - 0.0003281)	0.106	-0.0015605 (-0.003323 - 0.0002021)	0.082	-0.0009478 (-0.0017664 - -0.0001291)	0.024
Total Clinical Staff	0.0031175 (-0.0001223 - 0.0063572)	0.059	0.0031668 (0.0000665 - 0.006267)	0.045	0.0021023 (0.0006125 - 0.003592)	0.006
Dr/Nurse Ratio	-1.132929 (-6.724339 - 4.458481)	0.689	-	-	-	-
Clinical/Non-Clinical Ratio	-3.013071 (-8.549763 - 2.523621)	0.283	-2.641949 (-7.818671 - 2.534773)	0.314	-	-
Cons/Jnr Ratio	-1.708831 (-4.614477 - 1.196814)	0.247	-	-	-	-
Manager/Clinical Ratio	10.55644 (-13.57961 - 34.6925)	0.388	-	-	-	-
General Beds	0.0005654 (-0.0023841 - 0.0035149)	0.705	0.0006358 (-0.0021477 - 0.0034193)	0.652	-	-
ITU Beds	-0.0316422 (-0.636257 - 0.0003413)	0.052	-	-	-0.0271027 (-0.548871 - 0.0006818)	0.056
ITU Bed Occupancy	1.63864 (-2.019793 - 5.297072)	0.377	-	-	-	-
General Bed Occupancy	-1.548496 (-8.51251 - 5.415517)	0.66	-	-	-	-
Dr/Bed Ratio	-1.718863 (-0.1939128 - 1.467933)	0.063	-1.600161 (-3.368705 - 0.1683822)	0.076	-	-
Nurse/Bed Ratio	0.6370102 (-0.1939128 - 1.467933)	0.132	0.5840016 (-0.229551 - 1.397554)	0.158	-	-
Academic Status	0.4206681 (-0.9036788 - 1.745015)	0.531	0.3888338 (-0.8966197 - 1.674287)	0.55	-	-
GDE Status	-	-	-	-	-	-

Table 2.5c - Multivariate regression analysis matrix for Long Length of Stay (LLOS). Model 1 represents a kitchen sink approach with all covariates included, Model 2 includes only covariates that were significant at a univariate level and Model 3 utilises a backward stepwise regression model (0.1, 0.05) starting with all retained covariates (n=136, significance at $p < 0.05$)

Long Length of Stay (LLOS)						
Covariate	Multivariate Regression Analysis					
	Model 1 – Kitchen Sink		Model 2 – Significant Covariates		Model 3 – Backward Stepwise	
	Coefficient B (95% CI)	Sig (p)	Coefficient B (95% CI)	Sig (p)	Coefficient B (95% CI)	Sig (p)
Readiness Score	0.0291943 (-0.0004714 - 0.5886)	0.054	0.0210706 (-0.0072426 - 0.0493838)	0.143	0.0217422 (-0.006108 - 0.0495925)	0.125
Capability Score	0.001291 (-0.163439 - 0.0189259)	0.885	-0.0026664 (-0.0199366 - 0.0146038)	0.76	-0.0032678 (-0.0200492 - 0.0135136)	0.701
Infrastructure Score	0.016619 (-0.127001 - 0.160239)	0.819	0.0279537 (-0.1107542 - 0.1666617)	0.691	0.0316568 (-0.1047929 - 0.1681065)	0.647
A&E Attendance	-0.0000153 (-0.0000535 - 0.0000229)	0.428	-	-	-	-
Admissions	-0.0002401 (-0.0003347 - -0.0001445)	<0.0005	-	-	-0.0002406 (-0.0003255 - 0.0001556)	<0.0005
Total Staff	0.0051851 (-0.0194158 - 0.0091067)	0.21	0.0040313 (-0.0037569 - 0.0118194)	0.308	0.002271 (0.0010027 - 0.0035393)	0.001
Total Clinical Staff	-0.0051546 (-0.002959 - 0.0133292)	0.538	-0.0033743 (-0.0170455 - 0.0102968)	0.626	-	-
Dr/Nurse Ratio	7.67461 (-16.9384 - 32.28762)	0.476	-	-	-	-
Clinical/Non-Clinical Ratio	7.760256 (-16.61189 - 32.1324)	0.53	2.829652 (-20.12363 - 25.78293)	0.808	-	-
Cons/Jnr Ratio	-20.3853 (-33.17576 - -7.594847)	0.002	-22.62757 (-34.69417 - -10.56097)	<0.0005	-21.91996 (-32.68395 - -11.15597)	<0.0005
Manager/Clinical Ratio	7.109297 (-99.136 - 113.3546)	0.895	-	-	-	-
General Beds	0.0229891 (0.0100055 - 0.0359726)	0.001	0.208051 (0.088638 - 0.327463)	0.001	0.0206147 (0.0089212 - 0.323082)	0.001
ITU Beds	-15.2019 (-0.116126 - 0.1654525)	0.064	0.0291771 (-0.10777512 - 0.1661053)	0.674	-	-
ITU Bed Occupancy	-15.2019 (-31.30608 - 0.9022741)	0.064	-	-	-	-
General Bed Occupancy	20.05866 (-10.59646 - 50.71378)	0.198	-	-	-	-
Dr/Bed Ratio	5.894711 (-2.099425 - 13.88885)	0.147	-	-	-	-
Nurse/Bed Ratio	-2.299799 (-5.957467 - 1.357868)	0.216	-	-	-	-
Academic Status	4.580095 (-2.099425 - 10.40978)	0.122	5.578075 (0.1147176 - 11.04143)	0.045	5.629142 (0.9997511 - 10.25853)	0.018
GDE Status	-	-	-	-	-	-

Table 2.6 - Multivariate backward stepwise selection analysis matrix (0.1, 0.05) for each selected outcome variable (SHMI, HFC, LLOS) and aggregate CDMI score with all specified covariates included (n=136, significance at $p<0.05$)

Aggregate Clinical Digital Maturity Index (CDMI) Score						
Covariate	Multivariate Regression Analysis					
	SHMI		HFC		LLOS	
	Coefficient B (95% CI)	Sig (p)	Coefficient B (95% CI)	Sig (p)	Coefficient B (95% CI)	Sig (p)
Aggregate CDMI Score	0.0000426 (-0.000045 - 0.0001302)	0.337	0.0029215 (0.0009508 - 0.0048922)	0.004	0.0071856 (-0.0016309 - 0.0160021)	0.109
A&E Attendance	-	-	-	-	-	-
Admissions	-	-	-	-	-0.0002338 (-0.0003185 - 0.00149)	<0.0005
Total Staff	0.0000635 (0.0000271 - 0.0000998)	0.001	-0.0008611 (-0.0016621 - -0.0000601)	0.035	0.0021523 (0.0009564 - 0.0033481)	<0.0005
Total Clinical Staff	-0.000138 (-0.0001988 - -0.0000772)	<0.0005	0.0019482 (0.0004987 - 0.0033977)	0.009	-	-
Dr/Nurse Ratio	-0.2337211 (-0.4317183 - -0.035724)	0.021	-	-	-	-
Clinical/Non-Clinical Ratio	-	-	-	-	-	-
Cons/Jnr Ratio	-0.1409635 (-0.2523272 - -0.0295997)	0.014	-	-	-21.02906 (-31.6291 - -10.42901)	<0.0005
Manager/Clinical Ratio	-0.8596894 (-1.801148 - 0.0817694)	0.073	-	-	-	-
General Beds	0.0001277 (0.0000492 - 0.0002062)	0.002	-	-	0.0203946 (0.0089065 - 0.0318828)	0.001
ITU Beds	-	-	-0.026066 (-0.0536043 - 0.0014723)	0.063	-	-
ITU Bed Occupancy	-	-	-	-	-	-
General Bed Occupancy	-	-	-	-	-	-
Dr/Bed Ratio	0.403429 (0.0176662 - 0.0630196)	0.001	-	-	-	-
Nurse/Bed Ratio	-	-	-	-	-	-
Academic Status	-	-	-	-	5.674449 (1.078127 - 10.27077)	0.016

Table 2.7 - Multivariate regression analysis matrix for each domain of the Clinical Digital Maturity Index (CDMI) score. Model 1 includes only retained covariates that were significant at a univariate level and Model 2 utilises a backward stepwise regression model (0.1, 0.05) starting with all retained covariates (n=136, significance at $p<0.05$)

Covariates	Aggregate CDMI Score		Readiness Doman	
	Multivariate (B, p, 95% CI)		Multivariate (B, p, 95% CI)	
	Model 1	Model 2	Model 1	Model 2
A&E Attendance	0.0001074, $p=0.75$ (-0.0005593 - 0.0007741)	-	-	-
Admissions	-0.0007309, $p=0.37$ (-0.002338 - 0.0008761)	-	-0.0001006, $p=0.755$ (-0.0007384 - 0.0005372)	-
Total Staff	0.0224573, $p=0.525$ (-0.0472331 - 0.0921477)	0.0112734, $p=0.041$ (0.000477 - 0.220698)	0.0253805, $p=0.069$ (-0.0020333 - 0.527943)	0.0036834, $p=0.092$ (-0.0006141 - 0.0079809)
Total Clinical Staff	-0.0090668, $p=0.889$ (-0.137107 - 0.1189733)	-	-0.0356877, $p=0.155$ (-0.0850147 - 0.0136393)	-
Dr/Nurse Ratio	-	-	-	-
Clinical/Non-Clinical Ratio	-	-	-	-
Cons/Jnr Ratio	-	-	-	-
Manager/Clinical Ratio	-	-	-	-
General Beds	-0.0356829, $p=0.751$ (-0.2573008 - 0.185935)	-	-0.0208953, $p=0.646$ (-0.1108261 - 0.0690355)	-
ITU beds	0.3821212, $p=0.759$ (-2.080804 - 2.845046)	-	0.3267455, $p=0.52$ (-0.6750713 - 1.328562)	-
ITU Bed Occupancy	265.6463, $p=0.061$ (-12.12768 - 543.4202)	265.6463, $p=0.061$ (-14.6953 - 530.2386)	-	-194.1691, $p=0.066$ (-401.0341 - 12.69593)
General Bed Occupancy	-	-	-167.6819, $p=0.118$ (-378.6299 - 43.26606)	-
Dr/Bed Ratio	-167.1842, $p=0.019$ (-306.1874 - -23.18093)	-83.97831, $p<0.0005$ (-122.7506 - -45.20599)	-71.25716, $p=0.013$ (-127.3866 - -15.12768)	-31.008, $p<0.0005$ (-47.08712 - -14.92889)
Nurse/Bed Ratio	35.72022, $p=0.278$ (-29.14732 - 100.5878)	-	18.05697, $p=0.173$ (-7.998825 - 44.11277)	-
Academic Status	49.58193, $p=0.345$ (-53.86733 - 153.0312)	-	13.36323, $p=0.508$ (-26.47359 - 53.20005)	-
GDE Status	-	-	-	-

Covariates	Capability Domain		Infrastructure Domain	
	Multivariate (B, p, 95% CI)		Multivariate (B, p, 95% CI)	
	Model 1	Model 2	Model 1	Model 2
A&E Attendance	0.0000684, $p=0.77$ (-0.0003929 - 0.0005297)	-	-	-
Admissions	-0.0006909, $p=0.223$ (-0.001808 - 0.0004262)	-0.0006371, $p=0.094$ (-0.0013839 - 0.0001097)	-0.0000855, $p=0.227$ (-0.000225 - 0.000054)	-
Total Staff	0.0186644, $p=0.709$ (-0.080118 - 0.1174467)	0.0176932, $p=0.01$ (0.0043169 - 0.0310696)	-	-
Total Clinical Staff	-0.0058785, $p=0.947$ (-0.1793968 - 0.1676399)	-	-	-
Dr/Nurse Ratio	-	-	-	-
Clinical/Non-Clinical Ratio	85.08831, $p=0.562$ (-204.8123 - 374.9889)	-	-	-
Cons/Jnr Ratio	-	-	-	-
Manager/Clinical Ratio	-	-	-	-
General Beds	-0.0113801, $p=0.883$ (-0.1642104 - 0.1414503)	-	0.00944, $p=0.38$ (-0.0117518 - 0.0306317)	-
ITU beds	0.0403191, $p=0.963$ (-1.677693 - 1.758331)	-	-	-
ITU Bed Occupancy	219.9076, $p=0.025$ (27.8922 - 411.9231)	219.3528, $p=0.021$ (33.07929 - 405.6263)	-	-
General Bed Occupancy	-	-	-	-
Dr/Bed Ratio	-82.06591, $p=0.094$ (-178.2674 - 14.13556)	-48.26106, $p=0.001$ (-75.85706 - -20.66506)	-9.34858, $p=0.173$ (-22.84309 - 4.145928)	-9.34858, $p=<0.0005$ (-12.5778 - -5.427932)
Nurse/Bed Ratio	16.27364, $p=0.475$ (-28.72379 - 61.27106)	-	0.3142828, $p=0.921$ (-5.980279 - 6.608845)	-
Academic Status	22.99191, $p=0.525$ (-48.4584 - 94.224422)	-	5.500122, $p=0.15$ (-2.005075 - 13.00532)	-
GDE Status	-	-	-	-

Table 2.8 - Univariate regression analysis matrix showing the relationships between Clinical Digital Maturity Index (CDMI) Score and 2016 National Inpatient Patient Survey Scores (n=126, significance at $p < 0.05$)

		Independent Variables – 2016 National Inpatient Patient Survey Domains (B, p, 95% CI)					
		AW	SHQCC	BIMC	BR	CCFP	OPES
Dependent Variables – CDMI Domains	Aggregate CDMI Score	0.0012352, $p=0.427$ (-0.0018323 - 0.0043026)	0.0006532, $p=0.691$ (-0.0025968 - 0.0039032)	0.0008549, $p=0.563$ (-0.0020604 - 0.0037703)	0.0009117, $p=0.412$ (-0.0012823 - 0.0031057)	0.0005703, $p=0.572$ (-0.0014244 - 0.0025651)	0.0008629, $p=0.468$ (-0.0014841 - 0.0032099)
	Readiness score	-0.000969, $p=0.859$ (-0.0117438 - 0.0098058)	-0.0019301, $p=0.736$ (-0.0132346 - 0.0093744)	-0.0002382, $p=0.963$ (-0.0104896 - 0.010013)	-0.0004698, $p=0.902$ (-0.0080323 - 0.0070927)	0.001047, $p=0.768$ (-0.0059724 - 0.0080663)	-0.0004693, $p=0.910$ (-0.0086545 - 0.0077159)
	Capability Score	-0.0012243, $p=0.688$ (-0.0072379 - 0.0047893)	-0.003741, $p=0.243$ (-0.0100502 - 0.0025683)	-0.0015706, $p=0.588$ (-0.007292 - 0.0041508)	-0.0029894, $p=0.163$ (-0.0072101 - 0.0012314)	-0.0012403, $p=0.532$ (-0.0051579 - 0.0026774)	-0.0021685, $p=0.349$ (-0.0067368 - 0.0023998)
	Infrastructure Score	0.321704, $p=0.190$ (-0.0161945 - 0.0805353)	0.501647, $p=0.053$ (-0.0005781 - 0.1009074)	0.0267706, $p=0.252$ (-0.0192446 - 0.0727858)	0.0409908, $p=0.018$ (0.00700449 - 0.0749366)	0.144207, $p=0.367$ (-0.0170872 - 0.0459287)	0.331062, $p=0.077$ (-0.0036349 - 0.0698472)

Key:

AW – domain average for access and waiting

SHQCC – domain average for safe, high-quality and co-ordinated care

BIMC – domain average for better information and more choice

BR – domain average for building closer relationships

CCFP – domain average for clean, friendly and comfortable place to be

OPES – domain average for overall patient experience score

Table 2.9a - Kitchen sink multivariate regression analysis matrix for 2016 National Inpatient Patient Survey and aggregate Clinical Digital Maturity Index (CDMI) score with all covariates included (n=126, significance at $p < 0.05$)

		2016 National Inpatient Patient Survey Domains (B, p, 95% CI)		
		AW	SHQCC	BIMC
Covariate	Aggregate CDMI score	0.0003552, $p=0.832$ (-0.0029652 - 0.0036755)	0.0005328, $p=0.775$ (-0.0031467 - 0.00421123)	-0.0003706, $p=0.829$ (-0.0037616 - 0.0030204)
	A&E Attendances	-0.00017, $p=0.008$ (0.0000294 - -4.52 ⁻⁶)	-2.99 ⁻⁶ , $p=0.668$ (-0.0000168 - 0.0000108)	-8.36 ⁻⁶ , $p=0.195$ (-0.0000211 - 4.34 ⁻⁶)
	Admissions	-8.72 ⁻⁶ , $p=0.614$ (-0.0000429 - 0.0000255)	-8.02 ⁻⁶ , $p=0.676$ (-0.0000459 - 0.0000299)	-8.96 ⁻⁶ , $p=0.195$ (-0.0000211 - -0.0000259)
	Total Staff	0.0001047, $p=0.699$ (-0.0004305 - 0.00064)	0.0001236, $p=0.680$ (-0.0004695 - 0.0007167)	0.0002646, $p=0.339$ (-0.000282 - 0.0008113)
	Clinical/Non-Clinical Ratio	-1.076798, $p=0.659$ (-5.89286 - 3.739265)	-1.529314, $p=0.571$ (-6.6866259 - 3.807632)	-0.5361873, $p=0.829$ (-5.454684 - 4.382309)
	Dr/Nurse Ratio	-7.786506, $p=0.064$ (-16.03071 - 0.457702)	-5.41369, $p=0.243$ (-14.54955 - 3.722172)	-2.133943, $p=0.616$ (-10.5535 - 6.285612)
	Cons/Jnr Ratio	3.853653, $p=0.088$ (-0.5804903 - 8.287796)	8.526127, $p=0.001$ (3.612408 - 13.43985)	6.849499, $p=0.003$ (2.321045 - 11.37795)
	General Beds	0.0029973, $p=0.180$ (-0.0014089 - 0.0074035)	0.0004551, $p=0.854$ (-0.0044277 - 0.0053378)	0.000805, $p=0.724$ (-0.0036949 - 0.0053049)
	ITU Beds	0.0173694, $p=0.444$ (-0.0274516 - 0.621904)	0.0116876, $p=0.642$ (-0.037981 - 0.0613563)	0.0144835, $p=0.532$ (-0.0312908 - 0.0602578)
	General Bed Occupancy	-2.953508, $p=0.571$ (-13.26014 - 7.353126)	-5.852363, $p=0.312$ (-17.27371 - 5.568989)	-4.513537, $p=0.397$ (-15.03939 - 6.012311)
	ITU Bed Occupancy	-2.317902, $p=0.397$ (-7.71893 - 3.083125)	-1.75541, $p=0.562$ (-7.740588 - 4.229768)	-1.609175, $p=0.564$ (-7.125078 - 3.906728)
	Doctor/Bed Ratio	-1.610643, $p=0.247$ (-4.354267 - 1.13298)	-0.0600359, $p=0.969$ (-3.100397 - 2.980325)	0.4725648, $p=0.739$ (-2.329413 - 3.2745430)
	Nurse/Bed Ratio	0.4636612, $p=0.457$ (-0.7675756 - 1.694898)	0.0171957, $p=0.980$ (-1.347206 - 1.381597)	-0.1538637, $p=0.809$ (-1.1411288 - 1.103561)
	Academic Status	-0.228296, $p=0.822$ (-2.237509 - 1.780918)	-0.0283611, $p=0.32$ (-2.254882 - 2.19816)	-0.3926816, $p=0.705$ (-2.44463 - 1.659266)
	SHMI	-2.171982, $p=0.514$ (-8.749312 - 4.405348)	1.26399, $p=0.732$ (-6.024705 - 8.552703)	-5.590697, $p=0.102$ (-12.30792 - 1.126529)
	HFC	0.2221668, $p=0.129$ (-0.656906 - 0.5100243)	0.1588234, $p=0.326$ (-1.1601673 - 0.4778142)	0.1685568, $p=0.258$ (-0.1254231 - 0.46253680)
	LLOS	-0.0841049, $p=0.010$ (-0.1472866 - -0.0209232)	-0.038255, $p=0.281$ (-0.1082701 - 0.317601)	-0.0131117, $p=0.688$ (-0.0776372 - 0.0514138)

		2016 National Inpatient Patient Survey Domains (B, p, 85% CI)		
		BR	CCFP	OPES
Covariate	Aggregate CDMI score	-0.0000346, $p=0.975$ (-0.0022475 - 0.0021783)	-0.0008355, $p=0.442$ (-0.0029835 - 0.0013125)	-0.0000496, $p=0.969$ (-0.0025865 - 0.0024873)
	A&E Attendances	-0.0000153, $p<0.0005$ (-0.0000236 - -7.06 ⁻⁶)	-3.53 ⁻⁶ , $p=0.386$ (-0.0000116 - 4.51 ⁻⁶)	-9.62 ⁻⁶ , $p=0.047$ (-0.0000191 - -1.24 ⁻⁷)
	Admissions	2.98 ⁻⁷ , $p=0.979$ (-0.0000225 - 0.0000231)	-0.0000204, $p=0.070$ (-0.0000425 - 1.72 ⁻⁶)	-9.04 ⁻⁶ , $p=0.494$ (-0.0000351 - 0.0000171)
	Total Staff	0.0000655, $p=0.717$ (-0.0002912 - 0.0004222)	0.0001446, $p=0.410$ (-0.0002017 - 0.0004908)	0.0001456, $p=0.482$ (-0.0002633 - 0.0005546)
	Clinical/Non-Clinical Ratio	-3.999246, $p=0.015$ (-7.208907 - -0.7895852)	-4.000585, $p=0.012$ (-7.116134 - -0.8850364)	-2.231435, $p=0.232$ (-5.911093 - 1.448223)
	Dr/Nurse Ratio	-0.6566833, $p=0.813$ (-6.151028 - 4.837662)	-1.318932, $p=0.625$ (-6.652174 - 4.014311)	-3.409374, $p=0.286$ (-9.708267 - 2.889519)
	Cons/Jnr Ratio	5.090798, $p=0.001$ (2.135667 - 8.045929)	3.840146, $p=0.009$ (0.9716633 - 6.708628)	5.595879, $p=0.001$ (2.208022 - 8.983735)
	General Beds	0.0017452, $p=0.241$ (-0.0011913 - 0.0046817)	0.0026196, $p=0.071$ (-0.0002308 - 0.00547)	0.0017216, $p=0.313$ (-0.0016449 - 0.0050881)
	ITU Beds	0.0059286, $p=0.695$ (-0.0239423 - 0.357996)	0.0038269, $p=0.794$ (-0.0251681 - 0.032822)	0.0105358, $p=0.543$ (-0.0237091 - 0.0447808)
	General Bed Occupancy	-3.148883, $p=0.366$ (-10.01773 - 3.719965)	-2.779112, $p=0.411$ (-9.446555 - 3.888332)	-3.850717, $p=0.335$ (-11.72538 - 4.02395)
	ITU Bed Occupancy	-0.8976401, $p=0.622$ (-4.497151 - 2.70187)	-0.2677925, $p=0.880$ (-3.76176 - 3.226175)	-1.382454, $p=0.508$ (-5.509047 - 2.74414)
	Doctor/Bed Ratio	-0.4692164, $p=0.612$ (-2.297702 - 1.359269)	-1.364217, $p=0.131$ (-3.3139088 - 0.4106552)	-0.5808183, $p=0.584$ (-2.677053 - 1.515416)
	Nurse/Bed Ratio	0.14325, $p=0.730$ (-0.6773068 - 0.9638068)	0.5822944, $p=0.150$ (-0.2142025 - 1.378791)	0.1980669, $p=0.677$ (-0.7426457 - 1.138779)
	Academic Status	0.5298713, $p=0.435$ (-0.8091674 - 1.86891)	1.052707, $p=0.111$ (-0.2470693 - 2.352483)	0.1694005, $p=0.827$ (-1.365716 - 1.704517)
	SHMI	0.974176, $p=0.965$ (-4.286039 - 4.480874)	0.2894435, $p=0.893$ (-3.965484 - 4.544371)	-1.206703, $p=0.635$ (-6.232037 - 3.818632)
	HFC	0.1567435, $p=0.108$ (-0.0350988 - 0.2485859)	0.1962669, $p=0.039$ (0.0100497 - 0.3824842)	0.1816064, $p=0.105$ (-0.0383278 - 0.4015406)
	LLOS	-0.0079964, $p=0.707$ (-0.0501038 - 0.034111)	-0.0199526, $p=0.335$ (-0.0608253 - 0.0209201)	-0.0331363, $p=0.176$ (-0.0814095 - 0.151369)

Table 2.9b - Kitchen sink multivariate regression analysis matrix for 2016 National Inpatient Patient Survey and each Clinical Digital Maturity Index (CDMI) domain score with all covariates included (n=126, significance at $p<0.05$)

		2016 National Inpatient Patient Survey Domains (B, p, 95% CI)		
		AW	SHQCC	BIMC
Covariate	Readiness Domain	-0.0013397, $p=0.805$ (-0.012084 - 0.0094045)	-0.0048603, $p=0.415$ (-0.0166276 - 0.006907)	-0.0016946, $p=0.759$ (-0.126012 - 0.009212)
	Capability Domain	0.0006564, $p=0.828$ (-0.0053267 - 0.0066394)	-0.0019503, $p=0.556$ (-0.008503 - 0.0046025)	-0.0029106, $p=0.344$ (-0.0089841 - 0.0031628)
	Infrastructure Domain	0.0043873, $p=0.860$ (-0.0449235 - 0.053698)	0.0444364, $p=0.106$ (-0.0095697 - 0.0984426)	0.278369, $p=0.273$ (-0.0222191 - 0.0778928)
	A&E Attendances	-0.0000166, $p=0.012$ (-0.0000295 - -3.70 ⁻⁶)	-2.51 ⁻⁷ , $p=0.972$ (-0.0000144 - 0.0000139)	-6.73 ⁻⁶ , $p=0.311$ (-0.0000198 - 6.38 ⁻⁶)
	Admissions	-8.22 ⁻⁶ , $p=0.639$ (-0.0000429 - 0.0000264)	-7.53 ⁻⁶ , $p=0.695$ (0.0000455 - 0.0000304)	-9.47 ⁻⁶ , $p=0.595$ (-0.0000446 - 0.0000257)
	Total Staff	0.0001082, $p=0.698$ (-0.0004438 - 0.0006603)	0.0002172, $p=0.478$ (-0.00003874 - 0.0008218)	0.0003339, $p=0.240$ (-0.0002265 - 0.0008943)
	Clinical/Non-Clinical Ratio	-1.095972, $p=0.656$ (-5.963558 - 3.771615)	-1.40415, $p=0.603$ (-6.735234 - 3.926934)	-0.401033, $p=0.872$ (-5.34218 - 4.540114)
	Dr/Nurse Ratio	-7.906426, $p=0.064$ (-16.29202 - 0.4791655)	-6.346524, $p=0.174$ (-15.5306 - 2.837554)	-2.672149, $p=0.535$ (-11.18447 - 5.840114)
	Cons/Jnr Ratio	3.83965, $p=0.093$ (-0.6561034 - 8.335404)	8.166779, $p=0.001$ (3.242934 - 13.09062)	6.584711, $p=0.005$ (2.021016 - 11.14841)
	General Beds	0.0028392, $p=0.224$ (-0.0017636 - 0.0074421)	-0.000556, $p=0.827$ (-0.0055971 - 0.0044852)	0.0002718, $p=0.908$ (-0.0044006 - 0.0049441)
	ITU Beds	0.0178688, $p=0.436$ (-0.0274596 - 0.0631973)	0.0131164, $p=0.602$ (-0.0365283 - 0.062761)	0.0147443, $p=0.527$ (-0.0312692 - 0.0607577)
	General Bed Occupancy	-3.249384, $p=0.545$ (-13.86457 - 7.365798)	-5.902174, $p=0.316$ (-17.52815 - 5.723799)	-4.025618, $p=0.461$ (-14.80122 - 6.749985)
	ITU Bed Occupancy	-2.354758, $p=0.395$ (-7.823567 - 3.114052)	-1.577754, $p=0.603$ (-7.56731 - 4.411803)	-1.400132, $p=0.618$ (-6.951588 - 4.151325)
	Doctor/Bed Ratio	-1.676817, $p=0.238$ (-4.475942 - 1.122308)	-0.3412578, $p=0.826$ (-3.406919 - 2.2724404)	0.3638943, $p=0.800$ (-2.477533 - 3.205321)
	Nurse/Bed Ratio	0.4921109, $p=0.440$ (-0.7664701 - 1.750692)	0.1817783, $p=0.794$ (-1.196646 - 1.560203)	-0.719211, $p=0.911$ (-1.349522 - 1.20568)
	Academic Status	-0.2372672, $p=0.817$ (-2.267166 - 1.792632)	-0.1171405, $p=0.917$ (-2.340329 - 2.106048)	-0.4482619, $p=0.667$ (-2.508838 - 1.612314)
	SHMI	-2.046641, $p=0.549$ (-8.793791 - 4.70051)	0.9459415, $p=0.800$ (-6.443681 - 8.335564)	-6.070892, $p=0.082$ (-12.92001 - 0.7782238)
	HFC	0.2219898, $p=0.135$ (-0.07028 - 0.5142596)	0.1344241, $p=0.407$ (-0.185676 - 0.4545241)	0.149197, $p=0.321$ (-0.1474897 - 0.4458837)
	LLOS	-0.0827699, $p=0.012$ (-0.1470708 - -0.018469)	-0.0358523, $p=0.315$ (-0.106276 - 0.0345714)	-0.0135568, $p=0.681$ (-0.0788295 - 0.0517158)

		2016 National Inpatient Patient Survey Domains (B, p, 95% CI)		
		BR	CCFP	OPES
Covariate	Readiness Domain	-0.0013255, $p=0.713$ (-0.0084594 - 0.0058084)	-0.0010195, $p=0.77$ (-0.0079735 - 0.0059344)	-0.0019768, $p=0.633$ (-0.0101524 - 0.0061987)
	Capability Domain	-0.0011817, $p=0.557$ (-0.0051542 - 0.0027909)	-0.0008491, $p=0.665$ (-0.0047215 - 0.0030233)	-0.0012676, $p=0.582$ (-0.0058203 - 0.003285)
	Infrastructure Domain	0.0154645, $p=0.351$ (-0.0172765 - 0.0482055)	0.0000204, $p=0.999$ (-0.0318948 - 0.0319356)	0.0186251, $p=0.327$ (-0.0188966 - 0.0561468)
	A&E Attendances	-0.0000144, $p=0.001$ (-0.000023 - -5.84 ⁻⁶)	-3.47 ⁻⁶ , $p=0.412$ (-0.0000118 - 4.89 ⁻⁶)	-8.48 ⁻⁶ , $p=0.090$ (-0.0000183 - 1.35 ⁻⁶)
	Admissions	2.35 ⁻⁷ , $p=0.984$ (-0.0000228 - 0.0000232)	-0.0000203, $p=0.075$ (-0.0000428 - 4.89 ⁻⁶)	-8.97 ⁻⁶ , $p=0.502$ (-0.0000353 - 0.0000174)
	Total Staff	0.0001012, $p=0.585$ (-0.0002654 - 0.0004677)	0.000146, $p=0.420$ (-0.0002113 - 0.0005033)	0.000187, $p=0.379$ (-0.0002331 - 0.0006071)
	Clinical/Non-Clinical Ratio	-3.939388, $p=0.017$ (-7.161335 - -0.707441)	-4.000162, $p=0.013$ (-7.150594 - -0.8497293)	-2.168818, $p=0.248$ (-5.872684 - 1.535047)
	Dr/Nurse Ratio	-0.968496, $p=0.731$ (-6.536305 - 4.599313)	-1.33937, $p=0.626$ (-6.76675 - 4.08801)	-3.79569, $p=0.241$ (-10.17649 - 2.585112)
	Cons/Jnr Ratio	4.954229, $p=0.001$ (1.969169 - 7.93929)	3.834389, $p=0.010$ (0.9246167 - 6.744162)	5.437218, $p=0.002$ (2.016289 - 8.858146)
	General Beds	0.0014216, $p=0.359$ (-0.0016346 - 0.0044777)	0.0025956, $p=0.087$ (-0.0003835 - 0.0055747)	0.0013115, $p=0.460$ (-0.0021909 - 0.0048139)
	ITU Beds	0.0062449, $p=0.682$ (-0.023852 - 0.0363417)	0.003879, $p=0.794$ (-0.0254588 - 0.332168)	0.011031, $p=0.460$ (-0.0234605 - 0.0455225)
	General Bed Occupancy	-3.017608, $p=0.398$ (-10.06581 - 4.030589)	-2.799237, $p=0.421$ (-9.669668 - 4.071193)	-3.782835, $p=0.355$ (-11.86019 - 4.294516)
	ITU Bed Occupancy	-0.8077518, $p=0.660$ (-4.438895 - 2.823392)	-0.2678252, $p=0.881$ (-3.807386 - 3.271735)	-1.290628, $p=0.540$ (-5.451979 - 2.870723)
	Doctor/Bed Ratio	-0.5478774, $p=0.560$ (-2406422 - 1.310667)	1.050922, $p=0.116$ (-3.184021 - 0.4393169)	-0.6881018, $p=0.523$ (-2.818025 - 1.441821)
	Nurse/Bed Ratio	0.1945378, $p=0.645$ (-0.6411264 - 1.030202)	0.5863799, $p=0.156$ (-0.2282075 - 1.400967)	0.2639961, $p=0.586$ (-0.693689 - 1.221681)
	Academic Status	0.4989478, $p=0.465$ (-0.8488511 - 1.846747)	1.050922, $p=0.116$ (-2.628831 - 2.364728)	0.1318875, $p=0.866$ (-1.412713 - 1.676488)
	SHMI	-0.0938429, $p=0.967$ (-4.57377 - 4.386085)	0.2934054, $p=0.894$ (-4.073532 - 4.660342)	-1.389247, $p=0.593$ (-6.523319 - 3.744825)
	HFC	0.1470753, $p=0.136$ (-0.046984 - 0.3411346)	0.195927, $p=0.042$ (0.00614498 - 0.217848)	0.1705969, $p=0.131$ (-0.0517983 - 0.3929921)
	LLOS	-0.0077176, $p=0.721$ (-0.0504117 - 0.0349765)	-0.0198325, $p=0.347$ (-0.0614498 - 0.0217848)	0.1705969, $p=0.131$ (-0.0813831 - 0.0164731)

Key:

AW – domain average for access and waiting

SHQCC – domain average for safe, high-quality and co-ordinated care

BIMC – domain average for better information and more choice

BR – domain average for building closer relationships

CCFP – domain average for clean, friendly and comfortable place to be

OPES – domain average for overall patient experience score

SHMI – summary hospital-level mortality indicator

HFC – proportion of patients receiving harm free care

LLOS – relative risk of long length of stay

Table 2.10 - Univariate regression analysis matrix showing the relationships between Clinical Digital Maturity Index (CDMI) Score and 2016 NHS Staff Survey Scores (n=126, significance at $p < 0.05$)

		Independent Variables – 2016 NHS Staff Survey Domains (B, p, 95% CI)								
		KF1	KF2	KF7	KF9	KF14	KF30	KF31	KF32	Overall Engagement
Dependent Variables – CDMI Domains	Aggregate CDMI Score	0.0001919 $p=0.028$ (0.0000214 - 0.0003624)	0.000048 $p=0.331$ (-0.0000492 - 0.0001453)	0.00026 $p=0.130$ (-7.72 ⁻⁶ - 0.0000597)	0.0000106 $p=0.756$ (-0.0000571 - 0.0000784)	0.0000462 $p=0.355$ (-0.0000522 - 0.0001445)	0.000527 $p=0.212$ (-0.0000305 - 0.0001359)	0.0000806 $p=0.068$ (-6.02 ⁻⁶ - 0.0001672)	0.000281 $p=0.596$ (-0.0000765 - 0.0001328)	0.0000771 $p=0.098$ (-0.0000145 - 0.0001687)
	Readiness score	0.0005584 $p=0.067$ (-0.00004 - 0.0011568)	0.0002746 $p=0.114$ (-0.0000666 - 0.0006159)	0.0000812 $p=0.178$ (-0.0000375 - 0.0001999)	0.0002162 $p=0.073$ (-0.0000201 - 0.0004524)	0.0003782 $p=0.029$ (0.0000387 - 0.0007177)	0.0003171 $p=0.032$ (0.0000271 - 0.0006071)	0.0003401 $p=0.028$ (0.0000377 - 0.0006425)	0.0003719 $p=0.046$ (7.48 ⁻⁶ - 0.0007364)	0.0003168 $p=0.053$ (-3.96 ⁻⁶ - 0.0006376)
	Capability Score	0.0000452 $p=0.789$ (-0.0002888 - 0.0003792)	-0.000315 $p=0.744$ (-0.000222 - 0.000159)	0.0000165 $p=0.623$ (-0.0000375 - 0.0001999)	-5.52 ⁻⁶ $p=0.934$ (-0.0001374 - 0.0001263)	-0.0001292 $p=0.180$ (-0.0003187 - 0.0000603)	8.9 ⁻⁶ $p=0.913$ (-0.000153 - 0.0001708)	0.0000395 $p=0.644$ (-0.0001292 - 0.0002083)	-0.0000399 $p=0.699$ (-0.0002433 - 0.0001635)	0.0000128 $p=0.888$ (-0.0001663 - 0.0001918)
	Infrastructure Score	-0.0000789 $p=0.954$ (-0.0027651 - 0.0026073)	-0.0002185 $p=0.778$ (-0.0017503 - 0.0013133)	-0.0001256 $p=0.642$ (-0.0000498 - 0.0000828)	-0.0007214 $p=0.181$ (-0.0017818 - 0.000339)	0.0001726 $p=0.823$ (-0.0013512 - 0.0016963)	-0.0006875 $p=0.298$ (-0.0019892 - 0.0006143)	-0.0006628 $p=0.336$ (-0.0020201 - 0.0006946)	-0.000837 $p=0.313$ (-0.0024729 - 0.0007988)	-0.0003774 $p=0.605$ (-0.0018172 - 0.0010624)

Key:

KF1 – staff recommendation as a place to work or receive treatment
 KF2 – staff satisfaction with the quality of work and care they are able to deliver
 KF7 – % of staff able to contribute towards improvements at work
 KF9 – effective team working
 KF14 – staff satisfaction with resourcing and support

KF30 – fairness and effectiveness of procedures for reporting errors, near misses and incidents
 KF31 – staff confidence and security in reporting unsafe clinical practice
 KF32 – effective use of patient/service user feedback

Table 2.11a - Kitchen sink multivariate regression analysis matrix for 2016 NHS Staff Survey and aggregate Clinical Digital Maturity Index (CDMI) score with all covariates included (n=126, significance at $p<0.05$)

		2016 NHS Staff Survey Domains (B, p, 95% CI)				
		KF1	KF2	KF7	KF9	KF14
Covariate	Aggregate CDMI score	0.000071, $p=0.446$ (-0.000113 - 0.000255)	8.81 ⁻⁶ , $p=0.880$ (-0.0001062 - 0.0001238)	0.000017, $p=0.359$ (-0.0000198 - 0.0000542)	7.43 ⁻⁶ , $p=0.845$ (-0.0000675 - 0.0000824)	0.000013, $p=0.832$ (-0.0001049 - 0.0001301)
	A&E Attendances	-1.07 ⁻⁶ , $p=0.003$ (-1.76 ⁻⁶ - 3.81 ⁻⁷)	2.65 ⁻⁷ , $p=0.225$ (-1.66 ⁻⁷ - 6.95 ⁻⁷)	-1.10 ⁻⁷ , $p=0.117$ (-2.49 ⁻⁷ - 2.82 ⁻⁸)	-2.94 ⁻⁷ , $p=0.040$ (-5.74 ⁻⁷ - -1.33 ⁻⁸)	-1.43 ⁻⁷ , $p=0.522$ (-5.83 ⁻⁷ - 2.97 ⁻⁷)
	Admissions	-1.48 ⁻⁶ , $p=0.123$ (-3.38 ⁻⁶ - 4.09 ⁻⁷)	-1.02 ⁻⁶ , $p=0.092$ (2.20 ⁻⁶ - 1.68 ⁻⁷)	-2.96 ⁻⁷ , $p=0.127$ (-6.77 ⁻⁷ - 8.57 ⁻⁸)	-4.7 ⁻⁷ , $p=0.230$ (-1.24 ⁻⁷ - -1.33 ⁻⁸)	-8.22 ⁻⁷ , $p=0.181$ (-2.03 ⁻⁶ - 3.88 ⁻⁷)
	Total Staff	0.000018, $p=0.232$ (-0.0000117 - 0.0000476)	-6.81 ⁻⁶ , $p=0.468$ (-0.0000253 - 0.0000117)	5.16 ⁻⁶ , $p=0.090$ (-8.14 ⁻⁷ - 0.0000111)	0.000013, $p=0.031$ (1.22 ⁻⁶ - 0.0000254)	2.22 ⁻⁶ , $p=0.816$ (-0.0000167 - 0.0000212)
	Clinical/Non-Clinical Ratio	0.123326, $p=0.362$ (-0.1435488 - 0.3902)	0.050724, $p=0.548$ (-0.1160389 - 0.2174859)	0.067304, $p=0.015$ (0.0135802 - 0.1210277)	0.102568, $p=0.064$ (-0.0061005 - 0.2112358)	-0.52886, $p=0.540$ (-0.2233397 - 0.1175669)
	Dr/Nurse Ratio	0.578174, $p=0.014$ (0.1213344 - 1.035014)	0.015249, $p=0.916$ (-0.2702171 - 0.3007155)	0.631001, $p=0.177$ (-0.028865 - 0.1550651)	0.066129, $p=0.483$ (-0.1198912 - 0.2521484)	0.055625, $p=0.706$ (-0.2361597 - 0.3474094)
	Cons/Jnr Ratio	0.298462, $p=0.018$ (0.0527514 - 0.5441773)	0.021884, $p=0.778$ (-0.1316541 - 0.1754218)	0.054267, $p=0.032$ (0.0048039 - 0.1037306)	0.088781, $p=0.081$ (-0.011271 - 0.1888312)	0.093742, $p=0.239$ (-0.631946 - 0.2506777)
	General Beds	0.000183, $p=0.140$ (-0.0000609 - 0.0004274)	0.000118, $p=0.131$ (-0.0000356 - 0.0002696)	0.000021, $p=0.410$ (-0.0000286 - 0.0000697)	0.000022, $p=0.661$ (-0.0000773 - 0.0001215)	0.000109, $p=0.168$ (-0.0000469 - 0.000265)
	ITU Beds	0.000183, $p=0.186$ (-0.0007434 - 0.0042239)	0.001114, $p=0.158$ (-0.0004385 - 0.0026655)	0.000194, $p=0.443$ (-0.0003056 - 0.0006944)	0.000118, $p=0.817$ (-0.0008929 - 0.0011297)	0.000360, $p=0.653$ (-0.001226 - 0.0019467)
	General Bed Occupancy	-0.032498, $p=0.910$ (-0.6036238 - 0.5386274)	-0.98473, $p=0.586$ (-0.4553537 - 0.2584074)	0.51455, $p=0.377$ (-0.0635169 - 0.1664264)	0.047410, $p=0.687$ (-0.01851459 - 0.2799656)	-0.036545, $p=0.843$ (-0.4013245 - 0.328341)
	ITU Bed Occupancy	-0.213967, $p=0.159$ (-0.513256 - 0.0853226)	-0.118773, $p=0.211$ (-0.3057909 - 0.0682442)	-0.085183, $p=0.006$ (-0.1454319 - -0.0249338)	-0.063614, $p=0.303$ (-0.1854815 - 0.0582528)	-0.124724, $p=0.199$ (-0.3158808 - 0.0664328)
	Doctor/Bed Ratio	-0.158229, $p=0.042$ (-0.310263 - -0.0061959)	-0.75614, $p=0.118$ (-0.1706156 - 0.0193874)	-0.020361, $p=0.190$ (-0.0509666 - 0.0102443)	-0.043015, $p=0.171$ (-0.1049212 - 0.0188914)	-0.072103, $p=0.144$ (-0.1692068 - 0.0250015)
	Nurse/Bed Ratio	0.078027, $p=0.025$ (0.0098002 - 0.1462542)	0.040079, $p=0.065$ (-0.0025539 - 0.0827125)	0.011720, $p=0.094$ (-0.0020142 - 0.025455)	0.026377, $p=0.063$ (-0.0014045 - 0.054158)	0.035033, $p=0.114$ (-0.0085436 - 0.0786099)
	Academic Status	-0.068493, $p=0.255$ (-0.1798303 - 0.0428444)	-0.025636, $p=0.467$ (-0.0952076 - 0.0439357)	-0.25428, $p=0.027$ (-0.0478412 - -0.0030152)	-0.065686, $p=0.005$ (-0.1110213 - -0.0203508)	-0.008956, $p=0.803$ (-0.0800679 - 0.062155)
	SHMI	-0.175745, $p=0.341$ (-0.5402174 - 0.1887271)	-0.136052, $p=0.906$ (-0.2413538 - 0.2142433)	-0.02090, $p=0.574$ (-0.0942688 - 0.0524729)	-0.028510, $p=0.704$ (-0.1769186 - 0.1198991)	0.029341, $p=0.803$ (-0.2034479 - 0.2621307)
	HFC	0.23853, $p=0.004$ (0.0079021 - 0.0398044)	0.013111, $p=0.598$ (0.003144 - 0.0230789)	0.005400, $p=0.001$ (0.0021891 - 0.0086112)	0.010396, $p=0.002$ (0.0039006 - 0.0168908)	1.033995, $p=0.001$ (0.0050788 - 0.0254549)
	LLOS	0.000212, $p=0.905$ (-0.0032887 - 0.0037135)	0.000584, $p=0.598$ (-0.0016038 - 0.0027717)	0.000197, $p=0.582$ (-0.0005083 - 0.0009013)	0.000395, $p=0.584$ (-0.0010304 - 0.0018209)	-9.51 ⁻⁶ , $p=0.993$ (-0.0022457 - 0.0022267)

		2016 NHS Staff Survey Domains (B, p, 95% CI)			
		KF30	KF31	KF32	OES
Covariate	Aggregate CDMI score	-0.000012, p=0.798 (-0.0001055 - 0.0000813)	0.00006, p=0.237 (0.0000393 - 0.0001573)	-0.000018, p=0.771 (-0.000142 - 0.0001055)	0.000035, p=0.495 (-0.0000654 - 0.0001345)
	A&E Attendances	-2.51 ⁻⁷ , p=0.157 (-6.01 ⁻⁷ - 9.83 ⁻⁸)	-1.67 ⁻⁷ , p=0.371 (-5.35 ⁻⁷ - 2.01 ⁻⁷)	-3.47 ⁻⁷ , p=0.140 (-8.11 ⁻⁷ - 1.16 ⁻⁷)	-4.54 ⁻⁷ , p=0.018 (-8.28 ⁻⁷ - -7.95 ⁻⁸)
	Admissions	-4.97 ⁻⁷ , p=0.308 (-1.46 ⁻⁶ - 4.65 ⁻⁷)	-1.13 ⁻⁶ , p=0.029 (-2.14 ⁻⁶ - 1.20 ⁻⁷)	-1.53 ⁻⁶ , p=0.019 (-2.81 ⁻⁶ - -2.59 ⁻⁷)	-8.50 ⁻⁷ , p=0.104 (-1.88 ⁻⁶ - 1.79 ⁻⁷)
	Total Staff	0.000011, p=0.167 (-4.50 ⁻⁶ - 0.0000256)	0.000014, p=0.076 (-1.54 ⁻⁶ - 0.0000302)	0.000019, p=0.064 (-1.10 ⁻⁶ - 0.0000388)	9.83 ⁻⁶ , p=0.229 (-6.28 ⁻⁶ - 0.0000259)
	Clinical/Non-Clinical Ratio	0.105629, p=0.125 (-0.0298662 - 0.2411234)	0.83894, p=0.246 (-0.0586962 - 0.226484)	0.159619, p=0.081 (-0.0198965 - 0.3391349)	0.095941, p=0.192 (-0.0490343 - 0.2409165)
	Dr/Nurse Ratio	0.63022, p=0.591 (-0.1689202 - 0.2949638)	-0.011772, p=0.924 (-0.25586 - 0.2323158)	0.244018, p=0.118 (-0.0632799 - 0.5513152)	0.289934, p=0.022 (0.0417531 - 0.5380952)
	Cons/Jnr Ratio	0.131329, p=0.039 (0.0065795 - 0.2560793)	0.132732, p=0.048 (0.0014491 - 0.2640142)	0.151733, p=0.072 (-0.0135465 - 0.3170133)	0.148368, p=0.030 (0.0148892 - 0.2818466)
	General Beds	0.000043, p=0.497 (-0.0000813 - 0.0001666)	0.000082, p=0.215 (-0.0000483 - 0.0002126)	0.00015, p=0.073 (-0.0000142 - 0.0003143)	0.000100, p=0.137 (-0.0000324 - 0.0002329)
	ITU Beds	0.000785, p=0.22 (-0.0004765 - 0.0020455)	0.000878, p=0.193 (-0.0004495 - 0.0022046)	0.000384, p=0.650 (-0.0012871 - 0.0020543)	0.000772, p=0.259 (-0.0005771 - 0.0021214)
	General Bed Occupancy	0.72674, p=0.620 (-0.2172925 - 0.3626398)	0.104865, p=0.497 (-0.2002859 - 0.4100153)	-0.023900, p=0.902 (-0.408073 - 0.3602735)	0.04372, p=0.781 (-0.2665322 - 0.3539783)
	ITU Bed Occupancy	-0.154624, p=0.046 (-0.3065758 - -0.0026715)	-0.163279, p=0.045 (-0.3231861 - -0.0033675)	-0.089492, p=0.380 (-0.2908122 - 0.1118276)	-0.150387, p=0.069 (-0.3129714 - 0.0121973)
	Doctor/Bed Ratio	-0.077779, p=0.048 (-0.1549675 - -0.0005896)	-0.077569, p=0.061 (-0.1588002 - 0.0036618)	-0.031990, p=0.537 (-0.1342563 - 0.0702773)	-0.097812, p=0.021 (-0.180402 - -0.0152222)
	Nurse/Bed Ratio	0.038917, p=0.028 (0.0042772 - 0.0735563)	0.043366, p=0.020 (0.006912 - 0.0798189)	0.015596, p=0.502 (-0.0302973 - 0.0614899)	0.049671, p=0.009 (0.0126073 - 0.0867339)
	Academic Status	-0.031692, p=0.269 (-0.0882192 - 0.0248349)	-0.029844, p=0.497 (-0.0893307 - 0.0296436)	-0.064790, p=0.089 (-0.1396819 - 0.0101025)	-0.061134, p=0.048 (-0.1216167 - -0.000652)
	SHMI	-0.077449, p=0.409 (-0.2624947 - 0.1075977)	-0.048159, p=0.625 (-0.2428952 - 0.1465774)	-0.083650, p=0.500 (-0.3288161 - 0.1615156)	-0.110979, p=0.269 (-0.3089727 - 0.0870152)
	HFC	0.012730, p=0.002 (0.0046313 - 0.0208284)	0.009583, p=0.028 (0.0010603 - 0.0181056)	0.011755, p=0.032 (0.0010253 - 0.0224847)	0.012626, p=0.005 (0.0039608 - 0.0212913)
	LLOS	-9.7 ⁻⁶ , p=0.991 (-0.0017872 - 0.0017678)	-0.000637, p=0.501 (-0.0025075 - 0.0012338)	-0.001318, p=0.270 (-0.003673 - 0.0010372)	0.000534, p=0.579 (-0.0013683 - 0.024355)

Table 2.11b - Kitchen sink multivariate regression analysis matrix for 2016 NHS Staff Survey and each Clinical Digital Maturity Index (CDMI) domain score with all covariates included (n=126, significance at $p<0.05$)

		2016 NHS Staff Survey Domains (B, p, 95% CI)				
		KF1	KF2	KF7	KF9	KF14
Covariate	Readiness Domain	0.000614, $p=0.040$ (0.0000284 - 0.0011993)	0.000184, $p=0.328$ (0.0001866 - 0.0005538)	0.000077, $p=0.205$ (-0.0000425 - 0.0001961)	0.000236, $p=0.052$ (-2.23 ⁻⁶ - 0.0004736)	0.000357, $p=0.061$ (-0.0000163 - 0.0007303)
	Capability Domain	-0.000017, $p=0.916$ (-0.0003434 - 0.0003087)	-0.000055, $p=0.597$ (-0.0002613 - 0.000151)	3.72 ⁻⁶ , $p=0.912$ (-0.0000627 - 0.0000702)	-9.11 ⁻⁶ , $p=0.892$ (-0.0001416 - 0.0001234)	-0.000097, $p=0.357$ (-0.0003049 - 0.0001108)
	Infrastructure Domain	-0.001295, $p=0.342$ (-0.0039814 - 0.0013923)	-0.000110, $p=0.899$ (-0.0018085 - 0.0015896)	-0.000097, $p=0.722$ (-0.0006461 - 0.0004489)	-0.000753, $p=0.175$ (-0.0018444 - 0.0003394)	-0.000369, $p=0.670$ (-0.0020823 - 0.001344)
	A&E Attendances	-1.18 ⁻⁶ , $p=0.001$ (-1.88 ⁻⁶ - -4.76 ⁻⁷)	2.47 ⁻⁷ , $p=0.274$ (-1.98 ⁻⁷ - 6.92 ⁻⁷)	1.21 ⁻⁷ , $p=0.098$ (-2.64 ⁻⁷ - 2.27 ⁻⁸)	-3.50 ⁻⁷ , $p=0.017$ (-6.36 ⁻⁷ - 6.40 ⁻⁸)	-1.86 ⁻⁷ , $p=0.414$ (-6.34 ⁻⁷ - 2.63 ⁻⁷)
	Admissions	1.64 ⁻⁶ , $p=0.087$ (-3.53 ⁻⁶ - 2.44 ⁻⁷)	-1.08 ⁻⁶ , $p=0.076$ (-2.27 ⁻⁶ - 1.16 ⁻⁷)	-3.14 ⁻⁷ , $p=0.108$ (-6.99 ⁻⁷ - 2.27 ⁻⁸)	-5.30 ⁻⁷ , $p=0.174$ (-1.30 ⁻⁶ - 2.37 ⁻⁷)	-9.4 ⁻⁷ , $p=0.124$ (-2.14 ⁻⁶ - 2.64 ⁻⁷)
	Total Staff	0.000017, $p=0.275$ (-0.0000134 - 0.0000467)	-6.38 ⁻⁶ , $p=0.508$ (-0.0000254 - 0.0000126)	5.10 ⁻⁶ , $p=0.102$ (-1.03 ⁻⁶ - 0.0000112)	0.000012, $p=0.049$ (2.76 ⁻⁸ - 0.0000245)	2.67 ⁻⁶ , $p=0.783$ (-0.0000165 - 0.0000219)
	Clinical/Non-Clinical Ratio	0.129025, $p=0.337$ (-0.1361984 - 0.3942479)	0.054483, $p=0.521$ (-0.1132359 - 0.222201)	0.06813, $p=0.014$ (0.014089 - 0.122179)	0.103850, $p=0.059$ (-0.0039358 - 0.2116565)	-0.046368, $p=0.588$ (-0.2154736 - 0.1227371)
	Dr/Nurse Ratio	0.617899, $p=0.009$ (0.1609876 - 1.074809)	0.022337, $p=0.878$ (-0.2665986 - 0.3112735)	0.066855, $p=0.157$ (-0.0262507 - 0.1599605)	0.08613, $p=0.360$ (-0.0995606 - 0.2718147)	0.072230, $p=0.624$ (-0.2190944 - 0.3635551)
	Cons/Jnr Ratio	0.303696, $p=0.016$ (0.0587335 - 0.5486593)	0.020314, $p=0.795$ (-0.1345922 - 0.1752209)	0.05450, $p=0.033$ (0.0045795 - 0.1044125)	0.092864, $p=0.067$ (-0.0066886 - 0.1924163)	0.092154, $p=0.245$ (-0.0640336 - 0.2483413)
	General Beds	0.000235, $p=0.066$ (-0.0000157 - 0.0004859)	0.000128, $p=0.111$ (-0.0000302 - 0.000287)	0.000026, $p=0.322$ (-0.0000254 - 0.0000768)	0.000047, $p=0.364$ (-0.000055 - 0.0001488)	0.000134, $p=0.099$ (-0.0000259 - 0.000294)
	ITU Beds	0.001581, $p=0.207$ (-0.0008892 - 0.0040505)	0.001061, $p=0.181$ (-0.0005014 - 0.0026223)	0.000177, $p=0.488$ (-0.0003266 - 0.0000768)	0.000052, $p=0.918$ (-0.0009515 - 0.001056)	0.000257, $p=0.747$ (-0.0013181 - 0.0018314)
	General Bed Occupancy	0.060159, $p=0.837$ (-0.518237 - 0.6385548)	-0.059431, $p=0.748$ (-0.4251899 - 0.3063275)	0.062605, $p=0.295$ (-0.0552561 - 0.1804655)	0.081033, $p=0.496$ (-0.1540258 - 0.3160921)	0.036137, $p=0.846$ (-0.3326464 - 0.40492)
	ITU Bed Occupancy	-0.202862, $p=0.180$ (-0.5008447 - 0.0951201)	-0.112150, $p=0.241$ (-0.3005846 - 0.0762841)	-0.08364, $p=0.007$ (-0.1443604 - -0.0229196)	-0.060710, $p=0.323$ (-0.181809 - 0.0603899)	-0.113081, $p=0.241$ (-0.3030737 - 0.0769113)
	Doctor/Bed Ratio	-0.136864, $p=0.078$ (-0.2893818 - 0.0156535)	-0.069468, $p=0.156$ (-0.1659147 - 0.0269797)	-0.018094, $p=0.251$ (-0.491724 - 0.129852)	-0.033601, $p=0.285$ (-0.0955925 - 0.0283732)	-0.059651, $p=0.227$ (-0.1568954 - 0.0375941)
	Nurse/Bed Ratio	0.068738, $p=0.049$ (0.0001608 - 0.1373149)	0.037855, $p=0.086$ (-0.0055111 - 0.812207)	0.010782, $p=0.129$ (-0.003192 - 0.247562)	0.022028, $p=0.120$ (-0.0058413 - 0.0498979)	0.030295, $p=0.172$ (-0.0134296 - 0.0740194)
	Academic Status	-0.06548, $p=0.243$ (-0.1760804 - 0.451284)	-0.025288, $p=0.475$ (-0.0952301 - 0.0446551)	-0.025163, $p=0.029$ (-0.0477013 - -0.0026252)	-0.064057, $p=0.006$ (-0.1090068 - -0.19108)	-0.007982, $p=0.823$ (-0.0785026 - 0.0625393)
	SHMI	-0.214191, $p=0.251$ (-0.5818269 - 0.1534453)	-0.03339, $p=0.776$ (-0.2658721 - 0.1990901)	-0.025905, $p=0.494$ (-0.1008193 - 0.0490085)	-0.04039, $p=0.593$ (-0.1897926 - 0.1090206)	-0.006225, $p=0.958$ (-0.2406286 - 0.2281784)
	HFC	0.023967, $p=0.004$ (0.0080416 - 0.0398917)	0.012902, $p=0.013$ (0.002831 - 0.022972)	0.005386, $p=0.001$ (0.0021413 - 0.0086315)	0.010586, $p=0.002$ (0.004114 - 0.0170578)	0.014967, $p=0.004$ (0.0048134 - 0.0251209)
	LLOS	-0.000211, $p=0.905$ (-0.0037145 - 0.0032927)	0.000429, $p=0.702$ (-0.0017869 - 0.0026442)	0.000148, $p=0.682$ (-0.0005659 - 0.000862)	0.000228, $p=0.751$ (-0.0011955 - 0.0016522)	-0.000307, $p=0.786$ (-0.0025407 - 0.0019271)

		2016 NHS Staff Survey Domains (B, p, 95% CI)			
		KF30	KF31	KF32	OES
Covariate	Readiness Domain	0.000261, p=0.085 (-0.0000367 - 0.000558)	0.000320, p=0.046 (6.12 ⁻⁶ - 0.0006336)	0.000505, p=0.011 (0.0001187 - 0.0008915)	0.000357, p=0.027 (0.0000404 - 0.0006742)
	Capability Domain	-0.000061, p=0.464 (-0.0002269 - 0.0001042)	-2.82 ⁻⁶ , p=0.975 (-0.0001775 - 0.0001719)	-0.000101, p=0.352 (-0.0003166 - 0.0001138)	-8.32 ⁻⁶ , p=0.926 (-0.0001848 - 0.0001681)
	Infrastructure Domain	-0.00065, p=0.344 (-0.0020186 - 0.0007106)	-0.000422, p=0.562 (-0.001862 - 0.0010178)	-0.001352, p=0.134 (-0.0031256 - 0.0004211)	-0.000864, p=0.241 (-0.0023186 - 0.00059)
	A&E Attendances	-3.04 ⁻⁷ , p=0.095 (-6.62 ⁻⁷ - 5.33 ⁻⁸)	-2.10 ⁻⁷ , p=0.273 (-5.87 ⁻⁷ - 1.67 ⁻⁷)	-4.54 ⁻⁷ , p=0.055 (-9.18 ⁻⁷ - 1.07 ⁻⁸)	-5.24 ⁻⁷ , p=0.008 (-9.05 ⁻⁷ - 1.43 ⁻⁷)
	Admissions	-5.78 ⁻⁷ , p=0.234 (-1.54 ⁻⁶ - 3.80 ⁻⁷)	-1.21 ⁻⁶ , p=0.019 (-2.23 ⁻⁷ - -2.03 ⁻⁷)	-1.69 ⁻⁶ , p=0.008 (-2.93 ⁻⁶ - -4.40 ⁻⁷)	-9.42 ⁻⁷ , p=0.070 (-1.96 ⁻⁶ - 8.01 ⁻⁸)
	Total Staff	0.0001, p=0.197 (-5.26 ⁻⁶ - 0.0000253)	0.000014, p=0.085 (-1.98 ⁻⁶ - 0.0000303)	0.000018, p=0.083 (-2.32 ⁻⁶ - 0.0000374)	8.82 ⁻⁶ , p=0.285 (-7.46 ⁻⁶ - 0.0000251)
	Clinical/Non-Clinical Ratio	0.108757, p=0.112 (-0.025946 - 0.2434598)	0.087681, p=0.224 (-0.54455 - 0.2298165)	0.165007, p=0.064 (-0.0100448 - 0.3400586)	0.98808, p=0.175 (-0.0447514 - 0.2423671)
	Dr/Nurse Ratio	0.082197, p=0.484 (-0.1498616 - 0.3142549)	0.004210, p=0.973 (-0.2406529 - 0.2490734)	0.282626, p=0.066 (-0.018943 - 0.5841946)	0.315085, p=0.013 (0.0677 - 0.5624008)
	Cons/Jnr Ratio	0.133511, p=0.036 (0.0090984 - 0.2579244)	0.133474, p=0.046 (0.0021956 - 0.2647518)	0.156959, p=0.057 (-0.0047211 - 0.3186381)	0.152361, p=0.025 (0.0197687 - 0.2849543)
	General Beds	0.000068, p=0.293 (-0.0000594 - 0.0001953)	0.000104, p=0.127 (-0.0000302 - 0.0002386)	0.000200, p=0.018 (0.0000348 - 0.0003658)	0.000133, p=0.056 (-3.26 ⁻⁶ - 0.0002682)
	ITU Beds	0.000704, p=0.268 (-0.0005503 - 0.0019584)	0.0008, p=0.233 (-0.0005236 - 0.0021236)	0.000230, p=0.780 (-0.0014003 - 0.00186)	0.000678, p=0.317 (-0.0006591 - 0.0020146)
	General Bed Occupancy	0.120496, p=0.418 (-0.1732623 - 0.4142551)	0.154407, p=0.326 (-0.1555617 - 0.4643747)	0.064912, p=0.737 (-0.3168394 - 0.4466625)	0.096312, p=0.543 (-0.2167608 - 0.4093842)
	ITU Bed Occupancy	-0.148625, p=0.054 (-0.2999656 - 0.002716)	-0.156280, p=0.055 (-0.3159721 - 0.0034115)	-0.07896, p=0.428 (-0.25756293 - 0.1177174)	-0.144612, p=0.078 (-0.3059025 - 0.0166796)
	Doctor/Bed Ratio	-0.067144, p=0.089 (-0.1446058 - 0.0103171)	-0.067702, p=0.104 (-0.1494373 - 0.0140342)	-0.011353, p=0.823 (-0.1120176 - 0.0893108)	-0.084912, p=0.044 (-1.674664 - -0.0023577)
	Nurse/Bed Ratio	0.034355, p=0.053 (-0.0004745 - 0.069184)	0.039319, p=0.036 (0.002568 - 0.0760703)	0.006599, p=0.773 (-0.0386627 - 0.518613)	0.043940, p=0.021 (0.0068212 - 0.0810596)
	Academic Status	-0.030262, p=0.288 (-0.864363 - 0.0259123)	-0.028733, p=0.339 (-0.0880702 - 0.0305408)	-0.061847, p=0.096 (-0.1348478 - 0.0111537)	-0.059172, p=0.053 (-0.1190396 - 0.0006957)
	SHMI	-0.097785, p=0.301 (-0.2845017 - 0.0889322)	-0.070669, p=0.479 (-0.2676887 - 0.1263512)	-0.120302, p=0.328 (-0.3629483 - 0.1223437)	-0.131827, p=0.192 (-0.3308203 - 0.0671658)
	HFC	0.012753, p=0.002 (0.0046648 - 0.020841)	0.009503, p=0.029 (0.0009687 - 0.0180376)	0.018878, p=0.027 (0.0013671 - 0.0223887)	0.012760, p=0.004 (0.0041404 - 0.0213801)
	LLOS	-0.00022, p=0.803 (-0.0020044 - 0.0015544)	-0.000851, p=0.371 (-0.0027282 - 0.001027)	0.001725, p=0.142 (-0.0040373 - 0.0005876)	0.000287, p=0.765 (-0.0016093 - 0.0021836)

Key

KF1 – staff recommendation as a place to work or receive treatment

KF2 – staff satisfaction with the quality of work and care they are able to deliver

KF7 – percentage of staff able to contribute towards improvements at work

KF9 – effective team working

KF14 – staff satisfaction with resourcing and support

KF30 – fairness and effectiveness of procedures for reporting errors, near misses and incidents

KF31 – staff confidence and security in reporting unsafe clinical practice

KF32 – effective use of patient/service user feedback

OES – overall engagement score

SHMI – summary hospital-level mortality indicator

HFC – proportion of patients receiving harm free care

LLOS – relative risk of long length of stay

Chapter 3 - The impact of mobile technology on teamwork and communication: a systematic review

A key area where new technology has the potential to improve the quality of healthcare is through supporting better teamwork and communication. Mobile technologies have radically changed the way we live our lives but as of yet their penetration into supporting the direct delivery of care has been sparse. This chapter therefore seeks to understand the current impact of mobile technology on communication and teamwork within secondary care and the quality of evidence supporting its use through a systematic review of the literature.

3.1 - Introduction

Effective communication between healthcare professionals within hospitals is critical to clinical effectiveness and the safe delivery of care, but is frequently characterised by a reliance on aging technology, fragmentation and poor organisation. The delivery of high-quality care inherently relies upon effective communication and the inaccurate, incomplete, or delayed transfer of information can easily result in avoidable errors and patient harm^{19,253–255}. It is therefore of no surprise that failures in communication have been highlighted as occurring nearly twice as often as failures in care due to inadequate medical skill or knowledge²⁵⁶, and contribute to more than half of all adverse patient safety events^{254,257}.

Inter-professional communication and teamwork within hospitals still commonly relies upon multiple outdated and disparate technologies such as one-way pagers, fixed telephones and fax machines, supplemented by face-to-face conversation and newer technologies such as email and mobile phones. Outside of medicine there has been a technological revolution in handheld communication devices over the past decade, spawning whole new ways to effectively and reliably communicate, collaborate and share information. Whilst comparisons can be made with other sectors, the requirements for immediacy, accuracy and efficiency of communication within healthcare, together with the potentially harmful consequences of

communication failure means that the influence of emergent communication technologies and digital devices must be studied robustly. Any changes to clinical practice as a result of the deployment of new technologies must be based on evidence, and not upon transient technology trends or individual preference. Despite this, hospital communication systems still receive much less attention and focus than other areas of innovation such as electronic health records; forcing organisations and individuals to navigate an increasingly complicated and fragmented communication space with little evidence or insight upon which to base decisions.

The complexity of the hospital communication space requires healthcare providers to communicate through multiple disparate modes. Increasing age, and the relative maturity of a technology does not necessarily mean it is not fit for purpose, however, numerous problems have been highlighted with the traditional pagers that are responsible for a significant proportion of the communication burden in hospital. Commonly identified problems with this technology and the generalised fragmentation of communication include the communication burden, frustrations amongst staff, interruptive communication behaviours, and limitations in data transfer and the supply of supporting contextual information. These inefficiencies, problems and frustrations not only directly impact patients, but also lead to an estimated \$12 billion additional cost to hospitals in the US each year, which represents around \$4 million annually for a typical 500 bed hospital as a conservative estimate of the direct economic burden of poor communication²⁵⁸.

With regards workload and interruptions, clinicians can spend up to 3 hours per shift in communication of one form or another²⁵⁹, and typically receive up to 60 'pages' per shift with peaks in message volume seen during nursing handover and periods of reduced nursing workload, and only a matter of minutes between each page²⁶⁰. Meanwhile, it has been suggested that around a quarter of these disruptive messages may be unimportant or unnecessary with only one-third actually resulting in a change in clinical care^{261,262}. Furthermore, the expansion of the multi-disciplinary team and rapid proliferation of communication devices means the challenge of who to contact, and how to contact them,

particularly for routine clinical communications has also been highlighted as a long-standing problem²⁶³. Interruptions to communication and task events are a common source of error, and can add to cognitive load, trigger cognitive failures, increase stress and anxiety, inhibit decision-making and ultimately lead to errors or a failure to complete tasks^{264–266}. Hospital environments are dynamic, characterised by resource and time constraints and typically interruption-driven with a high multi-tasking workload²⁶⁷. Patient contact and safety critical tasks are frequently interrupted by traditional methods of communication such as pagers²⁶⁸, with the overwhelming majority of interruptions typically non-urgent²⁶⁹. These common communication behaviours experienced by clinicians can therefore lead an environment littered with interruptions and truncated or incomplete clinical tasks; contributing to inefficiency and the potential for harmful failures in patient care^{270–272}.

Traditional paging systems are inherently flawed by the unidirectional and constrained nature of data transfer and lack of supporting information to provide vital context to any message^{273,274}. Indeed, a significant number of alphanumeric pager messages lack sufficient information, do not indicate the urgency of the page, and still require immediate call-back by the doctor for clarification and further decision making and communication²⁷⁴. Meanwhile, automated systems which aim to alert clinicians to pertinent clinical information have, at best, had a modest impact on performance and outcomes²⁷⁵, whilst also being identified as a source of alert fatigue which in itself may lead to patient harm. The desensitisation to alarms or alerts, which may be false or clinically irrelevant can result in fatigue; a cacophony of alerts and alarms can rapidly become background noise or even an irritant, leading to them being disabled or ignored by clinicians which is a significant risk to safety in its own right^{276,277}.

In response to these problems, and in an attempt to address many of the frustrations experienced by clinicians a variety of mobile based solutions have been proposed and deployed. Mobile devices have been increasingly employed by clinicians for internet access, team coordination and information exchange²⁷⁸. Indeed, the use of mobile technology by clinical staff in their day-to-day work is virtually ubiquitous, although also largely based upon

the use of personal devices. Mobile-based technology certainly has the potential to tackle many of the challenges encountered with traditional forms of communication, whilst simultaneously acting to improve communication, enhance teamwork and widen access to clinical information. Despite these huge potential benefits, the rapid uptake of such technology in other sectors, and its widespread informal use by healthcare workers in other settings at work mobile technology has still not been widely formally adopted within the healthcare setting.

There has undoubtedly been rapid technological advances and proliferation of new communication technologies, however, there is little robust empirical evidence upon which to assess the relative advantages and disadvantages of such technologies²⁷⁹ in order to support the delivery of optimal smartphone-based communication strategies within the hospital setting. It remains to be robustly demonstrated that the increased breadth and depth of information sharing, and the improvements in quality and efficiency of communication that mobile-based communication can deliver has actually led to improved patient safety and a reduction in adverse events. Just as new medical devices, drugs and interventions must undergo a rigorous regime of transparent safety and efficacy testing, the same standards must be applied to new communication technologies. There is a careful trade-off to be made between those technologies which lead to increased complexity and cognitive overload, and those which can robustly demonstrate improvements in reliability, efficiency and simplicity which deliver meaningful improvements in communication, teamwork and patient safety²⁸⁰. There is a pressing need to apply best practice principles of independent evaluation and assessment to new communication technologies and deliver robust and reliable evidence for their impact on patients and staff.

3.2 - Aims

The principal aims of this systematic review are:

1. To evaluate the current breadth of evidence for the impact of mobile technologies on communication and teamwork within hospitals

2. To evaluate the quality of evidence for the impact of mobile technologies on communication and teamwork within hospitals against best practice guidelines

3.3 - Methods

This review was conducted in accordance with all best practice principles as outlined in the PRISMA Statement²⁸¹. The review protocol was prospectively registered with the PROSPERO Database as per best practice guidelines (CRD42017064128)²⁸².

3.3.1 - Data sources and search strategy

In consultation with an expert medical librarian at Imperial College MEDLINE, PsycINFO, EMBASE, CINAHL Plus, HMIC, The Cochrane Library and NIHR-HTA Database were searched for relevant literature published online or in print between 1st January 2007 and 1st January 2017. The search was run on the 3rd March 2017. The search strategy encompassed three broad categories: mobile technology, teamwork and communication and the hospital setting. The search terms and strategy employed for each respective database is summarised in *Appendix B*. In addition, the bibliographies of studies identified in the initial search were manually reviewed in order to identify further relevant studies for inclusion.

Table 3.1 outlines the pre-specified inclusion and exclusion criteria for the purposes of study identification. This review looked to focus on the impact of mobile technology on communication and teamwork within the real-life hospital setting, and therefore only two-way mobile-based interventions involved in direct patient care that took place within a real-life hospital setting were included. Studies involving one-way communication devices such as pagers, together with simulated studies were excluded. All studies evaluating the impact of specific technologies were included, even if the intervention studied did not form part of the study protocol (e.g. questionnaire studies reporting the impact of smartphones at work in general). There were otherwise no restrictions on study design, intervention or sample size, and both qualitative and quantitative studies were included.

3.3.2 - Study selection

Two reviewers (GM and AK) independently reviewed all titles and abstracts for eligibility against the specified inclusion and exclusion criteria in turn, and only those papers considered relevant advanced to full text review. Cohen's Kappa agreement (K) was calculated for each stage of screening and review, with disagreements in inclusion resolved through discussion and consensus agreement or adjudication by a third independent reviewer. The PRISMA Flowchart²⁸¹ for study inclusion is outlined in *Figure 3.1*.

A total of 8,072 studies were initially identified (MEDLINE = 1,392, PsycINFO = 536, EMBASE = 2,875, CINAHL Plus = 2,585, HMIC = 61, The Cochrane Library = 623 and NIHR-HTA Database = 0). After duplicates were identified and removed, a total of 5,683 papers remained eligible for screening and review. Inter-rater agreement for inclusion was "very good" throughout the screening process with a Cohen's K of 0.842-0.980 reported. 5,683 titles were screened of which 593 were initially included, and 5090 excluded with 59 reviewer disagreements (K = 0.9429, SE 0.0075, 95% CI 0.9283-0.9575). Following discussion and consensus agreement, a total of 570 papers were subsequently included for abstract review. Of the 570 abstracts reviewed 136 were initially included, and 434 excluded with 4 reviewer disagreements (K = 0.980, SE 0.010, 95% CI 0.961 – 1.000). Following discussion and consensus agreement 133 papers were included for full text review. Of the 133 papers reviewed in full 37 were initially included, and 95 excluded with 7 reviewer disagreements (K = 0.842, SE 0.054, 95% CI 0.736-0.948). Following consensus agreement in total 32 papers were subsequently retained for inclusion in the review. Of the 101 papers rejected, 37 were excluded as they were not full text peer review publications (e.g. published conference abstracts), 29 excluded as they did not relate to mobile device used at the point of care (e.g. e.g. one-way pager devices), 18 were excluded for being review or narrative articles, 8 were excluded for not being related to direct patient care (e.g. educational interventions), 6 were excluded for not reporting outcomes related to communication or teamwork (e.g. risk prediction models based on eHR alerting) and a further 3 were excluded for reporting simulation studies. Reference lists from all included studies were subsequently

hand-searched and a further 6 relevant papers identified, resulting in 38 papers being included for final analysis.

3.3.3 - Data extraction, quality assessment and synthesis of individual studies

For each study included in the final analysis an investigator extracted the relevant data on study design, population, intervention, comparators, outcomes and the setting. A second independent investigator subsequently reviewed this data extract for quality and accuracy prior to further analysis. A quality and risk of bias assessment was performed for all studies, with each rated as good, fair or poor according to the appropriate National Institute for Health Quality Assessment Tool for each study design²⁸³. All assessments were confirmed by consensus.

A further quality assessment of each interventional study was performed by assessing compliance to the mERA Checklist²⁸⁴, with all assessments once again confirmed by consensus. The mobile health (mHealth) evidence reporting and assessment (mERA) checklist was compiled by the WHO mHealth Technical Evidence Review Group and identifies a minimum set of information that is needed to define the content, context and technical features of a mHealth intervention to support the replication of an intervention and standardise the quality of evidence reporting; essentially a CONSORT²⁸⁵ or PRISMA²⁸¹ statement for mobile based health interventions. The mERA Checklist requires reporting across 16 core items and supports the transparent reporting and robust critical appraisal of studies reporting mobile based interventions in healthcare. It is a useful tool to assess the quality of reporting studies which include a mobile based intervention, and as far as the author is aware this review is the first time it has been employed and reported as part of a quality assurance process. As this tool has not previously been used to retrospectively assess the quality of studies, conducting an objective assessment of compliance, and therefore relative overall quality is challenging. As a result, for the purposes of this study the overall quality assessment of each study was defined by the relevant NIH Quality Assessment Tool. Each study was nonetheless assessed against the original definition for

each of the 16 core items included in the mERA Checklist. The studies were evaluated in their original published form and no further information was sought from the authors. If enough evidence was provided within the manuscript to meet the requirements of a core item then the study was deemed to be compliant. Compliance with each core item was determined, and a score out of 16 for compliance to the mERA checklist was subsequently provided to allow for a comparative assessment across the studies.

We summarised the data for each publication by study design, comparator group, setting, intervention, findings, compliance with the mERA checklist and quality assessment is included. Studies were grouped into six categories for further analysis: quantitative interventional studies (14/38), qualitative interventional studies (2/38), mixed-methods interventional studies (6/38), quantitative non-interventional studies (9/38), qualitative non-interventional studies (3/38) and mixed-methods non-interventional studies (4/38).

3.4 - Results

38 publications were identified from 30 unique studies. Of note, nine publications included in the final analysis reported overlapping data related to the same study investigating the introduction of smartphones and web-based messaging across a small number of general internal medicine teams within a single University Health Network^{286–294}. *Table 3.2* summarises the recorded data for each study included. Quality assessments for all studies included in the final analysis are summarised in *Table 3.3*, and mERA Checklist compliance for the 22 interventional studies included are summarised in *Table 3.4*. Overall the quality of studies included was sub-optimal, with 13 (34%) assessed to be of poor quality, 21 (55%) of fair quality and only four (11%) were deemed to be of good quality. Typically, those studies deemed to be of poor quality may be excluded from reviews for the purposes of final analysis, however, as they form a large bulk of the included studies in this instance it was decided to include them.

3.4.1 - Interventional studies

Twenty-two interventional studies were identified. Of these 14 reported quantitative outcomes^{287,289,302–305,290,295–301}, two qualitative outcomes^{306,307} and a further six mixed methods outcomes^{288,292,293,308,309}. Overall, the interventional study designs adopted were not robust, with only a single study involving any form of randomisation in its methodology³⁰⁴, and a further single study employing a crossover study design²⁹⁶; all other studies otherwise took the form of uncontrolled cohort studies. The populations studied were varied, but importantly were typically of limited size, with the mean number of participants reported in each study at only 63 (8-210). Importantly, six of the studies analysed reported results of an evaluation of a single intervention^{288–290,292,293}, therefore only 17 discrete interventions were available for comparison, and upon which conclusions can be drawn. Of these 17 specific interventions, eight involved the deployment of a bespoke mobile application^{287,295,296,299,300,302,304,309}, four the formalised adoption of WhatsApp messenger^{297,298,305,308}, three the introduction of generic smartphones^{301,303,307}, and finally two that utilised smartphones with a specific messaging or e-mail communication functionality; these reported their results across eight studies^{287–290,292,293,306,310}. Fourteen studies reported quantitative results across a range of methodologies. All studies except for two^{289,299} utilised questionnaires to obtain some or all of their data for evaluation. Seven studies assessed their chosen intervention through utilising content analysis to obtain data^{287,289,290,297,300,302,305}. Finally two studies utilised direct observational data collection methodologies, with one assessing the time taken to complete handover²⁹⁸ and another assessing the speed and latency of communication²⁹⁹. Two studies reported qualitative outcomes, with one study utilising semi-structured interviews and focus groups³⁰⁷, and the other adopting an exploratory case study approach to data collection with purposeful sampling and interviews across the multi-disciplinary team³⁰⁶. Six studies adopted a mixed-methods approach to data collection and outcome reporting. All studies included some form of content analysis of messages sent or received during the study period, a further four studies additionally employed structured interviews to obtain data^{288,292,293,308}, two employed additional questionnaire-based data collection^{309,310}, and two more collected further data via direct observational methods^{288,293}.

The quality of each of the 22 studies was also evaluated through assessing their compliance to the mERA Checklist²⁸⁴. Overall the quality of studies as judged through compliance with the mERA checklist was poor, with a mean score of 6.1/16 (range 3-11) and no study being fully compliant with the checklist. Of note, the potential limitations to delivery at scale and the replicability of the intervention were not reported by any study, whilst the contextual adaptability and usability of the intervention was only reported by a single study, and the inter-operability of the intervention within the wider health information system context was reported by just two studies. All studies understandably described the technology platform, and the vast majority reported the delivery and content of the intervention (18/22) and user feedback (17/22).

The included studies assessed the impact of a range of mobile interventions on communication and teamwork; from bespoke applications through to off the shelf messaging applications. It has been noted that on the whole the quality of the studies was poor, with only one containing any form of randomisation, and a further single further study adopting a crossover study design. Meanwhile, compliance to the mERA reporting standards was also universally poor. Despite this, there a number of cross-cutting themes to the reported findings including improvements in workflow, efficiency and the quality of communication; improvements in accessibility, responsiveness and inter-team relationships; and widespread acceptance that mobile devices should formally replace current methods of communication.

The mobile devices studied provided a range of functions. The most common purpose for communication was team organisation, patient flow, administration and education for unstructured messages; and treatment queries, transfer of clinical information and management of results for structured messages^{290,308}. In addition to multiple purposes, the devices studied also facilitated a range of communication modalities with images, text messages, e-mails, videos, voice calls and voice messages all utilised. Whilst a broad range of healthcare professionals were included in the study populations, junior doctors were the more prolific users of mobiles compared to other staff groups^{302,308}. In addition to characterising the prevalence and use of mobile devices, some studies also highlighted key

negative aspects of existing communication strategies such as pagers which are limited by the time wasted awaiting a response, the one-way nature of communication, the need to find a phone to respond, the need to remain near a phone whilst awaiting a response, the frequent need to re-page and the lack of acknowledgement of a receipt that a message has been received^{294,304}.

Broadly speaking the introduction of mobile devices to support communication and teamwork led to improvements in workflow, efficiency and the quality of communication. A number of papers reported significant streamlining of clinical workflows and improvements in the quality of clinical discussion^{296,304}, improvements in handover and patient care³⁰⁰, faster response times^{288,303}, and the elimination of redundant steps in vertical reporting within teams³⁰⁵. A further paper showed significant improvements in the effectiveness of communication, with greater efficiency and integration into existing workflows³⁰⁴, and another reported an improvement in the quality of information transfer and recall²⁹⁸. Another study reported that smartphones led to additional value in facilitating the easy delivery of non-urgent information, whilst also supporting triage and prioritisation, and improved the timeliness of communication³⁰⁶. Some studies looked to quantify these improvements in efficiency. The use of a mobile application led to significantly less disruption to clinical workflows than pagers in one study³⁰², another showed a 4 second (18 vs. 22) improvement in the speed of communication compared to traditional pagers²⁹⁹, and another a significant reduction in response times from 5.5 to 3 minutes³⁰⁹. Others studies reported a mean response time of 2-3 minutes with mobile devices^{287,297,308}, and that >50% of e-mail messages sent by smartphone were read in <1 minute³⁰². Importantly, the use of mobile devices also had a positive impact on inter-professional interactions and communications, and increased the involvement of senior decision makers in clinical care^{301,302,307}.

In addition to the many positive influences that were reported with the deployment of mobile devices there were also some negative consequences reported. The physical limitations of mobile devices were commonly highlighted as a weakness, with small screen size, poor battery life, the requirement to enter a password on a regular basis and unreliable

connectivity all identified as potentially limiting their effectiveness^{303,307,309}. In addition to their practical limitations, mobile devices were also reported to be regarded as less effective than face-to-face or direct communication for complex patient issues²⁸⁷, potentially giving an unprofessional appearance if used at the bedside³⁰⁷ and often used inappropriately for personal non-work related reasons³¹⁰.

As well as facilitating easy communication mobile devices can also be highly interruptive. One study identified 187,049 interruptions over an 18-month period, with an average of 42-51/day per team, and 'crisis mode' for 35mins/day where the level of communication events and interruptions reached a potentially dangerous level of overload²⁸⁹. Other studies identified that doctors frequently felt that since the introduction of mobile devices they were regularly interrupted with low-value and unnecessary information²⁸⁷, and that they were often overwhelmed by the volume of interruptions caused by the introduction of mobile devices²⁸⁸. A further study identified that the introduction of mobile devices had led to a large increase in the number of messages sent (710 vs. 2,196), and this resulted in a subsequent 233% increase in interruptions due to the elimination of traditional communication barriers such as the need to wait for a phone, improvements in access to other staff and impersonal nature of message-based communication²⁹². This increased communication burden may account for the fact that in one study up to 50% of messages did not get a response, and 28% requested an inappropriate response given the context²⁹⁰. Another consequence of the increased communication burden may be that it leads to the depersonalisation of the clinical team. Nurses reported feeling that mobiles may negatively impact inter-professional relationships due to a reduction in the face-to-face interactions that they value in helping to build relationships; conversely doctors did not report this and in fact felt this change was positive²⁸⁸. One study reported that doctors felt the frequent interruptions they received were often inappropriate given the content and context, which in turn led to the perception by nursing staff that they were not receiving their desired response²⁸⁷. Another study reported similar inter-professional conflict due to the different subjective assessment of the urgency and priority of messages, with increased accessibility often leading to an increase in disruptions and unnecessary communications³⁰⁶. Another study reported that increased

messaging by nurses was due to a push for accountability and reassurance, but this was perceived as an attempt to absolve themselves of responsibility by doctors, who also felt that nurses often exaggerated the severity or urgency of a issues to illicit a response, particularly at the end of a shift²⁹².

Despite these negative consequences, there was universal agreement that the use of mobile devices acted to remove barriers to effective communication³⁰⁸. In one study 87% of participants wanted to continue using their devices at the end of the study period³¹⁰, whilst in another the majority of users stated they would prefer to access information and communicate through a smartphone³⁰⁰. 85% of participants would recommend their widespread use³⁰⁴, and 92% agreed that mobile applications should replace traditional pager based methods of peer-to-peer communication, and that there is significant potential for far greater integration and expansion of their role in the hospital setting²⁹⁵.

3.4.2 - Non-interventional studies

Sixteen non-interventional studies were identified. Of these nine reported quantitative outcomes^{311–319}, three qualitative outcomes^{286,320,321} and a further four mixed-methods outcomes^{291,294,322,323}. All 16 studies adopted a cross-sectional study design, with 11 adopting a questionnaire-based study methodology^{312,313,323,314–320,322}, three an ethnographic study design^{286,294,321}, one an observational study design³¹¹, and a final study used a mixed-methods approach that combined direct observation, interviews and questionnaire based data collection²⁹¹. The populations studied were once again varied and included all members of the multi-professional team. This group of non-interventional studies on the whole sampled a larger population, with a mean number of participants of 220 (25-718). Fifteen of the studies looked to evaluate the prevalence, perception or use of mobile technology on communication in hospitals, with a single further study specifically characterising the impact of mobile phones on interruptions in the operating theatre³¹¹.

In assessing the prevalence and use of mobile communication technologies at work the key findings reported are consistent across all studies; namely the ubiquitous use of smartphones by healthcare professionals, the predominance of personal devices being used for work-related activity, the clear benefits that mobile based technologies bring despite well-articulated negative consequences, the potential risks to patient confidentiality and security and the broad support for the formal adoption of mobile technology by healthcare institutions.

Smartphones are used on a daily basis by the vast majority of healthcare professionals for work related activity. Doctors use their personal devices at work more frequently than other healthcare professionals with up to 95% reporting regular daily use and sharing of their personal number with other members of staff^{314,316,319}, compared to only around 50% of nurses^{316,322}. The messaging and e-mail functionality afforded by mobile devices is consistently highlighted as a significant benefit and principal reason for their use, with the majority of staff using this method of communication on a regular basis. One study reported that around 65% of staff use text applications³¹³, another that up to 88% use messaging or e-mails to communicate at work³¹⁴ and a further study reported 87% of staff use text messaging and a further 41% emails³¹⁷. Indeed, 72% of staff prefer text messaging to traditional pagers, a further 80% cite it as their preferred method of communication³¹⁸, and 68% of staff believe WhatsApp is a useful adjunct to clinical practice³¹². Messages are most commonly regarding clinical management queries, the giving of instructions, logistics and patient administration, social arrangements and for the transfer of information such as results^{312,319}.

There were a number of advantages to be gained with the use of mobile based communication devices. One study identified benefits including the ease of contact, the ability to see who is calling and reduced delays in answering³²¹, whilst another highlighted the promotion of information identification, integration and interpretation, and the positive impact this has on message exchanges and overall performance and quality³²⁰. Further studies found mobiles to be more convenient, less intrusive, more efficient and less

intimidating than more traditional methods of communication³¹⁹, whilst also helping deliver better context to messages and facilitating the easy coordination of teams²⁹⁴. In addition, a further study reported that mobiles improve communication, enhance access to information, and improve efficiency and decision making³²².

In addition to the benefits that mobile devices may bring, there were also a number of negative consequences identified across the majority of studies. One study described issues with mobiles including the cost, lack of institutional integration, poor battery life, small screen size and lack of support³¹⁵; a further study once again identified issues with battery life, and an increased prevalence of distractions³¹³; and another the cost, ambiguity of communication, reliability, slowness and potential for their use to appear impolite or unsocial³¹⁹. A further study identified how the use of mobile phones may promote a non-professional image through their use in front of patients³²¹. One study described how the use of mobile communication devices not only increases the communication burden, but also de-personalises and de-contextualises communication and introduces informal work-arounds compared to direct methods of communication such as face-to-face interactions or voice calls. This de-personalisation can form a barrier to effective inter-professional teamwork through a reduction in non-verbal cues such as eye contact, whilst de-contextualisation may result in the potential for misinterpretation and an increase in the time taken to resolve problems²⁸⁶. Mobile devices on the one hand may improve communication but can also lead to unwanted communication behaviours. It has been observed that mobiles can lead to an unwanted ripple effect by impacting those not directly involved in the communication event, such as disturbing nurses in the operating theatre, or by increasing the unwanted contact of doctors when not at work³²¹. Indeed, around one-third of doctors are contacted on a weekly basis, and over one-in-five on a daily basis when not at work³¹⁴. Furthermore, mobile devices may lead to an increase in potentially harmful interruptions with 100% of surgical procedures being interrupted on average 3 times per operation, with none of the interruptions being relevant to the case at hand³¹¹. Importantly, a number of studies identified the potential risk to security and the confidentiality of patient information, particularly with the use of personal devices^{291,313,315,318,319,323}. Despite these security

concerns a number of studies also highlighted how staff favour efficiency and mobility over security²⁹¹, that a minority perform any form of security risk assessment before using a device³²², that one-third of devices are not password protected³¹⁵, and that 71% of staff have received³¹⁸, and a further 28% regularly store confidential identifiable patient information on their personal device³¹⁶.

Despite the negative consequences of mobile device use in the hospital setting that have been identified, the vast majority of studies report that on the whole clinical staff advocate the use of mobile devices, and strongly support their wider formal deployment within hospitals. Indeed, one study reported that 98% of users thinking mobiles should be integrated with current hospital systems, with a further 79% supporting the replacement of existing pagers with hospital-issued mobile phones³¹³. Further studies also support this view, with one reporting 73% of staff feel pagers should be replaced with mobiles³¹⁴ and another reporting that 72% of doctors and 37% of nurses want a secure messaging platform integrated with their hospital systems³¹⁶,

3.5 - Discussion

Delivering high-quality, safe healthcare is a complex endeavour that requires the careful and precise coordination of numerous professionals in the care of a single patient; good teamwork and effective communication is fundamental to this. This review has found that overall there is a significant paucity of robust evidence evaluating the impact of mobile technology on communication and teamwork in the hospital setting. Of those studies published, the overall quality was poor with just 11% deemed to be of high-quality, and none complying with established best practice for the conduct and reporting of trials involving mobile technology. On the whole the interventional trials reported evaluated small populations in restricted environments that do not truly represent the real-world hospital setting. Despite this relative lack of evidence, this review reveals that mobile technology has the potential to significantly improve communication and teamwork within hospitals, provided that issues of negative communication behaviours, technological flaws, organisational

readiness, and security and privacy are adequately addressed, together with the delivery robust and transparent evidence for its safety and effectiveness.

3.5.1 - The impact of mobile technology on communication and teamwork

Whilst the evidence presented may be limited by methodological weaknesses, it does not prevent important lessons being learned which may inform the future design, deployment and evaluation of mobile-based communication technologies. Mobile and smartphone technology is ubiquitous, and widely used and valued by all staff working in hospitals. The evidence may be limited by quality, but it does support the conclusion that this technology may yield a number of significant benefits to both patients and staff. It is apparent that mobile devices are more convenient, less intrusive and far preferred to traditional pagers or other modes of communication. Furthermore, they may act to improve and streamline clinical workflows, and boost the efficiency and quality of communication. They act to increase the accessibility and responsiveness of staff, improve inter-professional teamwork and relationships, and support improved access to information and better decision making. The need to improve communication and teamwork is clear with one study showing only an 87% agreement between doctors and nurses on what procedures were planned for patients. This 13% rate of error is not indicative of a high performing environment, is entirely dependent on effective written and verbal communication and would not be tolerated in other industries; only 0.3% of luggage is lost by airlines, whilst patients frequently have procedures cancelled due to failures in communication and teamwork³²⁴.

In order to maximise the potential benefits from the adoption of mobile devices, there is also a need to consider both the expected, and unexpected negative consequences that may be seen with the deployment of any new technology. Clear physical and technological limitations have been identified with the mobile devices studied including poor battery life, small screen size, unreliable connectivity and the lack of consistent institutional integration with other electronic health systems. Furthermore, the potential for poor digital literacy

amongst healthcare staff may act as a barrier to their widespread adoption and prevent the realisation of the potential benefits that connected mobile devices may bring.

The majority of the evidence evaluated would support the notion that improved accessibility is a good thing, however, it has also been demonstrated to have a number of negative unintended consequences which must be considered and mitigated against. Making communication easier and improving access to clinicians results in a large increase in the communication burden. This vast increase in the volume of messages sent and received following the introduction of mobile devices is likely caused by the elimination of traditional communication barriers such as the need to wait for a phone, the impersonal nature of message-based communication, the flattening of hierarchical team structures and increased accessibility, responsiveness and accountability of clinicians. This increased communication burden can lead to overload, frustration and conflict. There is good evidence that increased accessibility leads to clinical staff being regularly contacted when not at work, which has important implications for work-life balance, accountability and responsibility. An increase in the communication burden can also facilitate the ripple effect, where communication activity acts as a harmful disruption to nearby staff. In addition, it is clear that with an increased communication burden there is the potential for cognitive overload, and a large increase in potentially harmful interruptions to clinically important tasks.

New communication technologies may also create unintended negative consequences for inter-professional relationships and teamwork. There is a need to ensure mutual understanding and agreement between staff on the correct use of communication technologies in order to bridge the divide between the expectations, behaviours and attitudes of different groups. Disagreements in the perceived need and urgency of messages have been identified as a real issue, with the perception that some staff groups may be trying to absolve themselves of responsibility for decision making, when in fact they are seeking accountability and reassurance leading to conflict and discourse. Furthermore, it has been highlighted that the severity or urgency of issues may be exaggerated in order to get a response from senior clinicians. A large proportion of the increased communication

burden is seen by some to be unimportant and of low-value and that the de-personalisation of communication may hinder the development of healthy inter-professional relationships. It is therefore crucially important to align the content and purpose of a message, against the process and mode of communication in order to mitigate against the risk that the increased accessibility and ease of communication provided by mobile devices does not lead to conflict, the development of harmful inter-professional relationships or resentment between different staff groups.

3.5.2 - Quality of the evidence

A clear barrier to the robust assessment of the impact of mobile technology on communication and teamwork that has been highlighted by this review is the lack of high-quality robust evidence. The evidence presented by the studies included is scant, and generally of poor quality. Indeed, 13 (34%) of the studies were assessed to be of poor quality, 21 (55%) of fair quality and only four (11%) were deemed to be of good quality. Meanwhile none of the 22 interventional studies evaluated were compliant with the mERA reporting standard. Crucially, nine publications included in the final analysis reported overlapping data related to the same study investigating the introduction of smartphones and web-based messaging across a small number of general internal medicine teams within a single University Health Network^{286–294}. This not only raises questions around duplicate reporting of results, but also acts to further limit the generalisability and robustness of the results presented.

It is difficult to draw clear conclusions because of methodological inadequacies such as the lack of prospective randomisation or assessment of matched comparator groups, the limited number of participants included in studies and truncated study length, and an inability to effectively pool results from multiple studies due to the substantial heterogeneity of study methodologies and outcomes used. The majority of studies were based in single centres, and the populations evaluated in the interventional studies were small with a mean size of only 63 (8-210). Meanwhile, 26 of the studies included some form of questionnaire-based

data collection, yet only six of these (23%)^{300,310,313,316,320,323} discussed conducting any form of evaluation or testing of the validity of the questionnaires used. Whilst some of these methodological flaws may be put down to the inherent difficulty of assessing such interventions in complex hospital settings, few studies clearly set-out to try and overcome these challenges in a meaningful way. Of the 22 interventional studies reviewed only two studies^{296,304} had any form of randomisation or prospective assessment of matched comparator groups, and in the remainder only five^{292,298,299,302,309} made reference to pre-intervention baseline data against which to compare the intervention. In order to robustly and transparently assess the impact of any intervention there is a requirement for high-quality level 1 evidence. It would never be acceptable to introduce a new medication, surgical implant or intervention into day-to-day practice without robust evidence for its safety and effectiveness, but this is sorely missing in this instance. Mobile technology is being used on a widespread basis without any evidence supporting its effectiveness or demonstrating its safety. Only two studies^{289,300} were published after the release of the mERA reporting standards for mobile interventions, but nonetheless compliance to this standard was universally poor. Vital evidence to understand the cost, security, fidelity and interoperability of new interventions included in this review was sorely missing, and only five studies^{299,302,304,308,310} scored 50% or more against the reporting standard. There is a pressing and urgent need to improve the quality, rigor and reporting of mobile-based healthcare interventions to ensure they deliver benefit and avoid harm.

3.5.3 - Why has the widespread institutional uptake of mobile technology been so poor?

It is apparent from the evidence presented that the uptake of mobile technology by professionals in the hospital setting has largely been driven on an ad-hoc basis by individuals or discrete teams in isolation. Despite the near ubiquitous use of smartphones by healthcare professionals outside of work³²⁵, there are a number of diverse organisational, individual and technological factors which are likely to impact the adoption of new communication technologies at an institutional level. The vast majority (13/22) of

interventions included in this review used off-the shelf consumer technology that was not developed to account for the specific needs of healthcare such as appropriate data security and confidentiality or need to prevent duplication of information and maintain a single record of events at all times. Only nine studies used specific mobile applications that considered the need for interoperability and integration with existing local electronic health systems or wider regulatory compliance. This apparent lack of widespread institutional adoption of new mobile technologies may be accounted for by a variety of technology and context specific barriers that have been identified as influencing the uptake of healthcare information technology more widely. The failure to adopt and deploy new technologies may be caused by a failure to appreciate and plan for the complexity and cost of a technology, a failure to gain buy-in and engagement from end-users, a failure to appreciate that new technology changes the work, the nature of work and who does that work, and that the speed of implementation often does not match the situation⁴⁵. Additionally, it has been identified that financial, legal, social and ethical factors, together with low digital literacy in clinicians, a shortage of evidence for their cost-effectiveness and poor inter-operability of systems also frequently prevents the rapid and widespread uptake of new technologies^{48,49}.

Despite electronic health system more generally being widely accepted as means of improving efficiency and quality, their widespread adoption is still challenged despite the \$19billion in financial incentives that came with the HITECH (Health Information Technology for Economic and Clinical Health) Act in the US, whilst the UK is still struggling with out-dated systems despite the £12.4 billion investment delivered through the now defunct NPfIT (National Program for IT)^{57,60}. No such schemes have been delivered, or even suggested in order to promote the deployment of mobile technology amongst clinical staff, although it is debated whether such investment would in fact deliver the intended return. In addition to these structural factors which impact the uptake of new mobile technology, it has also been identified that the extent to which mobile devices deliver benefit has been significantly under investigated, and there is an unmet need to address explicit questions about how and why this technology will improve communication and teamwork and deliver real benefits to patients and staff³²⁶. There is a need to promote the benefits of a 'mobile-first' culture within

healthcare organisations and provide the required leadership and resource to deliver it whilst concurrently being cognisant of the potential pitfalls and risks. Indeed, it has been estimated that the use of smartphones more widely within healthcare has the potential to improve productivity by over \$300 billion in the next decade through diminishing travel times, enhanced logistics and accelerated decision making³²⁵.

Quite rightly, a key issue raised in a number of the studies included in this review regarded concerns around patient privacy, data security and compliance with relevant data protection and security legislation; particularly when personal mobile devices are being used in the work setting. Despite this it was highlighted that staff typically prefer the benefits that using their personal device brings, despite the security and privacy concerns. Worryingly only nine studies made a specific reference to any data security or privacy considerations, or compliance to relevant legislation^{295,298,299,302,304,308–311}. In the US the need to comply with the minimum standards of physical, network and process security under HIPPA (Health Insurance Portability and Accountability Act) Act of 1996³²⁷ has certainly acted to limit the deployment of smartphone-based messaging, whilst similar barriers are seen in the UK with the requirement to comply with relevant legislation such as the Data Protection Act of 1998⁶⁹. Indeed, the use of SMS messaging for in-hospital communication has been discouraged by the Joint Commission in the US due to these security concerns³²⁸. The tension between the efficiency of mobile technology adapted into, but not designed for healthcare will continue as new technologies appear. Improving the awareness and training of staff with regards security and patient privacy comes hand-in-hand with developing compliant technology and addressing these security issues has the potential to greatly accelerate the development and uptake of new mobile technologies.

Many of the negative aspects of mobile technology identified in the studies evaluated were related to the technology itself; poor battery life, small screen size and lack of connectivity were all issues highlighted as impacting upon the use of mobile devices. In order to address these concerns, there is a need to design and develop technology specifically for the healthcare context and adapt work practices to alleviate some of these technological

limitations such as the provision of secure WIFI networks within institutions and adopting software designed specifically for a mobile interface. As devices become increasingly complex and data heavy, the importance of the underlying supporting infrastructure that is needed in order to securely and reliably store, process and transmit huge volumes of clinical and communication data becomes increasingly important³²⁹. In order to successfully support the deployment of large-scale mobile-based communication and data platforms within hospitals there is a need to provide sufficient and reliable supporting infrastructure.

Health information technology in general is in an awkward adolescence and is 10-20 years behind the best of consumer technology³³⁰. Healthcare professionals use innovative mobile technology on a daily basis outside of work to communicate and share information yet have to cope with outdated and inadequate technology to coordinate and deliver care at work. The poor experience of this technology results in the development of potentially harmful patchwork of informal workarounds and ad-hoc technology adoption which is used to deliver patient care without any robust supporting evidence.

3.6 - Conclusion

Mobile technology is still an emerging and rapidly developing area of innovation, but there is a tendency to view it as inherently better despite the absence of the robust supporting evidence that may be expected of other new innovations in healthcare. What is required is a robust evidence-based approach to development, deployment and evaluation of new mobile-based communication devices to fully understand how they influence clinical practice, care delivery and inter-professional working. In order to secure the 'right' technology it is important to recognise and understand both the advantages and disadvantages that any particular technology may bring, and how it is used in real-world clinical settings. There is a need to match the skills and needs of staff with organisational leadership, capability and resource in order to drive a 'mobile-first' culture of work. Mobile technology has the potential to transform inter-professional communication and teamwork and deliver very real benefits

for both patients and staff, provided a robust and evidence-based approach is taken to its design, deployment and evaluation.

This systematic review has highlighted that there is a lack of good evidence supporting the effectiveness and widespread deployment of new mobile technologies, and this has resulted in poor penetrance and limited widespread institutional uptake. A fundamental aspect of delivering a 'mobile-first' culture of work in hospital is the staff who deliver care. The next chapter therefore aims to further understand multi-professional perspectives on mobile-working in order to promote innovation and improve the deployment of new mobile technologies within secondary care.

Table 3.1 - Pre-specified inclusion and exclusion criteria

PICOS Element	Inclusion Criteria	Exclusion Criteria
<i>Populations</i>		
<i>Interventions</i>	- Point of care device - Mobile/smartphone device - Involved in direct patient care	- Bleep/pager devices - One-way communication devices
<i>Comparators</i>		
<i>Outcomes</i>	- Communication/teamwork outcomes reported	
<i>Setting</i>	- Hospital setting	- Primary care setting - Outpatient setting
<i>Study Design</i>		- Simulation studies
<i>Publications</i>	- Published between 1st January 2007 – 1st January 2017 - English language - Peer-reviewed full text article - Original research	- Systematic/narrative reviews

Figure 3.1 - PRISMA Diagram for study identification, screening and inclusion

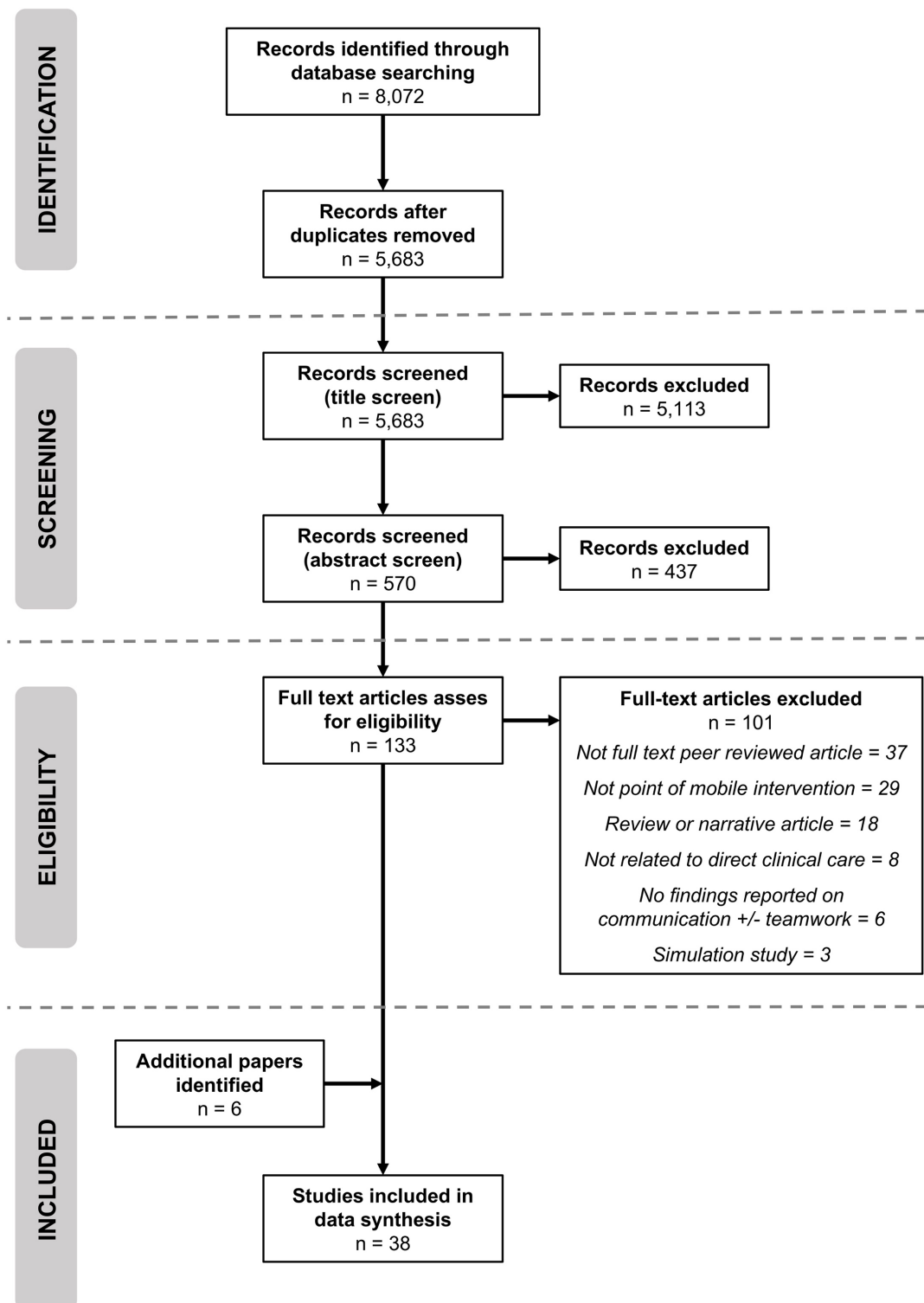


Table 3.2 - Included studies with data for each by study design, comparator group, setting, intervention, findings, compliance with the mERA checklist and quality assessment

Study	Study Design	Setting and Intervention	Findings (communication / teamwork)	Quality Assessment ²⁸³	mERA Assessment ²⁸⁴
<i>Interventional Studies – Quantitative Outcomes</i>					
Daruwalla <i>et al</i> 2014 ²⁹⁵	Prospective observational cohort study	Orthopaedic surgical team (25 participants) MyDoc - HIPPA compliant mobile application with messaging, case discussion, patient details and photo sharing functionality	- 23/25 (92%) agreed the application should replace current peer-to-peer communication methods - 23/25 (92%) agreed they could communicate easily using the application - 22/25 (88%) agreed that the potential for telerounding via the application may have advantages, e.g. out-of-hours	Poor	6/16
Duhm <i>et al</i> 2016 ²⁹⁶	Controlled prospective crossover study	University Hospital (14 participants) iPad with mobile eHR	- Application led to improvements in discussing clinical evidence with colleagues and streamlined clinical workflows	Fair	6/16
Gulacti <i>et al</i> 2016 ²⁹⁷	Retrospective observational cohort study	Tertiary Hospital Emergency Department (628 consultations) WhatsApp Messenger	- Message content: 510 images, 517 text messages, 59 videos, 10 voice messages across 519 patients - Median arrival time 3.94mins (1-34mins) and response time 2.83mins (1-29mins) - As a result of messaging 59.9% led to discharge of patient without a face-to-face specialty consultation and 71.6% out-of-hours consultations	Fair	5/16
Khanna <i>et al</i> 2015 ²⁹⁸	Pre-/Post-observational cohort study	Tertiary Orthopaedic Department (8 junior doctors, 25 consecutive patients pre/post intervention) Issued smartphone with WhatsApp Messenger	- 100% felt WhatsApp improved the efficiency of handover and patient care - Use of WhatsApp led to significant improvement in quality of information transfer and recall	Poor	7/16

Lane <i>et al</i> 2012 ²⁹⁹	Pre-/Post-observational cohort study	University hospital (40 participants) VigiVU - integrated mobile situational awareness application with monitoring, text and voice communication and access to eHR functionality	- Use of the application increased speed of communication compared to pagers (Latency 18secs vs. 22secs)	Poor	11/16
Motulsky <i>et al</i> 2017 ³⁰⁰	Prospective cross-sectional mixed-methods study	University hospital (124 participants) FLOW - in-house mobile application allowing free-text communication of 200 characters within eHR accessed through personal smartphones	- Number of 'flows' created mean 26/day, 8/patient/day - 72% used application to enter notes and communication. 70% to read notes. - Significantly higher usage to access notes from home - Nurses less likely than men to be comprehensive users - Majority of users would prefer to access information and communicate through a smartphone - Majority think application improves handover and patient care.	Fair	6/16
Ng <i>et al</i> 2007 ³⁰¹	Prospective observational cohort study	Neurosurgical team in University hospital (12 participants) Issued smartphone with multimedia messaging and picture capability	- Senior doctor perspectives: frequently used, improved confidence and decision making, improved inter-team communication and reduced need for call-back - Junior doctor perspective: frequently used, facilitated increased involvement of senior decision making from home	Poor	3/16
Patel <i>et al</i> 2016 ³⁰²	Pre-/Post observational cohort study	4x clinical teams in large University hospital (229 multi-professional participant's pre-intervention, 210 participants' post-intervention) Cureatr - HIPAA compliant smartphone application with encrypted messaging and other applications accessed through personal and issued devices	- 708,456 messages across 130,073 specific patient threads: 85.4% 2 people, 14.6% group messages - Junior doctors and nurses the largest senders: 5 (2-12) and 6 (2-13) per day with "hyper-users" contributed 20.5% of all messages - 67.7% of threads contained 3-10 messages, and 18.6% defined as quick replies containing only 2 messages - Messages sent by doctors shorter (28 vs. 41, p<0.001) - >50% of messages sent read in <1min - All staff found the application to cause significantly less disruption to workflows than pagers, with more responsive physicians and better transfer of information	Fair	10/16
Power <i>et al</i> 2014 ³⁰³	Prospective observational cohort study	Pharmacy team in hospital setting (90 participants) Issued iPhone with multiple generic functionalities	- Principal use as a communication device - 98% found it useful, 87% improved performance, 68% improved efficiency, - Positive impact: accessibility, rapid communication, easier management of email and calendar - Negative comments: small screen size, connectivity - iPhone used more often than any other communication device (225 times/8hr shift, 3.5hrs/day)	Fair	5/16

Przybylo <i>et al</i> 2014 ³⁰⁴	Controlled prospective cluster-randomised study	5 general medicine teams at a University hospital (26 control and 49 intervention participants) Medigram - HIPAA compliant group messaging application accessed through institutional or personal smartphones	- At baseline, no significant differences in groups - Key ineffective aspects of pagers: time wasted for responses, one-way nature of communication, needing to find a computer/phone, needing to remain near a phone whilst awaiting response - Key effective features of pagers: reliability, ease of use, responsiveness, brevity - At baseline majority (90.5%) already use text messaging - Compared to paging smartphones significantly more effective, allow clearer more efficient communication and integrate better into workflow - Satisfaction with smartphone higher. 85% would recommend its use - Most effective features being ease of use, group texting and speed	Good	10/16
Smith <i>et al</i> 2012 ²⁹⁰	Prospective observational cohort study	4 medical teams in 2 large hospitals (34 participants – analysis of 13,717 e-mails) Issued team and individual Blackberry smartphones with messaging/email functionality	- 7,784 structured and 5,933 unstructured messages - Senior Dr's receive 22.3 messages/day from nurses, 4/day from juniors - Senior Dr's send 4.3 messages/day to nurses, 4.8/day to junior doctors - 94.7% of structured e-mails from nurses: 39.1% requested a call-back, 18.9% an e-mail back and 42% information transfer only - Median response time 2.3mins, 50% did not get a response - 28.1% of emails requested an inappropriate response given content - Structured email content analysis: tone (49.6% courteous, 50.2% neutral), purpose (43.4% treatment/medication, 35.3% signs/symptoms, 29.3% investigation results) - Unstructured email content analysis: organisation of team (53.5%), patient flow (21%), education (9.4%)	Poor	3/16
Vaisman <i>et al</i> 2017 ²⁸⁹	Retrospective observational cohort study	8 clinical teams across 2 large academic hospitals (21 doctor participants over 18 months) Institutional smartphones with secure voice calls, messaging and e-mail functionality	- 187,049 interruptions identified (52.2% text messages, 23.9% voice calls, 20.9% e-mails) - Peak of interruptions at 11am-12pm and 2-3pm - Average daily interruptions 42.3-51.4/day/team - Crisis mode experienced 2.3/day/team with a mean duration of 35.1mins	Fair	4/16
Wani <i>et al</i> 2013 ³⁰⁵	Prospective observational cohort study	Plastic surgery department in academic hospital (116 communication events) Institutional smartphone with WhatsApp	- Response times for communication: <1min 51.7%, 1-5min 31.9%, 5-10min 5.2%, >10min 11.2% - Overall positive response to the efficacy of using WhatsApp as a means of communication - Led to elimination of redundant steps in vertical reporting within teams	Poor	6/16

Wu <i>et al</i> 2015 ²⁸⁷	Prospective observational cohort study	5 general medicine teams in 2 large academic hospitals (60,969 messages, 165 multi-professional participants) Clinical Message - bespoke application with secure messaging and handover tools accessed through institutional smartphone	- On average 14.8 messages/day/team - 76.5% requested a text reply, 7.7% a call-back and 15.7% no response - >2/3 of messages deemed urgent, 8.6% of messages requesting a reply did not get one. Median response time 2.3mins - 82.8% of doctors and 78.3% of nurses felt system improved care and speed of work - Majority felt it improved accountability, timeliness of communication and inter-professional relationships - Not seen as effective for communicating complex issues - Doctors felt frequently interrupted with low-value information, nurses conversely perceived a lack of desired response	Fair	6/16
Interventional Studies – Qualitative Outcomes					
Farrell 2016 ³⁰⁷	Retrospective cross-sectional interview study	Gynaecology ward (20 participants) iPhone with relevant generic medical applications e.g. MIMS drug information, MedCalc, Medscape	- Overall positive impact on inter-professional interactions and communication - Primary use for inter-professional communication - Improved communication with doctors - Nurses/AHPs are behind the curve with using mobile phones for professional communication - Negative aspects: screen size, battery life, connectivity unprofessional to use at bedside	Poor	6/16
Lo <i>et al</i> 2012 ³⁰⁶	Retrospective cross-sectional questionnaire study	General internal medicine teams (31 participants) in teaching hospital Individual and team Blackberry smartphones with web-paging/email functionality	- Positive impact of smartphones: value in delivery of non-urgent information, aid in triage and prioritisation, improvement in efficiency of communication and access to clinical staff, improved timeliness of replies compared to pagers - Negative impact of smartphones: conflict between nurses and doctors about correct communication method and subjective decision on urgency/priority, accessibility leads to increase in unnecessary communication, residents find increased calls disruptive - Important to align content and purpose against process and mode of communication: need to resolve discourse between doctors and nurses	Fair	4/16
Interventional Studies – Mixed Methods Outcomes					
Johnston <i>et al</i> 2015 ³⁰⁸	Prospective mixed methods cohort study	Acute general surgery team in a teaching hospital (40 participants, 1,140 hours of clinical communication with 1,495 communication events) WhatsApp messenger	- Median number of communication events within team 65.5/week. - Juniors doctors responsible for majority of events. - Message content: 39.3% communication events, 35.6% information giving, 60.5% administration - Median response time by senior doctors 7mins, and juniors 2mins. Senior doctors significantly slower than juniors - Juniors like the ability to send messages rather than voice calls, seniors like additional supervision. Universal agreement that it led to the removal of communication barriers	Fair	8/16

O'Connor <i>et al</i> 2009 ³¹⁰	Prospective mixed-methods cohort study	Intensive Care Unit in community hospital (106 multi-professional participants) Institutional Blackberry with messaging/e-mail functionality	- Staff sent a mean 5.2 messages and received 8.9/day - Only 4% uncomfortable with using device by end of trial - Positive perceptions – usability, impact on communication, team relationships and patient care, fast and reliable, improved doctor response times, improved coordination and job satisfaction - 81% reported no negative experiences - Negative experiences reported: impact on quality of communication, reduced face-to-face communication and inappropriate use of devices for personal reasons - 87% wanted to continue using the devices	Good	8/16
Quan <i>et al</i> 2013 ²⁹²	Pre-/Post observational cohort study	Four general internal medicine teams in academic hospital (17 multi-professional participants – 5 doctors, 8 nurses, 2 pharmacists, 2 social workers) Institutional Blackberry with email/messaging functionality	- Increase in number of messages 710 vs. 2,196 - 233% increase in interruptions to clinical tasks following introduction of smartphone - Increased interruptions due to elimination of traditional barriers (e.g. waiting for phone), ease of access and impersonal nature of communication - Staff frustrated by increase in message volume, but recognition alone not enough to change behaviour - Increased messaging from nurses due to push for accountability and reassurance, doctors saw this as nurses absolving themselves of responsibility - Nurses found to often exaggerate severity or urgency of issues to illicit a response, particularly at the end of a shift	Poor	5/16
Webb <i>et al</i> 2016 ³⁰⁹	Pre-/Post observational cohort study	2 academic hospitals and a satellite community hospital (104 multi-professional iPhone users with 49 web console users) Vocera Collaboration Suite - smartphone enabled application with call alerting, chat, voice calls	- Significant reduction in response times (5.5min vs. 3min p=0.027) - 85% of staff used mobile for day-to-day communication - 35% of staff used mobile for communication with patients - 81% of doctors positive about system - Positive aspects of system: reduction in interruptions, ability to answer in own time, ability to send additional information, receipt confirmation, convenience - Negative aspects of system: battery life, having to enter password every time, balance between interruptions and missing messages when on do not disturb	Fair	6/16

Wu <i>et al</i> 2011 ²⁸⁸	Prospective observational cohort study	General medicine teams in multiple academic hospitals (16 months data collection) Institutional Blackberry with email/messaging functionality	- Analysis of 13,717 calls: 41.2% answering external calls, 25.3% calling another team phone, 33.4% calling external number. Mean calls received 6.4/24hrs - Analysis of 12,936 e-mails: mean e-mails received 21.9, sent 6.9 vs. 1.8 and 2.3 face-to-face communication events - Efficiency: smartphones lead to faster response times and increased accessibility, and increase multi-disciplinary communication - Interruptions: smartphones lead to increase in interruptions through overall increase in number of calls/messages. Doctors often overwhelmed by volume of interruptions (4.6/hour) - Inter-professional relationships: nurses think smartphones reduce face-to-face interactions which are valued, makes it more difficult to build relationships and get to know doctors. Depersonalisation of the team is a big issue. Conversely doctors felt it improved relationships and there were no negative implications for team working or relationships - Perceived urgency: Nurses often felt doctors ignored messages, whilst doctors felt nurses made too many calls/messages about unimportant things - Professionalism: using phones during clinical activities seen to be unprofessional with negative perceptions from patients	Fair	5/16
Wu <i>et al</i> 2013 ²⁹³	Prospective observational cohort study	General medicine teams in multiple academic hospitals (16 months data collection) Institutional Blackberry with email/messaging functionality	- Impact on senders: frustrations with pagers (lack of response, wait for call back, no ability to identify caller, often need to re-page, lack of acknowledgement of receipt), Benefits of smartphones (quicker resolution, no need to wait by phone, can page and continue to work, acknowledgement of receipt and ability to convey urgency) - Impact on receiver: ability to defer, smartphones facilitate triage and prioritisation and make it easier to reply. Pagers hugely disruptive due to need to find phone, smartphones disruptive due to increased message/call load. Direct voice calls very disruptive - Other: lack of response from pager frustrating, easier to coordinate team with smartphones. Use of institutional phones improves security and influences adoption of unofficial communication techniques which may lead to confusion.	Fair	5/16
Non-Interventional Studies – Quantitative Outcomes					
Avidan <i>et al</i> 2017 ³¹¹	Cross-sectional observational study	Operating theatres (7207 mins of observation across 52 surgical procedures) No intervention – impact of mobile phones on interruptions	- 100% of procedures interrupted by phone calls - Median 3 calls/procedure (IQR 2-5) - 0% of incoming calls related to patient undergoing the procedure - 14.7% of calls led to a stoppage of care (mean duration 43.6secs)	Fair	

Ganasegeran <i>et al</i> 2017 ³¹²	Cross-sectional questionnaire study	General / Emergency Medicine (307 multi-professional participants) No specific intervention – benefits of WhatsApp	- 68.4% perceived WhatsApp to be useful adjunct to clinical practice - 5.6 hours/day on WhatsApp during clinical practice - Common reasons for use: clinical questions, information transfer, instruction giving, patient administration - Those clinicians who have been using WhatsApp for longer and more frequently report greater perceived benefit from its use	Fair	
Jamal <i>et al</i> 2016 ³¹³	Cross-sectional questionnaire study	17 specialties across two large academic teaching hospitals (101 doctor participants) No specific intervention – prevalence and perceptions of mobile phone use	- 99% mobile phone users, of which 54.5% iOS, 53.5% Android, 5% Blackberry and 3% Windows - Work-related use: 65.3% text applications and 64.4% voice calls - 98% agree integrating smartphones with hospital systems is a good idea, and 89% say mobiles useful for staff communication - 79% support replacing existing pagers with hospital-provided mobiles - Key issues highlighted: short battery life, distractions caused by mobiles, confidentiality and security	Fair	
Martin <i>et al</i> 2016 ³¹⁴	Cross-sectional questionnaire study	Hospital doctors (206 doctor participants) No specific intervention – prevalence and perceptions of mobile phone use	- 92% use their personal mobile for work voice calls, 88% messaging, 82% emails. 95% share their personal number with work colleagues, and switchboard hold personal numbers for 64% - 66% mobile is preferred method of communication vs. 6% for pagers - 77% discuss patient matters and 12% have sent a photo with PID - 48% prevented from communicating effectively due to poor connectivity - 32% contacted on a weekly basis, 21% on a daily basis when not at work - 73% feel pagers should be replaced with mobiles, and 6% support the use of personal mobiles at work	Poor	
Menzies <i>et al</i> 2012 ³¹⁵	Cross-sectional questionnaire study	Hospital doctors (850 doctor participants) No specific intervention – prevalence and perceptions of mobile phone use	- 51% of participants use smartphones for work, of which 49% iOS, 23% Windows, 10% Palm OS, 5% Symbian, 4% Blackberry and 3% Android - 26% stored patient data of which 31% were not password protected - Principal uses: emails/communication, informatics, sharing images - Issues with mobiles: cost, lack of institutional integration, battery life, screen size, user interface, dependency, lack of support, security concerns	Poor	
Mobasheri <i>et al</i> 2015 ³¹⁶	Cross-sectional questionnaire study	Large academic hospital (718 participants - 249 doctors and 469 nurses) No specific intervention – prevalence and perceptions of mobile phone use	- 98.9% of doctors and 95.1% of nurses own a smartphone - 92.6% of doctors and 53.2% of nurses use one for daily clinical practice - 93.8% of doctors and 28.5% of nurses communicate at work with smartphones, and 50.2 % use a smartphone in place of issue pager - Sending of PID by doctors: 64.7% by SMS, 33.1% by app-messaging, 46% picture messaging - Sending of PID by nurses: 13.8% by SMS, 5.7% by app-messaging, 7.4% picture messaging - 27.5% of doctors and 3.6% of nurses have PID on their phones - 71.6% want a secure messaging platform for identifiable data	Fair	

O'Connor <i>et al</i> 2014 ³¹⁷	Cross-sectional questionnaire study	Junior doctors in national training network (108 participants) No specific intervention - prevalence and perceptions of smartphone use	- 94.4% own a smartphone (67% iPhone, 27% Android) - 83.3% use their smartphone work related calls, 87.2% text messaging and 41.2% e-mails, 52.9% pictures	Fair	
Prochaska <i>et al</i> 2015 ³¹⁸	Cross-sectional questionnaire study	Two academic hospitals (132 doctor participants) No specific intervention – prevalence and perceptions of mobile phone use	- 71.7% prefer text messaging to pagers/landlines with 79.8% using it as their preferred method of communication - 82.5% though existing pagers better for security, but despite this 70.9% have received identifiable data on their mobile	Poor	
Wyber <i>et al</i> 2013 ³¹⁹	Cross-sectional questionnaire study	Large academic hospital (208 doctors) No specific intervention - prevalence and perceptions of mobile phone use	- 95.7% carried mobile phones at work (70.7% personal, 18.8% institutional and 7.6% both) - Content of messages: clinical management (61%), logistics (55%), social arrangements (42%), results (34%) - Rationale for using mobiles at work: more convenient, less intrusive, less reliable, more efficient, less intimidating - Barriers: cost, ambiguity of communication, reliability, patient confidentiality, impolite/unsocial, slowness, unsure of others use	Fair	
Non-Interventional Studies – Qualitative Outcomes					
Hsiao <i>et al</i> 2012 ³²⁰	Cross-sectional questionnaire study	Hospital based nursing staff (219 participants) No specific intervention – benefits of mobile nursing information system (mNIS)	- mNIS systems promote information identification, integration and interpretation - mNIS has a significant positive impact on message exchanges between healthcare professionals, facilitates communication with patients and improves overall performance and quality	Good	

Scholl <i>et al</i> 2012 ³²¹	Cross-sectional ethnographic study	Department of surgery in academic hospital (25 participants, 360hrs of data collection) No specific intervention – ethnographic study of mobile phone use	- Advantages of mobiles over pagers: ease of contact, displays who is calling, no need to find phone for call-back, reduced delays in answering - Disadvantages of mobiles: problematic contexts (busy environments, large number of devices, lack of usage policy), non-professional image in using in front of patients, interruption of work/life balance with interruptions and ease of contact when not at work - Increase in interruptions, dictated by technical, individual and social aspects of mobile communication - Use of mobiles leads to increased contact of doctors when not at work, particularly more senior doctors - Design for ripple effect: improve awareness that mobiles may impact those not directly involved in the communication (e.g. nurses in operating theatre) - Design for highly specialised and distributed work and better manage interruptions	Good	
Wu <i>et al</i> 2014 ²⁸⁶	Cross-sectional ethnographic study	General medicine wards in 5 hospitals with text-based mobile messaging systems (108 interviews, 260hrs of observation) No specific intervention – ethnographic study of text-based mobile messaging systems	- Key issues highlighted are de-contextualisation and de-personalisation of communication - Mobile based systems lead to increasing communication workload and asynchronous communication. - Text based messaging simplifies and de-contextualises content resulting in potential for misinterpretation and increase in time taken to resolve problems compared to direct communication - Depersonalisation of communication is a barrier to effective inter-professional teamwork through reduction in non-verbal cues (e.g. expressions, body language). Clinicians want a more personalised working relationship with direct contact	Fair	
Non-Interventional Studies – Mixed Methods Outcomes					
Moon <i>et al</i> 2014 ³²³	Cross-sectional questionnaire study	Academic hospital (122 multi-professional participants) No specific intervention – prevalence and perceptions of mobile phone use	- 56.5% use hospital-issued smartphones - 51.4% receive regular work-related calls, 37.5% messages - Attitude towards smartphones influenced by cost, quality, ease of use, support and security	Fair	
Moore <i>et al</i> 2014 ³²²	Cross-sectional questionnaire study	161 hospital organisations (416 participants – 82 nurses, 334 doctors) No specific intervention – prevalence and perceptions of mobile phone use	- 81% of doctors and 58% of nurses use their smartphones for work - Perceptions of smartphones at work: easy to use, improve safety, useful, save time - Smartphones improve communication, access to information, efficiency and decision making - Minority perform a risk assessment before using a phone (e.g. for storing using identifiable data)	Poor	

Tran <i>et al</i> 2014 ²⁹¹	Cross-sectional mixed methods study	General medicine teams in 4 academic hospitals No specific intervention – mixed methods study of mobile phone use	- 59% of respondents carry personal smartphones and use them as their primary method of communication - Acknowledgement of risk to security and confidentiality of information, but respondents favour efficiency and mobility over security - Minority of users observed using personal smartphones at work	Poor	
Wu <i>et al</i> 2013 ²⁹⁴	Cross-sectional ethnographic study	General medicine teams in 5 academic hospitals No specific intervention – mixed methods study of mobile phone use	- New communication methods impact senders and receivers, interprofessional collaboration and choice of informal communication methods - Pagers are frustrating, slower and deliver less context to the message than smartphones. Lack of response to pagers the major frustration - Smartphones make it easier to receive and respond to calls, and coordinate teams, but still highly disruptive. Direct calls to phones are very disruptive - Impact on privacy and security acknowledged - The use of hospital issued smartphones influences the adoption of informal communication (e.g. adding 911 to bleeps). Informal communication methods can cause confusion.	Fair	

Table 3.3 - Quality assessment for each study as per NIH Quality Assessment Tools²⁸³

Study	Quality Assessment ²⁸³	
	Tool used	Overall Quality Rating
Avidan <i>et al</i> 2017 ³¹¹	Cross-sectional Study Tool	Fair
Daruwalla <i>et al</i> 2014 ²⁹⁵	Observational Cohort Study Tool	Poor
Duhm <i>et al</i> 2016 ²⁹⁶	Controlled Intervention Study Tool	Fair
Farrell 2016 ³⁰⁷	Observational Cohort Study Tool	Poor
Ganasegeran <i>et al</i> 2017 ³¹²	Cross-sectional Study Tool	Fair
Gulacti <i>et al</i> 2016 ²⁹⁷	Observational Cohort Study Tool	Fair
Hsiao <i>et al</i> 2012 ³²⁰	Cross-sectional Study Tool	Good
Jamal <i>et al</i> 2016 ³¹³	Cross-sectional Study Tool	Fair
Johnston <i>et al</i> 2015 ³⁰⁸	Observational Cohort Study Tool	Fair
Khanna <i>et al</i> 2015 ²⁹⁸	Pre-Post (No Control) Study Tool	Poor
Lane <i>et al</i> 2012 ²⁹⁹	Pre-Post (No Control) Study Tool	Poor
Lo <i>et al</i> 2012 ³⁰⁶	Observational Cohort Study Tool	Fair
Martin <i>et al</i> 2016 ³¹⁴	Cross-sectional Study Tool	Poor
Menzies <i>et al</i> 2012 ³¹⁵	Cross-sectional Study Tool	Poor
Mobasheri <i>et al</i> 2015 ³¹⁶	Cross-sectional Study Tool	Fair
Moon <i>et al</i> 2014 ³²³	Cross-sectional Study Tool	Fair
Moore <i>et al</i> 2014 ³²²	Cross-sectional Study Tool	Poor
Motulsky <i>et al</i> 2017 ³⁰⁰	Observational Cohort Study Tool	Fair
Ng <i>et al</i> 2007 ³⁰¹	Observational Cohort Study Tool	Poor
O'Connor <i>et al</i> 2009 ³¹⁰	Observational Cohort Study Tool	Good
O'Connor <i>et al</i> 2014 ³¹⁷	Cross-sectional Study Tool	Fair
Patel <i>et al</i> 2016 ³⁰²	Pre-Post (No Control) Study Tool	Fair
Power <i>et al</i> 2014 ³⁰³	Observational Cohort Study Tool	Fair
Prochaska <i>et al</i> 2015 ³¹⁸	Cross-sectional Study Tool	Poor
Przybylo <i>et al</i> 2014 ³⁰⁴	Controlled Intervention Study Tool	Good
Quan <i>et al</i> 2013 ²⁹²	Pre-Post (No Control) Study Tool	Poor
Scholl <i>et al</i> 2012 ³²¹	Cross-sectional Study Tool	Good
Smith <i>et al</i> 2012 ²⁹⁰	Observational Cohort Study Tool	Poor
Tran <i>et al</i> 2014 ²⁹¹	Cross-sectional Study Tool	Poor
Vaisman <i>et al</i> 2017 ²⁸⁹	Observational Cohort Study Tool	Fair
Wani <i>et al</i> 2013 ³⁰⁵	Observational Cohort Study Tool	Poor
Webb <i>et al</i> 2016 ³⁰⁹	Pre-Post (No Control) Study Tool	Fair
Wu <i>et al</i> 2011 ²⁸⁸	Observational Cohort Study Tool	Fair
Wu <i>et al</i> 2013 ²⁹³	Observational Cohort Study Tool	Fair
Wu <i>et al</i> 2013 ²⁹⁴	Cross-sectional Study Tool	Fair
Wu <i>et al</i> 2014 ²⁸⁶	Cross-sectional Study Tool	Fair
Wu <i>et al</i> 2015 ²⁸⁷	Observational Cohort Study Tool	Fair
Wyber <i>et al</i> 2013 ³¹⁹	Cross-sectional Study Tool	Fair

Table 3.4 - Summary of mERA Checklist²⁸⁴ compliance for each interventional study included

Study	mERA Checklist Criteria ²⁸⁴ - see legend for definitions																
	1 - Infrastructure	2 - Technology platform	3 - Interoperability	4 - Intervention delivery	5 - Intervention content	6 - Usability	7 - User feedback	8- Access of participants	9 - Cost assessment	10 - Adoption inputs	11 - Delivery limitations	12 - Adaptability	13 - Replicability	14 - Data security	15 - Regulatory compliance	16 - Fidelity	TOTAL
Avidan <i>et al</i> 2017 ³¹¹																	
Daruwalla <i>et al</i> 2014 ²⁹⁵	X	X	-	-	X	-	X	-	-	-	-	-	-	X	X	-	6/16
Duhm <i>et al</i> 2016 ²⁹⁶	-	X	-	X	-	-	X	X	-	-	-	-	-	X	-	X	6/16
Farrell 2016 ³⁰⁷	-	X	-	-	X	-	X	X	X	X	-	-	-	-	-	-	6/16
Ganasegeran <i>et al</i> 2017 ³¹²																	
Gulacti <i>et al</i> 2016 ²⁹⁷	-	X	-	X	X	-	-	-	X	-	-	-	-	-	-	X	5/16
Hsiao <i>et al</i> 2012 ³²⁰																	
Jamal <i>et al</i> 2016 ³¹³																	
Johnston <i>et al</i> 2015 ³⁰⁸	X	X	-	X	X	-	X	-	X	-	-	-	-	X	-	X	8/16
Khanna <i>et al</i> 2015 ²⁹⁸	-	X	-	X	X	-	-	-	X	X	-	-	-	X	X	-	7/16
Lane <i>et al</i> 2012 ²⁹⁹	X	X	X	X	X	X	X	-	-	X	-	X	-	X	-	X	11/16
Lo <i>et al</i> 2012 ³⁰⁶	-	X	-	-	X	-	X	-	-	X	-	-	-	-	-	-	4/16
Martin <i>et al</i> 2016 ³¹⁴																	
Menzies <i>et al</i> 2012 ³¹⁵																	
Mobasheri <i>et al</i> 2015 ³¹⁶																	

Moon <i>et al</i> 2014 ³²³																	
Moore <i>et al</i> 2014 ³²²																	
Motulsky <i>et al</i> 2017 ³⁰⁰	-	X	X	X	X	-	X	-	-	-	-	-	-	-	-	X	6/16
Ng <i>et al</i> 2007 ³⁰¹	-	X	-	X	X	-	-	-	-	-	-	-	-	-	-	-	3/16
O'Connor <i>et al</i> 2009 ³¹⁰	-	X	-	X	X	-	X	-	X	-	-	-	-	X	X	X	8/16
O'Connor <i>et al</i> 2014 ³¹⁷																	
Patel <i>et al</i> 2016 ³⁰²	-	X	-	X	X	-	X	X	X	X	-	-	-	X	X	X	10/16
Power <i>et al</i> 2014 ³⁰³	-	X	-	X	X	-	X	-	-	X	-	-	-	-	-	-	5/16
Prochaska <i>et al</i> 2015 ³¹⁸																	
Przybylo <i>et al</i> 2014 ³⁰⁴	X	X	-	X	X	-	X	X	-	X	-	-	-	X	X	X	10/16
Quan <i>et al</i> 2013 ²⁹²	-	X	-	X	-	-	X	-	-	X	-	-	-	-	-	X	5/16
Scholl <i>et al</i> 2012 ³²¹																	
Smith <i>et al</i> 2012 ²⁹⁰	-	X	-	X	-	-	-	-	-	-	-	-	-	-	-	X	3/16
Tran <i>et al</i> 2014 ²⁹¹																	
Vaisman <i>et al</i> 2017 ²⁸⁹	-	X	-	X	X	-	-	-	-	-	-	-	-	-	-	X	4/16
Wani <i>et al</i> 2013 ³⁰⁵	-	X	-	X	X	-	X	-	X	X	-	-	-	-	-	-	6/16
Webb <i>et al</i> 2016 ³⁰⁹	X	X	-	X	X	-	X	-	-	-	-	-	-	-	X	-	6/16
Wu <i>et al</i> 2011 ²⁸⁸	-	X	-	X	X	-	X	-	-	-	-	-	-	-	-	X	5/16
Wu <i>et al</i> 2013 ²⁹³	-	X	-	-	-	-	X	X	-	-	-	-	-	X	-	X	5/16
Wu <i>et al</i> 2013 ²⁹⁴																	
Wu <i>et al</i> 2014 ²⁸⁶																	
Wu <i>et al</i> 2015 ²⁸⁷	-	X	X	X	X	-	X	-	-	-	-	-	-	-	-	X	6/16
Wyber <i>et al</i> 2013 ³¹⁹																	

Legend:

1. **Infrastructure (population level)** - Clearly presents the availability of infrastructure to support technology operations in the study location. This refers to physical infrastructure such as electricity, access to power, connectivity etc. in the local context. Reporting X% network coverage rate in the country is insufficient if the study is not being conducted at the country level
2. **Technology platform** - Describes and provides justification for the technology architecture. This includes a description of software and hardware and details of any modifications made to publicly available software
3. **Interoperability/Health Information Systems (HIS) context** - Describes how mHealth intervention can integrate into existing health information systems. Refers to whether the potential of technical and structural integration into existing HIS or programme has been described irrespective of whether such integration has been achieved by the existing system
4. **Intervention delivery** - The delivery of the mHealth intervention is clearly described. This should include frequency of mobile communication, mode of delivery of intervention (that is, SMS, face to face, interactive voice response), timing and duration over which delivery occurred
5. **Intervention content** - Details of the content of the intervention are described. Source and any modifications of the intervention content is described
6. **Usability/content testing** - Describe formative research and/or content and/or usability testing with target group(s) clearly identified, as appropriate
7. **User feedback** - Describes user feedback about the intervention or user satisfaction with the intervention. User feedback could include user opinions about content or user interface, their perceptions about usability, access, connectivity, etc

8. **Access of individual participants** - Mentions barriers or facilitators to the adoption of the intervention among study participants. Relates to individual-level structural, economic and social barriers or facilitators to access such as affordability, and other factors that may limit a user's ability to adopt the intervention
9. **Cost assessment** - Presents basic costs assessment of the mHealth intervention from varying perspectives. This criterion broadly refers to the reporting of some cost considerations for the mHealth intervention in lieu of a full economic analysis. If a formal economic evaluation has been undertaken, it should be mentioned with appropriate references. Separate reporting criterion are available to guide economic reporting
10. **Adoption inputs/programme entry** - Describes how people are informed about the programme including training, if relevant. Includes description of promotional activities and/or training required to implement the mHealth solution among the user population of interest
11. **Limitations for delivery at scale** - Clearly presents mHealth solution limitations for delivery at scale
12. **Contextual adaptability** - Describes the adaptation, or not, of the solution to a different language, different population or context. Any tailoring or modification of the intervention that resulted from pilot testing/usability assessment is described
13. **Replicability** - Detailed intervention to support replicability. Clearly presents the source code/screenshots/ flowcharts of the algorithms or examples of messages to support replicability of the mHealth solution in another setting
14. **Data security** - Describes the data security procedures/ confidentiality protocols
15. **Compliance with national guidelines or regulatory statutes** - Mechanism used to assure that content or other guidance/information provided by the intervention is in alignment with existing national/regulatory guidelines and is described
16. **Fidelity of the intervention** - Was the intervention delivered as planned? Describe the strategies employed to assess the fidelity of the intervention. This may include assessment of participant engagement, use of backend data to track message delivery and other technological challenges in the delivery of the intervention.

Chapter 4 - Exploring mobile working in healthcare: multi-professional perspectives on moving towards a 'mobile-first' culture of work

The previous chapter highlighted that although offering great potential, the deployment of mobile technologies at the bedside remains limited. Additionally, there is a paucity of high-quality evidence demonstrating the utility and impact of such technologies, nor providing the data required to support widespread adoption. This chapter therefore seeks to understand multi-professional perspectives on mobile-working in order to provide robust evidence and suggestions for how to successfully deliver a 'mobile-first' culture of work in secondary care.

4.1 - Introduction

The rapid development of IT and mobile devices has brought about palpable changes in the way people work, communicate, spend time and interact. It has led to profound effects on economic development, widened access to information and learning, revolutionised research and innovation and fundamentally expanded human capabilities³³¹. The telecommunications industry is one of the most rapidly growing areas of innovation across the globe³³², and worldwide mobile users have increased from 11 million in 1990 to more than 6 billion by 2014³³³. User need is commonly an important driver for innovation more so than potential market share. Indeed, users with higher than average unmet needs tend to be particularly keen innovators; extreme sports practitioners for example frequently innovate to develop new approaches to improve safety and deliver lifesaving solutions³³⁴. In many sectors therefore the end-users of technology are well recognised as an increasingly important source of innovation³³⁵, yet in the healthcare setting numerous multi-dimensional barriers have prevented this becoming a reality and therefore block the widespread adoption of new mobile technologies^{48,49,336}; innovation in healthcare is typically led by industry or IT professionals and not by clinical end-users innovating to satisfy their unmet needs.

New technologies can robustly demonstrate that they lead to improvements in the reliability, efficiency and simplicity of care delivery and also foster improvements in communication, teamwork and patient safety²⁸⁰. Nonetheless, as highlighted earlier in this body of work and elsewhere in the literature²⁷⁹ there is a relative paucity of high-quality robust evidence evaluating the introduction and impact of mobile devices in secondary care despite their undoubted potential. Moreover, it is clear that health IT, and in particular the use of mobile technology is in an awkward adolescence lagging 10-20 years behind consumer technology³³⁰, and penetrance of new technology into the sector remains poor³³⁷. Despite this lack of evidence and the relative absence and immaturity of hospital-wide mobile solutions personal mobile devices are virtually ubiquitous in the clinical environment, and may act directly to improve communication, enhance teamwork and widen access to clinical information²⁷⁸. Not only can mobile technologies drive improvements in quality and effectiveness, but it has been estimated that widespread uptake of mobile-based solutions has the potential to improve healthcare productivity by over \$300 billion in the next decade through diminishing travel times, enhanced logistics and accelerated decision making³²⁵.

Despite the clear need to tackle clinical challenges together with the overarching political imperative to drive forward the uptake of new technologies and deliver fully paperless healthcare systems^{45,125}, there is a sobering failure rate of new IT innovations in healthcare with only around 1 in 8 projects deemed to be implemented successfully^{338,339}. The perception is that emerging mobile technologies are a potential solution to many of the challenges facing healthcare, but they often fall short of aspirations and expectations due to the complex socio-technical milieu in which they are implemented³⁷. Given the many instances implementation failure and the disruptions to local practice and workflow that are often seen with the introduction of new technologies an in-depth evaluation of all end-user perspectives is required. It is crucial to fully understand current staff experiences of mobile working and health IT more widely, together with exploring the perceived challenges and opportunities that come hand-in-hand with mobile technology in order to successfully design, deploy and evaluate new mobile innovations and ways of working to support the transition to a 'mobile-first' culture of work within secondary care.

4.2 - Hypothesis, aim and objectives

4.2.1 - Hypothesis

The daily use of mobile technology has transformed modern society and people are ever more dependent upon it for their daily lives. Healthcare has embraced the use of new technologies, but the application of mobile devices to support the delivery of frontline care is still very much in its infancy and lagging behind most other aspects of daily life. By understanding current staff experiences of mobile working and defining key principles for the successful adoption of mobile technology it will be possible to support the adoption of a 'mobile-first' culture of work in secondary care; delivering a better experience for staff and improving the quality and efficiency of care for patients.

4.2.2 - Aim

The principal aim of this study is to explore current staff experiences of mobile working and new technology deployment, and to elicit key recommendations that may support the successful transition to a 'mobile-first' culture of work.

4.2.3 - Objectives

In order to fulfil the stated aim, this study will seek to fulfill the following objectives:

1. To scope the experiences, attitudes and behaviours of multi-professional clinical staff relating to mobile working in secondary care
2. To explore key barriers and facilitators experienced by multi-professional clinical staff to the deployment of new technologies in secondary care
3. To define key considerations for the successful deployment of mobile technologies and the adoption of a 'mobile-first' culture of work in secondary care

4.3 - Methods

4.3.1 - Semi-structured focus groups: interview schedule development

Semi-structured focus group interviews were undertaken with a range of multi-professional clinical staff working in secondary care. The focus groups were conducted according to a structured interview schedule developed from the “*Seven success factors for change*” framework³⁴⁰. This framework identifies local factors required for successful change and explains how conditions for successful change may be created within the NHS. Seven core factors are highlighted as being consistently relevant to supporting successful change in the NHS and these are presented in *Table 4.1*. The interview schedule is seen in *Appendix C*.

4.3.2 - Semi-structured focus groups: procedure and setting

Semi-structured focus groups and interviews were conducted with a range of multi-professional clinical staff working within in a self-contained medical unit at a large UK teaching hospital. Staff views on adopting a ‘mobile-first’ culture of work and experiences of previous digital technology deployments were explored. Participants were purposively recruited in order to ensure a representative sample of multi-professional staff was obtained. The research team (NS and GM) periodically visited the unit over the course of the 4-month recruitment period of the study and participants were recruited until all staff who could be approached had been exhausted and saturation reached. The adequacy of the target sample size was guided by repeated assessments of the emerging data, and guidance from previously published work. Thematic saturation typically occurs at around 12 interviews, and core themes commonly emerge in as few as six³⁴¹. Whilst necessarily heterogenous to ensure sampling of all multi-professional staff groups, both researchers agreed that the dataset held sufficient information power and was adequate for the stated objectives to be met³⁴².

In total 34 participants were recruited out of 41 staff approached to take part in the study; an overall recruitment of 82.9%. The 34 participants comprised 6 doctors, 6 senior nurses (Band 6 and above), 13 junior nurses (Band 5 and below), 3 Healthcare Assistants, 4 Allied Health Professionals and 2 Administration staff. 8 focus groups each containing 2-6

participants were conducted, and a further 6 individual interviews were performed in order to fit individual staff availability. All interviews and focus groups were recorded and transcribed verbatim.

This study was approved as part of a wider hospital quality improvement program to prepare for the deployment of a new mobile clinical application and therefore independent NHS REC approval was not required. Informed consent was obtained from all participants. All data was de-identified for the purposes of analysis with numeric codes assigned to each interview or focus group and generic job titles used throughout to avoid the identification of specific participants.

4.3.3 - Data analysis

A framework approach was employed as the principal method of data analysis. This approach is not aligned to a particular epistemological, theological or philosophical approach to analysis, and is instead a flexible and pragmatic approach to qualitative study. It aims to draw structured descriptive conclusions clustered around core themes by identifying commonalities, differences and relationships within qualitative data^{343,344}. A deductive approach was utilised with the “*Seven success factors for change*”³⁴⁰ forming the basis of an initial pre-defined coding framework and thus a consistent focus for interpretation. Interviews were transcribed, and following immersion and familiarisation were coded and indexed by two independent researchers with disagreements resolved through consensus. An iterative process of indexing and coding was adopted to allow codes to be expanded or redefined within the working analytical framework until consensus was reached and the codes accurately reflected the data. The coded data was then charted to emerging themes, summarised and mapped for final interpretation. All data was coded, indexed and charted using Microsoft Excel (Excel for Mac V16.13, Microsoft, USA).

4.4 - Results

The reported experiences, attitudes and behaviours of staff in relation to adopting a ‘mobile-first’ culture of work within hospital care, and key barriers, facilitators and considerations for the successful deployment of new mobile technology are described across three overarching themes identified during the study: integrating mobile working in hospital; addressing issues of data governance and accountability and handling the pace of change to digital technologies. The development of sub-themes and final overarching core themes are summarised in *Figure 4.1*.

4.4.1 - Integrating mobile working in hospital care

Understandably previous staff experiences of health IT, both good and bad, defined the context of how they perceived the development, deployment and day-to-day use of mobile technologies for delivering patient care. They recognised the utility, potential benefit and pragmatic limitations of mobile technologies and the need to balance competing priorities and aspirations with realistic practicalities in order to match clinical and operational needs.

4.4.1.1 - Utility of a ‘mobile-first’ way of working

The move away from paper and fixed workstation-based delivery of care to a ‘mobile-first’ model was met with a range of varied views on potential benefits and pitfalls; however, the vast majority saw it as a positive step for staff and patients:

“Going from paper notes and documentation to electronic, I think that’s gone really well and I think people are realising that it’s a much more efficient way of working. So, I think taking it another step, I think people would be ready for it.” (Nurse)

A clear unmet need that could be answered by mobile working was the potential utility of handheld electronic documentation and improved communication and task management. They identified the potential for mobile technology to support higher quality data capture, better informed decision making and improved communication and task management:

“It’s really lovely that... there’s a reminder of things like care plans and it [EPR system] flags up so it tells you exactly what you need to do because as a nurse, obviously, when you’ve got so many responsibilities it’s obviously normal for you to forget, so things that actually like bleep in your face, things that are highlighted, it makes you realise that, okay, this needs to be done” (Nurse)

“I’ve not really used any computer system to write something to the doctors. I’ve always called them and spoken to them on the phone, so at least if there is something, like a system, it can be logged and even they come back they can check on it” (Nurse)

Traditional methods of communication in hospitals such as pagers and landline telephones are ubiquitous despite their inherent flaws and outdated technology^{279,280}. Nonetheless, clinicians were open and honest about the current widespread use of mobile devices to circumvent current methods and improve the quality and timeliness of communication:

“People are definitely ready to use the smartphone to do the jobs that they are already using the smartphone to do” (Doctor)

“If I want to supply something but I’ve got a query where I need the doctor’s input... I could turn that WhatsApp like message [system]...because sometimes when you get a bleep you don’t know what is that bleep for, is it something that’s urgent that I need to respond to right now...” (Allied Health Professional)

4.4.1.2 - Perceived cultural and workflow limitations to mobile working

Whilst the majority of comments regarding the use of mobile technology were positive, not all staff were so upbeat with some reserving judgement about the potential benefits:

“I think one of the things we’ve talked about is whether it[mobile working] will actually increase our workload, whether it’s easier to send a job our way when you’re just using a device as opposed to having to pick up the phone, send a bleep, wait for a phone call back and when you don’t necessarily have that immediate two-way communication between somebody” (Doctor)

Some respondents felt that using mobile devices to communicate with other members of staff, or for allocation the recording and managing of clinical tasks may be more cumbersome, less productive and lead to lower quality interactions than speaking to colleagues face-to-face:

“If the nurses need to get you to do something, you’re like ten metres away down the hallway, and they’ll speak to you... rather than going, “Oh, we’ll put this in the thing [write task into the system]” (Doctor)

The preference for communicating via mobile devices was not universal and varied between different staff groups. Clinicians were broadly more positive and saw it as a means to facilitate the faster and better-quality exchange of information and were sceptical about whether other staff would be so receptive to change. Nonetheless clinicians were more likely to challenge any new technology they saw as burdensome or without merit. Meanwhile, some nurses viewed the use of mobile devices in the clinical setting to be unprofessional, or were fearful of being inappropriately judged by the managerial hierarchy and senior staff:

“I’m convinced will be a problem because I’m ever trying to get my nurses to WhatsApp me instead of bleep me, and the reason they don’t do it is because their nursing managers think they’re on Facebook” (Doctor)

“If the manager or someone sees you on your mobile it looks like, do you know what I mean?” (Nurse)

In addition to fears over the perception of use by managers and senior staff, there was also an understandable hesitance to use mobile devices during care delivery and in the clinical environment due to fears over how patients may perceive this behaviour:

“The patients actually give feedback to us, most of the nurses are spending more time talking to us [other staff] than with the patients, ... then we have to explain to that patient, ‘We are using the computer instead of using paper documentations’ because they are not aware of all the technology coming to NHS sites” (Nurse)

4.4.1.3 - Balancing priorities and practicalities of mobile working

Any new way of work or technology undoubtedly disrupts established workflows and processes. It is therefore vital that any innovation matches clinical need and improves the quality or efficiency of care delivered. Novel technologies such as mobile based aids may act to challenge current clinical practices and lead to the perception of a loss of professional autonomy by clinicians:

“I get the jobs, I do the jobs, whatever; and I will prioritise them in my own mind. It actually takes me longer to then have to prioritise them on a phone. I know what I need to do”
(Doctor)

“Am I really bothered about you implementing something new that’s got lots of potential hiccups? To be honest, I’d rather just stick with the system I know” (Allied Health Professional)

“If you’ve only got two nurses and one healthcare assistant looking after 28 patients at night, they don’t want to spend time putting the jobs out... they just weren’t happy about the time that they were spending putting the jobs down ... it wasn’t the technology side of it that was putting people off; I think it was the time” (Nurse)

The eagerness of healthcare organisations to adopt new technologies means that sometimes a solution is not found for a problem, but a problem is found for a technological solution. This may not only affect the quality and effectiveness of the technology adopted, but may also lead to solutions that lack purpose or utility, with technology adopted for innovations sake or to meet alternative agendas rather than to solve a specific problem or improve the quality and effectiveness of care:

“We have people who just want to digitise everything they touch and turn it into an app which is ... sort of ... understandable, but unrealistic... But it’s very, very difficult so, yeah, we know what it costs, ... that’s the kind of time motivation and investment it requires to build something that works, so I think people are quickly frustrated by the fact that they can’t just do that. Or to stick a PDF on a phone and call it an app and think that the job is done.”

(Doctor)

4.4.2 - Addressing issues of data governance and accountability

4.4.2.1 - Provision of data and security

Data gathered from mobile applications was perceived to be potentially intrusive or serving only to assess performance for business decisions made from an operational standpoint. Data captured needs to be meaningful for staff working on the floor, such as knowing whether their workload is changing as a result of using a new system or process.

Understanding what data is being scrutinised and why may ease clinicians’ concerns, and any data captured about clinicians’ workflow and movements needs to be justified. There was some unease amongst clinicians about data being captured about their performance, and whether they would be told they work too slowly or did not respond quickly enough to request from other staff. Nonetheless, the consensus was that the improved depth, quality and volume of data that could potentially be captured via mobile devices was welcome with its potential to improve the quality and effectiveness of care:

“It [mobile platform] could audit our interventions...if, say, I’ve had to change a dose or I’ve had a medication prescribed or I’ve had that interaction that’s actually an audit tool” (Allied Health Professional)

However, the benefits of better data provision may also be hindered by inadequate or untimely recording of data:

“Your challenge will be actually getting people to record accurately.” (Allied Health Professional)

Hand-in-hand with improving the capture of, and access to clinical data via mobile technology comes the obligation to safeguard and protect patients. Mobile devices present new, and potentially significant security and privacy risks through facilitating the access to data by multiple users across multiple devices in any location. A large number of respondents stated that this was a real concern for them:

“Here we have to think about confidentiality of the patient when communicating amongst ourselves, so I think there should be adequate education before it [mobile working] is then rolled out. Like, we have to think about patient safety and confidentiality” (Nurse)

“If I’ve got that on a handheld device I’ve got to then ensure the security of that device or some kind of encryption so if I lost it on the street nobody would have access into patient information” (Allied Health Professional)

4.4.2.2 - Transparency and accountability

In the context of delineating accountability of care delivery, transparency was expressed as a key factor to protect both data and people:

“I think it’s just having that reassurance about how data is kept safe and being completely transparent about how the system works and what it’s going to be used for, who has access to it, how they have access to it and I think if you can address those concerns then I think it [mobile working] should therefore be successful” (Doctor)

Uncertainty about how much data is needed, and for what purposes it is collected required clarification for many participants. The move to a mobile way of working raised questions about what was deemed auditable, whether tracking and monitoring all tasks and communications was necessary and whether there would be punitive outcomes for any oversights. There were genuine concerns around the transparency of data use, whether or not information would be used for the performance management of staff and whether or not the leadership and management of the organisation had alternative motives for the deployment of new mobile technology:

“From that sort of information governance point of view... how is that information going to be used? So, let’s say the nurses put down lots of things – you know, “You need to do this, you need to do this, you need to do this” – but based upon a personal discussion I’ve had with them, they say, “Actually, that doesn’t need to be done anymore”. Is that then going to time out and go, “Oh, you’ve taken three hours to do this,” where in actual fact, I haven’t: I’ve had a discussion with a nurse, that’s no longer needed; or I’ve had a quick chat with the patient, I just haven’t scored it off my list....” (Doctor)

“Does the fact that that’s in writing – that you were told to do that, and you’re like, “But I had a verbal conversation that negated that” – where are you, legally, in that?” (Allied Health Professional)

Understanding how mobile technologies are perceived by patients and the public is important and was also highlighted by some participants. Clearly identified was the need for all relevant stakeholders including patients, public, and healthcare professionals to be consulted in advance about the use of new mobile technologies to ensure concerns about

data management and sharing, governance and accountability, and information security are adequately addressed:

“Getting feedback from patients and members of the public as to what their concerns would be around this type of technology and then addressing those would probably sort that issue out entirely.” (Doctor)

“I guess one of the biggest concerns for the public will be in relation to information governance, data protection type information... I know that there have been concerns raised around Google in particular being involved within healthcare, bringing a company corporation like that with international health service, I think people have been quite edgy about that and I think that that could represent a barrier to the spread of this innovation”
(Doctor)

4.4.3 - Handling the pace of change to digital technologies

4.4.3.1 - Managing expectations and keeping staff engaged

The moves towards a fully digital healthcare system will have benefits not only for healthcare professionals in supporting improvements in quality and productivity but will also transform the way citizens access and use services and health data. The current transition from paper-based records to electronic health records across the NHS has inevitably changed healthcare professionals' perspectives on digital technologies. Previous deployments have paved the way for the widespread acceptance of new technologies, but importantly staff want a seamless transition and to avoid complex and lengthy change:

“The people on the ground and the people who are using these tools are keen and ready... but we know that everything will probably take longer than it is hoped for, planned for.”
(Doctor)

“I think it’s inevitable that we need to do something to update the bleep system, because it is somewhat archaic. It seems to work quite well, but only maybe because I’m so used to it. I am so receptive to a new system... but I can just see that it’s going to be complex” (Doctor)

The adoption and implementation of new technologies is often slow, with adaptations to the local context taking time and requiring the updating and upgrading of technologies and infrastructure. In the short term this disruption may increase workload for staff, particularly when implementation is poor resources are taken away or secondary effects are not anticipated; inevitably as a result new technology is often met with resistance, ingrained cynicism at collective inertia from end-users:

“I think that the necessary learning curve, teething – whatever that comes with change, makes people very, very resistant to it.” (Doctor)

“We’re in a phase of the NHS where there are new bits of technology being either put upon us, or introduced, and we’ve seen them not work very well” (Doctor)

Organisations that implement new technologies are perceived to be innovative and keeping a steady pace of change may help manage the expectations of staff, prepare them to be ready for new innovations and modify attitudes towards paperless or mobile ways of working. Dynamic and innovative organisations find change easy, whilst those organisations which fail to modernise, or in whom there is poor leadership and organisational inertia will struggle to deliver digital transformation:

“Our Trust is always changing. We’ve had a number of big particularly IT changes around first EDC, that’s Electronic Discharge, then with [EPR] electronic prescribing administration so I think we are ready.” (Allied Health Professional)

“Everything is moving at a very fast pace and therefore we need to upgrade ourselves to what technology is all about.” (Nurse)

Not all staff are so positive about the rapid pace of change however. Some raised concerns regarding the speed and volume of innovation and are likely to challenge or obstruct any new technology deployments if they are perceived to be burdensome, unnecessary or delivered for change sake. Doctors are harder to persuade to adapt to new ways of working more so than other healthcare professionals, particularly when it comes to changing methods for communication and teamwork, shifts in accountability or moves towards performance management and flattening of the clinical hierarchy:

“If they have a system where they can send me messages all the time about things, my worry is that they will just phone me more.” (Doctor)

“I suppose if you looked at the things that we struggled with, with [EPR system], it was getting doctors to document. Probably not with the more junior doctors and the prescribing, but definitely with the more senior, they weren’t documenting on [EPR system]” (Nurse)

Respondents also stated that they wanted transparency and openness as to why new technology is being introduced and what the organisational vision and direction of travel is. They want effective communication from their leadership and the opportunity to question why changes are being made, understand whether decisions are business-led or for the purposes of improving quality or patient experience, and to be able to influence decision making and feel they are part of a shared decision-making process:

“I don’t think that all the changes that are brought in are necessarily in response to direct problems that are faced by Trusts. So, it’s not often, “Here’s a new change, here’s a new innovation, everyone’s backing it and let’s all get on board” and everyone is, “Well that is a problem” ...there’s a lot of innovation for the sake of innovation that’s backing a new idea for the sake of looking trendy and, “Aren’t we doing new things?” (Doctor)

“I think knowing we can do something like Cerner implementation, which was massive, with maybe not the best amount of information coming out from the Trust” (Nurse)

4.4.3.2 - Too much innovation, too fast creates innovation fatigue

Participants highlighted that they felt at times new technologies were implemented back-to-back, with little consolidation or rest between change. As a result, any proposed long-term benefits from new technologies are too distant to be meaningful, changes in processes and pathways are not effectively embedded within teams to maximise their potential and staff find considerable difficulties in adjusting immediately after another period of change. This means that any potential unintended consequences for patient safety and care quality, or other negative secondary impacts may not be fully captured, understood and mitigated; organisations must be wary of innovation fatigue:

“I’m just also a little bit wary that – yeah, there’s a lot of different new technologies and new platforms coming out, and if we’re just introducing one more new thing for people to master, then I sort of feel like we haven’t entirely got [EPR system] working to its potential.” (Doctor)

4.5 - Discussion

4.5.1 - Summary of key findings

There has been considerable focus on the implementation of new digital technology in the NHS to support the transition to a ‘paperless’ healthcare system⁴⁵ and the potential benefits of health IT improving care delivery are increasingly clear¹⁰⁵. Despite this there is very little data examining the perspectives and experiences of clinical end-users, and even less regarding adopting a ‘mobile-first’ culture of work. This failure to focus on end-users despite the clear need to clarify the problems a technology is attempting to tackle, build consensus

across all stakeholders, select systems that meet clinical need, and maintain staff engagement to ensure success⁵⁶.

This study sought to explore current staff experiences with mobile working and the deployment of new technology in order to provide recommendations to support the successful transition to a 'mobile-first' way of working. In doing this three overarching themes that encompassed the experiences and attitudes of clinical end-users, together with potential challenges that need to be addressed in order to make this cultural and technological change to a 'mobile-first' way of working a reality were identified:

1. *Integrating mobile working in hospital care* - there is a need to balance different priorities with the practicalities of mobile working. Cultural and workflow limitations, together with a poor understanding of mobile working may slow adoption and so the utility of mobile working needs to be promoted and supported
2. *Addressing issues of data governance and accountability* - staff are hugely concerned about security, and organisational oversight of their use of mobile technology. Ensuring transparency and accountability, and supporting security and confidentiality are vital for success.
3. *Handling the pace of change* - the expectations of staff need to be managed from the outset and ongoing active engagement supported. Organisations must be cognizant that too much innovation, too fast can lead to innovation fatigue and avoidable failures in new technology projects

By considering the experiences and attitudes of clinical staff when designing, implementing and evaluating new mobile-based technologies in hospital it will be possible to realise their potential to transform the quality, effectiveness and efficiency of care for both staff and patients.

4.5.2 - Placing this study in the wider context

There have been well publicised failures in deploying new technology into the health sector such as those related to the National Program for IT in the UK³⁴⁵ and a national electronic health record and staff smartcard in Holland³⁴⁶. More widely as few as one in eight large information technology projects are considered successful and over half are delivered late and over budget³⁴⁷. Whilst there are still fundamental technical and infrastructure gaps that need to be addressed to support the introduction of new technologies, there is an emerging consensus that sociological and cultural issues are a more pressing concern³³⁸. This design-gap and failure to engage and empower staff is likely to be at least partly responsible for the significant number of IT failures seen in healthcare to date³⁴⁸, and it has been suggested that staff interfere or sabotage nearly half of IT projects within healthcare³⁴⁹. Whilst this seems implausibly high, the findings presented in our study have certainly highlighted the importance of effectively handling the pace of change when it comes to implementing new innovations and technology, ensuring that staff feel engaged and empowered, that solutions meet real clinical needs and priorities, and that organisations remain cognisant that innovation fatigue can lead to staff disengagement and inertia which can directly lead to project failure. The need for clinical engagement with, and endorsement of new digital health products and services is crucial³⁵⁰. Overcoming resistance to change requires a thoughtful approach to balance bureaucratic means and professional ends and understand the implications for social roles, relationships and interactions³³⁹.

The need to balance different priorities and practicalities, address perceived cultural and workflow limitations and promote the utility of mobile working were identified as key challenges which need to be addressed in order to successfully move towards the effective integration of mobile working. As already identified there is a paucity of literature looking at factors influencing the successful implementation of mobile solution, but important lessons from wider health IT projects provide relevant insights. Key issues that have been identified as barriers to successful implementation include liability concerns, interoperability issues, poor usability, high cost and poor acceptability for patients and staff^{50,351,352}. The issue of digital health of readiness is influenced by micro (e.g. public readiness, individual perceptions of digital health tools, professional readiness), meso (e.g. organisational culture,

strategic leadership, resource constraints) and macro (e.g. clinical endorsement, political readiness, market complexity) factors³⁵². These factors are not insurmountable, but their existence needs to be acknowledged and addressed if deployment of mobile solutions at scale in the healthcare sector is to be realised. A key method for tackling these barriers to successful technology implementation is improving organisational readiness. Organisational readiness is a multi-level, multi-faceted construct that explains the shared resolve to implement change together with the shared belief in the collective capability to change of an organisation and its members³⁵³. Addressing organisational readiness for change forms a key basis of the seven success factors for change that were used as the initial coding framework for analysis in this study³⁴⁰.

A key concern raised by participants in this study centered on issues around data governance, information security and patient confidentiality and how these may be impacted by the move towards mobile working. These very concerns, particularly if staff are encouraged to use their own personal devices to access patient information through a 'bring your own device' policy are entirely valid and must be addressed. It has previously been highlighted in this body of work that only a minority of studies looking at smartphone interventions address key security concerns, whilst the Joint Commission actively discourages the use of mobile phones for communication of patient information due to security concerns³²⁸. Improving the awareness and training of staff with regards security and confidentiality implications of moving to a mobile way of working comes hand-in-hand with developing compliant technology and addressing security concerns. Furthermore a greater emphasis needs to be placed on engaging the public in the risk versus benefit debate around the security and safety of new technologies to build trust and confidence³⁵².

In addition to concerns around security and confidentiality, mobile technology may enable the seamless capture of staff performance data. Participants rightly questioned what information would be collected and how it may be used. Some argued that improving the accountability of staff is an important opportunity for improving patient safety and the efficiency of care. Others conversely raised legitimate concerns about the need for

transparency around what data would be collected, how it may be used and knock-on effects on professional autonomy and privacy. Performance management is a well-established process in many sectors but currently has a limited role to play in healthcare despite being a feasible and evidence-based approach³⁵⁴. In addition there are currently no robust tools for evaluating the performance of clinicians in real-time, with the identification of concerns reliant on reactive and narrowly-focused tools³⁵⁵. The ability to use additional data to support the performance management of doctors through new mobile technology may challenge the status quo of professional autonomy, but evidence suggests that doing so may drive improvements in quality and performance, deliver effective reward and recognition, and help support the development of a high performance work system³⁵⁶.

4.5.3 - Strengths and limitations of this study

Whilst this study provides important insights into the experiences and perspectives of front-line users the findings must be interpreted within the context of its inevitable strengths and limitations.

Whilst the sample size of 34 is reasonably large for this type of research and the purposeful sampling means that a representative cross-section of end-users were included, given that all participants were recruited from a single institution the findings may not be widely generalisable; this is a common criticism of interview studies which necessitate focused exploration at the expense of breadth and size. In addition, the institution at which the study took place is a Global Digital Exemplar NHS Trust and as such is recognised as being a digitally advanced organisation with world-class health IT¹⁵⁷; this will inevitably influence the experiences and attitudes of staff that may further limit the generalisability of the findings presented. The use of both focus groups and individual interviews was necessitated by practical considerations and the need to obtain a large and representative cohort of participants. The use of a standardised interview schedule mitigates against the risk of these methodological variations influencing the responses of participants but is nonetheless a potential source of criticism. This study sampled a representative cross-section of clinical

staff to elicit their experiences and perspectives but did not include IT professionals. In order to further understand the pertinent issues at a granular level understanding their perspectives is vital. The attitudes and experiences of IT professionals are not commonly aligned to those of clinical end-users⁸³ but are nonetheless vital to support the effective and successful introduction of new technologies.

The framework assessment methodology has been used for over 25 years and is a well-established systematic method for qualitative analysis and is particularly relevant for understanding multiple perspectives across a range of complex issues such as those highlighted in this study; nonetheless it still possesses pitfalls and criticisms³⁴⁴. The systematic approach to coding and charting means that there is a risk of inappropriate and misleading quantification of qualitative data. Furthermore, the inevitable identities and experiences of each researcher may act to influence interpretation of the data; impacting meaning and significance and potentially leading to distorted or biased generalisations and findings³⁵⁷. Despite this the framework method does provide an open and systematic approach to qualitative data analysis and delivers credible and relevant findings.

4.5.4 - Implications for future work

Whilst this study has identified important findings which will inform and support the delivery of a 'mobile-first' culture of work in secondary care it has also identified a number of further unanswered questions and knowledge gaps.

The findings presented, whilst informative, are not necessarily immediately generalisable. Further work is required to build upon these foundations and understand whether or not the key issues identified persist across all healthcare settings and organisations. Whilst there will be a degree of commonality and shared outcomes, there will also inevitably be local nuances in staff attitudes, behaviours and experiences which will undoubtedly influence outcomes if repeated in alternative settings. By combining the key experiences of staff together with the principal challenges and opportunities for mobile working across a range of

settings it will be possible to establish a guiding set of universal principles that will support the wider roll-out of mobile working.

In order to successfully move towards a 'mobile-first' culture of work in health and overcome resistance to centrally driven technology solutions there is a need to engage in genuine dialogue with end-users right from the outset of design and implementation. New mobile technologies must take into account deeply held professional norms, values and roles in order to obtain buy-in and support from end-users and overcome resistance to change. Further work is required to understand how professionals and patients perceive the impact of new technology and ways of working on currently held beliefs and the downstream effects on clinical care, the symbolic role of the health professional and expectations for the care they receive and deliver. Whilst clinicians clearly have an important role to play in shaping technology, there is also a need to perform further work to understand how technology shapes clinicians and the knock-on implications for professional identity and care delivery.

This study has highlighted that 'know-do' gaps - where organisations and staff know things could be better, but lack the agency, knowledge or skills to effect change - remain a key challenge. Further research is required to understand how organisations can move from merely recognising the need to change to implementing effective change itself. Key outstanding knowledge include fully understanding how staff and organisations recognise the need to change, gain the motivation to change, build sufficient capability change and develop sufficient headspace to make change happen³⁴⁰. The "*Seven success factors for change*" that was used in this study provides a robust conceptual framework for understanding some of these challenges and to identify potential solutions. It is however a top level-centric tool and focuses on implementation matters at a broad organisational and operational level whilst failing to address how change is facilitated and driven at a local or individual level. Given the clear need to obtain local buy-in that has been identified in this study and others there is evidently a need to further develop a process and framework to identify factors for successful change at a more local level that acts to address the attitudes, beliefs and expectations of individuals staff and patients.

4.6 - Conclusion

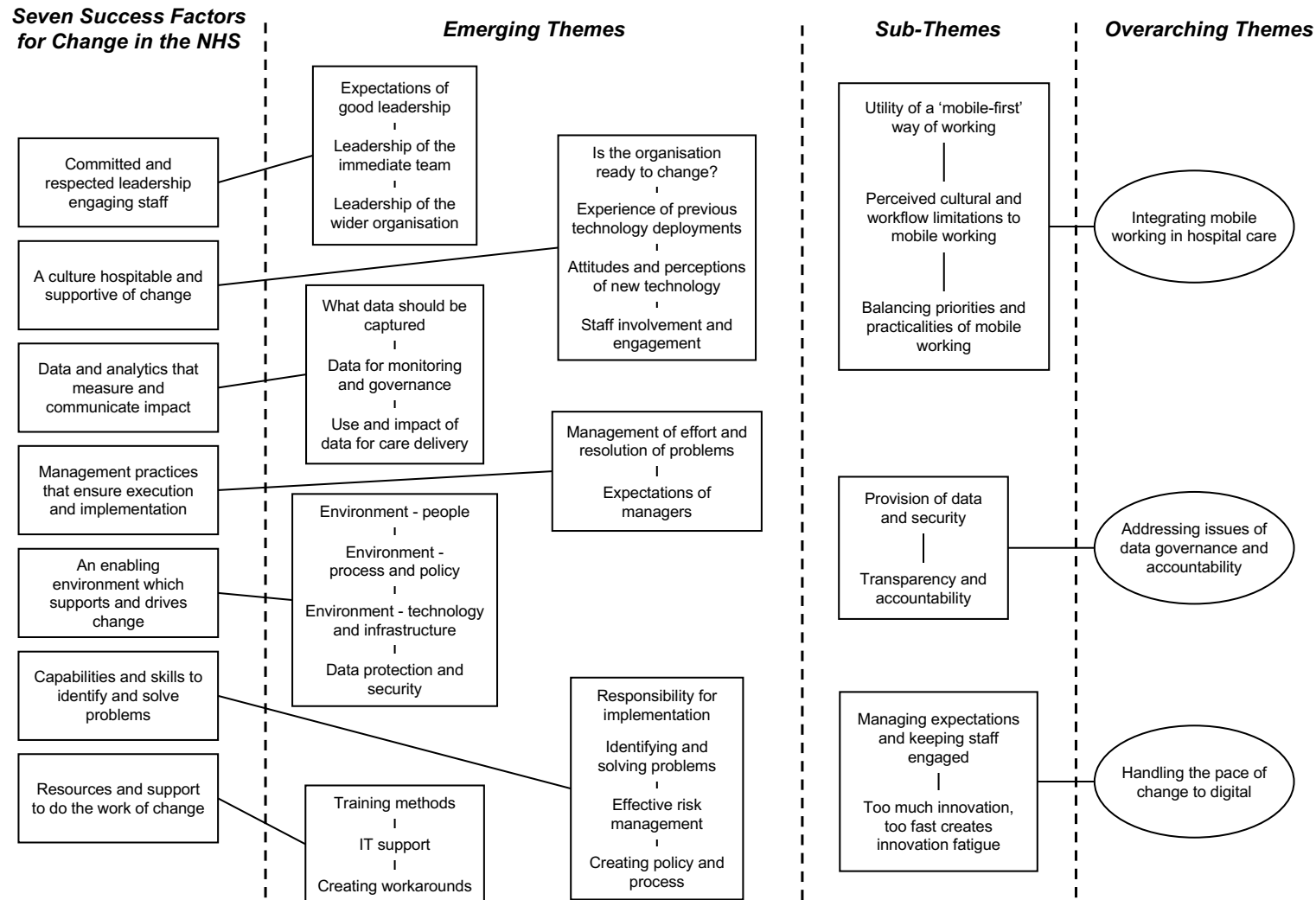
Using a representative sample of multi-professional clinical staff this study has identified a number of core themes that encompass the experiences and attitudes of clinical end-users moving to a 'mobile-first' culture of work in hospital, together with the potential challenges and opportunities that need to be addressed to make this significant cultural and technological change a reality. The deployment of new digital technologies in healthcare is frequently met with organisational inertia, staff resistance to change and solutions that are delivered late, over budget and which fail to meet expectations or real clinical needs. The advent of a 'mobile-first' culture of work has the potential to radically transform the delivery of care and support significant improvements in quality, efficiency and effectiveness. In order for this to be tangible there is a need to engage with end-users from the outset, balance competing priorities with the practicalities and realities of technology and mobile working, addresses the valid concerns of staff regarding knock-on effects on professional norms and the implications for data security and effectively manage the pace of change.

This chapter has highlighted a number of key factors that are required to support the transition to a 'mobile-first' culture of work. A major barrier to new mobile technologies is organisational inertia and staff resistance to change which is commonly due to poor satisfaction with the technology itself, or the process of change behind it. The next chapter therefore aims to further understand this phenomenon by examining the influence of health IT and organisational digital maturity on stakeholder satisfaction.

Table 4.1 - “Seven success factors for change in the NHS”³⁴⁰

Success Factors for Change	Description
<i>Committed and respected leadership engaging staff</i>	Leadership – particularly the ability to engage people with a clear vision for change, centred on patients – is arguably the most important factor for achieving successful change. Leadership needs to be collective and distributed throughout different levels of an organisation, with leaders facilitating collaboration and sparking enthusiasm.
<i>A culture hospitable and supportive of change</i>	A healthy culture (‘the way things are done around here’), harnessing the commitment staff have to patient care and engaging clinical staff in change is vital to making successful change. This means co-produced organisational values used in decision making, a positive attitude to risk taking, staff feeling valued and active engagement of patients.
<i>Data and analytics that measure and communicate impact</i>	Detailed, timely data and information are needed at all levels of the system – as well as staff with the skills to interpret them. Information allows frontline staff to understand and improve their care, boards to connect with their organisations, commissioners to know what their populations are experiencing and build the case for change, and national bodies to understand quality over the whole health service.
<i>Management practices that ensure execution and implementation</i>	Successful change cannot be delivered without effective operational management. This means both getting ‘the basics’ of management right through processes, governance and accountability; and expert management of change through a strategic approach, achievable expectations and a focus on execution.
<i>An enabling environment which supports and drives change</i>	The environment is a set of factors influencing change beyond the direct control of the unit making changes. For a clinical team, this will include supportive organisation-wide policies or national standards. For organisations or health economies, this will include strong local relationships, explicit permission from national bodies and politicians to take risks and learn from mistakes, and a set of national policies, for example financial incentives, which help not hinder change.
<i>Resources and support to do the work of change</i>	The majority of organisations or health economies committed to change have dedicated teams, in addition to frontline time dedicated to change. Adequately resourcing change means investment, but increases the likelihood of success, leading to greater efficiency and better outcomes in the long term. Practical support for change also matters, including providing expertise, coaching, peer support and facilitation of discussions
<i>Capabilities and skills to identify and solve problems</i>	At least three types of capability are needed to deliver change: ‘technical’ skills such as project management, clinical pathway design, change management or using practical quality improvement methodologies; ‘interpersonal’ skills such as good communication, conflict management and negotiation; and ‘learning’ skills including collective reflection and debate.

Figure 4.1 - Thematic map for semi-structured focus groups demonstrating developed sub-themes and core overarching themes



Chapter 5 - A regulatory perspective on the influence of health information technology on organisational quality and performance in England

Healthcare regulators are vital to any health system and provide independent objective assessments of quality and performance. This mixed-methods study therefore aims to investigate how health IT is currently reported and assessed during regulatory inspections, establish the relationship between the use of health IT and regulatory judgements of quality and provide evidence-based suggestions for how to assimilate formal assessments of health IT within existing regulatory frameworks.

5.1 - Introduction

Health IT has a fundamental role to play in improving patient safety and supporting the delivery of more efficient and effective care. Current evidence suggests that health IT adoption remains slow, and that new systems consistently fail to deliver their touted benefits³⁵⁸. Furthermore, as already identified in this body of work, there are often both substantial and unexpected risks and negative consequences, together with a shallow understanding of the true costs of health IT. With the rapid expansion in the deployment of new technologies, typically with little robust assessment of their impact on patients or organisations, there is an increasing realisation that not only are new approaches to understanding the problem required, but also that the unique safety risks posed by health IT must be considered carefully alongside the potential benefits and new ways of evaluating the full spectrum of risks identified¹⁶.

The current landscape for assessing the true impact of health IT in real-world settings is ad-hoc and patchy at best. The evidence that does exist often provides largely qualitative insights and commentary, is lacking in robust empirical evidence, and tends to focus on narrow organisational and process measures of success within a single organisation

following the deployment of a single product^{15,16,79,92,352,359,360}. Meanwhile, there have only been recent advances in developing and testing standardised measures of organisational digital maturity that are yet to be shown to be valid, useful or consistent^{107,122}. Whilst assessments of health IT across whole services are relatively immature, remarkably, there is little or no evidence assessing the effectiveness and usefulness of routine regulatory inspections to help highlight areas of best practice, and identify potential problems and risks related to health IT. Although not previously studied, by their very nature this standardised and universal process may represent a valuable repository of information and insights that can be deconstructed to illustrate both the challenges and opportunities for health IT, and also help proactively address all issues of safety and risk when designing, implementing and evaluating new technologies.

The Care Quality Commission (CQC) is England's independent quality regulator for health and social care, and currently oversees around 30,000 distinct organisations that provide care to patients³⁶¹. It monitors, inspects and regulates services to ensure that they meet fundamental standards of quality and safety through a standards-based inspection and monitoring regime that seeks to answer five key questions about an organisation³⁶²:

- Is it safe? - People are protected from abuse and avoidable harm
- Is it effective? - People's care, treatment and support achieves good outcomes, promotes a good quality of life and are based on the best available evidence
- Is it caring? - Staff treat people with compassion, kindness, dignity and respect
- Is it responsive to people's needs? – Services are organised so that they meet people's needs
- Is it well-led? - The leadership, management and governance of the organisation assures the delivery of high-quality person-centred care, supports learning and innovation, and promotes an open and fair culture

Based on their inspection of core services (e.g. surgery, maternity), population groups (e.g. long-term conditions or GP services) and the organisation as a whole, an overall quality and

performance rating is awarded to inform commissioners, providers and users, support better decision making about care choices and help drive improvements:

- Outstanding - the service is performing exceptionally well
- Good - the service is performing well and meets the CQC's expectations
- Requires improvement – the service isn't performing as well as it should and the CQC has told the service how it should improve
- Inadequate - the service is performing badly and the CQC has acted against the person or organisation that runs it

Since 2017 the UK Government has required all regulatory bodies, including the CQC, to follow a risk-based approach of assurance and regulation in order to reduce the administrative burden on those being inspected and ensure an evidence based prioritisation of resources^{363–365}. To achieve this objective the CQC has adopted a bespoke set of tools to *“predict where there may be problems and make better decisions about when, where and what to inspect”*³⁶⁶. Whilst this evidence-based intelligent approach to regulation is well established with some promising results³⁶⁷, there is increasing evidence that these tools are not able to robustly predict the performance and quality of an organisation; leading to a requirement for new sources of data and approaches to assurance³⁶⁸. Further to this, the tight fiscal landscape within healthcare in England means that the CQC is going to have to become ever more reliant on new sources of data and novel statistical surveillance tools to help plan and prioritise its inspection regime and identify emerging areas of risk.

This study aims to address gaps in the understanding of the emerging risks and benefits of health IT in real-world settings and provide further evidence to inform and support the quality assurance and regulation of healthcare providers. Mapping and characterising current regulatory insights into health IT will provide robust evidence that may help inform the implementation of new technologies, guide the development of policy, practice and regulation with regards health IT, and ultimately improve the quality, effectiveness and safety of care provided to patients.

5.2 - Hypothesis, aim and objectives

5.2.1 - Hypothesis

Current CQC inspection reports, together with assessments of organisational digital maturity may represent a valuable repository of information that can be deconstructed to illustrate the current challenges and future opportunities for health IT. By identifying the strengths and weaknesses of health IT as seen through the perspective of a regulator, it will be possible to inform the future development and regulation of new technologies in healthcare and support the successful advancement of health IT as a facilitator of safe, high-quality care.

5.2.2 - Aim

The principal aim of this study is to examine the impact of health IT on quality and performance in secondary care as judged by an independent quality regulator.

5.2.3 - Objectives

In order to fulfil the stated aim, this study will seek to fulfill the following objectives:

1. To perform a mixed-methods evaluation of CQC inspection reports to evaluate and characterise the use of health IT by care organisations in England
2. To understand whether or not the overall quality of care organisations in England is associated with organisational digital maturity and the positive or negative use of health IT
3. To provide evidence-based recommendations to improve the quality assurance and regulation of health IT in secondary care

5.3 - Methods

5.3.1 - Study design & sampling

130 consecutive CQC inspection reports from NHS Organisations published by the CQC³⁶² during an 18-month period from October 2014 to March 2016 were identified. These reports encompassed 83 secondary, 16 community, 9 integrated and 22 mental healthcare providers. This 18-month period was selected to include only reports performed under a new risk-based inspection regime introduced in 2014 following well-publicised failings in care at NHS hospitals, whilst also ensuring close alignment with the data collection period for the NHS Clinical Digital Maturity Index (CDMI) scores of organisational digital maturity first published in 2016³⁶⁹. The CDMI Tool has been previously described in this body of work. It is a self-reported score that allows NHS organisations to rate their own technical capabilities in IT and facilitate a better organisational understanding of how investing in, and effectively using digital technology can improve patient safety and outcomes, reduce bureaucracy, deliver efficiency gains, and facilitate the drive towards a paperless NHS.

The full text of each CQC report was reviewed, and subsequently re-reviewed to ensure full immersion in the data as per standard principles of qualitative research methodology³⁷⁰. Two independent and trained reviewers manually extracted and coded statements that referred to health IT via a manual approach so as to ensure true sensitivity of data capture. All references to health IT were included, with references to electronic staff rostering, patient feedback, patient facing digital tools (e.g. patient information, organisation website) and electronic incident reporting excluded. Extracted statements were defined as either positive or negative based upon their content and context, and their actual or potential influence on quality or safety. Extracted statements were then thematically analysed via a deductive approach utilising the Health Information Technology Safety Measurement (HITS) Framework as an initial coding template to further assesses health IT across three domains (safe health IT, using health IT safely and monitoring safety) and are summarised in *Appendix D*^{93,371,372}. The HITS Framework has previously been described in this body of work and provides a conceptual foundation for measuring, monitoring and improving the safety of health IT.

To further understand and characterise the influence of health IT on NHS organisations in England as seen through the CQC, a deductive thematic content analysis of all extracted statements was performed. The HITS Framework was used as an initial coding template from which specific categories were identified and subsequent themes developed. Data analysis was guided by Attride-Stirling's six-step thematic analytical technique to code and organise the data, and then abstract, illustrate, describe and explore the emergent themes³⁷³.

239 NHS organisations provided data to the 2015/16 CDMI assessment round¹²⁷. 125 organisations were identified as possessing both a valid CDMI score and published CQC report and so were eligible for full analysis; data was extracted, collated and analysed from the CDMI score and subsequently combined with the preceding CQC analysis. A summary flow diagram of sampling together with inclusions and exclusions is seen in *Figure 5.1*.

All data extraction and coding across all analyses was performed independently by two trained reviewers, with inter-rater agreement assessed via Cohen's kappa coefficient were appropriate and discrepancies in coding resolved via consensus.

5.3.2 - Statistical analysis

All data was arranged, structured and analysed utilising Microsoft Excel (Excel for Mac V15.22, Microsoft, USA) and IBM SPSS (SPSS for Mac V23, IBM Corporation, USA). Extracted data was assessed for normality via Q-Q Plots and Shapiro-Wilk tests; all data was not normally distributed and so non-parametric tests were used for all subsequent analyses. Wilcoxon Rank test was used to assess the overall differences in the frequencies of positive and negative references. Spearman's Correlation coefficient (2-tailed) was used to assess associations between the studied variables: overall trust rating, number of positive references, number of negative references and CDMI scores. Kruskal-Wallis and Mann Whitney tests were utilised to assess specific differences between overall trust ratings and the numbers of positive and negative references to health IT and CDMI scores.

5.4 - Results

5.4.1 - Evaluating the use of health IT by NHS care organisations in England

130 consecutive full text CQC reports published between October 2014 and March 2016 were initially analysed. 598 individual references to health IT were extracted, coded according to the HITS Framework, and subsequently judged as having either a positive or negative influence on safety or quality of care. These are summarised in *Table 5.1*. Inter-rater agreement for data extraction and coding was good, with an overall Cohens kappa coefficient of 0.89. Significantly more negative references were identified; nearly two-thirds (365/598, 61.0%, $p<0.05$) of references highlighting actual, or potential negative influences on either safety or the quality of care being delivered. The vast majority of references (74.7%, 447/598) related to three principal themes of the HITS Framework: data availability (174/598, 29.1%), surveillance and optimisation (140/598, 23.4%) and health IT system usability (133/598, 22.2%). The most commonly identified negative themes were those of usability (96/365, 26.3%), availability (86/365, 23.6%) and the complete/correct use of health IT (64/365, 17.5%). The most commonly identified positive themes were those of data availability (88/233, 37.8%), surveillance and optimisation (79/233, 33.9%) and usability (37/233, 15.9%). A comparison of the relative frequency of each theme across both negative and positive references is seen in *Figure 5.2* and highlights the key thematic differences between the two groups. Key examples of both positive, and negative references to health IT across all six thematic domains of the HITS Framework are seen in *Table 5.2*. There were no significant differences in reporting of health IT across the multiple organisation types analysed (secondary care, community care, integrated care and mental healthcare).

There is a common underlying theme identified in this analysis; failures of technology rather than the user, with poor IT design resulting in limited usability and inadequate use, leading to potentially harmful issues with data integrity and accuracy. There is clear evidence of problems with the usability of common healthcare IT systems in the NHS; usability accounting for 22.2% (133/598) of all references, of which 72.2% (96/133) were negative. Furthermore, there is also evidence of the failure of health IT to be implemented and used

as intended; whilst the complete/correct use of health IT only accounted for 14.4% (86/598) of references, the vast majority (64/86, 74.4%) were negative. These clear failures in the usability and correct use of health IT are likely to manifest themselves in problems with the accuracy of data, and concerns regarding the integrity of the data being recorded, accessed and acted upon; whilst only 9.1% (55/598) of references refer to data integrity they are universally negative (50/55, 90.1%). The surveillance and optimisation and data availability themes accounted for a significant number of references but had a fairly equal distribution of positive and negative references across each theme: 88/174 (50.6%) vs. 86/174 (49.4%), and 79/140 (56.4%) vs. 61/140 (53.6%) respectively

5.4.2 - Evaluating the impact of health IT on organisational quality and performance

Based on the outcomes of its inspection an overall rating is awarded by the CQC: inadequate, requires improvement, good and outstanding. Of the 130 CQC reports initially analysed as part of this study 11 (8.4%) organisations were deemed inadequate, 81 (62.3%) required improvement, 33 (25.4%) were assessed as good and only a single organisation was rated as outstanding. 3.1% (4/130) organisations were not given an overall rating as part of their report as they were either specific supplementary follow-up inspections or were performed outside of the normal inspection regime; thus 126 reports were utilised for the subsequent evaluation of the relationship between the use of health IT and organisational quality and performance. These 126 reports generated 585 (226 positive, 359 negative) references to health IT. The mean number of total references identified in each report was 4.64 (range 0-28), with the mean number of positive and negative references identified as 1.79 (range 0-11, median 1) and 2.85 (range 0-18, median 1) respectively. There was a significant difference between the frequency of negative and positive references identified, with significantly more negative statements extracted than positive ($p=0.004$) as illustrated in *Figure 5.3*.

The correlation between organisational quality rating and the frequency of positive and negative references to health IT was assessed via Spearman's Correlation Coefficient as the

data was non-parametric and is summarised in *Table 5.3*. Utilising a two-tailed hypothesis there was a weak, but significant correlation between the frequency of positive statements and an overall positive CQC rating ($r = 0.255$, $p=0.004$); the greater number of positive statements observed, the higher the quality rating. There was also a weak, but significant correlation between the number of positive and negative statements identified ($r = 0.224$, $p=0.012$); there is significant variation in the overall reporting of health IT across different CQC reports. There was however no correlation between the number of negative statements and overall trust quality rating ($r = -0.94$, $p=0.297$); all organisations, irrespective of their overall rating, had a similar number of negative impacts from their health IT identified by the CQC during the inspection process.

To further understand the relationship between health IT and overall organisational quality rating a post-hoc sub-group analysis was performed utilising Kruskal-Wallis and Mann Whitney tests to assess the differences between specific organisational ratings and the frequency of either positive or negative health IT references. There was no difference between specific quality ratings and the frequency of negative references to health IT ($p=0.751$) as seen in *Figure 5.4*. Despite the fact that far fewer positive statements were identified across all reports (226 vs. 359, $p=0.004$), there was a significant difference between the overall trust rating and the frequency of positive references reported ($p=0.019$). Investigating this observed difference further, it is possible to discriminate between specific ratings, with significant differences seen with inadequate vs. requires improvement (2.33 vs. 1.82, $p=0.012$), but no difference for requires improvement vs. good ($p=0.133$) or good vs. outstanding ($p=0.917$) as illustrated in *Figure 5.5*.

This analysis has identified that the CQC more often than not identifies the negative influences of health IT, and that across the six domains of the HITS framework there were a significantly greater number of negative references identified in three domains: data integrity, the complete/correct use of health IT and usability. These negative influences are correlated with an organisation's overall quality and performance rating.

5.4.3 - Characterising the influence of health IT on performance and quality: a thematic content analysis

A deductive thematic content analysis of all 585 references to health IT extracted from the 126 retained CQC reports was performed as previously described. A summary of the overall conceptual framework that was developed is seen in *Figure 5.6*. The HITS Framework provided the initial coding template, and also forms the overarching global themes for the thematic analysis. 585 extracted statements were reduced and refined to 34 basic themes or categories; 6 for data availability, 5 for data integrity, 5 for data confidentiality, 4 for the complete/correct health IT use, 6 for health IT system usability and 7 for surveillance and optimisation. These basic themes were further refined and arranged to generate 12 organising themes; 2 for data availability, 2 for data integrity, 3 for data confidentiality, 2 for complete/correct health IT use, 2 for health IT system usability and 3 for surveillance and optimisation. Inter-rater agreement for data extraction and coding was good, with an overall Cohens kappa coefficient of 0.89. Basic themes were created by abstracting the content of each health IT reference and arranging the into clusters. These basic theme clusters were then further organised and refined into organising themes which are mapped to the 6 global themes provided by the initial coding of the references, whilst the organising themes are higher-order themes formed by clustering and abstracting of the key concepts.

Two organising themes were identified within data availability. The importance of ensuring adequate and reliable access for all staff across all services and locations, particularly when working in the community or at satellite sites away from the main hospital was regularly identified as a concern, and clearly highlighted as negatively impacting quality and safety:

“Community staff were only able to access electronically held information about their patients’ care and treatment plans at their office base, and not while they were on home visits. Some teams, such as the evening district nurses and the rapid response team, had no access at all to the electronic system. This meant staff might not have the complete information they needed before providing care and treatment”

Two organising themes were identified within data integrity. Issues around the use of multiple legacy systems were regularly highlighted and identified, particularly when transitioning to new technologies and systems. Ensuring the accuracy of clinical data and delivering a 'single true record' is fundamental to patient safety. It is therefore important to minimise dual records systems, particularly when introducing new IT systems, and to reduce the use of multiple legacy IT systems as these can lead to confusion or recording error:

"There was a risk of discrepancies between the paper and electronic records which could place people at risk of unsafe treatment and care."

With regards to confidentiality of data, it was clearly highlighted that there was an important need to ensure that adequate security and privacy procedures are in place, and that these are supported with a robust and tested process for authenticating approved users and governing access to data. These processes must be supported by the effective protection of both hardware and software, a transparent and robust means of auditing access and compliance with all relevant regulation and legislation:

"[There is a need to] ensure that patients' records including confidential computerised patient records are stored appropriately in accordance with legislation at all times"

Two organising themes were identified with regards to the complete/correct use of health IT. The need for adequate training and support was frequently highlighted as fundamental to ensuring that staff use health IT systems safely and to their full potential. Importantly, the issue of temporary or locum staff not having access to health IT systems was commonly identified as a key patient safety risk that needs to be adequately addressed:

"The trust had a system where a medicines chart was manually printed, which agency nurses signed when they gave out medicines; the electronic system was then updated by a permanent member of staff. We saw that this caused delays in updating electronic records and also saw a delay in medication being administered. On one ward the electronic

prescription and administration record for patients being cared for by an agency nurse had not been updated to confirm that medicines had been given correctly two hours beforehand.”

Health IT systems must be designed to support day-to-day clinical activities, whilst the user interface must be intuitive and a delight to use otherwise staff will develop unsafe workarounds or devote additional time to administrative tasks to the detriment of patients. Clinician satisfaction is a legitimate and sensitive barometer for health IT success and should take precedence over the satisfaction of IT professionals who often have different objectives and priorities. The usability of health IT systems was therefore regularly highlighted as a key area of risk to both the efficiency and safety of care:

“Concerns remained about the length of time taken each day to manually complete patient records and then update the computer systems at a later time. Staff cited that they frequently worked an extra five hours plus per week to ensure records were up to date.”

The final global theme relates to surveillance and optimisation in which three core organising themes were identified. Best practice in high performing organisations demonstrated that active and visible organisational leadership, with a clear vision and direction of travel is vital to support staff, drive proactive improvements and harness the potential for new health IT systems, improved use of data, and the novel insights that they both can provide to support the delivery of improvements to care quality and service delivery.

“The trust had a strong information communications technology (ICT) department which was working hard to provide solutions to benefit staff and patients alike. There was a clear vision for ICT services which took the trust through to 2020. We saw some impressive use of technology which was making a real difference to the way care was being delivered across the trust. There was clinical engagement with the ICT projects, with nursing staff seconded to work with the ICT teams. This meant, services were developed that were meaningful and practical for front line staff. During our focus groups with staff at all levels, they told us how

proactive and forward thinking the trust was in the use of technology to help them do their jobs more efficiently.”

5.4.4 - Estimating the influence of organisational digital maturity on quality and performance

239 NHS Organisations completed the 2015/16 NHS CDMI assessment in order to rate their own technical capabilities and facilitate a better organisational understanding of how investing in, and effectively using digital technology can improve patient safety and outcomes, reduce bureaucracy, deliver efficiency gains, and facilitate the drive towards a paperless NHS. Raw CDMI scores from the 3 core themes and all 13 individual domains assessed in the tool were identified for the 125/126 (99.2%) NHS organisations previously evaluated as highlighted in *Figure 5.1*. Each domain is scored out of 100, with a maximum total overall score of 1400 available. The median overall CDMI score across the 125 organisations studied was 740 (mean 742.8, range 299 – 1253, SD 178.0). Descriptive statistics for each of the 3 core themes and 13 individual domains of the CDMI tool are seen in *Table 5.4*.

The correlation between overall CQC rating, CDMI domain score and overall CDMI score was assessed via Spearman's Correlation Coefficient as the data was non-parametric and is summarised in *Table 5.5*. Utilising a two-tailed hypothesis there was a weak, but significant association between an organisation's overall CQC rating and total CDMI score ($r = 0.186$, $p=0.038$). There was also a weak, but significant association between an organisation's infrastructure domain score and overall CQC rating ($r = 0.259$, $p=0.004$), and less so with readiness domain score ($r = 0.177$, $p=0.049$). There was no association between the domain score for capability and overall CQC rating ($r = 0.148$, $p=0.1$).

To further understand the association between CDMI scores and CQC ratings a post-hoc sub-group analysis was performed using Kruskal-Wallis and Mann Whitney tests. There was no relationship between specific CQC rating and the capability domain score ($p=0.406$),

or between specific CQC ratings and the readiness domain score ($p=0.105$). There was however a significant association between specific CQC rating and the infrastructure domain score ($p=0.023$) and seen in *Figure 5.7*. As demonstrated there is a significant difference between the median infrastructure domain score across the four different CQC ratings ($p=0.023$); inadequate (57), requires improvement (66), good (70) and outstanding (76). Further investigation allows for discrimination between the different ratings, with a significant difference in infrastructure domain scores in those organisations with an inadequate rating compared to those which are deemed to require improvement (57.0 vs. 66.0, $p=0.028$) as seen in *Figure 5.8*. There was however no significant difference when comparing those organisations requiring improvement vs. good ($p=1.00$), or good vs. outstanding ($p=0.659$). Furthermore, whilst there was a trend apparent there was no significant difference in the median overall aggregate CDMI score and trust rating ($p=0.161$) as seen in *Figure 5.9*.

The association between the number of positive and negative references to health IT and overall CDMI score was assessed via Spearman's Correlation Coefficient as the data was non-parametric. Utilising a two-tailed hypothesis there was no correlation between the number of negative CQC references and overall CDMI score ($r = -0.099$, $p=0.270$), or between the number of positive CQC references and overall CDMI score ($r = -0.063$, $p=0.486$) as seen in *Figure 5.10*. Furthermore, there was no correlation with the number of positive references to health IT identified, and either of the three CDMI domains - capability ($r = 0.015$, $p=0.864$), infrastructure ($r = -0.063$, $p=0.486$) or readiness ($r = -.030$, $p=0.738$). There was also no correlation between the number of negative references to health IT identified and either of the three CDMI domains – capability ($r = -0.97$, $p=0.283$), infrastructure ($r = -0.006$, $p=0.945$) or readiness ($r = -0.061$, $p=0.501$).

5.5 - Discussion

5.5.1 - Summary of key findings

This analysis shows that England's healthcare quality regulator – the CQC – regularly identifies and comments on the impact and influence of health IT on the quality of care provided to patients, with an average of 4.64 references in each report despite it not being part of the formal regulatory assessment framework. The majority of the insights identify the negative impact of health IT, and whilst this may reflect the understandable tendency for quality inspections to focus on areas for improvement rather than highlighting areas of good practice, it nonetheless provides potentially useful insights into the strengths and weaknesses of health IT with implications for future policy and practice.

The poor use of health IT is universal in NHS organisations with two-thirds of regulatory observations identifying negative impacts on care delivery. Whilst all organisations report a significantly greater number of negative consequences (61%, $p=0.<0.05$), there is importantly a weak, yet significant relationship between the positive use of health IT and better organisational quality ($r = 0.255$, $p=0.004$); organisations who are seen by the regulator to make good use of health IT are likely to have a higher quality rating. Furthermore, those organisations deemed to be inadequate by the CQC have significantly fewer positive observations of their health IT than better performing organisations ($p=0.012$). This suggests that those trusts which proactively invest in good technology and embrace it' effective implementation see significant benefit in performance and quality, which is reflected in a better regulatory judgement. These findings must however be interpreted with caution given the challenges in establishing direct causality and lack of significant relationships seen in the majority of areas studied.

The majority of regulatory observations about health IT fall into one of three core themes: data availability (29.1%), surveillance and optimisation (23.4%) and usability (22.2%). For example, this suggests that when the CQC highlights the use and impact of health IT it is most commonly due to failures in the technology rather than with the end-user: 22.2% of insights, of which 72.2% were negative, identified issues with the usability of IT systems as a key problem. Commonly the planning, design and implementation of new technologies led to a poor user experience, problems with the accuracy of data, and concerns regarding the

integrity of what was being recorded, accessed and acted upon by staff. Meanwhile 29.1% of insights, of which 49.4% were negative, highlighted potentially dangerous failings in the availability and access to data and systems for staff.

The results from the 2015/16 CDMI assessment demonstrate that levels of digital maturity are extremely variable across healthcare organisations in England (median 740, range 299 – 1253), with some organisations evidently pursuing the digitisation agenda with more success than others. An individual organisation's digital maturity is weakly, but significantly correlated with their overall quality rating ($r = 0.186$, $p=0.038$). More importantly from a policy and leadership perspective, higher scores in the infrastructure domain of the assessment – representing the extent to which an organisation has put in place essential infrastructure and services to support the effective use of health IT – are more significantly correlated with better organisational quality ratings ($r=0.259$, $p=0.004$). Furthermore, those organisations deemed to be inadequate by the CQC have a significantly lower median infrastructure score than their better performing peers ($p=0.028$). Although there is no significant association between the number of references to health IT found in their CQC reports and digital maturity, these findings do suggest that those organisations which invest in better technology and infrastructure are rewarded with improvements in performance, which are reflected in better regulatory judgements of organisational quality.

This study has provided insight into the current influence of health IT on the care delivered to patients in England through the lens of an independent quality regulator. It not only highlights the current status quo, but also has provided firm evidence that may be used to help improve health IT in the future, shape developments based on real-life experiences of the successes and failures of health IT in the English NHS and help improve the quality and safety of care provided to patients. These recommendations, based on the thematic content analysis of 585 regulatory observations about health IT in England are summarised in *Table 5.6*.

Organisations that invest time, people and resource into good health IT are more likely to be high performing organisations. Conversely, those organisations that are judged to be delivering inadequate care to their patients are more likely to have poor IT identified through both external regulatory assessment and self-reported measures of digital maturity. Health IT clearly holds great promise in its ability to support and enhance the coordination of care, reduce errors and improve quality. However, in order for it to meet its full potential and avoid costly failures and avoidable harm to patients it is important to develop and implement innovative and robust approaches to evaluation, regulation and oversight. It is vital to ensure that we keep pace with advances in technology and the inevitable changes in practice that they will bring; ensuring that potential risks are identified and addressed in a proactive and timely fashion, and that the rigorous evidence-based approach to innovation that is the norm in all other aspects of healthcare is equally applied and expected in the digital space.

5.5.2 - Placing the findings of this study in the wider context: explaining variation in digital maturity

As reinforced in this study health IT is ever more critical to securing the safe and sustainable delivery of healthcare and facilitate continuous quality improvement. Indeed, this study suggests that digitally mature organisations deliver higher quality care. This is probably not because of a direct causal link, but rather as both are independently correlated with good management and leadership. The current interest in the digitisation of healthcare is not new though; as early as 1970 Schwartz proposed that clinical computing would be *“commonplace in the not too distant future”*³⁷⁴, and arguably, despite many decades of work electronic health systems remain *“the wave that never breaks”*³⁷⁵. Whilst the implementation of new health IT has been piecemeal, prone to failure and under-delivery, and associated with broadly negative coverage to date, the continual influx of innovative technology is a predictable and inevitable characteristic of modern healthcare. Inevitably these hurdles, together with a failure to address them in a systemic and joined-up way means that there is persistent widespread variation in the digital maturity of individual institutions with no clear patterns or trends across the country. The results of the NHS CDMI assessment support this

assertion with scores ranging between 299 and 1253; evidently some organisations are pursuing the digitisation agenda with better success than others. This problem is not unique to the UK however, with a similar picture being seen in the US where there is a wide disparity in the adoption of information technology systems across different institutions and regions¹⁸⁵.

Ever since the failure of the £12.4 billion centralised National Programme for IT in the NHS (NPfIT) the UK has been left with a complex, hard to understand and fragmented landscape of health IT provision. Policy makers in the UK have rightly identified this as a key area for concern, but despite announcements of significant extra funding and support⁶³ the rising costs of healthcare as a consequence of rapidly changing demography, developments in new technology and a challenging fiscal climate means that it remains a major concern for commissioners, providers and policymakers alike. The wide scale adoption of new health IT and the technologies it can support has the potential to help address these rising costs through improvements in efficiency, quality and safety³⁷⁶. Indeed, although there is a relative paucity of literature the majority of studies to date indicate that the implementation of new health IT systems is associated with financial gain through savings on administrative goods and personnel, reductions in drug expenditure and improved revenue generation through better billing and cost recovery³⁷⁷. These savings are in spite of projected cost savings commonly being based upon overly-optimistic assumptions of the level of adoption and interoperability that are nowhere near achievable³⁷⁸.

Implementing new health IT systems may be prohibitively expensive for healthcare providers, particularly in the absence of clear evidence supporting their impact and effectiveness. Financial factors are commonly cited as a key driver for the adoption of new electronic health systems, with additional reimbursement for their implementation reported by over three-quarters of institutions as key part of their decision to invest in new technology¹⁸⁵. In the US the 2009 HITECH (Health Information Technology for Economic and Clinical Health) Act introduced a system of incentive payments for hospitals to use health IT to improve the delivery of care for Medicare patients. The introduction of this Act

resulted in a large increase in spending on health IT from around 3.1% to 5% of annual budgets; equating to a 60% year-on-year increase in those hospitals treating the greatest number of eligible patients¹²³. Meanwhile, in the UK NHS acute hospitals are currently spending around £830 million a year in IT, with 4% year-on-year increases being predicted despite overall budgets remaining relatively flat in real terms and rising patient demand³⁷⁹. Whilst early predictions of the scale and impact of digital adoption may have been overly optimistic - savings of up to \$81 billion per year being suggested in the US³⁸⁰ - in the absence of clear robust evidence for their benefit the need for financial incentives to drive the adoption of new health IT is still required.

In addition to financial considerations and the need to balance competing demands on limited resources within a constrained fiscal envelope, other factors may also influence the deployment of new health IT systems and improvements in digital maturity. Large academic hospitals and those located in urban areas spend up to 26% more on IT annually, and are more likely to be digitally mature than small, non-academic rural institutions^{123,185}. This variation in investment between academic and non-academic settings may be due to differences in the attitude of staff towards innovation and new technology, or differences in digital literacy. Furthermore, the close cooperation between clinicians and academics within these institutions, with research and academic output dependent upon effective use of data, may also be a key driver of digital maturity. Smaller hospitals with limited resources, or those located in disadvantaged areas serving poorer populations may lack the resource, knowledge and skill to embark on large, expensive and complex IT projects; the money must come from somewhere.

In addition to the financial and organisational factors that may influence the pace and scale of health IT adoption, staff attitudes are also fundamental. Resistance to change and organisational inertia are commonly implicated in the failure of new technology adoption and development of innovative changes to clinical practice and process. The use of electronic health records has been associated with an increase in administrative burden, a high risk of clinician burnout and low levels of satisfaction¹¹³, despite the vast majority of clinicians

reporting a positive attitude and expectation that health IT has the potential to improve the quality of care⁷⁵. New technology must be designed to support day-to-day clinical activities, whilst the user interface must be intuitive and a delight to use otherwise staff will develop unsafe workarounds and devote unnecessary additional time to administrative tasks to the detriment of patients^{83,381}. Clinician satisfaction is a legitimate and sensitive barometer of health IT and should take precedence over the satisfaction of IT professionals or managers who often have different or competing objectives and priorities. Negative attitudes to new technology are built on experience, and often foster resistance to change. Conversely, influence presented at the right time and in the right manner may easily counteract this and support the implementation of new technology³⁸². Staff engagement and buy-in is therefore fundamental to support the successful adoption and implementation of new technology and enable its potential to transform care delivery.

5.5.3 - Placing the findings of this study in the wider context: explaining variation in organisational performance and quality and the influence of health IT

The evidence that introducing widespread structural change, promoting system integration, and advocating the adoption of new technology leads to improvements in the quality and safety of care is fairly robust^{105,383,384}. Conversely, the evidence that the widespread adoption of new health IT lowers the cost of care, streamlines administration and improves efficiency is somewhat more underpowered. Given that the majority of studies evaluating the impact of new technologies tend to focus on narrow process led outcomes of specific technologies in a small number of institutions¹⁰⁹, the broader value of health IT and its influence on the overall quality of care remains largely unknown¹⁰⁸.

As previously highlighted, health IT has the potential to significantly improve patient safety, reduce adverse events and medical error, improve information quality and availability, support better decision making and communication, and foster improvements in workflow and culture⁶⁻¹³. On the other hand, there have also been numerous examples of new technology fostering error and harm rather than reducing their likelihood, and weakening

rather than strengthening the complex systems of people, technology and process that underpin the effective and safe delivery of care¹⁹. The majority of work estimating the influence of digital maturity has focused on specific examples, be they individual cases of computer failure causing harm or the impact on process and workflow. There is a relatively limited body of evidence evaluating the impact of new technology on quality and outcomes at a larger scale that considers the broader multi-faceted impact of new technology on safety and quality. Despite this relative gap in the literature, hospitals on the “most wired” list - suggesting higher levels of digital maturity - do show a weak trend towards higher composite quality scores³⁸⁵, whilst patients treated in digitally mature hospitals may have up to a 30% reduction in in-hospital adverse events⁹, and significant reductions in in-hospital mortality, length of stay and complications¹¹⁰.

This present analysis frequently identified the potential for health IT to lead to patient harm; *“many patients experienced delays in their treatment as a result of the poor implementation of the new IT system.”* There is however a paucity of literature reporting patient harm associated with health IT; it is estimated that just 0.2% of reported patient safety events relate to health IT³⁸⁶, and only 850 individual safety events associated with the NHS NPfIT were reported over a six-year period³⁶⁰. This low level of reported harm is most likely due to under-reporting rather than low numbers; the majority of healthcare risk managers and lawyers working in large US hospitals reported at least one health IT related serious safety event in the past 5 years, and 10% reported more than 20 such events⁸⁰. Voluntary reporting of adverse events only detects a small proportion of problems, and often neglects latent errors and near misses that could point to important safety issues that are associated with poor, but not catastrophic failures in care or process⁹⁶. There is a pressing need to develop formal mechanisms to identify, monitor and address health IT related safety issues to accompany the drive towards a paperless healthcare system. The wide-spread disruption to patient care in the NHS caused by the recent WannaCry cyberattack - driven by failures in health IT at both a local and national level - also acts to highlight the need to develop formal mechanisms to monitor, regulate and quality assure health IT as a fundamental pillar of patient safety and care quality^{387,388}.

Whilst causation cannot be definitively ascertained, the findings unearthed in this study do suggest that the better use of health IT and higher levels of digital maturity are associated with improvements in care quality and performance. The significant, albeit moderate association between CQC outcome - an overall independent and objective assessment of institutional quality and performance - and quality of digital infrastructure, overall organisational digital maturity and the number of positive observations about the use and impact of health IT is an important and consistent finding: good management and leadership is likely a common causal factor, but high-quality, high performing organisations make better use of health IT.

5.5.4 - Strengths and limitations of this study

This study has suggested that there is a relationship between the positive use of health IT and overall organisational quality and performance; these results must however be interpreted within the context of the strengths and limitations of the study and the presence of likely confounders.

As previously identified there is no formal mechanism or framework for identifying and evaluating the use and impact of health IT within the current CQC inspection framework. Nonetheless, 126 consecutive CQC reports were evaluated in full which yielded 598 specific references to health IT; representing a large, unique and rich source of data for analysis. An existing published framework³⁷¹ was utilised to perform the framework analysis and provide a coding template for the subsequent thematic content analysis; providing a robust, valid and evidence-based approach to analysis. Furthermore, the internal consistency and inter-rater agreement in both data extraction and subsequent coding of the data was good with an overall Cronbach alpha of 0.89. The NHS CDMI tool is a self-assessment framework that allows organisations to benchmark their digital maturity against their peers and identify key areas for development and improvement. Although it has yet to be validated against independent and meaningful measures of process or outcomes, it is nonetheless an

evidence-based and objective tool that attempts to account for not only the narrow focus on technology, resource and capability, but also the digital literacy, ability and motivation of staff to use new technologies; important broader aspects of digital maturity that are often not measured¹⁰⁷. It is therefore the best current measure of digital maturity available in England and provides a standardised and objective measure for all 239 NHS organisations that provided data. It is the first standardised and mandated assessment tool for digital maturity reported¹²², and whilst more work is required to better understand its potential, it remains a rich repository of information to analyse. The unique nature of the data, together with the volume and richness of content means that despite some limitations this largely remains a powerful and robust study.

Whilst this study possesses many strengths it also inevitably has a number of limitations, some of which have already been highlighted. CQC quality ratings consider a wide range of factors, and it is challenging to ascertain the direction of causality for the findings reported. The quality of care delivered to patients is dependent on a huge range of factors within an extremely complex and dynamic landscape. A large number of potential confounders are present, and the complexity of the relationships and determinants of outcomes means that determining causal inference is problematic.

The objective assessment of quality delivered by the CQC - be it inadequate, needs improvement, good or outstanding - is dependent not just on measures of quality, but also significant numbers of process, governance and administrative measures. Whilst some of this variance will be accounted for through the size of the dataset, it is still challenging to conclude that the observed associations between the use of health IT and organisational quality are causal and not the result of confounding. A key criticism of the study is the nature of the CQC reporting itself. There is no formal structure or framework upon which an assessment of the success or failure of health IT in an organisation is made. In the absence of this all observations are likely to be opportunistic and dependent upon the nuances of each inspection team - which are not consistent in composition, experience and skills – and also in the information that is provided to them by individual organisations. Differences in

emphasis and content are key, with organisations understandably highlighting areas of strength where at all possible. Meanwhile, inspectors are likely to have inevitable bias towards highlighting areas for improvement, rather than identifying those of good practice which also potentially influences the quality and completeness of the data. This unstructured reporting, whilst providing arguably a more authentic and real-life description of the influence of health IT may also result in inconsistencies and a subsequent impact on the overall findings and conclusions.

Effective and well-led organisations are likely to have a mature approach to health IT that is consistent with their overall organisational culture and leadership. Organisations with strong and proactive digital leadership and culture that promote the use of new technology - for example being a Global Digital Exemplar - are likely to make an active effort to highlight their health IT successes during an inspection and devote additional resource to them. Additionally, they are likely to complete the self-report CDMI tool with a different emphasis and detail; both of which may lead to artificial differences in how health IT is seen and reported that are potentially not related to the wider performance of the institution. We also know that the implementation of new technology is subject to multiple context- and institution-specific barriers that also correlate with overall organisational quality and performance^{48,49}. Large academic hospitals, and those located in urban areas tend to spend more on health IT^{123,185}, whilst smaller institutions may lack the knowledge, skills and resources to embark on complex IT projects. It is likely that these larger academic hospitals also deliver higher quality care; with greater specialist services, higher patient volumes and a greater breadth and depth of access to clinical and supporting services and infrastructure in comparison to smaller more isolated institutions^{144,146}. Finally, the focus on secondary care organisations in the study may limit the applicability of the findings to the wider healthcare economy. The vast majority of patient interactions with the NHS in England take place in primary care³⁸⁹ and these are not accounted for in this analysis.

5.5.5 - What is the impact of this study: suggestions for the future and implications for policy and practice

The renewed drive for a 'paperless NHS' is a key policy agenda for healthcare leaders. With arguably a limited and contradictory evidence base it is ever more important to truly understand the relationships in play, how health IT impacts the totality of outcomes, and how this can be used to drive improvements in technology and inform how health IT should be regulated and evaluated in the future. Within this context there are a number of challenges as well as opportunities. This study reveals a number of implications and considerations for all stakeholders, from individual clinicians and technology companies, through to healthcare institutions and regulators.

Tackling problems with software and hardware in isolation can only partially mitigate against the potential risks of new technology. It is important to tackle the entire scope of the socio-technical system³⁷ including people, organisations, systems, policies and processes as well as technology in order to fully address potential patient safety concerns and maximise the benefits that health IT can deliver. More generally, there is also a requirement to advance better, standardised measurements of health IT related harm and its impact on quality and safety in addition to developing alternative approaches for data collection and assessment to capture the full spectrum of risks³⁹⁰.

As alluded to in this study, the current regulatory regime in England is not designed for the digital age. Although it can provide useful insights into the influence of health IT on care quality and organisational performance, there is a need for a new approach to regulation to ensure that individuals, institutions and regulators keep pace with changes in technology and practice. The current CQC inspection framework provides a robust method for evaluating a full range of organisational factors and is well understood by all stakeholders. As a result, there is no need to depart from this well-established framework when proposing new methods for evaluating the impact of health IT. A new approach combining the CDMI self-assessment framework, together with an external assessment based upon the principles of the HITS Framework may provide a suitable method for assessing the impact of health IT on organisations without a radical departure from the status quo. A key focus for this is to ensure credible, consistent and comparable inspection ratings through the use of standard

sets of key lines of enquiry (KLOE's) that directly relate to the questions asked, and ratings given. As health IT plays an increasingly important role in the delivery of joined up health and social care, there will be a need to transition from the current ad-hoc approach to regulatory oversight and review, to a proactive formalised structure based upon the existing CQC framework utilising specific KLOE's for health IT based upon all existing evidence. A proposed model for this approach is seen in *Figure 5.11*.

To help support the future regulation of health IT there is also a need to provide clear guidance on what defines a 'never event' or 'near-miss event' with health IT in order to ensure effective reporting of error and harm. Furthermore, it is important to define and understand what meaningful measures of success look like for health IT; traditional measures of quality such as mortality or readmission rates may not be relevant or useful. Positive changes in flow or process, improvements in communication or information availability, and measures of usability and acceptability are likely to be better measures of success, as opposed to narrowly focusing on hard measures of use and uptake as is commonly done at the moment. The deployment and use of new technology must be a means to an end, rather than an outcome in itself.

In addition to developing new methods for evaluating and regulating the use of health IT across healthcare systems and organisations, it is also important to ensure effective evaluation and regulation of the technology itself. No other hazardous industry develops and implements safety-critical IT without some form of independent safety analysis; healthcare meanwhile does the exact opposite³⁵⁸. Healthcare regulators such as the Medicines and Healthcare Products Regulatory Agency (MHRA) in England should require technology companies to demonstrate independent evidence for the stability, safety and usability of their technology, rather than placing the burden on the customer and end-user as currently happens⁹¹. Whilst effective regulation is needed it can also be a double-edged sword. It is important that the inevitable burden of compliance and regulation does not stifle innovation or slow the adoption of new technology moving forwards. Effective and pragmatic regulation

may act as an enabler of new technology and can promote the digital agenda whilst assuring patient safety.

5.6 - Conclusions

The effective and meaningful use of health IT has the potential to transform and enhance the quality and safety of care, but it may also introduce new risks and cause unintentional harm to patients and organisations. This study performed a unique analysis of independent regulatory inspection reports and organisational digital maturity scores in order to understand and characterise the regulatory perspective and current influence of health IT on quality and performance in hospitals in England. The results highlighted that health IT is more often than not associated with reports of negative consequences for patients and organisations, and that better digital maturity and the positive use of health IT is significantly associated with overall organisational quality.

The relationship between health IT and quality is complex, and it is challenging to robustly assert causality with multiple confounders present. Despite the ad-hoc, opportunistic and unstructured nature of current practice the CQC does nonetheless frequently refer to health IT in their inspection reports. The poor usability of health IT, lack of easy access to systems and data, and the incorrect use of technology by staff are the most commonly identified areas that negatively influence the quality of care, whilst high performing organisations more commonly report the positive use of health IT. There is significant variability in the digital maturity of NHS organisations across England. Higher digital maturity, specifically in regards infrastructure spend and capability are associated with better organisational quality; those organisations which invest in health IT and which are more digitally mature are more likely to be high performing, high-quality providers of care.

There is a pressing need to understand the totality of the risks and benefits of health IT from all perspectives in order to inform future practice and regulation. The current CQC inspection framework does not provide a formal structure upon which to assess and evaluate the

impact of health IT. Meanwhile, formal assessments of digital maturity, whilst useful, are not currently validated to any meaningful measures of quality or performance and are principally used for technical benchmarking. This gap in knowledge and understanding, together with the current policy drive for a “paperless NHS” in England, means that there is a time-sensitive requirement for a new and robust regulatory approach to managing risk and supporting innovation in health IT. This new approach to regulation needs to align with current processes and understanding, but also needs to utilise novel sources of information and adopt new methods of evaluation in order to ensure that individuals, institutions and regulators keep pace with changes in technology and clinical practice to ensure the safety of patients and sustainability of the healthcare economy.

This chapter has identified that whilst good health IT can support better care, the poor use of health IT may cause harm and negatively impact the quality of care delivered to patients. To further expand on this area of interest the next chapter aims to take a more in-depth and granular look at rates of error and specific patient safety incidents related to health IT.

Figure 5.1 - Flow diagram for sampled NHS organisations with inclusion/exclusion criteria of the study

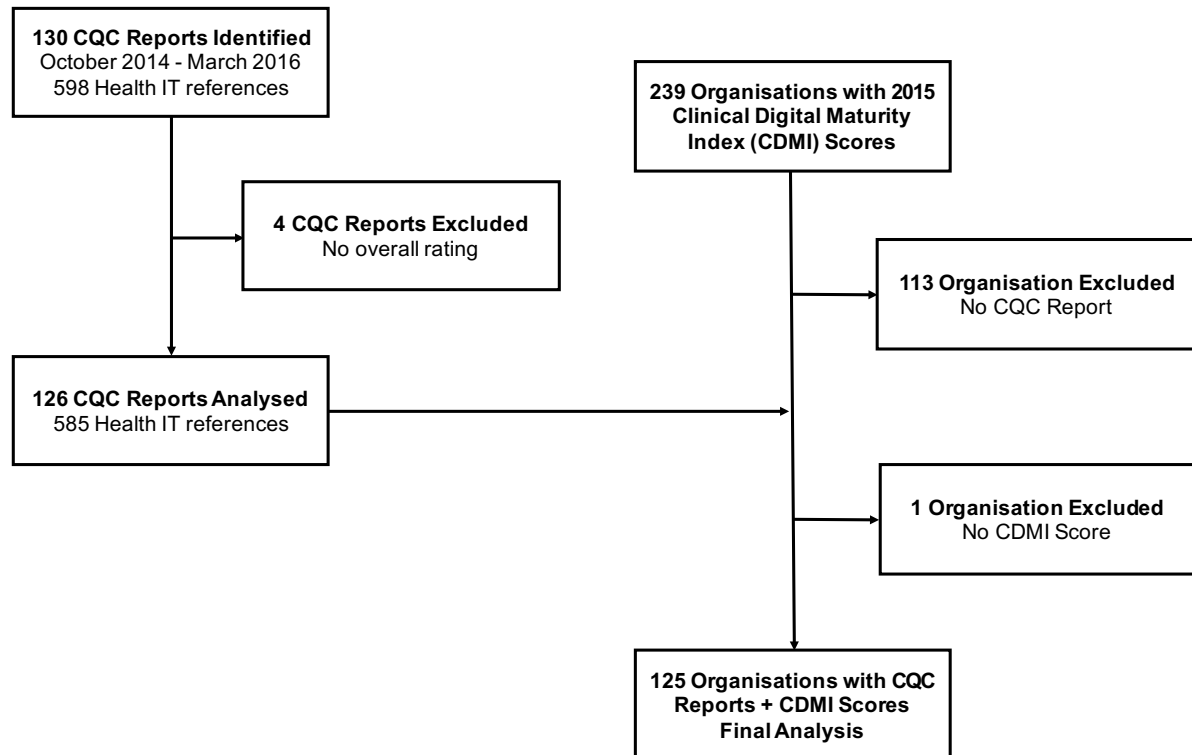


Table 5.1 - Summary of data extraction and coding via the six domains of the HITS Framework³⁷¹ for 598 references to health IT identified from 130 full CQC reports

Health Information Technology Safety Measurement Framework Domains	Positive References	Negative References	TOTAL (%)
<i>Data Availability</i>	88	86	174 (29.1)
<i>Data Integrity</i>	5	50	55 (9.2)
<i>Data Confidentiality</i>	2	8	10 (1.7)
<i>Complete/Correct Health IT Use</i>	22	64	86 (14.4)
<i>Health IT System Usability</i>	37	96	133 (22.2)
<i>Surveillance and Optimisation</i>	79	61	140 (23.4)
TOTAL (%)	233 (39.0)	365 (61.0)	598

Figure 5.2 - Radar plot comparing the relative frequency and key thematic differences between 233 positive and 365 negative references to health IT across the six domains of the HITS Framework³⁷¹

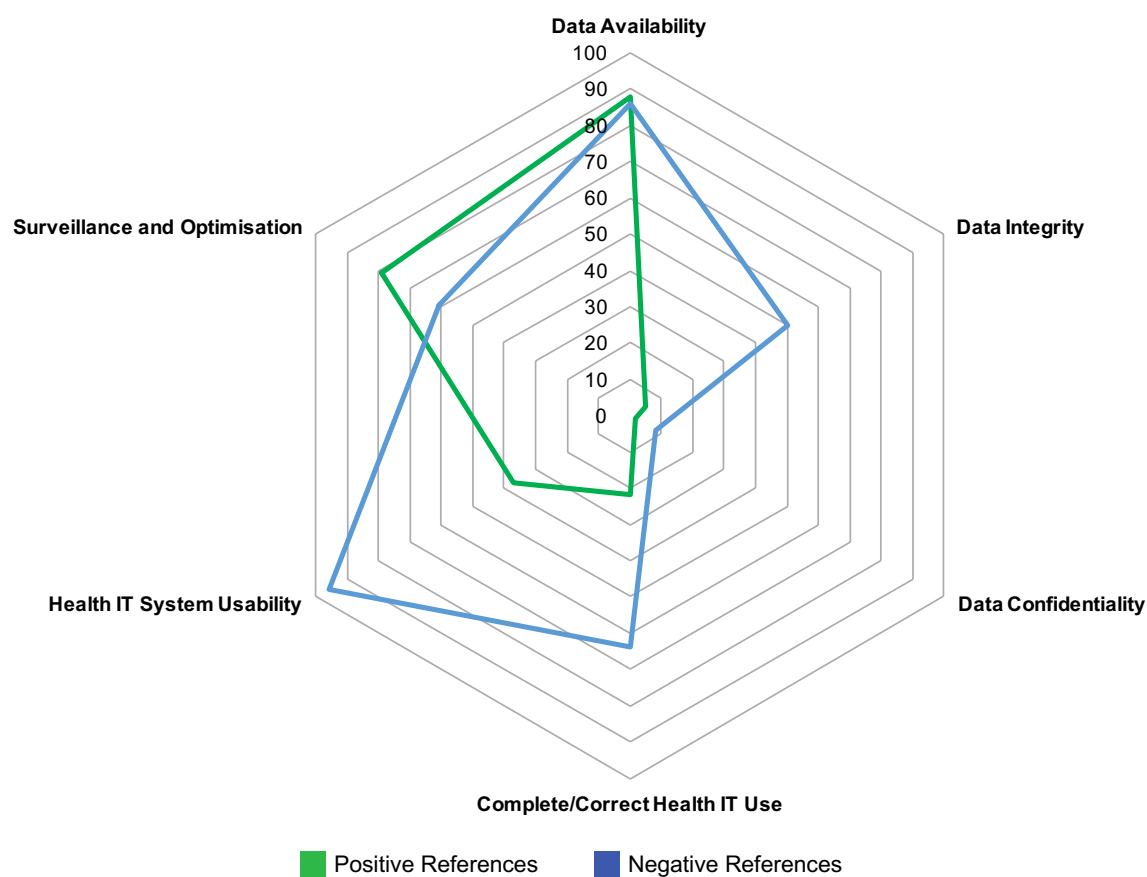


Table 5.2 - Specific examples of negative and positive references to health IT mapped to the HITS Framework³⁷¹

Safe Health IT Address safety concerns unique to technology	<i>Data Availability</i>	Positive - "... embracing the use of technology and community staff across the trust were increasing their use of mobile devices" Negative - "Due to connectivity issues with computers, electronic patient records were not always available"
	<i>Data Integrity</i>	Positive - "...a review of the paper and electronic records ensured that the recordings are complete, accurate and do not contain variances and discrepancies" Negative - "...in the community health services we found that some staff used electronic records but others used paper records. This presented a risk by having two systems complicating the process could lead to confusion or recording errors"
	<i>Data Confidentiality</i>	Positive: "...mobile access allowed them to update their documentation in a variety of private locations so that personal information about people who used the service was protected" Negative - "...safeguarding details were not sufficiently restricted to only allow access on a 'need to know' basis"
Using Health IT Optimise the safe use of technology	<i>Complete/Correct Health IT Use</i>	Positive - "...electronic prescribing and medicines administration system was in place on all wards and helped support safe and effective prescribing" Negative - "We tracked patients within the Trust's IT processes and it was clear the system was capable of providing intelligent timely information but the "operators" were not making the links and updating the screens"
	<i>Health IT System Usability</i>	Positive - "Parts of the system were being redesigned to address the issues identified. It was intended that information would be easy to enter and therefore save staff time" Negative - "The trust had an electronic record system, which caused frustration to many of the staff we spoke with. Staff expressed concern about its effectiveness, connectivity, lack of responsiveness and the additional workload that this added on a daily basis. Staff also commented that many of the templates were lengthy and difficult to use"
Monitoring Safety Use technology to monitor and improve patient safety	<i>Surveillance and Optimisation</i>	Positive - "The trust was undertaking a number of measures to deliver better working IT systems and access to data in a meaningful form to staff, patients, carers and researchers" Negative - "The trust board were aware of the inherent difficulties with the implementation of the software system but had failed to be proactive and plan ahead in preparation. Instead the trust took a reactive approach which left staff confused, frustrated and fire-fighting problems on a daily basis"

Figure 5.3 - Box and whisper plot (median, 95% CI) showing the overall distribution and frequency of positive and negative health IT references by overall CQC rating

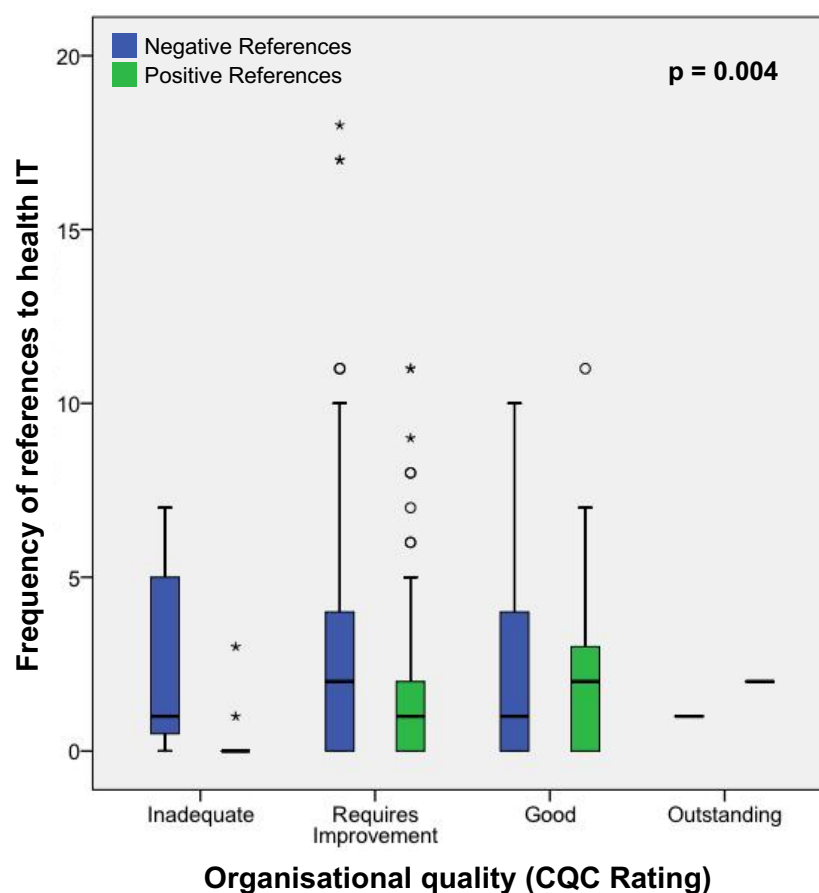


Table 5.3 - Spearman's Correlation (2-tailed) assessment of the relationship between overall quality rating and health IT references (n=126)

		Negative Statements	Positive Statements	CQC Rating
Negative Statements	Correlation Coefficient	.	0.224	-0.094
	Sig. (2-tailed)	.	0.012	0.297
Positive Statements	Correlation Coefficient	0.224	.	0.255
	Sig. (2-tailed)	0.012	.	0.004
CQC Rating	Correlation Coefficient	-0.094	0.255	.
	Sig. (2-tailed)	0.297	0.004	.

Figure 5.4 - Box and whisker plot (median, 95% CI) showing the frequency of negative references to health IT by specific CQC rating

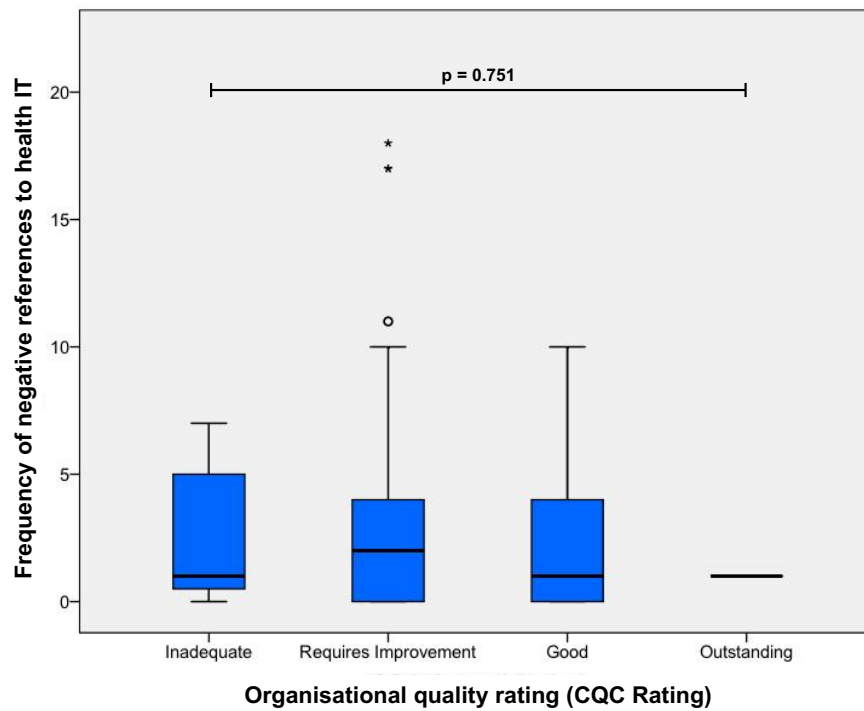


Figure 5.5 - Box and whisker plot (median, 95% CI) showing the frequency of positive references to health IT by specific CQC rating

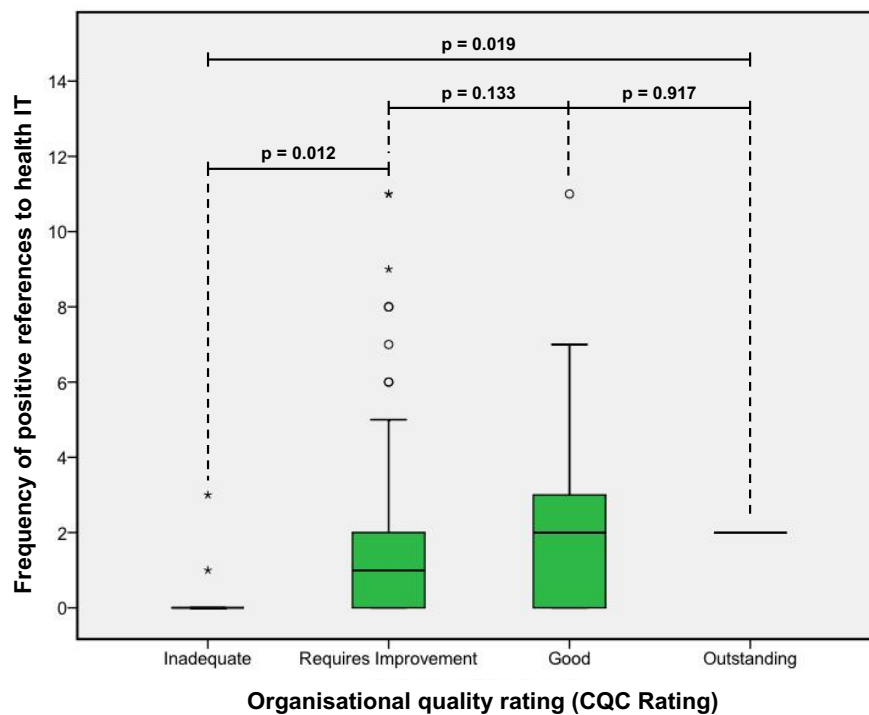


Figure 5.6 - Summary conceptual framework based upon a thematic content analysis of 585 references to health IT extracted from 126 full CQC inspection reports. Basic, organising and global conceptual themes are illustrated

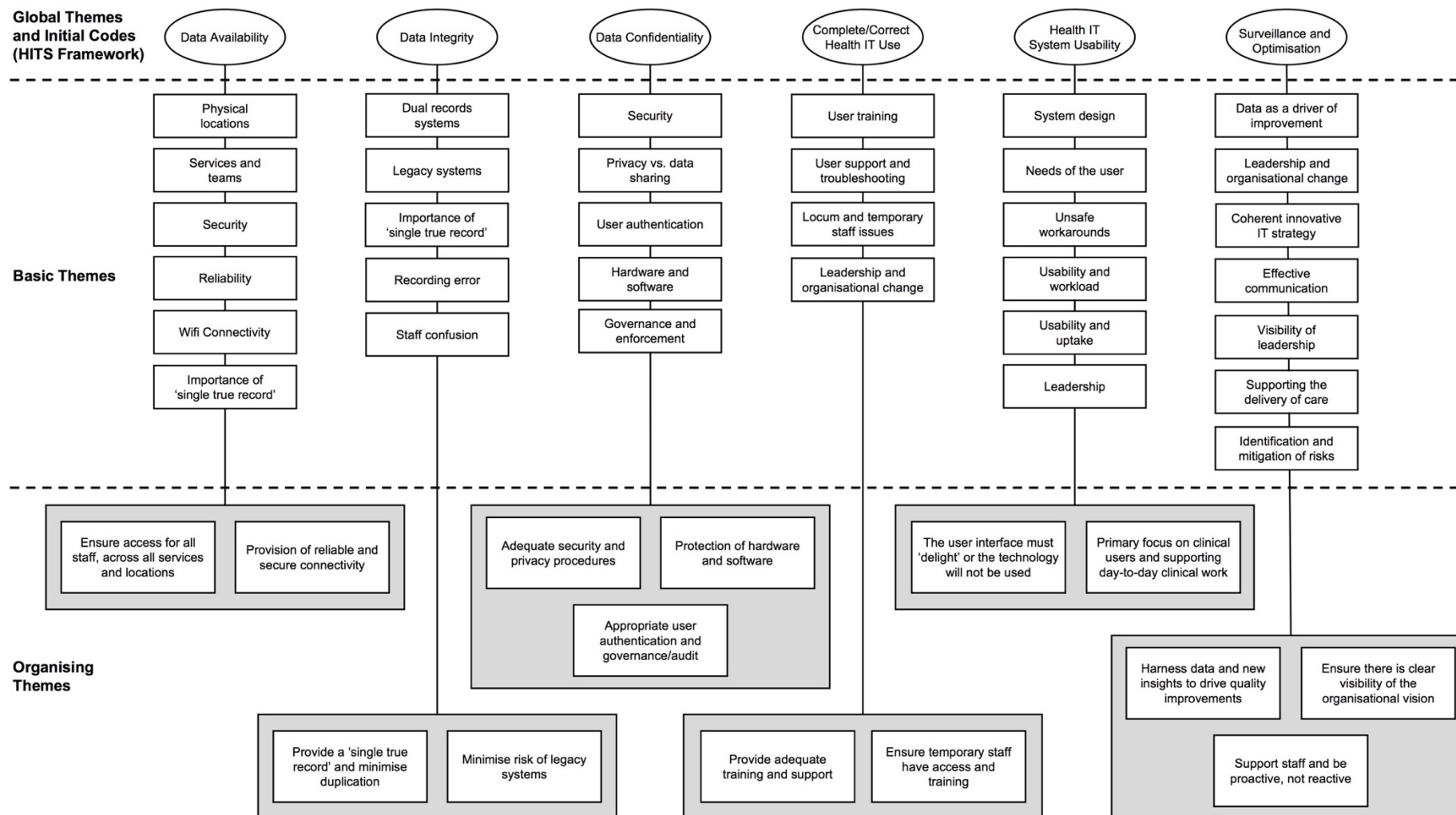


Table 5.4 - Results of the 2015/16 NHS Clinical Digital Maturity Index (CDMI) assessment for 125 selected organisations with 3 core themes and the 13 specific domains of the CDMI tool are identified

Theme	Domain (<i>score/100</i>)	Median Score	Range	Standard Deviation
READINESS	Strategic Alignment	75.0	19 – 100	17.2
	Leadership	80.0	20 – 100	20.2
	Resourcing	65.0	15 – 100	19.9
	Governance	75.0	10 – 100	18.9
	Information Governance	75.0	33 – 100	14.6
	<i>Overall (score/500)</i>	364.0	140 – 496	73.3
CAPABILITIES	Asset and Resource Optimisation	40.0	0 – 95	19.5
	Decision Support	33.5	0 – 95	22.0
	Medicines Management and Optimisation	17.0	0 – 99	25.3
	Orders and Results Management	53.0	9 – 100	24.1
	Records	43.0	0 – 94	20.0
	Remote and Assistive Care	25.0	0 – 92	18.7
	Standards	38.0	6 – 88	17.4
	Transfers of Care	48.5	0 – 100	21.3
	<i>Overall (score/800)</i>	309.5	108 – 671	117.1
INFRASTRUCTURE (<i>score/100</i>)		65.5	20 – 100	16.4
OVERALL (<i>score/1400</i>)		740.0	299 - 1253	178.0

Table 5.5 - Spearman's Correlation (2-tailed) assessment of the correlation between CQC rating and CDMI Scores (n=125).

		CQC Rating	Capability Score	Readiness Score	Infrastructure Score	Overall CDMI Score
CQC Rating	<i>Correlation Coefficient</i>	.	0.148	0.177	0.259	0.186
	<i>Sig. (2-tailed)</i>	.	0.100	0.049	0.004	0.038
CDMI Capability Score	<i>Correlation Coefficient</i>	0.148	.	0.452	0.578	0.875
	<i>Sig. (2-tailed)</i>	0.100	.	<0.0001	<0.0001	<0.0001
CDMI Readiness Score	<i>Correlation Coefficient</i>	0.177	0.452	.	0.666	0.797
	<i>Sig. (2-tailed)</i>	0.049	<0.0001	.	<0.0001	<0.0001
CDMI Infrastructure Score	<i>Correlation Coefficient</i>	0.259	0.578	0.666	.	0.749
	<i>Sig. (2-tailed)</i>	0.004	<0.0001	<0.0001	.	<0.0001
Overall CDMI Score	<i>Correlation Coefficient</i>	0.186	0.875	0.797	0.749	.
	<i>Sig. (2-tailed)</i>	0.038	<0.0001	<0.0001	<0.0001	.

Figure 5.7 - Box and whisker plot (median, 95% CI) showing differences between specific CQC ratings and individual CDMI domain scores

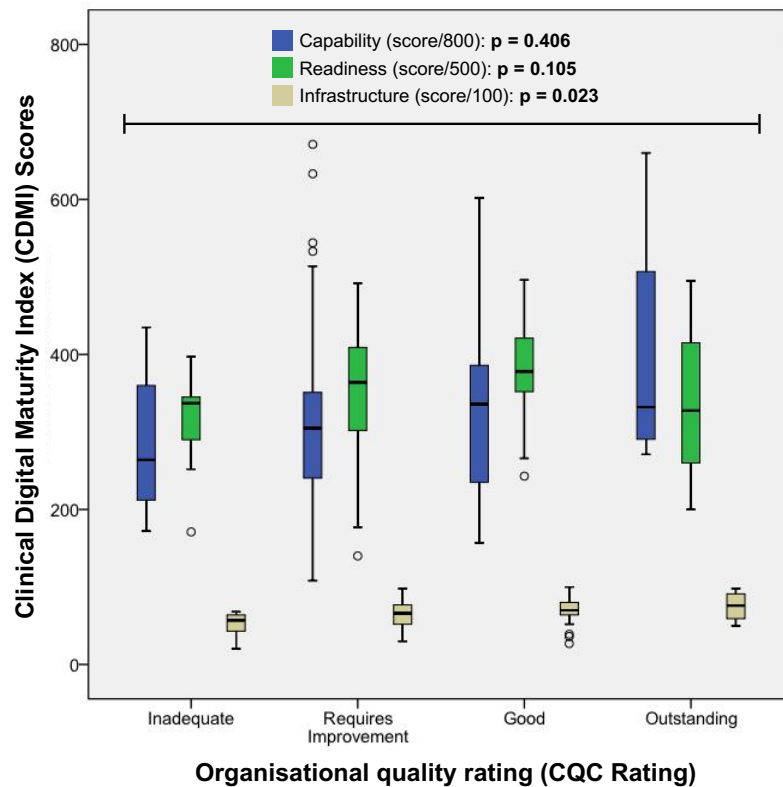


Figure 5.8 - Box and whisker plot (median, 95% CI) showing differences in infrastructure domain score and specific CQC ratings

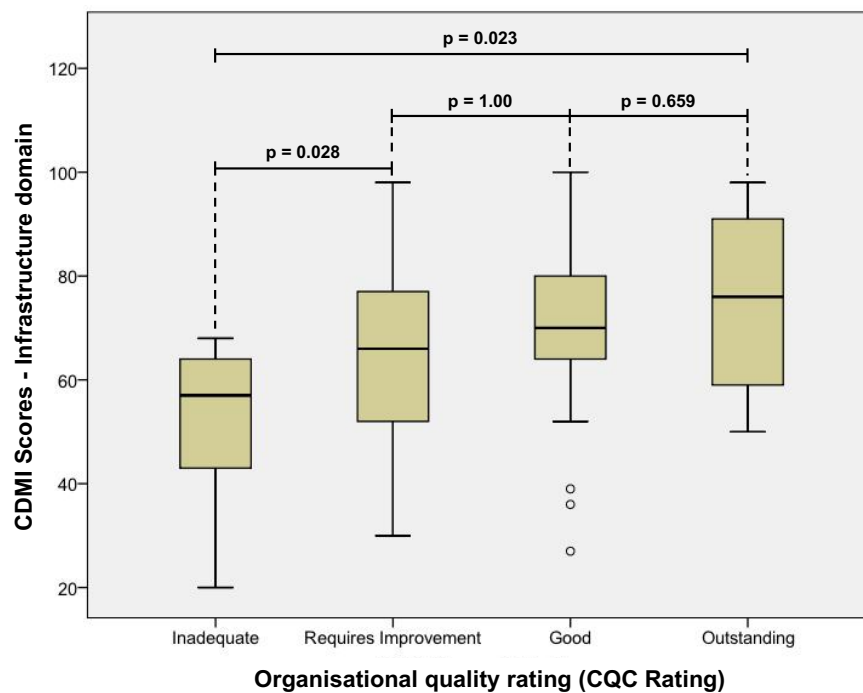


Figure 5.9 - Box and whisker plot (median, 95% CI) demonstrating that there is no difference in median overall CDMI score and specific CQC rating

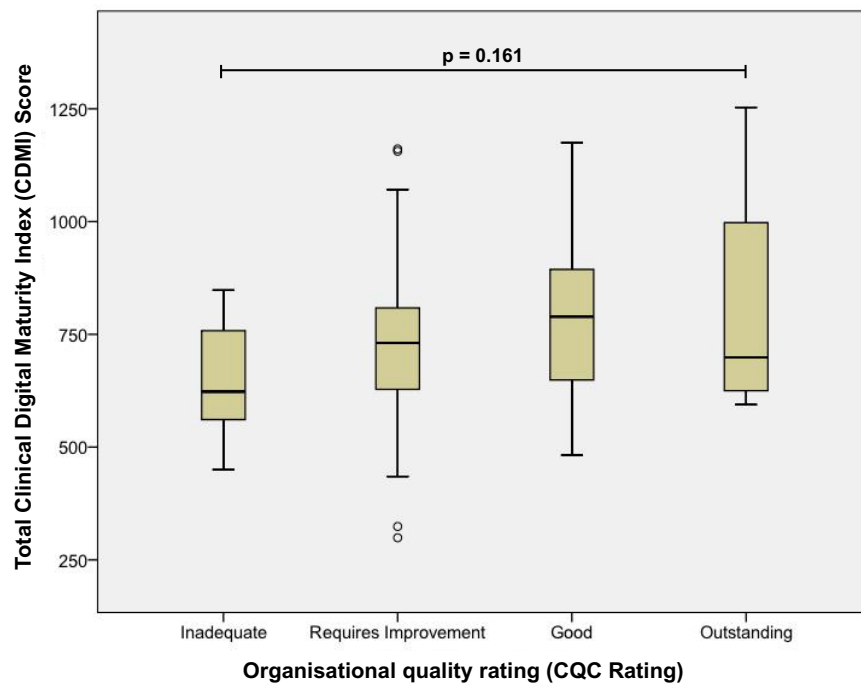


Figure 5.10 - Scatter plot demonstrating no significant correlation between the number of positive and negative references to health IT and total CDMI score

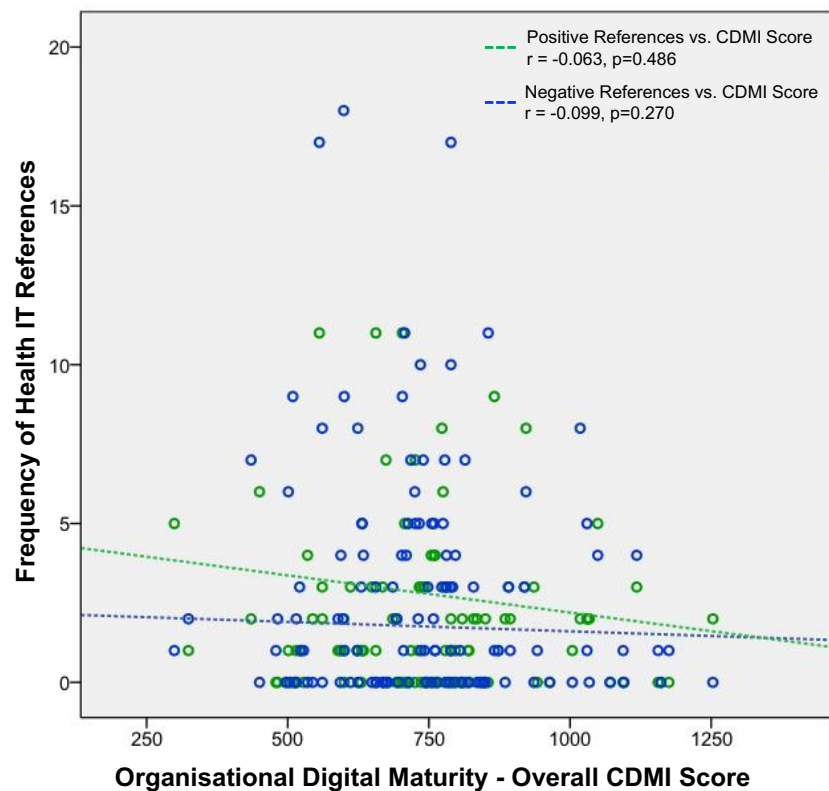
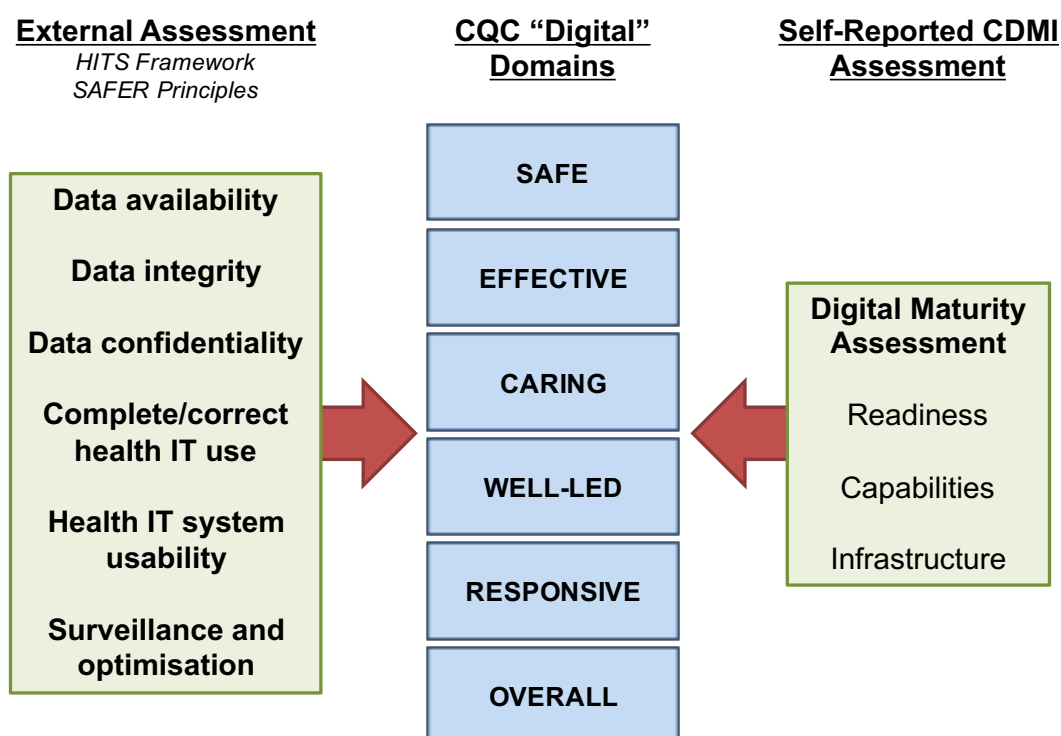
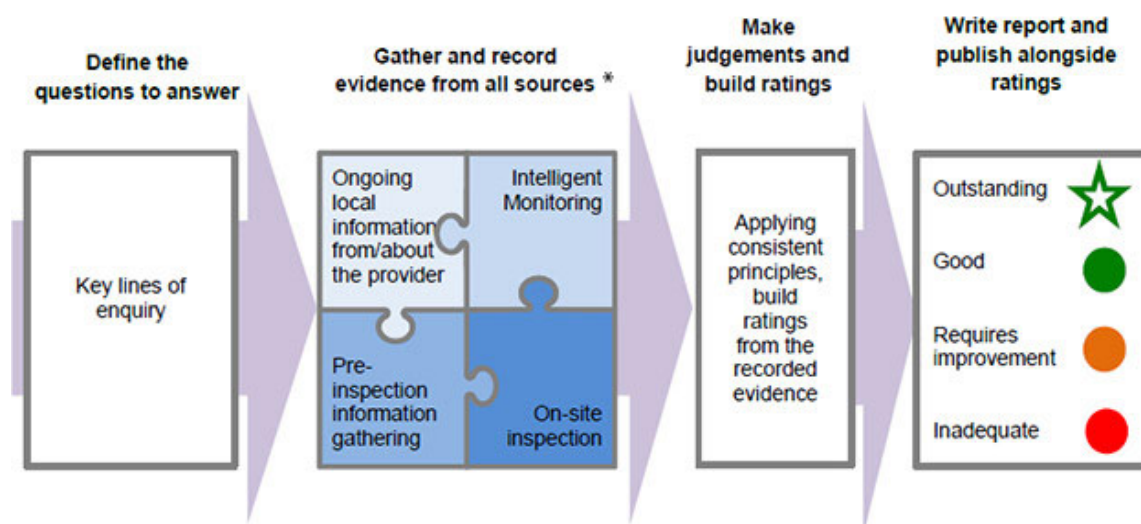


Table 5.6 - Key insights and recommendations from regulatory observations of NHS organisations in England to help support the effective use of health IT to improve safety and care quality

Principle	Insights and learning points
<i>Data availability</i>	- Ensure all staff, in all areas and locations have reliable access (e.g. mobile working for staff in the community) - Ensure access across services (e.g. primary through to secondary care) - Ensure reliable and secure connectivity (e.g. adequate Wi-Fi provision)
<i>Data integrity</i>	- Minimise dual records systems, (e.g. paper and electronic systems) which often leads to confusion, recording error and failure to provide 'a single true record' - Minimise and mitigate against the risks of using multiple legacy systems
<i>Data confidentiality</i>	- Ensure appropriate security and privacy policies and procedures are in place, and that these are supported by adequately protected hardware and software - Ensure appropriate authorisations and restriction of access to personal data is enforced and assured as required
<i>Complete/correct health IT use</i>	- Provide adequate training and ongoing support to ensure new IT systems are used as intended and to their full potential - Ensure there are appropriate procedures in places for locum or temporary staff to access and use IT systems correctly
<i>Health IT system usability</i>	- Strive to design simple systems that are designed for day-to-day clinical use; the user interface must 'delight' otherwise staff will not use the technology or develop unsafe workarounds - Poor usability creates greater workload for staff and increased time spent on administration; usability must be a top consideration
<i>Surveillance and optimisation</i>	- Harness new data and insights provided by health IT to drive service and quality improvements - Ensure there is clear visibility of leadership and communication of the organisational IT strategy, objectives and vision - Adopt a proactive, rather than reactive approach to health IT implementation; identifying and resolving risks before they impact patients - Aim to develop and implement strategies and technology that support clinical staff to perform their duties and add value as a primary objective

Figure 5.11 - A proposed model for the regulatory evaluation of health IT in England. CQC key lines of enquiry (KLOE's)³⁶² are explained, and a model proposed for aligning external assessment based on core aspects of the HITS Framework³⁷¹ and SAFER Principles⁹³ with organisational Clinical Digital Maturity Index scores to the existing CQC inspection framework



Chapter 6 - An evaluation of the impact of health IT failures on patient safety: what can we learn from a decade of patient safety incident reports in England?

It is clear from the limited existing literature and the findings reported previously in this thesis that health IT plays an important role in care quality. What is yet to be determined is the influence of health IT on error and adverse events. This chapter seeks to further investigate this phenomenon by examining the National Reporting and Learning System - a central repository of over 13 million patient safety incident reports - to identify those incidents related to failures in health IT, identify common trends and establish the preventability of such incidents in order to generate a set of evidence-based recommendations for improving the reporting of safety incidents related to failures in health IT.

6.1 - Introduction

A patient safety incident is *“any unintended or unexpected incident which could have, or did lead to harm for one or more patients receiving NHS care”*³⁹¹. These adverse incidents affect around 3-23% of hospital patients, contribute to the 3.6% of in-hospital deaths that are deemed to be avoidable³⁹²⁻³⁹⁶, and are subject to mandatory reporting at both a local and increasingly a national level. The introduction and use of safety reporting systems in healthcare has been based upon the experiences of other high risk industries such as aviation and the oil and gas industry where their benefits and success stories are well described³⁹⁷. A unified and open approach to incident reporting, transparent and robust analysis of events and their causality, widespread dissemination of findings and the fostering a cycle of continuous improvement is a crucial part of learning from patient safety incidents and improving the quality and safety of healthcare^{398,399}. Creating an open ‘blame-free’ culture is important in encouraging staff to report incidents and build an environment where incidents are treated as an opportunity for learning and development; triggering new safety

initiatives and interventions and reducing avoidable harm to patients^{398,400}. This approach to reducing risk and improving safety is supported by over 90% of members of the public⁴⁰¹.

In the UK, the now defunct National Patient Safety Agency established the National Reporting and Learning System (NRLS) in 2003 to enable analysis of frequently occurring and serious events in order to generate and disseminate national patient safety warnings and safety solutions. Since 1st April 2016 it has fallen under the auspices of NHS Improvement, and from a small start it has grown year-on-year and now receives >1million patient safety incident reports annually at a cost of around £1.1 million/year. It is currently the largest and most comprehensive patient safety reporting system in the world with over 10 million incident reports captured since its inception^{402,403}. Similar reporting systems also exist internationally such as the Advanced Incident Management System in Australia³⁹⁹, the Veterans Health Administration in the US³⁵⁹ and the Danish Patient Safety Database⁴⁰⁴.

The use of health IT is rapidly increasing across all health systems in order to improve the delivery, quality and safety of care. There is however an increasing realisation that the unique safety risks posed by new technologies must be carefully considered alongside the potential benefits¹⁶. Published examples of potential or actual adverse events stemming from health IT have included medication errors due to failures in patient identification²⁶, drug dosing errors²⁷, the unsafe disruption of traditional patterns of work, the death of patients due to incorrect data entry³³, the complete failure of complex integrated digital hospital records and care systems³⁴ and the loss of safety-critical applications to over 80 UK hospitals following failures in critical infrastructure and contingency systems³⁵. Identifying, analysing and preventing such adverse safety events caused by health IT is hugely challenging. Health IT safety events are commonly multi-faceted and involve not only hardware and software, but also user behaviours, organisational characteristics, and broader processes, rules and regulations that interact in a complex and poorly understood fashion^{36,37}.

Given the ubiquitous role of health IT in the delivery of care there is a relative paucity of evidence examining the reporting and impact of technology related safety incidents. Much of the published evidence relates to electronic prescribing as it is one of the more mature areas of health IT. An analysis of a national voluntary medication error-reporting database in the US for example identified over 7000 errors related to computerised ordering systems out of >250,000 medication errors reported, with just 0.1% of errors leading to patient harm⁴⁰⁵. More broadly one US study identified 44 injuries and six deaths over a two-year period due to failures of health IT⁴⁰⁶, and a further study identified 120 unique safety events associated with electronic health record systems out of more than 1.4 million medical device related incidents reported; the majority being the result of either poor user interface, failures in integration with other systems, errors in calculations or poor functionality¹⁵. Specific safety events related to unsafe technology such as unmet data-display needs as well as non-technical aspects of technology failures such as disruptions in workflow and failures in the human-computer interface have also been identified³⁵⁹. In Australia a search identified 99 incidents related to health IT which accounted for just 0.2% of all reported patient safety incidents. 55% of these incidents were associated with hardware failures and the remainder due to failures of human-machine interaction. 38% of incidents were reported to have a noticeable consequence but with no significant patient harm and 34% had no noticeable consequence for the patient at all³⁸⁶. In the UK the evidence is even more sparse, with a single study examining 850 individual patient safety events associated with the National Program for IT (NPfIT) over a six-year period. 68% of these events described potentially hazardous circumstances, 24% had an observable impact on care delivery, 4% were classified as near-misses, 3% were associated with patient harm and three attributable deaths were reported: a failure in patient identification resulting in a medication error; an error in communication resulting in a failure to rescue incident and finally a failure of information governance and data availability resulting in a death. The vast majority of incidents were related to technology rather than human factors, and system-wide events affecting multiple individuals or IT systems accounted for 23% of incidents and were significantly more likely to adversely affect the delivery of care or lead to patient harm³⁶⁰.

There is a relative paucity of evidence evaluating the impact of health IT failures on patient safety incidents at a system-wide level, and The National Reporting and Learning System offers a unique, and potentially important repository of evidence. This study therefore aims to evaluate health IT related harm in England over the past decade and provide national level evidence to inform the design, deployment and safety reporting of new health technologies.

6.2 - Hypothesis, aim and objectives

6.2.1 - Hypothesis

Creating an open 'blame-free' culture is important for encouraging staff to report incidents and foster an environment that sees patient safety incidents as an opportunity for learning and development rather than a punitive process; triggering new safety initiatives and reducing avoidable harm to patients. Importantly the use of national level reporting allows trends and patterns to emerge which are too infrequent to appear at a local level.

The National Reporting and Learning System is the world's largest incident reporting database and provides a rich repository of information on patient safety incidents. Through interrogating the database, we can uncover new insights into how health IT failures have affected patient safety in England; understanding the degree and frequency of harm, temporal patterns and key incident themes. This granular understanding of specific safety incidents related to health IT may inform the regulatory environment, identify specific patient safety concerns and help inform the future development, implementation and evaluation of new technology.

6.2.2 - Aim

The aim of this study is to identify, describe and evaluate health IT related patient safety incidents captured in the National Reporting and Learning System in England.

6.2.3 - Objectives

In order to fulfil the stated aim, this study will seek to fulfill the following objectives:

1. To develop, test and validate a novel and rigorous methodology for identifying patient safety incidents related to health IT in England from the National Reporting and Learning System (NRLS) database
 - a. To identify key trends, patterns and insights from health IT related safety incidents
 - b. The degree of harm and impact of incidents on patients
 - c. The preventability of incidents
2. To develop a core set of lessons learnt from a decade of patient safety incident reporting in England which may inform and guide the future use of health IT

6.3 - Methods

6.3.1 - National Reporting and Learning System (NRLS)

NRLS is currently the largest and most comprehensive patient safety reporting system in the world with over 10 million incident reports captured since its inception^{402,403}. The system collects safety incidents from local NHS organisations and has a number of key features which enables it to provide a unique source of evidence to both identify key safety concerns and support the promotion of patient safety and at a national level in England⁴⁰⁷:

- A voluntary system for NHS staff to report safety incidents and near misses
- Collects data principally through local risk management systems
- Reporters are identifiable at a local level, but anonymised at a national level
- Reports comprise a combination of structured data fields and free text narrative
- Local risk managers report to a central database hosted by Imperial College Healthcare NHS Trust and Imperial College London on behalf of NHS England
- Reports from NRLS form the basis of Patient Safety Alerts and advice from NHS England (formally the NPSA)

For the purposes of this study a total of 13,738,411 patient related safety incidents reported between January 2004 and March 2016 were included. Data for the following incident descriptors and characteristics was extracted for each of the 13,738,411 incidents:

- RP01 - incident ID number
- RP02 - care setting
- RP07 - NHS organisation code
- IN03 - incident location
- IN05 - incident category
- IN07 - incident description
- IN10 - actions taken to prevent recurrence
- IN11 - apparent cause of incident
- PD05 - specialty in which incident took place
- PD09 - degree of harm
- PD12 - impact prevented
- PD18 - degree of harm stored following local risk management review

6.3.2 - Database search strategy and methodology

Big data is a term used to describe data sets that have volume, variety, velocity and value, and which present significant problems with storage, analysis and visualisation⁴⁰⁸.

Managing, processing and understanding this data therefore can pose significant challenges. The NRLS database is the largest and most comprehensive patient incident reporting system in the world. It generates a huge amount of information of which a large proportion is unstructured and therefore particularly challenging to organise, search and analyse. Incidents related to health IT are not specifically coded within the IN05 domain of the database, and there is currently no established methodology for exclusively mining the free text incident descriptor within the IN07 domain to identify specific incident types. It was therefore necessary to develop and validate a novel search strategy in order to explore the IN07 free text description of each incident in order to correctly identify those related to health IT failures. A summary flow diagram of the search methodology is seen in *Figure 6.1*.

In order to identify relevant incidents from the free-text descriptor initially a simplistic bag-of-words approach to text mining was used to identify an initial corpus of incidents. A bag-of-word approach generates an orderless document representation of the corpus, where only the frequency of words is represented as a classifier without any spatial context⁴⁰⁹. Despite these limitations the bag-of-words approach provides greater search precision than more complex phrase or topic based approaches to classification⁴¹⁰. The initial words selected were “computer”, “system”, “workstation” and “network”. To further refine the corpus and improve the average precision of the search an n-gram model of searching was then applied; a probabilistic language model that provides a simple and scalable method to include spatial context to a corpus through identifying a contiguous sequence of words within the free text description of the incident. This approach was adopted to reduce potential problems presented by polysemous words with multiple meanings - such as “computer system” vs. “plumbing system” - and improve the identification of relevant safety incidents. An initial bigram approach was adopted with 1,643 prefixes and 1,393 suffixes identified. Manual review of these led to 348 unique prefixes and 32 unique suffixes being retained. This method was expanded to create a number of regular expressions (regex) that were run sequentially as per *Figure 6.1*. A regex is a sequence of characters or words which describe a search pattern and were first defined by the American mathematician Stephen Kleene in the 1950’s⁴¹¹. They represent specific, standard textual syntax which describe patterns within text; facilitating identification and automatic processing of patterns in a concise and flexible way via find-and-replace and splitting operations. Due to their versatility regexes are widely used in computer programming languages, text processing programs and advanced text editors principally for automated pattern matching and searching⁴¹². This is the first time this strategy has been employed to identify specific incidents the NRLS dataset.

Throughout the search a manual process of review and validation of both search inputs and outputs was performed by two independent reviewers in order to improve the precision of the search strategy. The final regex produced 2,809 incidents and independent manual review of all incidents produced agreement of 95.83% with a Cohens Kappa of 0.687

(SE=0.029, 95% CI 0.611-0.724) indicating a good level of inter-observer agreement. Consensus was reached on discrepancies and the final number of incidents included for subsequent analysis was 2,627 (0.00019% of all incidents).

6.3.3 - Analysis of the data

Standard descriptive statistics were employed to explore the extracted data for each of the 2,627 incidents identified. All data was arranged, structured and analysed utilising Microsoft Excel (Excel for Mac V15.22, Microsoft, USA) and IBM SPSS (SPSS for Mac V23, IBM Corporation, USA).

The degree of harm for each incident is recorded at the time of reporting and also following local risk management review. Standardised definitions are used:

- Low harm - any unexpected or unintended incident that required extra observation or minor treatment and caused minimal harm to one or more persons
- Moderate harm - any unexpected or unintended incident that resulted in further treatment, possible surgical intervention, cancelling of treatment, or transfer to another area, and which caused short-term harm to one or more persons
- Severe harm - any unexpected or unintended incident that caused permanent or long-term harm to one or more persons
- Death - any unexpected or unintended event that caused the death of one or more persons

To further understand the data, provide thematic context and evaluate how it fits within the context of the current published literature, all incidents were coded according to the Health Information Technology Safety Measurement (HITS) Framework. The HITS Framework assesses health IT across three domains (safe health IT, using health IT safely and monitoring safety) and has previously been described in this body of work for providing a conceptual foundation for measuring, monitoring and improving the safety of health IT^{93,371,372}. Data coding was performed with a second independent reviewer assessing a

randomly selected 10% subset to ensure accuracy of coding with inter-rater agreement assessed via Cohen's kappa coefficient. A summary of the HITS Framework has previously been displayed in *Appendix D*. Coding agreements for this study are shown in *Table 6.1*.

Each incident was then assessed for preventability, with coding based upon previously established methods; all incidents were coded on a 6-point Likert scale with those scoring 4 or more deemed to be preventable^{413,414}. Data coding was performed with a second independent reviewer assessing a randomly selected 10% subset to ensure accuracy of coding with inter-rater agreement assessed via intraclass correlation coefficient (ICC).

6.4 - Results

6.4.1 - Description of 2,627 health IT related patient safety incidents

13,738,411 incidents were reported to NRLS between January 2004 and March 2016 by 2,576 different NHS organisations. The mean number of incidents reported by each organisation was 364.54 (1-56,844, SD 1924.786). 2,627 of these incidents were identified as related to failures in health IT which represents just 0.00019% of all incidents reported. Only 337/2,576 (13.01%) of organisations reporting patient safety incidents reported any related to health IT with a mean number of incidents reported of 7.79 (1-64, SD 8.952). Incidents were reported by a range of organisation types with 2,162 (82.3%) reported by acute or general hospitals, 311 (11.8%) by community nursing, medical and therapy services, 80 (3.0%) by mental health services, 25 (1.0%) by general practice and 49 (1.9%) reported by other organisation types. As would be expected with the rising prevalence of health IT, and importantly the increased reporting of incidents through NRLS, there is a significant rise in reporting of health IT related incidents over time with just 17 incidents reported in 2004 and 368 reported in 2015.

Patient safety incidents related to health IT failures occurred in a wide variety of locations: 2,100 in general or acute hospital environments (853 inpatient areas, 530 support services,

outpatient areas 271, emergency departments 222, general area 133, day care services 59 and other locations 32); 175 in primary care settings (83 in health centres, 24 in GP surgeries, 14 in dental surgeries, 10 through NHS Direct and 44 in other locations); 99 in mental health facilities (46 inpatient areas, 20 general areas, 21 community mental health units and 12 in other locations); 98 in community hospitals; 66 in residences (49 in private homes, 9 in prisons and 9 in other locations); 77 in other locations and 12 incidents occurred in an unknown location. Summary descriptive statistics for the 2,627 health IT related safety incidents are seen in *Figure 6.2*.

Incidents are recorded against a specific pre-defined category and a detailed examination of all 2,627 incidents by recorded category type is seen in *Table 6.2*. Pertinent results demonstrate that 27.4% (721/2,627) of incidents were recorded as being related to infrastructure failures with the majority of these 498/721 (69.1%) as a direct result of IT/telecommunications failures. 16.8% (440/2,627) of incidents were recorded as being due to failures in clinical assessment, with the majority of these 249/440 (66.1%) being due to incorrect, missing or delayed test reports and results. 14.0% (367/2,627) of incidents were due to failures in documentation with the vast majority 262/397 (66.0%) due to missing, inadequate or absent documentation. 9.9% (259/2,627) of incidents were due to problems with devices or equipment, with the majority 192/259 (74.1%) due to failures. Finally, 6.5% (171/2,627) of incidents were categorised as medication incidents which are likely to be the result of problems or failures with electronic prescribing systems. Importantly, direct failures in IT, missing or delayed test results, missing, inadequate or absent documentation and the direct failure of equipment are all plausibly linked to failures in either hardware, software or the human-technical interface.

6.4.2 - Impact of health IT incidents on patients: degree of harm

68/2,626 (2.6%) of incidents that were returned in the search were related to delays in the recording of incidents due to failures in the electronic incident management software itself and were therefore excluded from this part of the analysis. 2,557 incidents were therefore

retained for further analysis of the harm caused to patients. 2,106/2,557 (82.4%) of incidents were recorded as causing no harm, 331/2,557 (12.9%) low harm, 102/2,557 (4.0%) moderate harm, 14/2,557 (0.5%) severe harm and 4/2,557 (0.2%) resulted in a patient death. None of the incidents identified had the reported degree of harm changed following internal risk management review and therefore kept the degree of harm identified by the person reporting the incident. Examples of incident descriptors related to each category of harm are seen in *Table 6.3*.

It is important to examine those incidents leading to moderate/severe harm or death in more detail in order to understand the wider impact of health IT safety incidents. 102/2,557 (4.0%) incidents were reported as causing moderate harm. Of these, 24 (23.6%) were caused by failures in laboratory or pathology systems, 21 (20.6%) due to failures in PACS or other radiology systems, 16 (15.7%) due to multiple system failures across a hospital network, 12 (11.8%) due to problems with electronic patient records systems, 8 (7.8%) due to failures in PAS and administration systems, 3 (2.9%) due to issues with pharmacy systems or electronic prescribing and 18 (17.6%) due to failures in miscellaneous other systems such as those used for appointments, equipment ordering or follow-up. Of the 14 incidents reporting severe harm to patients, 4 (28.6%) were due to failures in pathology/lab systems, 3 (21.4%) from failures in pharmacy or electronic prescription systems, 2 (14.3%) from failures in electronic patient record systems, 2 (14.3%) from failures in radiology or PACS systems and a single incident was reported from failures in appointment booking systems and equipment ordering systems.

Importantly 4/2,557 (0.2%) of incidents reported were associated with the death of a patient; all occurred in inpatient areas within acute hospitals and were as follows:

- Failure of pathology results system – missed/absent results led to delays in correct diagnosis and antibiotic administration
- Failure of PAS system – blood tests were lost or missing due to use of paper for ordering and processing requests which led to a 7-hour delay in obtaining results

- Failure of pathology results system – administration of incorrect anti-microbial therapy for *Clostridium difficile* infection due to an incorrectly recorded negative result as a consequence of system failure
- Failure of pathology results system – delay in obtaining blood results due to the failure of a computer system

6.4.3 - Preventability of health IT related patient safety incidents

All 2,627 incidents were assessed for preventability as part of the analysis via a previously established method with incidents coded on a 6-point Likert scale and those scoring 4 or more deemed to be preventable^{413,414}. The summary results of this preventability assessment, together with examples of each scoring category are displayed in *Table 6.5*. There were some challenges in determining preventability; key factors included whether or not the IT failure was managed with effective and resilient downtime procedures, the duration of the failure and whether or not the incident could have been foreseen or avoided with effective leadership. Indeed, just 12.8% (336/2,627) incidents were deemed to be clearly not preventable through being scored 1/2, and only 27.1% (711/2,627) were clearly preventable by scoring 5/6. The vast majority (60.1%, 1,580/2,627) were scored at 3/4 which would suggest that their preventability is debatable and they could have been classified either way. Despite these difficulties, the overall inter-rater coding agreement was excellent with an intraclass correlation coefficient of 0.926 (0.907 – 0.942, $p < 0.0005$)⁴¹⁵.

Overall 74.76% (1,964/2,627) of incidents were deemed to be preventable. Whilst all IT systems will occasionally be affected by system failures, there must be robust and effective back-up procedures and policies in place to prevent these failures causing delays in care or harm to patients; despite being ever more dependent on health IT organisations must be able to provide timely and safe care in its absence. Examples of such failures include:

“LabCentre computer system not available for 13 hours overnight. Patient bleeding in theatre... theatre staff were desperate for the products and there was a delay. Practical procedure followed but paperwork not available within time specified for blood products.”

“The main hub supplying various IT systems failed. The business continuity plans for key clinical systems were instigated however the contingencies were found to be inter-reliant therefore impacting on the ability to operate.”

“Mosaik oncology management system failure at 12.15pm and wider network problems... 167 patients were cancelled and did not receive radiotherapy on that day.”

A further key factor influencing the preventability of a number of incidents was a failure of IT departments to effectively communicate system upgrades or re-boots to clinical users, a failure to perform these planned tasks outside core business hours when the inevitable impact on patients will be reduced or carry out appropriate risk assessments for them:

“Patient asleep in theatre. Generator test performed - generator kicked in but all computer systems went down. Could not access scans so operation could not commence as could not confirm side. Patient had to be kept asleep for extra 45mins awaiting system to re-boot...”

“There was a significant IT systems failure resulting in a trust wide IT systems failure for several hours and there was resultant knock on effects and disruptions to various other IT systems across the trust. It is believed that the failure may have been precipitated by an electrical shutdown by one of the project officers working on the new Ashburton Wing which caused overheating and over loading of the IT servers. There doesn't appear to have been a necessary risk assessment carried out prior to the work commencing or contingencies put into place in case things went wrong. Also, there appears to be a lack of organisational and upline reporting of this incident.”

“The theatre management system went down. This was caused by an IT contractor working in the virtual servers... No prior notification of IT work on the servers was given which caused the department to not be in a position to instigate emergency contingency plans...”

A further key factor leading to preventable safety incidents was the failure of organisations to provide effective IT support for their systems in order to resolve issues in a timely fashion. This was particularly evident with IT systems supported by external providers who frequently were not contracted to provide out-of-hours support which resulted in unnecessary delays to return of service and completely avoidable harm to patients:

“At 11am the pharmacy Ascribe system stopped working... I rang the trust IT Dept, for which I was put through to an answer phone message explaining that the it dept was closed. The on-call IT manager explained that Ascribe and pharmacy was not supported at a weekend and there was nothing they could do. He suggested that I rang the ascribe company to see if they were able to help... I contacted ascribe but there was no answer”

“Laboratory computer system failure. All areas affected. Attempt to re-boot system failed. As a result, laboratory without computer system for more than 24 hours. System support (external supplier) is 8am-8pm Mon-Fri and Saturday morning only. Manual systems were used over weekend. Support contacted Monday AM and fault rectified within 1 hour...”

Of the 1,964 incidents deemed to be preventable 3 contributed to the death of a patient; 75% of all such incidents. A further 12 (0.6%) led to severe harm, 69 (3.5%) moderate harm and 217 (11.0%) low harm. 1,663 (84.7%) were recorded as causing no patient harm. This is a broadly similar pattern of harm seen across all incidents preventable or not.

6.4.4 - Understanding health IT safety incidents: framework analysis

To further understand the data, provide thematic context and evaluate how it fits within current literature all incidents were coded according to the Health Information Technology Safety Measurement (HITS) Framework as described in *Table 6.1*^{93,371,372}. As part of the coding process a randomly selected 10% subset of incidents was identified and independently examined by a second reviewer to ensure accuracy of coding. Disagreement in coding was seen in 14/263 (5.2%) incidents, partial agreement (1/2 categories match) in

33/263 (12.5%) of incidents and full coding agreement (match in all coded categories) in 216/263 (82.3%) of incidents. This resulted in a good level of inter-rater agreement with a Cohens Kappa of 0.727 (SE =0.037, 95% CI 0.654-0.800). Given this level of agreement second review of the remaining incidents was not performed.

2,627 incidents were coded according to the HITS Framework with the output summarised in *Table 6.4*. 2,028/2,627 (77.2%) of incidents were able to be coded to a single domain of the framework, 512/2,627 (19.5%) required coding to multiple domains as they did not discreetly fit within a single domain and the remaining 87/2,627 (3.3%) did not fit within any of the framework domains. Of those which were suitable for coding to a single domain the vast majority 1,783/2,028 (87.9%) pertained to the data availability theme. 125/2,028 (6.2%) of incidents related to health IT system usability, 111/2,028 (5.5%) to data integrity and a mere 7/2,028 (<0.1%) incidents to the complete/correct use of health IT. Data confidentiality, and the surveillance and optimisation domain accounted for only a single incident each.

512/2,627 (19.5%) of incidents contained multiple elements and therefore did not clearly fit the description of a single domain. In all these 512 incidents were coded into 1,029 different domains with data availability accounting for 480/1,029 (46.6%), data integrity 432/1,029 (42.0%), health IT system usability 99/1,029 (9.6%), the complete/correct use of health IT 13/1,029 (1.3%), data confidentiality 3/1,029 (0.3%) and surveillance and optimisation 2/1,029 (0.2%). The majority of overlap was seen between the data availability and data integrity domains with 394/512 (76.9%) of incidents coded into both, and the data availability and usability of health IT domains which had 66/512 (12.9%) incidents coded into both. 28/512 (5.5%) of incidents were coded into the data integrity and usability of health IT domains, and the remaining incidents were coded into combinations of domains which each accounted for <1% of the overall incidents.

6.5 - Discussion

6.5.1 - Summary of key findings

Health IT is ubiquitous in supporting the delivery of high-quality healthcare and is increasingly seen as the favored solution to tackle the challenges of variation in care, increasing demand and fiscal realities. Despite its central role in delivering care there is a paucity of evidence examining the impact of health IT on patient safety. By examining 13,738,411 patient safety incidents recorded over more than a decade in England we have identified the largest repository of health IT related patient safety incidents ever reported. Whilst currently accounting for a small proportion of patient safety incidents, health IT related events are only going to become more prevalent as care becomes ever more dependent on IT. The identification and study of 2,627 individual incidents related to failures in health IT has shown that a significant proportion lead to patient harm and even death, the vast majority are preventable, and that all healthcare organisations could take simple steps to reduce their likelihood and mitigate the risk by lessening the impact of these failures. Furthermore, it is highly likely that health IT failures are not seen as a patient safety problem by the majority of staff and so are grossly under reported within current incident reporting systems. In addition, we have developed and validated a novel methodology for examining free text incident descriptors within the NRLS dataset in order to identify specific safety events. This technique may be used in the future to identify further common safety events, maximise the potential of the NRLS dataset and help deliver real improvements in patient safety.

The 2,627 individual incidents identified in this study represents the largest reported series of health IT related patient safety incidents and is nearly 3x bigger than any previously published series^{15,359,360,386,406}. Our analysis reveals that 451/2,557 (17.6%) of health IT incidents impacting patients directly led to harm; with 102 incidents resulting in moderate harm to patients, 14 incidents resulting in severe harm and health IT failures contributing to a patient death in a further 4 incidents. Worryingly our analysis also revealed that three-quarters of incidents reported (74.7%, 1,964/2,627) were potentially preventable. These results, whilst informative, are likely to represent just the tip of the iceberg however. The 2,627 incidents identified represent just 0.00019% of all incidents reported which is likely to be due to under-reporting rather the absence of IT failures or patient harm. Importantly,

whilst the evidence of health IT contributing to preventable harm to patients is clear, this analysis has also identified some core failings which if addressed may help reduce the occurrence of incidents and mitigate risk by lessening their impact:

1. The majority of incidents were due to the non-availability of patient data or the failure of systems to support the delivery of correct test results in a timely fashion due to the failure of hardware or software; the dependence on legacy systems and inadequate investment in technology was evident in a large number of incidents
2. All IT systems will fail. However, when these systems are 'mission critical' and fundamental for the continuing delivery of safe care there is an absolute need for robust, tested and effective back-up systems and downtime procedures; these were absent or inadequate in a large number of incidents
3. Failures in health IT commonly exposed patients to prolonged avoidable harm due to inadequacies in technical support and difficulties in resolving failures in a timely fashion; multiple failures in the same systems and delays in fixing problems were common
4. Failings in health IT are under reported and frequently not seen as patient safety incidents; the culture must change with health IT and its successes and failures viewed as a fundamental tenant of patient safety

6.5.2 - Placing this study in the wider context and its implications for future policy and practice

6.5.2.1 - How big is the problem? Explaining the low reporting of health IT safety incidents:

In this analysis health IT related patient safety incidents represented just 0.00019% of all incidents reported. This low reporting rate is significantly below the 0.1-0.2% incident rate reported in similar analyses^{33,386} and likely multi-factorial. We developed and tested a new methodology for identifying specific incidents through a rules-based approach to text mining combined with manual expert validation. Whilst this approach has not been previously used to identify incidents within the NRLS dataset, similar automated text classification techniques

have been used to identify patient safety incidents and adverse events with good sensitivities and specificities^{416–418}. Without manual review of all 13,738,411 incidents the true sensitivity and specificity of the search methodology utilised cannot be calculated. Whilst the approach taken would appear robust, there is a chance that incidents were incorrectly classified and not identified.

A more likely reason for the low reporting rate seen in this study is a failure to report incidents. Whilst vast numbers of patient safety reports are collected annually, and despite the increased awareness and reporting of events, large reporting systems such as NRLS still significantly underestimate the incidence of adverse safety events and significantly under report harm. Indeed only around 5% of safety incidents in England are thought to be reported to the NRLS³⁹⁵, and only an estimated 14% of adverse events in hospitalised patients are thought to be reported formally in the US⁴¹⁹. Different healthcare professionals tend to focus on different types of safety incidents, for example clinicians are more likely to report deaths and harm incidents than other staff members, nurses are more likely to report incidents than doctors, and obstetrics and gynaecology patients are more likely to have no harm events reported⁴²⁰. Furthermore, near misses, whilst more common than adverse events are less likely to be documented and recorded despite providing valuable lessons⁴²¹. Doctors' reluctance to report incidents is likely to be multi-factorial: time constraints, medicolegal fears, lack of clarity on what constitutes an incident and its perceived harm, the subjective nature of identification and a paucity of feedback once the incident has been reported discouraging reporting of subsequent events⁴²²; indeed, over 40% of middle and senior grade doctors have never completed an incident report, and only around 60% believe acts of omission should be reported⁴²². The reporting of incidents and quality of data capture is evidently of concern and five key challenges have been identified that need to be tackled in order for incident reporting to meet its full potential in contributing to healthcare quality improvement: poor processing of incident reports (triaging, analysis, recommendations), inadequate engagement of doctors, insufficient subsequent visible action, inadequate funding and institutional support of incident reporting systems, inadequate use of evolving health information technology⁴²³.

In addition to the factors identified above there is also a significant correlation between reporting rate and organisational characteristics and culture⁴²⁰. Just 13.01% (337/2,576) of organisations included in this analysis reported incidents related to health IT, which is implausibly low. To place this startlingly low figure in context Imperial College Healthcare NHS Trust - a large multi-site NHS Trust – has around 15,000 incidents reported to its IT Helpdesk each month. Furthermore, only 273 (10.4%) incidents included in this analysis took place within primary or community care. Primary care accounts for the vast majority of patient contacts within the NHS and this low level of incidents is implausibly low and likely due to under reporting, the low utilisation of NRLS by primary care due to organisational arrangements and governance structures, and potentially the better use of health IT in the sector. Indeed, it has been previously highlighted that just 1% of incident reports are from primary care⁴⁰⁷ despite the fact they are the principal users of electronic health records and as they become increasingly integrated with secondary care the lack of co-ordination and information may significantly contribute to unsafe care.

6.5.2.2 - Improving the reporting and classification of health IT safety incidents

Patient safety incident reporting systems are here to stay and are an integral part of most developed healthcare economies. Despite agreement on the importance of incident reporting there remains a need to further improve reporting systems both in terms of uptake and productivity. Additionally, in the challenging fiscal climate there is also a need to consider their utility, outcome and value for money; the collection, consolidation and analysis of incident reports remains an unknown cost⁴⁰³. A key element to enhancing patient safety through reporting systems is to ensure a happy balance is struck between the provision of reporting, accountability and learning. Whilst reporting systems require mandatory reporting of specific events to facilitate quantifiable analysis and support investigation and accountability, learning systems tend to focus more on voluntary reporting of events that individuals feel are of interest, enabling the discovery of new types of events through qualitative analysis and providing a means to generate novel insights rather than holding

people to account; striking the right balance is important to maximise the impact and value of any patient incident reporting system. Key factors to maximise learning and improve accountability include a priority on protecting and educating staff through preserving anonymity, standardising data collection, educating staff and effectively prioritising events to report; identifying priorities for local and national reporting and promoting the sharing of local solutions at a national level; reinforcing local responsibility and accountability for investigating local reports, generating preventative action and solving safety problems⁴⁰⁰.

In addition to maximising learning, improving the user experience and minimising the administrative burden of reporting,^{400,407,424} this analysis has also identified the difficulties in quantifying and reporting harm and classifying incidents; the utility of incident reporting is compromised by significant variation and bias in the reporting and classification of incidents and weighting of near-miss incidents versus those which actually cause harm⁴²⁵. There are clear examples of similar incidents being recorded as both causing no harm or severe harm, and incidents being recorded as causing no harm when harm was clearly evident. Furthermore, there is considerable benefit in measuring the impact of near-miss events or voluntary error and attaching equivalent value to them as learning events despite the fact they are commonly ignored and not effectively investigated^{426–428}. In order to address these challenges there is a need to further develop an understanding of the impact and importance of an incident through a consistent and reliable method of grading severity, for example through utilising the Safety Assessment Code (SAC) Matrix which rates an incident on the basis of actual or potential severity and likelihood of recurrence⁴²⁹, or the Joint Commission on Accreditation of Healthcare Organisations (JCAHO) Patient Safety Event Taxonomy which facilitates a common approach to patient safety information systems⁴³⁰. Whilst the theory may be good, in practice clinicians are often uncertain of how to use such systems resulting in marked differences and poor inter- and intra-reporter reliability in the grading of incidents⁴³¹. It is hypothesised that clinicians may be unwilling to report the true severity of an incident through fear of formal investigation for themselves or colleagues, or conversely falsely assign a higher severity score to an incident if it serves them to escalate the matter for other reasons; whatever the underlying causation there is a lack of consistency as what

constitutes severity and risk across all incident reporting systems⁴³²; variation which must be reduced in order to maximise the utility and value of incident reporting systems.

There are important steps to take in order to improve safety incident reporting more generally, however, in order to improve the reporting of health IT safety incidents specifically there is a need for a bespoke approach. Strategies to minimise the risks of health IT and learn from incidents need to be based upon a full understanding of contributing factors and safety implications⁴³³. Analysis suggests that NRLS does not currently deliver this due to low reporting rates and a failure to effectively collect the necessary information. This failure to adequately report health IT incidents may be due to confused messaging as to where to report incidents. The vast majority are reported locally through IT departments (15,000 per month locally at Imperial College Healthcare NHS Trust), whilst others may be reported to centralised bodies such as NHS Digital in England³⁶⁰ or national regulators such as the FDA (Food and Drug Administration) in the US^{15,434}. This clear lacuna relates back to the fundamental differences in regulatory regimes, approval processes and post-market monitoring requirements between pharmacological interventions and those related to health IT or medical devices⁴³⁵ which means that there is no standardised central repository of health IT safety events or system failures. Furthermore, it is likely that staff see a computer failure as an IT issue rather than a patient safety issue and are therefore less likely to report it through established reporting systems, whilst those incidents that are reported are likely to reflect the expertise or bias of those reporting the incident who are commonly IT professionals⁴³⁶. In order to improve the systematic identification and recording of health IT failures and their impact on patient safety there is a need to consolidate and expand reporting through a standardised prospective reporting system.

In order for incident reporting systems to provide a more comprehensive understanding of the nature, consequences and outcomes of health IT failures there is a further requirement to develop a comprehensive common classification system for health IT failures⁴³⁷. Health IT related patient safety incidents are difficult to define as they are heterogenous, often occur in temporally or physically separate circumstances and generally involve complex interactions

between numerous technical and non-technical factors^{371,438}. Previous studies have attempted to tackle this challenge: one study identified 32 types of computer problems leading to safety failures, of which 55% were related to hardware or software and 45% to the human-computer interface³⁸⁶, whilst further study identified 22 distinct categories of computer failings related to medication errors⁴³⁹. The Health IT Safety (HITS) Framework utilised in this analysis integrates both retrospective and prospective measures of health IT safety, and aims to facilitate shared learning and provide comprehensive assessments of safety to better understand the safety implications of health IT³⁷¹. Our analysis demonstrated that although 96.7% of safety incidents could be coded according to the framework descriptors only 77.2% of incidents could be coded into a single category. Crucially, of these 87.9% fell within the data availability category of which 88% were the result of technical failures; arguably the HITS Framework is not sufficiently specific and does not provide the required granularity of information to be a useful adjunct to better understand health IT failings and their impact on patient safety. A modified HITS Framework is proposed in *Table 7.6* to provide further delineation of incidents based upon the 31 categories of health IT failings that were identified during the analysis and which were subsequently developed into 7 modified themes. By further delineating each category it is possible to better define incidents and provide the development of a comprehensive and meaningful taxonomy of health IT failings which lead to patient safety incidents. This may be used as a basis for the development of specific focused reporting systems, aid in the identification of interventions to reduce common health IT related adverse events and aid the dissemination of effective safety interventions into routine practice; three core goals of patient safety⁴⁴⁰.

6.5.2.3 - The impact of investment and resource on health IT failures and patient safety

Health IT has a central role to play in improving the quality, safety and efficiency of care. Quality concerns such as failures in the coordination of care, the ineffective use of information and data, and significance variance in care can only be addressed with adequate investment in technology⁴. Whilst investment in health IT is correlated with improvements in quality measures^{12,441}, quantifying the added value of health IT investment

is challenging. Evidence has suggested that effective investment in high-quality health IT can yield significant organisational benefit running into the billions of dollars⁴⁴² as long as a sufficient critical mass of investment is made and value is calculated over a 5-10 year period⁴⁴³. Despite this, healthcare continues to spend significantly less on IT than other technology dependent sectors; financial services spend around 10.5% of annual revenue on IT compared to 5% in healthcare even with significant increases in health IT spending over the past few years⁴⁴⁴. Furthermore, clear international standards for data exchange and technology are sorely lacking in healthcare compared to other information-intensive industries⁴⁴⁵. In addition to the cost calculation of the added value delivered by effective health IT, there are clear costs associated with patient safety incidents and avoidable harm. Adverse drug events can cost around \$2,200 per patient⁴⁴⁶, each preventable adverse event or patient safety incident may cost an organisation on average \$35,617⁴⁴⁷ and patients exposed to avoidable harm see up to a 4.5x increase in their overall cost of care⁴⁴⁸. In addition to these direct healthcare costs it is estimated that the 187,000 deaths and 6.1 million injuries each year in the US associated with adverse medical events result in an overall estimated societal cost of \$393-958 billion, or 18-45% of total US healthcare spending⁴⁴⁹. Effective health IT investment and patient safety are inextricably linked from a cost and benefit perspective.

The failure of health IT can pose significant safety hazards for patients, with important areas of risk including errors in patient identification and failures communication of clinical information⁴⁵⁰. Whilst some technology downtime may be planned for regular maintenance or updates, much of it is unplanned due to equipment failures, external events such as power failures or cyberattacks such as the recent WannaCry incident in the UK³⁸⁸. Underinvestment in health IT increases the risk of unplanned downtime and increases the rate of preventable patient harm. In the example of the WannaCry incident a failure to install a simple operating system patch due to the inadequate funding of support services led to the entirely preventable disruption of care for many thousands of patients³⁸⁸. This failure to invest in IT hardware and software was evident in this analysis with around 30% of safety incidents directly related to infrastructure failures. The failure to invest in appropriate support

services was also evident. There were a number of cases where IT systems support was either not provided at all or was out-sourced to external providers who commonly were not contracted to provide out-of-hours support, resulting in unnecessary, prolonged and avoidable patient harm due to delays in resolving faults and returning mission-critical services to use. This lack of investment was frequently compounded by inadequate or ignored downtime procedures and an inability for organisations to deliver safe care following even temporary IT failures; a consistent finding in other studies where around half of all incidents were affected by either downtime procedures not being in place or not being followed⁴⁵⁰. Effective investment in health IT delivers direct patient benefit and financial gain to healthcare organisations. Conversely, under investment in technology and limited resource directly impacts patient safety and can compound existing safety incidents resulting in a significant cost to healthcare providers and patients alike.

6.5.3 - Strengths and limitations of this study

This study has identified and quantified the nature of harm caused to patients by health IT failings over the past decade in the NHS in England. It has also suggested that the true rate of health IT failures and the subsequent impact on patients is likely to be vastly under reported. Nonetheless, there are pragmatic and achievable changes which all organisations can make to reduce the rate of IT failures and lessen the harm caused to patients. These results must however be interpreted and qualified within the strengths and weaknesses of the study.

A core strength of this study is the large, nationally representative data that has been used. Despite criticisms around reporting and data capture NRLS remains the largest and most comprehensive patient safety reporting system in the world with 13,738,411 incidents recorded to date^{402,403}. The 2,627 health IT related safety incidents identified in this analysis is the largest number of incidents previously examined and is at least 2.5x larger than any other published series in the literature. The consistency and completeness of the data across the dataset was excellent, allowing for a granular assessment of the type, nature,

contributing factors and preventability of incidents. Robust and defensible methods of analysis were selected with the liberal use of independent expert manual review and validation where required. Importantly this is the first study to examine the influence of health IT failures on patient safety in a nationally representative dataset in the NHS in England.

The analysis of free text incident descriptors to identify specific incident types poses unique challenges, particularly when the goal is knowledge discovery and real-time surveillance⁴⁵¹. Although similar techniques have been previously used to identify and classify patient safety incidents and adverse events with good reliability and validity^{416–418}, the approach has not previously been applied to the NRLS data set and therefore is a potential significant weakness of this study. A rules-based approach to text mining with manual expert validation was utilised to identify relevant safety incidents. Inherent weaknesses in this approach include the loss of contextual information, particularly relevant spatial information gleaned from the ordering of words. Utilising bigrams as we did in our strategy is a common method employed to reintroduce some of this useful contextual information, although it is debatable whether this approach actually acts to improve search performance, particularly when a manual approach to bigram selection is used⁴¹⁷. Additionally, the use of initial keywords may not lead to a representative corpus sample and therefore may miss some incidents. The homogeneity of the corpus however (e.g. staff refer to ‘computers’ by few other terms) means that increasing the number of keywords is unlikely to increase the number of incidents identified. The aim of the search strategy and methodology was to provide for a high level of recall (the proportion of relevant incidents identified by the search), and high precision (the proportion of retrieved incidents that are relevant) to ensure the capture of all relevant patient safety incidents for subsequent analysis; these measures of search effectiveness are widely accepted and used throughout the research community⁴⁵². Average precision is a well-recognised measure of recall and precision with an average precision calculated by measuring precision at different recall points⁴⁰⁹; the precision of the search strategy employed in this study was good, with a final round precision of 93.5%. Despite a high level of precision, it is likely that our search strategy failed to identify a number of relevant incidents; for our results to be generalisable it is vital that they are representative of

the complete corpus of safety incidents. The selection of alternative keywords and bigrams may improve the precision and accuracy of the search and yield a greater number of relevant safety incidents, whilst weaknesses such as the misspelling of words cannot be accounted for such as the 371 spellings of *clostridium difficile* that are present in the NRLS dataset⁴⁰⁷. Manual searching may provide insights that cannot be captured by automated processes, however, it is not possible to employ an entirely manual approach in such large datasets particularly when there are specified aims for real-time surveillance of safety incidents. Automated processes, despite their inherent weaknesses can nonetheless reduce the time and effort spent identifying incidence and provide useful aggregate data on relevant patient safety incidents.

Another criticism of this study is the valid concern regarding the quality of reporting and robustness of data capture within the NRLS reporting system. As previously identified, it is thought that only around 5% of safety incidents in England are captured in NRLS³⁹⁵ due to a multitude of reasons such as professional groups focusing on different types of safety incidents, the under-reporting of near miss incidents or the lack of feedback on incidents acting as a principal deterrent to reporting^{421,422}. As such, despite the large repository of information having the potential to unlock unique and important safety insights, it has been subject to valid external criticism about the quality, quantity and utility of the information collected and outputs generated: *“It is a significant criticism of the NRLS that its approach to data collection is ‘wide and shallow’, whereas it should be ‘narrow and deep’. The latter approach would entail focusing on gathering in- depth analysis of reported incidents that are less common in type and more serious in the degree of actual or potential harm associated with them”*⁴⁵³. Whilst this analysis represents the largest ever reported series of health IT related patient safety incidents analysed to date, it is almost certain that those examined represent just the tip of the iceberg and a tiny proportion of health IT related harm caused to patients in the NHS in England.

6.6 - Conclusion

Health IT is fundamental to the delivery of high-quality safe care yet there is a relatively poor understanding of the impact of failures on patient safety. These failures are challenging to unpick and involve numerous complex aspects of technology, people and the environment. Using a nationally representative incident reporting system this study has shown that health IT related patient safety incidents are plagued by under-reporting and poor-quality data capture, but nonetheless are a very real and potentially significant source of patient harm. The majority of incidents are due to failures in hardware or infrastructure and are commonly exacerbated by the use of outdated legacy systems, the lack of effective and robust back-up systems or downtime procedures and inadequate technical support. The failure to invest adequately in infrastructure, resources and people is a clear source patient harm. It is evident that there is significant under-reporting of health IT failures and this is likely due to the absence of a consolidated, unified and open approach to reporting of them. Reporting systems are a valuable instrument in the patient safety armoury but cannot act in isolation to improve safety. There is a need to change the culture of healthcare to see health IT as a fundamental aspect of patient safety, develop transparent and robust methods for the analysis of IT failures and their causality, disseminate learning and back practice, and foster a cycle of continuous improvement in health IT as a crucial part of learning from patient safety incidents and improving the quality and safety of care delivered. Health IT has the promise to transform healthcare, however in parallel there is a requirement to develop and implement effective processes for safety monitoring and reporting to enable organisations to adapt to digital ways of working, target investment in new technologies and protect patients from avoidable harm.

A further cause of harm to patients is the increasing dependency of healthcare organisations on IT to deliver safe care; failures in health IT and a lack of digital resilience may therefore be a major source of risk to patients. The recent WannaCry incident starkly illustrated the potential for cybersecurity incidents to cause failures in health IT, interrupt the delivery of care and have major implications for patient safety. Despite this there is a lack of published evidence exploring this area of interest which therefore forms the basis of the next chapter.

Figure 6.1 - Flow diagram of search methodology developed to explore free-text descriptions of 13,738,411 patient safety incidents

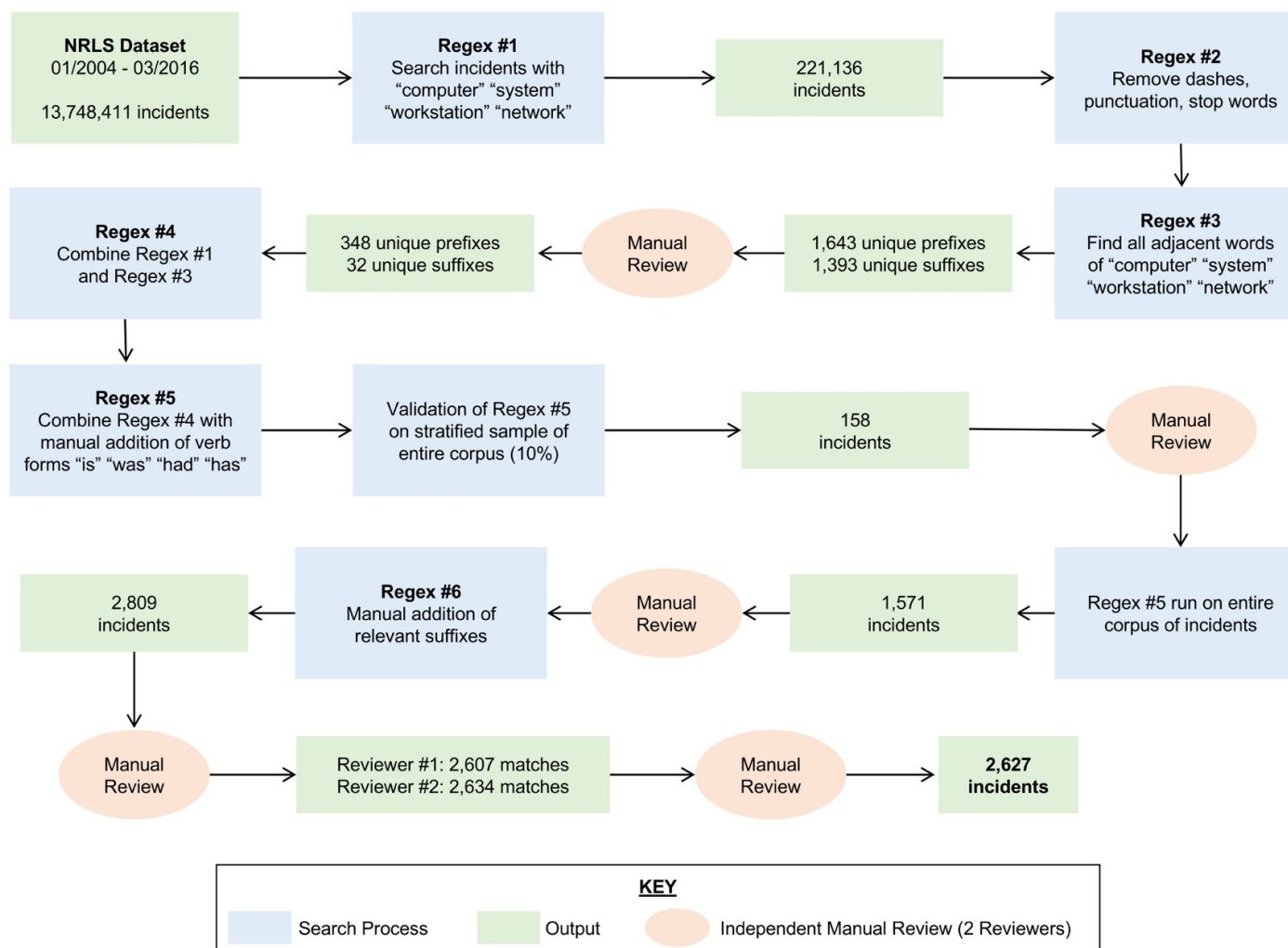


Table 6.1 - Coding agreement summary of health IT safety domains for 263/2,627 health IT related patient safety incidents reported 2003-16

		Reviewer 2							
		0	1	2	3	4	5	6	TOTAL
Reviewer 1	0	6	1	-	-	-	-	-	7
	1	1	193	4	-	-	7	-	205
	2	-	12	37	-	-	1	1	51
	3	-	-	-	1	-	1	-	2
	4	3	2	-	-	6	1	-	12
	5	-	7	1	-	-	25	-	33
	6	-	2	-	-	-	-	2	4
	TOTAL	10	217	42	1	6	35	3	314

0 – no appropriate coding category

1 – data availability

2 – data integrity

3 – data confidentiality

4 – complete/correct use of health IT

5 – health IT system usability

6 – surveillance and optimisation

Disagreement 14/263 (5.2%)

Partial agreement (1/2 categories match) = 33/263 (12.5%)

Full agreement (match in all coded categories) = 216/263 (82.3%)

Cohens Kappa agreement:

Kapa = 0.727 (SE =0.037, 95% CI 0.654-0.800) = “good” agreement

Figure 6.2 - Summary descriptive statistics for health IT related patient safety incidents 2003-16; rate of annual incident reporting 2003-2016 (Q1) (Fig 6.2a); rate of reporting by organisation type (Fig 6.2b); incident number by location (Fig 6.2c) and incident number by category type (Fig 6.2d)

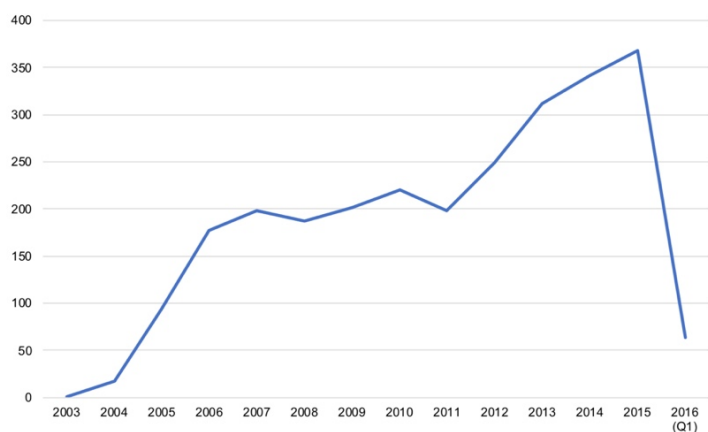


Fig 2a - Incident Reporting by Year 2003 - 2016 (Q1)

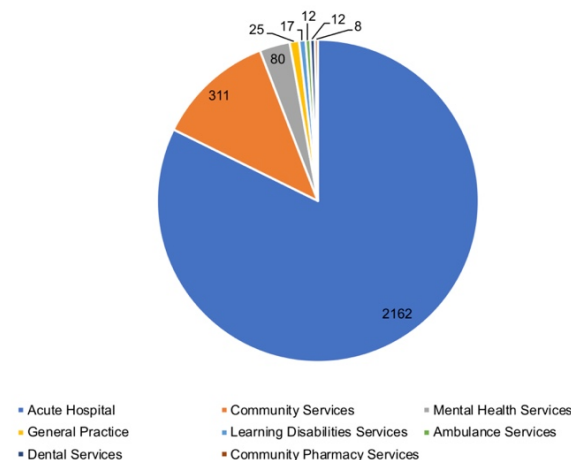


Fig 2b - Reporting Organisation Type

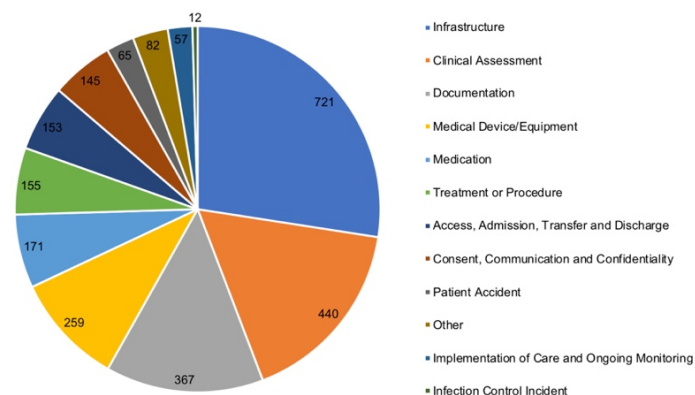


Fig 2d - Incident Category

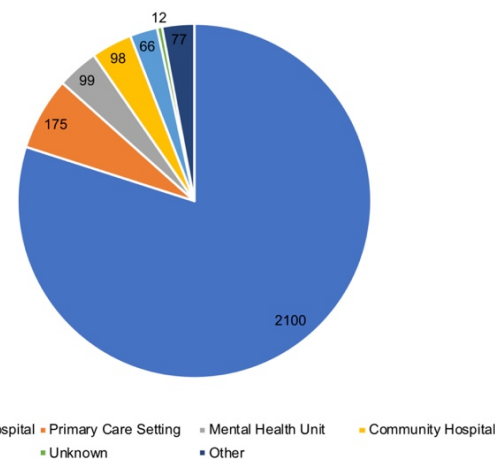


Fig 2c - Location of Incident

Table 6.2 - Detailed examination of health IT related patient safety incidents 2003-16 reported by recorded incident category

Incident Category 1 (number)		Incident Category 2 (number)	
Infrastructure (including staffing, facilities and environment)	721	IT/telecommunications failure or overload	498
		Lack of suitably trained/skilled staff	49
		Failure/delay in collection or delivery systems	13
		Other	161
Clinical assessment (including diagnosis scans tests and assessments)	440	Test results/reports (failure or delay to receive, incorrect or missing)	249
		Diagnosis or tests (delay or failure)	65
		Scans/X-rays/specimens (inadequate/incomplete, missing)	61
		Other	65
Documentation (including electronic and paper records, identification and drug charts)	367	Documentation (missing/inadequate/wrong, no access or delay in obtaining)	262
		Patient incorrectly identified	28
		Appointment recording error	17
		Test results/reports (failure/delay to receive)	14
		Other	46
Medical device/equipment	259	Failure device/equipment	192
		Lack/unavailability of device/equipment	40
		Other	27
Medication	171		
Treatment or procedure	155	Treatment/procedure (delay/failure or inappropriate/wrong)	101
		Other	54
Access, admission, transfer, discharge (including missing patients)	153	Transport, transfer or discharge (delay/failure)	53
		Access/admission (delay/failure in access to hospital/care)	30
		Failure in referral process	16
		Other	54
Consent, communication and confidentiality	145	Communication failure	74
		IT/telecommunications failure/overload	23
		Other	48
Other	216		

Table 6.3 - Examples of incident descriptors for level of harm reported in 2,557 patient safety incidents relayed to failures in health IT: no harm, low harm, moderate harm, severe harm and death

Reported Harm	Examples of Incident Descriptors
No Harm (82.4%)	<i>"Lorenzo system down so cannot do electronic discharge letter"</i> <i>"Arrived to the ward after being closed over the weekend to find all the network system was down and the computers were unable to access anything therefore patients could not be admitted to the unit and blood cards could not be printed for patients on the unit"</i>
Low Harm (12.9%)	<i>"A new patient was admitted to the unit and we had difficulty obtaining a medical record number for them due to the computer system failing. it was 5 hours after they arrived on the unit before we managed to obtain an emergency number. this resulted in a delay to their treatment as medical tests cannot be ordered without a medical record number"</i> <i>"Patient currently on iv heparin and requires 6 hourly blood test monitoring as infusion rate needs constant adjustments, due to pathology system unavailable no blood results for 24 hours. Patient safety at risk"</i>
Moderate Harm (4.0%)	<i>"Patient gent level not available as computer system crashed. Phoned lab - they are unable to access results also therefore gentamycin dose not given to cardiac baby on 3 antibiotics"</i> <i>"Apex LIMS system error resulted in approximately 1700 patient records having missing data items on attached specimen records. This caused multiple specimens to be inaccessible on Apex and EPR"</i>
Severe Harm (0.5%)	<i>"Main server for pharmacy IT system failed. No 24hr maintenance contracted for from server provider. No 24hr internal IT cover. Result complete failure of pharmacy operational system"</i> <i>"Computer system down since 12:30 in the afternoon. Woodside villa has had no access to Rio or any other network, preventing staff from doing their jobs properly. No change at 21:00"</i>
Death (0.2%)	<i>"Patient became acutely unwell overnight, had been seen by on call team during the previous day... Found to be in probable urinary sepsis. Later died. ICE system not working properly and so positive MSU from 4/7 earlier had been missed by ward team and on call team"</i> <i>"Patient arrived to ED as a priority call at 12:59 - seen promptly and referred to medical team on call. PAS system was down at the time and initial bloods taken were ordered on paper form. Medical Reg saw patient at approximately 1600 but no results on system. Called lab who stated that they could not find bloods. Many other samples had gone missing on this day. Medical Reg re-bled patient approximately at 1630 and sent to lab. Results from repeat bloods available on system at 19:49 and many results were critical. Patient deteriorated clinically and died after transfer to ITU"</i>

Table 6.4 - Examples from 2,028 health IT related patient safety incidents coded onto the Health Information Technology Safety Measurement (HITS) Framework^{93,371,372}

Safe health IT Address safety concerns unique to technology	Data availability 1,783/2,028 (87.9%)	<i>"Patient arrived and was booked in at reception. Due to computers failing the exact nature of the appointment was not clear. Notes were unavailable and the name was not on the pulling sheet"</i>
	Data integrity 111/2,028 (5.5%)	<i>"Pathology computer database crashed. GE Healthcare unable to restore transaction log. This resulted in the sample numbers listed being reallocated to other samples and the results from both sets of samples being mixed"</i>
	Data confidentiality 1/2,028 (<0.1%)	<i>'At the end of a very busy clinic our clerk was unable to log the patients notes on activity sheet on to computer due to computer error. As a result, inadvertently these notes were left out in public owing to having to leave the premises in haste"</i>
Using health IT safely Optimise the safe use of technology	Complete/correct health IT use 7/2,028 (<0.1%)	<i>"Following implementation of VPLS the new computer system failed to recognise the preventative flag of BMT which prevents electronic issue of red cells. On investigation it was discovered that the system had not been set up to recognise each patient episode"</i>
	Health IT system usability 125/2,028 (6.2%)	<i>"EPR system failing to print on ITU. Staff obliged to go to other wards to print specimen requests or write labels. Delay in sending specimens and therefore obtaining results"</i>
Monitoring safety Use technology to monitor and improve patient safety	Surveillance and optimisation 1/2,028 (<0.1%)	<i>"All linear accelerators have been linked to the hospital network since 2003. Today the entire hospital network failed so that it was impossible to treat any cancer patients. IT Dept is unable to tell us when the fault will be rectified. Prior to 2003 cancer services employed a senior IT technician to maintain the internal network"</i>
Not coded to HITS domain		<i>"There was a significant IT systems failure in the node 1 network room London Wing resulting in a Trust wide IT systems failure for several hours and there was then resultant knock on effects and disruptions to various other IT systems across the trust. It is believed that the failure may have been precipitated by an electrical shutdown by one of the project officers working on the new Ashburton wing which caused overheating and over loading of the IT servers. There doesn't appear to have been a necessary risk assessment carried out prior to the work commencing or contingencies put into place in case things went wrong"</i>

Table 6.5 - Preventability assessment of 2,627 health IT patient safety incidents (incidents scoring >4 deemed to be preventable)

Preventability Score		Count (n/2,627)	Example of Incident Descriptor
Unpreventable 663/2,627 (25.2%)	1	106 (4.0%)	<i>"...a clinician arrived, was informed of the computer failing and stated his clinic was cancelled. Another clinical area was offered where the IT system was working but the clinician stated he was not doing the clinic and walked away from the clinic."</i>
	2	230 (8.8%)	<i>"JAC prescribing system down, unable to access any computer on the ward, paper copies of medication drug charts being completed"</i>
	3	327 (12.5%)	<i>"Arrived on the mobile unit to find there was no paperwork for the days screening clients we were able to download the list from NBSS but if the computer system went down we would be forced to cancel the clinic as we would be unable to perform adequate identity checks..."</i>
Preventable 1,964 (74.8%)	4	1,253 (47.7%)	<i>"Blood science and microbiology laboratory IT system failed at 11:15 and was not restored until 13:10 causing a significant delay in processing and reporting laboratory tests..."</i>
	5	605 (23.0%)	<i>"The CRIS system crashed at 9.15am. The US dept is paperless, so no patient records could be tracked and patient details accessed. Although all original referral forms are kept they are not filed in either alphabetical or chronological order - the consequence of this was that it took ninety minutes to trace patient cards. This is the second time this has happened."</i>
	6	106 (4.0%)	<i>"Whole EPR system failure from 14:30hrs. No 24-hour cover provided by GrafNet the company who provide the EPR service. Unable as yet to identify cause of problem. Possible corruption in web server. No timescales identified for restoring the system at present. No data lost but issues with access. GrafNet will work until 9pm then return to work on the system again at 9am on the 9th May."</i>

Table 6.6 - A proposed modified Health IT Safety Framework³⁷¹ to better identify specific health IT related patient safety incidents

HITS Framework		Domain		Patient Safety Focused Modified HITS Framework
Descriptor	Principle		Modified Principle	Descriptor
The usability and accessibility of health IT. Are health IT systems easy to use, and are they available to staff when needed?	<i>Data Availability</i>	Safe Health IT	<i>Data Availability – Hardware Failure</i>	Failure of network infrastructure or electronic hardware resulting in inability to access electronic systems
			<i>Data Availability – Software Failure</i>	Authorised users are unable to access clinical systems or applications due to software or access failures
			<i>Data Availability - External Failures</i>	Failures in IT systems external to those of the reporting organisation impact patient safety
Accuracy and integrity of the data that is supplied to health IT users. Is data at risk of being lost, altered or destroyed? Is there only ever 'one true record' of care?	<i>Data Integrity</i>		<i>Ensuring the Integrity of the Patient Record</i>	Health data is correct, complete, accurate, up-to-date and has not been lost or changes whilst being entered, processed or retrieved
Systems and data are only accessed by authorised users. Are there effective processes in place to ensure the security and privacy of patient information?	<i>Data Confidentiality</i>		<i>Confidentiality of Health Data</i>	Health data is only available or disclosed to authorised persons in a proportionate manner
Features and functionality are implemented and used as intended. Are systems being used as intended, or are staff failing to maximise their potential due to poorly designed or functioning systems?	<i>Complete/Correct Health IT use</i>	Using Health IT Safely	<i>Human Factors and Usability</i>	Failures of the socio-technical interface between users, technology and the social environment prevents care being delivered promptly, efficiently or safely
Are users satisfied with the usability of a system, or does poor design and dissatisfaction lead to the development of potentially unsafe work-arounds or other concerns?	<i>Health IT System Usability</i>			
Processes and policies for monitoring, detecting and reporting health IT use and its impact on patient safety. Do organisations have effective processes for identifying and mitigating risks, delivering innovation, and leveraging health IT to reduce harm and improve safety?	<i>Surveillance and Optimisation</i>	Monitoring Safety	<i>Surveillance, Optimisation and Resilience</i>	As part of an ongoing assurance and improvement program mechanisms are in place to monitor, detect and report IT safety failures. Health IT is supported by robust and resilient back-up systems and downtime procedures

Chapter 7 - Digital resilience and healthcare cybersecurity is fundamental to patient safety: reframing the challenge and identifying research, practice and policy priorities

The previous chapters have demonstrated that health IT plays an important role in quality. As health systems become ever more dependent on IT and complex health data they may be increasingly susceptible to failures of their IT systems or security incidents and the misuse of data. These can have significant implications not only for patient safety, but also for trust. The current awareness, knowledge and capability needed to meet this challenge within the health sector is severely lacking as highlighted by the recent WannaCry incident in the NHS. This chapter therefore seeks to take a multi-modal approach to establishing key research, practice and policy priorities, and reframe the problem as one which is fundamentally a patient safety priority, rather than an IT challenge.

7.1 - Introduction

Cyber security has become a major concern for all organisations and individuals. Businesses, public sector organisations, governments, academic institutions and individual citizens around the world are routinely subject to cyber-attacks, most of which go unnoticed or unreported by their victims. The purpose of these attacks is usually to steal money, data or intellectual property, although in a growing number of cases the aim is to cause overt disruption or political effects. The small minority of known attacks that enter the public domain provide daily fodder for the news media; among the best-known recent examples are the major breaches at TalkTalk⁴⁵⁴, Office of Personnel Management⁴⁵⁵, Mossack Fonseca⁴⁵⁶, US Democratic National Committee⁴⁵⁷, World Anti-Doping Agency⁴⁵⁸, Bangladesh Central Bank⁴⁵⁹ and Yahoo⁴⁶⁰. The estimated total cost of cybercrime to companies globally in 2014 was up to \$575 billion⁴⁶¹.

Healthcare is in no way immune from the cyber threat. In several respects it faces even bigger risks than other sectors because of inherent weaknesses in its security posture. Healthcare is regularly identified as one of the most targeted sectors globally with over 80% of healthcare organisations in the USA compromised each year⁴⁶² and 49,917 unique malicious events across 375 compromised healthcare organisations reported in 2014⁴⁶³. It is estimated that around half of Americans have had their personal healthcare data compromised in the previous 12 months⁴⁶⁴ and that there has been a 300% increase in attacks against healthcare organisations in the three years up to 2016⁴⁶⁵. Recent examples of incidents affecting healthcare organisations include the theft of 80 million sets of personal records from the US health insurance company Anthem in 2015⁴⁶⁶, the 2016 ransomware attack on the Hollywood Presbyterian Medical Center in Los Angeles which shut down its network for 10 days until the hospital eventually paid the ransom (reportedly a mere 40 Bitcoins, or about \$17,000)⁴⁶⁷, a further ransomware attacks on the Boston Children's Hospital in 2014⁴⁶⁸ and a data breach at the Australian Red Cross Blood Service in which the records of half a million donors - including sensitive personal information such as sexual history – was dumped on the internet⁴⁶⁹. For the criminals and foreign states who are conducting cyber-attacks, the healthcare sector is an attractive target for two simple reasons. First, it is a rich source of financially valuable personal data. Second, it is a soft target. Many attacks remain undetected, and only half of healthcare providers feel they are capable of defending themselves from cyberattack⁴⁶².

The disruption to the National Health Service (NHS) caused by the WannaCry attack in 2017 was a wake-up call for the health and social sector in the UK. Whilst the attack did not specifically target the NHS it led to the disruption of care at least 81 out of the 236 hospital trusts and a further 595 GP practices in England resulting in the cancellation of an estimated 19,000 outpatient appointments and the closure of 5 hospitals to emergencies³⁸⁸. Whilst this was not the first incident to affect UK hospitals - with previous reported cyber incidents at Papworth hospital⁴⁷⁰, North Lincolnshire and Goole NHS Trust⁴⁷¹ and Barts Health⁴⁷² to name a few - it did demonstrate the soberingly poor state of cyber security and resilience within the NHS. The WannaCry incident acted as a canary in the mine for the general state

of digital resilience and cybersecurity within the NHS. The implicit approach of the UK Government and NHS leadership over a long-period has been to ignore the chronic risk of cyber security system fragility resulting in a prolonged 'time on risk'. Many NHS organisations continue to spend as little as 1-2% of their annual budget on IT compared with 4-10% in other critical sectors such as financial services and energy⁴⁷³, and failures of large-scale NHS IT programs have been well publicised³⁴⁵. In 2015 the UK Government elected to axe funding for ongoing support by Microsoft for Windows XP which meant that the operating system became obsolete, unsupported and unpatched in return for a mere £5.5 million in annual savings⁴⁷⁴. Despite this decision as late as 2016 90% of NHS Trusts were still using XP to some degree⁴⁷⁵ and in some organisations it remained in widespread use with one NHS Trust reporting having more than 10,000 XP-powered machines⁴⁷⁶. Crucially none of the 80 NHS organisations affected by WannaCry had applied the available patch to their Windows operating systems that would have prevented the infection despite being advised to do so some months before⁴⁷⁷. More worryingly a year before WannaCry the National Data Guardian and Care Quality Commission had written to the NHS and Secretary of State specifically warning of cyber risks to the NHS together with proposing specific recommendations to address basic cyber vulnerabilities; these went largely unheeded. If they had been followed the impact of WannaCry would have been largely neutralised⁴⁷⁸. According to the National Audit Office no organisations reported any harm to patients as a result of WannaCry, but the evidence is limited and worryingly there has been no attempt to quantify or estimate the immediate or delayed impact on patients; *"neither the Department [of Health] nor NHS England know how many GP appointments were cancelled, or how many ambulances and patients were diverted.... the Department [of Health] does not know the cost of the disruption to services"*³⁸⁸.

The WannaCry incident, together with numerous other examples highlights how the NHS is not equipped to deal with emerging cyber threats, nor has the required awareness, capability or resource to be a resilient system that supports the continuity of safe care in spite of health IT failures or cyber incidents. The NHS does not know the cost and impact of cyber incidents or health IT failures, and does not have the capability to respond to them effectively.

Healthcare cybersecurity and digital resilience must be seen and acted upon as not just an IT problem, but as a fundamental patient safety problem; wrong site surgery is a serious error resulting in harm to a single patient, but a cyber incident may cause harm to every patient across a healthcare system. In order to tackle this very real challenge there is a need to address the fragmentation of governance and change the mindset of the NHS to systematically and pragmatically evaluate, understand and mitigate against cyber threats⁴⁷⁹.

7.2 - Hypothesis, aim and objectives

7.2.1 - Hypothesis

Healthcare is increasingly dependent on IT to support the delivery of high-quality safe care. Limited resources, outdated infrastructure, fragmented governance and a weak security culture mean that the security posture and inherent resilience of the health sector is flawed, threatening the delivery of care and endangering patients. By reframing the cybersecurity challenge as a fundamental issue of patient safety, as opposed to an IT problem, and identifying key research and practice priorities, it should be possible to address key challenges, enhance the security posture and resilience of healthcare organisations, and improve care quality and patient safety.

7.2.2 - Aim

The principal aim of this study is to identify the key practice and research priorities to ensure effective cybersecurity in secondary care.

7.2.3 - Objectives

In order to fulfil the stated aim, this study will seek to fulfill the following objectives:

1. To redefine healthcare cybersecurity as a fundamental component of patient safety

2. To identify and synthesise key practice priorities to rapidly improve healthcare cybersecurity and digital resilience in the NHS
3. To identify and synthesise key research priorities in order to improve the understanding of healthcare cybersecurity and support future policy and practice developments

7.3 - Methods

A concurrent mixed-methods approach was adopted in order to identify and synthesise key research and practice priorities. This methodology was chosen in order to provide flexibility, promote collaboration and allow a broad and holistic approach to meeting the stated aims and objectives^{480,481}. Three concurrent approaches were adopted - an expert workshop, a meta-synthesis of comparative standards and a comparative in-depth case-study - in order to develop key outcomes as per *Appendix E*.

7.3.1 - Healthcare cybersecurity expert workshop

32 professional experts in cyber security and health from across academia, industry and healthcare took part in a full-day 'Cybersecurity in Healthcare Workshop' in order to collaboratively identify emerging research and practice priorities. Four sessions, each with a short expert presentation followed by a moderated discussion, were conducted covering day-to-day security challenges in the NHS and major incident response, medical device security, current threats, electronic health records and engaging patients, and future directions. Contemporaneous field notes and selected transcriptions of relevant discussions were recorded and subsequently analysed in conjunction with the agreed consensus priorities identified as part of the workshop.

7.3.2 - Meta-synthesis of comparative standards and best practice: what can healthcare learn from other critical sectors

Critical national infrastructure are those systems, facilities and people upon which essential services and daily life depends, and for which the loss or compromise would lead to severe economic or social consequences or loss of life. In the UK this includes chemicals, nuclear, defence, emergency services, energy, finance, food, government, health, space, transport and water⁴⁸². Effective cyber security and resilience is a fundamental part of protecting these critical sectors, both in the UK and globally. It is clear that the healthcare sector lags behind many of these other sectors⁴⁸³, and that they may also provide a useful source of best practice in order to support the development of priorities for the healthcare sector.

Following consultation with cyber security experts from the Institute for Security Science and Technology at Imperial College London, a range of best practice guidelines, regulations and legislation were selected for analysis. These were purposively sampled to be open-source and publicly available, and to represent a range of different critical sectors from around the globe to ensure they were representative and a rich source of data. The full text of each resource was reviewed and subsequently re-reviewed to ensure full immersion as per best practice³⁷⁰. Relevant themes and statements were manually extracted for each resource and then summarised via a manual approach to ensure true sensitivity of data capture.

Horizontal and vertical integration of themes was then performed across each individual extracted theme and resource respectively in order to develop and synthesise overarching emergent themes to inform the development of research and practice priorities for the healthcare sector. The following guidelines and standards were included for analysis: UK National Cyber Security Centre (NCSC) 10 Steps to Cyber Security⁴⁸⁴; US Department of Health and Human Services Top 10 Tips for Cybersecurity in Healthcare⁴⁸⁵; UK Cyber Essentials - HM Government Cyber Essentials⁴⁸⁶; Information Security Forum (ISF) The Standard of Good Practice for Information Security 2016⁴⁸⁷; Information Security Forum (ISF) Protecting the Crown Jewels⁴⁸⁸; CGI Cyber privacy and Cybersecurity for Health Data⁴⁸⁹; UK National Cyber Security Centre (NCSC) Common Cyber Attacks: Reducing the Impact 2016⁴⁹⁰; Bank of England CBEST Intelligence-Led Testing^{491–493}; Investment Industry Regulatory Organisation of Canada (IIROC) Cybersecurity Best Practices Guide⁴⁹⁴; National Institute of Standards and Technology (NIST) US Department of Commerce Framework for

Improving Critical Infrastructure Cybersecurity 2014⁴⁹⁵; 21 Steps to improve cyber security of SCADA Networks President's Critical Infrastructure Protection Board/Department of Energy 2011⁴⁹⁶; G7 Cyber Expert Group Fundamental Elements of Cybersecurity for the Financial Sector 2016⁴⁹⁷; UK National Data Guardian for Health and Care Review of Data Security, Consent and Opt-Outs 2016⁴⁹⁸; Security Standards for the Protection of Electronic Protected Health Information. Health Insurance Portability and Accountability Act (HIPAA) 1996. Department of Health and Human Services^{327,499,500}; and the FDASIA Health IT Report, The Office of the National Coordinator for Health Information Technology / US Food and Drug Administration 2014⁹⁴.

7.3.3 - In-depth comparative case study: the UK financial services sector

7.3.3.1 - Why the financial services sector?

The UK financial services sector employs around 1.1 million people, contributes 6.5% or £119 billion to the economy on an annual basis and certain crucial elements of it form part of the UK critical national infrastructure⁵⁰¹. As a sector it is heavily dependent upon robust and resilient information technology and is a prime target for cyber criminals; it therefore shares some similar attributes to the National Health Service (NHS) and can act as an effective comparator from which healthcare can gain considerable value and shared learning in order to improve digital resilience and cyber security. The UK financial services sector is acutely aware of cyber risk and the need for digital resilience and thus has a far more mature security posture than the health sector. It spends an estimated £700 million each year on cyber security⁵⁰² and more than 85% of senior industry leaders consider cyber insecurity as a major threat to their business⁵⁰³.

7.3.3.2 - Methodology: comparing the healthcare sector to the CBEST assurance framework

In early 2014 the growing cyber threat to the UK banking sector led the Bank of England to develop a new standardised and regulated process for evaluating the security and resilience of UK banks – CBEST⁵⁰⁴. The process aims to ensure business continuity and cyber

resilience for the UK financial services sector by conducting realistic simulated intelligence-led cyber-attacks on the people, processes and technology of individual banks. These red-teams are provided by accredited threat intelligence and penetration companies within a documented framework. This process is supported by a comprehensive assessment of a firm's cyber resilience capability, security strategy and incident response capacity^{493,504,505}. The CBEST regime, together with wider regulatory and sector-wide responses to the cyber threat are publicly available and therefore provides an effective case study to act as a comparison to the healthcare sector in England. For comparative purposes the financial services sector may be viewed as a gold-standard exemplar for sector-wide security preparedness.

The CBEST implementation and assessment guides were analysed in order to identify core principles which underpin the CBEST assessment framework. In conjunction with further open-source information a full picture of the current security posture and regulatory framework for the UK financial services sector was obtained^{491–493,504,506}. All resources were reviewed and then re-reviewed to ensure full immersion in the data. Emergent themes were manually extracted and developed in order to identify the core principles and processes of the CBEST regime. These core principles were then objectively compared to those shared with the NHS in England that were identified through review of relevant documentation^{388,479,507}. This comparative analysis enabled the identification of emerging gaps in the security preparedness of the NHS and supported the identification and development of research and practice priorities.

7.4 - Results

Findings from the expert workshop, meta-synthesis and comparative case study were amalgamated and refined to inform the development of key practice and research priorities as per *Figure 7.1*. Key priorities from the expert workshop were defined by those present, and further core themes identified following retrospective review of contemporaneous field notes and selected transcriptions. In order to perform the meta-synthesis of comparable

standards and guidelines from other sectors relevant documents were identified and all data extracted, synthesised and integrated. The findings from this exercise are presented in *Table 7.1*. To conduct the comparative case-study all relevant open-source information regarding the current cybersecurity and resilience posture of the UK financial services sector was obtained^{491–493,504,506}, together with the current position of the NHS in England through expert opinion and review of relevant documentary evidence^{388,479,507}. Following data synthesis, the comparative evaluation was then conducted and is presented in *Table 7.2*.

7.4.1 - Identification of practice and policy priorities

Five key elements were developed to provide an easily understood conceptual basis for the identification of comprehensive and pragmatic priorities to improve cyber security preparedness, mitigate the cyber threat and improve operational resilience. A summary of these key policy and practice priorities is seen in *Figure 7.1*.

7.4.1.1 - Awareness: getting attention, improving knowledge and encouraging people and organisations to talk about the issue

There is a pressing need to improve individual, organisational and system-wide awareness of current threats, vulnerabilities and the potential impact of cyber incidents. Health and social care must ensure the adequate provision of comprehensive advice, guidance and communication to support organisations in responding to cyber threats. Additionally, there is a need to develop and spread new methods to evaluate, quantify and report the direct and indirect impact of cyber incidents or health IT failures on patients and providers. Specific examples of actions to take in order to meet this priority include:

- Strengthen, expand and appropriately resource the current NHS Digital CareCERT⁵⁰⁸ program to provide a single strategic cyber forum that brings together a range of experts in order to share best practice, develop guidance for organisations and build sector wide capability and resilience

- Highlight and spread good practice and identify local exemplars of best practice in each region to support all organisations in improving their security awareness and posture. Funding from the Global Digital Exemplar¹⁵⁷ program should be ring-fenced to support the development of these local security champions
- Support and encourage open dialogue, scrutiny and consultation regarding both cyber security concerns, and concerns surrounding data security and confidentiality with patients and staff through a formal process of Patient and Public Involvement and Engagement

7.4.1.2 - Governance: supporting better decision making, maintaining trust in the system and ensuring organisations meet their responsibilities

There is a requirement to ensure clarity about where responsibility, accountability and authority lie. Leadership is key and the fragmentation of organisational structures - local, regional and national - must be avoided to ensure a consistent message is being delivered, resources are not being duplicated and that senior leaders have the authority and responsibility to effect positive change and be held account for failures. A comprehensive and standardised bespoke framework for cybersecurity assurance and testing in health and social must be developed; existing generic tools such as Cyber Essentials are not sufficient given the complexity, intricacies and unique aspects of the health and social care sector. Additionally, there is a need to provide further support, resource and guidance to ensure compliance with relevant legislation governing information and data security for healthcare organisations. Specific examples of actions to take in order to meet this priority include:

- Develop, test and implement a mandated bespoke framework for cyber security and operational resilience testing and assurance in the healthcare sector; a “CBEST for Healthcare”. Additionally, security preparedness and resilience must become part of the Single Oversight Framework⁵⁰⁹ upon which care providers are assessed and regulated.
- Provide specific support, guidance and funding to enable all organisations to meet existing legislative requirements on data security; specifically, the General Data

protection Regulation (GDPR)⁵¹⁰ and Directive of Security of Network and Information Systems (NIS Directive)⁵¹¹

- Replace the current opaque and ill-defined hierarchy of leadership and responsibility with a clear chain of command at both a local and national level. Without clearly defined roles and responsibilities leaders do not own the risk, lack the authority to effect change and are not held to account for failure; the current system facilitates buck-passing, does not support effective decision-making and avoids ownership and accountability.

7.4.1.3 - People: security is all about people and workplace culture

Even in security conscious organisations the click rate on well-crafted phishing emails can be up to 30%⁵¹², and the most common source of ransomware continue to be malicious email attachments that are inadvertently opened by staff. Meanwhile, one of the biggest threats to patient data is the insider threat; with easy and ready access to large amounts of sensitive personal information, the risk of accidental or deliberate compromise by individual staff members is ever present and must be tackled; organisations must be trusted by patients to secure their data and use it appropriately. All organisations need to develop and promote a security culture and ensure that the message being filtered is that cyber security is not just an IT concern, but a patient safety concern. Improving staff training and awareness of the implications of cyber-attacks, and what can be done to mitigate the risk is vital. Specific examples of actions to take in order to meet this priority include:

- Require the delivery of annual mandatory training in cyber security awareness and seek to embed a security culture across all organisations and staff.
- Identify and classify the cyber threat as a specific patient safety priority akin to those for infection prevention and control or medication safety⁵¹³ to improve awareness, develop shared learning and change culture.

7.4.1.4 - Technical: delivering secure infrastructure, promoting good cyber hygiene and ensuring security by design

Many decades of under-investment in IT infrastructure must be addressed. Organisations must ensure they have robust perimeter security (firewalls), effective protective monitoring (intrusion detection) and networks that are designed to support robust cybersecurity from the outset; all systems must be secure by design, not as an afterthought. There must be effective processes in place for the safeguarding and audit of data leaving networks. Good cyber hygiene is also vital – effectively managing privileges, ensuring appropriate encryption, utilising multi-factor authentication and ensuring systems are regularly patched and updated. The challenge of outdated medical devices and hardware running on legacy systems that are no longer supported must be tackled. Medical devices are a prime target for hackers and need to be independently assessed and catalogued, with security flaws being addressed by manufacturers on an urgent and compulsory basis. Specific examples of actions to take in order to meet this priority include:

- Introduce a “Cash for Clunkers” program to incentivize healthcare organisations to replace outdated and unsafe IT hardware and software in a targeted way
- Modify current NHS procurement rules to ensure that the security and resilience of health IT and medical devices is prioritised; changing purchasing decisions will force industry to improve the products and services on offer
- Develop and institute an independent registry of medical devices to assess and catalogue their security flaws against an open and transparent minimum standard

7.4.1.5 - Resilience: reducing risk by lessening impact

Safe organisations are resilient organisations. There is a need to develop and test effective incident management procedures and improve business continuity planning across the entire health sector. All organisations must be able to safely and effectively function without their electronic systems. Meanwhile, all data and systems must be securely backed-up and disaster recovery processes tested to ensure that the backup is isolated and cannot be erased or tampered with. A culture of learning from experience must be embedded across all organisations. Specific examples of actions to take in order to meet this priority include:

- Mandate the regular simulation and rehearsal of major cyber incidents and IT failures at both a local and national level to test and improve resilience much like other major incidents such as mass casualty events or fire evacuation drills. Additionally, testing of cyber resilience must form part of the regulatory framework.
- Develop a response to the regulatory, technical and public attitude barriers that currently prevent the widespread movement of health data and IT services to the cloud. Cloud computing in healthcare can dramatically improve resilience and also support the deployment of new real-time analytical techniques such as AI-enabled risk stratification or alerting

7.4.2 - Identification of research priorities

The five key concepts – awareness, governance, people, technical and resilience – that were identified to underpin the development of practice and policy priorities may also help determine key research priorities. However, a consistent theme that emerged during the expert workshop was that the immaturity of the healthcare sector's security posture is largely based upon a major gap in the basic understanding of the problem; we are simply unable to quantify the scale or impact of cyber incidents or health IT failings on the health and social care sector.

7.4.2.1 - Understanding the scale and impact of the problem

Prior to the development of complex research objectives, it is first crucial to fully understand the basics of a problem; the first overriding research priority must therefore be to develop a better understanding of the scale and impact of cyber incidents and health IT failings on both patients and organisations. Once the scale and impact of the problem is better understood we will have developed a basic understanding of the problem at hand; the first step in any improvement process:

- To develop and test a methodology for effectively quantifying the scale of cyber incidents and health IT failings across the NHS. This will require a multi-faceted

approach to ensure the capture of incidents which are currently recorded across multiple systems and sources (e.g. local IT helpdesks, local or national incident reporting systems such as NRLS or centrally to NHS Digital), or more likely not recorded at all. A robust quantification of the scale of the challenge is required to ensure adequate resource is directed towards tackling the threat.

- To develop and test a methodology for robustly quantifying the impact of cyber incidents and health IT failings on patients and organisations. The recording of patient harm is a key facet of patient safety and is effectively performed every day in the health sector. There is however currently no established and validated means of identifying the harm caused to patients by health IT failings or cyber incidents. Evaluating harm is required for estimating the scale of the problem, whilst in-depth analysis of specific adverse events will allow the development of new evidenced-based strategies to reduce avoidable harm caused by health IT failures. As previously identified in this body of work around 50% of all patient safety incidents related to health IT failures are potentially avoidable.

7.4.2.2 - Understanding resilience: mapping organisational inter-dependencies

The WannaCry attack demonstrated how fragile the system is, and how easily patient care can be disrupted by cyber or IT incidents. There is a need to model the impact of IT incidents across local, regional and national systems, understand how incidents may affect the business continuity of individual organisations and how this may in turn affect patients and neighbouring care providers. Health systems are becoming increasingly complex and interdependent, and increasingly rely on the integration of digital and physical systems; the failure of a single IT system or disruption in one organisation can have considerable secondary effects. For example, what would be the impact on patient flow, hospital demand and subsequent knock-on effects to other local services across the system if one of the Major Trauma Centres or a major A&E department was closed for a number of days due to an IT failure? This modelling information is required to inform effective operational resilience and business recovery plans, and target investment at crucial pinch points or critical

weaknesses. Much of the NHS is dependent on shared services and technology such as the N3 National Spine⁵¹⁴, and there is a paucity of understanding about the threats and opportunities this poses. As such there is a further need to establish and model technological inter-dependencies across services and systems and model the impact of failures in these. If a number of local hospitals share a single operating system or data server this may be a point of critical weakness and as such additional back-up or redundant systems may be required to prevent wide-spread disruption in the event of an incident. A summary of key initial research priorities identified is seen in *Figure 7.2*.

7.5 - Discussion

7.5.1 - Summary of key findings

It is clear that the NHS is not equipped with the capabilities or resources to deal with emerging cyber threats and that a lack of empirical evidence precludes a detailed understanding of the scale and impact of the problem. Through a mixed-methods approach the present study has identified a range of practice and policy priorities for the health and social care sector across five core themes: awareness, governance, people, technical and resilience. Additionally, key research priorities have been identified to facilitate a better understanding of the scale and impact of the problem and support the development of system resilience. These priorities provide a conceptual basis upon which specific interventions have been proposed to systematically and pragmatically evaluate, understand and mitigate against cyber threats. Crucially, in addition to specific proposals there is a need to change the culture and mindset of the health sector. It is evident that the current response to the cyber threat has too great a focus on local responsibility and solutions when a co-ordinated national response is required. Unlike the status quo there is a need for clear leadership and accountability, and for solutions to be delivered in an expedient fashion in order to respond appropriately to this pressing patient safety issue.

This study has provided new insights into the current state of cyber preparedness and resilience in the NHS in England. It suggests that the issue is not currently given the attention and resource required. Specific proposals for changes to policy and practice and directions for future empirical research have been identified, but importantly there is a fundamental need to change the culture of healthcare to see cyber security and digital resilience as primarily a patient safety problem and not just an IT problem.

7.5.2 - How can health systems respond to the challenge: practice and policy priorities in context

There has been much reassurance from central government regarding their response to the WannaCry incident. They have pledged investment of around £150 million to improve the capability of the health and social care sector to prevent attacks, detect threats and mitigate harm, launched many proposed initiatives to improve preparedness and resilience, such as encouraging all organisations to move to Windows 10, and produced further aspirations to improve policy and guidance and redesign leadership and governance structures and processes^{479,507,515}. What is telling however is the ponderous approach to the proposed timeframes for realising change – many of the solutions suggested to improve security and resilience are little more than statements of intent or have proposed implementation timeframes of years. When the safety of patients is undeniably at risk, there is a need for the NHS to approach the challenge with greater urgency and energy.

There are many examples from other sectors, and elsewhere in healthcare where speedier responses to concerns regarding safety or regulatory compliance are delivered. In the aviation industry all airlines in the US were forced to introduce new organisation-wide approaches to managing safety risk and assuring the effectiveness of safety risk controls in just 6 months⁵¹⁶, whilst in the UK organisations have just 90 days to fully comply with any new safety recommendations provided by the regulator⁵¹⁷. Within other sectors Ofcom, the national communications regulator in the UK, has the power to impose daily fines of up to £20,000/day whilst organisations are non-compliant with conditions and obligations based

upon them⁵¹⁸, and the Environment Agency can issue immediate enforcement and improvement notices on organisations⁵¹⁹. The healthcare sector, and specifically the NHS, does also have the capacity and capability to respond to safety concerns in a timely and efficient manner when it chooses to do so. The CQC has the power to impose enforcement notices which require organisations to make an initial response within 10 days, and subsequently comply with the demands to improve standards or meet other obligations within a further short time-limited interval⁵²⁰. Meanwhile, patient safety alerts issued by NHS Improvement to acquaint NHS organisations and other relevant stakeholders with safety critical information⁵²¹ are linked to a clear mechanism for evaluating compliance. They have been shown to deliver rapid improvements in safety-critical behaviours, and significantly reduce the risk to patients in a very short time-frame across a number of areas including the storage and administration of concentrated potassium chloride solutions⁵²² and wrong-site surgery⁵²³. More recently the Norman Williams Report into gross negligence manslaughter produced clear recommendations and time-scales for change in a matter of weeks following concern over the treatment of Dr Bawa-Garba and related implications for patient safety^{524,525}. The NHS can, when it chooses react quickly and effectively to safety and security concerns. It is notable that with regards to improving cyber security, preparedness and resilience, it appears to have chosen not to do so.

A key priority that requires a timely response is ensuring regulatory compliance. The General Data Protection Regulation (GDPR)⁵¹⁰ came into effect in May 2018 and aims to increase transparency and accountability in the use of personal data; unifying data protection for all individuals in the European Union and introducing significant penalties of up to 4% of annual turnover or €20 million, whichever is the greater, for organisations which fail to do so. GDPR has profound implications for medical research and direct patient care. Whilst there are some anxieties and confusion, particularly around participant consent, GDPR will likely in the long-run act to support the conduct of medical research⁵²⁶. Conversely, the implications for the day-to-day delivery of clinical care in the NHS are somewhat greater. Guidance has been slow to materialise, and so far it has failed to provide clear advice and support on how clinicians and organisations can remain compliant; the use

of popular smartphone apps for communication or data storage, the use of devices for taking clinical images or even the conduct of a clinical audit by a junior doctor all pose difficulties⁵²⁷. It is vital that the NHS responds to the challenges of GDPR by supporting compliant solutions, delivering meaningful training and support and taking centralised responsibility for the production of regular, concise and useful updates that support the rapid evolution of technology.

Whilst regulation provides a framework upon which to develop effective solutions, security is all about people, and a human-centered approach – encompassing staff and patients – to improving security and resilience has significant value. Understandably the culture of healthcare focuses on the core mission of caring for patients, even at the expense of good security behaviours. One symptom of this patient-first culture is the widespread sharing of passwords and IT credentials - a practice that undermines security, but nonetheless makes sense. Changing the culture and behaviours of staff can be done, but requires careful and persistent effort and is often done badly. There is considerable evidence for example of the impact of ‘nudging’ or providing educational interventions to clinicians to improve their hand hygiene behaviours^{528,529}, device-related infections⁵³⁰ and good prescribing behaviours^{531,532}. Improving awareness and training, changing the culture of healthcare to prioritise security-focused behaviours and identifying good security as fundamental to patient safety have the potential to significantly reduce the risk from cyber threats. Programs such as the NHS Digital Academy, which provides education and training for digital healthcare leaders in the NHS⁵³³, or the Faculty of Clinical Informatics - the new professional membership body for clinical informaticians in the UK⁵³⁴ - are a good start, although their focus is on senior leaders and not staff members delivering day-to-day clinical care. There is a need to deliver better training and embed a security-aware culture across all aspects of the health and social care sector.

In addition to people and culture another key aspect of effective security is technology. The central challenge in producing trustworthy medical devices is ensuring effective security whilst maintaining usability, regulatory alignment and value for money. Typically

manufacturers of medical devices use software with a 3-7-year lifecycle in products designed to be used for greater than 15 years⁵³⁵; when support ends these devices remain in service for more than a decade with an ever-growing number of vulnerabilities. With consumer 'Internet of Things' devices such as smart watches, CCTV cameras and children's toys there are clear minimum standards that embed security in the design process, together with a rigorous code of conduct to improve the security of consumer internet-connected devices whilst still supporting innovation⁵³⁶. There is no such regulation or best practice in healthcare; it must be of concern that attention is paid to the security of a FitBit, but we do not effectively regulate the security and trustworthiness of medical devices which deliver safety critical interventions to patients. Whilst within the UK and EU there is a clear legislative and regulatory requirement to ensure the safety of medical devices, this does not include any specific references to cyber security which at best has only implicit significance^{537,538}. This is in contrast to the US where the FDA provides guidance on addressing cyber threats⁵³⁵, and where manufacturers are required to follow specific post-market cyber security requirements on all medical devices⁵³⁹. Variable regulation across different jurisdictions has important implications for medical devices with the Food and Drug Administration (FDA) in the US typically being seen as the leader. The UK has much to learn from the US approach to cybersecurity in healthcare and medical device regulation and certification. Supporting security by design through the use of appropriate legislation and regulation will drive manufacturers to make safer medical systems, help identify and remedy device vulnerabilities and improve resilience.

7.5.3 - How can health systems respond to the challenge: research priorities in context

The first stage of solving a problem is to understand its scale and impact - this evidence can then be used to design, implement and evaluate evidenced-based solutions. When there is a clear area of uncertainty or controversy with limited evidence to support effective and meaningful decision-making then a strategic approach to research is required in order to support better choices to be made. It is hard to identify any other field of healthcare where

£12 billion would be spent to no avail on the basis of meagre evidence and failure to learn from previous experience, as happened with the now defunct National Program for IT (NPfIT) in the NHS in England⁵⁸. Given the history of failed endeavour and under-delivery in healthcare IT, and specifically cybersecurity and digital resilience, it is vital to have unbiased robust evidence to fully understand the problem and identify potential solutions. This requirement to build an evidence base to understand the level of cyber security maturity in health and social care organisations has already been identified by the NHS in its review of lessons learned from the WannaCry incident⁴⁷⁹.

In order to support the delivery of effective research there is a need to identify suitable sources of funding. Unfortunately, healthcare cybersecurity and resilience research funding remain orphans, sitting neither in basic health nor engineering research and thus presenting a challenge to win grant awards. Reframing the challenge as principally an issue of patient safety and changing the perception of healthcare leaders to see it in this way may support successful funding from the National Institute for Health Research (NIHR) Research for Patient Benefit stream which intends to generate evidence to improve, expand and strengthen the way healthcare is delivered for patients, the public and NHS⁵⁴⁰. Meanwhile, the Engineering and Physical Sciences Research Council (EPSRC) funds much healthcare technology research, yet it does not explicitly support work which seeks to improve computing technology or the reliability of hardware and software used in the delivery of frontline care or conduct of medical research⁵⁴¹. Failing to support research into improving the reliability and effectiveness of IT may not only impact direct clinical care but also dependent basic research; the discovery of a computer bug which has undermined many thousands of papers and years of research into certain neurological disorders being a clear example of this blind-spot in action⁵⁴².

The present study identified the need to further understand the inherent resilience of the health sector by mapping organisational inter-dependencies and how cyber incidents or IT failings may impact patient demand in order to develop effective business continuity procedures. The majority of the UK critical national infrastructure have mature and tested

resilience plans which include responses to cyber incidents and IT failure; an area which is notably absent in health⁵⁴³. The energy sector for example has legislative requirements for the restoration of supply within specified timeframes and well-rehearsed contingency procedures and capability for the restoration of supplies in case of a complete network shutdown; a black start⁵⁴⁴. By better understanding the inter-dependencies of different healthcare organisations and how IT failures may impact service demands and patient flow not only will it enable the development of targeted redundancy strategies, but also the development of a 'black start' capability to ensure the health sector can restore the delivery of safe care in the event of a complete IT shutdown.

7.5.4 - Strengths and limitations of this study

The findings of all studies must be interpreted and assessed within the context of their strengths and limitations. A core strength of this study is the use of multiple approaches to data collection and generation which ensures a full range of evidence is captured. Importantly, whilst some specific actions have been suggested, the focus was on identifying broad themes within which distinct solutions may be further developed. The rationale was to ensure that the outputs matched the quality of the data generated and that data redundancy - whereby resources are expended on generating data not relevant to the topic - was minimised and focused thematic outputs developed. The pragmatic focus on broad thematic outputs will help support the development of comprehensive, yet practical targeted solutions.

A potential criticism for this study is related to the availability of data, particularly for the meta-synthesis and comparative case study. All content examined was obtained through open-sources and given the sensitive nature of much of the subject matter at hand there is a significant chance that the data extracted does not represent a true picture of reality. Whilst in the round the available evidence together with the incontrovertible impact of the WannaCry incident does provide plausible support to the key themes and priorities identified, the possibility remains that information not readily available could have altered the ultimate findings if included for analysis. A mixed-methods approach was therefore adopted

to minimise the risk of data unavailability bias with the expert workshop acting as a key mechanism to ensure all relevant information and evidence was fed into the analysis and generation of practice and research priorities. Additionally, the financial services sector was chosen as a comparator not only due to its similarities to the healthcare sector from a practical security and resilience perspective, but also due to the quality and depth of information available through publicly available sources; comparison to the civil nuclear sector would for example have been far less productive for these reasons.

Criticism may also be levelled at the chosen methodology. Adopting a mixed-methods approach to research is a well-established technique with the triangulation of findings from different methods enabling the convergence of results and expansion of the breadth and range of enquiry⁴⁸⁰. Despite these advantages and the added ability to overcome deficiencies flowing from a single methodology, the technique may also be criticised on the grounds of ontological inconsistency⁴⁸¹. In order to address some of these concerns clear objectives and context were articulated prior to conducting the study, and further to this the risk of data redundancy was minimised by ensuring clarity of focus for the data generated prior to commencement of the analysis. The meta-synthesis of comparable standards and in-depth comparative case study were performed principally as a documentary content analysis. Whilst this approach has many strengths, such as elimination of the researcher effect and the ready accessibility to data across a broad range of sectors, the documents are nonetheless principally designed for practical application and not research. As such they may be idiosyncratic, focused on a narrow interpretation of problem, produced to meet alternative hidden agendas or lacking in theoretical context; for example, the NHS is likely to focus on publishing what it has done in response to the cyber threat, rather than being open and honest about its failings and areas of poor practice. Whilst the documents chosen were selected as legislative or regulatory standards, or objective guidelines from respectable independent organisations there is still a risk that such biases may influence the content and context of the data and thus the outcomes derived from the study.

7.6 - Conclusions

As the healthcare sector becomes ever more reliant on IT and complex data it is increasingly critical that effective cybersecurity is seen as a fundamental part of the patient safety culture across all health systems. The health care sector in the UK is highly deficient in resource and capability to deal with the threat, is reliant upon outdated and vulnerable technology and possess a culture which does not prioritise security conscious behaviours. There is a pressing need to change mindsets and adopt a pragmatic and comprehensive approach to cyber preparedness and resilience on the basis of a firm evidenced-based understanding of the risks, challenges and opportunities. Any breach, loss, corruption or tampering of patient data, or even the perception of it, can erode the trust of patients, whilst the failure of mission critical IT services may paralyse a hospital and prevent the delivery of safe care. Good security is more than just the absence of bad things happening, it is about understanding and controlling risk, reducing vulnerability and mitigating impact. More importantly, it is also about ensuring that we are free from the disruptive fear of bad things happening, and that people maintain trust in technology and those they give their personal data to for safe, high-quality care.

Table 7.1 - Comparison and meta-synthesis of comparative cybersecurity guidelines and standards

Key Findings and Requirements or Recommendations	Key guidelines and standards														
	NCSC 10 Steps ⁴⁸⁴	DHHS Top 10 Tips ⁴⁸⁵	Cyber Essentials ⁴⁸⁶	ISF Good Practice ⁴⁸⁷	ISF Crown Jewels ⁴⁸⁸	CGI ⁴⁸⁹	NCSC Cyber Attacks ⁴⁹⁰	CBEST ⁴⁹¹⁻⁴⁹³	IIROC ⁴⁹⁴	NIST ⁴⁹⁵	SCADA ⁴⁹⁶	G7 ⁴⁹⁷	Caldicott 3 ⁴⁹⁸	HIPAA ^{327,499,500}	FDASIA ⁹⁴
Network security - defend network perimeter, monitor and test controls and intrusion detection, understand and audit all network connections and permit only approved applications to operate on a network	X	X	X	X			X		X		X			X	X
Secure by design - ensure physical and technical defence in depth from an early stage of development	X	X	X		X		X		X		X			X	
User education, training and awareness of policies and education for acceptable and secure use	X	X	X				X		X		X			X	
Develop an organisational culture that sees good security practice and behaviours as the norm. The weakest link in the system is the user.		X					X		X		X	X			
Removable media controls – policies to control access, limit types and use and scan all devices for malware	X	X					X							X	
Secure configuration – apply security patches, define a baseline build for devices, disable remote file sharing and printing, do not rely on off the shelf options	X	X	X				X		X				X	X	
Home and mobile working – develop a mobile working policy, protect data in transit and at rest with appropriate encryption, ensure adequate protection and audit of mobile devices and have an MDM policy	X	X					X		X					X	X
Incident management – establish an incident response and disaster recovery capability, test incident management plans. Address decision-making responsibilities, define escalation procedures, and establish processes for communicating with internal and external stakeholders	X					X	X					X	X	X	

Build resilience - crucial to maintain critical services and functions in the event of disruption	X		X	X	X		X				X				
Manage user privileges – establish effective processes, limit the number of privileged accounts and monitor user activity	X	X	X			X	X		X				X	X	
Make cyber risk and effective security a priority for the leadership of the organisation	X					X	X	X							
Set up a cyber risk management regime and embed it across your organisation. Plan for the unexpected and prioritise relative to importance and risk	X	X					X	X	X		X	X		X	
Determine your risk appetite – guided by local, national and supranational best practice and regulation and what your cyber requirements are	X						X				X				
Wireless internet and network access should be secured. Sensitive data should not be transmitted across public networks without encryption. Visitor/guest devices must not be permitted to access the network or wireless internet.		X				X			X					X	
End-user devices with wireless (e.g. Wifi, RFID or Bluetooth) connectivity must have adequate protection		X				X			X					X	
Third-party suppliers – understand and control back door access to systems, ensure clear lines of responsibility and ensure suppliers are held to account		X											X	X	
Perform regular and reliable backups. Backup media must be tested for its ability to restore properly.		X							X		X			X	
Identify relevant regulatory and legislative requirements and ensure a plan is in place for monitoring and compliance				X		X			X		X	X	X	X	X
Organisations must identify and keep a record of mission-critical assets and prioritise their protection "crown jewels"					X	X			X						
Ensure consideration of the need to balance privacy and security with cost effectiveness						X						X	X	X	
Develop a comprehensive understanding of the risks of health data, engaging with patients and ensuring sensitive information is kept private and secure		X				X				X			X	X	
Understand that cyber privacy and cybersecurity are more than policies and audits, they are a core foundation upon which to deliver safe and effective care						X			X		X		X		
Identifiable data is often shared across networks, between different organisations both public and private and with patients themselves; an increasingly complex challenge for privacy, security, access and governance						X						X	X	X	

Understand that privacy and security risk can be managed, but cannot be eliminated	X	X	X			X									
Maintaining trust – patients trust that their data is stored securely, accessed only by authorised persons and used appropriately			X			X							X	X	
Privacy and security are not piecemeal or one-time things. They must be addressed in a lifecycle approach that involves management, technical and physical aspects			X			X			X						X
Develop a common model to assess and respond to threats so individual organisations can combine to provide an overall picture at a systemic level				X				X						X	X
Information sharing is an essential and there must be a view of collective good informing and supporting a sector wide approach									X				X	X	X
Healthcare is part critical national infrastructure				X	X					X				X	
Privacy and security go hand-in-hand and must incorporate privacy principles such as data minimisation, disclosure, retention policies, data integrity and issues of consent and data sharing				X	X	X		X		X			X	X	
There is a role for 'healthcare red teams' to independently evaluate possible attack scenarios and vulnerabilities as part of an independent security assurance and testing process				X	X			X	X		X		X		
Clearly define cyber security roles, responsibilities and authorities for managers, administrators and users within a clear organisational structure.				X	X			X	X		X	X			
Establish and maintain a cybersecurity strategy and framework tailored to specific cyber risks and appropriately informed by international, national and industry standards and guidelines				X				X	X			X	X	X	
Engage in timely sharing of reliable, actionable cybersecurity information with internal and external stakeholders on threats, vulnerabilities, incidents and responses to enhance defences, limit damage, increase situational awareness and broaden learning							X	X				X	X	X	
Understand that data breaches are often caused by people finding workarounds to burdensome processes and outdated technology				X			X						X		
Strategies for ensuring effective cyber security should be sufficiently flexible to accommodate the future and rapid evolution of health IT							X		X		X				X

Key to guidelines and standards:

NCSC 10 Steps - National Cyber Security Centre (NCSC) 10 Steps to Cyber Security⁴⁸⁴

DHHS Top 10 Tips - Department of Health and Human Services (USA) Top 10 Tips for Cybersecurity in Healthcare⁴⁸⁵

Cyber Essentials - HM Government Cyber Essentials⁴⁸⁶

ISF Good Practice - Information Security Forum (ISF) The Standard of Good Practice for Information Security 2016⁴⁸⁷

ISF Crown Jewels - Information Security Forum (ISF) Protecting the Crown Jewels⁴⁸⁸

CGI - CGI Cyber privacy and Cybersecurity for Health Data⁴⁸⁹

NCSC Cyber Attacks - National Cyber Security Centre (NCSC) Common Cyber Attacks: Reducing the Impact 2016⁴⁹⁰

CBEST - Bank of England CBEST Intelligence-Led Testing^{491–493}

IIROC - Investment Industry Regulatory Organisation of Canada (IIROC) Cybersecurity Best Practices Guide⁴⁹⁴

NIST - National Institute of Standards and Technology (NIST) Framework for Improving Critical Infrastructure Cybersecurity 2014⁴⁹⁵

SCADA - 21 Steps to improve cyber security of SCADA Networks, President's Critical Infrastructure Protection Board/Department of Energy⁴⁹⁶

G7 - G7 Cyber Expert Group. Fundamental Elements of Cybersecurity for the Financial Sector 2016⁴⁹⁷

Caldicott 3 - National Data Guardian for Health and Care. Review of Data Security, Consent and Opt-Outs 2016⁴⁹⁸

HIPPA - The Security Rule - Security Standards for the Protection of Electronic Protected Health Information. Health Insurance Portability and Accountability Act (HIPAA) 1996. Department of Health and Human Services^{327,499,500}

FDSIA - FDASIA Health IT Report. The Office of the National Coordinator for Health Information Technology / US Food and Drug Administration 2014⁹⁴

Table 7.2 - Comparative case study of cyber security maturity; UK financial services versus the National Health Service

Key Factors		UK Financial Services	National Health Service
Central point of contact and information on cyber threat intelligence, business continuity, operational resilience		YES	LIMITED – the CareCERT program provides limited national oversight of cyber resilience, threat intelligence and incident response. Emphasis is on local organisations to source external support
Single authority with clearly defined roles and responsibilities for overseeing cyber resilience and security preparedness		YES	NO – responsibility shared between NHS England, NHS Improvement, Department of Health and NHS Digital with no clear responsibility, authority or accountability.
Single defined mechanism to coordinate a sector-wide response to incidents		YES	LIMITED – “Cyber Handbook” describes top-level general approach only and does not detail local activities or approaches, or mechanisms for sector-wide communication and coordination in the event of an incident. LIMITED - an initial tender has been placed to industry for the establishment of a national Security Operations Centre to aid with incident response; this will not be in place until 2019/20 at the earliest NO – dialogue between stakeholders to identify local suppliers for testing is still in progress
Mandated testing of sector-wide response to cyber incidents including testing of communication lines, coordination arrangements and decision-making processes. Industry-owned playbooks setting out coordinated approaches to dealing with specific scenarios.		YES	NO – there has been no sector-wide testing, and the emphasis is on local organisations to test their own plans and processes
Industry specific bespoke framework for testing and assuring cyber resilience of individual organisations overseen by the appropriate regulatory body	Mandated red teaming and intelligence-led penetration testing	YES	NO – there is no bespoke or mandated security testing regime. 200 organisations have been tested against the generic “Cyber Essentials” standards and have all failed.
	Sector-wide consolidation of cyber threat intelligence		LIMITED – there is merely a requirement for Trusts produce an action plan to be “Cyber Essentials Plus” compliant by June 2018, with no enforced timeframe for actually achieving compliance
	Mandated cybersecurity maturity assessment KPI's		LIMITED – a working group is to be convened in 2018/19 to examine and consult on defining a set of guidelines for healthcare organisations
	Mandated security improvement plan for all organisations		LIMITED – dialogue between stakeholders to identify local suppliers for testing is still in progress

Mandated assessments of cyber resilience and security form part of the legislative and regulatory requirements for individual organisations	YES	NO – there are no specific regulatory requirements for healthcare organisations. Plans to integrate specific assurance processes into the routine CQC inspection regime are in progress NO – integrating data security into the Single Oversight Framework as part of decision-making on enacting special measures for individual Trusts is only under consideration LIMITED – enforcement of NIS Directive compliance is in progress, there is currently no published guidance for compliance against GDPR LIMITED – NHS Data Security Toolkit Compliance by individual Trusts is only required by March 2019 (toolkit yet to be updated and published)
Established strategic cyber forum to bring together a range of experts in order to share best practice, develop guidance for organisations and build sector wide capability and resilience	YES	LIMITED – CareCERT program provides a limited capability for the consolidation, synthesis and sharing of threat-intelligence, security alerts and best practice LIMITED – organisations have been encouraged to collaborate with relevant local stakeholders but there is no ringfenced resource or support it, nor a requirement to do it
Clearly defined process of collaboration across individual organisations, government agencies, arms-length bodies and regulators security posture and resilience	YES	LIMITED – handling plans have been disseminated to all stakeholder, but there remains no clear lines of responsibility and authority.
Comprehensive codes of conduct and guidelines for individuals and organisations to ensure quality of services, organisational integrity and adherence to policies, processes and procedures	YES	LIMITED – the “Information Governance Toolkit” which defines local implementation of standards is currently under review. LIMITED – technical “Good Practice Guides” are high level only and require further development to be practical and meaningful LIMITED – staff training on cyber awareness is suggested but not mandated
Security preparedness and resilience are a clear leadership and executive priority for local organisations, regulators and central government	YES	LIMITED – a CISO (Chief Information and Security Officer) was only appointed to NHS Digital in 2018 LIMITED – following WannaCry approximately £150million of central funding has been identified, but the emphasis is on local organisations to own the risk and fund their own solutions NO – cyber security preparedness and resilience is not a component of high-level corporate management (e.g. has been removed from NHS Improvement Executive Board) NO – there is still no requirement for every NHS Board to have a nominated Executive Director as data security lead
Sector approach to security and resilience is regarded to be an international gold-standard	YES	NO – the NHS lags well behind other healthcare systems, notably the USA

Figure 7.1 - Summary of key practice and policy priorities to improve cybersecurity preparedness and resilience in the NHS

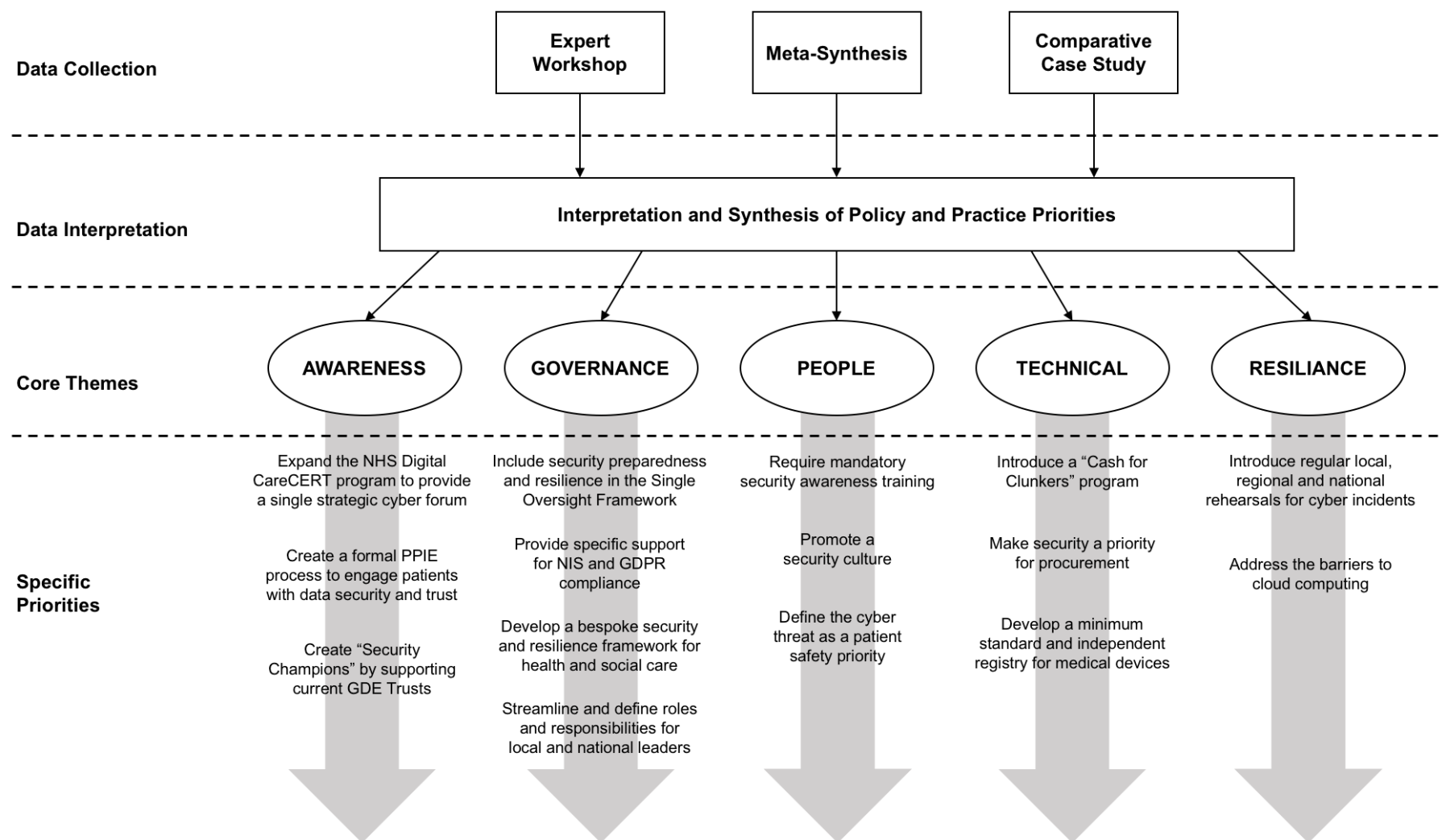
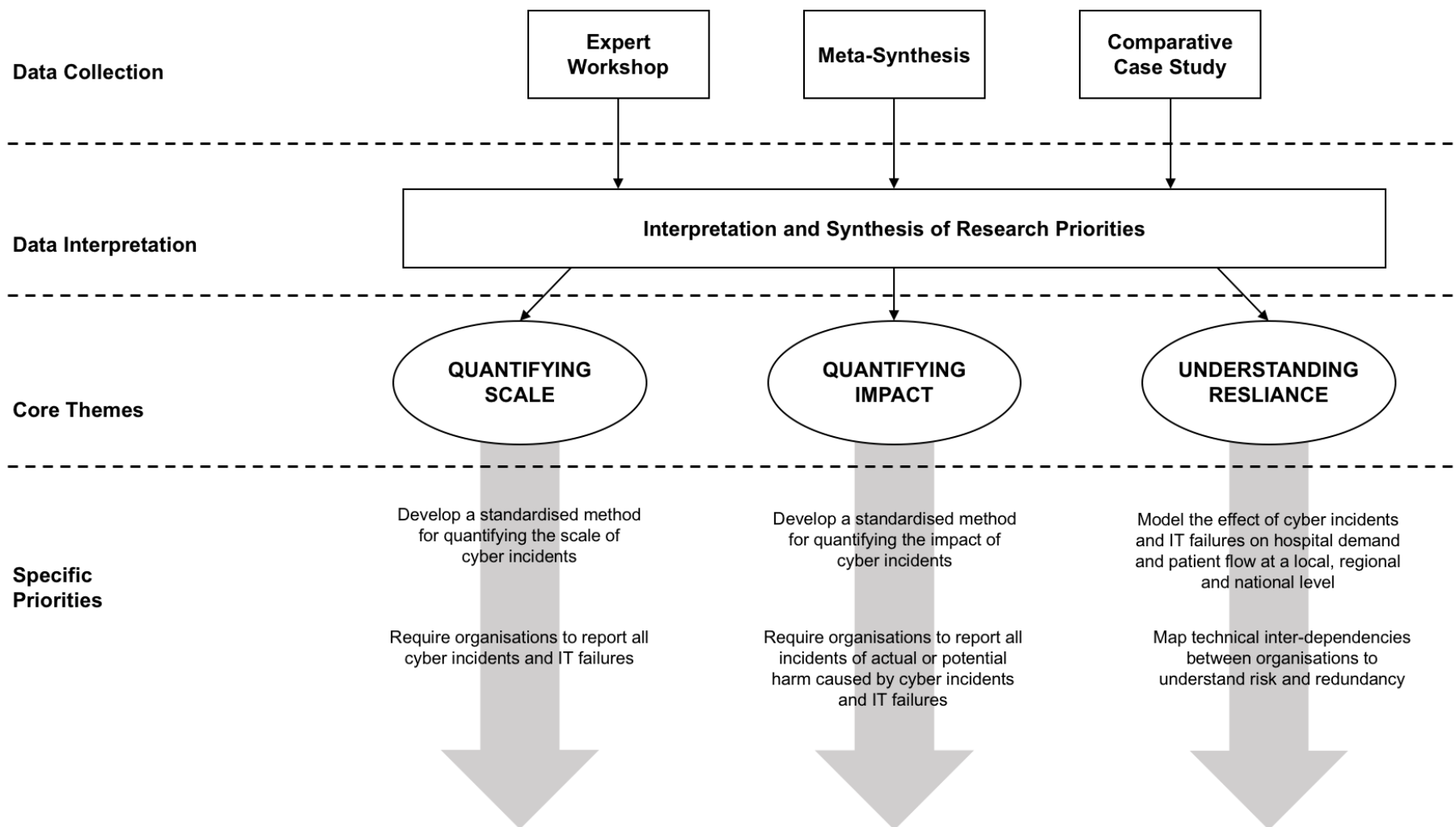


Figure 7.2 - Summary of key research priorities to improve cybersecurity preparedness and resilience in the NHS



Chapter 8 - Discussion

This final chapter provides an overview of this thesis and an exploration of the implications and recommendations for future work. A brief synopsis of the pertinent background is presented to provide context to the research followed by a summary of the key findings for each experimental chapter. The important limitations that were encountered together with associated methodological and conceptual considerations are also discussed. Implications for research, practice and policy are then outlined and recommendations for future work discussed. Finally, the chapter and this thesis conclude with my own personal reflections and experiences from completing this period of study.

8.1 - Synopsis of the problem

Reducing variation in care quality and improving patient safety continues to be a significant challenge for all healthcare systems. Up to one in ten patients admitted to hospital are affected by potentially avoidable adverse events¹⁰² and there remains significant variance in the quality, safety and effectiveness of care delivered to them^{103,104}. There is a growing consensus that new technologies can deliver solutions to these challenges¹⁰⁵, and as a result healthcare is increasingly dependent upon health IT to support the delivery of high-quality, efficient and safe care. Despite new technologies being lauded as a core building block of safer healthcare the implementation of new health IT within secondary care has been problematic to say the least. It is largely a story of lofty ambition and under-delivery, with healthcare remaining in an awkward adolescence that lags 10-20 years behind other critical sectors and commercial products it is beset with the poor penetrance of new technologies and failures of delivery^{47,58,330,337,345,346}. Despite the clear ambition to drive forward the uptake of new technologies and deliver paperless healthcare systems^{45,125} there is a sobering failure rate in health, with only around 1 in 8 health IT projects judged to be a success^{338,339}.

Given the very real difficulties that health IT has experienced to date much focus has been placed on recognising its benefits and understanding how it can be implemented successfully in order to maximise investment and realise its potential. Multiple context and innovation specific barriers to the successful implementation of new technology have been identified^{48,49}, but crucially there is limited high-quality evidence for the true impact of health IT on every stakeholder and all aspects of care delivery. The current evidence for the benefits of new technologies is mixed^{8,17,19} and largely focused on narrow operational or process led assessments of specific products and technologies within single institutions^{8,106–108}. There is a progressive realisation that the potential benefits and opportunities of health IT come hand-in-hand with substantial and often unexpected challenges and risks to patients. Increasingly it is recognised that health IT may in its own right cause harm to patients^{14,15,19,21–24}, whilst also acting as a source of negative experience, frustration and hindrance to routine care delivery for staff and patients^{13,52,74,83,117}.

The history of failed endeavor and under-delivery in health IT, together with the limited evidence for its true costs and benefits means it is vital to deliver unbiased and robust evidence to fully understand the true influence of new technologies on safety, performance and outcomes. It is also crucial to identify key practice and research priorities in order to improve the development, implementation and evaluation of health IT. In order to address these issues this thesis adopts a mixed-methods approach to systematically explore the current impact of health IT across three core aspects of healthcare quality - effectiveness, safety and experience.

8.2 - Summary of key findings

This thesis has fulfilled its aims and contributed to the development of new knowledge by providing a novel evaluation of the current influence of health IT on quality by examining its impact on the effectiveness, safety and experience of secondary care.

8.2.1 - Effectiveness

The effectiveness of care is commonly assessed by studying clinical outcomes which is examined in Chapter 2. The first step to understanding the role of health IT in influencing outcomes is to develop robust methods for assessing organisational digital maturity in healthcare. The NHS Clinical Digital Maturity Index (CDMI) is a self-assessment benchmarking tool that provides an objective measure of organisational digital maturity for all NHS providers in England. For the first time this thesis sought to evaluate this measure. Following evaluation of construct, criterion and discriminant validity the tool would appear to be a useful measure of organisational digital maturity despite significant variation between institutions. The CDMI tool plausibly acts as a marker for high performing organisations and is high likely to be linked to other important organisational attributes that impact quality and performance . The the tool was subsequently used to examine the impact of digital maturity on outcomes in all 136 acute hospital providers in England. This revealed that whilst there is an association between digital maturity and the delivery of harm free care, digital maturity was not found to influence adjusted mortality, readmission rates, long lengths of stay or complications of care. Factors such as staffing levels, staff skills mix and volume of work were found to have a far greater impact. As technology advances and healthcare providers become more digitally mature, they also become increasingly dependent upon health IT for the effective and uninterrupted delivery of care. The growing importance of developing institutional and system level digital resilience, and being able to effectively deliver care in spite of failures in health IT was identified and explored in Chapter 7.

Effective communication and teamwork are key to the delivery of both effective and safe care. Chapters 3 and 4 sought to examine the influence of mobile technology on quality in more detail. This field has not been previously explored in great depth, and Chapter 3 revealed that there is a distinct lack of high-quality robust evidence to support the efficacy of mobile technologies in improving communication and teamwork despite the clear potential for benefit. There were no published studies compliant with established best practice for the conduct and reporting of trials involving mobile technology, with most focusing on small populations in restricted environments that do not truly represent real-world hospital settings. Despite this, the potential for mobile technology to improve communication and teamwork

was clear. Chapter 4 went on to identify the potential challenges and opportunities that need to be addressed in order to support the adoption of new mobile technologies; engagement with end-users, balancing the practicalities of technology and practice, security and governance and the pace of change.

Chapter 5 went on to identify the influence of health IT on quality through the lens of an independent quality regulator. The significance of health IT is regularly cited by the Care Quality Commission in England, and the findings from this study suggest that organisations which are more digitally mature and which invest in better technology and infrastructure are rewarded with improvements in performance, safety and effectiveness that are in turn reflected by better regulatory judgements of organisational quality.

8.2.2 - Safety

Regulatory inspections not only assess how effective healthcare providers are, but also provide useful insights into the safety of the care they deliver. Chapter 5 of this thesis highlighted the predominantly negative consequences of health IT identified by the CQC and potential for new technologies to be a significant source of error and harm. In order to better understand the impact of health IT failings on patient safety from another perspective an evaluation of health IT related patient safety incident reports was performed in Chapter 6. 2,627 safety incidents related to health IT were identified from over 13 million incidents reported in England over the past decade. This study represents the largest ever reported series of such safety incidents. A significant proportion led to patient harm and over three-quarters were potentially avoidable. The study showed that the majority of safety incidents are due to the non-availability of patient data stemming from the failure of software or hardware, and that inadequate technical support or the lack of robust downtime procedures meant that patients were exposed to prolonged or preventable harm following IT failures. This study also suggested that IT failings are likely to be under reported and not commonly seen as patient safety incidents; a change in culture is therefore required to view health IT as a fundamental component of patient safety.

Continuing the examination of safety, early in the work leading to this thesis the potential for healthcare cybersecurity failings to affect patient safety was identified. Some six weeks after an initial healthcare cybersecurity workshop was completed the WannaCry incident significantly impacted the NHS and patients alike. This acted to reinforce the initial judgement that effective cybersecurity is essential to patient safety and also aiding in the development of objectives for this part of the thesis. It became evident that the healthcare sector in England at least, is not equipped to deal with emerging cyber threats and does not have the required awareness, capability or resource to be a resilient system that supports the continuity of safe care in spite of health IT failures or cyber incidents. Through a mixed-methods approach in Chapter 7 it became clear that there is a considerable lack of evidence and data in this area. Thus, key research priorities were identified to facilitate a better understanding of the scale and impact of the problem and support the development of improved system resilience. Additionally, five key practice and policy objectives were identified across core themes of awareness, governance, people, technical and resilience which provide the conceptual basis to develop specific interventions to evaluate, understand and mitigate cyber risks and improve digital resilience.

8.2.3 - Experience

Staff and patient experience are crucial elements of healthcare delivery and are legitimate measure of quality in their own right. In addition to examining the impact of organisational digital maturity on clinical outcomes, Chapter 2 therefore also sought to examine the impact on patient and staff experience. The better use of health IT is unlikely to directly boost satisfaction in isolation, but many of the benefits it can deliver may improve the day-to-day experiences of secondary care for all stakeholders. This evaluation demonstrated that selected elements of organisational digital maturity were associated with improved staff experience, but there was no association between patient experience and organisational digital maturity. Whilst challenging to directly assert causation, the relationship between staff experience and digital maturity is plausible and realistic.

User experience is also a key determinant for the uptake of new technology. The challenge of implementing technology developed in collaboration with clinical end-users that is secure, resilient and readily accessible at the point-of-care - key factors in supporting user experience - was further studied in Chapters 3 and 4. Chapter 3 highlighted a lack of robust evidence for the effectiveness of mobile technology and low levels of widespread institutional uptake. To further understand why mobile technology has not emerged on the frontline of healthcare Chapter 4 sought to elicit multi-professional perspectives on a mobile-first culture of work in order to identify key barriers and facilitators to the deployment of mobile technology in secondary care. This study showed that a mobile-first culture requires effective staff engagement, an understanding of differing priorities and incumbent cultural and workflow limitations and the need for a clearly defined problem that is to be addressed in order to effectively integrate technology into day-to-day practice. It also established the need to address concerns of data governance and security, transparency and accountability, and to ensure that staff expectations are adequately handled in order to successfully manage the pace of change and prevent innovation fatigue.

8.3 - A critique of the thesis: limitations and methodological considerations

The specific limitations of each individual study have been discussed in turn as part of the relevant chapter. Looking back across the thesis as a whole however there are some broad limitations worthy of further discussion.

The lack of robust evidence for evaluating the wider impact of health IT on quality and safety in secondary care was not only a principal driver for this thesis, but also acted as a limiting factor for the research methodologies chosen and findings reported. To compensate for the lack of specific evidence, much of the data examined and analytical methodologies adopted were pragmatic in nature and designed to produce results that reflect the current state of

play for health IT in secondary care. This pragmatism comes at a cost; imperfect methods and findings open for critique.

A significant proportion of the data used to examine the influence of organisational digital maturity and health IT on clinical outcomes, stakeholder satisfaction and regulatory judgements of quality was not originally collected for the purposes of this study. The use of routinely collected administrative data does allow for a detailed and comprehensive evaluation across a broad range of organisations and outcomes, but may also be criticised for the quality, accuracy, completeness and appropriateness of the data used. Similarly, criticisms may be levelled at the use of regulatory outcome data that has not been collected for specific purposes of evaluating health IT; unstructured and opportunistic reporting, whilst providing arguably a more authentic and real-life description of the influence of health IT may also result in inconsistent and variable findings. Finally, determinants of the high-level outcomes at a hospital or system level reported in the various studies included in this thesis are numerous and complex and reflect a wide range of inter-related variables. It is therefore challenging to establish a causal relationship and account for all confounders that may be present.

The examination of regulatory assessments, nationally reported patient safety incidents and cybersecurity preparedness has suggested that the health sector does not see the failure of health IT as a patient safety concern. This blind spot means that not only do organisations lack adequate awareness, capability and resilience to safely manage failures in their IT infrastructure, but also that a significant proportion, if not the majority, of the harm caused to patients by failures in health IT and other digital technologies is not reported or adequately captured. The failure to adequately measure and record the full spectrum of risks may limit the findings presented and hinder the development of effective evidence-based strategies for reducing patient harm.

Despite the criticisms there is concordance in the key overarching themes that appear throughout the thesis; namely that health IT has potential to improve the effectiveness,

safety and experience of care, but that generating robust evidence for its utility and effectiveness is both challenging and inadequate to date. Furthermore, the use of a multi-modal approach to data collection allowed for a broad and in-depth assessment of multiple facets of health IT. A greater emphasis needs to be placed on capturing and understanding the broader positive and negative impacts of new technologies across the sociotechnical system, reinforcing the importance of engaging end-users from the outset of design and implementation and changing the culture of healthcare to see the effective and resilient use of health IT as a fundamental component of patient safety.

Many of the limitations identified could potentially have been addressed if more time and resource had been available, however given the aims of this doctoral study the choices made were evidence-based and pragmatic. Equally it would be simplistic to conclude that greater resource would readily solve all problems. Arguably the time and resource required to collect bespoke focused data required for a more robust analysis of the impact of health IT would be excessive and unrealistic, and not justifiable for the likely marginal gains delivered. Adopting a pragmatic and cost-effective approach to evaluating health IT interventions is vital to ensure that robust evaluation strategies become embedded in the field. It is only right that the same demands for high-quality evidence demonstrating efficacy and safety are placed on health IT as are demanded for pharmaceuticals and medical devices. Given the scale and complexity of health IT this requires realistic and efficient approaches to evaluation.

8.4 - Implications of this work for future research, clinical practice and health policy

Specific implications for the findings presented in each chapter have been discussed previously. As highlighted above, the key priorities for future research, practice and policy are firstly to address the many limitations of the studies reported in this thesis, and secondly acting to support innovation and the implementation of new technology.

The first step is to improve the current evidence base for new technologies. Crucial are the development and testing of comprehensive methodologies for evaluating how health IT impacts care delivery in real-world settings, influences stakeholders across the care pathway, and acts to support and enable other drivers of quality and safety. Linked to this is the need to better understand how the widespread adoption of new technology influences the perceptions and experiences of patients and staff as they receive and deliver care. Developing better standardised measurements of the impact of health IT that robustly capture the full spectrum of risks and benefits will provide the evidential and conceptual basis to tackle the other key priorities identified in this thesis.

The next important step is to develop new methods for regulating and governing health IT. Regulatory frameworks - be they ethical, technical or safety focused - that are designed for pharmaceuticals and medical devices are not suited to this application and currently act as a barrier to digital innovation. Legislation and regulation must enable and support innovation whilst also ensuring safety and efficacy. Initially work is required to provide clear guidance on what defines a 'never event' or 'near-miss event' linked to health IT so as to ensure effective and transparent reporting of error and harm through a consolidated and standardised prospective safety reporting system. Secondly, there is a need to amend legislation to require technology companies to demonstrate independent evidence for the stability, safety and usability of their technology. This process must come hand-in-hand with the development of new mechanisms to support the effective and transparent ethical oversight of basic research conducted with new digital interventions. It is vital to learn the lessons of the past and ensure that patients are not harmed in the pursuit of advancing new technologies or testing novel digital interventions. Thirdly, there is a need to ensure that health systems and regulators provide the leadership needed in order to support innovation and ensure safety and resilience. A key outcome of good leadership would be to effect a change in culture. Not only is it important to see failures in health IT as a patient safety issue, as has been discussed, but it is also crucial to break down end-user resistance, remove institutional inertia and end cultural roadblocks to the adoption of new technology.

Setting the right market conditions and supporting innovation are also important. The huge resource required for the development and dissemination of new technology, together with an absence of minimum inter-operability standards and data standardisation means that small disruptive technology start-ups have been largely excluded from the field. Health IT to date has mainly been the preserve of large enterprises and technology companies with reimbursement and profits rewarded through back-end functions and a focus on successful billing rather than supporting day-to-day clinical practice. Moreover, as new innovations and technology become embedded in the healthcare economy, disruption cycles will be shortened and there will be increased competition on value and quality. In addition to ensuring access to the market and continued innovation, systems developers and technology companies must be clear and honest about the limitations of their technology and systems, focusing on realistic expectations, good system design and early involvement of clinicians. Technology companies and professionals must examine their motives and drivers, identify and fix errors in a visible and transparent manner and be more sensitive to the needs clinicians in order to close this satisfaction gap and deliver the shared goal of better, more efficient and higher quality healthcare.

8.5 - Personal reflections

Almost three years have passed since I embarked on this research to better understand the current influence of health IT on the quality and safety of patient care. Much has changed in this time and the field remains hugely dynamic with the continual evolution of new technologies, changing evidence and shifting priorities. This is most apparent in the realms of healthcare cybersecurity. When I started to examine this area, I was met with general indifference, including those at the centre of health IT in the NHS who did not see it as a relevant or important problem. Move the clock forwards two years and the issue cybersecurity is now a key priority for the NHS, has attracted tens of millions in new resource and funding and has been the topic of extensive media interest. The awareness of healthcare cybersecurity that is now apparent is palpably different from that experienced at the outset of this thesis. Equally, in the three years since I started the focus of discussion

around health IT has also dramatically changed; from that of a boring, but necessary process of under-funded technology adoption beset with failure, to one where the use of artificial intelligence and new digital tools delivering healthcare into the hands of patients is seen as the saviour of the NHS and the target of huge new investment. It seems as though the realisation that new technology has the potential to solve many of the challenges we face in delivering sustainable, effective and safe healthcare. It is crucial that this comes hand-in-hand with robust evidence of the efficacy and safety of new technologies, and a healthy awareness of the risks, harms and challenges that accompany the benefits and opportunities.

On a personal level, this period of doctoral study and opportunity to engage in a sustained period of research has been invaluable. I have learnt about many facets of research methods and now have a better awareness of the need to adequately and robustly evaluate new technologies in a holistic and broad fashion; the negative impacts of complex interventions are commonly unexpected and difficult to identify through traditional narrow approaches to evaluation. In addition, I have learnt to better manage my time, balance competing priorities more effectively and understand the importance of benefitting from the knowledge and skills of others – no doubt valuable skills that will translate to my everyday life as a practising surgeon. The journey has not always been straight-forward or easy and has been littered with difficulties and frustrations - none more so than the need for this body of work to evolve into something far away from that initially envisaged - as is the nature of research. On the flip side this frustration has been tempered by reward when perseverance pays off, ideas and thoughts are validated and hard work rewarded.

Whilst in isolation this thesis is unlikely to change practice, I am hopeful that it will strengthen the growing consensus that we must not be blinded by the allure of new technologies. The digital age of healthcare is upon us and it will undoubtedly transform the delivery of care. Nonetheless we must retain a degree of healthy cynicism, demand high standards of evidence and remain cognisant to the risks that may come with new technology. It is

important to consider that although digital technology is likely to be the future of many aspects of healthcare, it is not the answer to every challenge we face.

8.6 - Concluding remarks

To my knowledge this thesis represents the first in-depth multi-faceted evaluation of the current influence of health IT on quality in secondary care in England. This holistic approach has sought to understand the wider consequences of new technologies and underline the importance of robust evaluative data for the safety, efficacy and wider impact of all new innovations and capabilities. As healthcare becomes ever more dependent on digital technology it is imperative that health IT is viewed as a safety critical aspect of care delivery which is fundamental to patient safety.

The rapid evolution of health IT and emphasis on achieving a fully digital healthcare system is a laudable, compelling and largely evidence-based aspiration that will undoubtedly deliver tremendous benefits to patients, staff and healthcare providers alike. Historically the immaturity of technology within the health sector, a managerial focus on administrative revenue generating systems and process outcomes, poor usability and end-user resistance have all contributed to the slow, and largely unsuccessful attempts to bring healthcare into the digital age. Although many of these factors still persist, progress has been made; ongoing changes in clinicians' attitudes and perceptions, improved computer literacy, and most importantly, changes in healthcare policy together with increased support and resources for clinical computing are all steps in the right direction. As we progress it is crucial that health IT is not examined in isolation; it must be tailored to its users and environment and implemented and evaluated in a holistic and transparent fashion in order to deliver its full potential. The implementation of new technology must first and foremost be a process of whole organisational change. Many of the unintended consequences of health IT are the result of failures in design and deployment resulting from a mismatch in function and the practical realities of care delivery; in order to succeed, the gap between the technological and clinical worlds must be bridged.

Despite these challenges it is likely that the next decade will see further fundamental change in all aspects of healthcare delivery driven by new digital technologies. This exciting future must however be viewed with cautious scepticism. Firstly, it must be acknowledged that new technology in isolation cannot bridge the quality and cost-effectiveness chasm that has been so rightly identified as a key challenge for healthcare in the future. Secondly, it is crucial to remember that this digital revolution also represents a new source of potential harm which must be understood and mitigated. As healthcare becomes ever more dependent on technology it must never become so reliant upon it that the delivery of safe, high-quality and effective care will fail in its absence.

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Appendices

Appendix A - NHS Clinical Digital Maturity Index Assessment Tool

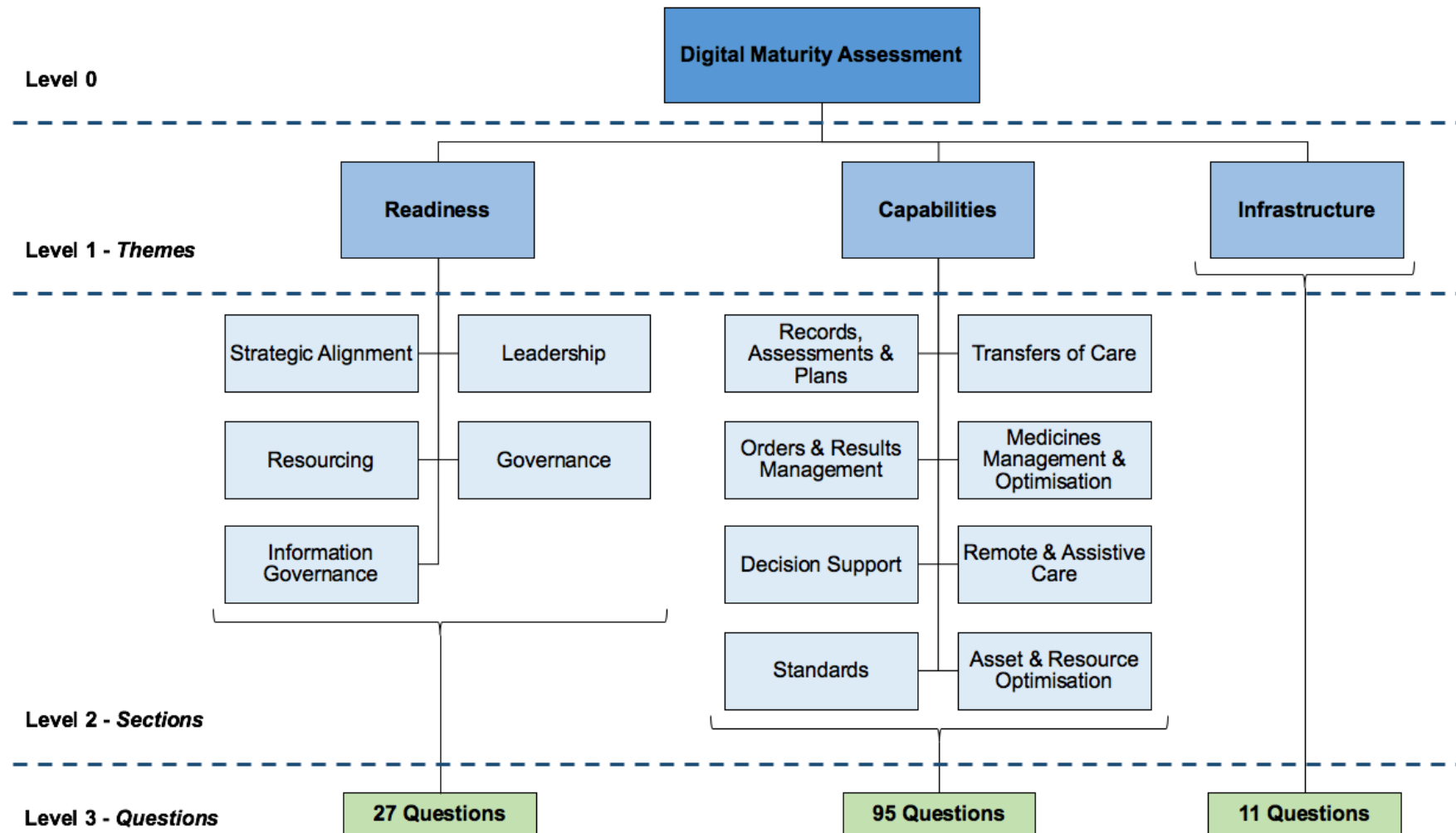
Appendix B - Systematic review search strategy

Appendix C - Finalised semi-structured focus group interview schedule

Appendix D - Health Information Technology Safety Measurement (HITS) Framework

Appendix E - Description of pragmatic and concurrent mixed-methods approach

Appendix A - NHS Clinical Digital Maturity Index Assessment Tool



Appendix B - Systematic review search strategy

Search Strategy 1 – MEDLINE, NIHR-HTA, Cochrane Library, HMIC	
#1	(smartphone OR cell phones OR cellular phone OR computers handheld OR mobile applications OR wireless technology OR hospital communication systems)[MH]
#2	(smartphone* OR smart phone* OR mobile phone* OR mobile telephone* OR mobile device* OR mobile app* OR cell phone* OR cellular phone* OR mobile technology OR tablet computer* OR tablet* OR digital technology OR communication technolog* OR mHealth OR mobile health OR eHealth OR electronic health OR electronic communication* OR digital health OR wireless technolog* OR wireless communication*):ti,ab
#3	#1 OR #2
#4	(patient care team OR interdisciplinary communication OR interprofessional relations OR physician-nurse relations OR communication OR health communication OR patient handoff)[MH]
#5	(patient care team* OR interdisciplinary communication* OR interdisciplinary relation* OR interprofessional relation* OR interprofessional communication* OR physician nurse relation OR doctor nurse relation* OR communication* OR team* OR collaboration OR cooperation OR handover* OR hand over* OR handoff* OR hand off*):ab,ti
#6	#4 OR #5
#7	(hospitals OR secondary care)[MH]
#8	(hospital* OR secondary care OR tertiary care OR ward* OR inpatient* OR institution*):ab,ti
#9	#7 OR #8
#10	#3 AND #6 AND #9 Limits: English language, 1/1/2007-1/12017
Search Strategy 2 – PsychINFO	
#1	cellular phones/ OR mobile devices/ OR computer applications/ OR mobile devices/ OR electronic communication/ OR communication systems/
#2	(smartphone* OR smart phone* OR mobile phone* OR mobile telephone* OR mobile device* OR mobile app* OR cell phone* OR cellular phone* OR mobile technology OR tablet computer* OR tablet* OR digital technology OR communication technolog* OR mHealth OR mobile health OR eHealth OR electronic health OR electronic communication* OR digital health OR wireless technolog* OR wireless communication*):ti,ab
#3	#1 OR #2
#4	interpersonal communication/ OR communication/ OR work teams/ OR teams/ OR cooperation/

#5	(patient care team* OR interdisciplinary communication* OR interdisciplinary relation* OR interprofessional relation* OR interprofessional communication* OR physician nurse relation OR doctor nurse relation* OR communication* OR team* OR collaboration OR cooperation OR handover* OR hand over* OR handoff* OR hand off*):ab,ti
#6	#4 OR #5
#7	hospitals/ OR hospitalized patients/ OR hospitalization/
#8	(hospital* OR secondary care OR tertiary care OR ward* OR inpatient* OR institution*):ab,ti
#9	#7 OR #8
#10	#3 AND #6 AND #9 Limits: English language, 1/1/2007-1/12/2017
Search Strategy 3 – EMBASE	
#1	"smartphone"/de OR "mobile phone"/de OR "mobile application"/de OR "wireless communication"/de
#2	"smartphone*" OR "smart phone*" OR "mobile phone*" OR "mobile telephone*" OR "mobile device*" OR "mobile app*" OR "cell phone*" OR "cellular phone*" OR "mobile technology" OR "tablet computer*" OR "tablet*" OR "digital technology" OR "communication technolog*" OR "mHealth" OR "mobile health" OR "eHealth" OR "electronic health" OR "electronic communication*" OR "digital health" OR "wireless technolog*" OR "wireless communication*":ti,ab
#3	#1 OR #2
#4	"interpersonal communication"/de OR "interdisciplinary communication"/de OR "doctor nurse relation"/de OR "teamwork"/de OR "clinical handover"/de OR "patient care team/de"
#5	"patient care team*" OR "interdisciplinary communication*" OR "interdisciplinary relation*" OR "interprofessional relation*" OR "interprofessional communication*" OR "physician nurse relation*" OR "doctor nurse relation*" OR "communication*" OR "team*" OR "collaboration" OR "cooperation" OR "handover*" OR "hand over*" OR "handoff*" OR "hand off*":ab,ti
#6	#4 OR #5
#7	"hospital"/de OR "hospital patient"/de OR "hospital based case control study"/de OR "university hospital"/de OR "teaching hospital"/de OR "public hospital"/de OR "private hospital"/de OR "general hospital"/de OR "hospital utilisation"/de OR "hospital care"/de
#8	"hospital*" OR "secondary care" OR "tertiary care" OR "ward*" OR "inpatient*" OR "institution*":ab,ti
#9	#7 OR #8
#10	#3 AND #6 AND #9 Limits: English language, 1/1/2007-1/12/2017
Search Strategy 4 – CINAHL Plus	
#1	MH (smartphone+ OR mobile applications+ OR computers, handheld+ OR cellular phone+ OR wireless communications+ OR computers, portable+)

#2	TI (smartphone* OR smart phone* OR mobile phone* OR mobile telephone* OR mobile device* OR mobile app* OR cell phone* OR cellular phone* OR mobile technology OR tablet computer* OR tablet* OR digital technology OR communication technolog* OR mHealth OR mobile health OR eHealth OR electronic health OR electronic communication* OR digital health OR wireless technolog* OR wireless communication*) OR AB (smartphone* OR smart phone* OR mobile phone* OR mobile telephone* OR mobile device* OR mobile app* OR cell phone* OR cellular phone* OR mobile technology OR tablet computer* OR tablet* OR digital technology OR communication technolog* OR mHealth OR mobile health OR eHealth OR electronic health OR electronic communication* OR digital health OR wireless technolog* OR wireless communication*)
#3	#1 OR #2
#4	MH (communication+ OR teamwork+ OR communication protocols+ OR hand off+ OR collaboration+ OR interprofessional relations+)
#5	TI (patient care team* OR interdisciplinary communication* OR interdisciplinary relation* OR interprofessional relation* OR interprofessional communication* OR physician nurse relation OR doctor nurse relation* OR communication* OR team* OR collaboration OR cooperation OR handover* OR hand over* OR handoff* OR hand off*) OR AB (patient care team* OR interdisciplinary communication* OR interdisciplinary relation* OR interprofessional relation* OR interprofessional communication* OR physician nurse relation OR doctor nurse relation* OR communication* OR team* OR collaboration OR cooperation OR handover* OR hand over* OR handoff* OR hand off*)
#6	#4 OR #5
#7	MH (hospitals+ OR hospital programs+ OR hospitals, veterans+ OR medical staff, hospitals+ OR inpatients+ OR secondary health care+)
#8	TI (hospital* OR secondary care OR tertiary care OR ward* OR inpatient* OR institution*) OR AB (hospital* OR secondary care OR tertiary care OR ward* OR inpatient* OR institution*)
#9	#7 OR #8
#10	#3 AND #6 AND #9 Limits: English language, 1/1/2007-1/12/2017

Appendix C - Finalised semi-structured focus group interview schedule

Imperial College London	Imperial College Healthcare NHS NHS Trust
<u>PRE-IMPLEMENTATION FOCUS GROUP/INTERVIEW - SCHEDULE</u>	
Explanation and consent process with opportunity for questions	
Brief introduction by each person present	
Opening discussion/starter – information from a survey already performed (ORIC) indicates that ICHNT is ready for change, does this fit with your view?	
<u>Questions/Discussion:</u>	
1) Background: a. Can you tell me about any previous experiences you have had where a new technology has been introduced here at ICHNT? b. Can you explain to me a little about the role you will play in the implementation of HARK?	
2) Leadership: a. Can you tell me a bit about the leadership of ICHNT, and how you think this might affect or change how we implement <i>Hark</i> at ICHNT? i. Local, departmental, organisational b. Are there any particular things we could do to moderate or mitigate these factors?	
3) Culture: a. What barrier are there to clinical staff being fully engaged/involved in the role out and use of <i>Hark</i>? i. Personal, departmental, organisational b. How do you think these barriers can be overcome, and if so, how can we facilitate this?	
4) Management: a. What processes do you think need to be in place to ensure accountability for timely and effective management/implementation? b. Have you got any examples where this has worked well/poorly before from which we can learn?	
5) Resources and Support: a. Do you feel that you have enough resource within your team/department to be able to implement and use <i>Hark</i>? b. If not, what do you feel is needed to facilitate the implementation of <i>Hark</i> within ICHNT?	
6) Data and Analytics:	
Version 1.2 4.5.2016	

Imperial College London	Imperial College Healthcare NHS NHS Trust
a. How do you think we should measure the success of <i>Hark</i>? b. What information would you like to see before, during and after implementation? c. Do you believe that sharing information about the success/challenges with implementation may help with the implementation of <i>Hark</i>? If so, why?	
7) Capabilities and Skills: a. Can you tell me what are the most important skills/capabilities associated with implementing new interventions within ICHNT? b. Which of these do you feel might be the most important to implementing <i>Hark</i>? c. Would training be useful for some/all members of staff, and if so, what would you recommend?	
8) Environmental: a. Are there any factors beyond the control of ICHNT e.g. policies, national standards that may affect or impact upon the implementation of <i>Hark</i>?	
9) Is there anything else you would like to add?	
Version 1.2 4.5.2016	

Appendix D - Health Information Technology Safety Measurement (HITS) Framework^{93,371,372}

Domain	Principle
Safe health IT Address safety concerns unique to technology	<i>Data availability</i> – the usability and accessibility of health IT. Are health IT systems easy to use, and are they available to staff when needed?
	<i>Data integrity</i> – accuracy and integrity of the data that is supplied to health IT users. Is data at risk of being lost, altered or destroyed? Is there only ever 'one true record' of patient care?
	<i>Data confidentiality</i> – systems and data are only accessed by authorised users. Are there effective processes in place to ensure the security and privacy of patient information?
Using health IT safely Optimise the safe use of technology	<i>Complete/correct health IT use</i> – features and functionality are implemented and used as intended. Are systems being used as intended, or are staff failing to maximise their potential due to poorly designed or functioning systems?
	<i>Health IT system usability</i> – are users satisfied with the usability of a system, or does poor design and dissatisfaction lead to the development of potentially unsafe work-arounds or other safety concerns?
Monitoring safety Use technology to monitor and improve patient safety	<i>Surveillance and optimisation</i> – processes and policies for monitoring, detecting and reporting health IT use and its impact on patient safety. Do organisations have effective processes for identifying and mitigating risks, delivering innovation, and leveraging health IT to reduce harm and improve safety?

Appendix E - Description of pragmatic and concurrent mixed-methods approach

