

THE ROLE OF THE PATIENT IN EVALUATING QUALITY OF CARE

Mr Jochem A. Caris MD MSc

Division of Surgery

Department of Surgery & Cancer

Imperial College London

Doctor of Philosophy (PhD) 2015

Supervisors:

Professor the Lord Darzi of Denham,

Professor Peter C. Smith &

Mr Erik K. Mayer

DEDICATION

To my wife Yulia, who with her everlasting love created the perfect environment for me to thrive as an academic, a clinician and mostly as a person. I am sorry about all those grumpy mornings

*And to my parents, who provided me with the right mix of intelligence, ambition and emotional support that is needed to be successful in life.
Bedankt Mam & Ouwe*

ABSTRACT

This thesis outlines the emerging role of the patient, central in the transition from a volume driven towards a patient-driven healthcare. Healthcare systems, regardless of region or economic status, must develop new ways to deliver care whilst at the same time improving both quality of care and containing costs. Today's society is increasingly 'horizontal' shaped by affiliations and networks, and this changes the way information flows, increasing people's willingness to participate in the decision-making process. Encouraging more patient involvement by promoting feedback will increase communication between system and users, this is important as it can improve quality of service. The inception and preliminary results of a national programme based around patient-reported health surveys, i.e. PROMs, are discussed together with the potential of the programme and its limited evidence on how this translates to quality of care for patients.

The feasibility of PROMs data, in order to investigate important difference as reported by patients in this large national cohort, is tested by segmentation into individual procedures. A subsequent risk analysis of important confounders demonstrates that poor mobility and self-reported depression are significant predictors of poor HRQoL outcomes as well as self-reported adverse events. A further comparison between self-reported and administrative collected comorbidities is undertaken to substantiate the reliability of self-reported comorbidities followed by the development of an accumulated risk prediction score generated from self-reported comorbidities to identify individual patient segments before treatment. And finally, a mixed method study is undertaken into factors behind poor unit response rates by exploring the patients' views on PROMs and their place in quality of care.

This thesis demonstrates the limitations of the current data dissemination of national PROMs data and proposes several steps of improvement to increase relevance to both patients and clinicians.

STATEMENT OF ORIGINALITY

All the work presented in this thesis is my own and it is the work upon which I expect to be examined. This work has not been previously submitted for a degree or diploma at any other higher education institution. To the best of my knowledge and belief, this thesis contains no material previously published or written by another person except where due references are made.

Signed:

Date:

COPYRIGHT DECLARATION

‘The copyright of this thesis rests with the author and is made available under a Creative Commons Attribution Non-Commercial No Derivatives licence. Researchers are free to copy, distribute or transmit the thesis on the condition that they attribute it, that they do not use it for commercial purposes and that they do not alter, transform or build upon it. For any reuse or redistribution, researchers must make clear to others the licence terms of this work’

ACKNOWLEDGEMENTS

I would like to thank my supervisors Professor Ara Darzi, Professor Pete Smith and Mr Erik Mayer for providing me with the opportunities to develop my skills in both the academic and clinic world. My role within the department, although, tough at times and in particular during early morning meetings with Prof after a night on call and operating, was perfectly suited to develop an even stronger sense of the importance of the role of the patients. I am grateful for been given the opportunity and responsibility to implement the ‘gold standard’ of short-term outcomes research programme from the American College of Surgeons that has accelerated my understanding of the health system.

I would also like to thank all those people at the department that where like mind and hearted and in no particular order; Myutan, you little big man, we could have been twins if it wasn't for being the exact physical opposites, keep up your clinical drive and I will be calling you Professor soon. Mark, working together was like therapy, the importance of our collaboration has already changed the world. Further big

thanks to TP, Suba, Shantanu and Alex. And last but not least, a special thanks to Chris, for helping me through some tough times and keeping my sanity throughout my time at the department and beyond.

TABLE OF CONTENTS

DEDICATION.....	2
ABSTRACT.....	3
STATEMENT OF ORIGINALITY.....	4
COPYRIGHT DECLARATION.....	5
ACKNOWLEDGEMENTS.....	5
TABLE OF CONTENTS.....	7
LIST OF FIGURES.....	11
LIST OF TABLES.....	12
LIST OF ACRONYMS.....	14
CHAPTER 1.....	16
LITERATURE REVIEW – INTRODUCTION.....	16
1.1 INTRODUCTION.....	17
1.1.1 <i>Defining quality of care.....</i>	<i>19</i>
1.1.2 <i>Measuring quality of care.....</i>	<i>21</i>
1.1.3 <i>The need for risk adjustment.....</i>	<i>23</i>
1.1.4 <i>Quality of life.....</i>	<i>25</i>
1.1.5 <i>Defining patient-reported outcomes measures (PROMs).....</i>	<i>28</i>
1.1.6 <i>EQ-5D index score.....</i>	<i>31</i>
1.1.7 <i>Identification and development of a valid PROMs.....</i>	<i>33</i>
1.1.8 <i>Current and past PROMs initiatives.....</i>	<i>37</i>
1.1.9 <i>The potential of nationally collected PROMs data.....</i>	<i>44</i>
1.1.10 <i>Methodological challenges using PROMs.....</i>	<i>45</i>
1.1.11 <i>PROMs and technology.....</i>	<i>47</i>
1.1.12 <i>Public health implications.....</i>	<i>49</i>
1.1.13 <i>Conclusion.....</i>	<i>51</i>
1.1.14 <i>Key points arising from chapter 1.....</i>	<i>53</i>
CHAPTER 2.....	54
ROUTINE MEASUREMENT OF PATIENT-REPORTED OUTCOMES IN ELECTIVE INGUINAL HERNIA REPAIR: RETROSPECTIVE ANALYSIS OF NATIONALLY COLLECTED DATA IN ENGLAND.....	54
2.1 INTRODUCTION.....	55
2.2 MATERIALS AND METHODS.....	57
2.2.1 <i>Study population.....</i>	<i>57</i>
2.2.2 <i>Data extraction.....</i>	<i>57</i>
2.2.3 <i>Clinical outcome variables.....</i>	<i>60</i>

2.2.4	<i>Statistical methodology</i>	61
2.3	RESULTS	62
2.3.1	<i>Demographics</i>	62
2.3.2	<i>Baseline HRQoL</i>	64
2.3.3	<i>Clinical outcomes</i>	64
2.3.4	<i>Postoperative HRQoL and satisfaction</i>	65
2.4	DISCUSSION	71
2.4.1	<i>Principal findings</i>	71
2.4.2	<i>Strengths and weaknesses of the study</i>	71
2.4.3	<i>Comparison with other studies</i>	73
2.5	CONCLUSIONS	76
2.6	KEY POINTS ARISING FROM STUDY ONE	77
CHAPTER 3		78
RISK PREDICTION OF HEALTH-RELATED QUALITY OF LIFE OUTCOMES IN GROIN HERNIA PATIENTS		78
3.1	INTRODUCTION	79
3.2	MATERIAL AND METHODS	80
3.2.1	<i>Candidate predictors</i>	80
3.2.2	<i>Statistical Analysis</i>	81
3.3	RESULTS	88
3.3.1	<i>Prediction of baseline HRQoL</i>	88
3.3.2	<i>Prediction of HRQoL outcomes</i>	89
3.4	DISCUSSION	95
3.4.1	<i>Principal findings</i>	95
3.4.2	<i>Strengths and weaknesses of the study</i>	96
3.4.3	<i>Comparison with other studies</i>	97
3.5	CONCLUSIONS	100
3.6	KEY POINTS ARISING FROM STUDY TWO	101
CHAPTER 4		102
THE CONCORDANCE BETWEEN PATIENT-REPORTED AND ADMINISTRATIVE DATA RECORDED COMORBIDITIES: ARE WE MISSING IMPORTANT INFORMATION FROM OUR PATIENTS?		102
4.1	INTRODUCTION	103
4.2	MATERIALS AND METHODS	104
4.2.1	<i>Study population</i>	104
4.2.2	<i>Data collection</i>	104
4.2.3	<i>Data analysis</i>	106

4.3	RESULTS.....	107
4.3.1	<i>Prevalence of comorbidity reporting.....</i>	<i>108</i>
4.3.2	<i>Levels of agreement.....</i>	<i>109</i>
4.4	DISCUSSION	113
4.4.1	<i>Principal findings.....</i>	<i>113</i>
4.4.2	<i>Strengths and weaknesses of the study</i>	<i>113</i>
4.4.3	<i>Comparison with other studies.....</i>	<i>115</i>
4.4.4	<i>Explaining overreporting.....</i>	<i>116</i>
4.4.5	<i>Explaining underreporting.....</i>	<i>116</i>
4.5	CONCLUSIONS.....	117
4.6	KEY POINTS ARISING FROM STUDY THREE	118
CHAPTER 5.....	119	
RISK PREDICTION IN HIP REPLACEMENT SURGERY USING A SIMPLE SELF- REPORTED COMORBIDITY ADJUSTED RISK (SCAR) INDEX	119	
5.1	INTRODUCTION	120
5.2	MATERIALS AND METHODS.....	121
5.2.1	<i>Study population.....</i>	<i>121</i>
5.2.2	<i>Data extraction.....</i>	<i>121</i>
5.2.3	<i>Outcomes</i>	<i>121</i>
5.2.4	<i>Construction of Self-reported Comorbidity Adjusted Risk (SCAR) index</i>	<i>122</i>
5.2.5	<i>Adjusting Charlson's comorbidity index for the sample population</i>	<i>122</i>
5.2.6	<i>Model validation.....</i>	<i>123</i>
5.3	RESULTS.....	125
5.3.1	<i>Validation of the SCAR index.....</i>	<i>125</i>
5.3.2	<i>Adjusting Charlson's comorbidities index</i>	<i>125</i>
5.3.3	<i>Model performance.....</i>	<i>130</i>
5.4	DISCUSSION	134
5.4.1	<i>Principal findings.....</i>	<i>134</i>
5.4.2	<i>Strengths and weaknesses of the study</i>	<i>135</i>
5.4.3	<i>Comparison with other studies.....</i>	<i>136</i>
5.5	CONCLUSIONS	138
5.6	KEY POINTS ARISING FROM STUDY FOUR.....	139
CHAPTER 6.....	140	

EXPLORING PATIENTS' ACCEPTANCE ON ELECTRONIC ALTERNATIVE IN ROUTINELY COLLECTED PROMS IN VARICOSE VEINS PATIENTS: A MIXED METHOD STUDY.....	140
6.1 INTRODUCTION.....	141
6.2 MATERIALS AND METHODS.....	142
6.2.1 Study population.....	142
6.2.2 Development of electronic version of PROMs questionnaire.....	142
6.2.3 Recruitment and follow-up.....	143
6.2.4 Patient pilot interview.....	146
6.2.5 Development of patient survey.....	147
6.2.6 Statistical analysis.....	148
6.3 RESULTS.....	148
6.3.1 Randomised trial.....	148
6.3.2 Qualitative assessment of patients' views.....	150
6.4 DISCUSSION.....	153
6.4.1 Principle findings.....	153
6.4.2 Strengths and weaknesses of the study.....	153
6.4.3 Comparison with other studies.....	154
6.5 CONCLUSIONS.....	156
6.6 KEY POINTS ARISING FROM STUDY FIVE.....	157
CHAPTER 7.....	158
CONCLUSIONS AND FUTURE WORK.....	158
7.1 CONCLUSIONS.....	159
7.2 UNANSWERED QUESTIONS AND FUTURE RESEARCH.....	164
APPENDIX T.....	169
APPENDIX U.....	170
APPENDIX V.....	171
APPENDIX W.....	174
APPENDIX X.....	178
APPENDIX Y.....	184
APPENDIX Z.....	186
REFERENCES.....	190

LIST OF FIGURES

Figure 1-1 Assessing quality of care	21
Figure 1-2 Examples of types and indicators as proposed by Donabedian.....	23
Figure 1-3: Schematic overview of Quality of Life	26
Figure 1-4: EuroQol's EQ-5D-3L questionnaire (UK version)	36
Figure 1-5: Elements of the PROMs questionnaires in the NHS national PROMs programme.....	40
Figure 2-1: Flowchart describing data segmentation into primary unilateral "open" and "laparoscopic" inguinal hernia repair in the national PROMs programme	59
Figure 2-2 a&b: Bar charts showing baseline (2.2a) and differences between baseline and follow-up HRQol (EQ-5D) (2.2b), distribution by EQ-5D index group.....	68
Figure 5.1: Distribution of SCAR index in validation set.....	131
Figure 5.2: Distribution of empirically assigned CCI	131
Figure 5.3: ROC curve for 6 month mortality models of empirical CCI with inclusion of demographics and general health	133
Figure 5.4: ROC curve for 6 month mortality models of SCAR index with inclusion of demographics and general health	133
Figure 6-1: Flowcharts recruitment into randomised trial evaluating an electronic alternative to traditional paper-based PROMs questionnaire	145
Figure 6.2: General themes and their subsequent prompt used during semi-structured interview study	147
Figure 7-1: Proposed PROMs feedback loop to improve relevance of national PROMs programme.....	163
Figure 7-2: Three level data for outcome measurement within the surgical care pathway	167

LIST OF TABLES

Table 1-1: Summary of most commonly used types of HRQoL measures	30
Table 1-2: Eight criteria to necessary to select most suitable PROM instrument	36
Table 1-3 Total volume of responses for the first three years of the national PROMs programme.....	41
Table 1-4: PROMs response rates for the national PROMs programme in the first 3 years after inception.....	41
Table 1-5: Response rates for all eligible patients in England and Wales by baseline and follow-up questionnaire response rates and per individual PROMs index procedure	42
Table 2-1: OPCS-4 codes used to determine primary unilateral MESH inguinal hernia repair	58
Table 2-2: Baseline characteristics of all primary unilateral MESH inguinal hernia repair patients by technique and response/ non-response with consequent p-values or standardised residuals.....	63
Table 2-3: Mean EQ-5D index scores at baseline (pre) and at follow-up (post). Higher scores equals better perceived wellbeing. Differences are shown between responders and non-responders, outcomes are only shown for responders (readmission (yes or no)), length of stay, complications and sensitivity analysis) .	67
Table 2-4: Distribution of patients reporting postoperative adverse events overall and by age group. (Differences are reported as unadjusted Odds ratios with 95% C.I. and p-value) Open technique acted as reference group)	69
Table 2-5: EQ-5D individual dimensions by treatment group.....	70
Table 2-6: Patients' satisfaction three months after surgery	70
Table 3-1: Univariate analysis of all PROMs and HES recorded variables in open and laparoscopic technique by baseline EQ-5D index groups (EQ-5D=1) and EQ-5D<1	82&83
Table 3-2: Univariate analysis of candidate predictors between Group 1 (Improvement) and Group 2 (Reduction) in HRQoL outcomes following "Open" surgery ...	84&85
Table 3-3: Univariate analysis of candidate predictors between Group 1 (Improvement) and Group 2 (Reduction) in HRQoL outcomes following "Laparoscopic" surgery	86&87

Table 3-4: Formation of groups differences between baseline.....	88
Table 3-5: Multivariate (logistic regression) analysis of potential predictors of patients reporting baseline “non” perfect HRQoL (EQ-5D of 1) in "OPEN" surgery	91
Table 3-6: Multivariate (logistic regression) analysis of potential predictors of patients reporting baseline “non” perfect HRQoL (EQ-5D<1) in "LAPAROSCOPIC" surgery	92
Table 3-7: Multivariate (logistic regression) analysis of potential predictors of reduction of HRQoL following "OPEN" surgery	93
Table 3-8: Multivariate (logistic regression) analysis of potential predictors of reduction of HRQoL following "LAPAROSCOPIC" surgery	94
Table 4-1: PROMs comorbidities with top 5 most commonly coded ICD-10-CM secondary diagnostic codes and total number within PROMs comorbidity in HES data	106
Table 4-2: Demographics for each PROMs procedure	108
Table 4-3: Prevalence of comorbidities and agreement between administrative and PROMs data per individual procedure	111
Table 4-4: Measures of sensitivity, specificity, positive and negative predictive value of comorbidities per procedure (HES administrative data served as gold standard for all measures)	112
Table 5-1: Weighted index of PROMs comorbidities	125
Table 5-2: Empirically assigned Charlson comorbidities weightings	124
Table 5-3: Demographics of patients undergoing hip replacement in the national PROMs programme between 2009-2011.....	127
Table 5-4: Logistic regression analysis of PROMs comorbidities predicting 6-month mortality for patient undergoing hip replacement.....	128
Table 5-5: Logistic regression analysis of Charlson's comorbidities predicting 6-month mortality for patients undergoing hip replacement	129
Table 5-6: Summary of model performance for the 3 individual scores for elective hip replacement patients	132
Table 6-1: Demographics and follow-up rate of patients in paper-based and electronic group undergoing minimally invasive varicose veins surgery	150

LIST OF ACRONYMS

ACS NSQIP	American College of Surgeons National Surgical Quality Improvement Program
CCG	Clinical Commissioning Group
CCI	Charlson Comorbidity Index
DoH	Department of Health
HES	Hospital Episode Statistic
HRQoL	Health-related Quality of Life
HSCIC	Health and Social Care Information Centre
ICD-9 / 10	International Classification of Disease (Ninth and tenth revision)
MID	Minimally Important Difference
NCD	Non-Communicable Disease
NHS	National Health Service
OECD	Organisation for Economic Cooperation
OPCS-4	Office of Population Censuses and Surveys Classification of Surgical Operations and Procedures 4 th revision
PROMs	Patient-reported Outcome Measures
QoL	Quality of Life
SCAR index	Self-reported Comorbidity Adjusted Risk index

“It is far more important to know what sort of person has the disease than to know what sort of disease the person has”

-Hippocrates (c. 460-400 BC)

“The physician should not treat the disease but the patient who is suffering from it”

-Maimonidis (c. 1137-1204 AD)

Chapter 1

LITERATURE REVIEW – INTRODUCTION

1.1 INTRODUCTION

Increasing awareness of variations in the quality of healthcare has helped propel a quality improvement movement. This growing attention for assessing quality of care has been a catalyst for assessing and improving healthcare on a local and international platform¹. Traditionally, quality assessment of hospitals has primarily been based around primary endpoints (i.e. mortality) and more recently with the use of evidence-based process measures, such as VTE prophylaxis in patients undergoing surgical interventions. To date, beyond a few specialist datasets the broader picture of quality of care in the United Kingdom is from administrative data, such as Hospital Episode Statistics (HES), which has presented researchers and policymakers with a means to assess quality on a national level^{2,3}. Administrative data is readily available as it is collected routinely for the purposes of financial reimbursement and provides no additional burden for hospitals. However, data generated by clinical registries abstracted from clinical notes is found to be more reliable and accurate⁴, particularly in collecting outcomes that occur in the community⁵. Moreover, clinical registries contain more detailed information that can provide more fitting risk adjustment. Nevertheless, the adoption of clinical registries is slow due to the additional resources required to collect data.

Therefore, health systems have looked for alternative opportunities to identify important trends in the provision of care in their search for more patient-centred and value-based care⁶. Patients themselves could provide a key element in re-designing performance measurement emphasising the need to measure the wider impact of medical and surgical conditions on overall wellbeing and Quality of Life (QoL). Measuring this directly at source (the patient) is far less expensive compared to bespoke clinical databases. These types of measures, frequently called Patient-reported Outcome Measures (PROMs), allow for direct comparison between symptoms, functional status and Health Related Quality of Life (HRQoL) in order to effectively measure the outcome of the care they received. PROMs data can be an effective tool to assess the performance of individual practitioners and large-scale

data collection could allow for analysis of variation in outcomes and test of appropriateness of treatment in particular patient groups.

This introduction forms a narrative review, which outlines current practices in assessing quality of care in surgery. Followed by a discussion of patient-reported outcomes and their emerging place in evaluating the effectiveness of care. Concluded by a description of the role for Information Technology (IT) that aims to facilitate users of routinely collected patient-reported outcome data in surgery and the importance of utilising technology to further advance our understanding of quality of care.

1.1.1 Defining quality of care

Surgical science has gone through landmark developments over the past centuries. Although, surgical techniques have been described as early as ancient Mesopotamia, it wasn't until *John Hunter*, a Scottish scientist, applied an empirical and experimental approach to reconstruct surgical knowledge. His work led to important innovations in the diagnosis and treatment of diseases, but he is most renowned for his position on surgical procedures, which he felt should only be used as a last resort⁷. The further introduction of ether as an anaesthetic in surgery, pioneered in Europe by *Nikolay Pirogov*, continued to increase our ability to safely undertake surgical procedures and make invasive treatment less traumatic to our patients. *Pirogov*, generally known as the founder of field surgery, derived many of his concepts from the Crimea War, where he piloted the earliest form of risk assessment, i.e. a triage system, in emergencies⁸. This early warning system of severity of injury or disease can arguably be seen as the first risk adjustment strategy in medicine.

Although, quality of care has significantly improved since those early years, hospitals and health systems alike still struggle with defining what good quality of care constitutes and there is no consensus what the best way is to appraise it. There are several definitions of quality of care, however, quality can have different meanings for health consumers and professionals. Whilst patients might desire a good overall experience, conversely, clinicians are primarily focussed on clinical outcomes by minimising complications and reducing length of stay and readmission rates. For a whole systems approach, however, these six pillars should be contained in defining quality:

- Effective; delivering healthcare that is adherent to an evidence base and results in improved health outcomes for individuals and communities, based on need;
- Efficient; delivering healthcare in a manner which maximises resource utilisation and avoidance of waste;

- Accessible, delivering health care that is timely, geographically reasonable, and provided in a setting where skills and resources are appropriate to medical need;
- Acceptable/patient-centered, delivering healthcare which takes into account the preferences and aspirations of individual service users and the cultures of their communities;
- Equitable, delivering healthcare which does not vary in quality because of personal characteristics such as gender, race, ethnicity, geographical location, or socioeconomic status;
- Safe, delivering health care, which minimises risks and harm to service users⁹.

Incorporating all six core dimensions to form an overall encompassing definition of quality of care is seemingly impossible. The Institute of Medicine's (IOM) definition is most widely used but remains vague and lacks clarity to what it actually exactly entails:

“The degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge”¹⁰

Quality in healthcare is a multidimensional concept and understanding it may require an interaction between several different measures or indicators to provide a comprehensive insight. Before adopting any measure to evaluate quality, it must pass against a wide range of technical criteria, principally: *validity* (Does the measure capture what it is supposed to?), *reliability* (How reproducible is the measure when taken at different times or in different circumstances?) and *sensitivity to change* (Will the measure discriminate between good and poor quality, and will it be able to detect perhaps small but worthwhile improvements?). Poor validity has been shown to undermine conclusions, while collecting unblinded data can undermine reliability^{11,12}.

1.1.2 Measuring quality of care

In the current economical climate, assessment of performance by measuring quality of care is essential to identify areas of poor performance and should act as the basis for health reforms. For proper quality assessment, it is required to develop and apply performance measures, i.e. explicit standards of care, against which actual care is judged¹³. This process might seem a simple endeavour, beginning with a decision on what to measure, identifying the proper measures along with their respective data sources, and culminating in the analysis, aggregation, understanding and dissemination of the results. However, as with most deceptively straightforward tasks, the difficulties lie in the details¹⁴.

The various elements that define quality of care can be derived from clinical pathway measures, such as outcomes, or can be directly measured from the patients themselves using health surveys (Figure 1.1).

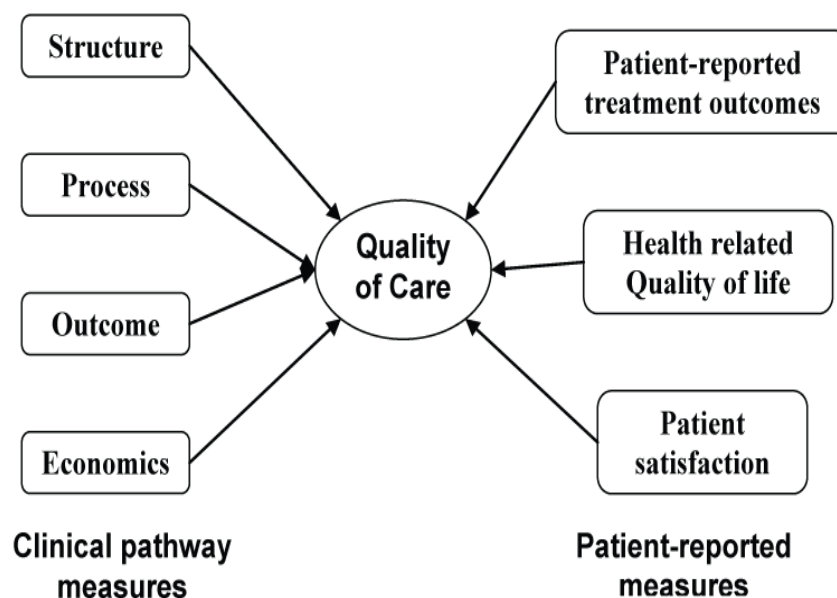


Figure 1-1 Assessing quality of care (reproduced from Mayer et al¹⁵)

The traditional approach to measure quality of care involved drawing indicators from a model proposed by *Avendis Donebedian* in the early eighties¹⁶. He developed a framework consisting of three dimensions: “structure”, “process” and “outcomes” that forms a basic process, where “outcomes” are determined by what is known about the environment (“structure”) in which they occur and whether medical practice is concurrent with best evidence (“process”) (Figure 1.2). He further emphasised that outcomes remained the ultimate validator of health care quality and effectiveness. In wider terms, outcomes attempt to describe the overall effect of care on patient populations. These end-points of healthcare delivery, such as mortality, usually have excellent face validity, however, the correlation between the quality of clinical practice and mortality is low and therefore it is neither a sensitive nor specific test for quality of care¹⁷. Despite these criticisms, governments have predominately been using mortality data in their attempt to identify variation in the provision of care and aim to publically report this data (i.e Hospital Standardised Mortality Ratios). Hospitals with higher than expected rates will be subject to in-depth analyses of clinical performance, however, the methodology applied has been heavily criticised and is mainly directed at the lack of proper case-mix and risk adjustment.

However, even if adequate case-mix or risk adjustment has been applied, the criteria used for each variable can lead to bias within the sample. In addition, there is insufficient evidence that quantifies the appropriateness of decision-making in surgical practice. For this reason, Clinical Commissioning Groups (CCG’s), that organise the delivery of NHS services, are increasingly introducing referral guidelines in order to provide guidance on whether treatment is appropriate based on best available evidence^{18,19}. This is normally a single guidance for all patients in that particular group and it doesn’t provide guidance on which treatment is most relevant to the individual patient. The traditional decision-making process is based around presentation of clinical symptoms, such as pain, but if these symptoms fail to impact on daily activities, treatment will not be approved. The formation of these guidelines have benefited from the introduction of patient-related outcomes, such as health-related quality of life, as a means to provide additional information that was normally not available to influence this process and by doing so has expanded our understanding of quality of care.

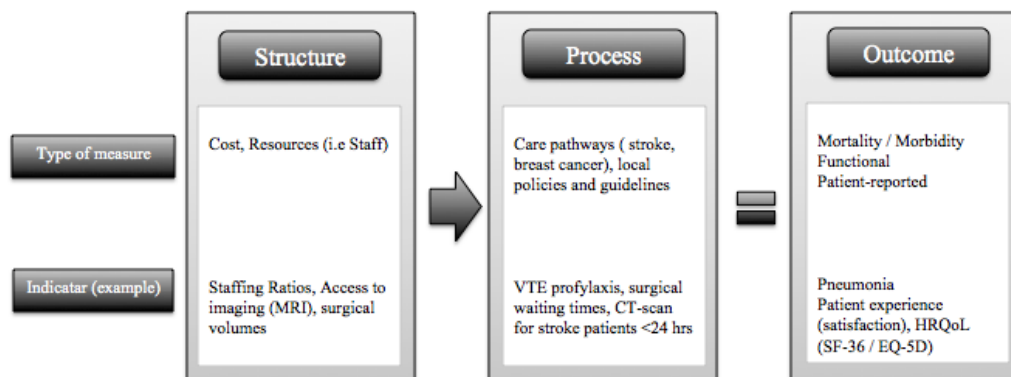


Figure 1-2 Examples of types and indicators as proposed by Donabedian¹⁶

1.1.3 The need for risk adjustment

To account for variations in outcomes, information on explanatory variables is fundamental to provide the evidence base that is needed to improve our understanding and initiate quality improvements. Risk adjustment is essential to explain the heterogeneity between individual patients as many risk factors (i.e. pre-existing illnesses, functional and socio-economic status) can impact on clinical outcomes following routine surgery. The majority of risk adjustment strategies are preformed retrospectively relying on variables made available from medical records, clinical application systems and administrative data.

Medical records review, currently considered the ‘gold standard’, provides the most accurate description of a patient health status. For small-scale studies, it can be feasible to obtain information directly from the medical notes and extend it with information available from clinical application systems. Claims or administrative data, designed for financial reimbursement, can provide an alternative source of health information from risk adjustment. This data source collects information on outcomes, such as mortality, contains information about outputs of care, such as length of stay and records a set of codes that describes the primary diagnosis and

treatment for which the patient was admitted in hospital. In addition, secondary diagnostic codes are collected that may influence the level of payment, however, this is dependent on local funding arrangements, meaning that priorities for collecting certain chronic diseases for coding departments can lead to either over- or underreporting. For researchers, these secondary codes have provided them with an opportunity to develop risk strategies. Charlson's Comorbidity Index (CCI), first described in the 1980s, is the most favoured strategy as it combines a set of pre-existing conditions, i.e. comorbidities, to form an overall score²⁰. The score was developed on a sample of medical patients and its primary focus was to estimate one-year mortality in that sample. Many studies have used this score in their risk adjustment of administrative data^{2,21}. However, the accuracy of pre-existing conditions recorded in administrative data is predominately impacted by its underestimation of comorbid conditions compared to medical record review²².

For surgical patients specifically, there are several risk adjustment strategies available that are collected prospectively and can inform clinicians immediately of risk of complications. In the early sixties, the American Society of Anaesthetist (ASA) adopted a 5-point scoring system developed by Saklad²³, to assess the fitness of a patient before surgery, commonly known as ASA grade or score. Although, the score is used prospectively to inform both anaesthetist and surgeon before the procedure and there is extensive evidence for its use retrospectively to predict mortality^{2,3}, it is still used with caution. The main criticism is based around the lack of consistency in assigning patient an ASA score of 3 (Middle group)²⁴, as it is subjected to clinician's interpretation leading to poor inter-rater reliability²⁵.

The P-POSSUM (Physiological and Operative Severity Score for the enUmeration of Mortality and Morbidity) developed by Copeland et al²⁶, is not dependent on interpretation and has similar predictive qualities as the ASA score. The disadvantage is that all variables need to be present, such as blood test results and intraoperative data for the score to be completed.

More recently, the increasing need for robust case-mix and risk adjusted outcome data collected by bespoke clinical registries has provided the evidence needed for quality improvement initiatives^{27,28}. The American College of Surgeons National

Quality Improvement Program (ACS NSQIP) based on the Veterans Affairs (VA) surgical outcomes programme, collects a wide range of variables that are updated yearly on their relevance to explain variation. The programme was designed to capture outcomes occurring within 30-days, either in-hospital or in the community. However, there is significant cost associated with the programme that requires engaging hospital management and clinicians. The burden of data collection could be reduced provided hospitals use more procedure-specific quality measures, thereby reducing the number of variables needed to be collected²⁹.

Information contained in medical records can provide the basis for all data sources available for quality assessment. Without the availability of fully integrated care with less fragmentation that increased the likelihood of information transfer errors, patients will continue to play a central role in retaining their own health information. Some argue that technology will provide the ultimate solution, however, there are concerns in terms of electronic health system fostering errors rather than reduce them³⁰.

1.1.4 Quality of life

As healthcare is slowly moving away from the traditional physician-led to a more patient-driven care³¹, the importance of collecting outcomes that matter to patients has increasingly been highlighted by several important government reports, business reviews and a wide range of academic papers^{6,32}. Particularly in areas in healthcare where endpoints, such as mortality, are low and new treatments are relatively expensive, the ability to identify treatments and/or interventions, which are most cost effective and therefore should be endorsed, is pertinent. Improving a populations' overall health is the ultimate goal of any health system and therefore measuring treatment impact from the patients' perspective should have priority. The rationale behind this understanding is that outcomes, as reported by patients, are driven by the belief that individuals are the best narrator of their own wellbeing.

An individual's Quality of Life (QoL) is influenced by an array of factors that can change from day to day (Figure 1.3). This multi-dimensional concept is principally influenced by a person's needs over its inabilities.

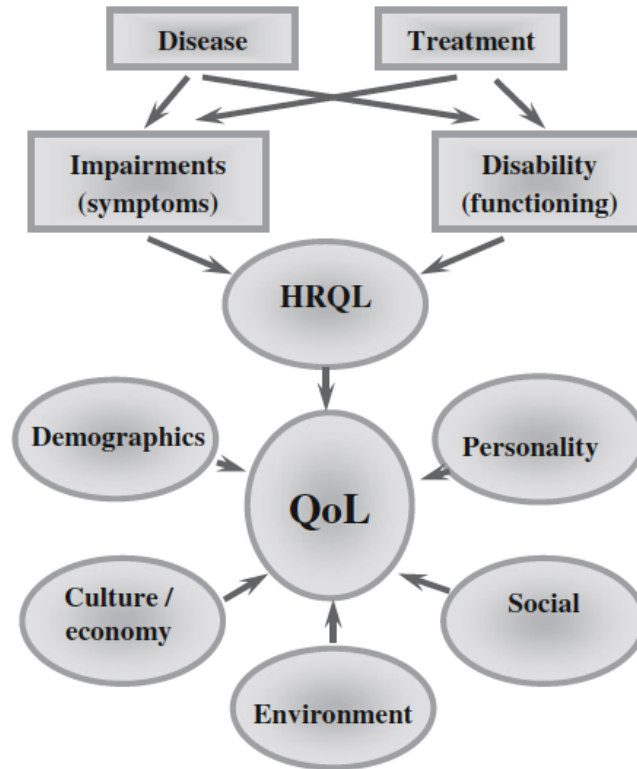


Figure 1-3: Schematic overview of Quality of Life (adopted from Doward et al³³)

Life satisfaction derives its quality from our ability and capacity to satisfy human needs³³. The socio-economic environment we grow up and reside in; our social interaction level; personal traits; employment and educational status are all part of this multi-dimensional concept. Each of these individual dimensions influences how a person, i.e. patient, perceives its own QoL. For healthcare specifically, the area that can directly be influenced is Health-Related Quality of Life (HRQoL) and this is thought to be of most value to the individual when illness affects role performance³⁴. Therefore, Guyatt and colleagues defined HRQoL broadly as:

“the capacity to perform the usual daily activities for a person’s age and major social role”³⁵

When an individual has no diseases and experiences no disabilities or symptoms and has full capacity to perform their usual daily activities, one can assume that their HRQoL is full/perfect. Given that the individual is affected by symptoms from either physical or cognitive origin then his or her HRQoL will be impaired. However, concerns have been raised with the term HRQoL, as it may imply that QoL is measured. Misinterpretation of study results can therefore occur when both terms are used interchangeably³⁶. There exists a natural decline in a population's self-reported sense of wellbeing, which is a direct consequence of ageing, with no observable difference between men and women. Moreover, there is evidence for a worsening perceived HRQoL in patients with comorbidities, who already display impaired HRQoL as a consequence to disease³⁷.

In addition, HRQoL scales might also not always address the primary concerns of the patient with that particular condition. Patients with chronic conditions can adjust their usual activities to their condition, replacing them with activities that are equally satisfying. This limitation is known to become particularly evident in outlier patients³⁸. For this reason, it is difficult to control for variation that occurs due to patient's experience of symptoms from conditions in a different way. However, HRQoL assessment was not intended to guide treatment choice in individual patients but to determine the appropriateness of treatment in patient groups.

The routine administration of HRQoL measures, i.e. PROMs, in specific patient populations can provide means to identify areas where the impact of symptoms of disease is greatest on experienced HRQoL and there is increased need for improvements.

1.1.5 Defining patient-reported outcomes measures (PROMs)

Patient-reported outcome measures are a widely described addition to our current understanding of measuring quality of care³⁹. Their ability to detect physical or psychological symptoms that are otherwise overlooked have broadened our perspective of the patients' views on healthcare. PROMs can measure both a single condition and its associated symptoms or can have a multi-dimensional character and can include any of the following concepts such as symptoms, health status, HRQoL and patient satisfaction.

The Food and Drug Administration (FDA) in the U.S. defines a patient-reported outcome as:

“Any report of the status of a patient’s health condition that comes directly from the patient, without interpretation of the patient’s response by a clinician or anyone else”⁴⁰.

PROMs can provide a unique real-time approach to understanding utilisation and outcomes of treatments across many conditions⁴¹. It has been argued that capturing the patient's perspective is central to comparative effectiveness research (CER) which provides the evidence-base for decision making in healthcare⁴². They can combine several elements to investigate specific areas, provide an overall score on a patient’s wellbeing and can contain questions on patient satisfaction.

Most PROMs are based on the inclusion of a HRQoL measure, which refers to those that evaluate the broader impact of disease on the functioning and wellbeing of a patient. These measures can typically be divided into two kinds; the first is specifically designed for one group or condition, i.e. disease-specific measures, the second can be used across different populations and is independent of the underlying condition, i.e. generic measures. Disease-specific measures are designed to study the most important effects of a disease, however, they are not suited to compare treatment results across a variety of diseases. Their main aim is to assess specific impact of a single disease on HRQoL and can assist in the clinical decision-making⁴³.

They are constructed to report on clinical symptoms alone and rarely include overall wellbeing elements, however they can produce a single accumulated score, which makes them desirable for evaluating treatment efficacy. Examples include, the Oxford Hip Score, frequently used to establish HRQoL in patients with osteoarthritis of the hip joint⁴⁴ and the Disability of Arm, Shoulder and Hand Questionnaire (DASH) that measures physical function and symptoms in people with any of several musculoskeletal disorders of the upper limb⁴⁵.

Generic measures can be used for different patient populations and are generally categorized into generic (or non preference-based) and preference-based measures (Table 1.1). The latter focuses on choice and strength of preference of health outcomes and if the value that patients attach to improvement is known, it can be used as an utility measure in economical evaluations⁴⁶. Generic measures of overall health status aim to provide a structured summary of the self-reported health of an individual by scoring distinct domains of wellbeing. The SF-36 is one of the most commonly used non-preference/generic measures of HRQoL and assesses health across eight dimensions, generating individuals' scores for each dimension, but does not allow these individual scores to be combined to a single index score⁴⁷. Another set of scores that were specifically constructed to provide a single index, such as EuroQol's measure EQ-5D index and Health Utility Index (HUI), allow for calculation of Quality Adjusted Life Years (QALYs)³⁴. Although, QALYs can assess a person's quality-adjusted life expectancy, their main use is within a framework of cost-effective analysis in order to assess the improvements as a consequence of an intervention in comparison to no intervention⁴⁸. Projects that do not use economical estimation measures can use mapping models to convert non preference-based measures to the EQ-5D scores, but they have a tendency to over-predict worse health states⁴⁹. When generic measures are not regarded to be appropriate for a condition, mapping cannot be used⁵⁰.

Patient satisfaction is measured by the perceived health experience and is moderated by the patients' expectations. This measure is important in assessing subjective quality of provision of care and processes, and is regarded as an important factor especially in health systems where patients have freedom of choice. In some areas

patient satisfaction has been relatively underrepresented even though it provides an ultimate endpoint to quality assessment⁵¹.

HRQoL measure	Most commonly used questionnaire		Advantages		Disadvantages
Generic / non preference-based	SF-36	-	Widely	-	Lack of overall index score
			evaluated/validated	-	Limited specificity / responsiveness
Generic / preference-based / utility	EQ-5D	-	Single index to	-	Copyright, initial cost and
	QWC-SA		estimate		user fees
	Health Utilities Index 2 and 3 ⁵²	-	Quality of adjusted	-	Lack of specific findings
	SF-6D ⁵³	-	life years (QALYs)		
Condition-specific		-	-Cost utility analysis		
	Oxford Hip Score (OHS) ⁴⁴	-	Symptoms comparison	-	Only relevant to condition it was intended for.
	Disability of Arm, Shoulder and Hand Questionnaire (DASH) ⁴⁵	-	High acceptability to evaluate a specific condition	-	Lack of comparability to other conditions

Table 1-1: Summary of most commonly used types of HRQoL measures

1.1.6 EQ-5D index score

The EuroQol group, established in 1987, is an international network of multidisciplinary researchers responsible for the development of the EQ-5D index (Figure 1.4) widely used in research and service evaluations⁵⁴. The EQ-5D index is a single index on a -0.59 to 1 scale, which can be used to calculate the cost-effectiveness of interventions using QALYs on population level. Although, a license fee will apply for service evaluations, it is estimated that around 50% of researchers use it in their studies evaluating HRQoL⁴³. The concept behind QALY is that outcomes from treatment consist of two components, the quantity and quality of life. QALY incorporate both and is the product of life expectancy and the quality of the remaining life-years. The amount of QALYs is dependent on the number of years of life added as a consequence of treatment. It is based on the assumption that one year lived in perfect health (utility of 1) is worth 1 QALY. When a patient requiring a hip replacement without treatment lives with a HRQoL of 0.5 for another 20 years, and after the intervention lives with a HRQoL of 0.75, the added number of QALYs is 5. Combining this with the costs that are associated with a particular intervention, the cost utility ratio can be calculated and this can subsequently be used for economical evaluations. In the UK, the costs associated with one additional QALY resulting from treatment should be less than the willingness to pay, which is currently set at £30,000 by the National Institute of Health and Care Excellence (NICE)⁵⁵. However, there are several challenges with estimating QALYs after interventions; the increase or decrease in utility score may have resulted from unrelated events, the inability to compare two competing treatments with similar profile, in chronic conditions where survival is not the main issue and the dependency on life context. However, it does provide policymakers with a means to prioritise treatment with maximum health gain in resource limited health system.

For researchers, the meaningfulness of the EQ-5D index depends predominately on their ability to interpret the scores that are generated within clinical conditions. The first approach and most frequently used is the Minimally (Clinically) Important Difference (MID), that is defined as the smallest change that is perceived by the

patient as beneficial or that would result in a change in treatment⁵⁶, which can be estimated using an anchor-based approach. Anchor-based approaches compare changes seen in an individual's HRQoL to an external criterion, such as a clinical measure or using a patient rated global change question⁵⁷. However, there is no universal anchor that can be used as a reference and has to be specific to each patient group. Although, average MIDs have been reported for general use⁵⁸, it is considered best practice to establish a MID for each condition of interest. Several MIDs have been reported for a variety of conditions^{57,59} and established the responsiveness of the index in specific populations.

The second approach is based around the assumption that analysis of individual PROMs items is more responsive than at aggregated level and introduces less bias caused by introduction of exogenous variation when using a single value based on weightings⁶⁰. The distribution of individual elements can provide explanation about the heterogeneity between different providers⁶¹. For example if in a specific population impaired HRQoL is predominantly caused by the mental component rather than a consequence of other pre-existing conditions impacting on the physical component, then improvements resulting from treatment are less sensitive to change in experienced HRQoL.

By placing a tick in one box in each group below, please indicate which statements best describe your own health state today.

Mobility

- I have no problems in walking about ☐
- I have some problems in walking about ☐
- I am confined to bed ☐

Self-Care

- I have no problems with self-care ☐
- I have some problems washing or dressing myself ☐
- I am unable to wash or dress myself ☐

Usual Activities (*e.g. work, study, housework, family or leisure activities*)

- I have no problems with performing my usual activities ☐
- I have some problems with performing my usual activities ☐
- I am unable to perform my usual activities ☐

Pain/Discomfort

- I have no pain or discomfort ☐
- I have moderate pain or discomfort ☐
- I have extreme pain or discomfort ☐

Anxiety/Depression

- I am not anxious or depressed ☐
- I am moderately anxious or depressed ☐
- I am extremely anxious or depressed ☐

Figure 1-4: EuroQol's EQ-5D-3L questionnaire (UK version)

1.1.7 Identification and development of a valid PROMs

For both researchers and policymakers identification of the appropriate PROM is vital to achieving a project's goals and several classification schemes have been proposed that can help facilitate this. Valderas and Alonso based their validated conceptual model mostly on Wilson and Cleary's concepts of bio-psychosocial

health outcomes model dating from 90s^{62,63}. Narrowing down to the three most relevant concepts, construct, population and measurement model, there is a requirement of at least 2 concepts to be present for the tool to be classifiable. These models can, however, be limited by oversimplification in their attempt to provide universal coverage. Research or clinical practice might only be interested in one particular symptom, such as pain, and these classification schemes don't allow identification of a single measure.

In the absence of a validated measure or when there is no possibility to use and adapt an existing one or collect validation data, an entirely new one can be developed using mixed methodology from quantitative and qualitative sources⁶⁴. The first step in the process is characterised by a conceptualisation phase, which gathers information from all available sources (patients, experts and literature). This concept then forms into a draft, where individual items are tested qualitatively by individual or focus groups interviews, to assess the content validity. This has been the focus of much debate following guidance published by the FDA⁴⁰. They argued that direct solicitation of the patients is necessary to ensure appropriate endpoints were used. The specific weight assigned to patients versus expert input in the decision to include or exclude elements is now central to the debate⁶⁵.

Practically, the most suitable PROMs should be identified using eight criteria (Table 1.2). It is important to establish the appropriateness by identification of any of three main measurement objectives. In the event there is no external validator, the ability to *discriminate* (measuring differences between patients) should be considered. Is the measure primarily used to *evaluate* a particular treatment effect before and after (where responsiveness of an instrument can also be tested), or is the measure used in the *prediction* of eligibility for treatment of individual patients or patient groups. This can then be followed by an assessment of the interpretability or meaningfulness of the data results; several strategies can be used to assess important significant differences that need to be established for a new treatment to provide benefit over no treatment; interpretation of scores using normative data, for example using information on normal values for age groups; or comparing results to previously published change scores using the same instrument in a different condition.

The precision of an instrument is concerned with the scaling of items that construct the questionnaire, the simplest form of observation is Yes or No and a seven point-Likert scale (for example, strongly disagree to strongly agree) is normally the most complicated observation for a patient. This should be considered as an important cause of patient compliance. Furthermore, this can be influenced by the acceptability of the instrument to the patient, such as instrument design, which can have a significant impact on unit response rate and therefore requires careful consideration when selecting an instrument.

The reliability of an instrument is concerned with measurement error and this is related to the sample size. Studies with a large measurement error require a larger sample size to reduce noise in order to obtain a signal. The validity of instruments consists of *content and face* validity (does it measure the domain of interest and construct validity that needs to be considered, in particular in multidimensional instruments with several constructs).

For smaller scale studies, the means to collect data can be burdensome, relying on interview techniques administered individually and this can impact on the feasibility of using a certain instruments. This is usually not available for large-scale population cohorts, which as a consequence rely completely on self-administration of questionnaires.

Criteria	Concepts
Appropriateness	Discrimination (if no external validator) Evaluation to track changes overtime Prediction of eligibility
Acceptability	Mode Questionnaire design Health status respondents
Feasibility	Administration (self or interviewer) Processing
Interpretability (Meaningfulness)	Comparison of changes to same instrument in different conditions Minimally clinically important difference Comparison to normative data
Precision	Scaling of items Range of constructs
Reliability	Internal consistency Reproducible
Validity	Construct Content & Face
Responsiveness to change	Change in score following treatment

**Table 1-2: Eight criteria to necessary to select most suitable PROM instrument
(generated from text available online at http://phi.uhce.ox.ac.uk/inst_selcrit.php)**

However, most researchers will opt for an existing measure, provided it has been validated in the patient population. For easy identification of a measure, The Patient-Reported Outcome and Quality of Life Instruments Database (PROQOLID) can be consulted to find the best suitable PROM⁶⁶. A similar database, On-Line Guide to Quality-of-life Assessment (OLGA)⁶⁷, categorises thousands of patient-reported outcomes measures. Both are best considered a reference source to potential users.

The ultimate choice for a specific PROMs measure should primarily be based around the aims of the project. The suitability of specific tool relies predominately on the content validity that determines the appropriateness of the measure for use in the target population.

1.1.8 Current and past PROMs initiatives

PROMs are widely used in early adopting countries such as the United States (U.S.), Canada and the UK. The Federal Drug Agency (FDA) in the U.S. currently recommends and publishes guidance for industry in medical product development to support labelling claims⁶⁸. When used correctly, they can provide support and information is therefore available on labels in medication for chronic conditions⁶⁹. In Europe, the European Medicines Agency (EMA) avoided publishing particular guidance and opted to only provide recommendations to existing guidance⁷⁰. Although, the uptake of PROMs in cancer studies and other clinical trials is variable and requires improvement⁴², the experience in observational studies and surveys in chronic conditions, such as HIV, has been more extensively reported^{71,72}. The experience of routine use of PROMs in medical management of patients with

Rheumatoid Arthritis (RA) over longer periods is also considerable⁷³. However, in more prevalent Non Communicable Diseases (NCDs), such as diabetes, PROMs have rarely been used and there is therefore potential to improve quality of care in these conditions for larger patient populations if applied routinely⁷⁴.

In surgery specifically, there is extensive evidence of the use of HRQoL measures to evaluate surgical practice. Measures, such as SF-36, have been used to objectify important differences in surgical outcomes for many procedures that aimed to establish patient preference for certain procedures^{75,76}. However, most of these studies collected these measures only as secondary outcomes, therefore limiting the interpretation of the data⁷⁷. Researchers have used systematic analysis to provide an exhaustive summary of the use of PROMs in different specialities to compensate for specifically designed trials. In particular in aesthetic surgery, there seems to be a lack of reliable and responsive measures, which is counterintuitive as improving a patients' wellbeing is the primary aim of the intervention⁷⁸.

One of the earliest large-scale attempts to investigate the feasibility of routine collection of PROMs data was the Regional Evaluation of Surgical Indications and Outcomes (RESIO) Project in British Columbia⁷⁹. During the late 1990s, HRQoL outcomes data using the SF-36 on six elective surgical procedures were collected at different time points and results were fed back to clinicians in real time. A substantial proportion (31%) of patients undergoing cataract surgery reported a perfect condition-specific score before their surgery, raising questions about the clinical need for intervention in this particular group. Although, the cost incurred for each patient was reasonable at \$12 a patient, clinicians were generally not positive about the project and it was therefore recommended that for PROMs data to be successful, shared accountability between management and clinicians was required⁸⁰.

During the same period, private sector hospitals in the UK had used SF-36 to evaluate surgical performance in support of clinical governance decisions⁸¹. Control charts were used to evaluate outcomes by alerting on variation or in the event of unusual results, prompting a review or improve processes by initiation of local audits or ideas about ways to improve response rates. The success of this programme led to

the inception of the national PROMs programme in the NHS in England and Wales after initial piloting by Browne et al⁸². The main aims of the programme are:

- To assist clinicians to provide better and more patient-centred care by monitoring of patients' conditions to help decision-making on patient groups;
- To allow for assessment and comparison between providers in order for patients to choose provider based on what other patients say; PROMs data can influence commissioning; increase providers' public accountability by publishing data; data can help with revalidation of doctor's.
- Providing a means of enhancing the calculation of healthcare productivity by including the outcome as well as the quantity of care⁸³.

PROMs have since formed an integral component of the quality accounts in the NHS⁸⁴. Following Lord Darzi's Next Stage Review of the NHS in 2008, routine collection now covers four elective surgical procedures; joint replacements (Hip and Knee), groin hernia and varicose veins. The PROMs questionnaire used in the national programme, contains several elements; the EQ-5D measure, which forms the basis for all individual procedure questionnaires; a condition specific HRQoL measure where available; patient satisfaction questions; twelve patient-reported comorbidities and general questions about health and disability (Figure 1.5). Annually, approximately 250,000 eligible episodes are recorded across the four index procedures. The response rates to the baseline PROMs increased overall from 66% in 2010 to 75% in 2012 from inception mainly determined by adequate response rates in joint replacements and their substantial proportion on overall questionnaires collected. However, there was a decline in the amount of follow-up questionnaires collected towards year 3 (Table 1.3& 1.4).



Figure 1-5: Elements of the PROMs questionnaires in the NHS national PROMs programme

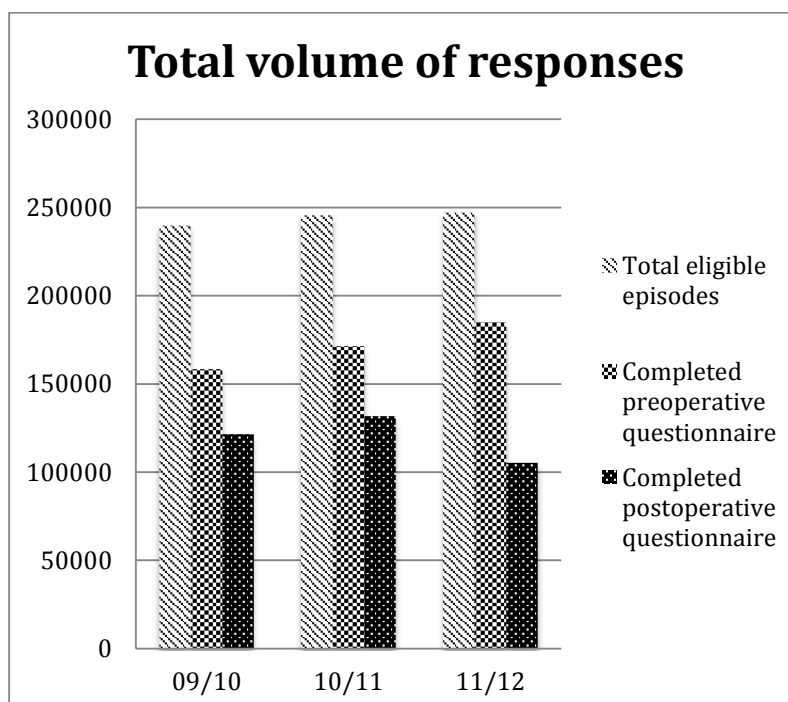


Table 1-3 Total volume of responses for the first three years of the national PROMs programme (adapted from PROMs annual report 2012)

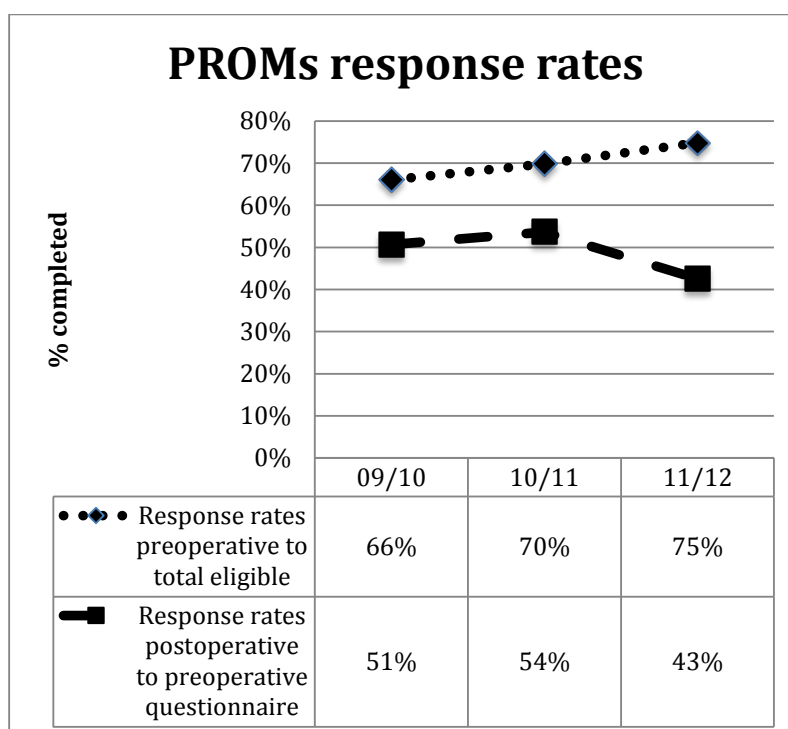


Table 1-4: PROMs response rates for the national PROMs programme in the first 3 years after inception (adapted from source: Information Centre websites: PROMs annual report 2012)

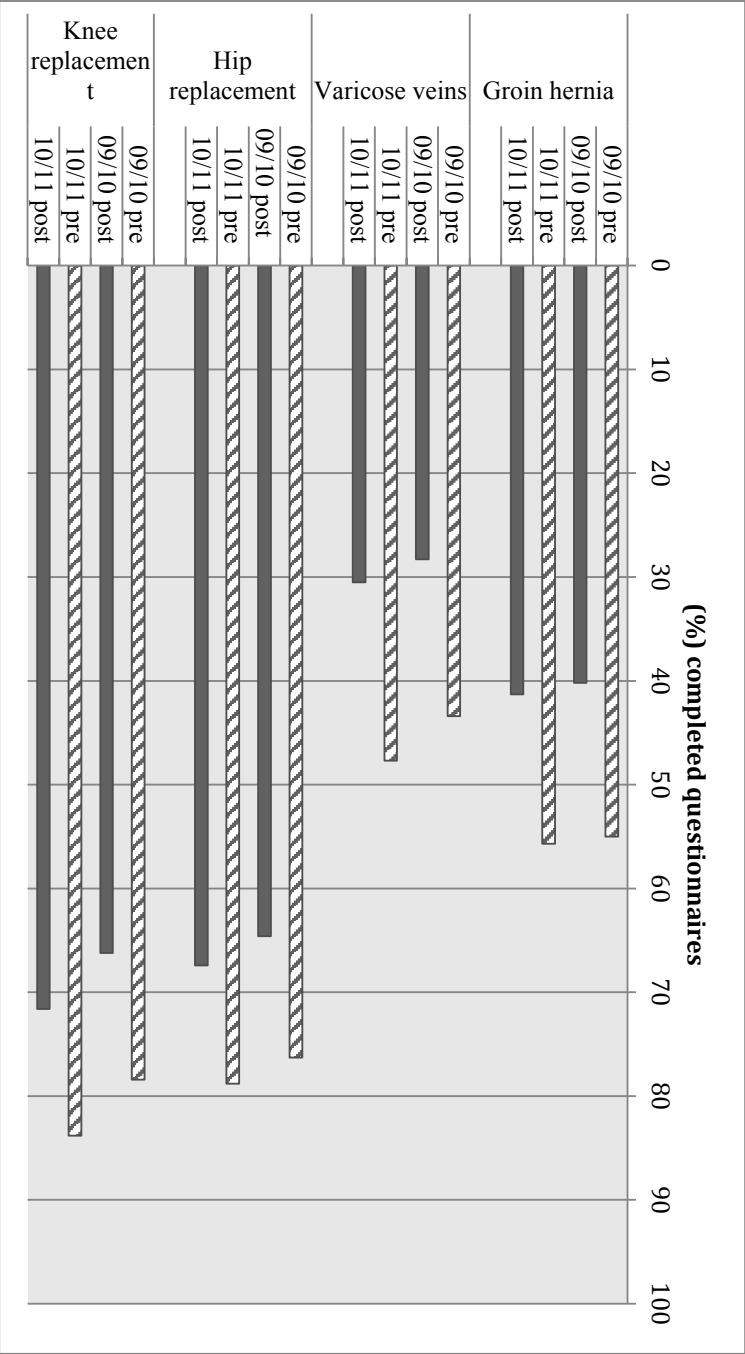


Table 1-5: Response rates for all eligible patients in England and Wales by baseline and follow-up questionnaire response rates and per individual PROMs index procedure (adapted from source Health and Social Care Information Centre)

The response rates for both joint replacement procedures to the baseline questionnaire were all above 75%, however, for the day-case procedures and in particular Varicose Veins were less than 50% (Table 1.5).

According to results published by the Department of Health (DoH), the majority (95%) of patients undergoing joint replacement improved their condition-specific score following surgery⁸⁵. Analysis of the average gain in EQ-5D index score, specifically looking at hip replacement, showed an average gain of 5.2 years of full health. The cost effectiveness ratio was only £1,800, which was significantly lower than the threshold as set by NICE⁵⁵. Currently, this initiative does not provide comprehensive patient-level feedback to clinical teams, which aside from acting as a method of closing an audit loop could provide the opportunity for improving interaction with patients.

Smaller scale initiatives include *PatientViewPoint*, championed by a team at Johns Hopkins hospital, linking routinely collected PROMs in cancer patients to electronic health record to aid patient management⁸⁶. Here, clinicians are provided with suggestions following from the completed questionnaires, allowing for a more patient-centred comparative approach. For patients, the ability to communicate directly with their doctors was of most interest. They are currently undertaken studies to evaluate the impact it has on patient care and outcomes.

The use of HRQoL measures in smaller-scale studies is extensive but is limited by their relative small size and the fact that HRQoL outcomes are predominately secondary outcomes in the trial design. Moreover, the relative small sample sizes hampers risk adjustment for important explanatory variables, such as age and gender, and equally important pre-existing conditions, i.e. comorbidities. Population cohort studies, such as the national PROMs programme, are unique in terms of their design as they aim to capture as many patients as possible. Therefore, they might provide an opportunity to investigate the impact of treatment on HRQoL by allowing for better segmentation of patient groups within the population.

1.1.9 The potential of nationally collected PROMs data

PROMs have the potential to transform and accelerate the way healthcare is delivered. It allows for tracking of performance over time and in the event the patient mix remains unchanged, improved outcomes could be contributed to improved processes or better quality of care. Although, PROMs to some may seem only a tool that quantifies health status, it can actually provide a deeper understanding of the relationship between healthcare inputs (human resources, capital, etc.) and outputs (units of service) to health outcomes that patients consider to be important⁸⁷. For many years, health systems have focussed primarily on measuring productivity by inputs and outputs and based performance on achieved volume. If PROMs are successful in their ability to establish the need and appropriateness of intervention in each patient, interventions that are not considered cost-effective can be avoided without impacting on the overall health status of the population.

Besides the opportunity to establish cost-effectiveness of treatments, the national PROMs linked to HES data includes a variety of patient-reported variables (Figure 1.6) that can facilitate our understanding of variation between patients. The four self-reported adverse events (allergy to drugs, urinary problems, bleeding and wound problems) were considered relevant by the PROMs programme board for patients in the postoperative period. Several studies have described that patients can identify a mixture of complications and process indicators reliably that occur in hospital⁸⁸. Complications that occur in-hospital should be recorded by clinical coders, however, as was previously discussed the accuracy of data collection depends on their potential to influence payment. If they are not considered relevant to the tariff then it is likely they will not be recorded. A recent study showed that the accuracy of HES data compared to medical record review was poor, highlighting the need to capture complication using alternative methods⁸⁹. The opportunity for PROMs lies in complementing the inaccuracies of in-hospital generated data, but more importantly to provide an insight into adverse events that occur in the community. In addition, the influence of adverse events on HRQoL outcomes is underreported in the

literature. This is a required step in further validation of patients reporting adverse events on a national setting.

To assist in risk adjustment of the data, the twelve patient-reported comorbidities (heart disease, high blood pressure, problems caused by stroke, leg pain due to poor circulation, lung disease, diabetes, kidney disease, nervous system disease, liver disease, cancer (within the last 5 years), depression and arthritis) could provide an alternative source of health status information on pre-existing conditions. If they are found to be important confounders in HRQoL outcomes in the national programme, then there is a need for assessment of the reliability of patient reporting information on comorbidities within the national programme. Bayliss and Katz, previously reported that patients can reliably report on their own conditions, however, this evidence comes from small sample sizes with designated follow-ups by researchers^{90,91}.

In conclusion, PROMs can facilitate the collection of outcomes that matter to patients in order to provide patient relevant information to improve patient engagement. As we are moving away from a ‘one size fits all’ approach in the decision-making process, data generated by the patient themselves, i.e. PROMs data, can assist in further segmentation of patients. Identification of important prognostic factors that determine the risks of success or failure and complication can be directly extracted and used in the decision-making process. Methodological issues, such as failing response rates, can influence the quality of the evidence that PROMs data can provide.

1.1.10 Methodological challenges using PROMs

Both research and clinical practice orientated towards patient-reported outcomes can be limited by incomplete data and variable response rates or unit non-response⁹². Unit response rates in smaller (more focused) studies are often better than those of larger studies but both can be affected by publication bias^{85,93}. Unit response rates

are a direct consequence of the method of data collection, which traditionally uses paper-based questionnaires. The underlying constructs in terms of patient-related factors that are frequently associated with non-response to follow-up questionnaires are young age and lower socio-economic status^{83,94,95}. Responding participants have normally better subjective health⁹⁶⁻⁹⁸. The importance of responder bias has been highlighted previously in the literature and non-response has been associated with poorer outcomes⁹². Controlling for this type of bias can improve statistical modelling⁹⁹. In addition, the inclusion of irrelevant content, be it only to the patient, can potentially alienate participants and form part of the explanation of lower response rates of overall questionnaires and incomplete forms¹⁰⁰. In addition, incomplete forms can also be impacted by item non-response, a concept that is not well documented in the literature but potentially can influence data quality¹⁰¹.

The *content* of a PROM can be divided into several elements; specific wording and instructions chosen for questions/statements; use of examples; response categories; visual design elements and questionnaire order. All these elements can influence the likelihood of response to each PROM questionnaire and item-response. Therefore qualitative research is required to evaluate the impact that these elements will have in order for successful implementation into routine practice. Even translation into another language can impact on the content validity of a specific score and validation is therefore required¹⁰².

The *mode*¹⁰³ and *instrument design*¹⁰⁴ are considered to be the two areas of interest in identifying potential concerns with data methodology. The mode of a questionnaire can be divided into two main groups; traditional or paper-based format relying on manual data collection in care settings (or postal in nature) and Health Information Technology (HIT) based, which employ any form of technology platform for data collection. The use of HIT in collecting healthcare data throughout the process remains disappointing, and this is not different in PROMs studies. Even though the rapid onset and availability of mobile technology platforms have provided opportunities to collect information from the patient and thereby reducing costs that are associated with paper data collection, resistance against the use of NTP remains, predominately around the inability of patients who do not have access to technology.

However, digitalising data from the time it is generated can bring about cost savings that struggling health systems desperately need.

1.1.11 PROMs and technology

As the previous section has highlighted, one of the most noticeable methodological challenges is to improve the way in which the data is collected. Traditional paper-based questionnaires are resource intensive and time consuming. Manual transformation of paper questionnaires to IT databases seems unnecessary in this day and age, where the Personal Computer (PC) has penetrated our homes so rapidly. In contrast to other industries, there has been a relative slower adoption of technology in healthcare¹⁰⁵. In recent years a surge in the use of technology to improve processes, i.e. the move from paper to electronic medical record keeping, has demanded a rapid increase in adoption from its users, in this case professionals. Besides collecting patient information with the help of automated processes, technology has also allowed for improvement and cost reduction in providing (customised) information to the patient, another step forward in improving communication between doctor and patient¹⁰⁶.

Technology's role in improving productivity is frequently dismissed based on cost grounds. However, as Brynjolfsson and Saunders indicate, information technology can increase productivity, but this has to be complemented with other interventions such as organisational restructuring, process changes and training¹⁰⁷. For healthcare an important dimension to this is the role of the patient, and facilitating their involvement through the use of technology has the potential to improve both quality and contribution to service productivity if combined with other interventions.

The scale and pace in society's use of technology highlights how the public has accepted this and arguably its role can be potentially unlimited. Technology's social ubiquity means that usage penetration is democratised across age groups and socio-economic classifications. For example, in 1994, 3 million people were connected to the Internet, today that number is approximately 2.1 billion or one-third of the world's population.

There are important factors that moderate the public's acceptance of technology in healthcare. The latest model, described by Venkatesh et al, highlighted several constructs that influence this acceptance¹⁰⁸. Whilst the difference in eventual usage based on gender has been explored in a number of studies, age is often an important consideration in healthcare^{109,110}. There exists an inverse correlation between age and the extent to which an individual found using technology is free from effort¹¹¹. Young individuals tend to require less support and feature increased adaptation compared to older individuals. However, Fisk et al. describe that despite age-related decline in physical abilities, older adults are remarkably adaptive and can continue to perform at a high level¹¹². It can be assumed that with increasing exposure to technology, the gap between young and old will gradually diminish, and this makes decision making about using technology less burdensome.

Computer Adaptive Testing (CAT) based tools have tested the advances in computer technology and the strengths of modern measurement theory. Computer adaptive testing in patient-reported outcomes provides the opportunity to tailor the questionnaires to the individual. They already have been applied to osteoarthritis and showed that a higher degree of precision can be achieved with shorter questionnaires, and statistical similarity was noted with the regular patient-reported outcome measures¹¹³. Computer adaptive testing based tools require a large pool of items from which the computer selects the most appropriate items for a patient. All items are calibrated on a common metric and allows for comparison irrespective of which items are answered.

One initiative that is based on computer adaptive testing principles is the Patient Reported Outcome Measurement Information System (PROMIS) project. The development of this project followed a programme initiated by the National Institute of Health (NIH). The programme promises to utilise rigorous qualitative and quantitative methods to develop, validate, and standardise PROMs tools¹¹⁴. Several areas in healthcare have reported satisfying completion rates using the 'PROMIS' item bank for specific populations^{115,116}. Access is currently not limited by licensing fees, however a technology platform, i.e. PC or tablet is needed. It is also possible to predict EQ-5D index scores from studies using the PROMIS item bank that lacks assessment of health preferences¹¹⁷.

Better access via multiple platforms to obtain self-reported HRQoL from disabled patients, more flexibility in form, more rapid collection of data and less processing errors and easier feedback to healthcare providers and researchers have been reported¹¹⁸. Leidy et al. previously discussed the movement in patient-reported outcomes towards paperless data capture but identified difficulties in adapting existing questionnaires because of validation of only one format¹¹⁹.

To date, integrated technology for patient-reported outcomes data collection has been underreported and looking forward provides the opportunity, not only to facilitate data collection, but achieve this in a cost effective and labour efficient manner. Currently most existing patient-reported outcome measures are validated and standardised but recent interest in customisation, which takes in the perspective of a single patient rather than the average patient, will add an extra 'dimension' to patient-reported outcome measurement.

1.1.12 Public health implications

The national PROMs programme has the potential to improve quality of care for patient undergoing elective surgical procedures. Moving away from volume-based care towards a more patient-centered approach, the patients can provide us with a unique insight into their health leading up to and following treatment. For this reason, routinely collected PROMs forms part of the NHS Outcomes Framework⁸⁴, which holds NHS England as overall provider of care accountable for performance. The data of all four procedures are now being consolidated into two indicators, one physical and one mental health, in line with the Government's focus on raising the profile and importance of mental health⁸⁴. However, PROMs data is a much richer data source that can provide the evidence needed to make important decisions about the 'value for money' of interventions. For commissioners, there is a constant requirement to establish the need for treatment in specific patient population that is delivered in a cost-effective way. Commissioning has traditionally focussed on single outputs of care and thereby sustaining a fragmented system that did not

encourage integration of care. The NHS Confederation, an organisation that represents institutions that commission and provide NHS services, has called for Outcome-based commissioning, a system where outcomes and experiences of patients are at the very centre of payment for health and care services. For surgical procedures, such as joint replacements, a pathway approach is preferred, which allows for longitudinal following of the patient¹²⁰. The Swedish Hip Arthroplasty Register has successfully adopted this approach as it encourages local and national improvement following analysis of routinely collected PROMs data¹²¹. However, no further information is provided as to how this can be achieved and the data is not shared publicly. By contrast, the data generated by the NHS PROMs programme are disseminated online via the government website [<http://www.hscic.gov.uk/proms>], however, there is no evidence that it has become meaningful to both patients and providers. This highlights the trend of a lack of publically available data that can inform patients in their health choices. It is difficult, if not impossible, for patients to make the right informed decision about which provider supplies the best quality of care.

For providers, the ability to compare performance using PROMs data could be the first step in quality improvement. Although, the fear of ‘naming and shaming’ in benchmarking can be justified, the approach hospitals should take its learning from better performers. For this, adequate case-mix and risk adjustment is required to allow for further segmentation of data on the individual procedures. Clinicians themselves should be encouraging data collection by patients, as they play a vital role in the success of PROMs. Explaining the importance of PROMs data to facilitate a patient-centered approach will hopefully close the gap between what they think is important and what patients believe is important. This misalignment between patients and clinicians is highlighted by evidence that describes that clinicians report fewer problems in association with conditions¹²², underestimate the severity of problems and overestimate the improvements causal to treatment^{123,124}.

For now, further adoption is prevented by a lack of evidence that utilising PROMs data actually has a positive impact on health outcomes¹²⁵⁻¹²⁷. Therefore, augmenting traditional outcomes with PROMs might provide us with a more holistic approach to

measuring quality of care. Further focus on the individual, the team and the overall organisation in the health system can lead to accelerated multi-level change¹²⁸.

As services will continue to move towards a more integrated format, the richness of data collected by primary care in a system that is patient-centred could pave the way to better understand true outcomes after surgery.

1.1.13 Conclusion

Established healthcare systems are struggling to deal with the socio-economic and health challenges now being witnessed globally. The ageing population carries with it a consequential increase in consumption of healthcare, forcing health systems to develop innovative ways to deliver care whilst improving quality of care and containing costs. One approach health systems are aiming to contain cost is by restricting access to treatments that are either too costly or provide no additional benefit to the patients by means of cost-effective analysis. This is measured by QALYs, which reflect how many years of high quality of life a patient gains from the intervention. These QALYs can be calculated from HRQoL outcomes collected before and after treatment directly from patients. Newly developed treatments can be compared to existing by calculating the cost-effectiveness ratio to determine the best value treatment. The importance of these analyses in the decision-making on a policy level highlights that outcomes that matter to patients are becoming central to the way care is measured and organised.

Although, the cost-effectiveness of most (new) treatments is predominately assessed in a small clinical trial setting, the measures that collect HRQoL outcomes, i.e. PROMs, on a national scale can facilitate the transformation of the way we evaluate treatments and improve our means to evaluate quality of care. These end-points of care provide a more comprehensive view on the impact of treatment on quality of care compared to traditional clinical outcomes, such as mortality and morbidity.

These measures will therefore likely be extended to cover a wider range of treatment available in the NHS.

The current use of nationally collected PROMs data, covering four index procedures, is limited to informing policymakers about overall improvement in the entire population. There is a deficiency of evidence of their influence on the decision-making process by clinicians or patients. It is here, where they might provide the most value in their ability to segment patient groups to allow for a more individualised decision-making process. By knowing which patient is at risk of a deterioration of HRQoL or adverse events, quality improvement can be directly targeted at those patients.

The success of PROMs will depend on clinicians' engagement, they should share accountability for outcomes produced and collected by PROMs data. The opportunity to compare performance, provided the methodological concerns are addressed, can promote sharing of experiences to improve quality. Moreover, it will improve patient engagement, as outcomes that matter to both stakeholders will be the priority.

1.1.14 Key points arising from chapter 1

- A multidimensional approach with a focus on patient-relevant outcomes to measuring quality of care is required to facilitate the transition from physician to patient-centered care models.
- Collecting PROMs on a national level have the potential to improve quality, however, current evidence generated from outputs of the national PROMs programme are limited to a policy level.
- Failing unit response rates, in particular for Varicose Veins patient, in the national PROMs programme, necessitate further research into explaining variables both quantitative and qualitative in origin.
- Clinicians' engagement is vital in the successful utilisation of PROMs data in terms of initiating quality improvement efforts.
- Health systems alike need to investigate the value of Information Technology (IT) solutions to promote cost-savings.
- PROMs can provide a bridge between primary and secondary care by objectifying what happens in 'real life' to patients in terms of their health status (HRQoL and pre-existing conditions), adverse events and patient satisfaction.

Chapter 2

ROUTINE MEASUREMENT OF PATIENT-REPORTED OUTCOMES IN ELECTIVE INGUINAL HERNIA REPAIR: RETROSPECTIVE ANALYSIS OF NATIONALLY COLLECTED DATA IN ENGLAND

The following chapter was submitted to:

- Journal of Health and Quality of Life outcomes
- Featured as a poster at European Hernia Society (EHS) 2014 in Edinburgh

2.1 INTRODUCTION

The introduction has highlighted the value of routinely collected PROMs data, particularly in joint replacement surgery, on a national setting. The impact of symptoms on daily activities associated with osteoarthritis of the hip joint on daily activities is well established through wide acceptance of the disease-specific score, i.e Oxford Hip Score (OHS). For inguinal hernia, one of the four index procedures, the use of a disease-specific score is not common practice, making it more challenging to assess change following treatment. The decision to include inguinal hernia in the national PROMs programme was primarily based around the direction of the National Audit Commission, a governing body in charge of protecting public spending. They consider an elective inguinal hernia operation mainly a ‘cosmetic’ procedure and therefore an area of interest to potentially restrict access¹²⁹.

Inguinal hernia repair is one of the most common general surgical procedures; around 60,000 are performed annually in England and Wales. Traditionally, this procedure is performed using the ‘Lichtenstein’ technique, a ‘tension free’ open approach where a MESH (synthetic patch) is placed over the defect. For patients, the decision-making process currently relies on individual surgeons assisted by national guidelines, suggesting that healthy male patients, with symptoms affecting daily life, should be offered open repair for a ‘simple’ primary unilateral hernia¹³⁰ and laparoscopic approach should be reserved for recurrent and/or bilateral repairs¹³¹. In asymptomatic patients, particularly in higher risk categories, a ‘watchful waiting’ approach can be considered¹³², although contemporary data has questioned the longevity of this approach¹³³.

The final decision making process, however, not only relies on the preferences and technical abilities of the surgeon, but also on the local availability of equipment, local hospital policies and funding arrangements. There is a significant amount of evidence exploring the differences between the open and laparoscopic approaches but a deficiency of evidence in adherence to clinical guidelines in the decision-

making process. Recent evidence suggests that pain, and in particular chronic pain, should be the driving factor in decision-making¹³⁴.

For inguinal hernia surgery, evidence from randomised trials reporting on Health-related Quality of Life (HRQoL) outcomes after different surgical techniques have marginally favoured laparoscopic repair over open, principally by demonstrating only early difference in the postoperative period whilst these differences normalise after three months and beyond¹³⁵⁻¹⁴⁰. These early differences in outcomes may not be considered relevant on a population health level, as the ultimate goal is to improve overall health status of patients irrespective of better short-term performance. Although, patients undergoing laparoscopic repair reported less pain and their return to usual activities is faster, the latter is very dependable on a patients' compliance to postoperative instructions.

Population level data has the opportunity to augment the evidence derived from RCTs and additionally provides a novel viewpoint. RCTs and their inherent strict inclusion criteria may fail to appreciate heterogeneity in patient demographics and the resulting variation in health needs. This can limit the applicability of evidence from RCTs to all patient groups.

The primary objective of this study was to assess the usability of population level routinely collected PROMs data for inguinal hernia repair to assess appropriateness of treatment and determine differences in patient-centred outcomes between the two approaches.

2.2 MATERIALS AND METHODS

2.2.1 Study population

The study cohort was identified from patients who participated in the national PROMs programme in the NHS in England¹⁴¹, between January 2009 and February 2011. This programme, mandatory for healthcare providers, offers all patients undergoing groin hernia repair the preoperative questionnaire in either the pre-assessment clinic or on admission asking them about their general wellbeing and two condition-specific questions (“Have you had a previous hernia operation on the side on which you are about to have surgery” and “For how long have you had symptoms of a hernia”). They are then posted a follow-up questionnaire at three months, where the same questions are repeated and extended with their views on the outcomes of their operation. All patients, responders and non-responders, who completed a preoperative PROMs questionnaire, were included in the baseline analysis, and patients who completed the follow-up questionnaire at three months, were included in the postoperative analysis. The raw dataset was obtained from the Health and Social Care Information Centre (HSCIC). At source, PROMs data was linked to the patient level Hospital Episode Statistics (HES) record to validate the individual patient. Both the baseline and the follow-up questionnaires are included (Appendix W).

2.2.2 Data extraction

Data for elective primary repair of inguinal hernia using insert of prosthetic material (Office of Population Censuses and Surveys Classification of Surgical Operations and Procedures 4th revision (OPCS-4) code T20.2), appearing in the primary procedural group, with or without Y75.X (Y75.1 or Y75.2), indicating laparoscopic approach to the abdomen, were extracted (Table 2.1).

<p>Primary procedure code</p> <p>Primary repair of inguinal hernia using insert of natural material (T20.1)</p> <p><u>Primary repair of inguinal hernia using insert of prosthetic material (T20.2)*</u></p> <p>Primary repair of inguinal hernia using sutures (T20.3)</p> <p>Primary repair of inguinal hernia and reduction of sliding hernia (T20.4)</p> <p>Other specified primary repair of inguinal hernia (T20.8)</p> <p>Unspecified primary repair of inguinal hernia (T20.9)</p>
<p>For laparoscopic group: T20.2 plus code(s)</p> <p><u>Laparoscopically assisted approach to abdominal cavity (Y75.1)*</u></p> <p><u>Laparoscopic approach to abdominal cavity NEC (Y75.2)*</u></p>
<p>Site</p> <p><u>Right (Z94.2)*</u></p> <p><u>Left (Z94.3)*</u></p> <p>Bilateral (Z94.1)</p> <p><u>Unilateral (Z94.4)*</u></p> <p><u>Laterality (Z94.9)*</u></p>

Table 2-1: OPCS-4 codes used to determine primary unilateral MESH inguinal hernia repair

Cases were excluded if they were emergencies, if the patient was under the age of 16, a bilateral or recurrent repair, the case was recorded as a mortality or a bowel resection was performed as part of the operation. All duplicate cases were identified (Figure 2.2)

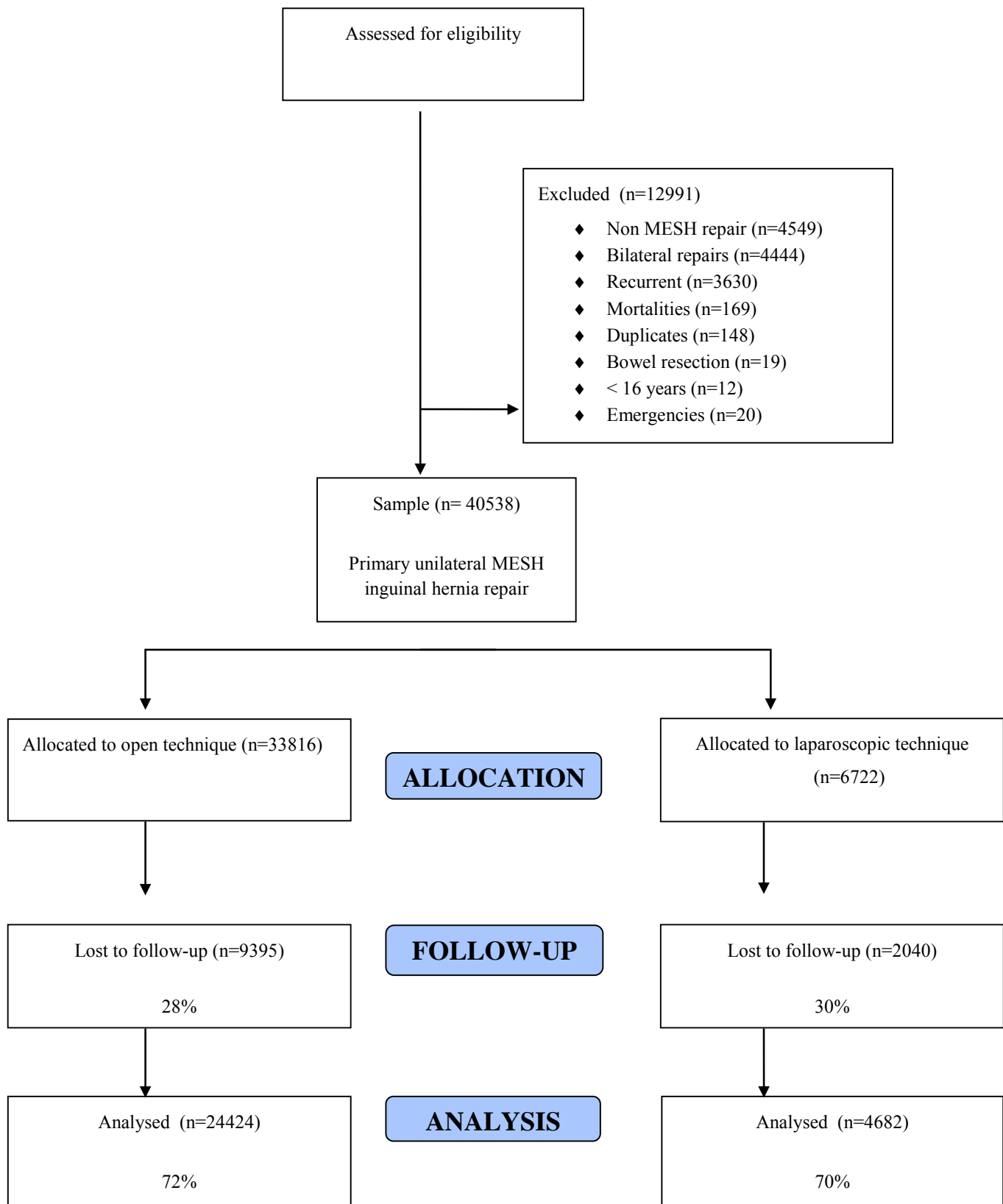


Figure 2-1: Flowchart describing data segmentation into primary unilateral "open" and "laparoscopic" inguinal hernia repair in national PROMs programme

The NHS classification service, responsible for maintaining clinical coding standards and promoting consistency of classification, was used to verify the OPCS-4 codes and coding combinations to ensure that the patient data extracted was consistent with the clinical question being asked.

2.2.3 Clinical outcome variables

The following parameters were obtained from the preoperative questionnaire, patients' age and gender and self-reported general health, comorbidities, duration of symptoms and having had previous surgery. Symptom duration was defined by two groups based on whether symptoms had been present for greater or less than one year. General health was scored using a Likert scale, with 1 being excellent and 5 being poor. Self-reported comorbidities were categorised into heart disease, high blood pressure, problems related to stroke, leg pain on walking due to poor circulation, lung disease, diabetes, kidney disease, liver disease, cancer, depression and arthritis. The primary outcome measures, derived by virtue of their inclusion on the PROMs questionnaire, were self-reported postoperative adverse events, hospital readmissions (defined as a new hospital admission after discharge from either outpatient surgery or an inpatient stay), length of stay, patient satisfaction, and the EQ-5D index score. Postoperative adverse events were classified as: (1) allergy or reaction to drug, (2) urinary problems, (3) bleeding and (4) wound problems. Patients' level of satisfaction was scored with two questions ("How would you describe the results of your operation?" and "Overall, how are your hernia problems now, compared to before your operation?"), with answers based on a five point likert scale ("excellent, very good, good, fair and poor" and "much better, a little better, about the same, a little worse and much worse" respectively).

In addition, socioeconomic deprivation and ethnicity were identified in the HES component of the dataset. Socioeconomic deprivation was measured using the English Index of Multiple Deprivation (IMD) for 33,482 areas based on patients' residential postcode¹⁴², that cover areas of about 400 households. The IMD is a weighted average of eight indices that cover income, employment, health and

disability, education skills and training, barriers to housing, living environment and crime. Quintile groups were formed, where group 1 was considered most deprived and group 5 was considered least deprived. Two categories were formed for ethnicity, white and non-white because of the small numbers in each of the ethnic subgroups.

Both the baseline and follow-up questionnaires included the EQ-5D index score (a generic preference-based measure of HRQoL)⁵⁴. This score is composed from five individual dimensions (mobility, self-care, daily activities, pain/discomfort and anxiety/depression), which are scored on a three point likert scale. These can be individually analysed or combined into a single index score (scores range from -0.59 (worse than death) to 1.00 (perfect health status). For the purpose of the analysis, the single index score was categorised into seven groups (-.59 to 0, 0.01 to 0.2, 0.21 to 0.4, 0.41 to 0.6, 0.61 to 0.8, 0.81 to 0.99 and 1) to allow for identification of differences between groups.

2.2.4 Statistical methodology

Categorical variables were analysed with the χ^2 test. For test of significance p values < 0.05 were considered statistically significant. SPSS version 19.0 (SPSS, IBM Chicago, Illinois, USA) was used for statistical analysis. The EQ-5D index score and individual dimensions were reported as means with standard deviation. The changes between baseline and three months (follow-up) were calculated and independent samples t-test in normally distributed data was used to determine whether statistical difference was seen. Linear trend was tested between length of stay and EQ-5D index means by linear by linear association χ^2 statistic.

2.3 RESULTS

2.3.1 Demographics

Across English NHS hospitals, 53,529 patients were identified having undergone a groin hernia procedure between January 2009 and February 2011. Of these 33,816 underwent open and 6,711 underwent laparoscopic primary unilateral open or laparoscopic inguinal repair and met the inclusion criteria. 29,106 (71.8%) patients completed the three-month follow-up questionnaire. Response rates were similar between both treatment groups 72% vs. 70% (Figure 2.1).

Table 2.2 shows the baseline characteristics of the patients according to the treatment groups. Across both groups, the majority of patients were white males. In the laparoscopic group, patients were on average younger compared with those in the open group (54.3 years SD 15.9 vs. 58.9 years SD 16.7 respectively), reported fewer comorbidities and were more likely to have had symptoms for less than a year. Patients in the laparoscopic group lived more frequently in the least deprived group and less frequently in more deprived areas due to smaller than expected proportions in group 1 (most) 2 and 3, compared with a greater than expected proportion of patients in the least deprived group (shown as standardised residuals).

Overall in both treatment groups, non-responders were significantly younger (62.3 years vs. 50.1 years in the open and 58.1 years vs. 45.6 years in the laparoscopic group), more frequently of non-white ethnicity and were living in more deprived areas. They also reported a lower prevalence of comorbidities with exception of depression.

	Open repair				Laparoscopic repair				Open vs Lap
	All patients	Responders	Non-responders		All patients	Responders	Non-responders		All patients
	% (std residual)	% (std residual)	% (std residual)	p-value	% (std residual)	% (std residual)	% (std residual)	p-value	p-value
N (number)	33816	24421	9395		6722	4682	2040		
Age in years (mean / SD)	58.9 / 16.7	62.3 / 14.7	50.1 / 17.9		54.3 / 15.9	58.1 / 14.5	45.6 / 15.7		<0.01
Gender									
male	93.2 (-.5)	92.9 (-.5)	94.1 (.9)		94.8 (1.1)	94.6 (.2)	95.1 (-.1)		
female	6.8 (1.9)	7.1 (2.0)	5.9 (-3.9)		5.2 (-4.2)	5.4 (.5)	4.9 (-.7)		
Ethnicity									
White	82.9 (-3.5)	84.1 (1.8)	79.4 (-3.0)		81.8 (3.5)	83.3 (.9)	78.2 (-1.3)		
Non-white	4.3 (3.5)	3.2 (-8.0)	7 (13.0)		4.2 (-3.5)	3.1 (-3.8)	6.8 (5.8)		
missing	12.9	12.6	13.5		14	13.6	15		
Self-reported Comorbidity									
Heart disease	9.7	10.7	7.0		5.7	6.7	3.3		<0.01
High blood pressure	26.1	29.2	18.2		21.8	25.4	13.6		<0.01
Problems caused by stroke	1.6	1.7	1.4		0.9	1.2	0.4		<0.01
Poor circulation	4.8	5.1	4.1		3.2	3.6	2.4		<0.01
Lung disease	6.2	6.6	5.2		4	4.2	3.5		0.15
Diabetes	5.1	5.5	4.0		3.6	4	2.7		<0.01
Kidney disease	1.4	1.5	1.1		0.7	0.9	0.4		0.03
Disease of nervous system	1	1.1	0.8		0.7	0.7	0.6		0.53
Liver disease	0.6	0.5	0.6		0.3	0.3	0.2		0.93
Cancer(within last 5 yrs)	4.4	5	2.8		2.5	3.1	1.2		<0.01
Depression	4.6	4.1	5.9		3.9	3.5	5		0.01
Arthritis	16.6	18.2	12.4		13.2	15	9.2		<0.01
General health									
excellent	10.2 (-1.9)	10.2 (.1)	10.1 (-.1)		12.3 (4.2)	12.8 (1.0)	11.1 (-1.5)		<0.01
very good	39 (-2.1)	39.9 (2.1)	36.7 (-3.4)		43.4 (4.6)	43.9 (.5)	42.3 (-.8)		
good	36.7 (.9)	36.3 (-.9)	37.5 (1.5)		35 (-2.0)	34.5 (-.6)	36.1 (.9)		
fair	11.2 (3.5)	10.9 (-1.5)	12 (2.4)		7.6 (-7.8)	7.3 (-.6)	8.1 (.9)		
poor	1.5 (2.2)	1.3 (-2.3)	19 (3.7)		0.6 (-4.9)	0.4 (-2.2)	1.2 (3.3)		
missing	1.4	1.3	1.7		1.1	1.1	1.3		
Social deprivation									
1- (most)	15.0 (1.2)	12.8 (-9.0)	20.8 (14.5)		13.5 (-2.7)	10.7 (-5.3)	20 (8.0)		<0.01
2	18.3 (1.5)	17.2 (-3.9)	21.1 (6.3)		16.3 (-3.4)	14.5 (-2.9)	20.1 (4.4)		
3	21.8 (1.0)	21.8 (0)	21.8 (0)		20.3 (-2.3)	20.7 (.7)	19.1 (-1.1)		
4	22.5 (-.8)	23.9 (4.7)	18.8 (-7.6)		23.8 (1.7)	24.8 (1.5)	21.2 (-2.3)		
5- (least)	21.9 (-2.6)	23.7 (6.2)	17 (-10.0)		26 (5.8)	29 (4.0)	19 (-6.1)		
missing	0.6	0.6	0.6		0.4	0.3	0.5		
Symptom period									
< 1 year	67.4 (-1.2)	68.4 (1.8)	64.7 (-2.9)		70.8 (2.6)	72.4 (1.3)	67.1 (2.6)		<0.01
> 1 year	31.7 (1.7)	30.8 (-2.6)	34.1 (4.3)		28.7 (-3.9)	27.1 (-2.0)	32.3 (-3.9)		
missing	0.9	0.8	1.2		0.5	0.4	0.6		
Previous surgery (% yes)	5.2	5.1	5.4		6.1	6.2	5.9		0.68
									<0.01

Table 2-2: Baseline characteristics of all primary unilateral MESH inguinal hernia repair patients by technique and response/ non-response with consequent p-values or standardised residuals

2.3.2 Baseline HRQoL

In the laparoscopic treatment group, patients reported proportionally better general health and patients in the open treatment group reported proportionally more fair and poor health than expected (Table 2.2).

The mean baseline EQ-5D index score of all patients in the open group was 0.78 and in the laparoscopic group was 0.80 (Table 2.3). This was similar when only considering responders who had completed a follow-up questionnaire (0.79 vs. 0.81). Non-responders reported a lower EQ-5D index mean. The majority of patients reported an EQ-5D index score between 0.61 and 0.80 irrespective of treatment group (58% versus 60%). 27.4% and 30.2% of patients reported perfect preoperative health in the open and laparoscopic group respectively (Figure 2.2a).

2.3.3 Clinical outcomes

Open repair, compared with laparoscopic repair, was associated with a reduced odd of urinary problems (OR 0.55, 95% C.I.=0.49-0.61, $p<0.01$). This was predominately determined by patients in all age groups above 35 (Table 2.4). There was an observed association between the number of reported urinary problems and increasing length of stay for patients irrespective if they were in the open or laparoscopic group (Appendix U). This association was more pronounced for the laparoscopic group with more than 50% of patients who stayed three or more nights reporting urinary problems.

Younger patients (<25 and between 35-44) undergoing open procedure reported significantly more bleeding (OR 3.2, 95% C.I.=1.24-8.23 and OR 2.14, 95% C.I.=1.02-4.47 resp) and wound problems (OR 2.14, 95% C.I.=1.02-4.47, $p=0.04$ and OR 1.70, 95% C.I.=1.22-2.35, $p<0.01$ resp). There was a trend towards decreased reporting of readmission across all age categories in open repair, however, only in two categories (25-34 and 35-44) this was significant (OR 0.54, 95% C.I.=0.30-0.98,

$p=0.04$ and OR 0.51, 95% C.I.=0.32-0.82, $p<0.01$ resp) (Table 2.4) Readmitted patients undergoing open repair were more likely to be older, more frequently report comorbidities along with fair and poor baseline general health. They were also more likely to be from socioeconomic deprivation group 1 (most) and less likely to be from socioeconomic deprived group 5 (least) and more likely to have had previous surgery (Appendix T).

2.3.4 Postoperative HRQoL and satisfaction

In both groups there was an increase in the mean postoperative EQ-5D index score (Table 2.3), with the open group reaching a mean of 0.87 and the laparoscopic group a mean of 0.90. The proportion of patients reporting a perfect health score of 1 increased significantly in both groups (27.4% to 55.8% in the open group and 30.2% to 66.4% in the laparoscopic group), with a similar decrease in the proportion of patients reporting a value of 0.61-0.80 (60.2% to 30.3% and 60.3% to 23.3% respectively) (Figure 2.2b).

A sensitivity analysis (Table 2.3), which excluded patients reporting perfect health preoperatively, resulted in larger difference between baseline and follow-up EQ-5D index score predominantly from a lower baseline score (open group 0.71 to 0.84, laparoscopic group 0.73 to 0.88).

Table 2.5 shows the difference in proportions for the five dimensions that generated the EQ-5D index score. Postoperatively the predominant change was the increased number of patients reporting a score of 1 (no problems / no) for the dimensions 'usual activities' and 'pain/discomfort'. This increase was more pronounced for the laparoscopic group (10.8% and 38.6% respectively) compared with the open group (6.5% and 32.6%).

Patients who were readmitted reported a smaller increase in their follow-up EQ-5D index score (open group 0.73 to 0.75, laparoscopic group 0.75 to 0.81), compared with non-readmitted patients (open group 0.79 to 0.88, laparoscopic group 0.81 to 0.91). For both open and laparoscopic repair, the occurrence of a complication

reduced the reported improvement in mean EQ-5D scores. Similarly, when patients were not treated as outpatient or overnight stay, the increase in postoperative EQ-5D was reduced, although for the laparoscopic group this was only true if the patient had a length of stay of three or more nights (Table 2.3). There was also an association between an increasing length of stay and a lower reported baseline EQ-5D (linear trend in both groups $p<0.01$).

For both the open and laparoscopic groups, the majority of patients reported 'excellent', 'very good' or 'good' satisfaction three months after surgery (total 92.6% and total 93% respectively) (Table 2.6). Similarly, 94.6% (open) and 95% (laparoscopic) of patients reported improvement in their symptoms following surgery.

		Open technique			Laparoscopic technique		
		baseline mean (SD)	postoperative mean (SD)*	Difference	baseline mean (SD)	postoperative mean (SD)*	Difference
All patients		0.78 (0.20)	0.87 (0.19)	0.09	0.80 (0.19)	0.90 (0.18)	0.1
Responders		0.79 (0.20)	0.87 (0.19)	0.08	0.81 (0.18)	0.90 (0.18)	0.11
Non responders		0.76 (0.22)	n/a	n/a	0.77 (0.21)	n/a	n/a
Age	UK average ¥						
16-24	0.94	0.80 (0.19)	0.91 (0.18)	0.11	0.79 (0.21)	0.93 (0.15)	0.14
25-34	0.93	0.78 (0.19)	0.88 (0.15)	0.11	0.80 (0.17)	0.91 (0.17)	0.11
35-44	0.91	0.78 (0.20)	0.87 (0.18)	0.09	0.79 (0.18)	0.91 (0.17)	0.12
45-54	0.85	0.78 (0.20)	0.87 (0.19)	0.09	0.79 (0.19)	0.89 (0.19)	0.10
55-64	0.80	0.79 (0.20)	0.89 (0.19)	0.10	0.81 (0.19)	0.91 (0.18)	0.10
65-74	0.78	0.79 (0.21)	0.87 (0.20)	0.09	0.81 (0.18)	0.90 (0.17)	0.09
75+	0.73	0.75 (0.23)	0.81 (0.23)	0.08	0.77 (0.22)	0.85 (0.20)	0.08
Readmission							
yes		0.73 (0.24)	0.75 (0.27)	0.02	0.75 (0.20)	0.81 (0.27)	0.06
no		0.79 (0.19)	0.88 (0.18)	0.09	0.81 (0.18)	0.91 (0.17)	0.10
Length of stay							
0 (daycase)		0.80 (0.19)	0.89 (0.18)	0.09	0.82 (0.18)	0.91 (0.17)	0.09
1 (overnight)		0.76 (0.21)	0.84 (0.21)	0.08	0.80 (0.18)	0.89 (0.19)	0.09
2		0.73 (0.23)	0.80 (0.23)	0.07	0.76 (0.22)	0.86 (0.21)	0.10
3 nights or more		0.70 (0.24)	0.75 (0.27)	0.05	0.72 (0.23)	0.77 (0.28)	0.05
Complications							
Any		0.76 (0.21)	0.81 (0.22)	0.05	0.78 (0.19)	0.85 (0.22)	0.07
allergy		0.77 (0.21)	0.83 (0.20)	0.06	0.79 (0.17)	0.88 (0.21)	0.09
urine		0.73 (0.23)	0.78 (0.23)	0.05	0.78 (0.20)	0.83 (0.24)	0.05
bleeding		0.76 (0.21)	0.81 (0.23)	0.05	0.78 (0.17)	0.83 (0.24)	0.05
wound		0.75 (0.22)	0.79 (0.22)	0.04	0.77 (0.18)	0.82 (0.22)	0.05
Sensitivity analysis excluded perfect health (EQ-5D index=1) at baseline		0.71 (0.23)	0.84 (0.21)	0.13	0.73 (0.22)	0.88 (0.20)	0.15

* non responders not included

¥ Kind P, Hardman G, Marcan S. UK Population Norms for EQ-5D. York: Centre for Health Economics Discussion paper 172 (1999)

Table 2-3: Mean EQ-5D index scores at baseline (pre) and at follow-up (post). Higher scores equals better perceived wellbeing. Differences are shown between responders and non-responders, outcomes are only shown for responders (readmission (yes or no)), length of stay, complications and sensitivity analysis)

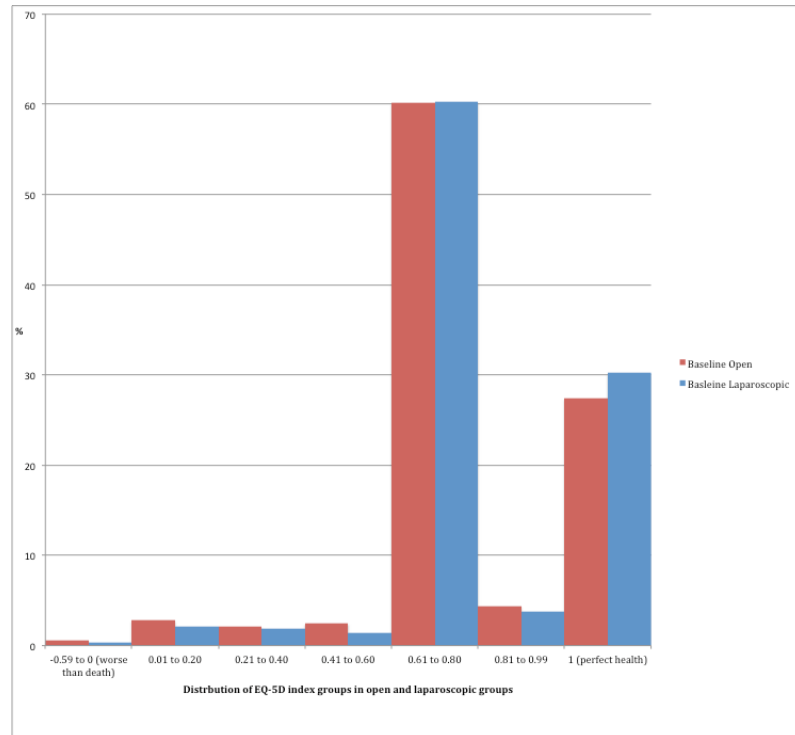
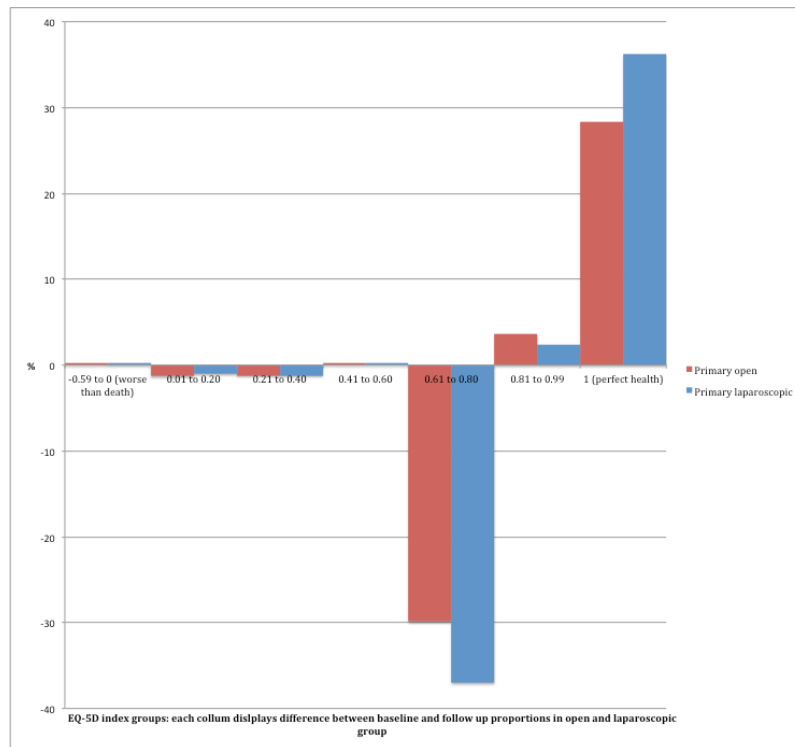


Figure 2-2 a&b: Bar charts showing baseline (2.2a) and differences between baseline and follow-up HRQol (EQ-5D) (2.2b), distribution by EQ-5D index group (-.59 to 0, 0.01 to 0.20, 0.21 to 0.40, 0.41 to 0.60, 0.61 to 0.80, 0.81 to 0.99, 1)

	Age groups							
	All	1 (16-24)	2 (25-34)	3 (35-44)	4 (45-54)	5 (55-64)	6 (65-74)	7 (75+)
N (number)								
Open	24421	368	792	1801	2954	5718	6177	4663
Laparoscopic	4682	98	226	490	731	1231	1055	490
Allergy								
Open (%)	4	5.7	5.8	4.4	4.7	5.0	3.8	3.5
Lap (%)	4.3	3.1	4.0	7.1	4.5	4.9	3.7	4.3
OR (95% C.I.)	0.93 (0.80-1.09)	1.92 (0.56-6.56)	1.49 (0.71 - 3.09)	0.54 (0.36- 0.82)	1.04 (0.71 - 1.54)	1.03 (0.77-1.37)	1.03 (0.73-1.46)	0.81 (0.51-1.29)
p-value	0.37	0.29	0.28	0.02	0.77	0.91	0.83	0.38
Urine								
Open (%)	6.7	4.4	5.1	4.9	5.3	6.4	7.1	11.2
Lap (%)	11.6	6.9	7.1	8.0	9.1	12.0	14.0	22.4
OR (95% C.I.)	0.55 (0.49-0.61)	0.61 (0.24-1.53)	0.70 (0.38-1.27)	0.58 (0.40-0.86)	0.57 (0.42-0.76)	0.31 (0.25-0.38)	0.47 (0.39-0.57)	0.44 (0.35-0.55)
p-value	<0.01	0.29	0.25	<0.01	<0.01	<0.01	<0.01	<0.01
Bleeding								
Open (%)	5.6	14.4	6.7	8.5	6.5	5.3	5.3	6.4
Lap (%)	4.7	5.0	5.4	4.8	6.3	5.6	4.0	5.6
OR (95% C.I.)	1.19 (1.03-1.38)	3.20 (1.24-8.23)	1.27 (0.66-2.41)	1.84 (1.18-2.89)	1.04 (0.75-1.46)	0.94 (0.72-1.24)	1.32 (0.95-1.84)	1.15 (0.77-1.73)
p-value	0.02	<0.01	0.46	<0.01	0.76	0.63	0.10	0.50
Wound								
Open (%)	11.2	16.8	14.6	15.3	14.1	12.6	10.4	9.9
Lap (%)	8.9	8.7	12.4	9.6	10.8	11.2	7.7	8.1
OR (95% C.I.)	1.28 (1.15-1.43)	2.14 (1.02-4.47)	1.21 (0.78-1.89)	1.70 (1.22-2.35)	1.38 (1.06-1.78)	1.14 (0.94-1.39)	1.39 (1.09-1.78)	1.25 (0.89-1.76)
p-value	<0.01	0.04	0.42	<0.01	<0.01	0.16	0.01	0.19
Readmission								
Open (%)	5	4.6	4.3	3.0	4.2	3.9	5.2	7.7
Lap (%)	5.5	5.7	7.6	5.6	4.3	4.1	6.0	9.7
OR (95% C.I.)	0.89 (0.77-1.02)	0.80 (0.31-2.08)	0.54 (0.30-0.98)	0.51 (0.32-0.82)	1.01 (0.68-1.50)	0.95 (0.70-1.29)	0.86 (0.65-1.12)	0.78 (0.57-1.06)
p-value	0.09	0.65	0.04	<0.01	0.93	0.69	0.25	0.10

Table 2-4: Distribution of patients reporting postoperative adverse events overall and by age group. (Differences are reported as unadjusted Odds ratios with 95% C.I. and p-value) Open technique acted as reference group)

(1-no, 2- moderate, 3- extreme)		Open		Laparoscopic	
		baseline n (%)	postoperative n (%)	baseline n (%)	postoperative n (%)
mobility	1	18947 (77.6)	19764 (80.9)	3919 (83.7)	4101 (87.6)
	2	5299 (21.7)	4474 (18.3)	738 (15.8)	548 (11.7)
	3	20 (0.1)	21 (0.1)	3 (0.1)	6 (0.1)
self-care	1	23245 (95.2)	22879 (93.7)	4571 (97.6)	4495 (96)
	2	924 (3.8)	1257 (5.1)	85 (1.8)	134 (2.9)
	3	42 (0.2)	62 (0.3)	2 (0)	8 (0.2)
usual activities	1	17309 (70.9)	18896 (77.4)	3444 (73.6)	3951 (84.4)
	2	6453 (26.4)	4981 (20.4)	1140 (24.3)	651 (13.9)
	3	506 (2.1)	371 (1.5)	76 (1.6)	52 (1.1)
pain/discomfort	1	7863 (32.2)	15828 (64.8)	1590 (34)	3399 (72.6)
	2	15381 (63)	7885 (32.3)	2910 (62.2)	1158 (24.7)
	3	943 (3.9)	437 (1.8)	148 (3.2)	82 (1.8)
anxiety/depression	1	20302 (83.1)	21063 (86.2)	4012 (86.3)	4127 (88.1)
	2	3647 (14.9)	2886 (11.8)	608 (13)	478 (10.2)
	3	218 (0.9)	214 (0.9)	28 (0.6)	29 (0.6)

Table 2-5: EQ-5D individual dimensions by treatment group

	Open	Laparoscopic
Satisfaction response	(%)	(%)
Excellent	32.8	38.4
Very good	39.3	38.4
Good	20.5	16.2
Fair	5.7	4.5
Poor	1.7	2.5
Comparison of symptoms pre and post		
Much better	84.7	87.7
A little better	9.9	7.3
About the same	3.3	2.8
A little worse	1.6	1.4
Much worse	0.6	0.8

Table 2-6: Patients' satisfaction three months after surgery

2.4 DISCUSSION

2.4.1 Principal findings

The main finding of this study was that, irrespective of whether a patient underwent open or laparoscopic inguinal hernia repair, there was an improvement in reported HRQoL principally resulting from reporting a decrease in pain and discomfort and an improvement in the ability to undertake usual activities. These differences were accentuated when patients who reported perfect health preoperatively were excluded from the analysis. The laparoscopic group attained a statistically significant greater improvement in the measured mean EQ-5D index score, however, this group had more favourable demographics.

In both techniques, younger patients attained a larger improvement, primarily caused by a lower baseline HRQoL compared to their counterparts in the general population matched by gender and age. However, compared with older patients, they reported significantly more bleeding and wound problems in the event they underwent an open procedure. The laparoscopic approach was associated with increased odds of urinary problems, and this increased with age and was the principle cause of prolonged length of stay and readmission when it occurred. Wound problems were more likely to be associated with patient readmission (40% increased odds) for the open group compared with the laparoscopic group.

2.4.2 Strengths and weaknesses of the study

The methodology of the PROMs programme, questionnaires used and outcomes chosen, were determined centrally by government prior to inception of the national programme and therefore the analysis was unbiased in its aim of assessing the value of routinely collected PROMs to determine the appropriateness of hernia repairs currently being undertaken and subsequent implications from a health policy perspective.

Although a mandatory national programme, the annual report of the PROMs programme for the period that this data was extracted only indicated a 55% return rate of the preoperative questionnaire⁸⁵. As this analysis is primarily based on administrative data, it does ensure that it is representative of patients treated in England but also compares favourably, in terms of patient characteristics, to a large-scale randomised controlled trial in the U.S²⁴ potentially allowing for extrapolation more widely. The non-response rate, after inclusion to the programme was 28% for the analysed period, with age, social deprivation and prevalence of comorbidities predicting the likelihood of patients' non-response, which correlates with findings of a previous study⁹². In addition, a lower proportion of patients reporting preoperative perfect health (22.1% in open group, 23.6% in laparoscopic group) was responsible for a lower baseline EQ-5D index in this group. It is not possible to fully explain the reasons behind non-response postoperatively, but poor understanding of the purpose of the programme and the traditional paper-based data collection methodology may have contributed. Improved response rates may result from using technology platforms to collect data, which has already been successful in collecting PROMs¹¹⁹.

There has always been a concern with the accuracy of HES data although audit data shows a continual improvement in data quality¹⁴³. Selecting only patients with primary hernia repair in the primary operation field reduced the potential for heterogeneity including patients undergoing hernia repair as part of another operation and allowed for a like for like comparison between techniques. It is acknowledged that laparoscopic repair is recommended in bilateral or recurrent repairs. Although patients were coded as primary repair there is still the possibility for them to have had a previous operation on either the ipsi- or contralateral side. The HES dataset provided by the HSCIC did not allow for revisiting of the original operation notes to investigate the clinical indication of the intervention or if it was performed under local or general anaesthetic. In addition, the dataset lacked information on important confounders, such as BMI, which might have influenced outcomes. Obese patients are known to have increased risk of wound infection for open compared with laparoscopic surgery¹⁴⁴.

Furthermore, it was not possible from the data to discriminate between the two most commonly used laparoscopic techniques, Transabdominal Preperitoneal (TAPP) and

Total Extraperitoneal (TEP) repair. TAPP repair carries the risk of more serious complications, such as bowel perforation, in the event they occur¹⁴⁵. However, intraoperative conversion rates and postoperative complications are more common in TEP¹⁴⁶.

In both groups the majority of patients reported symptoms for less than one year; the questionnaire did not give the option of reporting 'no symptoms', meaning that over-reporting of the existence of symptoms might have occurred. This is evidenced by a percentage of patients who reported EQ-5D score of 1 (perfect health/no pain or discomfort), but also symptoms for less than one year. The ability to identify, preoperatively, patients with no symptoms, along with those reporting perfect health on the EQ-5D score, may allow for better stratification of patients offered surgery. Adopting a watchful waiting policy in asymptomatic patients needs to be considered, as acute complications of incarcerated bowel leading to strangulation are rare^{147,148}, although development of symptoms does lead to surgical repair ultimately in a reasonable proportion of patients¹³³.

This analysis was limited by the relatively short three months follow-up mandated by the national programme, meaning that more traditional measures of outcome, recurrence rates and long-term pain i.e. neuralgia, at one year could not be compared between the surgical techniques. Future changes to the timing of questionnaire administered to patients could therefore encompass longer-term follow-up, as reported by patients, to improve the richness of data collected.

2.4.3 Comparison with other studies

The improvements in overall health status in our study, as a result of treatment, are consistent with findings in other studies^{76,135,136,149}. When compared with a UK population matched by age and gender¹⁵⁰, although the baseline EQ-5D index mean for the open group was comparable, that of the laparoscopic group was lower. This is probably explained by the relatively greater proportion of younger patients in the laparoscopic group who are known to report more severe pain both before and after surgery compared to older patients⁷⁶, which influences HRQoL outcomes. The

dataset lacked specific data on England and Wales, which form approx. 85% of the UK, using aggregate data from UK as whole was therefore necessary.

It is worth noting that current measures do not take account of expectations and cannot distinguish between changes in the experience of disease and changes in expectations of health¹⁵¹. Adaptation behaviour and different scales of reference can bias self-assessments of wellbeing by individuals. It is found that the scale of reference of the subjective health measure changes with age¹⁵². For example, when asked to complete a self-reported HRQoL focusing on their inguinal hernia symptoms, younger patients who might have limited exposure to ill health, might report worse health than older patients who might be more accepting of their symptoms due to their experience with ill health. Easily observed and distinctive differences between health states will be given more weight in judgments of health than they will have in reality. This conceptual contrast between internal perception of the patient and external observation by the medical expert, has been commented on by Sen¹⁵³, who warns that over-reliance on self-reported HRQoL can be misleading when used to inform policy.

Two methods have been proposed that evaluate treatment impact using the EQ-5D index score. The first, known as the Minimally Important Difference (MID), describes the smallest change in the EQ-5D index score that is perceived by patients as beneficial or that would result in a change in treatment⁵⁶ and has been reported in inguinal hernia at 0.03¹⁵⁴. Both treatment groups, in our study, increased well above the MID threshold. The second includes an analysis of individual dimensions of the EQ-5D index, which has been shown to be more discerning in variability of treatment impact⁶¹. Although changes in reported pain and discomfort were responsible for most of the improvement in EQ-5D index in our study, and was therefore a valid means of identifying treatment impact, the questionnaire itself and its timing did not allow for further characterisation of the pain (e.g. scrotal vs. groin) or differentiation between immediate postoperative pain and latent pain caused by neuralgia as well as detecting early differences in pain and return to usual activities, which are known to be present in the first few weeks after intervention^{137,138}. Pain after hernia repair is considered an important issue and outcome measure, particularly with hernia recurrence rates being so low with modern repair techniques.

The higher rate of bleeding and wound problems in open repair has been previously described¹⁵⁵ and is explained by the relatively larger wound size makes it more prone to haematoma formation and infection. In the laparoscopic approach, the greater risk of urinary problems may be attributable to the use of an indwelling urethral catheter^{137,156}, although other factors such as general anaesthetic and opioids are also associated with an increased frequency of urinary problems and in particular urinary retention¹⁵⁷. The postoperative questionnaire does not specify beyond 'urinary problems' and it is therefore impossible to comment further. A previous study reported that half of the patients undergoing laparoscopic repair reporting urinary problems were related to urinary retention¹⁵⁸. A further strategy to reduce urinary complications, and the associated morbidity of increased length of stay and readmission, has been to better risk stratify patients preoperatively based on history of pre-existence of lower urinary tract symptoms, female gender, diabetes and older age¹⁵⁹.

Readmission rates in inguinal hernia have not been commonly reported in the literature. Analysis of a preliminary administrative dataset from Southern England reported readmission rates of 1% for day case and 1.5% for inpatient stay¹⁶⁰. A more recent study, that used HES data, reported readmission rates of 0.7% and 0.8% in open and laparoscopic repair respectively¹⁶¹. This study has demonstrated that self-reported readmission rates, $\geq 5\%$, were higher when compared with that extracted from administrative (HES) data during the same period¹⁶². The inability to identify an association between readmission and the index procedure and the longer follow-up period used for the PROMs questionnaire (90 days), compared with the 30 days used for HES analysis, may have contributed to this difference. Self-reported comorbidities have been shown to be accurate as those extracted from administrative data⁹¹ and this adds weight to patients also being a reliable source for readmission data, which can be used as a cost-effective means of identifying variation between providers. The relevance of using readmission rates as a means to measure quality after inguinal hernia is unknown and warrants further investigation.

2.5 CONCLUSIONS

PROMs have provided the opportunity to better understand the impact of symptoms on daily life associated with an inguinal hernia, particularly in younger patients. Whilst younger patients (<55) reported worse baseline HRQoL and older patients (>64) better HRQoL compared to their counterparts in the general population, the use of the metric (EQ-5D index) chosen by the programme board to establish clinical need seems mostly acceptable in younger patients but not in older patients, who are also more likely to be affected by other pre-existing conditions. However, whilst the overall improvements in HRQoL demonstrated in both techniques and across all ages largely justified treatment in the majority of patients, a significant proportion of patients (>30%) reported perfect health and therefore showed no improvement. It seems unlikely that there is such a degree of intervention that will have had no opportunity to improve HRQoL, which if left untreated would result in a health burden beyond the timeframe of the PROMs programme's follow-up. These patients might therefore benefit from more careful decision-making and treatment by watchful waiting seems appropriate. Younger patients affected in their daily life, due to the 'focusing effect' of their hernia, could be offered laparoscopic technique as it can lead to improved HRQoL outcomes, however, for providers who are currently only assessed on their entire patient group, would not be inclined to offer laparoscopic technique as better HRQoL performance is not rewarded. Therefore, it can be argued that laparoscopic technique should be avoided entirely as complications associated with this technique predominately occur in hospital, such as length of stay and readmission, and have impact on important performance indicators. Whilst complications associated with open technique occur more frequently in the community and have no financial implication for providers. This approach should be avoided in older patients as it can cause increased hospital stay and readmission.

Health policy makers should have some reservations, using PROMs in its current format, in drawing firm conclusions as to the appropriateness of surgical interventions being undertaken on a national level. Certainly as applied to hernia repair, the response rates and the lack of risk adjustment limit the translatability to

the clinical setting. Future work should aim to identify important variables that can predict HRQoL between the two techniques to further add value to the data.

2.6 KEY POINTS ARISING FROM STUDY ONE

- The use of PROMs in inguinal hernia patients is appropriate in their ability to discriminate between different patients sub-groups with the assistance of administrative data and using it to evaluate HRQoL outcomes.
- The current PROMs questionnaire is unable to establish clinical need due to the inclusion of a generic HRQoL index (EQ-5D) that is limited by a significant ceiling effect and a large proportion of patients reporting full/perfect health.
- Patients provide important additional information regarding incidence of postoperative adverse events that occur both in the community and in-hospital.
- Older patients are generally healthier than their counterparts in the general population and previous experience with other condition may moderate their experience of hernia symptoms.
- Young patient with symptoms affecting daily life would benefit from laparoscopic over open repair due to the improved HRQoL outcomes that are associated with that technique.
- Laparoscopic repair is associated with an increased incidence in urinary problems potentially leading to increased length of stay and possible explanation for self-reported readmission.
- Satisfaction rates following both open and laparoscopic procedure are generally high.

Chapter 3

RISK PREDICTION OF HEALTH-RELATED QUALITY OF LIFE OUTCOMES IN GROIN HERNIA PATIENTS

3.1 INTRODUCTION

The previous study reported on important differences in patient-reported outcomes between the two most commonly performed techniques for treating a primary inguinal hernia in England and Wales. The improvements in HRQoL outcomes justified treatment in both groups, however, these improvements were lower than expected due to a significant proportion (>30%) of patients in both groups who reported perfect HRQoL, as measured by the EQ-5D index, and were thereby insensitive to change as a consequence of surgical intervention. In addition, the finding that older patients were reporting better HRQoL at baseline compared to their counterparts in the general population could fuel a debate as to whether treatment is appropriate at that stage.

Although, the appropriateness of the EQ-5D index to establish clinical indication was questioned in the previous chapter, its use will remain important to measure variation between providers. For these providers it will be pertinent to understand their patient population to make full use of PROMs data. The elements of the PROMs questionnaire described in the introduction (Figure 1.5) augmented with variables from administrative data available from the HES dataset component can provide an opportunity to identify significant predictors that help with risk adjustment of the data.

The primary aim of this study was to identify important patient-related predictors between patients reporting perfect health (EQ-5D=1) and patients who were not (EQ-5D<1) reported at baseline, followed by an investigation into the differences in factors that predict HRQoL outcomes following treatment between open and laparoscopic technique to add further predictive value to PROMs data.

3.2 MATERIAL AND METHODS

The data extraction from the PROMs linked to HES database and the outcome measure used (EQ-5D index score) has been previously described in section 2.2.

3.2.1 Candidate predictors

The candidate predictors for both study aims were collected from two separate sources. The primary independent, or predictor, variables of interest were extracted from data generated by the baseline PROMs questionnaire, which provided self-reported general health (Excellent, very good, good, poor and fair) and has been shown to be a strong predictor of HRQoL¹⁶³. Patients were also asked, as part of the baseline questionnaire, if their doctor had told them they had any of twelve common medical conditions. Each of these comorbidities were considered relevant as potential predictors, due to their potential to impact on either both physical and mental aspects of a generic HRQoL measure¹⁶⁴. From the postoperative PROMs questionnaire, information on self-reported adverse events was extracted as they were thought to be relevant to their potential negative impact on HRQoL experience following treatment and were used as independent variables in the second part of the study. Other included patient-related predictors have been previously described in section 2.2.1. The secondary independent variables of interest were extracted from the administrative data component (HES). The reliability of demographical variables, such as age; ethnicity and social deprivation, and Charlson's comorbidities²⁰ contained in administrative data is widely accepted.

For each of the techniques (open and laparoscopy) candidate preoperative patient and administrative reported variables available for risk adjustment at baseline were collected (Table 3.1). The dependent, or outcome, variable was the baseline EQ-5D index score separated into two groups of patients reporting perfect health (EQ-5D index of 1) and patients not reporting perfect health (EQ-5D index less than 1). The same variables extended with information available from follow-up were made available for the risk adjustment of patients reporting HRQoL outcomes following treatment (Table 3.2&3.3). In order to segment patients into groups to allow for regression analysis, HRQoL change score were calculated by subtracting the score obtained at three months follow-up from the baseline score. This led to the formation

of three groups, where an improvement of ≥ 0.03 was deemed improvement (Group 1), decrease of ≥ -0.03 was designated decrease (Group 2) and a score between -0.03 and $+0.03$ was designated the same (Group 3) displayed in Table 3.3. The dependent variable here was the postoperative EQ-5D index score from Group 1 (Improvement) and 2 (Reduction).

3.2.2 Statistical Analysis

All analyses were performed using SPSS version 19.0 (SPSS, IBM Chicago, Illinois, USA). Patient preoperative characteristics and postoperative adverse events were compared by univariate analysis, with Chi-square test or Fisher's exact test where appropriate. Independent variables that demonstrated a significant difference and were associated with a p-value less than or equal to 0.05 were considered significant predictors of either patient reporting perfect health at baseline or patients reporting a reduction following treatment. Individual levels from multi-level variables, such as general health, were included in the event they were significant provided their Standardised Residual (SR) was smaller than -1.96 or larger than 1.96. Formation of a dummy variable in this case was therefore necessary. Odds ratios were calculated for each of the independent variable in the multivariable models and 95% Confidence Intervals (C.I.) were calculated using maximum likelihood methods. .

Variable	Open technique EQ-5D			Laparoscopic technique EQ-5D		
	1	<1	p-value	1	<1	p-value
	N (%)	N (%)		N (%)	N (%)	
Number (N)	8554	23993		1853	4665	
Female gender	517 (6)	1636 (6.8)	0.01	87 (4.7)	244 (5.2)	0.37
Age groups						
1 (16-30)	680 (7.9)	1706 (7.1)	<0.01	190 (10.2)	445 (9.5)	<0.01
2 (31-40)	659 (7.7)	2048 (8.5)		196 (10.5)	556 (11.9)	
3 (41-50)	1114 (13)	3325 (13.9)		286 (15.4)	831 (17.7)	
4 (51-60)	1498 (17.5)	4368 (18.2)		379 (20.3)	998 (21.3)	
5 (61-70)	2485 (29.1)^	5959 (24.8)*		502 (26.9)	1101 (23.5)	
6 (71-80)	1650 (19.3)	4745 (19.8)		262 (14.1)	619 (13.2)	
7 (>81)	468 (5.5)*	1842 (7.7)^		48 (2.6)	134 (2.9)	
Ethnicity						
White	6918 (80.9)	20064 (83.6)	<0.01	1476 (79.1)	3885 (82.9)	<0.01
Mixed	26 (.3)	4 (.3)		10 (.5)	11 (.2)	
Asian	189 (2.2)	449 (1.9)		41 (2.2)	106 (2.3)	
Black	97 (1.1)	286 (1.2)		11 (.6)	43 (.9)	
Unknown	1261 (14.7)	2954 (12.3)		315 (16.9)	607 (13)	
General Health						
Excellent	1564 (18.3)^	1777 (7.4)*	<0.01	374 (20.1)^	430 (9.2)*	<0.01
Very good	4330 (50.6)^	8494 (35.4)*		970 (52.1)^	1893 (40.4)*	
Good	2327 (27.2)	9616 (40.1)^		461 (24.7)*	1828 (39)^	
Fair	226 (2.6)*	3347 (13.9)^		38 (2)*	444 (9.5)^	
Poor	5 (.1)*	464 (1.9)^		0*	42 (.9)	
Social deprivation						
1 (most)	981 (11.5)*	3828 (16)^	<0.01	217 (11.6)	660 (14.1)	<0.01
2	1436 (16.8)*	4484 (18.7)		274 (14.7)	785 (16.8)	
3	1921 (22.5)	5160 (21.5)		375 (20.1)	954 (20.4)	
4	2043 (23.9)	5328 (22.2)		472 (25.3)	1068 (22.8)	
5 (least)	2134 (24.9)^	5048 (21)*		519 (27.9)	1197 (25.6)	
Symptom period						
< 1year	5890 (68.9)	16139 (67.3)	0.03	1324 (71.1)	3328 (71.1)	0.98
>1 year	2587 (30.2)	7687 (32)		531 (28.5)	1337 (28.5)	
Previous surgery						
No	8131 (95.1)	22626 (94.3)	0.01	1739 (93.9)	4391 (93.7)	0.86
Yes	384 (4.5)	1246 (5.2)		11 (6.1)	277 (5.9)	
PROMs comorbidities						
Heart disease	577 (6.7)	2527 (10.5)	<0.01	78 (4.2)	298 (6.4)	<0.01
High blood pressure	2037 (23.8)	6472 (27)	<0.01	386 (20.7)	1032 (22)	0.24
Problems with stroke	69 (.8)	461 (1.9)	<0.01	18 (1)	42 (.9)	0.79
Problems with poor circulation	99 (1.2)	1409 (5.9)	<0.01	20 (1.1)	42 (.9)	<0.01
Lung disease	367 (4.3)	1653 (6.9)	<0.01	62 (3.3)	186 (4)	0.09
Diabetes	356 (4.2)	1272 (5.3)	<0.01	55 (3)	199 (4.2)	0.09

Kidney disease	86 (.1)	359 (1.5)	<0.01	8 (.4)	37 (.8)	0.11
Nervous system disease	35 (.4)	293 (1.2)	<0.01	9 (.5)	35 (.7)	0.24
Liver disease	31 (.4)	145 (.6)	<0.01	3 (.2)	12 (.3)	0.47
Cancer within 5 years	331 (3.9)	1099 (4.6)	<0.01	41 (2.2)	122 (2.6)	0.34
Depression	102 (1.2)	1387 (5.8)	<0.01	24 (1.3)	233 (5)	<0.01
Arthritis	797 (9.3)	4564 (19)	<0.01	163 (8.7)	699 (14.9)	<0.01
Charlson Comorbidities						
Myocardial infarction	53 (.6)	159 (.7)	0.67	2 (.1)	18 (.4)	0.07
Chronic heart failure	23 (.3)	160 (.7)	<0.01	0	9 (.2)	0.06
Peripheral Vascular Disease	32 (.4)	188 (.8)	<0.01	6 (.3)	18 (.4)	0.71
CVD	11 (.1)	29 (.1)	0.86	0	0	n/a
Dementia	3 (0)	53 (.2)	<0.01	0	6 (.1)	0.12
Pulmonary disease	535 (6.3)	2207 (9.2)	<0.01	106 (5.7)	305 (6.5)	0.22
Rheumatic disease	22 (.3)	194 (.8)	<0.01	5 (.3)	26 (.6)	0.13
Peptic ulcer disease	3 (0)	18 (.1)	0.21	1 (.1)	0	0.11
Mild liver disease	7 (.1)	54 (.2)	<0.01	0	5 (.1)	0.16
Diabetes no CC	282 (3.3)	978 (4.1)	<0.01	49 (2.6)	151 (3.2)	0.21
Diabetes with CC	2 (0)	22 (.1)	0.04	2 (.1)	0	0.03
Hemiplegia	3 (0)	25 (.1)	0.06	0	1 (0)	0.53
Renal disease	45 (.5)	202 (.8)	<0.01	4 (.2)	17 (.4)	0.34
Any malignancy	63 (.7)	198 (.8)	0.43	12 (.6)	16 (.3)	0.09
Liver disease	0	6 (0)	0.15	0	0	n/a
Metastatic cancer	1	4 (0)	0.75	0	0	n/a
Aids	0	0	n/a	0	0	n/a

(*) SR < -1.96

(^) SR > 1.96

(-) -1.96 < SR < 1.96

Table 3-1: Univariate analysis of all PROMs and HES recorded variables in open and laparoscopic technique by baseline EQ-5D index groups (EQ-5D=1) and EQ-5D<1

Variable	Group		p-value	Variable	Group		p-value
	1 Improvement N (%)	2 Reduction N (%)			1 Improvement N (%)	2 Reduction N (%)	
N (number)	11389	4055		General Health			
Age (average)	61.8 (14.64)	63 (15)		Excellent	1009 (8.9)∧	280 (7)*	<0.01
				Very good	4532 (40)∧	1307 (32.6)*	
				Good	4459 (39.4)	1607 (40.1)	
Female gender	690 (6)	349 (8.6)	<0.01	Fair	1194 (10.5)*	704 (17.6)∧	
				Poor	125 (1.1)*	110 (2.7)∧	
PROMs comorbidity				Age groups			
Heart disease	1166 (10.2)	558 (13.7)	<0.01	1 (16-30)	423 (3.7)	128 (3.1)	<0.01
High Blood pressure	3404 (29.7)	1256 (30.8)	0.19	2 (31-40)	657 (5.7)	212 (5.2)	
Problems with stroke	190 (1.7)	108 (2.7)	<0.01	3 (41-50)	1303 (11.4)	515 (12.6)∧	
Problems with poor circulation	549 (4.8)	319 (7.8)	<0.01	4 (51-60)	2199 (19.2)	671 (16.5)*	
Lung disease	757 (6.6)	341 (8.4)	<0.01	5 (61-70)	3381 (29.5)	1118 (27.4)	
Diabetes	610 (5.3)	255 (6.3)	0.03	6 (71-80)	2589 (22.6)	996 (24.5)	
Kidney disease	169 (1.5)	92 (2.3)	<0.01	7 (>81)	891 (7.8)*	433 (10.6)∧	
Nervous system disease	103 (0.9)	81 (2)	<0.01	Social deprivation			
Liver disease	59 (0.5)	27 (0.7)	0.28	1 (most)	1437 (12.6)*	639 (15.8)∧	<0.01
Cancer within 5 years	550 (4.8)	238 (5.8)	0.01	2	1962 (17.3)	757 (18.7)	
Depression	486 (4.2)	248 (6.1)	<0.01	3	2478 (21.8)	911 (22.5)	
Arthritis	1912 (16.7)	1092 (26.8)	<0.01	4	2797 (24.6)	905 (22.5)	
				5 (least)	2698 (23.7)	842 (20.8)*	
Charlson Comorbidities							
Myocardial infarction	85 (0.7)	36 (0.9)	0.38				

Chronic heart failure	69 (0.6)	32 (0.8)	0.21	Symptom period < 1 year > 1 year	7923 (69.7)	2744 (68)	0.05
Peripheral Vascular Disease	89 (0.8)	51 (1.3)	<0.01		3451 (30.3)	1292 (32)	
CVD	8 (0.1)	8 (0.2)	0.03				
Dementia	13 (0.1)	12 (0.3)	0.01	Previous surgery No Yes			
Pulmonary disease	984 (8.6)	405 (9.9)	0.01		10860 (95.4)	3828 (94.4)	0.02
Rheumatic disease	71 (0.6)	53 (1.3)	<0.01		529 (4.6)	227 (5.6)	
Peptic ulcer disease	9 (0.1)	1 (0)	0.24	Complications Allergy to drug Urinary problems Bleeding Wound problems			
Mild liver disease	22 (0.2)	10 (0.2)	0.52		419 (3.9)	213 (5.9)	<0.01
Diabetes no CC	481 (4.2)	204 (5)	0.03		673 (6.4)	454 (12.5)	<0.01
Diabetes with CC	10 (0.1)	2 (0)	0.45	Self-reported readmission	559 (5.3)	340 (9.4)	<0.01
Hemiplegia	10 (0.1)	3 (0.1)	0.8		1105 (10.3)	759 (20.2)	<0.01
Renal disease	93 (0.8)	55 (1.4)	<0.01				
Any malignancy	101 (0.9)	45 (1.1)	0.2				
Liver disease	0	1 (0)	0.09				
Metastatic cancer	0	1 (0)	0.09				
Aids	n/a	n/a	n/a		471 (4.2)	328 (8.2)	<0.01
Ethnicity							
White	9704 (91.5)	3439 (85)	<0.01				
Mixed	22 (0.2)	8 (0.2)					
Asian	133 (1.2)*	90 (2.2)^					
Black	95 (0.8)	47 (1.2)					
Unknown	1428 (12.5)	460 (11.4)					

(*) SR < -1.96
 (^) SR > 1.96
 (no sign) -1.96 < SR < 1.96

Table 3-2: Univariate analysis of candidate predictors between Group 1 (Improvement) and Group 2 (Reduction) in HRQoL outcomes following "Open" surgery

Variable	Group		p-value	Variable	Group		p-value
	1	2			1	2	
Improvement	Deterioration	N (%)	p-value	Variable	Improvement	Deterioration	p-value
N (%)	N (%)				N (%)	N (%)	

N (number)	2331	627		General Health	268 (11.6)	45 (7.2)*	<0.01
Age (average)	57.4 (14.6)	60 (13.7)		Excellent	1027 (44.3)	217 (34.9)*	
				Very good	868 (37.5)	252 (40.5)	
Female gender	105 (4.5)	44 (7)	0.03	Good	149 (6.4)*	101 (16.2)^	
				Fair	5 (0.2)	7 (1.1)^	
				Poor			

PROMs comorbidity				Age groups			
Heart disease	159 (6.8)	50 (7.9)	0.32	1 (16-30)	122 (5.2)	18 (2.9)*	<0.01
High Blood pressure	571 (24.4)	173 (14.3)	0.12	2 (31-40)	207 (8.8)	43 (6.8)	
Problems with stroke	23 (1)	9 (1.4)	0.34	3 (41-50)	366 (15.6)	84 (13.3)	
Problems with poor circulation	72 (3.1)	45 (7.1)	<0.01	4 (51-60)	523 (22.4)	153 (24.3)	
Lung disease	87 (3.7)	35 (5.6)	0.04	5 (61-70)	682 (29.2)	179 (28.4)	
Diabetes	93 (4)	37 (5.9)	0.04	6 (71-80)	364 (15.6)	120 (19)	
Kidney disease	20 (0.9)	8 (1.3)	0.34	7 (>81)	75 (3.2)	33 (5.2)	
Nervous system disease	15 (0.6)	7 (1.1)	0.22	Social deprivation			
Liver disease	7 (0.3)	2 (0.3)	0.94	1 (most)	241 (10.3)	92 (14.6)^	0.02
Cancer within 5 years	70 (3)	26 (4.1)	0.15	2	335 (14.4)	98 (15.6)	
Depression	68 (2.9)	41 (6.5)	<0.01	3	498 (21.4)	140 (22.2)	
Arthritis	302 (12.9)	158 (25.1)	<0.01	4	567 (24.3)	149 (23.7)	
				5 (least)	690 (29.6)	151 (24)*	

Charlson Comorbidities				Symptom period			
Myocardial infarction	12 (0.5)	1 (0.2)	0.23	< 1 year	1726 (74.1)	431 (68.8)	0.01
Chronic heart failure	3 (0.1)	2 (0.3)	0.3	> 1 year	603 (25.9)	195 (31.2)^	
Peripheral Vascular Disease	6 (0.3)	4 (0.6)	0.15				
CVD	n/a	n/a	n/a				

Groups EQ-5D index score (Postoperative score - baseline score)	
Group 1 "Improvement"	≥ 0.03
Group 2 "Decrease"	≥ -0.03
Group 3 "Same"	$-0.03 < \text{EQ-5D} < 0.03$

Table 3-4: Formation of groups differences between baseline

3.3 RESULTS

3.3.1 Prediction of baseline HRQoL

A total of 39,065 patients underwent inguinal hernia surgery, of which 83.3% underwent open and the remainder (16.7%) underwent laparoscopic repair. Of those, 26.3% and 28.4% respectively reported perfect health at baseline. In the open group, the univariate analysis revealed that there were significant differences between patients reporting perfect health and patients reporting any other EQ-5D index score (Table 3.1). These differences, i.e. variables, were considered potential predictor and used as independents in multivariate modelling. For patient undergoing open surgery and reporting perfect health, 25 variables were considered potential predictors of patient not reporting perfect health. These were age groups (5&7), general health (all except good), social deprivation (1,2 and 5), all PROMs comorbidities and nine of

the Charlson's' comorbidities. Of these, the most positively predictive variables were excellent general health (OR 3.34, 95% C.I 3.06 to 3.63, $p<0.01$), very good general health (OR 1.97, 95% 1.85 to 2.10, $p<0.01$) and age between 61 and 70 (OR 1.27, 95% C.I. 1.20 to 1.35, $p<0.01$). Conversely, there was a negative association with patients reporting perfect health for poor and fair general health (OR 0.06, 95% C.I. 0.02 to 0.15, $p<0.01$ and OR 0.34, 95% C.I 0.29 to 0.39, $p<0.01$ resp.) and three of the PROMs comorbidities; depression (OR 0.31 95% C.I. 0.25 to 0.38, $p<0.01$), leg pain when walking due to poor circulation (OR 0.42, 95% C.I. 0.33 to 0.52, $p<0.01$) and arthritis (OR 0.64, 95% C.I. 0.59 to 0.70, $p<0.01$). For the laparoscopic group, where 6 variables were considered, only excellent general health in patients undergoing laparoscopic surgery was positively associated with perfect health at baseline (OR 1.67, 95% C.I. 1.42 to 1.96, $p<0.01$) and fair general health (OR 0.20, 95% C.I 0.14 to 0.28, $p<0.01$), and the same PROMs comorbidities as in the open procedure group were negatively associated with perfect health at baseline (Table 3.5&3.6).

3.3.2 Prediction of HRQoL outcomes

The response rate for the follow-up questionnaire at three months was 47%. In Table 3.2 & 3.3, the baseline characteristics of patients in the different group are compared. In the open technique, patients with a reduction (>0.03) in the baseline EQ-5D score differed significantly from patients with an improvement (>0.03) on 26 variables. These were female gender, Asian ethnicity, PROMs comorbidities (Heart Disease, High Blood Pressure, Problems due to stroke, Problems due to poor circulation, Diabetes, Lung Disease, Kidney Disease, Nervous system disease, Cancer within 5 years, Depression and Arthritis) and HES comorbidities (Peripheral Vascular Disease, Dementia, Pulmonary Disease, Rheumatic disease and Renal Disease), general health (Excellent, Very good, Fair and Poor), age >81 , social deprivation, all four self-reported adverse events and readmission (Table 3.2). In the multivariate risk model, poor general health (OR 2.20 (95% C.I. 1.61 to 3.02, $p\text{-value}<0.001$) was most predictive of reduction in HRQoL, followed by wound problems (OR 1.81, 95% C.I. 1.58 to 2.1, $p\text{-value}<0.001$), Nervous system disease (OR 1.74, 95% C.I. 1.25 to 2.42, $p\text{-value}=0.001$), Arthritis (OR 1.64, 95% C.I. 1.48 to 1.81, $p\text{-value}<0.001$ and Asian ethnicity (OR 1.64, 95% C.I. 1.20 to 2.24, $p\text{-value}=0.002$) (Table 3.7).

In the laparoscopic group, there were 17 variables significantly different in univariate analysis, which were subsequently considered potential predictors of reduction in HRQoL following surgery. These were, female gender, Asian ethnicity, age group 1 Problems due to poor circulation, Diabetes, Lung disease, Depression, Arthritis, general health (fair, poor), symptom period (>1 year), previous surgery and all four self-reported adverse events and readmission (Table 3.8). Only 5 of these – fair general health (OR 2.08 95% C.I. 1.51 to 2.87, p-value<0.001), Arthritis (OR 2.03, 95% C.I. 1.58 to 2.62, p-value<0.001), Depression (OR 1.64, 95% C.I. 1.02 to 2.65, p-value=0.045) and urinary problems (OR 1.63, 95% C.I. 1.19 to 2.23, p-value=0.002) –independently predicted a reduction in HRQoL.

Both models in the open and laparoscopic group had moderate discriminative power (ROC 0.634 and 0.694 resp.) In addition, there was no value greater than 0.8 in both correlation matrixes, in other words, none of the independent predictors were correlated.

Variable	Coefficient	SE	p-value	OR	95% CI
Demographics					
Female gender	0.044	0.06	0.440	1.05	0.94 to 1.17
Age >81	0.056	0.06	0.350	1.06	0.94 to 1.19
Age 61-70	0.24	0.03	0.000	1.27	1.20 to 1.35
Social deprivation (worst)^	-0.253	0.04	0.000	0.78	0.71 to 0.85
Social deprivation (2)	-0.111	0.04	0.003	0.90	0.83 to 0.96
Social deprivation (best)^	0.068	0.03	0.040	1.07	1.00 to 1.14
General Health					
Excellent*	1.204	0.04	0.000	3.34	3.06 to 3.63
Very good*	0.676	0.03	0.000	1.97	1.85 to 2.10
Fair*	-1.079	0.07	0.000	0.34	0.29 to 0.39
Poor*	-2.904	0.50	0.000	0.06	0.02 to 0.15
PROMs comorbidities					
Heart disease	0	0.05	0.990	1.00	0.90 to 1.11
High blood pressure	0.068	0.03	0.040	1.07	1.01 to 1.14
Problems after stroke	-0.161	0.14	0.260	0.85	0.64 to 1.13
Problems due to poor circulation	-0.88	0.11	0.000	0.42	0.33 to 0.52
Lung disease	0.086	0.07	0.230	1.09	0.95 to 1.26
Diabetes	0.115	0.11	0.300	1.12	0.90 to 1.39
Kidney disease	0.274	0.14	0.050	1.32	1.00 to 1.73
Nervous system disease	-0.278	0.20	0.160	0.76	0.51 to 1.11
Liver disease	0.41	0.23	0.070	1.51	0.96 to 2.36
Cancer (within last 5 years)	0.116	0.07	0.100	1.12	0.98 to 1.29
Depression	-1.184	0.11	0.000	0.31	0.25 to 0.38
Arthritis	-0.45	0.04	0.000	0.64	0.59 to 0.70
Charlson comorbidities					
Chronic heart failure	-0.27	0.24	0.260	0.76	0.47 to 1.22
Peripheral Vascular disease	-0.07	0.21	0.740	0.93	0.62 to 1.40
Dementia	-0.825	0.62	0.180	0.44	0.13 to 1.46
Pulmonary disease	-0.07	0.06	0.240	0.93	0.83 to 1.05
Rheumatic disease	-0.462	0.24	0.054	0.63	0.39 to 1.01
Diabetes (no complications)	0.012	0.12	0.920	1.01	0.80 to 1.29
Renal disease	0.035	0.19	0.850	1.04	0.72 to 1.49
Mild liver disease	-0.674	0.43	0.110	0.51	0.22 to 1.17
Symptom period (>1yr)	0.046	0.04	0.292	1.05	0.96 to 1.14
Previous surgery	0.131	0.09	0.158	1.14	0.95 to 1.37

^Reference category: 4

*Reference category: Good

SE, Standard Error; OR, Odds Ratio; CI, Confidence Interval

Table 3-5: Multivariate (logistic regression) analysis of potential predictors of patients reporting baseline “non” perfect HRQoL (EQ-5D of 1) in "OPEN" surgery

Variable	Coefficient	SE	P-value	OR	95% C.I.
General Health					
Excellent*	0.511	0.08	0.000	1.67	1.42 to 1.96
Good*	-0.652	0.07	0.000	0.52	0.46 to 0.59
Fair*	-1.605	0.18	0.000	0.20	0.14 to 0.28
Poor*	-20.219	6086.00	0.997	0.00	0
PROMs comorbidities					
Heart disease	-0.035	0.14	0.800	0.97	0.74 to 1.27
Problems due to poor circulation	-0.742	0.25	0.003	0.48	0.29 to 0.78
Depression	-0.97	0.22	0.000	0.38	0.25 to 0.59
Arthritis	-0.283	0.10	0.003	0.75	0.62 to 0.91
Charlson comorbidities					
Diabetes (with complications)	22.895	28155.00	0.990	<0.01	0

^Reference category: 4

*Reference category: Very Good

SE, Standard Error; OR, Odds Ratio; CI, Confidence Interval

Table 3-6: Multivariate (logistic regression) analysis of potential predictors of patients reporting baseline “non” perfect HRQoL (EQ-5D<1) in "LAPAROSCOPIC" surgery

Variable	Coefficient	SE	P-value	OR	95% CI
Demographics					
Female gender	0.247	0.08	0.002	1.28	1.10 to 1.49
Age >81	0.18	0.07	0.020	1.19	1.04 to 1.38
Asian ethnicity	0.494	0.16	0.002	1.64	1.20 to 2.24
Social deprivation (worst)^	0.169	0.06	0.005	1.18	1.05 to 1.33
Social deprivation (best)^	-0.072	0.05	0.150	0.93	0.84 to 1.03
General Health					
Excellent*	-0.137	0.08	0.090	0.87	0.74 to 1.02
Very good*	-0.102	0.05	0.030	0.90	0.82 to 0.99
Fair*	0.43	0.06	0.000	1.54	1.36 to 1.74
Poor*	0.79	0.16	0.000	2.20	1.61 to 3.02
PROMs comorbidities					
Heart disease	0.125	0.07	0.056	1.13	0.98 to 1.29
High blood pressure	-0.071	0.05	0.120	0.93	0.85 to 1.02
Problems after stroke	0.1	0.15	0.490	1.10	0.83 to 1.47
Problems due to poor circulation	0.021	0.09	0.810	1.02	0.86 to 1.22
Lung disease	-0.023	0.08	0.780	0.98	0.84 to 1.14
Diabetes	0.027	0.09	0.760	1.03	0.86 to 1.22
Nervous system disease	0.55	0.17	0.001	1.74	1.25 to 2.42
Cancer (within last 5 years)	0.052	0.09	0.570	1.05	0.88 to 1.26
Depression	0.127	0.09	0.170	1.14	0.95 to 1.36
Arthritis	0.492	0.05	0.000	1.64	1.48 to 1.81
Charlson comorbidities					
Peripheral Vascular disease	0.209	0.21	0.310	1.23	0.83 to 1.84
Dementia	0.249	0.46	0.590	1.28	0.53 to 3.14
Pulmonary disease	-0.017	0.08	0.840	0.98	0.84 to 1.16
Rheumatic disease	0.252	0.21	0.220	1.29	0.86 to 1.93
Diabetes (no complications)	0.126	0.16	0.430	1.14	0.83 to 1.56
Renal disease	0.383	0.21	0.061	1.47	0.98 to 2.19
PROMs adverse events					
Allergy to drug	0.296	0.11	0.008	1.34	1.08 to 1.68
Urinary problems	0.465	0.08	0.000	1.59	1.36 to 1.87
Bleeding problems	0.12	0.09	0.210	1.13	0.93 to 1.36
Wound problems	0.59	0.07	0.000	1.81	1.58 to 2.1
Readmission	0.33	0.09	0.000	1.39	1.16 to 1.67

^Reference category: 4

*Reference category: Good

SE, Standard Error; OR, Odds Ratio; CI, Confidence Interval

Table 3-7: Multivariate (logistic regression) analysis of potential predictors of reduction of HRQoL following "OPEN" surgery

Variable	Coefficient	SE	P-value	OR	95% CI
Demographics					
Female gender	0.347	0.22	0.12	1.42	0.92 to 2.19
Asian ethnicity	0.658	0.35	0.057	1.93	0.98 to 3.80
General health					
Fair*	0.732	0.17	0	2.08	1.51 to 2.87
Poor*	1.398	0.84	0.1	4.05	0.77 to 21.17
PROMs comorbidities					
Problems due to poor circulation	0.758	0.24	0.001	1.42	0.92 to 2.19
Lung disease	-0.138	0.27	0.6	0.87	0.51 to 1.47
Diabetes	0.351	0.24	0.14	1.42	0.90 to 2.25
Depression	0.497	0.24	0.04	1.64	1.02 to 2.65
Arthritis	0.71	0.13	0	2.03	1.58 to 2.62
PROMs adverse events					
Allergy to drug	0.06	0.28	0.83	1.06	0.62 to 1.83
Urinary problems	0.49	0.16	0.002	1.63	1.19 to 2.23
Bleeding problems	0.16	0.25	0.51	1.17	0.73 to 1.90
Wound problems	0.48	0.18	0.006	1.62	1.14 to 2.28
Readmission	0.245	0.22	0.26	1.28	0.84 to 1.96
Symptom period (>1 year)	0.184	0.11	0.11	1.2	0.96 to 1.50

^Reference category: 4; *reference category: Good

*Reference category: Good
SE, Standard Error; OR, Odds Ratio; CI, Confidence Interval

Table 3-8: Multivariate (logistic regression) analysis of potential predictors of reduction of HRQoL following "LAPARASCOPIC" surgery

3.4 DISCUSSION

3.4.1 Principal findings

In both groups, excellent general health as reported by patients, was significantly associated with patients reporting perfect baseline HRQoL. Patients not reporting perfect health were at significant odds of reporting fair general health and any of three PROMs comorbidities (arthritis, depression and leg pain when walking due to poor circulation) as collected by the baseline PROMs questionnaire. The significance of these comorbidities lies in their (in)direct association with individual dimensions of the EQ-5D index score, where arthritis and leg pain due to poor circulation lead to decreased mobility and depression influences the mental health component. Moreover, the same comorbidities were also predictive of patients reporting a reduction in HRQoL following surgery. The implication may be that these patient-reported factors can explain variation and therefore are important in risk adjustment of PROMs data.

Both wound and urinary problems after surgery were independent predictors of a reduction in HRQoL in both groups. Patients with a complicated postoperative recovery, i.e experienced a complication as recorded by the PROMs questionnaire, were at risk of reporting a reduction in several of the EQ-5D index dimensions. For example, anxiety levels may have increased as a patient was not expecting a complication and/or consequent treatment was inadequate, or symptoms from complications may have exacerbated pre-existing symptoms affecting daily life, either way it is not possible to understand if these changes in HRQoL present at three months after treatment were a direct consequence of a complication or based on a patients recall of the event.

And finally, Asian patients undergoing open surgery were more likely to report reduction in HRQoL and there was a further trend towards Asian patients reporting a reduction after the laparoscopic procedure, however, this was not statistically significant with a p-value of 0.057.

3.4.2 Strengths and weaknesses of the study

As highlighted in the previous study (Section 2.4.2), it was not possible to influence the selection of predictors made available from the PROMs linked to HES database. Of the elements available, several have been associated with predicting (HRQoL) outcomes. Self-reported general health has consistently been a strong predictor of both HRQoL and clinical outcomes¹⁶⁵⁻¹⁶⁷. Gender and ethnicity have been known to influence perceived health as well social deprivation¹⁶⁸, where poor perceived health is associated with low incomes and educational level¹⁶⁹. In this study, only the worst social deprivation categories (1 and 2) were prognostic of not reporting perfect health for the open technique.

The linked data contained both patient-reported and administratively collected information on pre-existing conditions, i.e. comorbidities. The use of comorbidities extracted from administrative data for risk adjustment in surgical procedures and medical conditions has been widely described^{2,20}. However, this evidence seems to focus on more complex surgery or sicker patients, as higher incidence in the sample population will lead to smaller standard errors and earlier significance. For this sample, it may be more appropriate to use comorbidities as reported by patients themselves. Bayliss et al. found patients to be a reliable source of comorbidity information^{90,91}.

The EQ-5D index scores reported in the data by the national programme were based on the UK population norms endorsed by NICE, which originated from Dolan's Time Trade Off (TTO) data¹⁷⁰. The preference weights used for this hernia sample were therefore not based on different health status, illnesses or conditions and limited interpretation of the data. Estimation of EQ-5D index score is difficult as it exhibits a ceiling effect with a significant number of respondents reporting perfect health¹⁷¹⁻¹⁷³. To avoid bias using this data caused by this censoring, the modelling to estimate the baseline score should rely on Tobit analysis or Censored Least Adjusted Deviations (CLAD) regression, particularly in the event that the data might not be normally distributed and there is heteroskedasticity.

To determine if treatment was meaningful, the use of MID is well established, however, it is dependent on the baseline severity of the condition¹⁵⁴. For example, symptoms associated with an inguinal hernia are considered less debilitating compared to patients needing joint replacement. The level of MID is therefore variable amongst different conditions and this impacts on our ability to undertake comparisons. The timing of the follow-up questionnaire in terms of demonstrating changes in HRQoL was appropriate to establish if the changes that occurred were related to the surgery. Assuming that the follow-up would be longer, although, it would allow for measurement of long-term pain, i.e. neuralgia, there is potential for additional confounders that may influence results. It is thought that this difference, for both an improvement as well as a reduction, is most likely related to surgical intervention rather than an artefact from unknown confounders.

3.4.3 Comparison with other studies

This study appears to be the first of its kind to report on both administrative and patient-reported variables that predict baseline or postoperative HRQoL in inguinal hernia repair. Traditional research focuses on short and long term outcomes, comparing difference between techniques in terms clinical variables, such as postoperative pain and recurrence rates. The role of comorbidities as predictors of health-related quality of life has been well described¹⁷⁴. In other research, depression and anxiety were important independent predictors of HRQoL in a sample of COPD patients¹⁷⁵. For this study, depression, as reported by the patient and independently from the EQ-5D index, was a strong predictor of patients not reporting perfect health at baseline for both techniques. This appears to correlate with the depression/anxiety dimension that is contained within the EQ-5D index score. In addition, depression was predictive of a reduction in HRQoL in laparoscopic patients. For hernia surgery in particular, it has been previously reported that female gender is a significant risk factor for pain/discomfort and fatigue following inguinal hernia surgery¹⁷⁶. Patients with depression or depressive symptoms experience and manage pain in a different way, leading frequently to worsening symptoms, although, Powell et al. previously

did not find a relation between depression and postoperative chronic pain in inguinal hernia patients¹⁷⁷.

Two PROMs comorbidities; arthritis and leg pain due to poor circulation that are thought to impact on physical aspect of HRQoL, were in fact predictive of both patients reporting other scores than perfect health and a reduction of HRQoL following surgery in both groups. The influence of (osteo)arthritis on functional capacity primarily and mental health secondarily is well established^{178,179}. The pre-existence of musculoskeletal illnesses and its consequential impact on HRQoL has to be taken into account by researchers. Patients with reduced mobility may not experience the potential benefits of fixing a hernia in terms of a reduction in pain, and therefore in this group the potential benefits of hernia surgery when primarily measured by generic HRQoL will be marginal. Leg pain due to poor circulation, as interpreted by the patients, further influences function and mobility. However, the reliability of this patient-reported comorbidity can be argued as for clinicians it will mean Peripheral vascular Disease (PVD) leading to difficulties whilst walking caused by pain, but patients probably are not able to discriminate between different causes, which warrants further exploration or reconsideration about including this particular element.

One additional PROMs comorbidity, that was exclusively predictive of a reduction in HRQoL in the open group, was Nervous system disease. Patients diagnosed with Parkinson's disease can be prone to reduced function in limb resulting in reduced mobility and capacity of self-care. These patients are prone to develop a prolonged or complicated postoperative recovery due to general anaesthetic used and reduced function. However, it was not possible to distinguish between different neurological conditions, further warranting examination of patients reported nervous system disease.

For both techniques, the occurrence of urinary and wound problems was similarly predictive of reporting a reduction in HRQoL following surgery. The previous study reported an increased odds of urinary problems leading to prolonged Length of Stay (LOS) for laparoscopic technique, however, LOS was not used in the model due to lack of significance in univariate analysis. Patients with a prolonged length of stay

don't necessarily report a reduction of HRQoL. In terms of wound problems, the presence of any of the features that characterise a surgical site infection (SSI) as defined by the Centre for Disease Control (CDC)¹⁸⁰, are likely to impact on the postoperative recovery experience and lead to a reduction in HRQoL. Whitehouse et al. reported a greater physical limitation and a significant reduction in HRQoL for patients diagnosed with a SSI following orthopaedic surgery¹⁸¹. SSI's are a frequent source of morbidity leading to increased health burden for patients. Prevention of both complications should not be limited to the technique with the highest incidence but across techniques as it can prevent reduction of HRQoL.

Asian ethnicity was a significant predictor in open surgery and there was a trend in the laparoscopic group to report reduction in HRQoL following surgery. There exists important ethnic variation in clinical risk factors, such as comorbidity status, and (socio) cultural parameters, that determines a patient experience¹⁸². This is to my best knowledge, the first time ethnicity is an important predictor of HRQoL outcomes in hernia surgery. Recognition that these patients are at increased odds to report a reduction is important in evaluating performance at the national level.

3.5 CONCLUSIONS

Patient-reported variables used in this study were better suited to assist in risk adjustment of PROMs data compared to administrative data collected. Although, there were differences in the amount of predictors that were significant between the two procedures, overall, there were predominately similarities in their ability to predict both baseline and changes in HRQoL. The five item-scale of self-reported general health and three PROMs comorbidities (depression, arthritis and leg pain due to poor circulation) were consistently prognostic of HRQoL at baseline and following surgery, emphasising the importance of these variables.

Furthermore, results from this study and study 1 have highlighted the importance of collecting traditional clinical outcomes by patients, and their potential ability to explain variation between institutions should future comparisons be undertaken. Providers with high incidence(s) of adverse event(s) and poor HRQoL outcomes, can benefit from this data to identify areas for process change in their quality improvement initiatives. However, there remains a question surrounding the reliability of patient-reported information in this national setting, in particular, around the data accuracy in this predominately day-case procedure. Although, in smaller trials the reliability of patients reporting information about their pre-existing conditions was excellent, on a population health level, there is currently no evidence. There is therefore a need to further assess the validity of self-reported information against an established source of health information, i.e. HES, to establish the value that patients can add in the current system.

3.6 KEY POINTS ARISING FROM STUDY TWO

- Risk adjustment of HRQoL outcomes at baseline and following inguinal hernia surgery is feasible using PROMs data.
- Three self-reported comorbidities, i.e. leg pain due to poor circulation; depression and arthritis, were consistently prognostic of patients not reporting perfect health and patients reporting a reduction in HRQoL after surgery due to their direct influence on their corresponding dimensions contained in the EQ-5D index score.
- Administratively collected comorbidities were not independent predictors of baseline health or HRQoL outcomes in inguinal hernia patients.
- Self-reported adverse events (urinary and wound problems) were associated with a reduction in HRQoL following both open and laparoscopic treatment and quality improvement should be aimed at prevention to enhance overall performance.
- Female gender and Asian ethnicity were predictive of patient reporting an impacted HRQoL at baseline and a reduction following surgery, these factors should be taken into account at the decision-making stage.
- Further testing of the reliability of patient-reported comorbidities is indicated in order to provide validation of PROMs in terms of their ability to measure health status.

Chapter 4

THE CONCORDANCE BETWEEN PATIENT-REPORTED AND ADMINISTRATIVE DATA RECORDED COMORBIDITIES: ARE WE MISSING IMPORTANT INFORMATION FROM OUR PATIENTS?

The following chapter was presented at:

International Forum of Quality in Healthcare in Paris 2014

4.1 INTRODUCTION

The previous chapter identified the presence of both patient-related and administrative data collected variables that can predict whether a patient will report a worse baseline EQ-5D score, or whether a patient will report an improvement. The presence of self-reported comorbidities was an important confounder in both treatment groups. However, the presence of administrative collected comorbidities was not predictive of HRQoL outcomes.

The effectiveness of Charlson's comorbidities index (CCI) in studies, where HRQoL outcomes are the primary outcomes, has been previously assessed and was not recommended due to its inability to explain variation in the mental aspect of the score used (SF-36) in the analysis¹⁸³. For population health studies, the lack of high quality clinical databases, such as ACS's NSQIP programme, forces researchers and policymakers alike to analyse administrative data. Although, it provides a relatively inexpensive and quick source of health information, the accuracy of administrative data compared to medical notes collected has been poor^{22,184}. The recording of comorbidities from medical record review, carried out by clinicians is considered the reference or the 'gold standard', routine use of it is not considered cost-effective and is currently mainly limited to research or audits. There might be an opportunity for patients to add important value to administrative data. Existing studies investigating patient-reported comorbidities have shown promising results with similar performance to medical record review in smaller cohorts^{90,91,185}. However, for national cohorts, such as the PROMs programme, the validity of patients reporting pre-existing conditions remains to be investigated. Nevertheless, patients have remained underutilised as an important resource for recording comorbidities for use in subsequent risk-adjusted analysis of performance outcomes.

The primary objective of this study was to determine the agreement between directly patient-reported (PROMs) versus traditional administrative datasets (HES) recorded comorbidities for four elective surgical procedures.

4.2 MATERIALS AND METHODS

4.2.1 Study population

The study cohort was identified from patients participating in a national programme routinely measuring PROMs in England between January 2009 and February 2011. All patients undergoing elective joint replacement (hip or knee) and two mainly day-case procedures (varicose veins and groin hernia surgery) who had completed a preoperative PROMs questionnaire were included.

4.2.2 Data collection

The data extraction from the PROMs linked to HES database has been previously described in section 2.2. For the time period covered by the dataset, all hospitals in the English and Welsh National Health Service (NHS) were using ICD-10 CM for coding of up to 19 secondary diagnoses for each patient episode uploaded nationally. These secondary codes were considered as potential comorbidities.

The local clinical coding department of a large teaching hospital (St. Mary's Hospital part of Imperial College NHS Trust) and the NHS classification service were consulted to correlate all twelve PROMs comorbidities with their corresponding ICD-10 CM codes. (Appendix V). For each 'group' of ICD-10 CM codes corresponding to each of the PROMs comorbidity, only codes indicating chronic diagnoses were included and codes indicative of an acute episode, for example pneumonia, were excluded. In the event that was unclear whether a diagnosis was chronic or acute it was included so as not to exclude any potentially relevant comorbidities. Aggregating the data for analysis required three main steps. Firstly, to iterate through each of the 19 available HES columns per patient to identify any of the ICD-10 CM codes deemed relevant to the PROMS comorbidities. Secondly, to identify where the administrative-coded (HES) data correlated with the PROMs data. Following this a simple 'truth' table score was used to mark if the comorbidity was

found in one source, the other, or both sets of data. And finally, the top 5 codes per comorbidity group could be reported, comparing results of both sets (Table 4.1). The product of each iteration for this large sample required several millions of calculations and look-ups, which could only be achieved using the aggregate and indexing capabilities of a SQL database. The ICD-10 CM codes provided by the local hospital coding team acted as the look-up table, with each code mapped to the PROMs comorbidity group. The main table held PROMs and HES data on a single row per patient, comprised of all 19 HES ICD-10 CM columns, a column for each PROMs comorbidity group and its corresponding 'truth' column. Having identified a relevant ICD-10 CM code in any one column, a case statement could be used to update the 'truth' value for that PROMs comorbidity group and this made it possible to identify the most common ICD-10 codes, grouped by disease and compared between sets.

PROMs comorbidity	ICD-10-CM	N	total	% of total	Description
Heart Disease	I48.X	10200	39379	25.9%	Atrial Fibrillation flutter
	I20.9	8562	39379	21.7%	Angina pectoris, unspecified
	I25.8	6669	39379	16.9%	Chronic ischaemic heart disease
	I25.9	5053	39379	12.8%	Chronic ischaemic heart disease NOS
	I25.2	1507	39379	3.8%	Old myocardial infarction
High blood pressure	I10.X	83559	83654	99.9%	Essential hypertension
	I15.1	63	83654	0.1%	Hypertension secondary to other renal disorders
Problem caused by stroke	G81.9	233	263	88.59%	Hemiplegia, unspecified
	G82.2	9	263	3.42%	Paraplegia, unspecified
	G83.1	9	263	3.42%	Monoplegia of lower limb
Leg pain due to poor circulation	M79.66	13	13	100.0%	Limb pain, unspecific lower limb
Lung disease	J45.9	17832	25908	68.8%	Asthma, unspecified
	J44.9	5455	25908	21.1%	Chronic obstructive pulmonary disease, unspecified
	J43.9	688	25908	2.7%	Emphysema, unspecified
	J47.X	600	25908	2.3%	Bronchiectasis
	J44.8	299	25908	1.2%	Other specified Chronic Obstructive Pulmonary Disease
Diabetes	E11.9	17574	18964	92.7%	Non Insulin Dependent Diabetes Mellitus without complications
	E10.9	787	18964	4.1%	Insulin Dependent Diabetes Mellitus without complications
	E14.9	294	18964	1.6%	Unspecified Diabetes Mellitus without complications
	E11.3	113	18964	0.6%	Non Insulin Dependent Diabetes Mellitus with ophtalmic complications
Kidney disease	N18.9	849	1573	54.0%	Chronic kidney disease, unspecified
	N19.X	304	1573	19.3%	Unspecified kidney failure
	N28.9	211	1573	13.4%	Disorder of kidney and ureter, unspecified
	N18.0	58	1573	3.7%	Chronic kidney disease
	Q61.3	45	1573	2.9%	Polycystic kidney, unspecified
Nervous system disease	G40.9	1610	3564	45.2%	Epilepsy, not other specified
	G20.X	963	3564	27.0%	Parkinson disease
	G35.X	246	3564	6.9%	Multiple sclerosis
	G30.9	135	3564	3.8%	Alzheimer disease
Liver disease	K76.0	125	490	25.5%	Fatty (change of) liver, not elsewhere classified
	K70.3	66	490	13.5%	Alcoholic cirrhosis of liver
	B18.2	64	490	13.1%	Hepatitis B
	K70.9	62	490	12.7%	Alcoholic liver disease, not other specified
Cancer (within last 5 years)	C91.1	204	1182	17.3%	Acute lymphoblastic leukemia (ALL)
	C50.9	112	1182	9.5%	Malignant neoplasm of breast, unspecified
	C79.5	94	1182	8.0%	Secondary malignant neoplasm of bone and bone marrow
	C85.9	91	1182	7.7%	Non Hodgkin Lymphoma
	C78.7	81	1182	6.9%	Secondary malignant neoplasm of liver and intrahepatic bile duct
Depression	F32.9	2816	2908	96.8%	Depressive episode, not other specified
	F33.9	66	2908	2.3%	Recurrent depressive disorder
Arthritis	M17.9	1184	5565	21.3%	Gonarthrosis, unspecified
	M16.9	881	5565	15.8%	Coxarthrosis, unspecified
	M15.9	632	5565	11.4%	Polyarthrosis, unspecified
	M06.9	483	5565	8.7%	Rheumtoid arthritis ,unspecified
	M10.9	386	5565	6.9%	Gout, unspecified

Table 4-1: PROMs comorbidities with top 5 most commonly coded ICD-10-CM secondary diagnostic codes and total number within PROMs comorbidity in HES data

4.2.3 Data analysis

The level of agreement between PROMs and ICD-10 CM recorded comorbidities was quantified using Cohen's kappa coefficient (κ) (A kappa value above 0.75 indicates an excellent level of agreement beyond chance, 0.40 through 0.75

represents fair to good agreement and kappa value less than 0.4 indicates a poor agreement). Sensitivity, specificity, positive predictive value (PPV) and negative predictive value (NPV) were calculated for each comorbidity reported through PROMs by designating the HES data, an established source of health data, to serve as the gold standard. Sensitivity, for instance, was defined as the proportion a comorbidity registered in PROMs data was also recorded by administrative data. Whilst specificity was defined as the proportion of a comorbidity not ticked by patients and was also not recorded in HES data. A Pearson's correlation for the incident of each comorbidity in both data sets was also undertaken. SPSS version 19.0 (SPSS, IBM Chicago, Illinois, USA) was used for statistical analysis.

4.3 RESULTS

A total of 236,439 patients underwent elective surgery for the four index procedures and completed the preoperative PROMs questionnaires. Both knee and hip replacement surgery formed the majority of the data (35% and 32% respectively) and in these groups patients were on average between 68 (± 11.1) and 69 (± 9.4) years of age. In addition, most of these patients were white females, reported fair general health pre-operatively and had an average length of stay of between 5 and 6 days. Groin hernia repair and varicose veins surgery contributed 22% and 10% to the overall data and had a lower mean age of 58 (± 15.6) and 50 (± 16.4) years respectively. Both procedures were predominantly undertaken on a day-case basis (88% for varicose veins and 70% for groin hernia repair) and most patients reported very good pre-operative general health on their baseline questionnaire (Table 4.2).

Demographics	Hip replacement overall	Knee replacement overall	Varicose Veins overall	Groin hernia overall
N (total number)	76557	82472	24346	53064
Age				
mean (SD)	68.1 (11.12)	69.2 (9.4)	50.0 (15.6)	58.4 (16.4)
Gender (%)				
male	40	43.4	36.7	92.9
female	60	56.5	63.3	7.1
Ethnicity (%)				
White	88.7	86.5	81.4	82.2
None-white	1.5	4.5	5	4.2
missing / not stated	9.8	9	13.6	13.6
Baseline general health (%)				
Excellent	4.5	3.3	9.1	10.4
Very good	26.1	23.1	38.2	39.7
Good	41.8	42.6	38.2	36.4
Fair	19.1	22.1	10.5	10.9
Poor	4.2	4	1.4	1.3
missing	4.3	4.9	2.6	1.4
Social deprivation (%)				
1- (most)	12.3	15.2	20.2	14.8
2	17	18.6	20.7	17.7
3	22	22	21.2	21.5
4	24.3	22.4	20.3	22.9
5- (least)	23.1	20.6	17	22.6
missing	1.2	1.1	0.7	0.5
Length of stay (%)				
Mean LOS	5.74 (5.01)	5.61 (4.4)	0	0
Day Surgery (0)	0.6	0.5	88.3	69.8
overnight (1)	0.7	0.6	10.5	25.3
Two nights (2)	4.4	3.7	0.8	3
Three to five nights (3-5)	58.2	59.9	0.3	1.5
Six to ten nights (6-10)	29	28.8	0	0.3
More than 10 nights (>10)	7.2	6.6	0	0.1

Table 4-2: Demographics for each PROMs procedure

4.3.1 Prevalence of comorbidity reporting

There were similar prevalence rates reported across both datasets for high blood pressure and diabetes in both joint replacements (hip and knee), but in both outpatient procedures only nervous system disease had similar prevalence rates (Table 4.3). Lung disease was consistently underreported in PROMs data compared to HES data for all four procedures ($p < 0.01$). Although, both Heart disease and Nervous system disease were underreported in PROMs data in both joint

replacements procedures ($p<0.01$), the same was not true for the outpatient procedures, as it did not reach statistical significance ($p=0.10$ and $p=0.12$).

In contrast, Leg pain due to poor circulation; Kidney disease; Liver disease; Cancer and Depression were all overreported in PROMs data across all four procedures ($p<0.01$). In addition, three further comorbidities were significantly overreported in outpatient-based procedures (High blood pressure, Diabetes and Arthritis) compared to both joint replacements (Table 4.3).

4.3.2 Levels of agreement

The level of agreement, i.e. whether HES and PROMs identified the same patient with or without the condition, was determined with Cohen's kappa coefficient (κ) and ranged from $\kappa = 0$ (no agreement) to $\kappa = 0.86$ (excellent agreement). The highest kappa values were reported in Diabetes ($\kappa = 0.86$), followed by High blood pressure ($\kappa = 0.6$) in hip replacement and Heart disease ($\kappa = 0.59$) in groin hernia repair. The lowest levels of agreement were found in Leg pain due to poor circulation ($\kappa = 0$) and Problems due to stroke ($\kappa = 0.03$), which was consistent across all procedures. In Heart disease and High blood pressure, other comorbidities; Nervous system disease: Liver disease, Cancer, Depression and Problems due to stroke showed poor agreement across all procedures. In day-case procedures, statistical agreement in four comorbidities was lower compared to joint replacements (Lung disease, Diabetes, Liver disease and Depression).

Considering that HES data represented a validated means of recording comorbidities; sensitivity; specificity; positive and negative predictive value were calculated. For all four index procedures, there were five comorbidities with sensitivity greater than 50 percent and this indicated that patients were more likely to identify these comorbidities when they were also recorded in HES data in this comparison. These were Heart disease (56.9%), High blood pressure (76.6%), Problems due to stroke (62.0%), Diabetes (89.0%) and Depression (60.5%) (Table 4.4).

The specificity for most comorbidities was good with values of greater than 95%, meaning that if patients did not report them in PROMs data, they were also unlikely to be coded by administrative data. Lower specificity (<95%) in joint replacement was reported in High blood pressure, Leg pain due to poor circulation and Depression (with no values for Arthritis). For both outpatient groups, Arthritis had lowest values (<86%) followed by High blood pressure and Depression only in varicose veins surgery (to note, there were no values recorded for Leg pain due to poor circulation).

The PPV for the comorbidities ranged from <0.01% to 85%. Four comorbidities in particular had PPV of less than 15 percent across all four surgical procedures. These conditions were: Problems due to stroke, Depression, Cancer and Kidney disease. Patients also significantly overreported all four of these comorbidities.

The NPV was greater than 90% for all comorbidities recorded for groin hernia surgery. It was also greater than 90% for all varicose veins procedures except for Diabetes (40%) and Arthritis (86.9%). For knee replacement surgery, the NPV was less than 90% for High blood pressure (79%) and Liver Disease (79.7%). For hip replacement surgery, the NPV was less than 90% for Heart disease (81%), High blood pressure (82.9%) and Cancer (81.2%).

Procedure	PROMs comorbidity	HES		PROMS		Kappa (95%CI)
		%	n	%	n	
Hip replacement	Heart disease	14.81%	11341	10.10%	7730	0.57 (0.49-0.65)
	High blood pressure	41.15%	31500	39.58%	30302	0.6 (0.54-0.66)
	Leg pain due to poor circulation	0.01%	7	7.33%	5615	0
	Problems due to stroke	0.12%	95	1.57%	1201	0.08 (0.06-0.1)
	Lung disease	11.84%	9066	6.49%	4970	0.49 (0.48-0.5)
	Diabetes mellitus	8.45%	6472	8.84%	6764	0.86 (0.8-0.92)
	Kidney disease	0.70%	535	1.69%	1296	0.14 (0.12-0.16)
	Nervous system disease	1.55%	1190	0.82%	626	0.36 (0.33-0.39)
	Liver disease	0.26%	196	0.53%	406	0.31 (0.26-0.36)
	Cancer	1.76%	1351	4.55%	3483	0.25 (0.23-0.27)
	Depression	1.43%	1095	7.55%	5780	0.17 (0.06-0.23)
	Arthritis	n/a	76557	70.73%	54146	n/a
Knee replacement	Heart disease	15.87%	13087	11.23%	9263	0.56 (0.55-0.56)
	High blood pressure	47.04%	38795	46.03%	37964	0.57 (0.56-0.58)
	Leg pain due to poor circulation	0.01%	6	9.30%	7666	0
	Problems due to stroke	0.14%	116	1.68%	1383	0.08 (0.06-0.1)
	Lung disease	12.93%	10665	6.96%	5740	0.47 (0.46-0.48)
	Diabetes mellitus	11.87%	9788	12.59%	10387	0.85 (0.84-0.86)
	Kidney disease	0.63%	516	1.76%	1454	0.13 (0.11-0.15)
	Nervous system disease	1.76%	1454	0.92%	761	0.38 (0.36-0.4)
	Liver disease	0.23%	189	0.54%	446	0.28 (0.23-0.33)
	Cancer	1.31%	1084	4.17%	3437	0.19 (0.18-0.2)
	Depression	1.58%	1304	8.22%	6780	0.17 (0.06-0.23)
	Arthritis	n/a	82472	76.98%	63483	n/a
VV	Heart disease	3.13%	759	3.82%	926	0.54 (0.51-0.57)
	High blood pressure	10.33%	2501	16.47%	3988	0.55 (0.53-0.57)
	Leg pain due to poor circulation	n/a	0	16.51%	3998	n/a
	Problems due to stroke	0.01%	3	0.64%	155	0.1 (0.07-0.13)
	Lung disease	5.89%	1425	3.89%	943	0.35 (0.33-0.38)
	Diabetes mellitus	2.38%	576	3.50%	847	0.71 (0.69-0.74)
	Kidney disease	0.10%	25	0.78%	190	0.08 (0.03-0.12)
	Nervous system disease	0.48%	116	0.44%	107	0.2 (0.13-0.26)
	Liver disease	0.13%	31	0.48%	116	0.23 (0.14-0.32)
	Cancer	0.40%	97	1.67%	404	0.18 (0.14-0.23)
	Depression	0.69%	168	7.62%	1844	0.09 (0.07-0.11)
	Arthritis	1.42%	343	16.08%	3894	0.09 (0.08-0.1)
Hernia	Heart disease	9.24%	4903	9.02%	4787	0.59 (0.6)
	High blood pressure	20.22%	10729	25.36%	13459	0.59 (0.58-0.6)
	Leg pain due to poor circulation	n/a	0	4.48%	2379	n/a
	Problems due to stroke	0.07%	38	1.46%	773	0.03 (0.01-0.05)
	Lung disease	8.50%	4511	5.88%	3122	0.34 (0.33-0.35)
	Diabetes mellitus	3.85%	2043	4.73%	2512	0.79 (0.78-0.8)
	Kidney disease	0.32%	168	1.19%	632	0.17 (0.14-0.2)
	Nervous system disease	1.16%	618	0.95%	502	0.4 (0.36-0.43)
	Liver disease	0.15%	79	0.46%	245	0.21 (0.15-0.25)
	Cancer	1.26%	671	4.00%	2122	0.23 (0.21-0.25)
	Depression	0.61%	322	4.57%	2423	0.13 90.12-0.15)
	Arthritis	1.88%	996	16.19%	8593	0.11 (0.1-0.12)

Table 4-3: Prevalence of comorbidities and agreement between administrative and PROMs data per individual procedure (VV=Varicose Veins and Hernia=Groin hernia)

PROMs comorbidity		Sensitivity		Specificity		PPV		NPV	
		%	95% C.I.	%	95% C.I.	%	95% C.I.	%	95% C.I.
Hip replacement	Heart disease	52.0	51.4-52.9	92.7	92.3-93.0	76.3	75.4-77.3	81.0	80.6-81.5
	High blood pressure	74.9	74.4-75.4	85.1	84.8-85.4	78.8	77.4-78.3	82.9	82.5-83.2
	Leg pain due to poor circulation	14.3	1.0-58.2	55.8	55.0-56.7	<0.01	<0.01	99.9	98.8-100
	Problems due to stroke	56.8	46.3-66.8	98.4	98.3-98.5	4.5	3.4-5.9	99.9	99.9-99.9
	Lung disease	30.9	28.5-33.4	94.7	94.4-95.0	25.9	23.9-28.1	95.8	95.53-96.1
	Diabetes mellitus	88.8	88.2-89.6	98.7	98.5-98.8	85.0	84.1-85.8	99.0	98.8-99.0
	Kidney disease	22.5	19.4-25.8	98.5	98.4-98.6	11.7	10.1-14.0	99.3	99.2-99.4
	Nervous system disease	27.7	25.2-30.4	99.6	99.5-99.7	52.7	48.7-56.7	98.9	98.8-98.9
	Liver disease	48.5	41.3-55.7	99.6	99.5-99.6	23.4	19.4-27.9	99.9	99.8-99.9
	Cancer	48.6	48.5-49.5	96.3	96.1-96.3	18.8	17.5-20.2	81.2	79.8-82.4
	Depression	59.9	56.9-55.9	93.2	93.0-93.3	11.3	10.5-12.2	99.4	99.3-99.4
Arthritis		n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
Knee replacement	Heart disease	52.3	51.5-53.1	96.5	96.4-96.7	74.0	73.1-74.9	91.4	91.3-91.7
	High blood pressure	75.9	75.6-76.4	80.5	80.2-80.9	77.6	77.2-78	79.0	78.7-79.4
	Leg pain due to poor circulation	16.7	1.0-64.2	90.7	90.5-90.9	<0.01	<0.01	1.0	<0.1
	Problems due to stroke	58.6	49.1-67.5	98.2	98.1-98.3	4.7	3.7-5.9	99.9	99.9-99.9
	Lung disease	39.7	38.7-40.6	97.9	97.8-98.0	73.7	72.5-74.8	91.6	91.4-91.8
	Diabetes mellitus	89.2	88.6--89.9	97.7	97.6-97.8	84.0	83.3-84.8	98.5	98.4-98.6
	Kidney disease	24.0	20.9-27.6	98.4	98.3-98.5	10.7	9.2-12.5	99.4	99.3-99.4
	Nervous system disease	29.3	27.2-31.7	99.6	99.5-99.6	56.0	52.4-6.0	98.7	98.7-98.8
	Liver disease	46.6	39.3-53.9	99.6	99.5-99.6	20.3	16.7-24.5	79.7	75.5-83.3
	Cancer	42.1	39.1-45.1	96.4	96.2-96.5	13.3	12.2-14.5	99.2	99.1-99.3
	Depression	59.7	57.2-62.4	92.7	92.4-92.8	11.5	10.7-12.3	88.5	87.7-89.3
Arthritis		n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
Varicose veins	Heart disease	61.1	57.6-64.6	98.0	97.1-98.2	50.1	46.0-53.3	98.7	98.6-98.9
	High blood pressure	79.0	76.8-80.1	90.7	90.3-91.1	50.1	46.8-53.4	98.7	98.6-98.9
	Leg pain due to poor circulation	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
	Problems due to stroke	66.7	12.5-89.2	99.4	99.2-99.5	1.3	<0.01	98.7	94.9-99.8
	Lung disease	30.9	28.5-33.4	97.8	97.6-97.9	46.7	43.4-49	95.8	95.5-96.1
	Diabetes mellitus	88.5	85.5-90.9	98.5	98.4-98.7	60.2	57-63	40.0	36-43
	Kidney disease	32.1	16.6-52.4	99.2	99.1-99.4	4.7	2.3-9.7	99.9	99.8-100.0
	Nervous system disease	19.8	13.2-28.4	99.7	99.6-99.7	21.5	14.4-30.7	99.6	99.5-99.7
	Liver disease	54.8	36.3-72.2	99.6	99.5-99.7	14.3	8.9-22.1	99.9	99.9-100
	Cancer	47.4	37.3-57.8	98.5	98.3-98.7	11.4	8.5-14.9	99.7	99.7-99.8
	Depression	62.2	54.3-69.5	92.8	92.4-93.1	5.5	4.6-6.7	99.7	99.6-99.7
Arthritis		70.0	66.5-73.3	85.7	85.2-86.1	13.1	12.1-14.2	86.9	85.8-87.9
Groin hernia	Heart disease	62.1	60.7-63.5	96.4	96.2-96.5	63.6	62.2-64.9	96.1	95.9-96.3
	High blood pressure	76.7	75.8-77.4	88.0	87.2-87.9	61.1	60.3-61.9	93.6	93.2-93.9
	Leg pain due to poor circulation	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
	Problems due to stroke	65.7	48.6-79.9	98.6	98.4-98.7	3.2	2.1-4.8	1.0	99.9-100
	Lung disease	43.5	41.7-44.6	97.9	97.4-97.7	62.3	60.6-64	94.9	94.7-95.1
	Diabetes mellitus	89.5	88.1-90.8	98.7	98.6-98.9	72.8	71.0-74.5	99.5	99.5-99.6
	Kidney disease	38.9	32.0-46.1	98.9	98.9-99.0	11.9	9.5-14.7	99.8	99.7-99.8
	Nervous system disease	36.9	33.1-40.8	99.5	99.4-99.5	45.5	41.0-49.9	99.2	99.2-99.3
	Liver disease	43.0	32.1-54.6	99.6	99.5-99.7	13.9	9.9-19.0	99.9	99.8-99.9
	Cancer	50.8	47.0-54.7	96.6	96.5-96.8	16.1	14.5-17.7	99.4	99.3-99.4
	Depression	60.2	54.7-65.6	95.8	95.6-95.9	8.0	7.0-9.2	99.7	99.7-99.8
Arthritis		68.2	65.2-71.0	84.8	84.5-85.1	7.9	7.4-8.5	99.3	99.2-99.4

PPV= Positive Predictive Value

NPV= Negative Predictive Value

95% C.I.= 95% Confidence Interval

Table 4-4: Measures of sensitivity, specificity, positive and negative predictive value of comorbidities per procedure (HES administrative data served as gold standard for all measures)

4.4 DISCUSSION

4.4.1 Principal findings

This large-scale study using routinely collected patient-reported data augmented with administrative data has investigated the feasibility of linking PROMs comorbidities to their corresponding ICD-10 CM codes. Although, there was moderate to excellent agreement in Heart disease, High blood pressure and Diabetes across all procedures, most comorbidities showed poor agreement, exposing potential gaps in both data sources. In comorbidities where there was no or poor agreement, patients consistently overreported these (except for Nervous system disease) and this was more pronounced in the day-case procedures.

4.4.2 Strengths and weaknesses of the study

This analysis used a large administrative dataset, ensuring that it was representative of the general population of patients undergoing routine surgical procedures in England and Wales, and linkage of administrative with PROMs data allowed for analysis at the individual patient level. Although, the response rates in joint replacement surgery in the investigated period were 80% of the total sample, the response rates in inguinal hernia repair and varicose veins surgery were only 55% and 43% respectively⁸⁵.

Although, previous studies have validated and shown the reproducibility of a self-reporting instrument for comorbidities¹⁸⁶, which performed similarly to medical notes review⁹¹, the large dataset used to determine the concordance between both datasets has its own limitations. Firstly, comorbidity is generally measured by medical record extraction but due to the sample size in this study it was not economic and ethically feasible to further investigate the validity of our findings with the aid of medical records review. Comparison of routinely collected patient-reported data to medical records could assist in this further. Secondly, the retrospective nature of the data analysis did not allow for the investigation of characteristics of non-responders to the preoperative questionnaire in any of the four procedures. Although,

this programme is mandatory for providers, engagement of clinical teams in offering patients the PROMs questionnaires may have contributed to poorer response rates in day-case procedure. Most patients undergoing joint replacement surgery will be assessed pre-operatively in outpatient clinics and this offers an extra opportunity for data collection. Thirdly, the study was limited by the twelve PROMs comorbidities as the study had no influence on both their inclusion or specific wording used in the PROMs questionnaire. A committee of clinicians and public health experts selected these twelve PROMs comorbidities, on the basis of their relevance to explain heterogeneity amongst patients undergoing these index procedures. Therefore mapping of certain comorbidities posed challenges with regards to identifying comparable ICD-10 CM codes. Furthermore, patient interpretation of the twelve comorbidities could have moderated their responses leading to both under and over-reporting. For example, in the PROMs questionnaire patients are asked about the presence of ‘Leg pain due to poor circulation’, which has only one specific corresponding ICD-10 CM code (M79.66), that coders in turn would interpret as ‘Non-specific limb pain of the lower leg’. This particular PROMs comorbidity was probably designed to identify a specific arterial condition, i.e. “Intermittent claudication”. However, patients would not necessarily consider circulation an arterial problem and this can easily be misconstrued as either pain due to varicose veins or coxarthrosis (or OA) of the hip, explaining the disproportionately high incidence of this diagnosis in PROMs compared to administrative data. In the PROMs comorbidity ‘Problems caused by stroke’, the overreporting can be explained by a lack of available ICD-10 CM codes describing chronic problems, i.e. physical and mental, occurring after having undergone a stroke specifically. Investigating the exact diagnosis behind the patient-reported comorbidity through review of medical notes could have elucidated any potential inaccuracies in defining matching ICD-10 CM codes to the PROMs comorbidities. And finally, Arthritis acted as the primary diagnostic code in joint replacement surgery and it was therefore not possible to report on agreement between secondary diagnostic codes in HES and PROMs data. However, around 71% of hip replacement patients reported having arthritis, this was only marginally lower than a large population cohort, which reported that 85% of patients undergoing hip replacement had a primary diagnosis of arthrosis or arthritis¹⁸⁷. This could in turn support the reliability of patient’s self-reported arthritis.

4.4.3 Comparison with other studies

Although, several studies have compared the accuracy of administrative data to medical record review, universally accepted as the ‘gold standard’, and consistently reported underestimation by administrative data^{22,188-191}, only one previous study reported on agreement between patient-reported and administrative data and found similar agreement for the comorbidities of Diabetes and High blood pressure¹⁸⁶. Comorbidity extraction by clinical coders is dependent on the availability of patient health records to identify secondary diagnostic codes. These records, however, may not always be available thereby limiting coders to information secondary data sources, such as discharge summaries databases and other IT systems¹⁹². In the NHS, clinical coders act within guidance that dictates that comorbidities can only be coded if there is evidence for them in the medical record as described by the admitting clinician for that particular encounter^{193,194}. This is subsequent to the perception that information available from previous encounters, i.e. pre-assessment or previous admissions, is thought to be out-dated and therefore its use is advised against as a direct source to obtain comorbidity information. Including this information from previous encounters might, however, improve the accuracy of existing administrative data. This does have financial implications because of the Payment by Results (PbR) structure that incorporates some comorbidity information in determining reimbursement for healthcare in the NHS. Only certain types of comorbidities, however, can influence the level of payment and therefore others might be considered less of a priority to local coding departments¹⁹⁵, providing further explanation for underreporting of certain comorbidities in administrative data.

While the impact of chronic heart and lung disease and diabetes on risks associated with general anaesthetic and postoperative recovery is well documented^{196,197}, other comorbidities may not be considered, by clinicians, as relevant to a particular hospital episode and therefore not routinely documented. This may also explain some of the discordance between patient-reported and administrative data reported comorbidities and be especially pertinent for outpatient procedures because of the relatively reduced patient contact time in the secondary care healthcare setting.

4.4.4 Explaining overreporting

Patients consistently overreported Depression compared to HES data in all four procedures. Although self-reported Depression in the PROMs questionnaire wasn't collected using a validated measure, Depression has been shown to be associated with increased length of stay; mortality; readmission and can impact on HRQoL^{198,199}. Therefore the PROMs questionnaire might be a useful tool in screening for Depression, most validated HRQoL measures contain at least one psychosomatic element^{47,54} and correlating the self-reported to a generic HRQoL measure can help establish the validity of self-reported depression going forward.

In addition, Kidney disease and Cancer (within the last 5 years) were overreported by patients and this was further supported by their low PPV. There may be a number of reasons for this relationship. For example, Kidney disease is part of the annual Quality and Outcomes Framework (QOF) checks in the primary care setting and patients are routinely invited for blood tests to determine their kidney function. This continuous re-iteration of their kidney function by their primary care physician is likely to lead to a greater number of patients reporting this disease. For Cancer, clinicians might not feel comfortable to actively ask patients if they have had cancer in the past five years, especially when they do not believe it will influence outcomes.

4.4.5 Explaining underreporting

PROMs data underreported both Heart and Lung disease in both joint replacements compared to HES data. In terms of Heart disease, this may be contributed to patients who don't consider 'Atrial Fibrillation' (AF), which represented almost a quarter of the diagnostic codes captured by administrative data (Table 4.1), a serious heart disease but rather a minor problem. This finding has been previously reported in a qualitative survey of patients with AF, which also found that healthcare professionals were twice as likely to recognise severe consequences associated with AF²⁰⁰. However, it is important to recognise that AF is a meaningful comorbidity due to its

association with increased complication rates and prolonged length of stay²⁰¹. For lung disease, the majority were coded as ICD-10-CM code J45.9 ('Asthma, unspecified'), and although the PROMs questionnaire specifically mentioned Asthma as one of the examples, patients might have only experienced asthma as a child and do not use any regular treatment for this. There is currently no standardised criteria to assign this comorbidity variable in administrative coding and may explain this discordance. Besides the increased prevalence of Heart and Lung disease, PROMs data also identified fewer patients with Nervous system disease, which was more prominent in joint replacement surgery. This decreased reporting was mainly determined by occurrence of ICD-10-CM code indicating 'Epilepsy'. Although, patients might not consider epilepsy specifically a Nervous system disease, it is felt that patients who take preventive medication for seizures would normally consider 'ticking the box' on the PROMs questionnaire. Medical therapy compliance has been reported to be dependent on information provision²⁰² and therefore might explain patients underreporting certain comorbidities in our sample.

4.5 CONCLUSIONS

This study has demonstrated that the concordance between patient-reported and administratively extracted comorbidities was, apart from three commonly encountered, inadequate in most comorbidities as reported by patients. There was a further trend towards decreased concordance in most comorbidities in day-case procedures over joint replacement surgery, which further establishes the validity of patient-reported comorbidities, particularly for healthcare services delivering outpatient-based interventions. Contemporary health information systems are ill equipped to facilitate integration of information collected directly from patients by either health surveys or checklists. Medical practitioners should assist with this process and objectify comorbidities in a standardised manner and as a consequence both patient administration systems and health services research can benefit directly from better utilisation of patients as a direct source of health information, ultimately

leading to more accurate patient data, which can potentially influence reimbursement or explain variations between providers.

4.6 KEY POINTS ARISING FROM STUDY THREE

- The concordance between administrative and patient-reported comorbidities was poor except in three common conditions (Heart disease, High blood pressure and Diabetes) with increased discordance caused by overreporting in PROMs in day-case procedures compared to mainly inpatient procedures.
- Current guidance in the NHS in terms of comorbidity extraction from clinical medical records relies on physician's objectifying comorbidities during patient encounters providing no standardised accumulation of them for use in risk adjustment of data at a later stage.
- Patients are a primary source of health information, collecting comorbidities through PROMs can improve our understanding of patients' heterogeneity.
- In order to explain variations in healthcare, risk adjustment strategies should rely on a variety of data sources. Doing this in a more standardised manner has the potential to initiate quality improvement efforts.
- There is need to further establish the value of patient-reported comorbidities and their potential to predict traditional outcomes.

Chapter 5

RISK PREDICTION IN HIP REPLACEMENT SURGERY USING A SIMPLE SELF- REPORTED COMORBIDITY ADJUSTED RISK (SCAR) INDEX

5.1 INTRODUCTION

The importance of identifying explanatory variables for risk adjustment in outcome measurement for specific patient population groups has been highlighted in chapter 3. In more traditional outcome measurement, particularly in retrospective cohort analyses extracted from administrative data, heavy reliance on the accuracy of patient-related factors, such as comorbidities, influences the capability to adequately adjust for individual risk factors. Comorbidity, a pre-existing condition that is unrelated to the primary diagnosis, can influence a wide range of outcome measures and these can include mortality and morbidity as well as quality indicators of care utilisation²⁰³. The prevalence of patients with more than one comorbidity, i.e. multimorbidity, will continue to increase in this ageing society²⁰⁴. For risk adjustment in the analysis of population cohorts, combining several comorbidities to an overall risk index has clear advantages over single use of comorbidity. Whilst the ease of use is preferred over complexity, risk indices usually contain a set of comorbidities that are thought to be most relevant to explain variation in outcomes²⁰⁵. Most validated measures use a weight-based methodology to create an overall score that predicts outcomes better than accumulation alone, where higher reported scores are associated with worsening outcomes¹⁸³. As previously described, the Charlson Comorbidity Index (CCI) remains the most popular tool, which normally relies on administrative data but has also been generated based on patient-reported data²⁰⁶.

The previous studies have highlighted the inability of HES recorded comorbidities to predict HRQoL outcomes and discordance between those comorbidities and self-reported comorbidities. To further assess the validity of self-reported information of participants in the national PROMs programme, a singular index could provide an inexpensive means of risk adjusting patients both before and after surgery. For patients undergoing joint replacement, in particular those with multimorbidity, functional outcomes will remain priority, however, the risk of death (mortality), although, increasingly rare, is an outcome that is naturally important to patients. The

delay in obtaining information from administrative data for risk adjustment means there is an opportunity for self-reported comorbidity data to replace or complement current risk adjustment strategies.

The primary aim of this study was to identify whether a PROMs multimorbidity index can predict mortality in patients undergoing hip replacement surgery with the secondary aim to compare its performance against an established means of risk adjustment of administrative data using both the original and modified CCI.

5.2 MATERIALS AND METHODS

5.2.1 Study population

The methodology of patients participating in the national PROMs programme has been previously described in section 2.1. For hip replacement patients, the baseline questionnaire is, in most cases, collected at the pre-admission clinic as compared to collection on the day of surgery, which is the predominate methodology in day-case procedures. The follow-up period is at 6 months.

5.2.2 Data extraction

The PROMs linked to HES database is divided into four index procedural code groups, for this study the code (hip) assigned by the PROMs questionnaire was used and this was validated using OPCS-4 codes describing the primary procedure as hip replacement/arthroplasty. The primary procedure codes that were included in this study have previously been described²⁰⁷.

5.2.3 Outcomes

The primary outcome of interest was all cause mortality measured at six months after admission, obtained from the administrative data component, which include mortality data over the period between completion of the baseline and follow-up questionnaire obtained through the Office of National Statistics (ONS).

5.2.4 Construction of Self-reported Comorbidity Adjusted Risk (SCAR) index

Descriptive statistics were used to assess baseline demographics in this study population. To develop a Self-reported Comorbidity Adjusted Risk (SCAR) index, based on all twelve PROMs comorbidities, the entire cohort of patients was randomly divided into two equal groups; a development and validation group. The development group was used to test the association between PROMs comorbidities and assigned a 'weighting'. Single variables were tested in univariate analysis in both groups. To assess the independent association between individual comorbidities and death at 6-month, multiple logistic regression models were constructed with death as the dependent variable and all 12 PROMs comorbidities as candidate independent variables. Stepwise backward selection was used to select only comorbidities with a p-value <0.10 to remain in the model. Using methodology originally described by Sullivan et al, the significant estimates from the model were then converted into an overall index by assigning a 'weighting' to each comorbidity. The number equalled its regression coefficient divided by the coefficient with the smallest absolute value, rounding this number to nearest integer number. Each comorbidity was then compared to the weakest significant variable comorbidity, which was assigned a value of 1, and therefore a 'weight' of 2 indicated double the log odds of mortality, and half as 'strong' as a value of 4. The individual scores could then be enumerated to a single index, where a higher number conveys higher risk. The components and their consequent weighting are shown in Table 5.1. The maximum score a patient could achieve was 15.

5.2.5 Adjusting Charlson's comorbidity index for the sample population

The administrative data component (HES) allowed for extraction of Charlson's comorbidities using Quan's ICD-10 coding algorithm²⁰⁸, to calculate a CCI for each individual patient. The use of CCI in the target population has previously been validated²¹. Using the same method as described in the previous section, each individual Charlson comorbidity was assigned a new 'weighting' and comparison between original weightings are shown in table 5.2.

5.2.6 Model validation

To test for face validity, the ability of the SCAR index to discriminate between a patient who died and one who did not, was tested in the validation group. This process was repeated for the old and new Charlson weighting, to allow for comparison of performance between the newly developed SCAR and an established method. The first set of logistic regression models produced c-statistics, a measure of discrimination, and the generalised Nagelkerke R-square that explains variance (goodness of fit). The c-statistic (above 0.7 for reasonable and above 0.8 as strong) corresponds to the area under the curve (ROC) and is a model of discrimination. A value above 0.7 indicates reasonable beyond chance, whilst above 0.8 suggest good discrimination. A second and third set of models, which were first adjusted for demographics (age and gender) followed by further inclusions of self-reported general health as covariates in order to improve discrimination. For this study, IBM SPSS version 21 was used to conduct all statistical analysis.

Assigned weighting per disease	PROMs conditions
0	Lung disease Kidney disease Problems due to stroke Depression Diabetes mellitus Nervous system disease Arthritis
1	High blood pressure
2	Leg pain due to poor circulation
3	Heart disease Cancer
6	Liver disease

Total equals the score, for example: heart disease (3) and liver disease (6) equals (9)

Table 5-1: Weighted index of PROMs comorbidities

Charlson comorbidity	Original Charlson Weights	Empirical Weights
Myocardial infarction	1	5
Congestive heart failure	1	4
Peripheral vascular disease	1	3
Cerebrovascular disease	1	0
Dementia	1	5
Chronic Pulmonary disease	1	1
Rheumatic disease	1	2
Peptic ulcer disease	1	0
Mild liver disease	1	0
Diabetes without chronic complications	1	0
Diabetes with chronic complications	2	0
Hemiplegia or paraplegia	2	0
Renal disease	2	4
Any malignancy	2	4
Moderate or severe liver disease	3	9
Metastatic solid tumour	6	11
Aids(*)	6	0
Total	33	48

Table 5-2: Empirically assigned Charlson comorbidities weightings

5.3 RESULTS

76,557 patients, who underwent elective hip replacement and participated in the national PROMs programme, were included. The demographics characteristics of patients in the overall and development group were similar (Table 5.3). The patients had an average age of 68 years (SD +/- 11.1) and the majority of patients were white females. The prevalence of PROMs reported comorbidities ranged from 0.5% for liver disease to 70.7% for arthritis and 39.6% for high blood pressure. The most commonly coded Charlson comorbidity was chronic pulmonary disease with 11.5% and peptic ulcer disease, mild liver disease and hemiplegia were only present in 0.1% of the patients. AIDS was absent and therefore excluded from the CCI models. The all cause mortality rate at six months was 0.6% in the entire sample population.

5.3.1 Validation of the SCAR index

The results of the multiple logistic regression models with 6-month mortality as dependent variable revealed that heart disease, high blood pressure, leg pain due to poor circulation, diabetes, liver disease and cancer (within the last 5 years) were all significantly associated ($P < 0.05$) with mortality. The stepwise selection process further excluded diabetes due to its low coefficient and large standard error. The remaining comorbidities were assigned a 'weight' and were included in the index. The other seven PROMs comorbidities were all not significant and therefore assigned a weight of 0 (Table 5.1). The maximum achievable score was 15.

5.3.2 Adjusting Charlson's comorbidities index

Of the Charlson components, the most commonly recorded was Chronic pulmonary disease (11.5%) in the logistic regression model; it was the 'weakest' predictor acting as the smallest absolute value to assign weights to other significant candidate predictors. The variable, Metastatic solid tumour, was most predictive of 6-month mortality, and was assigned a value of 11. The sample weights for the CCI were very

different to the original weights used by Charlson. For example, Dementia and Myocardial infarction were originally assigned a value of 1, and in this sample a value of 5. In general, the level of the individual weights were greater in the event they were assigned a weighting compared to the original Charlson. Seven of Charlson's comorbidities were not predictive and therefore assigned a value of 0. The maximum achievable score for the original score was 33, based on the empirical evidence from the hip replacement patient population was 48.

	All	Development sample
Number (N)	76557	38273
Age (mean / SD)	68.12 (11.12)	68.2 (11.1)
Gender		
Male	40	39.9
Female	60	60.1
Baseline general health (%)		
Excellent	3470 (4.5)	1774 (4.6)
Very good	19977 (26.1)	9898 (25.9)
Good	31967 (41.8)	15946 (41.7)
Fair	14627 (19.1)	7342 (19.2)
Poor	3220 (4.2)	1615 (4.2)
missing	3296 (4.3)	1698 (4.4)
Self-reported comorbidity (%)		
Heart disease	7730 (10.1)	3858 (10.1)
High blood pressure	30302 (39.6)	15083 (39.4)
Problems caused by stroke	1201 (1.6)	586 (1.5)
Leg pain due to poor circulation	5615 (7.3)	2815 (7.4)
Lung disease	4970 (6.5)	2480 (6.5)
Diabetes	6764 (8.8)	3454 (9)
Kidney disease	1296 (1.7)	663 (1.7)
Disease of nervous system	626 (.8)	298 (.8)
Liver disease	406 (.5)	192 (.5)
Cancer (within last 5 years)	3483 (4.5)	1772 (4.6)
Depression	5780 (7.5)	2870 (7.5)
Arthritis	54146 (70.7)	27101 (70.8)
Charlson Comorbidities (%)		
Myocardial infarction	672 (0.9)	317 (.8)
Congestive heart failure	699 (0.9)	370 (1)
Peripheral vascular disease	714 (0.9)	331 (.9)
Cerebrovascular disease	173 (0.2)	78 (.2)
Dementia	184 (0.2)	102 (.3)
Chronic pulmonary disease	8804 (11.5)	4412 (11.5)
Rheumatic disease	2586 (3.4)	1295 (3.4)
Peptic ulcer disease	114 (0.1)	42 (.1)
Mild liver disease	202 (0.3)	112 (.3)
Diabetes without chronic complications	6405 (8.4)	3243 (8.5)
Diabetes with chronic complications	164 (0.2)	82 (.2)
Hemiplegia or paraplegia	115 (0.2)	51 (.1)
Renal disease	1679 (2.2)	827 (2.2)
Any malignancy, including leukaemia	750 (1)	374 (1)
Moderate or severe liver disease	20 (0)	13 (0)
Metastatic solid tumour	28 (0.0)	15 (0)
AIDS (*)	n/a	n/a
6 month mortality	487 (0.6)	228 (.6)

* Excluded due to absence in sample.

Table 5-3: Demographics of patients undergoing hip replacement in the national PROMs programme between 2009-2011

PROMs Comorbidity				
	Coefficient	S.E.	C.I.	P-value
Heart disease	0.76	0.17	(1.54/2.96)	<0.01
High blood pressure	0.24	0.08	(0.96/1.45)	0.06
Problems due to stroke	0.3	0.15	(0.62/2.94)	0.45
Leg pain due to poor circulation	0.53	0.19	(1.16/2.50)	<0.01
Lung disease	0.19	0.24	(0.76/1.92)	0.37
Diabetes mellitus (*)	0.18	0.2	(0.80/1.79)	<0.01
Kidney disease	0.45	0.35	(0/78/3.12)	0.04
Nervous system disease	-0.41	0.7	(0.17/2.60)	0.36
Liver disease	1.41	0.43	(1.78/9.78)	<0.01
Cancer (within last 5 years)	0.83	0.22	(1.51/3.52)	<0.01
Depression	-0.16	0.25	(0.87/1.81)	0.8
Arthritis	-0.18	0.15	(0.63/1.11)	0.22

S.E = standard error

C.I.= Confidence Interval

* Excluded from the final model

Table 5-4: Logistic regression analysis of PROMs comorbidities predicting 6-month mortality for patient undergoing hip replacement

Charlson comorbidity				
	Coefficient	S.E	95% C.I.	p-value
Myocardial infarction	1.65	0.29	1.78-9.79	<0.01
Congestive heart failure	1.62	0.32	1.86-8.92	<0.01
Peripheral vascular disease	1.08	0.39	1.35-6.35	<0.01
Cerebrovascular disease	-15.67	4201	0	0.99
Dementia	1.53	0.6	1.43-15.07	0.01
Chronic Pulmonary disease	0.32	0.18	0.96-1.98	0.08
Rheumatic disease	0.59	0.28	1.04-3.14	0.03
Peptic ulcer disease	1.43	1.02	0.56-30.70	0.16
Mild liver disease	1.15	0.64	0.90-11.02	0.07
Diabetes without chronic complications	0.95	0.75	0.59-11.20	0.21
Diabetes with chronic complications	0.07	0.022	0.70-1.65	0.73
Hemiplegia or paraplegia	-15.02	5045	0	0.99
Renal disease	1.27	0.24	2.23-5.68	<0.01
Any malignancy	1.41	0.33	2.18-7.84	<0.01
Moderate or severe liver disease	2.81	0.88	2.95-92.62	<0.01
Metastatic solid tumour	3.52	0.65	9.42-120.25	<0.01
Aids(*)	n/a	n/a	n/a	
(*) Excluded (not in sample)				

Table 5-5: Logistic regression analysis of Charlson' comorbidities predicting 6-month mortality for patients undergoing hip replacement

5.3.3 Model performance

Using the weights derived from the model developed in the development group, a SCAR score was generated for each patient in the validation set. The mean score was approx. 1.01 (SD 1.49) and the distribution of scores are displayed in Figure 5.1 and showed a non-normal distribution. In contrast, the majority of patients scored 0 points using the newly assigned empirical weights in the CCI (Figure 5.2). Table 5.6 shows the performance of the models for all three indices. The C statistics for models without additional predictors, showed similar performance of discrimination, although the model fit of the SCAR index was (0.08) lower than the empirical CCI. The ROC-curve of both the extended SCAR index and the modified CCI is displayed in Figure 5.3 & 5.4. In all of the models, the predictive accuracy increased upon adjustment with age, gender and general health in term of discrimination and proportionally to each other. However, both the original and empirical CCI had better model fit compared to the SCAR index.

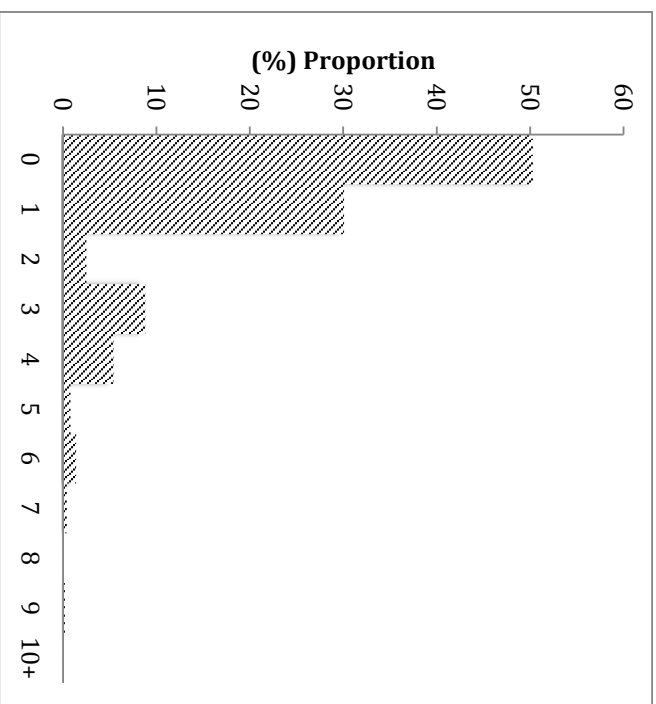


Figure 5-1: Distribution of SCAR index in validation set

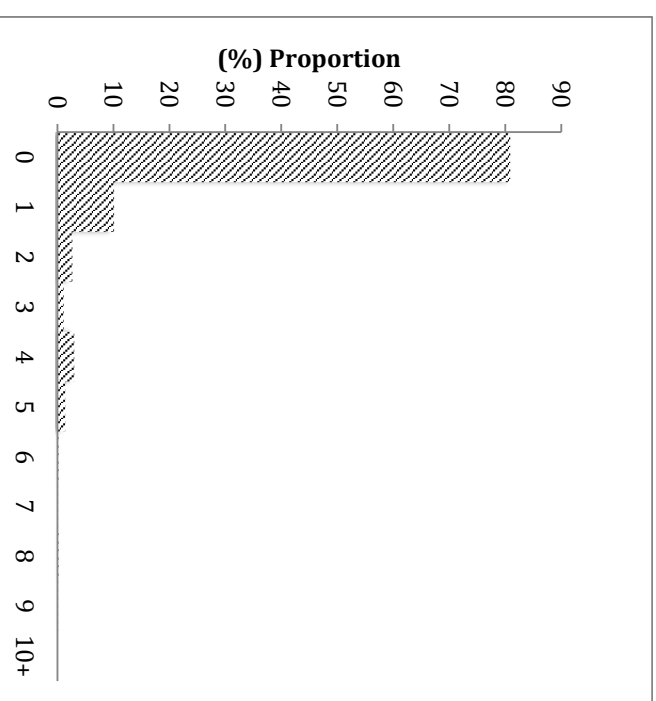


Figure 5-2: Distribution of empirically assigned CCI

Model and measure(s)	SCAR index	Original Charlson Weights	Empirically adjusted Charlson
Index			
C-statistics	0.64	0.65	0.63
95% C.I.	0.60-0.68	0.61-0.68	0.59-0.67
R-square	0.043	0.048	0.051
Index +demographics			
C-statistics	0.74	0.76	0.76
95% C.I.	0.71-0.77	0.73-0.79	0.73-0.79
R-square	0.063	0.085	0.086
Index +demographics/general health			
C-statistics	0.76	0.78	0.78
95% C.I.	0.73-0.79	0.75-0.81	0.75-0.81
R-square	0.077	0.101	0.102

Abbreviations: SCAR: Self-reported Comorbidity Risk index; demographics (Age&Gender)

Table 5-6: Summary of model performance for the 3 individual scores for elective hip replacement patients

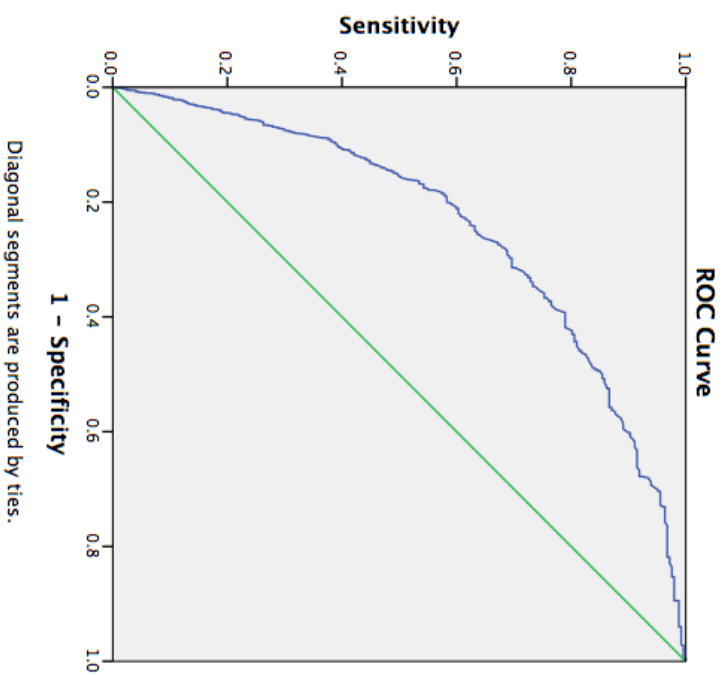


Figure 5-3: ROC curve for 6-month mortality models of empirical CCI with inclusion of demographics and general health

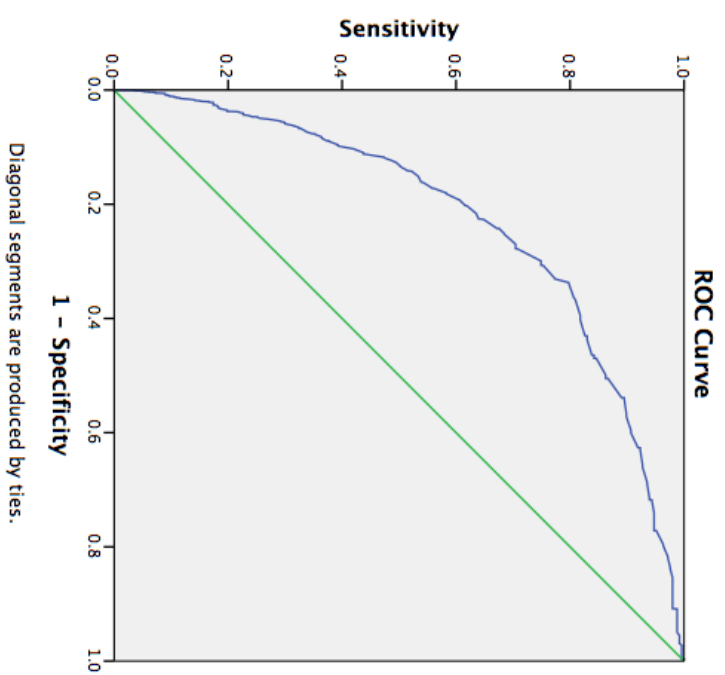


Figure 5-4: ROC curve for 6-month mortality models of SCAR index with inclusion of demographics and general health

5.4 DISCUSSION

5.4.1 Principal findings

Prediction of mortality following hip replacement surgery using a single index (SCAR) generated from twelve PROMs comorbidities did not perform better compared to an established method frequently used of risk adjustment where mortality is the outcome of interest. This was predominately caused by an inferior performance in the ability to explain variance. However, the discrimination of all models, including the SCAR index, were acceptable and comparable to previous studies²⁰⁹⁻²¹¹. The addition of age and gender, available from both the PROMs questionnaire and HES data component, offered better fitting models, in particular for the original and modified Charlson. Further improvements were achieved by addition of “fair” and “poor” self-rated general health, however, there were no additional differences between the patient-reported and administrative generated indices observed.

Between both indices, several comorbidities (heart disease, liver disease, cancer and peripheral vascular disease) were consistently associated with mortality and therefore included in each of the models. As was highlighted in the previous chapter, there were discrepancies between both data sources except for heart disease. The implication of this might be that there is potential for both data sources to complement each other and thereby improve their ability to predict mortality based on comorbidities. Identification of patients with comorbidities with low prevalence but high prediction capability, such as liver disease, is required to adequately adjust the data for clinical outcomes, where the focus is on smaller groups and/or individuals. In particular, in patient-centered care models, where better-informed patients will demand more personalised information. The method described in this study can easily be replicated in the event of adjustment of PROMs comorbidities to provide a better fit with a target population or with the outcome of interest.

5.4.2 Strengths and weaknesses of the study

The introduction and previous studies have highlighted that the meaningfulness of the PROMs data is determined by the generalisability of the sample analysed. With an overall response rates of around 80% and of those a substantial proportion completing the follow-up questionnaire, the PROMs data in terms of hip replacement can be assumed to provide an accurate representation of the entire patient population in England and Wales. Furthermore, the accuracy of the data is strengthened by the consistency of the administrative data reported mortality rate with previous studies²¹²⁻²¹⁴. However, most of these studies reported on 90-day mortality and the follow-up period of 6-months in the PROMs programme was chosen in light of the impact of surgery on functional outcomes when the patients' current health status has improved much beyond their preoperative pain and dysfunction level. Furthermore, the availability of administrative collected mortality, without data on timing of death and the inability to ascertain the cause of death, has influenced this study design. The risk of mortality associated with comorbidity is frequently measured by cox proportional regression models that aim to establish the potential 'hazard' that they pose within a certain follow-up period and allow for assignment of individual weightings^{20,209,210,215,216}. The applicability is, however, dependent on the timing of death and the HES dataset only contained single time-point mortality. Therefore, the use of Sullivan's methodology was considered appropriate by virtue of previous published studies applying this method similarly in their attempt to assign weights to independent predictors of mortality^{211,217}.

Both methods benefit from their ability to create a single index available for stratification of patients. For most clinical studies, it is usually not possible to analyse patients with particular outcomes in more than two groups at a time. An accumulated score with higher risk with increasing number can be adjusted to suit the likelihood of the outcome of interest²⁰. For example, when the largest proportion of patients are free from comorbidity, comparison between patients with any score can be attempted, however, when most patients report at least one comorbidity then

comparison between that group and patients with higher index score can be undertaken.

The advantage of a PROMs comorbidity accumulated score over scores that rely on administrative data relates to its timing. Having a simple score available at the time of the decision to operate can improve the informed consent process for both patients and surgeons. As previously mentioned, adjustment of the PROMs comorbidities to suit the target population is therefore required. The current comorbidities included in the questionnaire were not selected based on their relevancy to explain variation in hip replacement but due to the patients' ability to report them accurately⁹⁰. It is important to bear in mind that the sample used by Bayliss et al. had high incidence of comorbidities and focussed predominately on HRQoL outcomes. However, as the findings of study 2 suggested, only three PROMs collected comorbidities were predictive of HRQoL outcomes and therefore if others are considered non-relevant, further investigation into comorbidities that are most predictive of the outcomes of interest may be required.

5.4.3 Comparison with other studies

For patients undergoing elective hip replacement, comorbidity is a significant predictor of serious complications^{218,219}, (long-term) mortality^{220,221} and increased length of stay²²². The most frequently reported comorbidities are Cardiovascular disease, Renal disease and Dementia^{221,223}. Bozic et al. analysed 40,000 patients and reported a large number of comorbidities that were associated with mortality at 90 days and proposed the use of this information in counselling and risk adjustment following surgery²²⁴. Similarly, Jansen et al. concluded that patients, with a diagnosis of 'Dementia', required more careful consideration before proceeding to surgery. Although, the HES component allowed for extraction the ICD-10-CM code 'Dementia', and in this study it was also a significant predictor of mortality, it formed no part of the examples in the PROMs comorbidity (neurological disease) that seemed most fitting. Instead, it includes Multiple Sclerosis (MS) as example, which has not shown to be of influence on morbidity and mortality following

surgery²²⁵. The relevance of other comorbidities, such as diabetes, which is not considered to be associated with worsening clinical or HRQoL outcomes²²⁶, is however associated with increased incidence of wound infections.

Self-reported general health has been an important predictor of poor HRQoL and mortality²²⁷, even in models adjusted for important covariate such as age and comorbidity. In our models, the ability to explain variance improved upon addition of “fair” and “poor” self-reported health, and this promotes the use in risk assessment model using PROMs linked to HES data. With the absence of functional status, which is a strong independent predictor of mortality²²⁸, as a variable in administrative data, self-reported general health will remain an important potential predictor in traditional and HRQoL outcomes research.

5.5 CONCLUSIONS

Risk adjustment of mortality data using comorbidity information directly obtained from the patient is possible, however, traditional strategies that were specifically developed for this purpose performed better. There is a need for modification of the comorbidities chosen in the national PROMs programme to suit the specific patient population by inclusion of more relevant ones. The opportunity for routine collection of this information lies in their ability to allow for segmentation of patients prior to surgery leading to improved and more standardised decision-making. For ageing populations living longer and with more comorbidities, the benefit of outcome data that are relevant to the individual will potentially allow for better patients' choice and lead to less variation which coincides with the aims of the national PROMs programme as described in the introduction. Going forward, a future tool based on best available evidence that is easy to collect and provides relevant information can improve the informed consent process without the need for clinician's subjective interpretation.

5.6 KEY POINTS ARISING FROM STUDY FOUR

- Using a statistically reliable methodology to generate an accumulated index score predicting mortality based on patient-reported comorbidities is feasible, although, while it did provide similar statistical discrimination, the variance was less compared to an established risk index (Charlson's).
- The majority of patient-reported and administrative recorded (Charlson's) comorbidities were not predictive of mortality and were therefore assigned a zero value. Substituting them for more relevant comorbidities could further improve the predictability of the models.
- The inclusion of self-reported general health as independent predictor of mortality improved the modelling and can therefore provide an alternative to functional status in research lacking information on this.
- The value of standardised PROMs questionnaires is in the fact that it can assist in segmentation of patients into groups before surgery, potentially allowing for a better informed consent process.

Chapter 6

EXPLORING PATIENTS' ACCEPTANCE ON ELECTRONIC ALTERNATIVE IN ROUTINELY COLLECTED PROMS IN VARICOSE VEINS PATIENTS: A MIXED METHOD STUDY

6.1 INTRODUCTION

In order for PROMs to be meaningful, high response rates and fully completed questionnaires (unit response) are crucial to avoid response bias^{83,229}. Although, the response rates in joint replacement surgery in the national PROMs programme were satisfactory, the response rates in day-case procedures and in particular those for patients undergoing varicose veins surgery were poor as was highlighted in the introduction (Table 1.4). It is generally accepted that poor response rates are associated with young age⁸³, social deprivation and poor subjective health⁹⁴, and this was also recognised in the demographics of non-responding varicose veins patients in the national PROMs programme. Further potential explanations for low response rates can include the method of data collection, i.e. traditional paper-based versus technology. The PROMs programme was designed around pencil-and-paper methodology followed by a postal survey, however, this is thought to be resource intensive as a number of stakeholders are involved before data can be transformed into information. Therefore, introducing technology to aid data collection has the potential to improve response rates, data analyses and dissemination of findings. Previous studies have shown promising results in using a technological alternative^{230,231}, however, these studies were specifically designed for research purposes and this can lead to bias. A further added benefit of using technology to capture PROMs data is that it is the preferred environment in terms of sensitive information^{232,233}. Paper questionnaires can be lost at any point in time containing important personal information.

The analysis of the PROMs data have primarily focussed on quantitative elements such as patient-related factors, i.e demographics, and there has been a lack of evidence in terms of qualitative factors such as the patient's understanding and views of the national PROMs programme. Patients themselves can provide a novel view in order to further evidence factors explaining non-response in routinely collected PROMs.

This study had three aims: firstly to test the feasibility of using a user-friendly software platform that allows technology assisted collection of PROMs, second to, compare completion rates of an electronic alternative to the traditional paper-based questionnaire in a randomised setting in varicose veins patients. And thirdly, to explore patient-related factors in relation to their personal view on the questionnaire and overall PROMs programme as a potential explanation for unit non-response.

6.2 MATERIALS AND METHODS

6.2.1 Study population

All patients referred for minimally invasive treatment for varicose veins at two hospital sites within one Hospital Trust in England were eligible to participate in this study. There were two main study arms, firstly the randomised trial, which aimed to investigate the feasibility of using novel technology platform (web app) as an alternative to traditional paper-and-pencil questionnaires and secondly the qualitative arm consisting of a qualitative survey generated from a series of semi-structured interviews. For both arms, patients were approached, at two teaching hospital part of the same hospital trust, before undergoing outpatient treatment by a trained researcher. During data collection, both hospitals were required to submit their PROMs data for all patients undergoing treatment; special approval had therefore be granted by the Department of Health. Ethical approval for this study was obtained from the NRES Committee North West-Preston (ref 12/NW/0371).

6.2.2 Development of electronic version of PROMs questionnaire

Through an iterative user-centred design process, an electronic version of the national PROMs programme Varicose Veins Questionnaire was developed (Appendix Y). This version was made available as a ‘web application’ on all existing novel technology platforms and interacted with regular finger touch, as on mobile devices, but was also usable on Personal Computers (PCs). The main aim was to

have a near identical design of the questionnaire with the same questions and colour scheme. The final questionnaire differed from the original paper-based EQ-5D form in terms of the EQ-VAS score, which for the study was designed as a thermometer and patients had to start from score 50. Furthermore, the web application development process was restricted in terms of the ability to reproduce the exact picture of legs included in the Aberdeen Varicose Veins Score and it was therefore decided to separate both legs into eight segments (front and back; left and right and upper and lower). The electronic version was tested on a small sample of patients using a 9.7-inch tablet device and the design was adjusted accordingly.

6.2.3 Recruitment and follow-up

Recruitment commenced in March 2013 and lasted until March 2014. A total of 128 patients were eligible, of which 15 were excluded because they declined to participate, had no access to any novel technology platform or had limited understanding of the English language. After inclusion to the study, a further 17 patients (15%) were excluded because of cancellation of the procedure whilst they were in the treatment room. Treatment was discontinued due to venous spasm, making catheterisation impossible or there was presence of competent veins requiring no treatment. After consent to the study, patients were randomised using “blocked randomisation” principle. The block was the day of data collection and patients were assigned to one of the groups alternating after each assignment. Leading to 48 patients being randomised in the traditional paper-based (Group A) and 48 patients were assigned the electronic version (Group B) (Figure 6.1).

Each individual patient was assigned a study number to allow for tracking in the groups and linkage to their follow-up questionnaire. The follow-up questionnaire was posted (Group A) or text messaged/emailed (Group B) three months after intervention. If they failed to respond, they were sent one additional reminder and this was in accordance with national PROMs programme methodology. Patients in Group B were not required to login to complete the questionnaire, the hyperlink that was incorporated in the email brought them directly to question 1 of their individual

questionnaire. The data was held anonymously on a remote server, which also allowed patients to revisit the questionnaire if they had failed to complete it the first time round. Although data security was discussed with the participants, none expressed any concerns. Primary outcome was response rates to the follow-up questionnaire, secondary outcomes were improvement in Health-related Quality of Life (HRQoL), measured by the Aberdeen Varicose Veins Score (AVVQ) and EuroQol's EQ-5D.

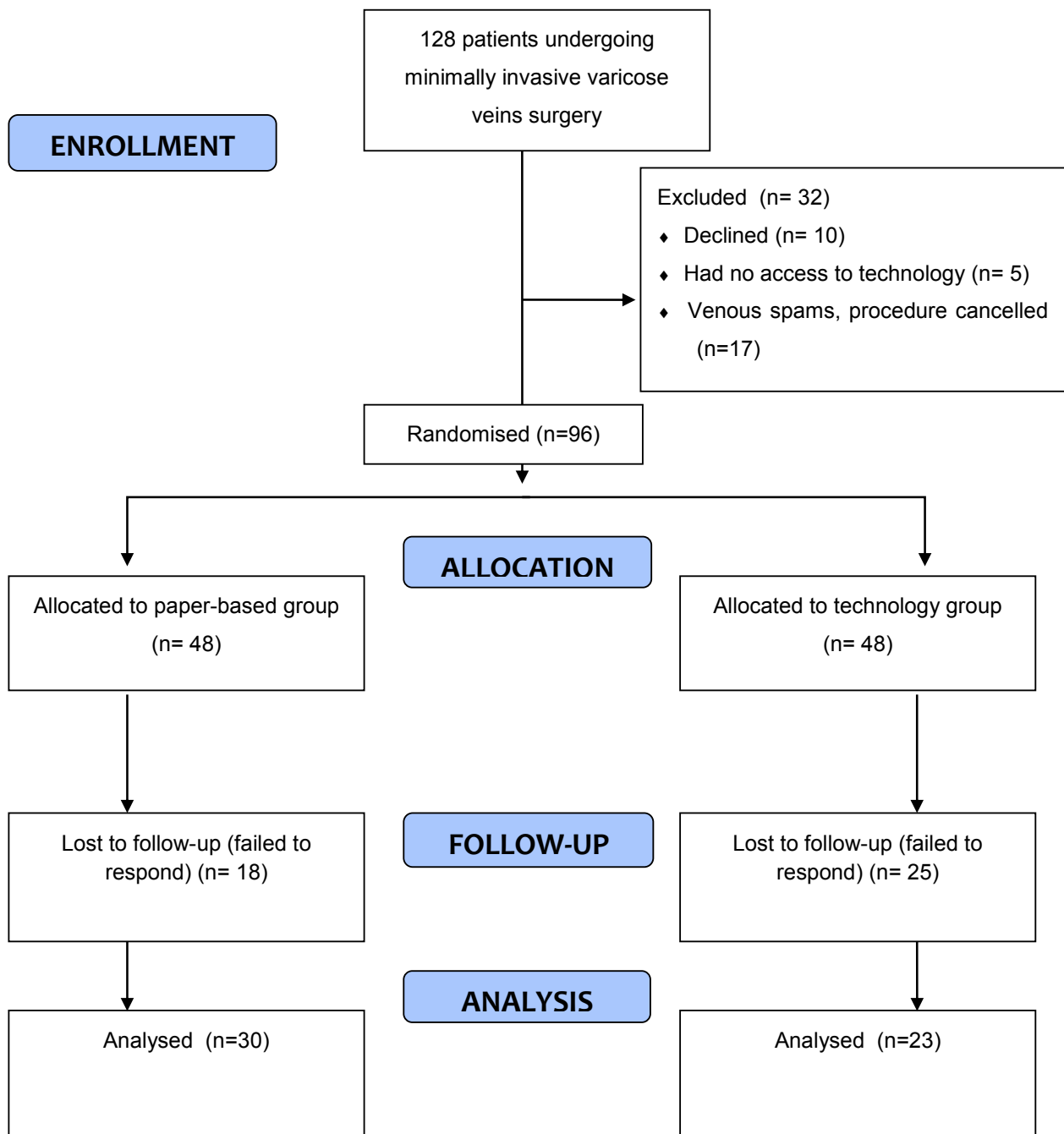


Figure 6-1: Flowcharts recruitment into randomised trial evaluating an electronic alternative to traditional paper-based PROMs questionnaire

6.2.4 Patient pilot interview

To assess patients' attitude towards the national PROMs programme and use of questionnaires to collect the data, four patients were invited to participate in face-to-face semi-structured interviews held at an acceptable place to the participant and were digitally recorded for subsequent verbatim transcription. After having obtained informed consent, patients were asked open-ended questions to investigate their attitude towards surgery in general and the use of PROMs to evaluate quality of care and their views on the paper-based and electronic format of the questionnaire. During the interviews patients were given time to elaborate on items they found important about health questionnaires. To further guide interviews, 'prompts' were given if patients did not cover certain topics as set out in interview schedule (Figure 6.2).

For example, most patients did not fully understand the purpose of the national PROMs programme and in particular the implication of their answers on service provision for future patients. In addition, they were told that the response rates in the varicose veins patients across England were poor and the study sought to improve them by exploring the feasibility of electronic means to capture data. Consequently, patients were shown the electronic version of the PROMs questionnaire on a tablet computer for comparison.

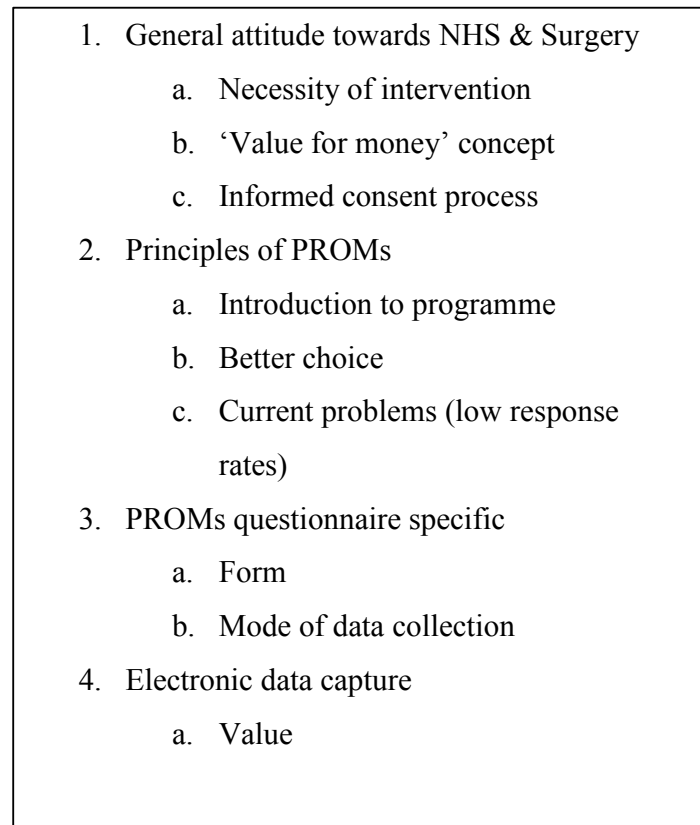
- 
1. General attitude towards NHS & Surgery
 - a. Necessity of intervention
 - b. 'Value for money' concept
 - c. Informed consent process
 2. Principles of PROMs
 - a. Introduction to programme
 - b. Better choice
 - c. Current problems (low response rates)
 3. PROMs questionnaire specific
 - a. Form
 - b. Mode of data collection
 4. Electronic data capture
 - a. Value

Figure 6-2: General themes and their subsequent prompts used during semi-structured interviews

6.2.5 Development of patient survey

Following the pilot interviews, 5 statements were generated in each theme that represented the items covered in the interviews in order to form a short survey that could be administered to a larger group of patients undergoing varicose veins surgery. The survey aimed to obtain a deeper understanding of the methodological issues affecting completion rates of the national PROMs programme. Each item was phrased as a statement e.g. 'It is clear to me why I need to complete the PROMs questionnaire', 'I am not aware that I will have to complete a follow-up questionnaire at three months', 'If available, I would prefer filling this in electronically' and respondents rated the degree to which they agree with each statement on a likert scale (1=strongly disagree, 7=strongly agree). Patient characteristics and ownership of technology platforms were collected. The survey instrument was pilot tested for

face validity among a sample of ten patients. Based on the feedback, minor changes were made to the wording of the items. Four statements were identified, which were consequently re-phrased to improve comprehension as per pilot study.

6.2.6 Statistical analysis

Data were analysed using IBM SPSS version 19 software. Simple descriptive statistics were used to report on primary outcomes in Stage 1 study. Independent t-test was used to report on statistical difference between the groups.

The interview transcripts were analysed using a thematic approach using NVivo software to organise the data. Four potential themes were identified from the interviews that were concurrent with the predetermined interview schedule. A second reviewer (SM) analysed the 2 of the 4 interviews to account for inter-rater reliability and control for bias.

For the patient survey, responses to each of the items on the questionnaire were grouped into the following categories: disagree (scores of 1-2), neither agree nor disagree (scores of 3-5) and agree (scores of 6-7). The percentage (%) of patients falling into these three categories were computed separately for each item and tabulated.

6.3 RESULTS

6.3.1 Randomised trial

There were no significant difference between the paper-based and electronic group in terms of age, gender, having had previous treatment and symptom period (Table 6.1). Although, the baseline condition specific (AVVQ) scores were comparable, there

was a significant difference in baseline EQ-5D index score (0.61 in Group A and 0.76 in Group B).

There was an obvious difference in response rates between both groups, 63% of patients in the paper-based group responded compared with only 48% in the electronic group, however, this difference was not statically significant ($p=0.15$) due to the relative small sample size. Non-responders seemed to be of younger age in the paper-based group (59 vs. 52.8), but this was also not significant ($p=0.12$). There was no difference between responders and non-responders in terms of presentation of different levels of symptoms (i.e chronic ulcer, eczema, pain and itchiness) caused by their varicose veins.

In both groups there was statistically significant improvement in the mean postoperative EQ-5D index score. There was significantly greater improvement in AVVQ score in Group B compared to Group A (26,1 to 15,5 vs. 27,5 to 23,4 resp.) after treatment ($p<0.04$).

Demographics	Paper-based	Responders	Non-responders	Novel technology platform	Responders	Non-responders	p-value
N (number)	48	30	18	48	23	25	
Age (mean / SD)	56.7 (13.3)	58.97 (11.2)	52.8 (15.9)	53.9 (12.7)	54.3 (13.9)	53.5 (11.6)	0.3
Gender (%)							
male	44	43.3	50	41.7	43.5	40	0.68
female	56	56.7	50	58.3	56.5	60	
Self-reported comorbidity (%)							
Heart disease	8 (4)	6.7	5.6	6.3 (3)	8.7	4	1
High blood pressure	38 (17)	33.3	44.4	20.8 (10)	26.1	16	0.07
Problems caused by stroke	8 (4)	3.3	11.1	0	0	0	0.08
Poor circulation	50 (25)	50	44.4	25 (12)	17.4	32	0.02
Lung disease	6 (3)	10	0	6.3 (3)	13	0	1
Diabetes	12 (6)	10	16.7	4.2 (2)	8.7	0	0.14
Kidney disease	0	0	0	0	0	0	*
Disease of nervous system	0	0	0	0	0	0	*
Liver disease	0	0	0	2.1 (1)	4.3	0	0.32
Cancer(withihn last 5 yrs)	6 (3)	10	0	2.1 (1)	4.3	0	0.31
Depression	8 (4)	10	5.6	6.3 (3)	8.7	4	0.7
Arthritis	26 (13)	26.7	16.7	14.6 (7)	8.7	20	0.3
Previous treatment (%)	43.8%	43.3%	44.4%	41.7%	29.1%	44.0%	0.84
Symptom period (%)							
< 1 year	4.0%	3.3%	5.6%	6.0%	4.3%	8.0%	0.16
1-5 yrs	29.2%	23.3%	38.9%	14.6%	17.4%	12.0%	
6-10 yrs	12.5%	16.7%	5.6%	27.1%	21.7%	32.0%	
>10 yrs	54.2%	56.7%	50.0%	52.1%	56.5%	48.0%	
Follow-up (%)	63%	n/a	n/a	47.9%	n/a	n/a	0.15
HRQoL scores							
Q1 EQ-5D	0.61 (0.30)	0.58 (0.33)	0.66 (0.27)	0.76 (0.24)	0.78 (0.25)	0.74 (0.23)	0.01
Q2 EQ-5D	0.70 (0.26)*	0.70 (0.26)	n/a	0.88 (0.15)*	0.88 (0.15)	n/a	0.05
Q1 AVVS	27.5 (14.0)	28.2 (11.4)	26.7 (18.5)	26.1 (14.2)	23.7 (13.3)	28.3 (14.9)	0.59
Q2 AVVS	23.4 (14.6)*	23.4 (14.6)	n/a	15.5 (10.8)*	15.5 (10.8)	n/a	0.035

*=only responders

Table 6-1: Demographics and follow-up rate of patients in paper-based and electronic group undergoing minimally invasive varicose veins surgery

6.3.2 Qualitative assessment of patients' views

6.3.2.1 Demographics

There were 75 participants in the survey study and of those 57% were female and most were of white ethnicity. A wide age range was represented in the sample (mean= 54.6, range 26-91). Most participants (72%) had access to a Personal Computer (PC), and 22.7% of the total also had access to all novel technology platforms, i.e. PC/tablet and smartphone. To note, only 9.3% of this sample had no access to any form of platform and their average age was 70 years old. A third of patients were considered to have had an employment history that is associated with a

higher risk of developing varicose veins, such as hairdresser, bartender and teacher. To note, 28% of all participants were retired individuals.

6.3.2.2 General Attitude towards surgery and national PROMs programme

The majority of patients (97%) thought it was important to ask patients about their experiences following surgery and generally thought more patient involvement was needed in the NHS (76%). There was no consensus regarding the number of questionnaires being used in NHS, 40% didn't think there were too many, whilst 36% thought there were too many questionnaires.

Quote M54: "There are not enough questionnaires in the NHS, this is how the NHS will know better how patients feel and can improve"

Quote F45: "I have filled in three questionnaire already today, they looked alike"

The majority of patients (68%) found the aims of the national programme unclear, and 51% wanted to know the output of the programme before coming to the hospital if this was available. However, no one communicated that they had accessed the national website, nor was any information researched prior to surgery.

Although, they were divided in terms of knowing the performance of the hospital against the national average in this particular treatment, the majority (83%) would consider travelling elsewhere if the quality of care was significantly better. A few patients emphasised that their own experiences with the hospital were more important compared to what would be available online:

Quotes: F60 "My own experiences with this hospital are more important than data results"

The majority of patients (71%) were not asked specifically by their treating surgeon to complete the PROMs questionnaire, and were also not aware that they were going

to be sent a follow-up questionnaire (92%). But in general, they did not mind filling in a follow-up questionnaire, or be reminded multiple times if they failed to complete it the first time. They did, however, understand that completing the questionnaire was voluntary (83%), as this was well identified from information displayed on the coversheet of the questionnaire. Patients mostly agreed (77%) to complete the questionnaire even though the data would be mainly used by the DoH.

6.3.2.3 Principles of PROMs

The majority of patients felt that the PROMs Varicose Veins questionnaire was easy to read (96%). They agreed mostly that the questionnaire itself wasn't too long (59%) and that it shouldn't be shorter if that would affect the content and therefore the quality of the data (60%).

Interestingly, a small majority of patients (43%) actually preferred completing the questionnaire on paper over an electronic alternative, with only 24% preferring electronic to paper. However, younger patients (<41) were significantly more likely to prefer electronic data capture. In addition, they were more likely to agree that electronic data capture would be quicker (78% vs. 48% in over 60s).

Quote: F40: "Using a paper and pen is so much easier, you'll focus more as you think it is more important"

Quote M23: "A few clicks and you are done, it is better for environment as well."

Similarly, younger patients (<41) were more likely to agree with sharing their health data online than older individuals.

As part of the AVVQ score, patients were required to draw their own varicose veins onto a predetermined picture of their own legs as it is weighted into the overall score. However, the majority of patients found it generally difficult to complete, although, they understood what was being asked (59% vs. 28%).

Quote M65: “I have been told I have Varicose Veins, but I do not know where they are”

Quote M32: “It is difficult to draw my varicose veins on the back of my legs as I can’t see them myself”

6.4 DISCUSSION

6.4.1 Principle findings

This chapter has demonstrated that patients were more likely to respond to a paper-based questionnaire compared to an electronic equivalent. In both groups, older patients were more likely to respond to the follow-up questionnaire. Qualitative assessment of patients’ attitude towards the national PROMs programme and specifically the mode and content of the questionnaire used, revealed that patients preferred completing the questionnaire using paper-pencil method and thought the questionnaire itself was acceptable. Although, the response rates in the study were better than in the national programme, they remained suboptimal, possibly due to lack of understanding of the aims and questionnaire fatigue.

6.4.2 Strengths and weaknesses of the study

By adhering to the exact methodology of the national programme, the principal findings may be extrapolated to the wider varicose veins population. By separating this study into a quantitative and qualitative arm, the same patient population was sampled but consenting the same patient twice was avoided to reduce the possibility of increased anxiety in the patients. Collecting data on the day of treatment greatly benefited the ability to follow patients in the treatment process after completion of the questionnaire. Participation in the study was considered to be of minimal impact to the patients as they had already been asked to complete the PROMs questionnaire by clinical nursing staffing.

The intuitive approach chosen for development of the electronic version improved the patients' acceptability and by making the electronic version available on all technology platforms discrimination was averted. At follow-up, patients in the electronic group were not required to login into the system, avoiding the scenario that patients were unable complete the questionnaire. In addition, verification of the email address took place to avoid 'bounce' rates. For follow-up questionnaires sent by post, a designated routine was set up using appropriate mail stamps ensuring delivery. Unfortunately, there was no possibility to gather information on acceptance of delivery. Furthermore, involvement of the responsible officers at the DoH provided an alternate view on the project to test face validity.

The pilot nature and the small number of participants limited this study, in particular the randomised trial investigating the feasibility of an electronic alternative. During the study period, as part of the on-going programme, both centres remained mandated to upload their PROMs data, which coincided with this study. Although local ethical approval was granted, a delay of six months occurred which further impacted on the ability to collect data.

6.4.3 Comparison with other studies

Drummond et al. reported excellent acceptability of an electronic alternative to paper-and-pencil with almost perfect response rates as early as the mid nineties²³⁴. The administration of electronic questionnaires in preoperative clinics has been acceptable²³⁵⁻²³⁷ and nearly all research comparing electronic versus paper-based questionnaires have reported equal or improved response rates in the electronic group. However, these studies have been specifically designed to test feasibility in a research setting and may not be an accurate representation of 'real-life'. Only a single study done by Rolfson et al. reported similar findings of decreased response rates for the electronic version in hip replacement patients in a national PROMs programme²³⁸. The benefits of administering electronic PROMs, such as economical considerations, data accessibility, improved data quality are all important items to consider for researchers, however, there are challenges that are mainly around

resistance of the research community in the design and integration phase of studies²³⁹. Overall, patients have responded positively to the introduction of electronic platforms in the collection of health surveys^{232,240}.

Patients undergoing joint replacement are more likely to respond in the national PROMs programme, benefiting from a relatively older age and a scheduled follow-up. However, this follow-up appointment is scheduled between 6 and 8 weeks post surgery, and the PROMs questionnaire is collected after 6 months. This implies that these patients voluntarily responded to the follow-up questionnaire. A more plausible explanation for non-response is the lack of interest in returning the questionnaire, particularly in younger patients²⁴¹. Participants' lack of understanding of the trial, which is known to be inversely associated with their likelihood to respond could subsequently lead to further non-response²⁴². In addition, explanation to patients of the need to complete the questionnaire, irrespectively of the clinical outcome, could motivate them and avoid alienation. This may be particularly important in day-case procedures, as patients will have less contact time with their clinician and there is usually no routine follow-up scheduled.

In surgical procedures with immediate effect, such as joint replacements, the use of PROMs to measure treatment impact has been more successful¹²¹, however, for treatments with predominately a preventive strategy, such as varicose veins, measuring quality through PROMs is more challenging. Routinely, patients will have had several interventions scheduled to treat one leg or have both legs treated with an interval. In this sample size, some questionnaires were completed and subsequent treatment was cancelled, leading to direct non-response if clinical teams did not bear this in mind. Completion rates are currently audited by hospital management in terms of quantity and do not distinguish if a patient actually underwent treatment. Identifying these patients early in the process can partially explain inadequate response rates.

A key area that traditionally does not play an important role, after implementation of a quality improvement strategy, are the patients themselves. Although, they are important stakeholders in the development of questionnaires, their views on overall service evaluations are usually not routinely available. However, information on

patients' views can influence and improve healthcare delivery²⁴³ or can endorse quality improvement initiatives²⁴⁴. As applied to the national PROMs programme, increasing patients understanding of the programme has the potential to improve response rates and this is particularly important in conditions treated predominately as a day-case.

6.5 CONCLUSIONS

The use of PROMs data to accurately assess and compare performance between different providers is influenced by their response rates. Identifying factors that determine patients' non-response is an important step towards further adoption of PROMs data. The potential of the data by linkage to meaningful clinical data has helped in assisting service provision and longitudinal studies²⁴⁵.

Although, technological advances will continue to replace traditional methods of data collection, patients themselves require further persuasion about its merits. Increasing the use of a patient-centred approach, championed by members of the responsible clinical team, should identify different types of patients and their (un)willingness to participate in their care and to provide feedback. Patients themselves and technology will have to act as partners to provide vital information to the system. For publically funded health system, the continuous search to contain costs will mean that varicose veins will remain an area of interest. In particular for patients referred with symptoms affecting daily life and who don't have a clear indication for treatment (venous ulcer / bleeding varicosity / recurrent superficial thrombophlebitis or other skin problems). For these patients, the threshold for treatment should be dependant on strict referral criteria to avoid abuse in the system. Only here will routinely collected PROMs provide added benefit to test decision-making. Patients who want treatment based on psychological symptoms alone will have their HRQoL impacted but in that case it is important to investigate the individual items that construct the score. Clinicians play a vital role in ensuring only those that are eligible will receive treatment for only those that benefit most from it.

6.6 KEY POINTS ARISING FROM STUDY FIVE

- Patients were more likely to respond and preferred using traditional paper-based questionnaire compared to an electronic alternative.
- There were few issues with the content and design of the PROMs questionnaire providing no explanation to clarify low response rates in varicose veins patients.
- A small proportion of patients (13%) completed their preoperative questionnaire, although, their procedure was subsequently cancelled, exclusion of these patients in the overall statistics can improve unit response rates.
- Most patients were not asked to complete nor explained the need of completing the PROMs questionnaire, providing plausible explanation for unit non-response, particularly for the follow-up questionnaire.
- Patients were overall positive about the presence of questionnaires in the NHS as a means to improve quality of care and were open to consider information on quality based on PROMs data in their decision of where to receive treatment.

Chapter 7

CONCLUSIONS AND FUTURE WORK

7.1 CONCLUSIONS

This thesis has investigated the appropriateness of evaluating quality of care using routinely collected PROMs on a national setting and provided evidence that the data generated by the national programme has potential to enhance readily available administrative data, however, the current programme setup in terms of data analysis, collection and feedback requires further adjustments to improve meaningfulness for patients and clinicians alike.

The need for measuring quality from the patients' perspective to facilitate the transformation from a physician-led towards a patient-driven health service has been extensively highlighted by publications ranging from Michael Porter to Governmental reports^{6,32}. Particularly, in surgery where there is generally a clear start and end-point and most treatments have the potential to improve symptoms that affect HRQoL, the preferred approach is by applying validated health surveys, i.e. PROMs. There is value in collecting this on a national scale where it, in theory, can inform policymakers on the effectiveness of different treatments for the same conditions; allow for provider comparison; track performance over time and compare treatment for different conditions²⁴⁶. However, implementation of the national PROMs programme has produced limited evidence on individual or system level change that has led to improvements in quality of care. The findings of study 1 highlighted the difficulties in analysing PROMs data in the context of inguinal hernia surgery, as limited response rates did not allow for provider comparison and the usability of a generic HRQoL measure (EQ-5D) to establish clinical need was restricted due to a large proportion of patients reporting perfect health preoperatively. It was, however, feasible to compare different treatments on an aggregate level for the same condition and this was dependent on appropriate case-mix adjustment relying on the accuracy of clinical coding and the availability of patient-reported factors used for risk adjustment of the data.

Using these patient-reported factors for subsequent risk adjustment of HRQoL data for patients undergone inguinal hernia repair implied that similar patient-reported factors (comorbidities and general health) were associated with patient not reporting full/perfect health for each of the PROMs index procedures. These factors were similar across both techniques, however, open technique produced additional factors that appeared to be influenced by the relatively larger sample size. In accordance with these findings, a reduction in HRQoL outcomes following treatment could be predicted with the same factors in both techniques. It could therefore be concluded that it was likely that differences in outcomes could be contributed in a greater extent to difference in surgical technique rather than to heterogeneity between the groups. The importance of this finding is in the fact that future changes in outcomes with a similar population mix, can be contributed to differences in process rather than patient characteristics.

Besides the three PROMs comorbidities, Depression, Leg pain due to poor circulation and Arthritis, which were consistently predictive of HRQoL scores in inguinal hernia patients, other comorbidities were found to be predictive, however, there was no consistency between the groups for both preoperative and postoperative HRQoL. Although, research has shown that patients can reliably report on their own pre-existing conditions, the analysis of Chapter 4 on all four PROMs index procedure revealed that patients persistently overreported certain comorbidities compared to administrative data recorded. This was particularly evident in the day-case procedures (inguinal hernia and varicose veins) and it is here that larger gaps exist and PROMs data enhances administrative data and could prove to be a more reliable source.

The appraisal of PROMs data was further expended to assess the capability of patient-reported comorbidities to predict traditional outcomes. Although, mortality after elective hip replacement is a rare occurrence, it remains an important indicator, particularly in an increasingly ageing population. The ability of a patient generated comorbidity index (SCAR index) to predict mortality preformed slightly worse against an established method of risk adjustment using administrative data. Refinement of the comorbidities chosen to the individual procedure could lead to improved modelling, especially if further adjusted to an appropriate outcome of

interest. The value here would be to allow for preoperative risk stratification of patient groups and to provide more representative and patient centred information to the patient.

However, it is important to bear in mind that factors, which can assist in explaining variation, could change over time requiring constant modification of the modelling for it to remain accurate. Yet, this feature will be pertinent in securing credibility of the PROMS data if provider comparisons will be successfully undertaken in this growing environment of (public) accountability. At present, the dissemination of PROMs data results is limited to overall group performance on indicator level providing no basis for quality assessment and improvement by individual providers. Qualitative assessment of patient's views on the PROMs programme confirmed the lack of public awareness of the national PROMs programme. Although, the response rates in joint replacement surgery were adequate due to favourable demographics, response rates in day-case procedures are unsatisfactory, this can possibly be explained by a lack of understanding of the need for completing PROMs questionnaires. The patients' willingness to participate at baseline was found to be acceptable, however, receiving a questionnaire after three months without a comprehensible explanation is a likely contributor of unit non-response to the follow-up questionnaire. In this group, introduction of an electronic alternative seems less feasible but could provide cost-savings and improve feedback to clinical teams.

Collecting health information directly from the patient will remain important, as they are the ultimate end-user of care. Increasingly, public accountability will force health systems alike to invest in their ability to classify performance using validated quality metrics that are used for the purpose they were originally designed for. For routinely collected PROMs to be successful and meaningful, five steps are crucial:

- Improve data analysis; for PROMs to be meaningful to both clinical teams and patients, appropriate case-mix and risk adjustment is of critical importance. This in turn will allow for comparisons between healthcare professionals or organisations and improve patient segmentation. (Bi)Annual risk adjustment can identify important trends to explain variation.

- Improve dissemination of programme findings, ensuring cooperation from clinician with the programme is vital to improve response rates and to allow for better usability of data. Rewarding good performance and engagement with national programme in annual appraisals or revalidation remains an important option to consider.
- Increase awareness to patients directly by improvement of the communication by hospitals, i.e clinical teams and leaflets / poster, and indirectly through media and digital channels such as the NHS Choices website (<http://www.nhs.uk>) to improve patient participation; stressing the importance of participation in order to improve care for everyone.
- Improvement of unit response rates could be achieved by adjusting the design and providing an electronic alternative, however, caution has to be taken into account and rigorous testing will be necessary before implementation. Further adjustment of the information contained in the questionnaire and assessment of reliability of patients reporting this, will help improve data quality.
- Each individual step in the cycle has the potential to improve data quality and this enhances the credibility of data in order to improve engagement from both clinicians and patients.

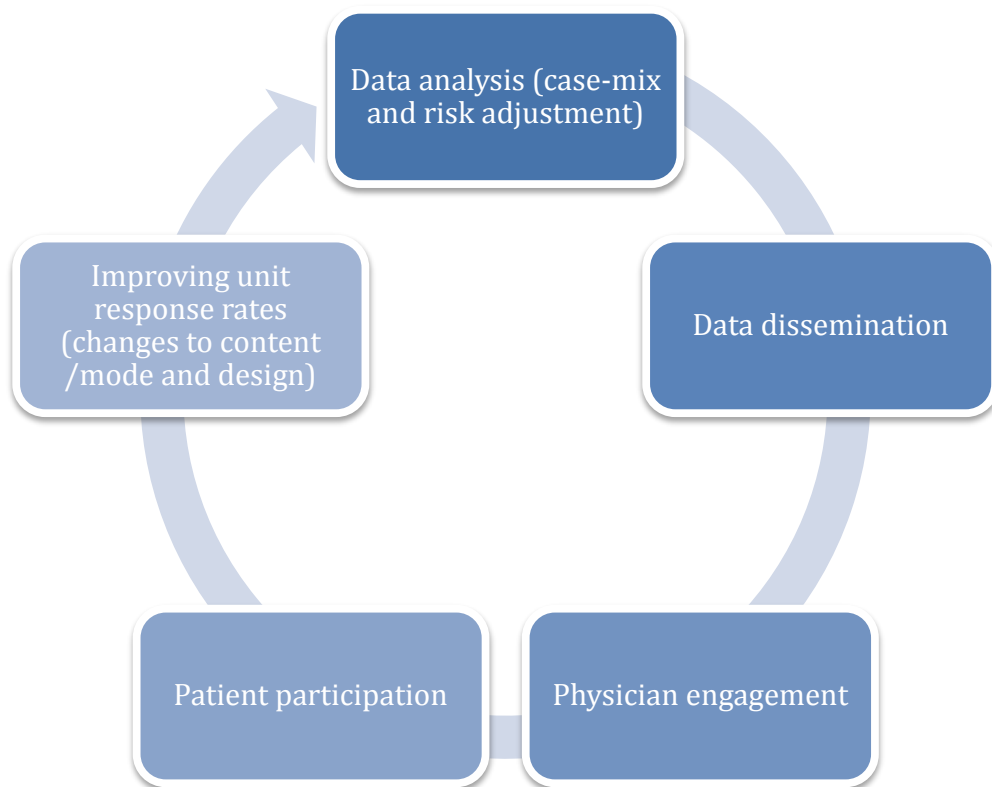


Figure 7-1: Proposed PROMs feedback loop to improve relevance of national PROMs programme

7.2 UNANSWERED QUESTIONS AND FUTURE RESEARCH

The role of PROMs data augmented by administrative data investigated in this thesis is part of a wider quality of care framework that aims to combine health information from different sources generated by healthcare providers and patient's experiences in order to provide the foundations for improvements in the system. These improvements should be based around their relevance to patients and their ability to independently assess performance.

In first instance, future research should be aimed at additional testing of the comparability of treatment options for the same condition in other index procedures included in the national PROMs programme using appropriate case-mix and risk adjustment strategies. Data analysis should focus on each of the explanatory factors, i.e. procedure codes, the organisation (Hospital Trusts) and its guidelines, and the individual surgeons that contribute to difference in outcomes and in doing so could enhance the credibility of the PROMs data. This could then lead to better segmentation of patient groups before surgery using data reports generated by nationally collected PROMs data, rather than using general statistics of mortality and morbidity that is currently used in the majority of informed consent process. PROMs data can inform the surgeon and the individual patient about;

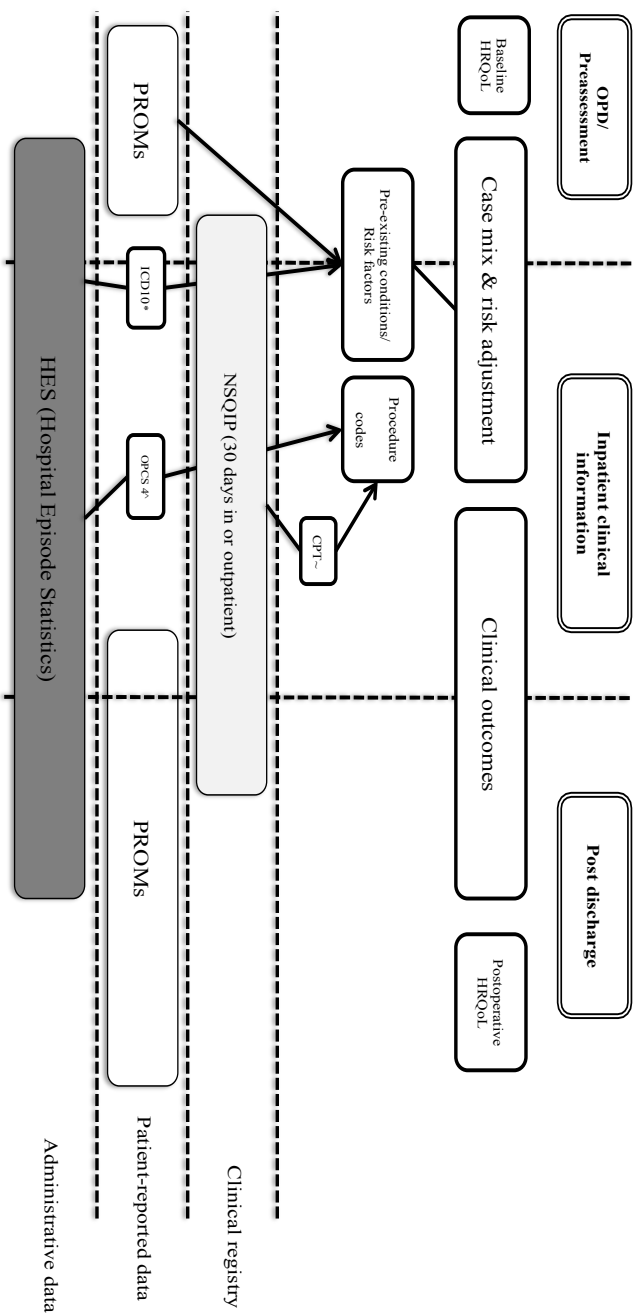
- The likelihood and possible margin of improvement of HRQoL outcomes
- The individual risk of patient-reported adverse events
- Average length of stay
- To set baseline expectations

Using a standardised approach for the decision-making process, assisted by both condition specific (where applicable) and generic HRQoL scores, could allow for improved capability to measure treatment indication in order to explain variation between clinicians and/or providers. For example, for inguinal hernia patients, the

exact symptoms or reason why it affects their daily life could provide a better insight in the preoperative variation in patient presenting with symptoms. The Carolinas Comfort Scale (CCS), developed specifically for mesh inguinal hernia repair, is known to provide better assessment of QoL compared to SF-36, however, it only provides a single overall score by combining preoperative and postoperative data²⁴⁷. A condition specific inguinal hernia score that allows for comparison between before and after surgery should be developed to determine the viability of establishing a threshold supporting the decision-making process. Moreover, a condition-specific score is better at establishing clinical need and set baseline expectations. Patient groups with few or no symptoms are at risk of reporting a reduction in HRQoL in the event of postoperative complications and the use of generic HRQoL measure is therefore suboptimal. The use of a threshold in conjunction with information generated from the referral guideline could limit variation and further improve comparability of PROMs data.

For clinicians, further efforts should be directed to increase their understanding of the importance of PROMs in outcomes assessment. In the absence of clinical registries that are externally audited, such as the ACS's NSQIP programme as described in the introduction (Section 1.1.3) that does add burden to hospitals both financially and on clinical teams, the NHS in England and Wales will remain reliant on data from administrative and patient in origin. Understanding the limitations and strengths of each data source is vital in quality of care measurement. The accuracy of information on pre-existing conditions, i.e. comorbidities, relies on the quality of data contained in medical records (for clinical registry and administrative data) and PROMs questionnaires (Figure 7.2). This is also applicable to collecting outcomes, where inpatient complications are recorded in clinical notes or at follow-up appointments. Both patients and clinicians play a vital role in generating information and both should be targeting in order to increase data reliability. However, further validation of all of the described levels of data is possible by comparing it to observational data that is readily available from primary care providers. For research on patient in the NHS, the Clinical Practice Research Datalink (CPRD) data can provide information on health status as well as outcomes, i.e. surgical site infections, following elective surgery. The patient's GP practice provides the central point of care from where a patients is referred into the system and it is here that PROMs data

can assist in choosing which providers are most suitable. For example, one centre might have better outcomes treating patients above the age of 80 years based on outcomes. The introduction of freedom of provider choice in 2007 has not led to significant migration of patient groups for the reason that individual patients are not simple market-based consumers with an unified demeanour, but rather vary in terms of health literacy, mobility and their overall needs. They are currently mostly concerned about retaining the public and universal access aspect of the system and would trade that in for freedom of choice. However, in a system that is essentially free of barriers and patients are willing to consider going elsewhere provided the care at that location is better, they require better and more easily available information.



*ICD10: International Classification of Disease 10th revision
 ^OPCS-4: Office of Population Censuses and Surveys Classification of Surgical Operations and Procedures 4th revision
 ~CPT: Current Procedural Terminology (used by American Medical Association) US equivalent to OPCS4

Figure 7-2: Three level data for outcome measurement within the surgical care pathway

Finally, existing measures of overall health status, i.e generic HRQoL measure such as the EQ-5D, fail to appreciate the impact of disease on overall wellbeing. As generic HRQoL measures are dependable on age and pre-existing conditions, it only provides us with information about health and its influence on quality of life. Comparison of HRQoL outcomes using generic measures across different conditions is hampered by difficulties in equally estimation of counterfactual pathways, even amongst elective surgical procedure., For example, patients after hip replacement will likely return to full health appropriate for their age and comorbidity status and before symptoms caused by coxarthrosis impacted their HRQoL, however, treatment for varicose veins patients is less likely to lead such large difference following treatment. The continued use of patient-reported outcomes, in particular the quantification of health-related quality of life in surgery, will remain a priority for health systems to evaluate provider performance and identify variation. Although, the use of a generic HRQoL index (EQ-5D) can assist in stratification of patients, the existence of confounders, i.e. previous or on-going experience of other medical conditions, in a rapidly ageing society will make decisions about resource allocation difficult. Prioritisation of treatments on a system level could benefit from additional information, such a subjective wellbeing measures, which aim to objectify a patient's life satisfaction based on emotional reactions and cognitive judgements. Having patients with poor life satisfaction undergo treatment that does not improve their quality of life seems wasteful and therefore comparison between a condition specific and generic HRQoL, and subjective wellbeing is warranted.

Appendix T

Baseline characteristics of patients reporting readmission Yes/No for both open and laparoscopic group in study period.

	Open			Laparoscopic		
	Yes % (Std residuals)	No % (Std residuals)	p-value	Yes % (Std residuals)	No % (Std residuals)	p-value
N (numbers)	1192	21358		257	4305	
Age (mean / SD)	65.79 / 14.7	61.97 / 14.6	<0.01	60.11 / 16.33	57.96 / 14.35	<0.01
Gender						
male	92.8 (0.0)	92.9 (0.0)		92.2 (-.4)	94.8 (0.1)	
female	7.2 (0.2)	7.1 (0.0)		7.8 (1.7)	5.2 (-.4)	
Ethnicity						
White	87.9 (-.4)	84 (0.1)		86.4 (-.2)	83.1 (0.0)	
None-white	3.8 (1.0)	3.1 (-.5)		5.4 (1.0)	2.9 (-.2)	
missing	8.3	12.9		8.2	14	
Self-reported comorbidity						
Heart disease	18.7	10.2	<0.01	8.6	6.5	0.2
High blood pressure	34.3	28.9	<0.01	24.5	25.3	0.79
Problems caused by stroke	3.6	1.6	<0.01	1.2	1.1	0.91
Poor circulation	12	4.7	<0.01	6.2	3.4	0.02
Lung disease	10.5	6.3	<0.01	4.3	4.1	0.87
Diabetes	6.6	5.4	0.07	4.3	3.9	0.78
Kidney disease	2.9	1.4	<0.01	0.8	0.9	0.86
Disease of nervous system	1.7	1.1	0.06	1.2	0.7	0.36
Liver disease	0.8	0.5	0.16	0	0.3	0.42
Cancer(withihn last 5 yrs)	6.7	4.9	<0.01	3.9	3	0.39
Depression	5.7	4	<0.01	4.7	3.3	0.25
Arthritis	26.3	17.7	<0.01	17.9	14.8	0.17
Baseline general health						
excellent	3.9 (-3.9)	10.4 (0.9)		10.9 (-.7)	14.4 (.2)	
very good	22.8 (-5.9)	38.5 (1.4)		30 (-2.0)	42.9 (.5)	
good	38.7 (1.2)	37.4 (-.3)		37 (1.6)	33.2 (-.4)	
fair	24.4 (10.4)	11.5 (-2.4)		17.5 (2.2)	8.4 (-.5)	
poor	8.8 (7.3)	1.8 (-1.7)		4.7 (n/a)	0.9 (0.0)	
missing	1.5	0.5			0.5	
Social deprivation						
1- (most)	15.5 (2.6)	12.6 (-.6)		11.7 (.5)	10.6 (-.1)	
2	18 (.7)	17.7 (-.2)		17.5 (1.2)	14.4 (-.3)	
3	22.8 9.7)	21.7 (-.2)		14.8 (-2.1)	21 (.5)	
4	22.8 (-.8)	24.0 (.2)		28 (1.0)	24.7 (-.2)	
5- (least)	20.3 (-2.4)	24.0 (.6)		28 (-2.8)	29.1 (.1)	
missing	0.6	0.6		0	0.3	
Symptom period						
< 1 year	66.4 (-1.1)	69.1 (.2)		77.0 (.8)	72.6 (-.2)	
> 1 year	33.6 (1.6)	30.9 (-.4)		23.0 (-1.3)	27.4 (.3)	
missing						
Previous surgery (% Yes)	6.9	5	<0.01	7	6.1	0.5

Appendix U

Distributions of patient reporting postoperative adverse events overall and by length of stay. (difference is reported as unadjusted Odds Ratios (OR) with 95% C.I and p-value)

	Treatment group	Responders n (%)	Day case (0) n (%)	1 night n (%)	2 nights n (%)	3 nights or more n (%)	Readmitted (Y) n (%)
Overall (Responders)	Open		17761 (72.7)	5642 (23.1)	631 (2.6)	536 (1.3)	
	Laparoscopic		3214 (68.7)	1292 (27.6)	123 (2.6)	52 (0.2)	
Adverse event							
Allergy or reaction to drug	Open	972 (4)	622 (3.5)	288 (5.1)	40 (6.3)	22 (5.7)	112 (11.5)
	Laparoscopic	200 (4.3) <i>p-value</i> 0.37	103 (3.2) <i>p-value</i> 0.37	84 (6.5) <i>p-value</i> 0.05	9 (7.3) <i>p-value</i> 0.74	4 (7.7) <i>p-value</i> 0.32	16 (8.0) <i>p-value</i> 0.12
OR (95% C.I.)		1.07 (0.92-1.25)	0.91 (0.73-1.12)	1.25 (0.99-1.65)	1.13 (0.53-2.41)	1.77 (0.57-5.47)	0.65 (0.38-1.12)
Urinary problems	Open	1632 (6.7)	805 (4.5)	615 (10.9)	123 (19.5)	89 (23.1)	255 (25.8)
	Laparoscopic	542 (11.6) <i>p-value</i> <0.01	250 (7.8) <i>p-value</i> <0.01	208 (16.1) <i>p-value</i> <0.01	56 (45.5) <i>p-value</i> <0.01	28 (53.8) <i>p-value</i> <0.01	89 (38.2) <i>p-value</i> <0.01
OR (95% C.I.)		1.80 (1.62-2.00)	1.75 (1.51-2.03)	1.54 (1.3-1.82)	3.45 (2.27-5.24)	3.82 (2.07-7.06)	1.78 (1.32-2.40)
Bleeding	Open	1370 (5.6)	968 (5.5)	303 (5.4)	51 (8.1)	48 (12.4)	223 (22.7)
	Laparoscopic	222 (4.7) <i>p-value</i> 0.02	154 (4.8) <i>p-value</i> 0.13	57 (4.4) <i>p-value</i> 0.16	8 (6.5) <i>p-value</i> 0.59	3 (5.8) <i>p-value</i> 0.29	40 (19.0) <i>p-value</i> 0.25
OR (95% C.I.)		0.84 (0.73-0.97)	0.87 (0.73-1.04)	0.81 (0.61-1.08)	0.81 (0.37-1.75)	0.52 (0.15-1.76)	0.80 (0.55-1.16)
Wound problems	Open	2735 (11.2)	1950 (11)	624 (11)	103 (16.3)	58 (15)	327 (31.3)
	Laparoscopic	418 (8.9) <i>p-value</i> <0.01	266 (8.3) <i>p-value</i> <0.01	132 (10.2) <i>p-value</i> 0.48	15 (12.2) <i>p-value</i> 0.33	4 (7.7) <i>p-value</i> 0.35	47 (21.5) <i>p-value</i> <0.01
OR (95% C.I.)		0.79 (0.71-0.88)	0.74 (0.64-0.84)	0.93 (0.76-1.13)	0.75 (0.41-1.34)	0.6 (0.2-1.77)	0.60 (0.42-0.84)
Readmission	Open	1195 (5)	714 (4)	364 (6.5)	63 (10.1)	54 (14)	
	Laparoscopic	257 (5.5) <i>p-value</i> 0.09	156 (4.9) <i>p-value</i> 0.03	79 (6.1) <i>p-value</i> 0.65	13 (10.6) <i>p-value</i> 0.84	9 (17.6) <i>p-value</i> 0.57	
OR (95% C.I.)		1.13 (0.98-1.30)	1.22 (1.02-1.45)	0.94 (0.73-1.21)	1.07 (0.57-2.00)	1.25 (0.58-2.72)	

Appendix V

Individual PROMs comorbidities and their corresponding ICD-10-CM codes with description

PROMs Comorbidity	ICD-10-CM codes	Description
Heart Disease	I03-09 I10.0;I10.9 I20 I25 I31 I34-36 I42 I44-45 I48-49 I50 I51 Q22-26	Chronic rheumatic heart disease Hypertensive heart disease Angina Pectoris Chronic ischaemic heart disease Other diseases of pericardium Valve disorders Cardiomyopathy Conduction disorders Atrial fibrillation and flutter, other cardiac arrhythmias Heart failure Complications and ill-defined descriptions of heart disease Congenital malformations of heart and valves
High blood pressure	I10 I15	Essential hypertension Secondary hypertension
Problems caused by stroke	G81 G82 G83.0;G83.1;G83.2	Hemiparesis Para/tetraplegia Mono (di)plegia of limbs
Leg pain when walking due to poor circulation	M79.66	Leg pain, unspecified
Lung disease	J40 J41 J42 J43-45 J47 J60 J61 J62-63	Bronchitis, not specified as acute or chronic Simple or mucopurulent chronic bronchitis Unspecified chronic bronchitis Emphysema, Chronic obstructive pulmonary disease (COPD), Asthma Bronchiectasis Coal worker pneumoconiosis Pneumoconiosis due to asbestos Pneumoconiosis due to dust / other inorganic dust

		J64	Unspecified pneumoconiosis
		J65	Pneumoconiosis associated with tuberculosis
		J66-70	Other airway disease
		J82	Pulmonary eosinophilia, NOS
		J84-86	Other interstitial pulmonary diseases
		J98-99	Other respiratory disorders
		D86.0	Sarcoidosis of lung
		B66.4	Paragonimiasis of lung
		A16	Tuberculosis of the lung
	Diabetes	E10	Insulin dependant diabetes mellitus (IDDM)
		E11	Non insulin dependant diabetes mellitus (NIDDM)
		E12	Malnutrition-related diabetes mellitus
		E13	Other specified diabetes mellitus
		E14	Unspecified diabetes mellitus
	Kidney disease	N03	Chronic nephritic syndrome
		N04	Nephrotic syndrome
		N05	Unspecified nephritic syndrome
		N07	Hereditary nephropathy
		N11	Chronic tubulo-interstitial nephritis
		N13-15	Chronic and reflux uropathy / Tubulo-interstitial disease
		N18	Chronic kidney failure
		N19	Unspecified kidney failure
		Q61	(Multiple) Renal cyst
		C65	Malignancy of renal pelvis
		D09.1	Carcinoma in-situ (CIS) of urinary organs
		D30.0;D30.1	Benign neoplasm of urinary organs
	Nervous system disease	G10	Huntington disease
		G11-13	Hereditary ataxia / Spinal muscular atrophy / System atrophies
		G20	Parkinson disease
		G21	Secondary parkinsonism
		G22	Parkinsonism in diseases classified elsewhere
			Other degenerative diseases of basal ganglia / dystonia / other
		G23-25	extrapyramidal
		G30-32	Degenerative diseases of nervous system
		G35	Multiple Sclerosis (MS)
		G40	Epilepsy
		G80	Cerebral palsy
		G90.8;G90.9	Disorder of autonomic nervous system
		G91	Hydrocephalus
		G96.8;G96.9	Disorder of central nervous system
		G98	Nervous system disorder not other specified

Liver disease	K70	Alcohol fatty liver
	K71	Toxic liver disease
	K72.1;K72.9	Chronic hepatic failure
	K73	Chronic hepatitis
	K74	Fibrosis and cirrhosis of liver
	K76	Other diseases of liver
	Q44.6	Cystic disease of liver
	D01.5	Carcinoma in-situ (CIS) of liver
	D37.6	Neoplasm of uncertain or unknown behaviour of liver
	B18-19	Chronic viral hepatitis / unspecified hepatitis
	I82.0	Budd-chiari syndrome
Cancer	C00-75	Malignant neoplasms
	Z85	Personal history of malignant neoplasm
	D37-48	Neoplasm of uncertain or unknown behaviour
Depression	F32	Mild depressive episode
	F32	Recurrent depressive episode
Arthritis	M02	Reactive arthropathies
	M03	Post-infective and reactive arthropathies
	M05	Seropositive rheumatoid arthritis
	M06	Other rheumatoid arthritis
	M07	Psoriatic and enteropathic arthropathies
	M08-9	Juvenile arthritis
	M10-12	Other arthropathies (gout etc)
	M13-14	Other arthritis
	M15	Poly arthrosis
	M16	Coxarthrosis
	M17	Gonarthrosis
	M18-19	Other arthrosis

APPENDIX W



Hernia Surgery Questionnaire

Before your operation

Hernia Surgery Questionnaire – Before your operation

Patient Information

What is this questionnaire for?

The purpose of collecting information in this questionnaire is to find out about the quality of care you receive from your healthcare provider. The information that you give us will help to measure and improve the quality of health services.

Why have I been invited to complete this questionnaire?

All NHS patients undergoing a Groin hernia operation are invited to fill in this questionnaire.

Do I have to take part?

No. Your participation is voluntary. If you do not want to take part, do not fill in the questionnaire.

Do I have to give my consent to participate?

We need your consent for your personal details to be used. Your personal details will be used to send you an **After your operation** questionnaire in three months time. They will also be used to link the information you give us to other information relevant to your Groin hernia operation.

Can I change my mind?

Yes. You can choose to withdraw your information any time up to the point that data are analysed and personal details removed. Withdrawing your information will not affect your medical or legal rights. To do so please notify the programme by telephone, in writing or by e-mail (see over for contact details).

What happens next?

Once you have given your consent to participate please fill in and return this questionnaire. Your personal details will be held and stored by the Health and Social Care Information Centre so that we can send you an **After your operation** questionnaire to fill in and send back in three months time.

What will happen to the information I give you?

Your personal details will be used to link the data you give us to other data held by the NHS and partner organisations about you. Your personal details will also be used to send you an **After your operation** questionnaire. We will hold your personal details for up to a year. If we want to use your information for other uses or to hold your information for longer, we will write to you to ask your permission.

Why are third party organisations used?

Some third party organisations are employed to support the NHS to handle and analyse the data you give us. Only organisations with expertise in these areas have been chosen to support the NHS.

Will my personal details be safe?

All organisations involved with handling patient information must meet strict requirements on the handling and storage of personal information. Published reports will not contain any personal details.

2

Hernia Surgery Questionnaire – Before your operation

Consent Form

The purpose of collecting information in this questionnaire is to find out about the quality of care you receive from your healthcare provider. To make sure that the information we collect is useful, we need to collect your personal details and to access information held about you in other NHS databases.

To do this we need your consent.

Please read the following statements carefully. If you agree with them please sign and date this form, below.

I agree that my personal details and relevant health information related to this operation will be held and used by the Health and Social Care Information Centre, including information held about me by the Patient Demographics Service, the National Strategic Tracing Service, the Secondary Uses Service and other NHS databases.

I agree that my personal details will be used to send me an **After your operation** questionnaire in three months time.

I agree that my personal details and health information can be held and used by third party organisations, working on behalf of the Health and Social Care Information Centre, for this project.

I understand that my personal information will not be released by the Health and Social Care Information Centre or third party organisations working on its behalf, unless required by law or where there is a clear overriding public interest.

I understand that I can withdraw the information I give the NHS in these questionnaires upon request, up to the point at which data are analysed and personal details removed.

Print Name _____

Signature _____

Date _____

PATIENT COPY

Contact us for further details:

- Freephone: 0800 917 1163
- E-mail: doh.helpforpatients@nhs.net
- Write: PROMs Survey, PO Box 909, Aylesbury, HP22 9HT
- Website: www.nhs.uk/proms



Hernia Surgery Questionnaire – Before your operation

Patient Details

If you have agreed to take part, would you please write your name and address in CAPITAL LETTERS BELOW so that we can contact you by post.

Title: Mr ☐ 1 Mrs ☐ 2 Miss ☐ 3 Ms ☐ 4 Dr ☐ 5

Other (please specify) _____

First Name: _____

Surname: _____

House No./ Name: _____

Street: _____

Town/City: _____

County: _____

Postcode: _____

Which statement best describes your living arrangements?

- I live with partner/spouse/family/friends ☐ 1
I live alone ☐ 2
I live in a nursing home, hospital or other long-term care home ☐ 3
Other ☐ 4

1

Q1. Is anyone helping you fill in this questionnaire?

Yes ☐₁ No ☐₂

If the answer is yes, please give the relationship to you of the person assisting you

Family member e.g. spouse, child, parent ☐₁ Other relative ☐₂ Carer ☐₃ Friend/ neighbour ☐₄ Healthcare professional e.g. nurse/doctor ☐₅ Other ☐₆

If you are helping to complete this questionnaire on behalf of the patient, please ensure that the information given below is that of the patient and not your own.

Some questions about your health

Please mark the boxes below with a tick or numbers where appropriate.

Q2. Are you?

Male ☐₁ Female ☐₂

Q3. What is your date of birth?

D D M M Y Y Y Y

Q4. Have you had a previous hernia operation on the side on which you are about to have surgery?

No ☐₁ Yes ☐₂

Q5. For how long have you had symptoms of a hernia?

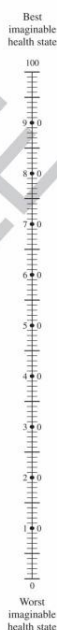
Less than 1 year ☐₁ More than 1 year ☐₂

2

Q11. To help people say how good or bad a health state is, we have drawn a scale (rather like a thermometer) on which the best state you can imagine is marked 100 and the worst state you can imagine is marked 0.

We would like you to indicate on this scale how good or bad your own health is today, in your opinion. Please do this by drawing a line from the box below to whichever point on the scale indicates how good or bad your health state is today.

Your own health state today



4

By placing a tick in one box in each group (Questions 6–10) below, please indicate which statements best describe your own health state today.

Q6. Mobility

I have no problems in walking about ☐₁
I have some problems in walking about ☐₂
I am confined to bed ☐₃

Q7. Self-Care

I have no problems with self-care ☐₁
I have some problems washing or dressing myself ☐₂
I am unable to wash or dress myself ☐₃

Q8. Usual Activities

(e.g. work, study, housework, family or leisure activities)
I have no problems with performing my usual activities ☐₁
I have some problems with performing my usual activities ☐₂
I am unable to perform my usual activities ☐₃

Q9. Pain/Discomfort

I have no pain or discomfort ☐₁
I have moderate pain or discomfort ☐₂
I have extreme pain or discomfort ☐₃

Q10. Anxiety/Depression

I am not anxious or depressed ☐₁
I am moderately anxious or depressed ☐₂
I am extremely anxious or depressed ☐₃

3

Q12. In general, would you say your health is:

Excellent ☐₁ Very good ☐₂ Good ☐₃ Fair ☐₄ Poor ☐₅

Q13. Have you been told by a doctor that you have any of the following? (Tick all that apply to you)

Heart disease (for example angina, heart attack or heart failure) ☐₁ Kidney disease ☐₇
High blood pressure ☐₂ Diseases of the nervous system (for example Parkinson's disease or multiple sclerosis) ☐₈
Problems caused by a stroke ☐₃ Liver disease ☐₉
Leg pain when walking due to poor circulation ☐₄ Cancer (within the last 5 years) ☐₁₀
Lung disease (for example asthma, chronic bronchitis or emphysema) ☐₅ Depression ☐₁₁
Diabetes ☐₆ Arthritis ☐₁₂

Q14. Today's date

D D M M Y Y Y Y

Q15. Do you consider yourself to have a disability?

Yes ☐₁ No ☐₂

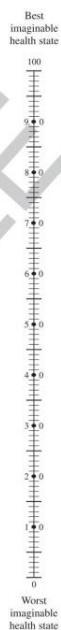
Thank you for your help

Please return this questionnaire to the person who gave it to you

5

Q16. To help people say how good or bad a health state is, we have drawn a scale (rather like a thermometer) on which the best state you can imagine is marked 100 and the worst state you can imagine is marked 0.

We would like you to indicate on this scale how good or bad your own health is today, in your opinion. Please do this by drawing a line from the box below to whichever point on the scale indicates how good or bad your health state is today.



Q17. Today's date (day, month, year)

				2	0		
D	D	M	M	Y	Y		

Q18. Do you consider yourself to have a disability?

Yes	No
☐ 1	☐ 2

Thank you for your assistance.

Please return this questionnaire in the envelope provided.
You do not have to use a stamp – the postage is already paid.

Contact us for further details:

- Freephone: 0800 917 1163
- E-mail: doh.helpforpatients@nhs.net
- Write: PROMs Survey, PO Box 909, Aylesbury, HP22 9HT
- Website: www.nhs.uk/proms

© Crown copyright 2008. Except where expressly stated to the contrary, this questionnaire is protected by Crown copyright.

Any and all copyrights in question 5 vest in London School of Hygiene and Tropical Medicine.

Any and all copyrights in questions 11–16, their order, layout, and images printed on page 5 vest in the EuroQol Group. The EuroQol Group reserves all rights. © 1992 EuroQol Group. EQ-5D™ is a trademark of the EuroQol Group.

Hernia Surgery Questionnaire

After your operation

About three months ago you had a Hernia Operation. You may remember that you agreed that we could send you an *After your operation* questionnaire. Please can you fill in this questionnaire and return it using the provided pre-paid envelope. Thank you for your help.

Q1. Is anyone helping you fill in this questionnaire?

Yes ☐ ₁ No ☐ ₂

If the answer is yes, please give the relationship to you of the person assisting you

Family member e.g. spouse, child, parent ☐ ₁ Other relative ☐ ₂ Carer ☐ ₃ Friend/ neighbour ☐ ₄ Healthcare professional e.g. nurse/doctor ☐ ₅ Other ☐ ₆

If you are helping to complete this questionnaire on behalf of the patient, please ensure that the information given below is that of the patient and not your own.

Q2. What is your date of birth?

D D M M Y Y Y Y

Hernia Surgery Questionnaire – After your operation

Q7. Have you had another operation on your groin area?

Yes ☐ ₁ No ☐ ₂

Q8. In general, would you say your health is:

Excellent ☐ ₁ Very good ☐ ₂ Good ☐ ₃ Fair ☐ ₄ Poor ☐ ₅

Q9. How would you describe the results of your operation?

Excellent ☐ ₁ Very good ☐ ₂ Good ☐ ₃ Fair ☐ ₄ Poor ☐ ₅

Q10. Overall, how are your hernia problems now, compared to before your operation?

Much better ☐ ₁ A little better ☐ ₂ About the same ☐ ₃ A little worse ☐ ₄ Much worse ☐ ₅

A question about your current home circumstances

Q3. Which statement best describes your living arrangements?

I live with partner/spouse/family/friends ☐ ₁
I live alone ☐ ₂
I live in a nursing home, hospital or other long-term care home ☐ ₃
Other ☐ ₄

Q4. Please confirm when your hernia operation took place (day, month, year).

D D M M Y Y

Some questions about your surgery and your health

Please mark the boxes below with a tick or numbers where appropriate. If you are unsure about how to answer a question, please give the best answer you can.

Q5. Did you experience any of the following problems after your operation? Please tick Yes or No for each problem.

	Yes ☐ ₁	No ☐ ₂
Allergy or reaction to drug	☐ ₁	☐ ₂
Urinary problems	☐ ₁	☐ ₂
Bleeding	☐ ₁	☐ ₂
Wound problems	☐ ₁	☐ ₂

Q6. Have you been readmitted to hospital since your hernia operation?

Yes ☐ ₁ No ☐ ₂

2

Hernia Surgery Questionnaire – After your operation

By placing a tick in one box in each group (Questions 11–15) below, please indicate which statements best describe your own health state today.

Q11. Mobility

I have no problems in walking about ☐ ₁
I have some problems in walking about ☐ ₂
I am confined to bed ☐ ₃

Q12. Self-Care

I have no problems with self-care ☐ ₁
I have some problems washing or dressing myself ☐ ₂
I am unable to wash or dress myself ☐ ₃

Q13. Usual Activities

(e.g. work, study, housework, family or leisure activities)
I have no problems with performing my usual activities ☐ ₁
I have some problems with performing my usual activities ☐ ₂
I am unable to perform my usual activities ☐ ₃

Q14. Pain/Discomfort

I have no pain or discomfort ☐ ₁
I have moderate pain or discomfort ☐ ₂
I have extreme pain or discomfort ☐ ₃

Q15. Anxiety/Depression

I am not anxious or depressed ☐ ₁
I am moderately anxious or depressed ☐ ₂
I am extremely anxious or depressed ☐ ₃

4

3

APPENDIX X



Varicose Veins Surgery Questionnaire

Before your operation

Varicose Veins Surgery Questionnaire - Before your operation

Patient Information

What is this questionnaire for?

The purpose of collecting information in this questionnaire is to find out about the quality of care you receive from your healthcare provider. The information that you give us will help to measure and improve the quality of health services.

Why have I been invited to complete this questionnaire?

All NHS patients undergoing a Varicose Veins operation are invited to fill in this questionnaire.

Do I have to take part?

No. Your participation is voluntary. If you do not want to take part, do not fill in the questionnaire.

Do I have to give my consent to participate?

We need your consent for your personal details to be used. Your personal details will be used to send you an **After your operation** questionnaire in three months time. They will also be used to link the information you give us to other information relevant to your Varicose Vein operation.

Can I change my mind?

Yes. You can choose to withdraw your information any time up to the point that data are analysed and personal details removed. Withdrawing your information will not affect your medical or legal rights. To do so please notify the programme by telephone, in writing or by e-mail (see over for contact details).

What happens next?

Once you have given your consent to participate please fill in and return this questionnaire. Your personal details will be held and stored by the Health and Social Care Information Centre so that we can send you an **After your operation** questionnaire to fill in and send back in three months time.

What will happen to the information I give you?

Your personal details will be used to link the data you give us to other data held by the NHS and partner organisations about you. Your personal details will also be used to send you an **After your operation** questionnaire. We will hold your personal details for up to a year. If we want to use your information for other uses or to hold your information for longer, we will write to you to ask your permission.

Why are third party organisations used?

Some third party organisations are employed to support the NHS to handle and analyse the data you give us. Only organisations with expertise in these areas have been chosen to support the NHS.

Will my personal details be safe?

All organisations involved with handling patient information must meet strict requirements on the handling and storage of personal information. Published reports will not contain any personal details.

Consent Form

The purpose of collecting information in this questionnaire is to find out about the quality of care you receive from your healthcare provider. To make sure that the information we collect is useful, we need to collect your personal details and to access information held about you in other NHS databases.
To do this we need your consent.

Please read the following statements carefully. If you agree with them please sign and date this form, below.

I agree that my personal details and relevant health information related to this operation will be held and used by the Health and Social Care Information Centre, including information held about me by the Patient Demographics Service, the National Strategic Tracing Service, the Secondary Uses Service and other NHS databases.

I agree that my personal details will be used to send me an **After your operation** questionnaire in three months time.

I agree that my personal details and health information can be held and used by third party organisations, working on behalf of the Health and Social Care Information Centre, for this project.

I understand that my personal information will not be released by the Health and Social Care Information Centre to third party organisations working on its behalf, unless required by law or where there is a clear overriding public interest.

I understand that I can withdraw the information I give the NHS in these questionnaires upon request, up to the point at which data are analysed and personal details removed.

Print Name

Signature

Date

PATIENT COPY

Contact us for further details:

- Freephone: 0800 917 1163
- E-mail: doh.helpforpatients@nhs.net
- Write: **PROMS Survey, PO Box 909, Aylesbury, HP22 9HT**
- Website: www.nhs.uk/proms



Varicose Veins Surgery Questionnaire - Before your operation

Patient Details

If you have agreed to take part, would you please write your name and address in CAPITAL LETTERS BELOW so that we can contact you by post.

Title: Mr ☐ Mrs ☐ Miss ☐ Ms ☐ Dr ☐

Other (please specify)

First Name:

Surname:

House No./ Name:

Street:

Town/City:

County:

Postcode:

Which statement best describes your living arrangements?

- I live with partner/spouse/family/friends ☐
- I live alone ☐
- I live in a nursing home, hospital or other long-term care home ☐
- Other ☐

Q1. Is anyone helping you fill in this questionnaire?

Yes ☐ No ☐

If the answer is yes, please give the relationship to you of the person assisting you

Family member
e.g. spouse,
child, parent ☐

Other
relative ☐

Carer ☐

Friend/
neighbour ☐

Healthcare
professional
e.g. nurse/doctor ☐

Other ☐

If you are helping to complete this questionnaire on behalf of the patient, please ensure that the information given below is that of the patient and not your own.

Some questions about you and your health

Please mark the boxes below with a tick or numbers where appropriate.

Q2. Are you?

Male ☐ Female ☐

Q3. What is your date of birth?

Q4. Have you had previous treatment on your varicose veins, such as injections or surgery?

Yes ☐ No ☐

Q5. For how long have you had varicose veins?

Less than 1 year ☐ 1 to 5 years ☐ 6 to 10 years ☐ More than 10 years ☐

2

Varicose Veins Surgery Questionnaire – Before your operation

Q8. During the last two weeks, on how many days did you take painkilling tablets for your varicose veins?

(Please tick one box)

None at all ☐
Between 1 and 5 days ☐
Between 6 and 10 days ☐
For more than 10 days ☐

Q9. During the last two weeks, how much ankle swelling have you had?

(Please tick one box)

None at all ☐
Severe ankle swelling ☐
Moderate ankle swelling ☐
(e.g. causing you to sit with your feet up wherever possible)
Severe ankle swelling ☐
(e.g. causing you difficulty putting on your shoes)

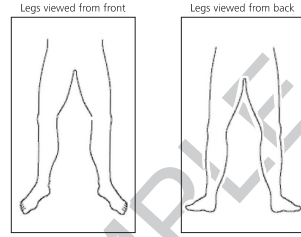
Q10. In the last two weeks, have you worn support tights or stockings?

(Please tick one box for each leg)

Right Leg ☐ Left Leg ☐
No ☐ ☐
Yes, those I bought myself without a doctor's prescription ☐ ☐
Yes, those my doctor prescribed for me which I wear occasionally ☐ ☐
Yes, those my doctor prescribed for me which I wear every day ☐ ☐

4

Q6. Please draw in your varicose veins in the diagram(s) shown here.



Q7. In the last two weeks, for how many days did your varicose veins cause you pain or ache?

(Please tick one box for each leg)

Right Leg ☐ Left Leg ☐
None at all ☐ ☐
Between 1 and 5 days ☐ ☐
Between 6 and 10 days ☐ ☐
For more than 10 days ☐ ☐

Q11. In the last two weeks, have you had any itching in association with your varicose veins?

(Please tick one box for each leg)

Right Leg ☐ Left Leg ☐
No ☐ ☐
Yes, but only above the knee ☐ ☐
Yes, but only below the knee ☐ ☐
Both above and below the knee ☐ ☐

Q12. Do you have purple discolouration caused by tiny blood vessels in the skin, in association with your varicose veins?

(Please tick one box for each leg)

Right Leg ☐ Left Leg ☐
Yes ☐ ☐
No ☐ ☐

Q13. Do you have any rash or eczema in the area of your ankle?

(Please tick one box for each leg)

Right Leg ☐ Left Leg ☐
No ☐ ☐
Yes, but it does not require any treatment from a doctor or district nurse ☐ ☐
Yes, and it requires treatment from my doctor or district nurse ☐ ☐

Q14. Do you have a skin ulcer associated with your varicose veins?

(Please tick one box for each leg)

Right Leg ☐ Left Leg ☐
Yes ☐ ☐
No ☐ ☐

3

Varicose Veins Surgery Questionnaire – Before your operation

5

Q15. Does the appearance of your varicose veins cause you concern?
(Please tick one box for each leg)

	Right Leg	Left Leg
No	☐	☐
Yes, their appearance causes me a slight concern	☐	☐
Yes, their appearance causes me a great deal of concern	☐	☐

Q16. Does the appearance of your varicose veins influence your choice of clothing including tights?
(Please tick one box)

No ☐

Occasionally ☐

Often ☐

Always ☐

Q17. During the last two weeks, have your varicose veins interfered with your work/housework or other daily activities?
(Please tick one box)

No ☐

I have been able to work but my work has suffered to some extent ☐

I have been able to work but my work has suffered to a moderate extent ☐

My veins have prevented me from working one day or more ☐

Q18. During the last two weeks, have your varicose veins interfered with your leisure activities (including sport, hobbies and social life)?
(Please tick one box)

No ☐

Yes, my enjoyment has suffered to a slight extent ☐

Yes, my enjoyment has suffered to a moderate extent ☐

My veins have prevented me from taking part in any leisure activities ☐

6

Varicose Veins Surgery Questionnaire – Before your operation

Q24. To help people say how good or bad a health state is, we have drawn a scale (rather like a thermometer) on which the best state you can imagine is marked 100 and the worst state you can imagine is marked 0.

We would like you to indicate on this scale how good or bad your own health is today, in your opinion. Please do this by drawing a line from the box below to whichever point on the scale indicates how good or bad your health state is today.

Best imaginable health state

100

90

80

70

60

50

40

30

20

10

0

Worst imaginable health state

Your own health state today

8

By placing a tick in one box in each group (Questions 19-23) below, please indicate which statements best describe your own health state today.

Q19. Mobility

I have no problems in walking about ☐

I have some problems in walking about ☐

I am confined to bed ☐

Q20. Self-Care

I have no problems with self-care ☐

I have some problems washing or dressing myself ☐

I am unable to wash or dress myself ☐

Q21. Usual Activities
(e.g. work, study, housework, family or leisure activities)

I have no problems with performing my usual activities ☐

I have some problems with performing my usual activities ☐

I am unable to perform my usual activities ☐

Q22. Pain/Discomfort

I have no pain or discomfort ☐

I have moderate pain or discomfort ☐

I have extreme pain or discomfort ☐

Q23. Anxiety/Depression

I am not anxious or depressed ☐

I am moderately anxious or depressed ☐

I am extremely anxious or depressed ☐

7

Varicose Veins Surgery Questionnaire – Before your operation

Q25. In general, would you say your health is:

Excellent ☐

Very good ☐

Good ☐

Fair ☐

Poor ☐

Q26. Have you been told by a doctor that you have any of the following? (Tick all that apply to you)

Heart disease (for example angina, heart attack or heart failure) ☐

Kidney disease ☐

High blood pressure ☐

Diseases of the nervous system (for example Parkinson's disease or multiple sclerosis) ☐

Problems caused by a stroke ☐

Liver disease ☐

Leg pain when walking due to poor circulation ☐

Cancer (within the last 5 years) ☐

Lung disease (for example asthma, chronic bronchitis or emphysema) ☐

Depression ☐

Diabetes ☐

Arthritis ☐

Q27. Today's date

Day: Month: Year:

Q28. Do you consider yourself to have a disability?

Yes ☐

No ☐

Thank you for your help

Please return this questionnaire to the person who gave it to you.

9

Varicose Veins Surgery Questionnaire

After your operation

About three months ago you had a Varicose Veins Operation. You may remember that you agreed that we could send you an *After your operation* questionnaire. Please can you fill in this questionnaire and return it using the provided pre-paid envelope. Thank you for your help.

Q1. Is anyone helping you fill in this questionnaire?

Yes ☐ No ☐

If the answer is yes, please give the relationship to you of the person assisting you

Family member e.g. spouse, child, parent ☐ Other relative ☐ Carer ☐ Friend/ neighbour ☐ Healthcare professional e.g. nurse/doctor ☐ Other ☐

If you are helping to complete this questionnaire on behalf of the patient, please ensure that the information given below is that of the patient and not your own.

Q2. What is your date of birth?

D D M M Y Y Y Y C

Varicose Veins Surgery Questionnaire – After your operation

Q7. Have you had another operation on your varicose veins?

Yes ☐ No ☐

Q8. In general, would you say your health is:

Excellent ☐ Very good ☐ Good ☐ Fair ☐ Poor ☐

Q9. How would you describe the results of your operation?

Excellent ☐ Very good ☐ Good ☐ Fair ☐ Poor ☐

Q10. Overall, how are the problems now with your varicose veins on which you had surgery, compared to before your operation?

Much better ☐ A little better ☐ About the same ☐ A little worse ☐ Much worse ☐

A question about your current home circumstances

Q3. Which statement best describes your living arrangements?

I live with partner/spouse/family/friends ☐
I live alone ☐
I live in a nursing home, hospital or other long-term care home ☐
Other ☐

Q4. Please confirm when your varicose veins operation took place (day, month, year).

D D M M Y Y Y Y C

Some questions about your surgery and your health

Please mark the boxes below with a tick or numbers where appropriate. If you are unsure about how to answer a question, please give the best answer you can.

Q5. Did you experience any of the following problems after your operation? Please tick Yes or No for each problem.

Allergy or reaction to drug ☐ Yes ☐ No ☐
Urinary problems ☐ Yes ☐ No ☐
Bleeding ☐ Yes ☐ No ☐
Wound problems ☐ Yes ☐ No ☐

Q6. Have you been readmitted to hospital since the operation on your varicose veins?

Yes ☐ No ☐

2

Varicose Veins Surgery Questionnaire – After your operation

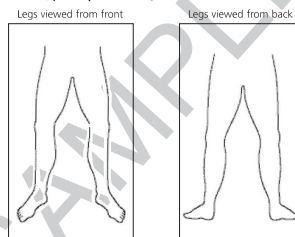
The following questions relate to problems commonly associated with varicose veins. We appreciate that you may no longer have any visible varicose veins after your surgery but please try and answer each question as best you can.

Q11. Do you have any visible varicose veins on your legs at the moment?

(Please tick one box for each leg)

Right Leg ☐ Left Leg ☐
Yes ☐ No ☐

Q12. If Yes, please draw in your visible varicose veins in the diagram(s) below. If No, please proceed to Q13.



Q13. In the last two weeks, for how many days did your varicose veins cause you pain or ache?

(Please tick one box for each leg)

Right Leg ☐ Left Leg ☐
None at all ☐ Between 1 and 5 days ☐
Between 6 and 10 days ☐ For more than 10 days ☐

3

4

Q14. During the last two weeks, on how many days did you take painkilling tablets for your varicose veins?
(Please tick one box)

None at all ☐₁
Between 1 and 5 days ☐₂
Between 6 and 10 days ☐₃
For more than 10 days ☐₄

Q15. In the last two weeks, how much ankle swelling have you had?
(Please tick one box)

None at all ☐₁
Severe ankle swelling ☐₂
(e.g. causing you to sit with your feet up wherever possible) ☐₃
Severe ankle swelling ☐₄
(e.g. causing you difficulty putting on your shoes)

Q16. In the last two weeks, have you worn support tights or stockings?
(Please tick one box for each leg)

	Right Leg	Left Leg
No	☐ ₁	☐ ₂
Yes, those I bought myself without a doctor's prescription	☐ ₃	☐ ₄
Yes, those my doctor prescribed for me which I wear occasionally	☐ ₅	☐ ₆
Yes, those my doctor prescribed for me which I wear every day	☐ ₇	☐ ₈

Q17. In the last two weeks, have you had any itching in association with your varicose veins?
(Please tick one box for each leg)

	Right Leg	Left Leg
No	☐ ₁	☐ ₂
Yes, but only above the knee	☐ ₃	☐ ₄
Yes, but only below the knee	☐ ₅	☐ ₆
Both above and below the knee	☐ ₇	☐ ₈

5

Varicose Veins Surgery Questionnaire – After your operation

Q23. During the last two weeks, have your varicose veins interfered with your work/housework or other daily activities?
(Please tick one box)

No ☐₁
I have been able to work but my work has suffered to some extent ☐₂
I have been able to work but my work has suffered to a moderate extent ☐₃
My veins have prevented me from working one day or more ☐₄

Q24. During the last two weeks, have your varicose veins interfered with your leisure activities (including sport, hobbies and social life)?
(Please tick one box)

No ☐₁
Yes, my enjoyment has suffered to a slight extent ☐₂
Yes, my enjoyment has suffered to a moderate extent ☐₃
My veins have prevented me from taking part in any leisure activities ☐₄

7

Q18. Do you have purple discolouration caused by tiny blood vessels in the skin, in association with your varicose veins?
(Please tick one box for each leg)

	Right Leg	Left Leg
Yes	☐ ₁	☐ ₂
No	☐ ₃	☐ ₄

Q19. Do you have any rash or eczema in the area of your ankle?
(Please tick one box for each leg)

	Right Leg	Left Leg
No	☐ ₁	☐ ₂
Yes, but it does not require any treatment from a doctor or district nurse	☐ ₃	☐ ₄
Yes, and it requires treatment from my doctor or district nurse	☐ ₅	☐ ₆

Q20. Do you have a skin ulcer associated with your varicose veins?
(Please tick one box for each leg)

	Right Leg	Left Leg
Yes	☐ ₁	☐ ₂
No	☐ ₃	☐ ₄

Q21. Does the appearance of your varicose veins cause you concern?
(Please tick one box for each leg)

	Right Leg	Left Leg
No	☐ ₁	☐ ₂
Their appearance causes me slight concern	☐ ₃	☐ ₄
Yes, their appearance causes me a great deal of concern	☐ ₅	☐ ₆

Q22. Does the appearance of your varicose veins influence your choice of clothing including tights?
(Please tick one box)

No ☐₁
Occasionally ☐₂
Often ☐₃
Always ☐₄

6

Varicose Veins Surgery Questionnaire – After your operation

By placing a tick in one box in each group (Questions 25–29) below, please indicate which statements best describe your own health state today.

Q25. Mobility

I have no problems in walking about ☐₁
I have some problems in walking about ☐₂
I am confined to bed ☐₃

Q26. Self-Care

I have no problems with self-care ☐₁
I have some problems washing or dressing myself ☐₂
I am unable to wash or dress myself ☐₃

Q27. Usual Activities
(e.g. work, study, housework, family or leisure activities)

I have no problems with performing my usual activities ☐₁
I have some problems with performing my usual activities ☐₂
I am unable to perform my usual activities ☐₃

Q28. Pain/Discomfort

I have no pain or discomfort ☐₁
I have moderate pain or discomfort ☐₂
I have extreme pain or discomfort ☐₃

Q29. Anxiety/Depression

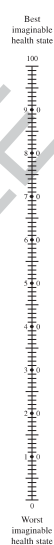
I am not anxious or depressed ☐₁
I am moderately anxious or depressed ☐₂
I am extremely anxious or depressed ☐₃

8

Q30. To help people say how good or bad a health state is, we have drawn a scale (rather like a thermometer) on which the best state you can imagine is marked 100 and the worst state you can imagine is marked 0.

We would like you to indicate on this scale how good or bad your own health is today, in your opinion. Please do this by drawing a line from the box below to whichever point on the scale indicates how good or bad your health state is today.

Your own health state today



Q31. Today's date (day, month, year)

Day	Month	Year
2	0	

Q32. Do you consider yourself to have a disability?

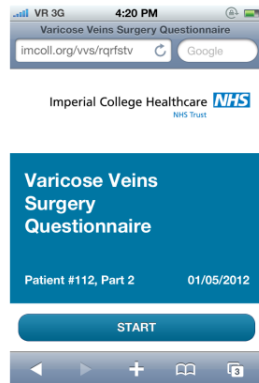
Yes	No
☐	☐

Thank you for your assistance.

Please return this questionnaire in the envelope provided. You do not have to use a stamp - the postage is already paid.

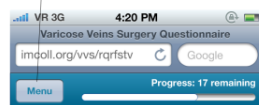
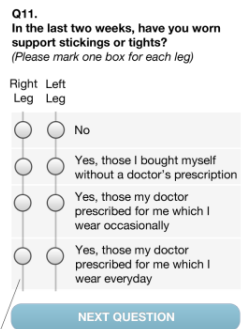
APPENDIX Y

Initial landing page



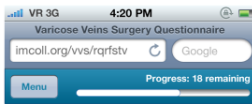
Key information displayed as well as start button

Menu button presents user with list of all questions

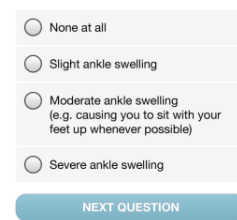


Lines enhance usability by indicating each leg to make choice easier

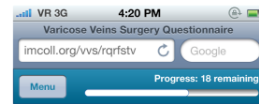
Progress bar to indicate how many questions remain



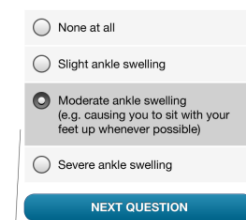
Button is greyed out until option has been chosen



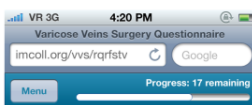
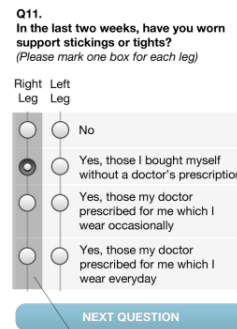
Button is greyed out until option has been chosen



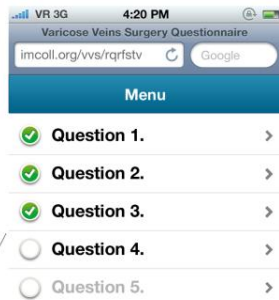
Selected option background is darker to highlight choice



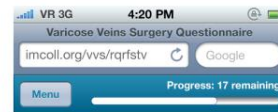
Selected option background is darker to highlight choice



Each leg 'highlights' to make choices easier.



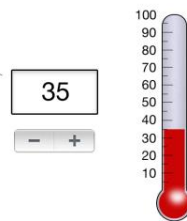
Menu page shows overview of all answered questions



Q25.
To help people say how good or bad a health state is, please use the thermometer below on which the best state you can imagine is marked 100 and the worst state you can imagine is marked 0.

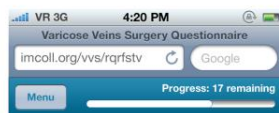
Please tap on the + and - controls to indicate on this scale how good or bad your own health is today, in your opinion.

Text box for manual fine-tuning

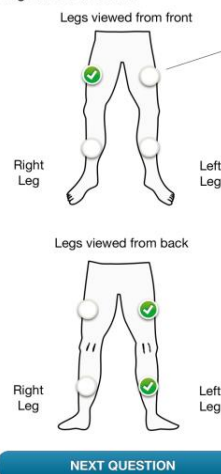


Stepper jumps in 5 step increments
Visual indicator

NEXT QUESTION

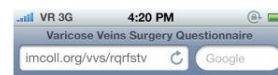


Q7.
Please mark in your varicose veins in the diagrams shown here.



4 circles on each set of legs.
Tapping toggles each leg point

Each point is spaced a finger-width apart to aid usability



Imperial College Healthcare NHS Trust

All done!
Thank you for answering these questions.
Patient #112, Part 2 01/05/2012



Detailed completion message similar to start screen for familiarity

APPENDIX Z

Patient-reported Outcome Measures: Varicose Veins survey

Please read each of the following statements carefully and select the answer for each statement that best reflects your own views about the PROMs.

To what extent do you agree or disagree that...?

Please tick one box only for each statement

1 ----- 2 ----- 3 ----- 4 ----- 5 ----- 6 ----- 7
Strongly Neither Strongly
disagree agree or disagree agree

General attitude towards NHS and Surgery

		1	2	3	4	5	6	7
Q1	The symptoms I am experiencing warrant an operation on my varicose veins today	1	2	3	4	5	6	7
Q2	There are different treatment options available to treat varicose veins. I was asked about my choice of treatment							
Q3	I trust my surgeon to chose the right treatment for me							
Q4	I don't want to participate too much in the decision-making process							
Q5	This is a simple procedure and I am not worried about undergoing it							
Q6	I have been given sufficient information and know what I can expect today							
Q7	It is important that this operation is free of charge							
Q8	If there is no improvement in symptoms in the majority of patients undergoing varicose veins surgery, funding by NHS should be cut.							
Q9	If there is no improvement in quality of life in the majority of patients, funding by NHS should be cut.							
Q10	My quality of life is affected by having varicose veins							
	Patient reported outcomes in surgery							
Q11	I think it is important that patients are asked about their experience after surgery							
Q12	The information captured by the PROMs questionnaire is not routinely fed back to your surgeon and is only used by the Department of Health: I would still be happy to complete it							
Q13	More patient involvement is needed in the NHS							

Q14	Currently there is no funding available in the NHS to routinely follow you up after your surgery; therefore it is acceptable that my GP does this.	
Q15	There are too many questionnaires in the NHS	
Q16	The data collected by the PROMs questionnaire can identify how this hospital compares to the national average, I want to know this before my operation	
Q17	It does not matter to me how this hospital preforms to the national average with regards to this operation	
Q18	If the quality of care in my local hospital is worse than a hospital further away, I would consider going there instead of my local hospital for my operation	

Please use this space to provide any other comments or suggestions. (e.g. regarding the PROMs questionnaire and patient involvement in the NHS).....

Section 2. PROMs questionnaire specific

1 ----- 2 ----- 3 ----- 4 ----- 5 ----- 6 ----- 7
Strongly Neither Strongly
disagree agree or disagree agree

Q19	It is clear to me why I need to complete the questionnaire before my surgery						
Q20	I am not aware that I will have to complete a follow up questionnaire at 3 months						
Q21	I understand that my participation is voluntary						
Q22	The PROMs questionnaire is easy to read						
Q23	The PROMs questionnaire is too long						
Q24	The questionnaire should be shorter, even though that might decrease quality of the questionnaire						
Q25	If available, I would prefer filling this in electronically						

Q26	Looking at question 7 on the blue PROMs questionnaire It is clear to me what I need to draw.							
Q27	Looking at question 25 It is difficult to interpret what I need to do here							

Please use this space to provide any other comments or suggestions. (e.g. regarding the PROMs questionnaire and patient involvement in the NHS).....

1 ----- 2 ----- 3 ----- 4 ----- 5 ----- 6 ----- 7
Strongly Neither Strongly
disagree agree or disagree agree

Electronic data collection

Q28	Using electronic means to capture data is quicker than using paper forms							
Q29	I prefer using mobile devices compared to Personal Computer (PC) to share health information							
Q30	My health information should be available on one system and be accessible to all doctors that treat me (GP&surgeon)							
Q31	I do not want to be reminded multiple times about my follow up questionnaire if I don't return the first follow-up questionnaire							

Section 3. Personal Wellbeing & Health Policy

1 ----- 2 ----- 3 ----- 4 ----- 5 ----- 6 ----- 7
Strongly Neither Strongly
disagree agree or disagree agree

Q32	I would be more satisfied with life and be happier if I did not have varicose veins							
Q33	Doctors should be more interested in my overall wellbeing as part of my care process							
Q34	Questionnaires such as PROMs are used by the government to decide if operations such as varicose vein surgery are good 'value-for-money'. I am aware that my answers to these questions can affect which operations the NHS will fund.							

Q35	The surgeon that has scheduled the operation for me has asked me to complete the PROMs questionnaire															
Q36	Any operation that can improve patients' wellbeing and quality of life is worth funding by the NHS.															
Q37	I would sacrifice my spare time to help improve the NHS by actively engage with patient support groups if my doctor would ask me															
Q38	My expectation of the NHS is influenced by the media coverage of the NHS															
Q38	Decisions about the NHS should be made by (If selected multiple; write number next to ticked box in order of importance) 1- most etcetera	<table> <tr> <td>Healthcare professionals</td> <td>...</td> </tr> <tr> <td>Managers</td> <td>...</td> </tr> <tr> <td>Policymakers</td> <td>...</td> </tr> <tr> <td>Patients</td> <td>...</td> </tr> </table>							Healthcare professionals	...	Managers	...	Policymakers	...	Patients	...
Healthcare professionals	...															
Managers	...															
Policymakers	...															
Patients	...															

Sex: Male / Female	Age: _____	Occupation : _____	Ethnicity: _____
I own a:	PC	Tablet	Smartphone _____

Thank you for your help!

Please use this space to provide any other comments or suggestions. (e.g. regarding the PROMs questionnaire and patient involvement in the NHS).....

EQ-5D profile:

AVVQ:

REFERENCES

1. Legido-Quigley. Assuring the quality of health care in the E.U. : European Observatory; 2008.
2. Faiz O, Warusavitarne J, Bottle A, Tekkis PP, Darzi AW, Kennedy RH. Laparoscopically assisted vs. open elective colonic and rectal resection: a comparison of outcomes in English National Health Service Trusts between 1996 and 2006. *Diseases of the colon and rectum* 2009;52:1695-704.
3. Mayer EK, Bottle A, Darzi AW, Athanasiou T, Vale JA. The volume-mortality relation for radical cystectomy in England: retrospective analysis of hospital episode statistics. *BMJ (Clinical research ed)* 2010;340:c1128.
4. Iezzoni LI. Assessing quality using administrative data. *Annals of internal medicine* 1997;127:666-74.
5. Lawson EH, Louie R, Zingmond DS, et al. A comparison of clinical registry versus administrative claims data for reporting of 30-day surgical complications. *Annals of surgery* 2012;256:973-81.
6. Porter ME. A strategy for health care reform--toward a value-based system. *The New England journal of medicine* 2009;361:109-12.
7. Moore W. *The Knife man: The extraordinary life and times of John Hunter, father of modern surgery*: Broadway; 2005.
8. Voloshin I, Bernini P. Nickolay Ivanovich Pirogoff: Innovative Scientist and Clinician. *Spine* 1998;23:2143.
9. WHO. *Quality of Care: A process for making strategic choices in health systems*: World Health Organisation; 2006.
10. Lohr KN, Schroeder SA. A strategy for quality assurance in Medicare. *The New England journal of medicine* 1990;322:707-12.
11. Davies H. *Measuring and reporting quality of health care: NHS Quality Improvement Scotland* 2006.

12. Powell AE, Davies HT, Thomson RG. Using routine comparative data to assess the quality of health care: understanding and avoiding common pitfalls. *Quality & safety in health care* 2003;12:122-8.
13. Measuring and improving quality of care: a report from the American Heart Association/American College of Cardiology First Scientific Forum on Assessment of Healthcare Quality in Cardiovascular Disease and Stroke. *Circulation* 2000;101:1483-93.
14. Loeb JM. The current state of performance measurement in health care. *International Journal for Quality in Health Care* 2004;16:i5-i9.
15. Mayer EK, Chow A, Vale JA, Athanasiou T. Appraising the quality of care in surgery. *World journal of surgery* 2009;33:1584-93.
16. Donabedian. Evaluating the Quality of Medical Care. *The Milbank Memorial Fund Quarterly* 1966;44:166-203.
17. Lilford RJ, Brown CA, Nicholl J. Use of process measures to monitor the quality of clinical practice. *BMJ (Clinical research ed)* 2007;335:648-50.
18. Worcester Health Authority. Commissioning Policy: Varicose Veins Referral Guideline. Available at:
<http://www.worcestershire.nhs.uk/EasySiteWeb/GatewayLink.aspx?allId=3725>. Accessed July 2015
19. Clinical Commissioning Group: Vale of York. Procedures of limited clinical value referral form. Available at:
<http://www.valeofyorkccg.nhs.uk/rss/data/uploads/polvs/referral-forms/15.-hernia-referral-form.doc>. Accessed July 2015.
20. Charlson ME, Pompei P, Ales KL, MacKenzie CR. A new method of classifying prognostic comorbidity in longitudinal studies: development and validation. *Journal of chronic diseases* 1987;40:373-83.
21. de Vries LM, Sturkenboom MC, Verhaar JA, Kingma JH, Stricker BH. Complications after hip arthroplasty and the association with hospital procedure volume. *Acta orthopaedica* 2011;82:545-52.
22. Powell H, Lim LL, Heller RF. Accuracy of administrative data to assess comorbidity in patients with heart disease. an Australian perspective. *Journal of clinical epidemiology* 2001;54:687-93.
23. Saklad M. Grading of patients for surgical procedures. *Anaesthesiology* 1941.

24. Jacqueline R, Malviya S, Burke C, Reynolds P. An assessment of interrater reliability of the ASA physical status classification in pediatric surgical patients. *Paediatric anaesthesia* 2006;16:928-31.
25. Aronson WL, McAuliffe MS, Miller K. Variability in the American Society of Anesthesiologists Physical Status Classification Scale. *AANA journal* 2003;71:265-74.
26. Copeland GP, Jones D, Walters M. POSSUM: a scoring system for surgical audit. *The British journal of surgery* 1991;78:355-60.
27. Fink AS, Campbell DA, Jr., Mentzer RM, Jr., et al. The National Surgical Quality Improvement Program in non-veterans administration hospitals: initial demonstration of feasibility. *Annals of surgery* 2002;236:344-53; discussion 53-4.
28. Hall BL, Hamilton BH, Richards K, Bilimoria KY, Cohen ME, Ko CY. Does Surgical Quality Improve in the American College of Surgeons National Surgical Quality Improvement Program. *Transactions of the Meeting of the American Surgical Association* 2009;127:7-20.
29. Dimick JB, Osborne NH, Hall BL, Ko CY, Birkmeyer JD. Risk adjustment for comparing hospital quality with surgery: how many variables are needed? *Journal of the American College of Surgeons* 2010;210:503-8.
30. Ash JS, Berg M, Coiera E. Some unintended consequences of information technology in health care: the nature of patient care information system-related errors. *J Am Med Inform Assoc* 2004;11:104-12.
31. Stewart M, Brown JB, Donner A, et al. The impact of patient-centered care on outcomes. *The Journal of family practice* 2000;49:796-804.
32. Darzi A. High quality care for all: NHS Next Stage Review final report (2008). Available at:
http://www.dh.gov.uk/en/Publicationsandstatistics/PublicationsPolicyAndGuidance/DH_085825. Accessed May 2012.
33. Doward LC, Meads DM, Thorsen H. Requirements for quality of life instruments in clinical research. *Value in health : the journal of the International Society for Pharmacoeconomics and Outcomes Research* 2004;7 Suppl 1:S13-6.
34. Kaplan RM, Feeny D, Revicki DA. Methods for assessing relative importance in preference based outcome measures. *Qual Life Res* 1993;2:467-75.
35. Guyatt GH, Feeny DH, Patrick DL. Measuring health-related quality of life. *Annals of internal medicine* 1993;118:622-9.

36. Bradley C. Importance of differentiating health status from quality of life. *Lancet* 2001;357:7-8.
37. Tuominen U, Blom M, Hirvonen J, et al. The effect of co-morbidities on health-related quality of life in patients placed on the waiting list for total joint replacement. *Health Qual Life Outcomes* 2007;5:16.
38. McKenna SP. Measuring patient-reported outcomes: moving beyond misplaced common sense to hard science. *BMC medicine* 2011;9:86.
39. Garratt A, Schmidt L, Mackintosh A, Fitzpatrick R. Quality of life measurement: bibliographic study of patient assessed health outcome measures. *BMJ (Clinical research ed)* 2002;324:1417.
40. Arpinelli F, Bamfi F. The FDA guidance for industry on PROs: the point of view of a pharmaceutical company. *Health Qual Life Outcomes* 2006;4:85.
41. Frost J, Okun S, Vaughan T, Heywood J, Wicks P. Patient-reported outcomes as a source of evidence in off-label prescribing: analysis of data from PatientsLikeMe. *J Med Internet Res* 2011;13:e6.
42. Wu AW, Snyder C, Clancy CM, Steinwachs DM. Adding the patient perspective to comparative effectiveness research. *Health Aff (Millwood)* 2010;29:1863-71.
43. Rasanen P, Roine E, Sintonen H, Semberg-Konttinen V, Ryyanen OP, Roine R. Use of quality-adjusted life years for the estimation of effectiveness of health care: A systematic literature review. *International journal of technology assessment in health care* 2006;22:235-41.
44. Dawson J, Fitzpatrick R, Carr A, Murray D. Questionnaire on the perceptions of patients about total hip replacement. *The Journal of bone and joint surgery British volume* 1996;78:185-90.
45. Hudak PL, Amadio PC, Bombardier C. Development of an upper extremity outcome measure: the DASH (disabilities of the arm, shoulder and hand) [corrected]. The Upper Extremity Collaborative Group (UECG). *American journal of industrial medicine* 1996;29:602-8.
46. Lenert L, Kaplan RM. Validity and Interpretation of Preference-Based Measures of Health-Related Quality of Life. *Medical care* 2000;38:138-50.
47. Brazier JE, Harper R, Jones NM, et al. Validating the SF-36 health survey questionnaire: new outcome measure for primary care. *BMJ (Clinical research ed)* 1992;305:160-4.

48. Sassi F. Calculating QALYs, comparing QALY and DALY calculations. *Health Policy Plan* 2006;21:402-8.
49. Rowen D, Brazier J, Roberts J. Mapping SF-36 onto the EQ-5D index: how reliable is the relationship? *Health Qual Life Outcomes* 2009;7:27.
50. Brazier J, Tsuchiya A. Preference-based condition-specific measures of health: what happens to cross programme comparability? *Health economics* 2010;19:125-9.
51. Chow A, Mayer EK, Darzi AW, Athanasiou T. Patient-reported outcome measures: the importance of patient satisfaction in surgery. *Surgery* 2009;146:435-43.
52. Horsman J, Furlong W, Feeny D, Torrance G. The Health Utilities Index (HUI): concepts, measurement properties and applications. *Health Qual Life Outcomes* 2003;1:54.
53. Brazier J, Roberts J, Deverill M. The estimation of a preference-based measure of health from the SF-36. *Journal of health economics* 2002;21:271-92.
54. EuroQol--a new facility for the measurement of health-related quality of life. The EuroQol Group. *Health policy (Amsterdam, Netherlands)* 1990;16:199-208.
55. Devlin N, Appleby J. Getting the most out of PROMs: Putting health outcomes at the heart of the NHS decision-making: The King's fund; 2010.
56. Revicki DA, Cella D, Hays RD, Sloan JA, Lenderking WR, Aaronson NK. Responsiveness and minimal important differences for patient reported outcomes. *Health Qual Life Outcomes* 2006;4:70.
57. Pickard AS, Johnson JA, Feeny DH. Responsiveness of generic health-related quality of life measures in stroke. *Qual Life Res* 2005;14:207-19.
58. Walters SJ, Brazier JE. What is the relationship between the minimally important difference and health state utility values? The case of the SF-6D. *Health Qual Life Outcomes* 2003;1:4.
59. Walters SJ, Morrell CJ, Dixon S. Measuring health-related quality of life in patients with venous leg ulcers. *Qual Life Res* 1999;8:327-36.
60. Parkin D, Rice N, Devlin N. Statistical analysis of EQ-5D profiles: does the use of value sets bias inference? *Medical decision making : an international journal of the Society for Medical Decision Making* 2010;30:556-65.
61. Gutacker N, Bojke C, Daidone S, Devlin N, Street A. Analysing hospital variation in health outcome at the level of EQ-5D dimensions: University of York; 2012.

62. Valderas JM, Alonso J. Patient reported outcome measures: a model-based classification system for research and clinical practice. *Qual Life Res* 2008;17:1125-35.
63. Wilson IB, Cleary PD. Linking clinical variables with health-related quality of life. A conceptual model of patient outcomes. *JAMA : the journal of the American Medical Association* 1995;273:59-65.
64. Rothrock NE, Kaiser KA, Cella D. Developing a valid patient-reported outcome measure. *Clin Pharmacol Ther* 2011;90:737-42.
65. Magasi S, Ryan G, Revicki D, et al. Content validity of patient-reported outcome measures: perspectives from a PROMIS meeting. *Qual Life Res* 2012;21:739-46.
66. Emery MP, Perrier LL, Acquadro C. Patient-reported outcome and quality of life instruments database (PROQOLID): frequently asked questions. *Health Qual Life Outcomes* 2005;3:12.
67. Erickson P, Taeuber RC, Scott J. Operational aspects of Quality-of-Life Assessment. Choosing the right instrument. *PharmacoEconomics* 1995;7:39-48.
68. Guidance for industry patient-reported outcome measures: use in medical product development to support labelling claims. US Food and Drug Administration & Center for Biologics Evaluation and Research, Center for Devices and Radiological Health, ed.2009.
69. Willke RJ, Burke LB, Erickson P. Measuring treatment impact: a review of patient-reported outcomes and other efficacy endpoints in approved product labels. *Control Clin Trials* 2004;25:535-52.
70. European Medicines Agency (EMA). Reflection paper on the regulatory guidance for the use of health-related quality of life (HRQL) measures in the evaluation of medicinal products. London, 27th July 2005.
71. Bing EG, Hays RD, Jacobson LP, et al. Health-related quality of life among people with HIV disease: results from the Multicenter AIDS Cohort Study. *Qual Life Res* 2000;9:55-63.
72. Hays RD, Cunningham WE, Sherbourne CD, et al. Health-related quality of life in patients with human immunodeficiency virus infection in the United States: results from the HIV Cost and Services Utilization Study. *Am J Med* 2000;108:714-22.

73. Her M, Kavanaugh A. Patient-reported outcomes in rheumatoid arthritis. *Curr Opin Rheumatol* 2012;24:327-34.
74. Brasil F, Pontarolo R, Correr CJ. Patient Reported Outcomes Measures (PROMs) in diabetes: Why are they still rarely used in clinical routine? *Diabetes Res Clin Pract* 2012.
75. Sosin M, Patel KM, Nahabedian MY, Bhanot P. Patient-centered outcomes following laparoscopic ventral hernia repair: a systematic review of the current literature. *American journal of surgery* 2014;208:677-84.
76. Hawn MT, Itani KM, Giobbie-Hurder A, McCarthy M, Jr., Jonasson O, Neumayer LA. Patient-reported outcomes after inguinal herniorrhaphy. *Surgery* 2006;140:198-205.
77. Coulman KD, Abdelrahman T, Owen-Smith A, Andrews RC, Welbourn R, Blazeby JM. Patient-reported outcomes in bariatric surgery: a systematic review of standards of reporting. *Obesity reviews : an official journal of the International Association for the Study of Obesity* 2013;14:707-20.
78. Reavey PL, Klassen AF, Cano SJ, et al. Measuring quality of life and patient satisfaction after body contouring: a systematic review of patient-reported outcome measures. *Aesthetic surgery journal / the American Society for Aesthetic Plastic surgery* 2011;31:807-13.
79. Wright CJ, Chambers GK, Robens-Paradise Y. Evaluation of indications for and outcomes of elective surgery. *CMAJ : Canadian Medical Association journal = journal de l'Association medicale canadienne* 2002;167:461-6.
80. McGrail K, Bryan S, Davis J. Let's all go to the PROM: the case for routine patient-reported outcome measurement in Canadian healthcare. *HealthcarePapers* 2011;11:8-18; discussion 55-8.
81. Vallance-Owen A, Cubbin S, Warren V, Matthews B. Outcome monitoring to facilitate clinical governance; experience from a national programme in the independent sector. *J Public Health (Oxf)* 2004;26:187-92.
82. Browne JA. Patient Reported Outcome Measures (PROMs) in elective surgery: Report to the Department of Health: London School of Hygiene and Tropical Medicine; 2007 December.
83. Black N. Patient reported outcome measures could help transform healthcare. *BMJ (Clinical research ed)* 2013;346:f167.

84. NHS Outcomes Framework 2015-2016. Available at:
<https://www.gov.uk/government/publications/nhs-outcomes-framework-2015-to-2016>. Accessed July 2015
85. Finalised Patient reported Outcome Measures (PROMs) in England: April 2009-2010: Pre- and post-operative data. London 2010 Available at:
<http://catalogue.ic.nhs.uk/publications/hospital/proms/proms-eng-apr-09-mar-10-final/proms-eng-apr-09-mar10-oper-data-expe-meth.pdf> . Accessed July 2012
86. Snyder CF, Blackford AL, Wolff AC, Carducci MA, Herman JM, Wu AW. Feasibility and value of PatientViewpoint: a web system for patient-reported outcomes assessment in clinical practice. *Psycho-oncology* 2013;22:895-901.
87. Lewis S. Realizing the PROMise of PROMs. *HealthcarePapers* 2011;11:20-3; discussion 55-8.
88. Zhu J, Stuver SO, Epstein AM, Schneider EC, Weissman JS, Weingart SN. Can we rely on patients' reports of adverse events? *Medical care* 2011;49:948-55.
89. Parthasarathy M, Reid V, Pyne L, Groot-Wassink T. Are we recording postoperative complications correctly? Comparison of NHS Hospital Episode Statistics with the American College of Surgeons National Surgical Quality Improvement Program. *BMJ Qual Saf* 2015.
90. Bayliss EA, Ellis JL, Steiner JF. Subjective assessments of comorbidity correlate with quality of life health outcomes: initial validation of a comorbidity assessment instrument. *Health Qual Life Outcomes* 2005;3:51.
91. Katz JN, Chang LC, Sangha O, Fossel AH, Bates DW. Can comorbidity be measured by questionnaire rather than medical record review? *Medical care* 1996;34:73-84.
92. Hutchings A, Neuburger J, Grosse Frie K, Black N, van der Meulen J. Factors associated with non-response in routine use of patient reported outcome measures after elective surgery in England. *Health Qual Life Outcomes* 2012;10:34.
93. Gurland B, Alves-Ferreira PC, Sobol T, Kiran RP. Using technology to improve data capture and integration of patient-reported outcomes into clinical care: pilot results in a busy colorectal unit. *Diseases of the colon and rectum* 2010;53:1168-75.
94. Ekholm O, Gundgaard J, Rasmussen NK, Hansen EH. The effect of health, socio-economic position, and mode of data collection on non-response in health interview surveys. *Scandinavian journal of public health* 2010;38:699-706.

95. Polk A, Rasmussen JV, Brorson S, Olsen BS. Reliability of patient-reported functional outcome in a joint replacement registry. A comparison of primary responders and non-responders in the Danish Shoulder Arthroplasty Registry. *Acta orthopaedica* 2013;84:12-7.
96. Volken T. Second-stage non-response in the Swiss health survey: determinants and bias in outcomes. *BMC Public Health* 2013;13:167.
97. Littman AJ, Boyko EJ, Jacobson IG, et al. Assessing nonresponse bias at follow-up in a large prospective cohort of relatively young and mobile military service members. *BMC medical research methodology* 2010;10:99.
98. Kypri K, Samaranayaka A, Connor J, Langley JD, MacLennan B. Non-response bias in a web-based health behaviour survey of New Zealand tertiary students. *Preventive medicine* 2011;53:274-7.
99. Sales AE, Plomondon ME, Magid DJ, Spertus JA, Rumsfeld JS. Assessing response bias from missing quality of life data: the Heckman method. *Health Qual Life Outcomes* 2004;2:49.
100. Doward LC, Gnanasakthy A, Baker MG. Patient reported outcomes: looking beyond the label claim. *Health Qual Life Outcomes* 2010;8:89.
101. Yan T, Curtin R. The Relation Between Unit Nonresponse and Item Nonresponse: A Response Continuum Perspective. *International Journal of Public Opinion Research* 2010;22:535-51.
102. Klem TM, Sybrandy JE, Wittens CH. Measurement of health-related quality of life with the Dutch translated Aberdeen Varicose Vein Questionnaire before and after treatment. *European journal of vascular and endovascular surgery : the official journal of the European Society for Vascular Surgery* 2009;37:470-6.
103. Bowling A. Mode of questionnaire administration can have serious effects on data quality. *J Public Health (Oxf)* 2005;27:281-91.
104. Betts P, Lound C. The application of alternative modes of data collection on UK Government social surveys. In: *Statistics OfN*, ed.2010.
105. Shortliffe EH. The evolution of health-care records in the era of the Internet. *Studies in health technology and informatics* 1998;52 Pt 1:suppl 8-14.
106. Dijkstra A, De Vries H. The development of computer-generated tailored interventions. *Patient Educ Couns* 1999;36:193-203.
107. Brynjolfsson S. *Wired for Innovation*. The MIT press 2009.

108. Venkatesh V, Thong J, Xu X. Consumer Acceptance and Use of Information Technology: Extending the Unified Theory of Acceptance and Use of Technology. *Management Information Systems Quarterly* 2012;36:157-78.
109. David Gefen DWS. Gender Differences in the Perception and Use of E-Mail: An Extension to the Technology Acceptance Model. *MIS Quarterly* 1997;21:389-400.
110. Venkatesh V, Morris MG. Why Don't Men Ever Stop to Ask for Directions? Gender, Social Influence, and Their Role in Technology Acceptance and Usage Behavior. *MIS Quarterly* 2000;24:115-39.
111. Gibson F, Aldiss S, Taylor RM, et al. Utilization of the Medical Research Council evaluation framework in the development of technology for symptom management: the ASyMS-YG Study. *Cancer nursing* 2010;33:343-52.
112. Fisk A, Rogers W. Health care of older adults: the promise of human factors research. *Human Factors Intervention for the Health Care of Older Adults*. New Jersey: Georgia Institute of Technology; 2002.
113. Kosinski M, Bjorner JB, Ware JE, Jr., Sullivan E, Straus WL. An evaluation of a patient-reported outcomes found computerized adaptive testing was efficient in assessing osteoarthritis impact. *Journal of clinical epidemiology* 2006;59:715-23.
114. Cella D, Yount S, Rothrock N, et al. The Patient-Reported Outcomes Measurement Information System (PROMIS): progress of an NIH Roadmap cooperative group during its first two years. *Medical care* 2007;45:S3-S11.
115. Jensen RE, Potosky AL, Reeve BB, et al. Validation of the PROMIS physical function measures in a diverse US population-based cohort of cancer patients. *Qual Life Res* 2015.
116. Irwin DE, Atwood CA, Jr., Hays RD, et al. Correlation of PROMIS scales and clinical measures among chronic obstructive pulmonary disease patients with and without exacerbations. *Qual Life Res* 2015;24:999-1009.
117. Revicki DA, Kawata AK, Harnam N, Chen WH, Hays RD, Cella D. Predicting EuroQol (EQ-5D) scores from the patient-reported outcomes measurement information system (PROMIS) global items and domain item banks in a United States sample. *Qual Life Res* 2009;18:783-91.
118. Reeve BB. Special issues for building computerized-adaptive tests for measuring patient-reported outcomes: the National Institute of Health's investment in new technology. *Medical care* 2006;44:S198-204.

119. Leidy NK, Vernon M. Perspectives on patient-reported outcomes : content validity and qualitative research in a changing clinical trial environment. *Pharmacoeconomics* 2008;26:363-70.
120. NHS_Confederation. Beginning with the end in mind: How outcomes-based commissioning can help unlock the potential of community services. 2014.
121. Rolfson O, Karrholm J, Dahlberg LE, Garellick G. Patient-reported outcomes in the Swedish Hip Arthroplasty Register: results of a nationwide prospective observational study. *The Journal of bone and joint surgery British volume* 2011;93:867-75.
122. Hewlett SA. Patients and clinicians have different perspectives on outcomes in arthritis. *The Journal of rheumatology* 2003;30:877-9.
123. Martin RL, Mohtadi NG, Safran MR, et al. Differences in physician and patient ratings of items used to assess hip disorders. *The American journal of sports medicine* 2009;37:1508-12.
124. Wehmeier PM, Kluge M, Schacht A, Helsberg K, Schreiber W. Correlation of physician and patient rated quality of life during antipsychotic treatment in outpatients with schizophrenia. *Schizophrenia research* 2007;91:178-86.
125. Greenhalgh J, Meadows K. The effectiveness of the use of patient-based measures of health in routine practice in improving the process and outcomes of patient care: a literature review. *Journal of evaluation in clinical practice* 1999;5:401-16.
126. Dawson J, Doll H, Fitzpatrick R, Jenkinson C, Carr AJ. The routine use of patient reported outcome measures in healthcare settings. *BMJ (Clinical research ed)* 2010;340:c186.
127. Valderas JM, Kotzeva A, Espallargues M, et al. The impact of measuring patient-reported outcomes in clinical practice: a systematic review of the literature. *Qual Life Res* 2008;17:179-93.
128. Ferlie EB, Shortell SM. Improving the quality of health care in the United Kingdom and the United States: a framework for change. *Milbank Q* 2001;79:281-315.
129. Audit Commision: Reducing spending on low clinical value treatments. 2011 Available at: <http://www.rightcare.nhs.uk/index.php/2011/04/audit-commission-health-briefing-reducing-spending-on-low-clinical-value-treatments/> . Accessed December 2014

130. Rosenberg J, Bisgaard T, Kehlet H, et al. Danish Hernia Database recommendations for the management of inguinal and femoral hernia in adults. *Danish medical bulletin* 2011;58:C4243.
131. National Institute for Health and Clinical Excellence. Laparoscopic surgery for inguinal hernia: TA 83. Available at: <http://www.nice.org.uk/nicemedia/live/11542/32926/32926.pfd> . Accessed Jan 2013.
132. Simons MP, Aufenacker T, Bay-Nielsen M, et al. European Hernia Society guidelines on the treatment of inguinal hernia in adult patients. *Hernia : the journal of hernias and abdominal wall surgery* 2009;13:343-403.
133. Fitzgibbons RJ, Jr., Ramanan B, Arya S, et al. Long-term results of a randomized controlled trial of a nonoperative strategy (watchful waiting) for men with minimally symptomatic inguinal hernias. *Annals of surgery* 2013;258:508-15.
134. Kehlet H. Laparoscopic versus open groin hernia repair: are we getting closer to specific clinical recommendations? *Hernia : the journal of hernias and abdominal wall surgery* 2010;14:553-4.
135. Myers E, Browne KM, Kavanagh DO, Hurley M. Laparoscopic (TEP) versus Lichtenstein inguinal hernia repair: a comparison of quality-of-life outcomes. *World journal of surgery* 2010;34:3059-64.
136. Lawrence K, McWhinnie D, Jenkinson C, Coulter A. Quality of life in patients undergoing inguinal hernia repair. *Annals of the Royal College of Surgeons of England* 1997;79:40-5.
137. Wellwood J, Sculpher MJ, Stoker D, et al. Randomised controlled trial of laparoscopic versus open mesh repair for inguinal hernia: outcome and cost. *BMJ (Clinical research ed)* 1998;317:103-10.
138. Cost-utility analysis of open versus laparoscopic groin hernia repair: results from a multicentre randomized clinical trial. *The British journal of surgery* 2001;88:653-61.
139. Abbas AE, Abd Ellatif ME, Noaman N, et al. Patient-perspective quality of life after laparoscopic and open hernia repair: a controlled randomized trial. *Surgical endoscopy* 2012;26:2465-70.
140. Liem MS, Halsema JA, van der Graaf Y, Schrijvers AJ, van Vroonhoven TJ. Cost-effectiveness of extraperitoneal laparoscopic inguinal hernia repair: a

randomized comparison with conventional herniorrhaphy. Coala trial group. *Annals of surgery* 1997;226:668-75; discussion 75-6.

141. Grosse Frie K, van der Meulen J, Black N. Relationship between patients' reports of complications and symptoms, disability and quality of life after surgery. *The British journal of surgery* 2012;99:1156-63.

142. Noble M, McLennan D, Wilkinson K et al. *The English Indices of Deprivation 2007*. London: HMSO, 2008. Available at: <http://www.communities.gov.uk/documents/communities/pdf/733520.pdf>. Accessed March 2013

143. Right data, right payment: Annual report on the Payment by Results data assurance programme 2011/12: Audit commision; 2012.

144. Shabanzadeh DM, Sorensen LT. Laparoscopic surgery compared with open surgery decreases surgical site infection in obese patients: a systematic review and meta-analysis. *Annals of surgery* 2012;256:934-45.

145. McCormack K, Wake B, Perez J, et al. Laparoscopic surgery for inguinal hernia repair: systematic review of effectiveness and economic evaluation. *Health technology assessment (Winchester, England)* 2005;9:1-203, iii-iv.

146. Gass M, Banz VM, Rosella L, Adamina M, Candinas D, Guller U. TAPP or TEP? Population-based analysis of prospective data on 4,552 patients undergoing endoscopic inguinal hernia repair. *World journal of surgery* 2012;36:2782-6.

147. O'Dwyer PJ, Norrie J, Alani A, Walker A, Duffy F, Horgan P. Observation or operation for patients with an asymptomatic inguinal hernia: a randomized clinical trial. *Annals of surgery* 2006;244:167-73.

148. Fitzgibbons RJ, Jr., Giobbie-Hurder A, Gibbs JO, et al. Watchful waiting vs repair of inguinal hernia in minimally symptomatic men: a randomized clinical trial. *JAMA : the journal of the American Medical Association* 2006;295:285-92.

149. Kingsnorth AN, Bowley DM, Porter C. A prospective study of 1000 hernias: results of the Plymouth Hernia Service. *Annals of the Royal College of Surgeons of England* 2003;85:18-22.

150. Kind P, Hardman G, Macran S. *UK population norms for EQ-5D: The University of York*; 1999.

151. Carr AJ, Gibson B, Robinson PG. Measuring quality of life: Is quality of life determined by expectations or experience? *BMJ (Clinical research ed)* 2001;322:1240-3.

152. Groot W. Adaptation and scale of reference bias in self-assessments of quality of life. *Journal of health economics* 2000;19:403-20.
153. Sen A. Health: perception versus observation. *BMJ (Clinical research ed)* 2002;324:860-1.
154. Browne JP, van der Meulen JH, Lewsey JD, Lamping DL, Black N. Mathematical coupling may account for the association between baseline severity and minimally important difference values. *Journal of clinical epidemiology* 2010;63:865-74.
155. Neumayer L, Giobbie-Hurder A, Jonasson O, et al. Open mesh versus laparoscopic mesh repair of inguinal hernia. *The New England journal of medicine* 2004;350:1819-27.
156. Majeed AW, Plura M, Priest S, Johnson AG. Is it necessary to catheterise the bladder before laparoscopy? *Surgical laparoscopy & endoscopy* 1998;8:157-8.
157. Jensen P, Mikkelsen T, Kehlet H. Postherniorrhaphy urinary retention--effect of local, regional, and general anesthesia: a review. *Regional anesthesia and pain medicine* 2002;27:612-7.
158. Oehlenschlaeger J, Hjerne FP, Albers M, et al. Fewer urological complications after laparoscopic inguinal hernia repair without indwelling catheter. *Danish medical bulletin* 2010;57:A4176.
159. Stephan F, Sax H, Wachsmuth M, Hoffmeyer P, Clergue F, Pittet D. Reduction of urinary tract infection and antibiotic use after surgery: a controlled, prospective, before-after intervention study. *Clinical infectious diseases : an official publication of the Infectious Diseases Society of America* 2006;42:1544-51.
160. Primates P, Goldacre MJ. Inguinal hernia repair: incidence of elective and emergency surgery, readmission and mortality. *International journal of epidemiology* 1996;25:835-9.
161. El-Dhuwaib Y, Corless D, Emmett C, Deakin M, Slavin J. Laparoscopic versus open repair of inguinal hernia: a longitudinal cohort study. *Surgical endoscopy* 2013;27:936-45.
162. Sanders D, Kurzer M. Groin hernia guidelines. London: ASGBI; 2013. Available at: <http://www.asgbi.org.uk/download.cfm?docid=21BC920F-290E-4CDE-B415CA77DFF1E0A0>. Accessed July 2013

163. Siebeling L, Musoro JZ, Geskus RB, et al. Prediction of COPD-specific health-related quality of life in primary care COPD patients: a prospective cohort study. *NPJ primary care respiratory medicine* 2014;24:14060.
164. Al-Ruzzeh S, Athanasiou T, Mangoush O, et al. Predictors of poor mid-term health related quality of life after primary isolated coronary artery bypass grafting surgery. *Heart (British Cardiac Society)* 2005;91:1557-62.
165. Dowd JB, Zajacova A. Does the predictive power of self-rated health for subsequent mortality risk vary by socioeconomic status in the US? *International journal of epidemiology* 2007;36:1214-21.
166. Mossey JM, Shapiro E. Self-rated health: a predictor of mortality among the elderly. *American journal of public health* 1982;72:800-8.
167. Idler EL, Benyamini Y. Self-rated health and mortality: a review of twenty-seven community studies. *Journal of health and social behavior* 1997;38:21-37.
168. Skarupski KA, de Leon CF, Bienias JL, et al. Black-white differences in health-related quality of life among older adults. *Qual Life Res* 2007;16:287-96.
169. Zunker CL, Cummins JJ. Elderly health disparities on the U.S.-Mexico border. *Journal of cross-cultural gerontology* 2004;19:13-25.
170. Dolan P. Modeling valuations for EuroQol health states. *Medical care* 1997;35:1095-108.
171. Sullivan PW, Ghushchyan V. Preference-Based EQ-5D index scores for chronic conditions in the United States. *Medical decision making : an international journal of the Society for Medical Decision Making* 2006;26:410-20.
172. Sullivan PW, Ghushchyan V. Mapping the EQ-5D index from the SF-12: US general population preferences in a nationally representative sample. *Medical decision making : an international journal of the Society for Medical Decision Making* 2006;26:401-9.
173. Sullivan PW, Lawrence WF, Ghushchyan V. A national catalog of preference-based scores for chronic conditions in the United States. *Medical care* 2005;43:736-49.
174. Jain S, McGory ML, Ko CY, et al. Comorbidities play a larger role in predicting health-related quality of life compared to having an ostomy. *American journal of surgery* 2007;194:774-9; discussion 9.
175. Blakemore A, Dickens C, Guthrie E, et al. Depression and anxiety predict health-related quality of life in chronic obstructive pulmonary disease: systematic

review and meta-analysis. *International journal of chronic obstructive pulmonary disease* 2014;9:501-12.

176. Tolver MA, Strandfelt P, Rosenberg J, Bisgaard T. Female gender is a risk factor for pain, discomfort, and fatigue after laparoscopic groin hernia repair. *Hernia : the journal of hernias and abdominal wall surgery* 2013;17:321-7.

177. Powell R, Johnston M, Smith WC, et al. Psychological risk factors for chronic post-surgical pain after inguinal hernia repair surgery: a prospective cohort study. *European journal of pain (London, England)* 2012;16:600-10.

178. Woolf AD, Pfleger B. Burden of major musculoskeletal conditions. *Bulletin of the World Health Organization* 2003;81:646-56.

179. Picavet HS, Hoeymans N. Health related quality of life in multiple musculoskeletal diseases: SF-36 and EQ-5D in the DMC3 study. *Annals of the rheumatic diseases* 2004;63:723-9.

180. Mangram AJ, Horan TC, Pearson ML, Silver LC, Jarvis WR. Guideline for Prevention of Surgical Site Infection, 1999. Centers for Disease Control and Prevention (CDC) Hospital Infection Control Practices Advisory Committee. *American journal of infection control* 1999;27:97-132; quiz 3-4; discussion 96.

181. Whitehouse JD, Friedman ND, Kirkland KB, Richardson WJ, Sexton DJ. The impact of surgical-site infections following orthopedic surgery at a community hospital and a university hospital: adverse quality of life, excess length of stay, and extra cost. *Infection control and hospital epidemiology* 2002;23:183-9.

182. Leow MK, Griva K, Choo R, et al. Determinants of Health-Related Quality of Life (HRQoL) in the Multiethnic Singapore Population - A National Cohort Study. *PloS one* 2013;8:e67138.

183. Fortin M, Hudon C, Dubois MF, Almirall J, Lapointe L, Soubhi H. Comparative assessment of three different indices of multimorbidity for studies on health-related quality of life. *Health Qual Life Outcomes* 2005;3:74.

184. Humphries KH, Rankin JM, Carere RG, Buller CE, Kiely FM, Spinelli JJ. Co-morbidity data in outcomes research: are clinical data derived from administrative databases a reliable alternative to chart review? *Journal of clinical epidemiology* 2000;53:343-9.

185. Silliman RA, Lash TL. Comparison of interview-based and medical-record based indices of comorbidity among breast cancer patients. *Medical care* 1999;37:339-49.

186. Robinson JR, Young TK, Roos LL, Gelskey DE. Estimating the burden of disease. Comparing administrative data and self-reports. *Medical care* 1997;35:932-47.
187. Malchau H, Herberts P, Ahnfelt L. Prognosis of total hip replacement in Sweden. Follow-up of 92,675 operations performed 1978-1990. *Acta orthopaedica Scandinavica* 1993;64:497-506.
188. Chong WF, Ding YY, Heng BH. A comparison of comorbidities obtained from hospital administrative data and medical charts in older patients with pneumonia. *BMC Health Serv Res* 2011;11:105.
189. Malenka DJ, McLerran D, Roos N, Fisher ES, Wennberg JE. Using administrative data to describe casemix: a comparison with the medical record. *Journal of clinical epidemiology* 1994;47:1027-32.
190. Hawker GA, Coyte PC, Wright JG, Paul JE, Bombardier C. Accuracy of administrative data for assessing outcomes after knee replacement surgery. *Journal of clinical epidemiology* 1997;50:265-73.
191. Romano PS, Roos LL, Luft HS, Jollis JG, Doliszny K. A comparison of administrative versus clinical data: coronary artery bypass surgery as an example. Ischemic Heart Disease Patient Outcomes Research Team. *Journal of clinical epidemiology* 1994;47:249-60.
192. Jameson SS, Khan SK, Baker P, et al. A national analysis of complications following hemiarthroplasty for hip fracture in older patients. *QJM : monthly journal of the Association of Physicians* 2012;105:455-60.
193. NHS. National clinical coding standards ICD-10 4th edition reference book. 2013.
194. NHS. Coding clinic. Section 1: ICD-10 guidance, Ref 88: Coding of Comorbidities. September 2013.
195. Right data, right payment: Annual report on the Payment by Results data assurance programme: Audit Commision; 2011/12.
196. Das S, Forrest K, Howell S. General anaesthesia in elderly patients with cardiovascular disorders: choice of anaesthetic agent. *Drugs & aging* 2010;27:265-82.
197. Leavitt BJ, Sheppard L, Maloney C, et al. Effect of diabetes and associated conditions on long-term survival after coronary artery bypass graft surgery. *Circulation* 2004;110:II41-4.

198. Prina AM, Deeg D, Brayne C, Beekman A, Huisman M. The association between depressive symptoms and non-psychiatric hospitalisation in older adults. *PloS one* 2012;7:e34821.
199. Bayliss E, Ellis J, Steiner J. Seniors' self-reported multimorbidity captured biopsychosocial factors not incorporated in two other data-based morbidity measures. *Journal of clinical epidemiology* 2009;62:550-7 e1.
200. Yankelovich. Out of Sync: The state of AFib in America Survey: Part of Futures Company; 2009.
201. Aggarwal VK, Tischler EH, Post ZD, Kane I, Orozco FR, Ong A. Patients with atrial fibrillation undergoing total joint arthroplasty increase hospital burden. *The Journal of bone and joint surgery American volume* 2013;95:1606-11.
202. Gascon JJ, Sanchez-Ortuno M, Llor B, Skidmore D, Saturno PJ. Why hypertensive patients do not comply with the treatment: results from a qualitative study. *Family Practice* 2004;21:125-30.
203. Rochon PA, Katz JN, Morrow LA, et al. Comorbid illness is associated with survival and length of hospital stay in patients with chronic disability. A prospective comparison of three comorbidity indices. *Medical care* 1996;34:1093-101.
204. Salive ME. Multimorbidity in older adults. *Epidemiologic reviews* 2013;35:75-83.
205. Radley DC, Gottlieb DJ, Fisher ES, Tosteson ANA. Comorbidity Risk-Adjustment Strategies are Comparable Among Persons with Hip Fracture. *Journal of clinical epidemiology* 2008;61:580-7.
206. Chaudhry S, Jin L, Meltzer D. Use of a self-report-generated Charlson Comorbidity Index for predicting mortality. *Medical care* 2005;43:607-15.
207. 11th Annual Report 2014: National Joint Registry for England, Wales and Northern Ireland 2014.
208. Quan H, Sundararajan V, Halfon P, et al. Coding algorithms for defining comorbidities in ICD-9-CM and ICD-10 administrative data. *Medical care* 2005;43:1130-9.
209. Fan VS, Au D, Heagerty P, Deyo RA, McDonnell MB, Fihn SD. Validation of case-mix measures derived from self-reports of diagnoses and health. *Journal of clinical epidemiology* 2002;55:371-80.

210. Miskulin D, Bragg-Gresham J, Gillespie BW, et al. Key comorbid conditions that are predictive of survival among hemodialysis patients. *Clinical journal of the American Society of Nephrology : CJASN* 2009;4:1818-26.
211. Bottle A, Aylin P. Comorbidity scores for administrative data benefited from adaptation to local coding and diagnostic practices. *Journal of clinical epidemiology* 2011;64:1426-33.
212. Khan SK, Malviya A, Muller SD, et al. Reduced short-term complications and mortality following Enhanced Recovery primary hip and knee arthroplasty: results from 6,000 consecutive procedures. *Acta orthopaedica* 2014;85:26-31.
213. Hunt LP, Ben-Shlomo Y, Clark EM, et al. 90-day mortality after 409,096 total hip replacements for osteoarthritis, from the National Joint Registry for England and Wales: a retrospective analysis. *Lancet* 2013;382:1097-104.
214. Sharkey PF, Shastri S, Teloken MA, Parvizi J, Hozack WJ, Rothman RH. Relationship between surgical volume and early outcomes of total hip arthroplasty: do results continue to get better? *The Journal of arthroplasty* 2004;19:694-9.
215. Kan WC, Wang JJ, Wang SY, et al. The new comorbidity index for predicting survival in elderly dialysis patients: a long-term population-based study. *PloS one* 2013;8:e68748.
216. St Germaine-Smith C, Liu M, Quan H, Wiebe S, Jette N. Development of an epilepsy-specific risk adjustment comorbidity index. *Epilepsia* 2011;52:2161-7.
217. van Walraven C, Austin PC, Jennings A, Quan H, Forster AJ. A modification of the Elixhauser comorbidity measures into a point system for hospital death using administrative data. *Medical care* 2009;47:626-33.
218. Imamura K, Black N. Does comorbidity affect the outcome of surgery? Total hip replacement in the UK and Japan. *International journal for quality in health care : journal of the International Society for Quality in Health Care / ISQua* 1998;10:113-23.
219. Wu CH, Cheng RM, Tsai HC, et al. How comorbidities and preoperative expenditures correlate with postoperative adverse outcomes. *The American journal of managed care* 2012;18:e405-15.
220. Singh JA, Lewallen DG. Ninety-day mortality in patients undergoing elective total hip or total knee arthroplasty. *The Journal of arthroplasty* 2012;27:1417-22 e1.
221. Jansen E, Puolakka T, Eskelinen A, et al. Predictors of mortality following primary hip and knee replacement in the aged. A single-center analysis of 1,998

primary hip and knee replacements for primary osteoarthritis. *Acta orthopaedica* 2013;84:44-53.

222. Browne JA, Sandberg BF, D'Apuzzo MR, Novicoff WM. Depression is associated with early postoperative outcomes following total joint arthroplasty: a nationwide database study. *The Journal of arthroplasty* 2014;29:481-3.

223. Buller LT, Best MJ, Klika AK, Barsoum WK. The influence of psychiatric comorbidity on perioperative outcomes following primary total hip and knee arthroplasty; a 17-year analysis of the National Hospital Discharge Survey database. *The Journal of arthroplasty* 2015;30:165-70.

224. Bozic KJ, Bashyal RK, Anthony SG, Chiu V, Shulman B, Rubash HE. Is administratively coded comorbidity and complication data in total joint arthroplasty valid? *Clinical orthopaedics and related research* 2013;471:201-5.

225. Makris A, Piperopoulos A, Karmaniolou I. Multiple sclerosis: basic knowledge and new insights in perioperative management. *Journal of anesthesia* 2014;28:267-78.

226. Jorgensen CC, Madsbad S, Kehlet H. Postoperative morbidity and mortality in type-2 diabetics after fast-track primary total hip and knee arthroplasty. *Anesthesia and analgesia* 2015;120:230-8.

227. DeSalvo KB, Bloser N, Reynolds K, He J, Muntner P. Mortality prediction with a single general self-rated health question. A meta-analysis. *Journal of general internal medicine* 2006;21:267-75.

228. Davis RB, Iezzoni LI, Phillips RS, Reiley P, Coffman GA, Safran C. Predicting in-hospital mortality. The importance of functional status information. *Medical care* 1995;33:906-21.

229. Hufford MR, Shiffman S. Methodological issues affecting the value of patient-reported outcomes data. *Expert review of pharmacoeconomics & outcomes research* 2002;2:119-28.

230. Gwaltney CJ, Shields AL, Shiffman S. Equivalence of electronic and paper-and-pencil administration of patient-reported outcome measures: a meta-analytic review. *Value in health : the journal of the International Society for Pharmacoeconomics and Outcomes Research* 2008;11:322-33.

231. Ward A, Abisi S, Braithwaite BD. An online patient completed Aberdeen Varicose Vein Questionnaire can help to guide primary care referrals. *European*

journal of vascular and endovascular surgery : the official journal of the European Society for Vascular Surgery 2013;45:178-82.

232. Dupont A, Wheeler J, Herndon JE, 2nd, et al. Use of tablet personal computers for sensitive patient-reported information. The journal of supportive oncology 2009;7:91-7.

233. Smith SK, Rowe K, Abernethy AP. Use of an electronic patient-reported outcome measurement system to improve distress management in oncology. Palliative & supportive care 2014;12:69-73.

234. Drummond HE, Ghosh S, Ferguson A, Brackenridge D, Tiplady B. Electronic quality of life questionnaires: a comparison of pen-based electronic questionnaires with conventional paper in a gastrointestinal study. Qual Life Res 1995;4:21-6.

235. VanDenKerkhof EG, Goldstein DH, Blaine WC, Rimmer MJ. A comparison of paper with electronic patient-completed questionnaires in a preoperative clinic. Anesthesia and analgesia 2005;101:1075-80, table of contents.

236. Salaffi F, Gasparini S, Ciapetti A, Gutierrez M, Grassi W. Usability of an innovative and interactive electronic system for collection of patient-reported data in axial spondyloarthritis: comparison with the traditional paper-administered format. Rheumatology (Oxford, England) 2013;52:2062-70.

237. Salaffi F, Gasparini S, Grassi W. The use of computer touch-screen technology for the collection of patient-reported outcome data in rheumatoid arthritis: comparison with standardized paper questionnaires. Clinical and experimental rheumatology 2009;27:459-68.

238. Rolfson O, Salomonsson R, Dahlberg LE, Garellick G. Internet-based follow-up questionnaire for measuring patient-reported outcome after total hip replacement surgery-reliability and response rate. Value in health : the journal of the International Society for Pharmacoeconomics and Outcomes Research 2011;14:316-21.

239. Schick-Makaroff K, Molzahn A. Strategies to use tablet computers for collection of electronic patient-reported outcomes. Health Qual Life Outcomes 2015;13:2.

240. Basch E, Goldfarb S. Electronic patient-reported outcomes for collecting sensitive information from patients. The journal of supportive oncology 2009;7:98-9.

241. Kotaniemi JT, Hassi J, Kataja M, et al. Does non-responder bias have a significant effect on the results in a postal questionnaire study? *European journal of epidemiology* 2001;17:809-17.
242. Nakash RA, Hutton JL, Lamb SE, Gates S, Fisher J. Response and non-response to postal questionnaire follow-up in a clinical trial--a qualitative study of the patient's perspective. *Journal of evaluation in clinical practice* 2008;14:226-35.
243. Wensing M, Elwyn G. Research on patients' views in the evaluation and improvement of quality of care. *Quality & safety in health care* 2002;11:153-7.
244. Russ SJ, Rout S, Caris J, et al. The WHO surgical safety checklist: survey of patients' views. *BMJ Qual Saf* 2014;23:939-46.
245. Ashley L, Jones H, Forman D, et al. Feasibility test of a UK-scalable electronic system for regular collection of patient-reported outcome measures and linkage with clinical cancer registry data: the electronic Patient-reported Outcomes from Cancer Survivors (ePOCS) system. *BMC medical informatics and decision making* 2011;11:66.
246. Smith PC, Street AD. On the uses of routine patient-reported health outcomes data. *Health economics* 2012.
247. Heniford BT, Walters AL, Lincourt AE, Novitsky YW, Hope WW, Kercher KW. Comparison of generic versus specific quality-of-life scales for mesh hernia repairs. *Journal of the American College of Surgeons* 2008;206:638-44.