IMPROVING SAFETY AND QUALITY IN GASTROINTESTINAL ENDOSCOPY
PATIENT PATHWAYS

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Declaration

I declare that I am the sole author of this thesis and all the work presented within this is my own, except where it is referenced or conducted in collaboration with others who are appropriately credited.

Signed:  
Date: 21.12.2017

Dr Manmeet K Matharoo
Abstract

Patient safety is a key priority as it is acknowledged that medical error is common, multifactorial and often avoidable. Gastrointestinal endoscopy is increasingly a therapeutic procedure not without risk. Current training in endoscopy focuses on technical aspects with no formal recognition of non-technical skills such as communication, leadership, decision-making and teamwork. Error analysis in other medical specialties suggests that non-technical skills are often implicated. Recognition, understanding and training in endoscopic non-technical skills may enhance team-working skills and contribute towards patient safety.

The overarching aim of this thesis is to understand the breadth of errors that occur in endoscopy and to objectively evaluate non-technical skills and teamwork in endoscopy and the colorectal cancer multi-disciplinary team. Based on this, measures to mitigate error enhance teamwork and non-technical skills will be implemented and evaluated.

Part A of this thesis focuses on identifying and defining problems impacting patient safety in endoscopy. The introductory chapter details the emergence of patient safety and quality within healthcare and contextualises the importance of these concepts for endoscopy. In Chapter 2 endoscopy team members’ attitudes towards patient safety in endoscopy are explored coupled with a prospective evaluation of the frequency, type and severity of patient safety incidents. Teamwork processes are examined and presented in Chapters 3 and 4 by scientifically evaluating safety checks, technical and non-technical skill by endoscopy teams conducting elective and emergency procedures respectively. Chapter 5 evaluates the extended endoscopy pathway by measuring performance in the colorectal cancer MDT by assessing teamwork, decision-making and errors across key patient groups. Educational strategies and quality improvement interventions are implemented to support patient safety beyond endoscopy.

In part B of this thesis specific interventions to enhance the safety and quality issues identified in part A are presented. Chapter 6 aims to determine the feasibility and effectiveness of a novel multi-disciplinary team training intervention for bowel cancer screening teams by targeting non-technical skills, error analysis and enhanced team performance strategies. Finally in Chapter 7 an endoscopy safety checklist is proposed and implemented into clinical practice. The checklist was prospectively evaluated in detail to examine effects on safety checks, patient safety incidents, technical and non-technical skills. In summary, this thesis serves to identify clinically transferable approaches to improve patient safety within endoscopy.
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I would like to thank the influential leaders that inspired me to pursue safety and quality research, in particular Roland Valori, Charles Vincent and Atul Gawande. I am deeply grateful to my many collaborators, in particular Ian Jenkins, Omar Faiz, David Burling, Rachel Baldwin, Sarah Marshall, Kinesh Patel, Paul Bassett, Tajana Soukoup and Steven Preston for their time, hard work and expertise.

I am indebted to my supervisors Adam Haycock, Nick Sevdalis and Siwan Thomas-Gibson for their academic prowess, dedication to supporting me in completing this work, constructive criticism to ensure I met their high standards and inspirational mentorship. I am grateful to my family who have supported me through the countless hours spent at work and encouraged me to follow my passion for medicine.

Finally and most importantly I am thankful to my sons Jai and Ram for their love, good humour, resilience and quiet satisfaction that, ‘Mum goes to work to fix peoples bowels’, as without this, none of this work would have been possible.
Dedication

My passion for patient safety and quality is a personal one. My eldest son Jai underwent an urgent surgical procedure at an eminent teaching hospital when he was two weeks of age. What was supposed to be a routine operation culminated in a series of small errors that resulted in him receiving a ten-fold intravenous paracetamol overdose in the operating theatre. The consultant anaesthetist made a decimal error in diluting the drug.

Fortunately there were no significant consequences and he recovered. The story may have led to a fatal outcome on another day…

I dedicate my work in patient safety and quality to my sons Jai and Ram.

‘Discipline Makes Daring Possible’ (Atul Gawande 2014)
Peer Reviewed Publications And Presentations

Awards

● Winner of the John Nicholls Prize for Research at St. Mark’s Hospital (2016)

● Winner of the Norgine Bursary award to present research at the British Society of Gastroenterology annual meeting (2016)

● Runner up for the London North West Hospitals NHS Trust Research and Development Award (2016)

● Shortlisted for the Shire Award for Gastrointestinal Excellence (SAGES) Award (2013)

● Top poster presentation prize for United European Gastroenterology Week (UEGW) ‘Improving quality and safety in GI Endoscopy: An analysis of endoscopic non-technical skills and adverse events’ (2011)

Publications

● Haycock, Matharoo & Thomas-Gibson, ‘Effective Teamworking in Gastroenterology’ Frontline 2011 doi:10.1136/fl gastro-2011-100048


● Matharoo M and Thomas-Gibson S. Safe Endoscopy. Frontline Gastroenterology 2017 8: 86-89 doi 10.1136/flgastro-2016-100766
Invited Presentations

International

● 2015 – European Society of Gastrointestinal Endoscopy (ESGE) Quality in Colonoscopy (Prague) ‘The CRC MDT: How many errors occur, do they matter and can they be averted’.

‘Quality Improvement in the CRC MDT: A prospective evaluation of team factors’

● 2013 – united European Gastroenterology Week (UEGW) (Amsterdam) ‘Mandated Endoscopy Safety Checklists: A tick box exercise or a useful clinical intervention?’

● 2012 – UEGW (Amsterdam) ‘A Prospective Analysis of Colorectal Cancer MDT Team Function: How Can Quality be Improved?’

● 2012 Behavioural Sciences Applied to Acute Care Teams (BSAS) (Copenhagen) ‘A prospective Analysis of CRC MDT Team Function’

‘Endoscopic non-technical skills training for Bowel Cancer screening teams: Evaluation of a novel training Intervention

‘A structured Evaluation of Patient Safety Incidents and Never Events in Endoscopy


● 2011 – BSAS (Zurich) ‘Improving Quality and Safety in Gastrointestinal Endoscopy’

● 2011 – Asian Institute of Gastroenterology, Hyderabad, India. Board Meting Presentation, ‘Errors in Endoscopy: Scope to Improve?’

National

● 2016 – British Society of Gastroenterology (BSG) 2016: ‘How can Endoscopic Non-Technical Skills and Team Training Improve Quality Across the Board’ (Endoscopy Bowel Cancer Screening section).

● 2015 – St Mark’s Grand Round: PhD Research Overview and Viva

● 2015 – St Mark’s Foundation Dinner: Presentation for the Centre for Patient Safety and Quality at St Mark’s Hospital
• 2015 – BSG DDF, ‘The Colorectal Cancer MDT: How many errors occur, do they matter and can they be averted’.

‘Quality Improvement in the CRC MDT: A prospective evaluation of team factors’


• 2014 – St Mark’s Association Day ‘Creating a more safe environment for surgical and endoscopic procedures’

• 2014 – Regional BSG Meeting (Royal College of Physicians), ‘Compliance with an Endoscopy Safety Checklist: Lessons Learnt’

• 2013 – GI Grand Round at Imperial College ‘Endoscopy Safety Checklists’

• 2013 – Clinical Leadership for Educational Supervisors, (The London Deanery) ‘Presenting a Quality Improvement Project’

• 2013 – St Mark’s Grand Round, ‘Enhancing Colorectal Cancer MDT function’

• 2013 – St Mark’s Governance meeting, ‘Endoscopy Checklist Compliance Audit’

• 2013 – St Mark’s Governance meeting, ‘The Friday afternoon stent” Learning from an SUI’

• 2012 – BSG DDF Meeting, ‘Patient Safety Incidents and Never Events in Endoscopy’

• 2012 – St Mark’s Frontiers Meeting, ‘Endoscopy Safety Checklists’

• 2012 – St Mark’s Hospital Polypectomy Course, ‘Top-tips- The Polypectomy Team’

• 2012 – St Mark’s Research Forum, ‘Organising a Research Forum for Research Fellows’


• 2012 – St Mark’s Governance, ‘Learning from a Serious Untoward Incident’

• 2011 – St. Mark’s Governance, ‘To err is Human’

• 2011 – Northwick Park Medical Grand Round, ‘Safety in Endoscopy’
• 2011 – St. Mark’s Grand Round (Research Plan Presentation): ‘Errors in Endoscopy: Scope to Improve?’

• 2011 – St Mary’s Surgical Team Training Project

• 2011 – Royal College of Physicians Gut Club NW London Gastroenterology, ‘Errors in Endoscopy: Scope to Improve’
Table of Contents

Copyright Declaration ............................................................................................................. 2
Declaration................................................................................................................................. 2
Abstract..................................................................................................................................... 3
Acknowledgements .................................................................................................................. 4
Dedication ................................................................................................................................. 5
Peer Reviewed Publications And Presentations .................................................................... 6
Invited Presentations............................................................................................................... 7
List of Tables .......................................................................................................................... 23
List of Figures ......................................................................................................................... 26
Thesis Aims............................................................................................................................... 28
Part A: Identifying Problems................................................................................................. 29

Chapter 1: Introduction ........................................................................................................ 30
  1.1 Safety and Quality in Healthcare .................................................................................. 30
      1.1.1 What is safety? ........................................................................................................ 30
      1.1.2 Medical Error ........................................................................................................ 31
          1.1.2.1 Definition ....................................................................................................... 31
          1.1.2.2 Incidence ....................................................................................................... 32
          1.1.2.3 Illustrations of Medical Error ...................................................................... 32
      1.1.3 What is Quality? .................................................................................................... 33
      1.1.4 The Relationship Between Quality and Safety .................................................. 36
      1.1.5 Quality Assurance ............................................................................................... 37
  1.2 Patient Safety and Quality in Context ...................................................................... 38
      1.2.1 US Perspectives ................................................................................................. 38
      1.2.2 UK Perspectives ................................................................................................. 39
      1.2.3 Never events ....................................................................................................... 39
      1.2.4 Poor care in the public spotlight ........................................................................ 39
          1.2.4.1 Bristol ......................................................................................................... 40
          1.2.4.2 Mid Staffordshire .................................................................................... 40
1.2.5 Regulation of Healthcare: The Care Quality Commission ...............41
1.3 Human Factors and Risk Management ............................................41
  1.3.1 Accident causation models .........................................................42
  1.3.2 High Reliability Organisations (HRO) .........................................44
  1.3.3 Crew Resource Management (CRM) ...........................................44
  1.3.4 Aviation to Anaesthetics: Translating Safety Concepts from Industry to Healthcare .........................................................45
1.4 Healthcare Teams ...........................................................................46
  1.4.1 Defining Teams, Teamwork and Team Performance ......................46
  1.4.2 Teamwork Skills ........................................................................47
  1.4.3 Non-Technical Skills ..................................................................48
  1.4.4 Challenges for Healthcare Teams .................................................48
1.5 Endoscopy Patient Pathways ..............................................................49
  1.5.1 Urgent Suspected Cancer Pathway (Two Week Wait Pathway) ..........49
  1.5.2 Symptomatic Patient Pathway .....................................................50
  1.5.3 Bowel Cancer Screening Pathway ..............................................51
  1.5.4 Tertiary Referral Pathways .........................................................52
  1.5.5 Endoscopy and the Colorectal Cancer Multi-Disciplinary Team Meeting (CRC MDT) .................................................................52
1.6 Endoscopy Patient Safety and Quality ..................................................53
  1.6.1 Endoscopy in the pre-screening era ..............................................54
    1.6.1.1 UK colonoscopy audit ...............................................................54
    1.6.1.2 National Confidential Enquiry into Patient Outcomes and Death (NCEPOD) .................................................................54
  1.6.2 The Joint Advisory Group on Gastrointestinal Endoscopy (JAG) ......55
  1.6.3 The National Endoscopy Training Programme (NET) .....................55
  1.6.4 Endoscopy training ......................................................................55
    1.6.4.1 The changing shape of endoscopy training ...............................57
    1.6.4.2 Technical skills training and Simulation ..................................57
    1.6.4.3 Fundamentals of endoscopy safety .........................................58
    1.6.4.4 Training vs. service provision vs. patient safety ......................59
  1.6.5 Endoscopy high quality .................................................................59
    1.6.5.1 The Global Rating Scale (GRS) for Endoscopy .........................60
    1.6.5.2 Implementing Endoscopy Quality and Safety ..........................60
Chapter 2: Identifying Patient Safety Issues in Endoscopy

2.1 Chapter Overview

2.2 Introduction

2.3 Aims

2.3.1 Safety Attitudes Questionnaire Study

2.3.2 Patient Safety Incidents Study

2.4 Methods

2.4.1 Safety Attitudes Questionnaire Study

2.4.2 Prospective observational study of Patient Safety Incidents (PSIs) in Endoscopy

2.5 Results

2.5.1 Safety Attitudes Questionnaire Study

2.5.2 Prospective observational study of Patient Safety Incidents (PSIs) in Endoscopy

2.5.1.1 Demographic data

2.5.1.2 Questionnaire Findings

2.5.2.1 Demographic data and Study Participants

2.5.2.2 Incidence of PSIs

2.5.2.3 Severe PSIs and Never Events

2.5.2.4 Intermediate and Minor PSIs

2.5.2.5 Incidence of PSIs according to key themes

2.5.2.6 Detailed analysis of PSI and educational strategies
Chapter 3: Identifying and Measuring Factors Affecting Patient Safety in Routine Endoscopy Teams

3.1 Chapter Overview ........................................................................................................... 94

3.2 Introduction.................................................................................................................... 94

3.2.1 Complexity of endoscopy ......................................................................................... 94

3.2.2 Endoscopic non-technical skills – definitions and relevance ................................. 94

3.2.3 Non-technical and technical skills ........................................................................... 95

3.2.4 The endoscopy team and patient centeredness ..................................................... 95

3.3 Aims.................................................................................................................................. 96

3.4 Methods .......................................................................................................................... 96

3.4.1 Study Design ............................................................................................................. 96

3.4.2 Participants, procedures and setting .......................................................................... 96

3.4.3 Skills and behaviour measurement ........................................................................... 97

3.4.3.1 Technical Skill (DOPS) ..................................................................................... 98

3.4.3.2 Non-Technical Skill (ENTS) ............................................................................ 99

3.4.3.3 In room Safety Checks (SC) .......................................................................... 99

3.4.3.4 Patient Safety Incidents.................................................................................... 100

3.4.4 Ethical Approval ....................................................................................................... 101

3.4.5 Data analysis ............................................................................................................. 101

3.4.5.1 Experts and trainees ......................................................................................... 101

3.4.5.2 Diagnostic and therapeutic procedures ......................................................... 101
3.5 Results ................................................................................................................. 102
    3.5.1 Demographics data ............................................................................... 102
    3.5.2 Technical skills .................................................................................... 102
    3.5.3 Non-Technical skill .............................................................................. 102
    3.5.4 In room Safety Checks ......................................................................... 103
    3.5.5 Patient Safety Incidents (PSIs) ............................................................. 104
    3.5.6 Inter-rater reliability ............................................................................. 105
    3.5.7 Sub-group analyses: Experts and trainees ............................................ 106
    3.5.8 Sub-group analyses: Medical, surgical and nurse endoscopists .......... 106
    3.5.9 Correlational relationships ................................................................... 107
    3.5.10 Qualitative themes ............................................................................... 110
        3.5.10.1 Sub teams ........................................................................ 110
        3.5.10.2 Hierarchy and problem escalation ...................................... 111
        3.5.10.3 Training, supervision and specialities ................................. 112
        3.5.10.4 Reactive, opportunistic and proactive problem solving..... 112

3.6 Discussion ............................................................................................................ 113
    3.6.1 Summary .............................................................................................. 113
    3.6.2 Implications of Study Findings ............................................................ 113
        3.6.2.1 Technical skills ................................................................... 113
        3.6.2.2 Non-technical skills ............................................................ 114
        3.6.2.3 Safety Checks ...................................................................... 114
        3.6.2.4 Patient Safety Incidents ....................................................... 115
        3.6.2.5 Correlations ......................................................................... 116
        3.6.2.6 Subgroup analyses .............................................................. 116
    3.6.3 Limitations ........................................................................................... 117
    3.6.4 Future Work ......................................................................................... 117

3.7 Conclusion ........................................................................................................... 118

Chapter 4: Identifying and Measuring Factors Affecting Patient Safety in
Emergency Endoscopy Teams .................................................................................... 119
4.1 Chapter Overview .............................................................................................. 119
4.2 Introduction ....................................................................................................... 119
4.2.1 Emergency endoscopy ................................................................. 119
4.2.2 Patient factors ........................................................................... 120
4.2.3 Skills and expertise of the endoscopist ......................................... 120
4.2.4 The emergency endoscopy team .................................................. 121
4.2.5 Service provision and Organisational challenges ......................... 123
4.3 Aims .................................................................................................. 124
4.4 Methods .......................................................................................... 124
4.4.1 Study Design ............................................................................... 124
4.4.2 Participants, procedures and settings ............................................ 124
4.4.2.1 Emergency procedures ......................................................... 124
4.4.2.2 Routine procedures .............................................................. 125
4.4.3 Case selection ............................................................................. 125
4.4.4 Exclusion criteria ........................................................................ 126
4.4.5 Primary measures: Skills, behaviours and errors ............................ 126
4.4.5.1 Technical Skill (DOPS) ....................................................... 127
4.4.5.2 Non-Technical Skill (ENTS) ............................................... 127
4.4.5.3 Safety Checks (SC) ............................................................. 128
4.4.5.4 Patient Safety Incidents (PSI) ............................................. 128
4.4.6 Secondary Measures ................................................................... 129
4.4.7 Ethical Considerations ................................................................. 129
4.4.8 Data analysis ................................................................................ 130
4.4.8.1 Combined emergency and routine cases .............................. 130
4.4.8.2 Comparison between emergency and routine cases ............... 130
4.5 Results .............................................................................................. 131
4.5.1 Demographics and Study Participants .......................................... 131
4.5.2 Combined Emergency and Routine Case Analysis ....................... 132
4.5.2.1 Technical and Non-Technical Skills .................................... 132
4.5.2.2 Safety Checks through the Checklist (SC) ............................ 132
4.5.2.3 Patient Safety Incidents (PSI) ............................................. 133
4.5.2.4 Correlational Analyses ....................................................... 133
4.5.3 Emergency and Routine Case Comparative Analysis: Primary Measures .................................................. 134
4.5.4 Secondary Measures ................................................................... 135
4.5.4.1 Emergency Case Severity ................................................... 136
4.5.4.2 Referral to Endoscopy lead time ........................................... 136
4.5.4.3 Procedure and Checklist Team Membership ...................... 136
4.5.4.4 Procedures conducted out of routine working hours ........... 137
4.5.5 Qualitative themes ............................................................................... 138
4.5.5.1 Planning, coordination and organisation ............................. 138
4.5.5.2 Endoscopic Procedures conducted out of hours ................. 139
4.5.5.3 Technical Factors ................................................................ 139
4.5.5.4 Complex communication and decision making ............... 140
4.6 Discussion ............................................................................................................ 140
4.6.1 Summary .............................................................................................. 140
4.6.2 Primary measures ................................................................................. 141
4.6.2.1 Technical Skill .................................................................... 141
4.6.2.2 Non-Technical Skill ............................................................ 142
4.6.2.3 Safety checks ...................................................................... 142
4.6.2.4 Patient Safety Incidents (PSI) ............................................. 144
4.6.3 Secondary measures ............................................................................. 144
4.6.4 Study Limitations ................................................................................. 145
4.6.5 Future work .......................................................................................... 146
4.7 Conclusion ........................................................................................................... 147

Chapter 5: Identifying and Measuring Factors Affecting Patient Safety in Colorectal Cancer Multidisciplinary Teams ............................................................. 148
5.1 Chapter Overview ................................................................................. 148
5.2 Introduction ............................................................................................... 148
5.2.1 Definition of Cancer Multidisciplinary Teams .......................... 149
5.2.2 Quality Assurance of Cancer Multi-Disciplinary Teams ......... 149
5.2.3 Characteristics and Value of Cancer Multidisciplinary Teams 149
5.2.4 Quality and Safety extended across the endoscopy pathway .. 150
5.2.5 Sub-optimal MDT processes impacting endoscopy patients ... 151
5.3 Aims ............................................................................................................. 151
5.4 Methods .................................................................................................. 152
5.4.1 Ethical Considerations ................................................................. 152
5.4.2 Development of MDT assessment tool..................................... 152
5.4.2.1 Focus group and expert consensus .................................................. 153
5.4.2.2 Modification of MDT rating tool .................................................... 153

5.4.3 Study Design ..................................................................................... 154

5.4.4 Participants, patients and settings .................................................... 155

5.4.5 Data collection .................................................................................. 155

5.4.6 Data analysis .................................................................................... 155

5.4.7 Statistical Analysis .......................................................................... 156

5.4.7.1 Information, Team and Global scores ........................................ 156
5.4.7.2 Inter-rater reliability .................................................................... 156
5.4.7.3 Decision Outcome ....................................................................... 156
5.4.7.4 Correlational analysis .................................................................. 156
5.4.7.5 Pre and post intervention analysis ............................................. 156
5.4.7.6 Patient pathways ......................................................................... 157

5.5 Patient Safety Incidents (PSIs) ............................................................ 157

5.5.1 Incidence of PSI in relation to the MDT meeting: ............................ 157
5.5.2 Severity of the PSI based on actual or potential clinical impact ....... 157
5.5.3 Thematic analysis of PSIs ................................................................. 157

5.6 Quality Improvement Interventions ...................................................... 158

5.6.1 MDT education through self reflection .......................................... 158
5.6.2 Minimum dataset ........................................................................... 158
5.6.3 Leadership through effective Chairmanship .................................... 159
5.6.4 Documenting outcomes .................................................................. 159
5.6.5 Awareness of MDT PSIs ................................................................. 160
5.6.6 Physical MDT environment .............................................................. 160
5.6.7 Feedback on performance ............................................................... 160

5.7 Results ................................................................................................. 160

5.7.1 Reliability of evaluations ................................................................. 162
5.7.2 Information and team contribution scores ....................................... 163
5.7.3 Patient pathway and global patient population analyses ............... 164
5.7.4 Patient Safety Incidents (PSIs) ......................................................... 167

5.7.4.1 Patient Safety Incidents and patient pathways ........................... 167
5.7.4.2 Patient Safety Incidents and temporal incidence ....................... 167
5.7.4.3 Patient Safety Incident Severity ............................................... 168
5.7.4.4 Patient Safety Incident thematic categorisation ............................................. 170

5.8 Discussion ................................................................................................................ 173

5.8.1 Summary of Main Findings .................................................................................. 173

5.8.1.1 Assessment of MDT Information and Team Contribution .................................. 174

5.8.1.1.1 Information .................................................................................................. 174

5.8.1.1.2 Team Contribution ..................................................................................... 174

5.8.1.2 Characteristics of Key Patient Pathways ......................................................... 175

5.8.1.3 Patient Safety Incidents (PSIs) ...................................................................... 175

5.8.2 Clinical Implications ........................................................................................... 176

5.8.3 Limitations ........................................................................................................... 176

5.8.4 Future Work ......................................................................................................... 177

5.9 Conclusion .............................................................................................................. 177

Part B: Evaluating Solutions .......................................................................................... 178

Chapter 6: Developing, Implementing and Evaluating an Endoscopy Team Training Intervention .............................................................................................................. 179

6.1 Chapter Overview .................................................................................................. 179

6.2 Introduction .......................................................................................................... 179

6.2.1 The emergence of high quality endoscopy training ............................................. 179

6.2.2 Concepts in Endoscopy Training ...................................................................... 179

6.2.3 Training in Endoscopy for the Individual ......................................................... 181

6.3 Aims ....................................................................................................................... 182

6.4 Methods ............................................................................................................... 182

6.4.1 Study Design .................................................................................................. 182

6.4.2 Ethical considerations ...................................................................................... 182

6.4.3 Recruitment of participants .............................................................................. 183

6.4.4 Development of training contents and assessments ........................................... 183

6.4.4.1 Development of Training Contents .............................................................. 183

6.4.4.2 Development of Training Assessments ......................................................... 184

6.4.4.2.1 Patient Safety Knowledge ........................................................................ 184

6.4.4.2.2 Patient Safety Attitudes ......................................................................... 184

6.4.5 Delivery of Training ......................................................................................... 184

6.4.6 Pre and post Training Assessments ................................................................. 185
6.4.7 Training Evaluation and Expert focus group ....................................... 186
6.4.8 Data Analysis ....................................................................................... 186
6.5 Results ................................................................................................................. 186
6.5.1 Demographic results ............................................................................ 186
6.5.2 Patient Safety Knowledge .................................................................... 187
6.5.3 Patient Safety Attitudes........................................................................ 187
6.5.4 Global Course Evaluation ..................................................................... 188
6.6 Discussion ............................................................................................................ 190
6.6.1 Summary .............................................................................................. 190
6.6.2 Implications .............................................................................................. 191
6.6.2.1 Patient Safety Knowledge Implications ...................................... 191
6.6.2.2 Patient Safety Attitudes Implications ........................................ 192
6.6.2.3 Expert focus group ........................................................................ 192
6.6.3 Limitations ............................................................................................... 193
6.6.3.1 Study design limitations .............................................................. 193
6.6.3.2 Training intervention limitations .............................................. 194
6.6.4 Future developments ............................................................................. 195
6.7 Conclusion ........................................................................................................... 196

Chapter 7: Development, Implementation and Evaluation of an Endoscopy Safety Checklist ....................................................................................................................... 197
7.1 Chapter Overview ........................................................................................ 197
7.2 Introduction .................................................................................................... 197
7.2.1 Checklist origins .................................................................................. 197
7.2.2 What is a safety checklist? ................................................................. 198
7.2.3 How should a safety checklist be used? ............................................ 198
7.2.4 Checklists beyond Aviation ................................................................. 199
7.2.4.1 Evidence for Checklists in Medicine ...................................... 199
7.2.4.2 Evidence for Checklists in Surgery ......................................... 200
7.2.5 Strengths and Weaknesses of Checklists ............................................ 201
7.3 Aims ..................................................................................................................... 201
7.4 Methods ............................................................................................................ 202
7.4.1 Checklist development ......................................................................... 202
7.4.1.1 Defining checklist functions ...................................................... 202

19
7.4.1.2 Endoscopy Staff Attitudes to Safety Checks
Questionnaire study ............................................................ 202
7.4.1.3 Patient Safety Incidents Study ........................................ 202
7.4.1.4 WHO Surgical Safety Checklist: Translating concept and adapting content ........................................................... 203
7.4.1.5 Expert focus group........................................................... 203
7.4.1.6 Checklist Feedback and Modification ............................ 203
7.4.2 Checklist Patient Opinion Questionnaire Study ................. 204
7.4.3 Checklist Implementation Strategy ...................................................... 204
7.4.3.1 Further Checklist Feedback and Modification.................... 205
7.4.4 Checklist Evaluation Study Design ..................................................... 205
7.4.4.1 Ethical Considerations........................................................ 205
7.4.4.2 Participants, Procedures and Settings ................................. 206
7.4.4.3 Skills and Behaviours assessment (ENTS DOPS SC)........... 206
7.4.4.4 Comparison of Skills and Behaviours Assessments Pre and Post Checklist ........................................................ 207
7.4.4.5 Checklist Measures ............................................................. 207
7.4.4.6 Incidence of Patient Safety Incidents ................................. 208
7.4.5 Longitudinal Evaluation of Checklist Compliance ............... 208
7.4.6 Wider Checklist Dissemination .................................................. 209
7.4.7 Statistical Methods............................................................................... 209
7.4.7.1 Patient Opinion Questionnaire ............................................ 209
7.4.7.2 Safety Skills and Behaviours Assessments......................... 209
7.4.7.2.1 Comparison between Experts and Trainees............. 210
7.4.7.2.2 Comparison between Bowel Cancer Screening (BCS) and Non-Screening procedures. ...................................... 210
7.4.7.3 Checklist Completion.......................................................... 210
7.4.7.4 Evaluation of Patient Safety Incidents (PSIs)..................... 211
7.4.7.5 Checklist Compliance ......................................................... 211
7.4.7.6 Comparison pre and post checklist intervention ............... 211
7.5 Results ................................................................................................................. 212
7.5.1 Checklist Patient Opinion Questionnaire.......................................... 212
7.5.2 Observational Study Evaluating Safety Behaviours:
Demographics and Study Participants ........................................ 218
7.5.3 Skills and Behaviours assessment ........................................................ 220
  7.5.3.1 Sub-group Analyses of Experts and Trainees ............................ 220
  7.5.3.2 Sub-group analyses of Bowel Cancer Screening (BCS) and non screening procedures ......................................................... 221
7.5.4 Quantitative Checklist assessment ..................................................... 223
  7.5.4.1 Degree of checklist completion ................................................ 223
  7.5.4.2 Time taken to complete Checklist ............................................ 223
7.5.5 Qualitative Checklist assessment .......................................................... 223
  7.5.5.1 Leadership ............................................................................. 223
  7.5.5.2 Compliance ........................................................................... 224
  7.5.5.3 Efficiency ............................................................................. 224
7.5.6 Incidence of Patient Safety Incidents (PSIs) ........................................ 224
  7.5.6.1 PSI Categorisation by Theme and Severity ............................... 225
7.5.7 PSI Incidence in Expert and Trainee Endoscopists .......................... 226
7.5.8 PSI Incidence in Bowel Cancer Screening (BCS) and Non-Screening Endoscopists ................................................................. 227
  7.5.8.1 Patient Safety Incidents in Relation to the Checklist .............. 228
7.5.9 Checklist Compliance at 11 and 16 months following implementation. ...................................................................................... 229
  7.5.9.1 Factors Affecting Checklist Compliance ..................................... 230
7.5.10 Comparison of safety and quality pre and post checklist ............ 232
7.5.11 Comparison of Non-Technical (ENTS), Technical (DOPS) and Safety Scores (SC) Pre and Post Checklist ........................................... 233
7.5.12 Comparison of Patient Safety Incidents (PSIs) Pre and Post Checklist 234
7.6 Discussion ................................................................................................. 236
  7.6.1 Summary ...................................................................................... 237
  7.6.2 Implications ................................................................................... 238
    7.6.2.1 Patient Opinion ................................................................... 238
    7.6.2.2 Endoscopist Sub-groups ...................................................... 238
    7.6.2.3 Checklist Effects ................................................................... 238
  7.6.3 Limitations ...................................................................................... 239
  7.6.4 Future work ................................................................................... 240
7.7 Conclusion ............................................................................................... 241
Chapter 8: Thesis Discussion ................................................................. 242

8.1 Chapter Outline .................................................................................. 242
8.2 Defining the Problem ........................................................................... 242
8.3 Summary of thesis findings ................................................................. 243
8.4 Fulfilling Aims .................................................................................... 243
8.5 Limitations ......................................................................................... 245
  8.5.1 Evidence base .............................................................................. 245
  8.5.2 Sampling and Generalisability .................................................... 245
  8.5.3 Patient Involvement ................................................................. 246
  8.5.4 Observational assessments ....................................................... 246
  8.5.5 Observational rating tools ......................................................... 247
  8.5.6 Patient Safety Incidents and Analysis ....................................... 248
  8.5.7 Quality improvement interventions ......................................... 248
8.6 Implications for Endoscopy practice ................................................ 249
  8.6.1 General implications ............................................................... 249
  8.6.2 Specific implications ............................................................... 249
8.7 Implications for Training and assessment .......................................... 250
8.8 Implications for Patient Safety ........................................................ 251
8.9 Future Work .................................................................................... 251
8.10 Personal Reflections ......................................................................... 252

References ............................................................................................... 255

Appendix 1 ............................................................................................... 276
Appendix 2 ............................................................................................... 278
Appendix 3 ............................................................................................... 282
Appendix 4 ............................................................................................... 291
Appendix 5 ............................................................................................... 301
List of Tables

Table 2.1. Component responses for ‘Other’ Safety Checks ............................................. 71
Table 2.2. Component responses for ‘Other’ additional Safety Checks ......................... 73
Table 2.3. PSI Incidence according to diagnostic and therapeutic procedure subtype ...... 76
Table 2.4. Severe PSIs and proportion of Never Events................................................ 78
Table 3.1. Degrees of Safety Checks (SC)...................................................................... 100
Table 3.2. Comparison of Patient Safety Incidents in diagnostic and therapeutic procedures. ............................................................................................................. 105
Table 3.3. Comparison of percentage diagnostic procedures for Group A endoscopists (experts) and Group B endoscopists (trainees) ........................................... 105
Table 3.4. Comparison PSIs incidence between Group A endoscopists (experts) and Group B endoscopists (trainees) with adjustments for diagnostic / therapeutic case mix................................................................. 105
Table 3.5. Comparison of Endoscopic non-technical skills (ENTS), Technical skills (DOPS) and Safety checks (SC) scores in Group A endoscopists (experts) and Group B endoscopists (trainees).................................................. 106
Table 3.6. Comparison of Endoscopic non-technical skills (ENTS), Technical skills (DOPS) and Safety checks (SC) between Medical, Surgical and Nurse endoscopists. ............................................................................................ 107
Table 3.7. Spearman’s rho correlations between non-technical skill (ENTS), technical skill (DOPS), safety checks (SCs) and PSI incidence ..................... 108
Table 4.1. Croskerry’s Principle characteristics of Type 1 and Type 2 decision making processes ........................................................................................................ 121
Table 4.2. Spearman’s Rank Correlational analysis for Skills and PSI across Routine and Emergency cases (n=82) .......................................................... 134
Table 4.3. Comparison of Skills and PSI between Emergency and Routine cases ......... 135
Table 4.4. Correlational Analysis between Case Severity and Primary Measures ........ 136
Table 4.5. Comparison of relative numbers in checklist and procedure team members using the one sample t test. ................................................................. 136
Table 4.6. Comparison of Checklist and Procedure Team Members in Emergency and Elective cases using the paired t test. ....................................................... 137
Table 4.7. Comparison of Skills and PSI measures for procedures within (IH) and outside (OOH) of routine working hours (defined as 0800-1800)............... 137
Table 4.8. Illustration of multiple PSI and sub-optimal Non-Technical Skills in a single procedure .................................................................................................. 143
Table 5.1. CRC MDT meeting characteristics ................................................................. 161
Table 5.2. Numbers of patients in each patient pathway.................................161
Table 5.3. Pre and post Intervention Information Scores.................................163
Table 5.4. Pre and post Intervention Team Contribution Scores ......................163
Table 5.5. Descriptive Statistics for Patient Pathways pre and post Intervention..165
Table 5.6. Comparison of pre and post intervention mean scores by sub-group and overall patient populations .........................................................166
Table 5.7. Proportion of patients with one or more PSI recorded......................167
Table 5.8. Number of PSIs per Patient Pathway ...........................................167
Table 5.9. Proportion of PSIs occurring pre, intra and post MDT meeting ..........168
Table 5.10. Proportion of PSIs categorised by severity ....................................169
Table 5.11. Thematic categorisation of PSIs: Component and Major themes ......170
Table 5.12. Thematic Incidence of Patient Safety Incidents.............................171
Table 6.1. Participants’ demographics ..............................................................187
Table 6.2. Participants (n=23) patient safety knowledge assessment: Multiple Choice Question (MCQ) scores pre and post training .........................187
Table 6.3. Participants (n=23) patient safety attitudes pre and post training on a 5-point Likert scale (1= Strongly disagree, 5 = Strongly agree) ......................188
Table 6.4. Summary of quantitative course evaluation for 23 participants following the training intervention on a 5-point Likert scale (1= Strongly disagree, 5 = Strongly agree) ......................................................189
Table 6.5. Summary of qualitative course evaluation .........................................190
Table 7.1. Percentage of responses according to three main categories: 1. Disagree (scores 1-2) 2. Neither agree / disagree (scores 3-5) 3. Agree (scores 6-7) ..........212
Table 7.2. Percentage of responses within three main categories by gender ....214
Table 7.3. Percentage of responses within three main categories in relation to whether a previous endoscopy had been performed or not ..................216
Table 7.4. Procedure Characteristics between Experts and Trainees ..................220
Table 7.5. Comparison of Technical skill (DOPS), Non-Technical skill (ENTS) and Safety Check scores between Experts (Consultants) and Trainees (Registrars) .................................................................221
Table 7.6. Procedure Characteristics between BCS and non-BCS procedures ........221
Table 7.7. Comparison of Technical skill (DOPS), Non-Technical skill (ENTS) and safety check scores between BCS and non BCS groups .............................222
Table 7.8. Description of Severe PSIs ..............................................................225
Table 7.9. Comparison of Patient Safety Incidents (PSI) in Expert and Trainee Endoscopists .................................................................227
Table 7.10. Comparison of Patient Safety Incidents (PSI) in Expert and Trainee Endoscopists .......................................................................................................................... 227
Table 7.11. Summary of Targeted Training Intervention to Enhance Checklist Compliance.................................................................................................................. 232
Table 7.12. Summary of Factors Affecting Checklist Compliance Pre and Post Targeted Training Interventions .......................................................................................... 232
Table 7.13. Comparison of Procedure and Endoscopist Sub-types in pre and post checklist data sets .......................................................................................................................... 233
Table 7.14. Comparison of Non-Technical Skill (ENTs), Technical Skill (DOPS), Safety checks, and Patient Safety Incidents (PSIs) Pre and Post Checklist .......................... 233
Table 7.15. Comparison of Patient Safety Incidents (PSIs) Pre and Post Checklist ........ 234
List of Figures

Figure 1.1. Terminology of medical error. Adapted from Hofer et al.11 ............................. 32
Figure 1.2. Donabedian’s systems based model for assessing quality of care with illustrative example. Adapted from Campbell et al.24 ............................... 35
Figure 1.3. The quality / safety continuum. Adapted from Brown et al.36 Examples of errors A – D illustrate varying degrees of immediacy and causality .......... 36
Figure 1.4. The Relationship Between Safety and Quality ................................................. 37
Figure 1.5. Stages of Development of Organisational Accidents (Image adapted from Reason57 ............................................................................................................ 43
Figure 1.6. Swiss Cheese Model of Accident Causation (Image adapted from Reason55 and Runciman58) ................................................................................................ 43
Figure 1.7. Framework for teamwork adapted from McGrath’s74 Input – Process – Output model. Figure adapted Vincent 5 ........................................................... 47
Figure 1.8. Pathways into endoscopy .................................................................................. 53
Figure 1.9. Pathways out of endoscopy ........................................................................... 53
Figure 1.10. Overview of Endoscopy training provision in the UK.139 .................................. 56
Figure 2.1. What pre-procedural checks are currently undertaken ...................................... 70
Figure 2.2. Who is responsible for completing existing safety checks .................................. 72
Figure 2.3. Which safety checks in addition to current safety checks are required? ........... 72
Figure 2.4. Endoscopy lists observed by speciality of the endoscopist............................... 75
Figure 2.5. Endoscopy lists observed by speciality and expertise of the endoscopist........... 75
Figure 2.6. Patient Safety Incidents Categorised by Severity ............................................. 77
Figure 2.7. ‘Swiss Cheese’ model illustrating the coalition of minor errors leading to significant Patient Safety Incidents (PSIs) in one observed case. (Image adapted from Reason18 and Runciman21) ........................................................................... 78
Figure 2.8. PSI Categorisation according to theme and severity ......................................... 80
Figure 3.1. Audio-visual training link displaying multi-split views to include luminal views (bottom right panel) scope position guide (top right panel) and team views (left panel) ........................................................................................................ 98
Figure 3.2. Specific examples of endoscopic non-technical skills at both ends of the scale ............................................................................................................. 103
Figure 3.3. Robustness of Safety Checks ......................................................................... 104
Figure 3.4. Correlation between Safety Check score and PSI ............................................. 108
Figure 3.5. Correlation between ENTS scores and PSIs .................................................... 109
Figure 3.6. Correlation between ENTS and Safety Checks scores ..................................... 109
Figure 3.7. Correlation between ENTS and DOPS scores ................................................ 110
Figure 4.1. The wider multi-disciplinary endoscopy team ............................................. 122
Figure 4.2. Emergency Procedure Indications (as stated on request form) ..................... 132
Figure 4.3. Schema summarising Patient Safety Incidents in relation to the Endoscopy Safety Checklist .............................................................................................................. 133
Figure 5.1. Study Design Overview .................................................................................. 154
Figure 5.2. Proportion of patients within each pathway (Pre-intervention) ...................... 162
Figure 5.3. Proportion of patients within each pathway (Post-intervention) ....................... 162
Figure 5.4. Pre-Intervention Patient Safety Incident severity categorisation ................... 169
Figure 5.5. Post-Intervention Patient Safety Incident severity categorisation .................. 170
Figure 5.6. Thematic comparison of Patient Safety Incidents pre and post intervention 172
Figure 5.7. Categorisation of pre-intervention Patient Safety Incidents by major themes .............................................................................................................. 172
Figure 5.8. Categorisation of post intervention Patient Safety Incidents by major themes .............................................................................................................. 173
Figure 6.1. Steps towards attaining competency ............................................................... 181
Figure 6.2. Overview of Training Format ......................................................................... 185
Figure 7.1. Endoscopy lists by endoscopist grade .......................................................... 218
Figure 7.2. Endoscopy lists and procedures by endoscopist speciality ............................. 219
Figure 7.3. Number of procedure subtypes ..................................................................... 219
Figure 7.4. PSI Categorisation by Severity ..................................................................... 225
Figure 7.5. PSI Categorisation by Theme and Severity .................................................... 226
Figure 7.6. Schema summarising Patient Safety Incidents in relation to the Endoscopy Safety Checklist .............................................................................................................. 228
Figure 7.7. Checklist compliance 11 months post implementation ................................... 229
Figure 7.8. Checklist compliance 16 months post implementation ................................... 230
Figure 7.9. Factors affecting checklist compliance at 11 months (pre intervention) and 16 months (post intervention) ................................................................. 231
Figure 7.10. Comparison of Patient Safety Incidents (PSIs) by Severity Pre and Post Checklist .............................................................................................................. 235
Figure 7.11. Comparison of Patient Safety Incidents (PSIs) by Theme Pre and Post Checklist .............................................................................................................. 236
**Thesis Aims**

The overarching aim of this thesis is to identify and examine patient safety and quality issues that impact patients undergoing gastrointestinal endoscopy and to devise, implement and evaluate interventions to enhance safety and quality.

Associated secondary aims include:

1. Increase our understanding of patient safety incidents in endoscopy (Chapter 2)

2. To determine the role of non-technical skills in endoscopy and educational strategies to enhance these skills (Chapters 3 and 6)

3. To identify differences in patient safety issues in elective and emergency endoscopy settings (Chapter 4)

4. To examine opportunities to enhance endoscopy safety and quality by evaluating colorectal cancer multi-disciplinary team working (Chapter 5)

5. To develop an endoscopy safety checklist and implement into clinical practice (Chapter 7)
Part A: Identifying Problems

The first part of this thesis provides a critical evaluation of the current issues impacting patient safety and quality in Endoscopy.
Chapter 1: Introduction

1.1 Safety and Quality in Healthcare

Globally, there is growing demand for healthcare, which is increasingly advanced, ambitious and complex. Whilst this provides great opportunity for individual and population health improvement, it has to be balanced against resource constraints and the considered judgement of the risks and benefits to provide care that remains in the patient’s best interest. Additionally, patient populations and disease patterns are changing such that modern medicine faces the challenges of an ageing population, multiple comorbidities and chronic disease management as opposed to acute episodic care.

The delivery of medical care is increasingly through healthcare systems rather than by individuals. Donabedian’s seminal work underpinning a ‘systems approach’ provides a framework to think about healthcare holistically. This model also situates the complexities of safety and quality for patients within complex organisations.

Healthcare interventions should be a dialogue between the patient and the professional with the shared aim of providing effective, appropriate and safe care for the patient, not simply what is technically possible: The art of medicine today is to deliver individualised, patient centred, high quality care safely within a complex system. Over the last decade, safety and quality in healthcare have justifiably become key priorities for governments, clinicians and above all patients who are at the core of Medicine.

This chapter provides the context for patient safety and quality in gastrointestinal endoscopy and outlines some of the achievements and future challenges in this domain.

1.1.1 What is safety?

The first dictum of medicine is, ‘primere non nocere’ and from Antiquity there is reference to medicine carrying risk with the potential for significant harm. The concept of the ‘dark side’ of medicine is familiar to the profession and encapsulates care that is actively harmful rather than just being sub-optimal. Patient safety can be defined as, ‘the avoidance, prevention and amelioration of adverse outcomes or injuries stemming from the process of healthcare’. This definition stresses not only the importance of preventing error, but also proactively managing the consequences of error for the patient and those involved. The Institute of Medicine’s seminal report, ‘To Err is Human’ defines safety very broadly as, ‘freedom from accidental
injury’. However, patient safety supersedes the accepted notion of minimising harm and should also focus on reducing medical errors that may or may not lead to harm. Patient safety is a broad concept comprising medical error, quality of care and a professional conscience to do the right thing.

### 1.1.2 Medical Error

Adverse patient outcomes are often multifactorial and may include patient factors such as comorbidity and aggressive disease as well as iatrogenic error from the healthcare process. The role of the clinician is to provide thoughtful judgement on the risk / benefit balance for the individual patient with the underlying intention of patient safety. Medical error however is a loaded subject and in Leap’s words: ‘The professional cultures of medicine…use blame to encourage proper performance. Errors are caused by a lack of sufficient attention, or, worse, lack of caring enough to make sure you are correct’. With a greater understanding of error and human fallibility, there is a move towards a systems approach to understand how and why errors occur rather than simply apportioning individual blame. Given the complexity of medical error how is it defined and how common is it?

#### 1.1.2.1 Definition

Conceptually, Reason identifies two main types of error: Firstly, errors of execution where the correct actions are not implemented as intended (e.g. incomplete polypectomy in a benign lesion) and secondly, errors of planning where the original intended actions are deemed incorrect (e.g. polypectomy for an advanced malignant lesion unsuitable for endoscopic resection).

There are multiple terms used in everyday parlance as well as in the literature to describe medical error: Errors, adverse events, patient safety incidents, near misses, mistakes, harm, iatrogenic injury and negligence to name a few. Hofer et al summarise how the, ‘conceptual definitions of these terms overlap’ (Figure 1.1) and the notable omissions of studies establishing causality between error and adverse patient outcome. This descriptive nomenclature and the variation therein, needs to be taken into consideration when comparing studies. It is true that not all errors will necessarily lead to patient harm but they nevertheless provide an indication of weaknesses in the system that may be implicated in future harm. Put simply, adverse events can be defined as ‘unintended injuries or complications caused by medical management as opposed to the disease process itself’.
Figure 1.1. Terminology of medical error. Adapted from Hofer et al.\textsuperscript{11}

1.1.2.2 Incidence

There is a plethora of evidence supporting the premise that the incidence of medical error is significant. International studies across America,\textsuperscript{13}\textsuperscript{15} Europe\textsuperscript{16}\textsuperscript{17} and Australia\textsuperscript{12}\textsuperscript{18} have deduced that 3.7\%–16.6\% of hospitalised patients are likely to encounter an adverse event. The range is partly due to the definitions of error adopted in the respective studies, but consistent across the studies was that up to half of these adverse events were deemed to be preventable.\textsuperscript{16}

In the USA it was estimated that medical error accounted for 44,000 to 98,000 deaths per year, superseding mortality from breast cancer.\textsuperscript{6} In the UK, Vincent et al’s analysis of 1014 patients revealed that adverse events occurred in 10.8\% of hospital admissions, with half deemed to be preventable and a third leading to moderate disability or death. Furthermore, it was estimated that preventable adverse events could save the NHS £1 billion a year in extra bed days alone\textsuperscript{16} aside from the wider socio-economic ramifications of additional healthcare, disability and lost working days, underlining the gravity of the situation.

1.1.2.3 Illustrations of Medical Error

Error in medicine is widespread and not a recent phenomenon. Nightingale in the nineteenth century meticulously noted that mortality was higher for casualties of war who were treated
in hospital compared to those who were not. Semelweiss displayed remarkable insight when he observed that puerperal fever and maternal mortality was rife in the hands of medical students but not so when these women were attended to by midwives. Semelweiss scientifically deduced that mortality rates reversed when the carers changed places, that mortality could be considerably reduced with effective hand hygiene and proposed that transference of germs was implicated. Despite this foresight he received considerable hostility from the medical community and his ideas were rejected. Although he discovered an opportunity for patient safety he was unable to effectively implement the necessary change.

With advances in medicine, the nature of medical error has changed given the complexity of the systems within which patients are cared for. The influential report from the Institute of Medicine opens with emotive cases of medical error; a fatal chemotherapy overdose and wrong leg amputation are cited as ‘horrific cases at the tip of the iceberg’. The impact and public perception of such ‘celebrated’ cases is important and Cook et al state, ‘the reactions to these tragic losses become the obstacles and opportunities to enhance safety’. There is as much to learn about the epidemiology of error from low-level frequent mistakes as well as such high profile ones.

These examples serve to illustrate the changes in socio-cultural attitudes towards risk, error and the doctor-patient relationship. Previously there was an understanding that error was the inevitable price one paid for advanced treatment, but this viewpoint is increasingly unacceptable. For example, hospital acquired infections are a serious threat to patient safety and although multifactorial are largely preventable and hence not acceptable to both clinicians and patients. Safety in healthcare has become a moving target as technology and health care delivery evolves.

In considering medical error we understand important constituents of patient safety. Whilst reducing and managing errors are important components of patient safety, it is more than that: Safety is the fundamental foundation of quality.

1.1.3 What is Quality?

Quality is defined as ‘the standard of something as measured against other things of a similar kind; the degree of excellence of something’. Defining quality within healthcare is elusive and broad concepts as well as specified detail have been proposed. Campbell et al summarise generic definitions of quality to include, ‘excellence, fulfilling expectations, abolishing
defects and fitness for use'. Quality can also be considered as a multidimensional concept with specific measurable attributes. This necessitates objective evidence and Maxwell coined the six core dimensions of healthcare quality, all of which continue to have relevance today:

- Accessibility of services
- Relevance (to the population)
- Effectiveness (for the individual)
- Equity
- Acceptability
- Efficiency

The classic Donabedian model of ‘structure, process and outcome’ is summarised in Figure 1.2. This model highlights that quality is significantly more than traditional patient outcomes of morbidity and mortality and can be applied across the organisation of healthcare. This model emphasises that quality is not simply to do with clinical excellence but also the humanity and compassion with which care was delivered. The relationships are dynamic with outcomes being affected directly or indirectly by structures and processes of healthcare. For example, a patient may present with acute obstruction secondary to bowel cancer (outcome) because a screening service was not available to them (structure) or because their iron deficiency anaemia was not thoroughly investigated (process) Figure 1.2. This model incites consideration, measurement and evaluation of quality across various aspects of healthcare.
Figure 1.2. Donabedian’s systems based model for assessing quality of care with illustrative example. Adapted from Campbell et al.24

The Institute of Medicine’s definition of quality developed over a decade ago is widely cited: “Quality of care is the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge.”27 This definition of quality emphasises the effectiveness of healthcare by practicing contemporaneous evidence based medicine and thus continually revising measures of quality in light of new professional best practice guidance.28 For example, considering advancements in colonoscopy: adenoma detection rate and effective polypectomy29 are good quality measures30 reflecting the ‘process’ and are closely linked with an important ‘outcome’ measure of colorectal cancer incidence31 and thus provide a useful and meaningful measure of quality.

The World Heath Organisation (WHO) defines quality of care as the amount of potential health gain delivered. Quality reflects the gap between what can be achieved and what actually happens: A small gap reflects high quality and a large gap low quality5 and this gap within healthcare has been described as a ‘chasm’.32

Defining quality is difficult and it is evident that it can adopt various meanings in differing contexts. The unifying theme from these definitions is aspiring to excellence by adhering to best practice and this is the definition that will be adopted for this thesis.
1.1.4 The Relationship Between Quality and Safety

Although safety and quality are separate entities, they can also be considered on a spectrum with ‘safety at the sharp end’ and quality the opposite, with significant overlap in between. Safety is also described as a key component and pre-requisite of quality: ‘although all safety issues are quality issues the reverse is not so’. Brown et al eloquently conceptualise failures with high impact, immediacy and causality are more likely to be labelled as safety issues. These errors may be disastrous for the individual patient but occur relatively rarely, an example being wrong site surgery. More widespread issues with low immediacy and causality are likely to be conceptualised as quality issues. An example would be failure to organise an appropriate surveillance colonoscopy in a patient with inherited polyposis who subsequently presents with colorectal cancer. This concept is exemplified in Figure 1.3.

The relationship between quality and safety is fluid and many failures in medicine will have attributes of their care that were unsafe as well as of poor quality. The aim should be to build a strong foundation of safety, from which quality can develop with an aspiration to excellence (Figure 1.4). Both quality and safety is what all stakeholders share a common interest in – patients, doctors, nurses, managers, commissioners, providers and governments.

**Figure 1.3.** The quality / safety continuum. Adapted from Brown et al. Examples of errors A – D illustrate varying degrees of immediacy and causality
A. Fatal gastrointestinal haemorrhage due to delayed endoscopic management
B. Failure to eradicate Helicobacter Pylori resulting in duodenal ulceration
C. Failure to use endoscopic clips resulting in further haemorrhage
D. Failure to clear benign polyps resulting in further benign polyps at follow up

<table>
<thead>
<tr>
<th>Error</th>
<th>Causality</th>
<th>Immediacy</th>
</tr>
</thead>
<tbody>
<tr>
<td>A. Fatal gastrointestinal haemorrhage due to delayed endoscopic management</td>
<td>High</td>
<td>High</td>
</tr>
<tr>
<td>B. Failure to eradicate Helicobacter Pylori resulting in duodenal ulceration</td>
<td>High</td>
<td>Low</td>
</tr>
<tr>
<td>C. Failure to use endoscopic clips resulting in further haemorrhage</td>
<td>Low</td>
<td>High</td>
</tr>
<tr>
<td>D. Failure to clear benign polyps resulting in further benign polyps at follow up</td>
<td>Low</td>
<td>Low</td>
</tr>
</tbody>
</table>

Figure 1.4. The Relationship Between Safety and Quality

1.1.5 Quality Assurance

Quality assurance is the systematic evaluation of various aspects of a service to ensure that standards of quality are being met. There is a growing interest in quality assurance with an emphasis on both efficient use of resources and on the effectiveness of care delivered. Problems with quality and thus avenues for improvement have been divided into three areas: Underuse, overuse and misuse. Underuse is the failure to implement beneficial healthcare such as providing measles immunisation. Overuse is providing a healthcare intervention when potential harm outweighs the benefit such as antibiotics for minor self-limiting infection. Misuse is when an appropriate healthcare is delivered but a preventable complication occurs and thus the patient does not reap the full benefits of the intervention. An example of misuse would be avoidable complications of surgery. By addressing overuse and misuse there is an opportunity to improve quality and reduce cost, whilst addressing underuse will improve quality but at an increased cost (in the short term at least).

Approaches to achieving quality improvement include regulation, continuous quality improvement, competition, and financial incentivisation and in reality a combination of these is likely to be effective. The ‘regulatory’ approach defines minimum standards, aims to identify outliers and remove ‘bad apples’ to improve quality. In contrast, the continuous quality improvement model aims to shift the entire bell curve of performance upwards.
enhancing quality and productivity. This encourages a vision towards excellence rather than simply fulfilling minimum standards. Additionally, exemplary performance at the opposite end of the curve should be rewarded and highlighted such that knowledge is shared and effective practices can be more widely disseminated. Raising standards of care has been described as the ‘sine qua non of professional responsibility’ however objective measures of quality, programmes for improvement and subsequent quality assurance are essential to provide effective, safe, patient centred care across the board. ‘It maybe human nature to err but so is creating solutions finding better alternatives and meeting the challenges ahead’.

1.2 Patient Safety and Quality in Context

The previous section has outlined how patient safety, risk management and healthcare intervention necessitate a fine balance to be subtly modified for each individual patient. The emergence of patient safety as a definitive entity has galvanised the medical community, political leaders as well as the wider public to take note of the hazards of healthcare. There has been a shift change in the acceptability of medical error and our wider attitude towards safety and quality in healthcare. This has been led by key events that are summarised below.

1.2.1 US Perspectives

The 1999 Institute of Medicine report, ‘To err is human’ was a key development firmly placing patient safety at the top of the professional and political agenda. The main recommendations from this report incited nationwide efforts involving clinicians, accreditors, regulators and healthcare organisations to achieve: mandatory and voluntary reporting of error, implementation of medication safety practices, legislation for peer review protection of patient safety data and prioritisation of patient safety improvement initiatives with ‘defined executive responsibility’. In summary, the report recommended a national focus to enhance knowledge and research into patient safety, learning from errors, raising standards in safety improvement and creating safe systems within healthcare organisations. The headline from this report remains the statistic that between 44,000 and 98,000 patients die a year as a consequence of medical error. Importantly, this report incentivised other professional and government bodies to take a similar stance and thus catalysed patient safety efforts.
1.2.2 UK Perspectives

In parallel, the UK government published a White Paper entitled ‘The New NHS: Modern and Dependable’ laying down a ten year modernisation strategy and addressing quality of care. Clinical governance defined as, “A framework through which NHS organisations are accountable for continuously improving the quality of their services and safeguarding high standards of care by creating an environment in which excellence in clinical care will flourish”, was highlighted as a responsibility at the organisation level.

In this context, the UK’s Department of Health published ‘An organisation with a memory’ in 2000 led by Sir Liam Donaldson. This report similar in outlook to the Institute of Medicine’s report, emphasised the ‘distinction between passive learning (lessons identified but not implemented) and active learning (where lessons are embedded into practices and culture) as key to understanding why learning within the NHS often fails to occur’. In comparison to the US report this account placed greater importance on learning from other high-risk industries such as aviation, a change in culture and a systems approach for understanding error. These official positions were clearly important when we consider how high profile failings in medical care were dealt with in the NHS

1.2.3 Never events

In the context of unacceptable medical error, healthcare organisations have collated lists of ‘never events’. Never events are defined as serious but preventable patient safety incidents (PSIs). These include wrong site surgery, retained instruments post operatively, overdose of midazolam during conscious sedation and misplacement of nasogastric tubes. In the UK, the list has recently been revised, but previously also included patient mis-identification and failure to monitor and respond to oxygen saturations all of which have relevance to gastroenterology and endoscopy patients. Hospital trusts are incentivised to prevent never events as significant financial penalties are incurred across the episode of care, should a never event occur. Whilst never events are relatively infrequent, the same issues re-occur leading to the proposition that they are a ‘surrogate marker of unsafe hospital systems and poor safety cultures’.

1.2.4 Poor care in the public spotlight

Whilst medical error has always occurred, it has been viewed as an inevitable consequence of healthcare. However, this attitude has changed and key events at Bristol and Mid
Staffordshire (summarised in the next two sections) placed the notion of medical error firmly in the public domain.

1.2.4.1 Bristol
The substandard care provided by Bristol Royal Infirmary in the 1980s was widely publicised. Concerns were raised about the standard of paediatric cardiac surgery and an unacceptably high post-operative morbidity and mortality. Despite concerns being raised internally, there was inter-speciality conflict between anaesthetists, surgeons, cardiologists and managers leading to the issues being escalated to the Royal College of Surgeons and the Department of Health. It was agreed that a specialist paediatric cardiac surgeon should be employed and a moratorium observed in the interim. Before this could be achieved a child ‘scheduled for surgery against the advice of some clinicians and the Department of Health died post-operatively’. This eventually culminated in cessation of paediatric cardiac surgery and an external enquiry costing £14 million. Although three doctors were found guilty of serious professional misconduct, the investigation notably adopted a systems approach and poor performance was seen as a product of the wider system and not simply consequent of errant individual action.

1.2.4.2 Mid Staffordshire
In 2009 a similar narrative emerged from Mid Staffordshire NHS Trust with higher than expected mortality rates amongst a series of other failures raising questions about the safety and quality of healthcare. There was intense public and media scrutiny of the way patients were treated with reports of patients not being assisted with basic hydration and nutrition and being left to sit in their own excrement for prolonged periods. A public campaign group ‘Cure the NHS’ led by a bereaved relative was key to instigating a full public inquiry chaired by Sir Robert Francis. Evidence suggested that ‘patients were failed by a system which ignored warning signs and put corporate and financial self interest ahead of patients and their safety’. The final report accrued from reviewing a million pages of evidence and costing £10 million, made 290 recommendations including openness, transparency, a statutory duty of candour and support for compassionate care.

There are similarities in failings, insights and lessons from both of these inquiries despite an emphasis following Bristol to prevent such shortcomings from re-occurring. Moreover, it was noted that professionals were aware of the shortcomings in care but unable to raise concerns and correct problems secondary to being criticised as ‘whistleblowers’. Although
professional self-regulation remains important, it was clear that revision of independent regulatory mechanisms was required in response to these events.

1.2.5 Regulation of Healthcare: The Care Quality Commission

The Care Quality Commission (CQC) was established in 2009 as the independent external regulator for health and social care in England.\(^5^2\) Broadly, the CQC sets, monitors and inspects standards of care delivered by providers. The CQC is a non-departmental public body accountable to parliament as well as the general public. Assessments are made by asking five questions of a healthcare organisation: Is it safe, effective, caring, responsive (to patients’ needs) and well led. Initial inspections have revealed that trusts tend to score highly for ‘caring’ but ‘safety’ scores remain low.\(^5^3\) By publishing performance ratings, action can be taken to address poor care, acknowledge outstanding practice and guide informed patient choice. The aims of the CQC are very much in line with the recommendations from the Francis report and the overarching theme of providing safe, good quality care in a consistent manner.

1.3 Human Factors and Risk Management

In considering patient safety and risk management many lessons can be drawn from the science of Human Factors. This can be defined as a way of ‘enhancing clinical performance through an understanding of teamwork, tasks, equipment, workspace, culture and organisation on human behaviour and abilities, and application of that knowledge in clinical settings’.\(^5^4\) This concept linked to cognitive psychology and engineering, fully acknowledges human error, the fallibility of human performance and rejects the ‘perfectibility model’ entrenched in medicine.\(^7\)

Human error can be considered within two models – the person approach and the systems approach. The person approach views errors as the result of individual misdemeanour with resultant blame. The systems approach in contrast, views errors as consequences of deficiencies ‘upstream’ within the organisation the individual works within.\(^5^5\)

The professional cultures within medicine have traditionally adopted the person approach and used blame to encourage skilled performance. Doctors view error as a ‘failure of character’\(^7\) caused by a lack of diligence, skill or caring. This is not conducive to an open culture of learning from error as there is fear of reprisal and the perception of individual ineptitude.
Human factors though well developed in other safety critical industries, is still emerging within healthcare although there is growing awareness of the importance of human cognition, complex work environments and their interaction with the unpredictability of patients and their disease states.

1.3.1 Accident causation models

The systems approach contextualises safety obstacles and opportunities at the organisation level as well as the sharp end, or at the doctor – patient interface. It is important to understand the global safety climate as well as the situational and task level risks that contribute to error (Figure 1.5). Adverse events often arise from multiple systems failures as depicted in Reason’s ‘Swiss Cheese’ model (Figure 1.6) of accident causation. In this model the slices of cheese represent the defences in the system with the weaknesses or holes opening and closing and changing location. Multiple benign seemingly inconsequential errors will be endemic, but when combined with active failures and alignment of the ‘holes’ the adverse event is carried through to the patient. For example, staff shortages alone may be well compensated, but coupled with equipment breakdown, teamwork failures and a critical patient the detrimental outcome is translated through to the patient.

This model draws our focus to the series of seemingly minor errors that often precede a major patient safety incident: Error commonly arises from a combination of ‘latent conditions’ and ‘active failures’. Latent conditions are often deeply rooted within a system usually at the organisational level and can lie dormant for some time (e.g. staff shortages). Active failures are unsafe acts (errors or violations) at the sharp end of care (e.g. equipment breakdown). This model illustrates how healthcare providers at the frontline are often ‘inheritors rather than instigators of an accident sequence’ and although accountability for error should not be overlooked, the multi-factorial aetiology of the error (and hence necessary solutions) becomes apparent. By understanding these systemic issues and using the science of ergonomics, technology and human factors, health care workspaces, policies and pathways can be optimised such that it is hard for the individual to do the wrong thing.
Figure 1.5. Stages of Development of Organisational Accidents (Image adapted from Reason\textsuperscript{57})

Figure 1.6. Swiss Cheese Model of Accident Causation (Image adapted from Reason\textsuperscript{55} and Runciman\textsuperscript{58})
1.3.2 High Reliability Organisations (HRO)

It has been said that quality improvement aspires to industrial processes of efficiency and productivity, whilst the patient safety movement looks to model itself on high reliability industries.\(^5\) The change in direction to a systems approach for patient safety comes largely from aviation\(^59\) as well as the military. In such safety critical industries, human error is well recognised and strengthening systems by targeting latent and active failures enhances resilience and is an established approach to error reduction.\(^55\)\(^60\) The systems approach adopted in aviation includes identifying, analysing and acting upon critical incidents as well as near misses\(^61\) and providing timely feedback to the reporter.\(^62\) The aviation reporting system receives notification of 600 incidents, 30 serious incidents and 10 accidents for every one fatal accident.\(^40\) This exemplifies the learning that occurs from near misses or sentinel events (warnings) as well as the open, blame free culture around error. In addition, minimum safety standards are consistently upheld and specialised training for individuals and teams (including simulation) is thorough and well regulated.\(^63\)\(^64\)

1.3.3 Crew Resource Management (CRM)

It is well established that human error and teamwork failures are more commonly implicated in industrial accidents than ‘mechanical malfunction’.\(^65\) The aviation industry recognised the importance of this in the 1970s following a series of accident investigations by NASA.\(^66\) To address human factors in accidents, aviation led the way in developing specialised training known as Crew Resource Management (CRM).

This can be defined as an approach to limiting human error by making use of all available resources – information, equipment and other team members to enhance safety and efficiency.\(^67\) For example, the KLM runway collision in 1977 identified low assertiveness, leadership, decision-making and fatigue as key causative factors.\(^65\) Importantly, CRM training has undergone modifications to ensure that it is relevant to aviation teams globally and supported by pilots themselves as well as the regulatory bodies such that it is embedded in training, assessment and licence renewal.\(^66\) The more successful CRM models retain error reduction at their core and aim to equip teams with a set of countermeasures towards human error. Ultimately, CRM aims to provide knowledge, skills and attitudes towards error management by focussing on cognitive processes and teamwork (non-technical skills) irrespective of individual personality or cultural attributes such as questioning of authority.
CRM is not only part of aviation internationally, but has been adopted by others including nuclear, oil and rail industries.

1.3.4 Aviation to Anaesthetics: Translating Safety Concepts from Industry to Healthcare

From the cockpit to the operating theatre, there are many similarities and lessons to be learnt. This is not to say that these environments are interchangeable. Concepts of error management akin to CRM have been successfully translated to Anaesthetics. The safety profile of anaesthesia has been transformed over the last 50 years and this is likely to be a result of technological developments as well as strong leadership addressing and responding to error.\textsuperscript{68}

There are many similarities between high-risk industries and healthcare: they are often large complex organisations with highly trained individuals, operating in shifts of teams and interacting with complex technology. Considering this, there are clearly analogous solutions to safety including error management, human error and teamwork.

There are however notable differences that mean safety and quality interventions cannot simply be exported. When significant errors occur in industry they are very high profile and many fatalities may occur simultaneously: When a plane crashes hundreds of people (including the pilot) may die with immediate environmental and economic fallout in addition to the loss of human life. Whilst the scale of medical harm globally is huge, harm occurs more insidiously and the consequences are most deleterious for the patient as opposed to the doctor.

High-reliability organisations strive for standardisation and consistency and this is attainable to some degree as tasks are more clearly defined with emergency situations representing a deviation from the norm. Implementing standard operating procedures reliably is therefore possible. Healthcare, humans and disease processes on the other hand are inherently more diverse and unpredictable with routine and emergency work intermingled and thus ‘high levels of uncertainty are tolerated in medicine’.\textsuperscript{5} The concepts of safety developed in industry provide invaluable lessons for medicine but these strategies need to be designed, implemented and modified within specific healthcare teams for maximal effectiveness.
1.4 Healthcare Teams

Patients receive healthcare through teams constituting an array of individual expertise. As the volume and complexity of tasks within healthcare grows, our reliance on teams’ increases. Specialist interdisciplinary teams are ubiquitous in healthcare and patients as well as professionals exist within different teams. A patient may be under the care of a particular consultant, but the number of different professionals and teams they will encounter through primary and secondary care is high. Additionally, healthcare teams are complex, dynamic and have challenging tasks to fulfil under pressured situations. Despite such complexities, healthcare teams are not selected, designed and maintained for optimal performance, but often loosely formed and governed by availability of resources. Teams are critical for high reliability organisations and consequently there is a plethora of research focussing on team effectiveness for productivity and efficiency as well as error management.69,70 Traditional models of medical education have focussed on individual task-based competency but less so on teams.63 Considering human error and the principles of safety outlined in Crew Resource Management (CRM) - teams, teamwork and effective team performance71 are essential components for patient safety. Paris summarises this eloquently: ‘Teams are more than collections of individuals and teamwork is more than the aggregate of their individual behaviours’.69 So how do we define teamwork?

1.4.1 Defining Teams, Teamwork and Team Performance

Teams are groups of professionals and teamwork reflects the co-ordinated interdependent components of individuals completing tasks. Team performance is a collective of task and teamwork skills at the individual and team level.71 Salas defines a team as, ‘a distinguishable set of individuals with assigned roles who interact dynamically, interdependently and adaptively towards achieving a valued, common goal’.72,73

Whilst this definition resonates, healthcare teams are often fragmented, assembled at short notice, members may not know each other’s names let alone roles and they may not be united in a common goal particularly if they perceive their own task or contribution as a priority for the patient.

The importance of teamwork in safety critical industries is clear particularly when, ‘errors lead to severe consequences, task complexity exceeds individual capacity, task environments
are ill defined, ambiguous and stressful, multiple quick decisions are required and when the lives of others depend on the collective insight of individual members’.\textsuperscript{71}

1.4.2 Teamwork Skills

Various models and components of teamwork have been described in the literature.\textsuperscript{5,71} Simply, the input - process - output model provides a good framework for considering team skills and Figure 1.7 summarises key characteristics.

![Figure 1.7. Framework for teamwork adapted from McGrath’s\textsuperscript{74} Input – Process – Output model. Figure adapted Vincent \textsuperscript{5}](image)

Effective teamwork has many traits and these can be considered under five themes.\textsuperscript{70} Good team ‘leadership’ will identify individual strengths and weaknesses and distribute tasks effectively to fulfil goals. By tracking progress through ‘mutual performance monitoring’
teams can anticipate problems and employ ‘adaptability’ skills’. Effective team leaders may adopt ‘backup behaviours’ where tasks may be re-distributed to other team members during stressful situations for example. This form of team situation awareness can limit the negative impact of stress on performance.33 Strong ‘team orientation’ refers to the attitude of the team that their collective efforts are superior than the sum of their individual inputs and strengthens team cohesion and resilience.

1.4.3 Non-Technical Skills

Non-technical skills can be considered an important component of teamwork. These skills are defined as, ‘the cognitive, social and personal resource skills that complement technical skills and contribute to safe and efficient task performance’.33 In practice, these skills comprise communication, situation awareness, leadership, judgement and decision-making as well as coping strategies for stress and fatigue. Non-technical skills and teamwork are closely related and some of the skills bridge these domains. Good non-technical skills are nested within teamwork. For example effective exchange of information, closed loop communication and active listening can all be individual non-technical skills but also are an essential part of teamwork. Good non-technical skills and effective teamwork are often what separates out the performance of experts who draw on these resources in parallel to superior technical performance for enhanced patient outcomes.75,76

Non-technical skill is not a novel concept, but has relatively recently been formally articulated within medicine, specifically anaesthesics77,78,79, Surgery Yule80,81 as well as endoscopy.82 Identification of specific observable behaviours has enabled the formulation of behavioural marker systems78,83 to facilitate training and assessment of non-technical skills at the individual and team level.

1.4.4 Challenges for Healthcare Teams

The challenge for medical teams rests with combining good non-technical and teamwork skills with technical proficiency to deliver safe effective care. Professional (i.e. doctor – nurse) speciality (i.e. physician – surgeon) and hierarchical (i.e. consultant – trainee) subgroups with set boundaries are embedded in healthcare. Healthcare teams adapt from routine to emergency work streams84 requiring high vigilance despite multiple distractions and yet still shy away from acknowledging the negative effects of stress and fatigue on performance. Although there are the beginnings of a cultural shift within medicine, this is far
from the open culture seen in aviation where questioning authority is acceptable and encouraged, particularly if there is a safety concern.

Teams can be a defence or a hazard for patient safety. Poorly functioning teams may precipitate further errors whereas highly functioning teams may be able to mitigate errors and achieve greater productivity.

‘A team of experts does not make an expert team’,85 and addressing human factors, non-technical skills and teamwork in Medicine through CRM type training strategies coupled with a safety culture will begin to shape high team performance.

1.5 Endoscopy Patient Pathways

Thus far the systems approach and the complexity of healthcare teams has been laid out and the next section focuses these concepts within gastrointestinal (GI) endoscopy. Patients present commonly with gastrointestinal symptoms86 and these may reflect localised (i.e. rectal bleeding) or systemic (i.e. anaemia) disease.87 Endoscopy has become a useful, accessible and relatively non-invasive method of investigating such patients. The decision to utilise endoscopy, which procedure and at which time point all remain variable, as the risk / benefit for the patient needs to be individualised.

Additionally, the UK’s national colorectal cancer screening programmes utilise lower GI endoscopy with the aim of improving cancer outcomes in the asymptomatic population. There are various pathways for patients to be investigated for GI symptoms, cancer detection and prevention and these are exemplified by colorectal cancer pathways87 and summarised below. These ‘routes’ into endoscopy provide an example of the complexity of clinical pathways and the intra and inter team coordination required between primary, secondary, tertiary and screening sectors as well as associated specialities such as colorectal surgery, radiology and histology. Importantly, whichever pathway is adopted shared decision-making, patient choice and patient involvement in the process are important aspects of the patient experience.88

1.5.1 Urgent Suspected Cancer Pathway (Two Week Wait Pathway)

There is variability in cancer survival rates, with England comparing unfavourably with European counterparts of similar economic status.89 This may relate to symptom recognition, possible diagnostic delays and consequent manifestation of advanced disease. In order to
address this, the Department of Health published the NHS Cancer Plan\textsuperscript{90} as a strategy to reform cancer services by addressing cancer prevention, diagnosis, treatment, care and research with a view to providing more equitable care. In addition, mandatory requirements for specialist review and instigation of treatment were defined. This included a maximum two-week wait for patients with symptoms suggestive of cancer from primary care referral to secondary care specialist review. Furthermore, targets of 31 days from the decision to treat to implementing treatment, and 62 days from primary care referral to initiation of definitive treatment were stipulated. This has been supported by NICE guidance\textsuperscript{91} but the evidence base for patient outcomes is limited.\textsuperscript{92,93,94}

To accelerate the diagnostic pathway further, appropriately selected patients can be diverted to the ‘straight to test’ (STT) pathway as opposed to an index outpatient appointment.\textsuperscript{95} For colorectal cancer, this may be a flexible sigmoidoscopy for rectal bleeding or a computerised tomography colonography (CTC) if anaemia and altered bowel habit predominate with selective use of colonoscopy thereafter.\textsuperscript{96} STT pathways potentially allow a cancer diagnosis to be reached sooner\textsuperscript{97} and preserves outpatient clinic capacity, although there are still ‘costs’ to the patient with potential additional investigations\textsuperscript{98}, time pressure and limited patient centred communication which may induce anxiety.

1.5.2 Symptomatic Patient Pathway

Gastrointestinal symptoms are common and diverse amongst primary care populations\textsuperscript{99} and are not necessarily a sensitive indicator of gastrointestinal malignancy. Furthermore, symptomatic patients are more likely to present with advanced disease and the attendant detrimental consequences of greater morbidity and mortality. The challenge is to identify higher risk patients given their symptoms\textsuperscript{100} hereditary and lifestyle risk factors,\textsuperscript{101,102,103} and investigate and refer them appropriately.

National bowel cancer awareness programmes such as, ‘Be clear on cancer’\textsuperscript{104} substantially increased referrals under the 2 week wait pathway. This resulted in significant pressure on limited NHS resources due to the increased demand for endoscopic, radiological and histology assessments. Despite this, the diagnostic yield remained low due to the overall increase in referrals with a greater representation of higher social grades.\textsuperscript{105}
Furthermore, symptomatic patients presenting as an emergency with bowel obstruction for example, have significantly lower one-year survival rates\textsuperscript{106} compared to patients presenting via other routes. Importantly, diagnosing colorectal cancer efficiently \textit{after} the onset of symptoms does not necessarily equate to an early cancer stage or improved survival\textsuperscript{107,108} but is clearly important in managing associated complications of the disease and patient expectations. In the UK, the Department of Health’s National Awareness and Early Diagnosis Initiative (NAEDI) focuses on earlier stage diagnosis in symptomatic patients which remains a complex socio-economic issue.\textsuperscript{86} Screening for colorectal cancer during the asymptomatic phase addresses some of the challenges posed by symptomatic colorectal cancer.

\textbf{1.5.3 Bowel Cancer Screening Pathway}

Screening for colorectal cancer in asymptomatic individuals can reduce both the incidence and mortality of colorectal carcinoma.\textsuperscript{109,110,111} The NHS bowel cancer screening programme utilising faecal occult blood (FOB) screening\textsuperscript{112} to select participants for colonoscopy, is well established in the UK for individuals aged 60-74. Following the success of the FOB pathway,\textsuperscript{113} colorectal cancer screening is being extended to include a once off flexible sigmoidoscopy at the age of 55 given that two thirds of adenomas and cancers are situated in the rectum and sigmoid.\textsuperscript{31 114 115}

The main aim of screening is to reduce mortality by early detection and treatment of cancer.\textsuperscript{116} Secondarily, screening aims to detect and resect adenomas and thus prevent progression to cancer by interrupting the adenoma – carcinoma sequence.\textsuperscript{30,117} Importantly, early endoscopic treatment of invasive lesions can be ‘less detrimental for quality of life’.\textsuperscript{118}

Computed tomography colonography (CTC) is well established as a safe and accurate\textsuperscript{119 120} means of imaging the large bowel and has an important role for patients who may be unsuitable for colonoscopy or where colonoscopy is incomplete, with the advantage of providing extra-colonic imaging.\textsuperscript{121,122} In the context of an incomplete initial assessment, coordinating these two investigations (ideally at the same hospital attendance) is a key consideration for the asymptomatic screening patient who will already have undergone a form of bowel preparation.

Colorectal cancer incidence is set to increase in developed and less well developed health care settings.\textsuperscript{123} and it follows that earlier stage of disease at diagnosis is not only beneficial for patient prognosis, but is also cost effective\textsuperscript{124}. Consequently the necessary increase in
accredited endoscopy capacity to provide national screening is an important consideration, particularly in the context of patient safety at a population level.\textsuperscript{30,125} This is well summarised in European guidelines which state that, ‘Provision of the service must take into account the perspectives of endoscopists and public health to ensure that the experience is high quality, safe, efficient as well as people orientated.’\textsuperscript{118} Furthermore, the rigorous quality assurance processes that underpin bowel cancer screening, set the standard for best practice with a positive ripple effect on the symptomatic endoscopy service as well as allied CTC radiology services.

1.5.4 Tertiary Referral Pathways

Complex patients, or those with complex disease requiring super-specialised medical care may be referred by secondary to tertiary hospital services. These patients may be more medicalised than the ‘average’ patient having already been through diagnostic and / or therapeutic interventions elsewhere. Such patients may require an expert endoscopist’s diagnostic skill and or therapeutic intervention. Conversely, tertiary patients may be considered for novel endoscopic techniques through clinical trials or may be seeking a second opinion following a medical error for example. Alternatively, patients may be referred to endoscopy through other specialities, such as Haematology due to their symptomatology or for investigation of incidental lesions found on imaging. Tertiary referral pathways add another layer of complexity with processes and information transfer requiring coordination within and between three separate health care organisations (primary, secondary and tertiary) and their specialist teams, whilst maintaining a focus on the patient.

1.5.5 Endoscopy and the Colorectal Cancer Multi-Disciplinary Team Meeting (CRC MDT)

As detailed in the last section, endoscopy patient pathways are numerous and complex requiring significant coordination to optimise patient care. There is significant investment in diagnostic pathways with the underlying aim of diagnosing cancer early. Similar consideration needs to be given to the process following a positive diagnosis and this is within the realm of the Cancer Multi Disciplinary Team (MDT) meeting. These issues are relevant to upper and lower Gastrointestinal Cancer MDTs, but for the purposes of the thesis the focus will be on colorectal cancer MDTs. Additionally, MDT discussions for colorectal patients often generate endoscopy referrals both diagnostic and therapeutic including complex interventions such as colonic stent insertion. This bridge between endoscopy and the
CRC MDT is an opportunity to galvanise expert opinion from relevant specialities, but is also potentially a pitfall in the process vulnerable to miscommunication, time delays and a focus on pathology rather than the patient. For optimal patient centred care, consideration of pathways into, within and out of endoscopy is necessary. The complexity of these pathways and teams is illustrated in Figures 1.8 and 1.9

**Figure 1.8.** Pathways into endoscopy

**Figure 1.9.** Pathways out of endoscopy

### 1.6 Endoscopy Patient Safety and Quality

GI Endoscopy is generally conceived as being a minimally invasive procedure that is relatively low risk.\textsuperscript{126} Whilst this is true, particularly in comparison to surgery, endoscopy is not without risk. Considering the increasing volume of procedures undertaken in comorbid patients\textsuperscript{127} as well as the advances in technology and therapeutic intervention, a balanced assessment of safety, risk and quality underpin an effective service for patients. Over the last decade, quality in Endoscopy has become an important issue globally. This has largely been led by efforts to improve endoscopy in England\textsuperscript{128, 129} and reinforced by the US (ASGE)\textsuperscript{130} and
European (ESGE) professional societies issuing guidance reflecting the importance and urgency of quality improvement. Such a proactive stance lead by the profession independently averts the risk of having ‘performance indicators externally imposed’ by regulatory bodies that may not be so well versed in the details of quality and safety as balanced with service provision. The next section outlines the main drivers towards safety and quality in endoscopy.

1.6.1 Endoscopy in the pre-screening era

1.6.1.1 UK colonoscopy audit

In 2000 endoscopy patients in England experienced variable and often substandard services with reported waiting times of up to a year. In 2004 Bowles et al conducted a UK wide audit of colonoscopy practice, which outlined significant issues. Caecal intubation rates confirmed by ileal intubation or ileo-caecal valve identification were reported at 56.9% and the commonest reasons for incomplete procedures were patient discomfort and looping, both of which could be considered surrogate markers for technical proficiency. In the patient questionnaire section of this study it was clear that the consent process was sub-optimal, with 54.8% of written consent undertaken within the procedure room itself. Sedation practice showed variability with intravenous access and administration of oxygen: 6.9% of sedated patients did not have intravenous access and where access was obtained 10.9% had a ‘butterfly’ needle and not a secure indwelling plastic catheter. Furthermore, oxygen was not administered to 11.4% high ASA grade ‘at risk’ patients. Examining the 30-day mortality, procedure related mortality was higher than expected at 1:537 and 4 out of the 10 deaths were attributed to severe comorbidity raising the question of appropriate patient selection.

1.6.1.2 National Confidential Enquiry into Patient Outcomes and Death (NCEPOD)

At the same time, the 2004 National Confidential Enquiry into Patient Outcomes and Death (NCEPOD) following gastrointestinal endoscopy, sought to further understand patient safety issues contributing to 30-day mortality. This report emphasised issues with sedation and monitoring techniques and equipment availability. In relation to this, clearly defined protocols for safe sedation were highlighted given the wide range of specialties involved in GI endoscopy. Similar to Bowles’ data, patient selection and pre-procedural optimisation were highlighted as important issues given that, ‘19% of percutaneous endoscopic gastrostomy (PEG) procedures were futile or not indicated at all’. Although these studies were conducted over a decade ago, they raise key considerations for endoscopy patient safety, which are still relevant today.
In response to this, there have been significant improvements in endoscopy\textsuperscript{125} in the UK underpinned by addressing the training issues and driven by the requirement for a national bowel cancer screening programme\textsuperscript{30, 134} necessitating consistent high quality practice.

\subsection*{1.6.2 The Joint Advisory Group on Gastrointestinal Endoscopy (JAG)}

The Joint Advisory Group on Gastrointestinal Endoscopy (JAG) was created in 1994 under the auspices of the Academy of Medical Royal Colleges. The JAG’s initial remit was to oversee endoscopy training and subsequently developed to include quality assurance of service provided to patients in preparation for national screening programmes. The JAG consist of two working groups managing the quality assurance of training and endoscopy units.\textsuperscript{135} The achievements of JAG have been immense and characterised by good leadership to ensure that the varied professional members (physicians, surgeons, nurses, radiologists, paediatricians and general practitioners) are engaged in the training and quality assurance goals.\textsuperscript{128}

\subsection*{1.6.3 The National Endoscopy Training Programme (NET)}

In view of the need to enhance endoscopy services to deliver national screening the NHS cancer plan (2000)\textsuperscript{90} allocated resources to support improvements in endoscopic training. In parallel the NHS Modernisation Agency evaluated demand and capacity with a view to improving productivity. In the UK the National Endoscopy Team (NET) was devised funded by the Department of Health to coordinate training nationally. The NET’s goals have largely been achieved through JAG by utilising standardised assessment tools and accredited courses delivered through dedicated endoscopy training centres.\textsuperscript{136} Standardising training processes was the starting point for addressing the variability in practice.

\subsection*{1.6.4 Endoscopy training}

Historically, endoscopy training has been experiential, opportunistic and with variable supervision resulting in many endoscopists being ‘self-taught’. In order to address the deficiencies raised in the Bowles study, a thorough reformatting of training from the trainee, trainer and unit perspectives was undertaken.

Endoscopy training is overseen by the Joint Advisory Group for Endoscopy’s (JAG) dedicated endoscopy training system (JETS).\textsuperscript{137} The JETS e portfolio enables both trainees
and trainers to electronically document procedures, key performance indicators*, training goals and assessments using the validated ‘Directly Observed Procedural Skills (DOPS) assessment tool.’ These assessments are conducted both formatively (to aid in setting learning objectives) and summatively (to determine overall competence). In addition, trainees provide feedback on trainers, which is reviewed regionally. Once standards have been met and the trainee is deemed to be competent by a number of measures, the trainee can apply for JAG certification enabling independent practice. This process is summarised in the figure below. and the achievements of the JAG process provide an international model of excellence. This approach represents a shift in conceptual thinking of competence from quantity of procedures to quality. JAG accredited national and regional training centres provide basic and advanced skills training courses through JETS and thereby set the standard. Importantly, a highly skilled endoscopist does not equate to a competent endoscopy trainer, as this requires additional skill sets. Continuing high quality training at the base unit is facilitated by ‘train the trainers’ courses disseminating optimal endoscopy training techniques further. Training units are required to have a key number of trainers with this qualification supporting a ‘sustainable and self-improving national training programme’. These key developments through JAG (which contribute to the GRS dataset) have secured the quality assurance of endoscopy training through continuous evaluation of training, units and individuals. [Dunckley, 2011 #1482]

* Key Performance Indicators (KPIs) include caecal intubation rate ≥ 90%, withdrawal time ≥ 6 minutes, Adenoma Detection Rate (ADR) ≥15% and Polyp Retrieval Rate ≥90%.
1.6.4.1 The changing shape of endoscopy training

With the introduction of the European working time directive\(^{143}\) and restriction in working hours, training opportunities have also reduced\(^{144}\) impacting procedural based specialities in particular. Additionally, there is variability in endoscopy training pathways according to speciality: The Bowles audit showed that medical trainees performed 14.5% of colonoscopies and surgical trainees 3.7% with only 17% receiving supervised training for their first 100 procedures.\(^{132}\) Globally, there is variability amongst regulatory bodies regarding the minimum numbers of procedures for training: In the US 50 colonoscopies is deemed sufficient for training\(^{145}\), in the UK JAG recommends 200 procedures\(^{146}\) and some European figures show trainees achieve a caecal intubation rate > 90% after 280 colonoscopies.\(^{147}\) This should be considered in the context of service provision demands and waiting list targets balanced with safety.

Endoscopy training through JETS aims to increase not only the effectiveness but also the efficiency of training\(^{142}\) by unifying the training and assessment approach for all the various specialities i.e. medical, surgical, nursing, paediatric, primary care and radiology. ‘Using quality benchmarking … will remove the “turf” wars between specialties by simply requiring high quality examinations by all endoscopists.’\(^{136}\) With advances in endoscopic techniques and increasing sub-specialisation there is also an awareness that not all trainees need to certify in all types of endoscopic procedures such as Endoscopic Retrograde Cholangio-Pancreatography (ERCP) which is technically challenging and reasonably high risk\(^{148}\). In order to competently perform endoscopy procedures, exposure to volume and intensity of procedures\(^{146}\) i.e. sufficient numbers on a regular basis, is a pre-requisite with a life-long commitment to endoscopy training. The focus shifted to training smarter not harder and an understanding that not all endoscopists should perform all types of endoscopic procedures.

1.6.4.2 Technical skills training and Simulation

Learning the science and art of endoscopy is complex. Technical motor skills requiring hand eye coordination are an important aspect. This is in addition to the cognitive skills necessary for diagnostic and therapeutic intervention.\(^{149}\) These essential psychomotor skills run in parallel to ‘clinical judgement, communication, decision making and patient focussed interaction’.\(^{150}\) Experts have defined the technical skills required to perform colonoscopy to include ‘loop reduction, endoscope advancement and torque steering, navigating flexures, snare polypectomy, retroflexion, use of control knobs for targeted biopsy, controlled
withdrawal with adequate mucosal visualisation, use of accessory devices with stable scope position, maintaining lens clarity, use of suction and irrigation, gauging force application, photo-documentation and responding to patient discomfort\(^{151}\). These technical skills have to be mastered in order to provide a safe, high quality procedure.

A structured approach to procedural skills training using simulation in clinical context, maximises learning whilst maintaining patient safety\(^{150,152}\). There is a growing evidence base for simulation training in laparoscopic surgery\(^{153,154}\) where operative sequences can be broken down and practiced. Similarly, simulation can accelerate the first part of the endoscopy learning curve\(^{155}\) and therefore useful for novice trainees\(^{156,157}\) when scope handing and manipulation skills are being acquired. Deconstructing colonoscopy into its basic components by using kinematic motion analysis is useful for endoscopy simulation training. Specific motor skills (e.g. torque steering) can be trained and assessed in ‘part task training boxes’ with the ability to distinguish novices from experts\(^{158}\). Endoscopy differs in comparison to surgery, where multiple technical skills are required simultaneously as opposed to the sequential nature of tasks in laparoscopic surgery for example. It has been established that intensive endoscopy skills training over one week leads to a sustained improvement in knowledge, technical skill and performance\(^{159}\) but acknowledged that this should be embedded into a wider training strategy. Furthermore, with increasing therapeutic demand, dedicated training and assessment of complex aspects such as polypectomy have been developed\(^{160,161,162}\) in addition to traditional methods. In summary: “Effective skills training requires specific individualised training, supported by performance enhancing instruction and feedback. This cannot be achieved by observation or simple supervision, but requires attentive and observant trainers with appropriate training in how to train in endoscopy.”\(^{139}\)

**1.6.4.3 Fundamentals of endoscopy safety**

Basic principles of safety in endoscopy feature in current endoscopy training programmes, but safety is not explicitly defined or taught. Complications of endoscopy, notably haemorrhage and perforation are the key safety issues emphasised. However, important safety aspects pertain to pre-procedural patient preparation (fasting, bowel preparation\(^{163,164}\), management of anticoagulation\(^{165,166}\)), sedation, procedural complications, staffing levels, effective equipment (endoscope, accessories, diathermy, oxygen, patient monitoring), endoscope decontamination processes and infection control for example. Safety is often
presented as a unit responsibility\textsuperscript{167} and hence not at the forefront of training for the endoscopist. The American guidance for safety in the endoscopy unit\textsuperscript{167} makes reference to ensuring the correct patient and procedure are verified but no further detail on how these team processes should be conducted.

As previously outlined sedation selection, administration, monitoring and titration are important safety issues with wide variance in practices nationally and internationally\textsuperscript{168,169}. Whether endoscopy teams use conscious or deep sedation\textsuperscript{170}, nurse or anaesthetist led sedation, ultimately the endoscopist performing the procedure should be trained in sedation administration and monitoring as they have overall responsibility. Whilst dedicated sedation training and guidance is available\textsuperscript{171,172} this remains speciality specific (endoscopist, nurses, anaesthetists) although multi-disciplinary curricula have been developed.\textsuperscript{173}

\subsection*{1.6.4.4 Training vs. service provision vs. patient safety}
With the technological developments in endoscopy and the demand for procedures, effective and efficient training in endoscopy is critical. However, endoscopy training sessions are threatened, ‘with increasing pressure from service provision and competition for limited … resources’.\textsuperscript{139} This is contentious as there is an increasing therapeutic workload, requiring skilled endoscopists to perform higher risk procedures in co-morbid patients. A fine balance between meeting service provision needs with appropriate training to enhance patient safety needs to be struck in order for providers to make best use of endoscopy services.

\subsection*{1.6.5 Endoscopy high quality}
The evolution of endoscopy in the UK illustrates how a, ‘transformation in quality, safety and patient experience’ can be achieved with a, ‘strategic, centrally led and modestly resourced approach’.\textsuperscript{128} The UK endoscopy programme has strived ahead in the quality agenda internationally over the last decade\textsuperscript{129} This has been achieved by taking a broad view on training, accredited units, competency based assessment for individual endoscopists and ultimately a patient orientated view on quality improvement. This has been led by the Global Rating Scale and the Joint Advisory Group for Endoscopy and these concepts of measuring reporting and improving quality standards in an nationally coordinated fashion have been adopted in several countries internationally.\textsuperscript{128}
1.6.5.1 The Global Rating Scale (GRS) for Endoscopy

The ‘Global Rating Scale’ (GRS)\textsuperscript{174,175} was launched in 2004 by the National Endoscopy Team, as an approach to quality assurance at the endoscopy unit level. The GRS is a web-based quality improvement and assessment tool, which has focussed UK endoscopy to provide high quality patient centred care. Professional guidance and societal position statements on quality indicators in endoscopy are in the most part procedure focussed. The Global Rating Scale was developed primarily from the patients’ perspective.\textsuperscript{176} Endoscopy units use this tool to self-evaluate every six months with data submission overseen by the clinical lead and opportunities to identify areas for improvement.

The GRS defined quality standards by asking patients and staff what was of importance to patients undergoing endoscopy. From these key items two dimensions were set; clinical quality and quality of patient experience and training and workforce domains were subsequently added. Within these domains units can self assess against specified items with scores ranging from A (excellent) through to D (basic) services. Importantly, the GRS contains a ‘Knowledge Management System’ (KMS) where high performing units (A*) can share guidance and policies with others thus disseminating good practice and improved GRS scores for other units. GRS data metrics are overseen by JAG and in order to receive JAG accreditation, units are visited and evaluated in depth by the JAG team every 5 years.\textsuperscript{177} JAG accreditation enables endoscopy training to take place and importantly complete financial reimbursement for endoscopic procedures. JAG accreditation is also a pre-requisite to conducting bowel cancer screening services, a surrogate marker of quality, and thus helps drive up the quality of all endoscopy\textsuperscript{178}. Accreditation itself inspires a culture of excellence. The GRS process has good compliance (98%) with initial low scores showing improvement over time such that 90% of units achieve level B or above for all items.\textsuperscript{128} Whilst this biannual census provides incentive to improve services, it does not accurately reflect day-to-day patient safety issues and is not a mandatory process although it has been widely adopted. Essentially, the GRS data and JAG accreditation process ‘promotes quality improvement by facilitating the nationwide sharing of good patient centred care’.\textsuperscript{136}

1.6.5.2 Implementing Endoscopy Quality and Safety

Within the UK quality and safety aspects of endoscopy have been considered in detail. Specific indicators for both quality and safety have been defined alongside GRS items.
Quality statements highlight the benefits of endoscopy and safety items reflect potential harm,\textsuperscript{179} with clearly defined minimum standards and aspirational goals.

The GRS and the JAG accreditation and training processes set the framework for units to provide a safe and quality assured service, but how is this conducted at the unit level given the variability in NHS trust structures? Local endoscopy leadership and partnership with key stakeholders is crucial and units should have a designated endoscopy clinical lead and nursing lead with managerial support. It is key for clinical leads to have a clear understanding of their roles, which require varied skills including education, staff recruitment, procurement, resource allocation and management of patient complaints amongst others.\textsuperscript{128} Furthermore, motivated endoscopy teams invested in quality improvement are required to carry out the necessary change for service improvement.\textsuperscript{177} Engaging teams within accreditation processes is challenging, but an understanding of these obstacles and opportunities is important as valued and motivated staff are more likely to support change, foster innovation and contribute to organisational efficiency.\textsuperscript{180}

Endoscopy leads have responsibility for managing their team as well as GRS data and JAG requirements with the overriding aim of providing patient centred care. Given this, quality assurance systems need to take a broad view of safety and quality from individual endoscopist parameters, to team processes, unit facilities and patient outcomes.\textsuperscript{181}

Despite the importance of endoscopy lead roles, formal leadership training is not widespread. This has been considered and the Team Leadership Programme (TLP) was created to support those in lead roles,\textsuperscript{182} but not disseminated to allied senior endoscopists. Existing quality assurance measures in Endoscopy have been well structured and coordinated and coupled with strong leadership have changed the face of UK endoscopy. This has been achieved nationally, regionally (through unit level quality assurance) and for individual endoscopists. The template has been set for further improving quality and safety for individual endoscopists in the context of their immediate core and wider clinical teams.

\textbf{1.7 Summary}

This chapter has defined quality and safety in healthcare within the context of human factors, teamwork and medical error. The complex patient pathways navigated through endoscopy highlight the challenges of complex teams, communication and multidisciplinary teamwork that underpin modern healthcare delivery. Gastrointestinal endoscopy plays a key role within
diagnostic, therapeutic and cancer services and technological advancements provide further management options. The existing quality assurance mechanisms through the National Endoscopy Team, the Global Rating Scale and the The Joint Advisory Group in Endoscopy were catalysed by the need for national bowel cancer screening, but have been readily adopted by endoscopy services across the board. The improvements in UK endoscopy have been immense and the infrastructure is in place to further scrutinise services to achieve higher levels of quality and excellence on a wide scale.

Existing strategies have particularly improved quality at the level of individual endoscopist by standardising high quality training and monitoring key performance indicators. The endoscopy unit performance has been developed through GRS evaluation and improvement in service provision in a patient centred fashion. Quality assurance of endoscopy on a national level has been possible due to both professional management of endoscopy through JAG and the delivery of the vast majority of endoscopy services through NHS trusts.

Although endoscopy is perceived to be relatively safe the risks should not be underestimated considering the potential for therapeutic intervention as well as the complexity and comorbidity of patients that may not be suitable surgical candidates. Considered decision-making with a multi-disciplinary team allows individualised management to be discussed with patients. Whilst endoscopy has significantly improved, ‘obstacles remain in sustaining positive change particularly with increasing volume of endoscopy and rapid adoption of new technologies’. The safety and quality attributes of individual endoscopists in the context of their endoscopy team require further attention as current training, accreditation and service evaluation does not explicitly evaluate this in measurable detail. Enhanced teamwork and non-technical skills are opportunities to avert medical error, improve quality and improve the patient experience and are recognised as required future developments by the profession itself.

1.8 Thesis Aims

1.8.1 Primary Aims

- Identify and assess patient safety issues in endoscopy
- Devise implement and evaluate solutions to improve patient safety and quality in endoscopy
1.8.2 Secondary Aims

1. Increase understanding of Patient Safety Incidents in Endoscopy

2. To determine the role of non-technical skills in endoscopy and educational strategies to enhance these skills

3. To identify differences in patient safety issues in elective and emergency endoscopy

4. To examine opportunities to enhance endoscopy safety and quality by evaluating colorectal cancer multi-disciplinary team working

5. To develop an endoscopy safety checklist and implement into clinical practice

1.9 Overall hypothesis

Endoscopy patient safety and quality can be improved by addressing errors and enhancing teamwork in Endoscopy
Chapter 2: Identifying Patient Safety Issues in Endoscopy

2.1 Chapter Overview

The previous chapter provided the context for safety and quality in healthcare and the opportunities to enhance these in Endoscopy. In this chapter, specific current patient safety issues in endoscopy are examined. This is investigated by two methods: Firstly, endoscopy team member’s knowledge and attitudes towards safety were examined and secondly endoscopy procedural observations were undertaken to identify which patient safety incidents occur in practice. A brief introduction to patient safety incidents is presented leading on to the study aims and methodology implemented to address these. The results of the endoscopy team attitudes questionnaire and the patient safety incidents are presented along with the discussion that outlines the relevance of these findings for patient safety.

2.2 Introduction

Medical error is ubiquitous and factors implicated often relate to human error, patient complexity, technology and coordination of healthcare processes and systems as detailed in Chapter 1. Whilst this has been well acknowledged in other areas of medicine, the breadth and depth of patient safety incidents in endoscopy requires further work. Indicators of safety compromise in endoscopy have been identified\(^1\) and set the foundation for addressing these issues in individual practice. There is acknowledgement from the profession that broader recognition and documentation of endoscopic adverse events is important: The American Society of Gastrointestinal Endoscopy (ASGE) developed a detailed lexicon for considering adverse events in endoscopy\(^2\), highlighting the importance placed on error by professional bodies.

Although adverse endoscopic events are well recognised\(^3\) the focus primarily remains on technical procedural outcomes. Reported adverse events therefore tend to be procedure specific\(^4\) \(^5\) and concentrate on the severe end of the spectrum as opposed to the minor, seemingly inconsequential, more frequent events. The NCEPOD report outlined many concerns regarding sub-optimal patient care including careful consideration of procedure indications,\(^6\) as ‘complications are never acceptable if the procedure is not indicated’.\(^7\) Similarly, serious avoidable patient safety incidents termed ‘never events’ (section 1.2.3) have received significant attention. Much effort is invested in determining the incidence of adverse events but it may be prudent to delineate the underlying characteristics of adverse
events to guide improvement efforts. This is particularly relevant given the variation in endoscopic practices for individuals, teams, units and countries.

The ASGE taskforce on quality in endoscopy highlights the importance of addressing quality and complications across pre, intra and post procedural phases of endoscopy and stated, ‘there is an urgent need for a prospective study to identify the circumstances and risk factors associated with adverse outcomes related to endoscopy’. Other research questions posed relate to complication rates and the effectiveness of reporting and feedback on error incidence. Given that errors are commonplace, it is important to note that well managed errors are indicators of ‘effective team performance’ and even a marker of high quality and thus should be proactively addressed. These positions represent a shift towards accurate, detailed, transparent adverse event data that will inform an understanding of the aetiology of error in endoscopy.

### 2.3 Aims

#### 2.3.1 Safety Attitudes Questionnaire Study
- To determine the attitude of endoscopy team members towards endoscopy risk and endoscopy safety checks

#### 2.3.2 Patient Safety Incidents Study
- To determine the frequency, type and severity of patient safety incidents (PSIs) in routine endoscopy
- To identify the care delivery problems and contributory factors to endoscopy PSIs
- To deliver educational strategies to aid wider learning from error

### 2.4 Methods

#### 2.4.1 Safety Attitudes Questionnaire Study

To gain an understanding of the wider endoscopy team’s opinion on endoscopy risk, patient safety and safety checks, a questionnaire study was designed and conducted in a single tertiary endoscopy unit (The Wolfson Unit for Endoscopy at St Mark’s Hospital). This was a concise questionnaire devised by research fellow (MM) in conjunction with the consultant clinical lead for endoscopy (STG) and the consultant endoscopy training lead (AH).
The questionnaire was conducted prospectively by research fellow (MM) who had consented the teams and patients for observation of consecutive procedures in a list. The questionnaire was limited to <10 questions in order to obtain as full a completion rate as possible. Participants were recruited at the end of the endoscopy list and verbally invited to complete responses on paper. Completed responses were prospectively collated by MM at the same time point. Participants included the endoscopist conducting the list (medical, surgical and nurse) as well as the assisting endoscopy nurses (all grades).

Questionnaire items were categorised into two broad themes: a. Safety checks and b. Teamwork. Within safety checks, items aimed to explore which endoscopy safety checks staff members thought were necessary and who’s responsibility it was to complete them. Members were asked if they were aware of the World Health Organisation (WHO) surgical safety checklist and whether a safety checklist would be desirable for endoscopy. In evaluating teamwork, questions asked if team members had a clear ‘escalation point’ if there was a problem in the endoscopy room and whether they knew the names of the members of their team. (See Appendix 1.1 for complete questionnaire).

2.4.2 Prospective observational study of Patient Safety Incidents (PSIs) in Endoscopy

2.4.2.1 Study Design, Participants and Settings

This was a prospective observational study of patient safety incidents in a single tertiary endoscopy referral centre in the UK. Procedures were observed from within the endoscopy room by a Gastroenterology research fellow (MM) trained in teamwork observations and medical error. Patients undergoing lower and upper gastrointestinal endoscopic examinations were included and cases were both diagnostic and therapeutic. Endoscopists performing the procedures were experts and trainees, including medical gastroenterologists, colorectal surgeons and independent endoscopy nurse practitioners. Expert endoscopists were defined as medical surgical and endoscopy nurse consultants. Trainee endoscopists were defined as all other doctors of non-consultant grade i.e. gastroenterology and surgical registrars and endoscopy clinical fellows.

Additional measures relating to teamwork were conducted for a proportion of these observations and this is presented in chapter 3.
2.4.2.2 Ethical Approval

Ethical approval for both studies was obtained from the National Research Ethics Service (NRES) Committee London, Reference 08/H0719/54. Informed consent to observe each endoscopy procedure was obtained from the patient and the endoscopist conducting the procedure. Endoscopy teams were informed that observations were being undertaken to evaluate team processes and safety in endoscopy. All patient safety incidents arising during this study period were dealt with according to the normal unit protocol where significant adverse events are escalated to the nurse in charge and the unit manager and subsequent incident form submission to the hospital’s adverse event reporting system.\textsuperscript{11}

2.4.2.3 Definition of Patient Safety Incidents

Patient safety incidents (PSIs) were defined as any safety issue that had the potential to, or directly adversely affected patient care: PSIs with and without immediate consequences were included. Specifically, PSIs were defined as near misses, recognised procedural complications, adverse events and never events according to the Department of Health’s classification at the time of the study\textsuperscript{12}

2.4.2.4 PSI data collection and analysis

PSIs were recorded whilst the patient was in the endoscopy unit across pre, intra and post procedural phases of care. These were defined as follows:

- Pre-procedural (following patient admission to the endoscopy suite)
- Procedural (within the endoscopy suite)
- Immediately post-procedure (within the recovery area)

The patient’s medical record, nursing notes and endoscopy reports were also reviewed.

This methodology was optimised to enhance the sensitivity of PSI detection\textsuperscript{13,13,14} and was based on similar research undertaken in surgery\textsuperscript{15} but modified to suit the endoscopy environment\textsuperscript{16}.

PSIs were recorded per procedure and per list and were measured on a continuous scale. PSI incidence was compared between diagnostic and therapeutic cases. As a single patient could experience more than one PSI, the number of PSIs was assumed to follow a Poisson
distribution and thus the rate of PSIs per patient was considered. Comparisons between PSI incidence for diagnostic and therapeutic cases were made using Poisson regression.

Sub-group analysis was conducted for expert and trainee endoscopists. The PSIs were non-normally distributed and comparisons were made with the Mann-Whitney test. Comparisons between the three professional sub-groups of endoscopists (medical, surgical and nurse) were made using the Kruskall-Wallis test.

2.4.2.5 PSI categorisation by theme and severity
All observed PSIs were qualitatively recorded during the observation period and subsequently categorised by expert consensus (two expert endoscopists (STG and AH) and a psychologist (NS) with extensive patient safety expertise). The recorded PSIs were grouped into themes and categorised according to severity: minor, intermediate and severe defined by the actual / potential impact of the incident to the patient and adherence to accepted best practice.

2.4.2.6 Detailed analysis of PSI and educational strategies
As medical error is common and frequently multifactorial, determining the ‘root cause’ may be a misnomer as it implies a single causative factor. As outlined in Chapter 1 (section 1.3) it is important to understand the systems approach advocated by Reason\textsuperscript{17,18} when considering medical error, as causative factors can be found at the level of the individual, task, team, work environment as well as the organisation. Vincent et al provide a framework for risk analysis (The London Protocol) structured to these factors to enable an understanding of the anatomy of the error and target future preventative strategies.\textsuperscript{19 20}. The chronology of the incident must first be determined and three key concepts comprising this framework are defined:

**Care Delivery Problems (CDPs)**
These are defined as errors (actions or omissions) by individuals / teams in the process of healthcare. The action / inaction represents a deviation from accepted best practice resulting in a direct or indirect effect on the eventual adverse event. Examples include failure to observe deterioration in the patient’s conscious level, monitor vital signs and act promptly to reverse sedation.
Clinical Context

Care delivery problems can only be meaningfully interpreted in the clinical context in which they occur. Considering the sedation example above, it would seem this is an act of omission by the endoscopist who has overall responsibility. However, if this occurred in the context of an acute arterial bleed that the endoscopist was trying to manage urgently and thus had appropriately delegated monitoring of sedation but the nurse had been called away as their were staff shortages – the error is perceived differently. Understanding the clinical context is crucial to identifying the background issues feeding care delivery problems.

Contributory Factors (CFs)

As indicated in the clinical context, care delivery problems can have many contributory factors. A structure for considering contributory factors with examples is summarised:

<table>
<thead>
<tr>
<th>Contributory Factor</th>
<th>Examples</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient Factors</td>
<td>Disease severity, language barriers, psycho-social status, personal wishes</td>
</tr>
<tr>
<td>Individual factors</td>
<td>Lack of knowledge, expertise, insight to seek help</td>
</tr>
<tr>
<td>Task Factors</td>
<td>Unclear protocols, inadequate equipment, poor ergonomics</td>
</tr>
<tr>
<td>Team Factors</td>
<td>Poor communication, hierarchical barriers</td>
</tr>
<tr>
<td>Work Environment</td>
<td>High workload, inadequate staffing levels</td>
</tr>
<tr>
<td>Organisational</td>
<td>Financial resources, organisational structure, safety culture</td>
</tr>
</tbody>
</table>

This framework was used to dissect important and severe incidents observed during this study and to disseminate lessons learnt to individuals, core and wider teams. Information about the PSIs was gathered from the observational field notes, medical and nursing notes, and interviews with key individuals where possible.

2.5 Results

2.5.1 Safety Attitudes Questionnaire Study

2.5.1.1 Demographic data

Data from 29 respondents was analysed (response rate 100%). This constituted 16 endoscopy nurses, 9 medical doctors (gastroenterology trainees and endoscopy fellows) and 4 consultants (2 medical and 2 surgical).
2.5.1.2 Questionnaire Findings

Safety Check Items
All 29 respondents stated that they were aware of pre-procedural safety checks. When asked what pre-procedural checks are currently undertaken (Figure 2.1 and Table 2.1) and who is responsible for conducting them (Figure 2.2) an array of responses were obtained. The most frequently cited safety checks were consent documentation \( n=14 \) patient identity \( n=13 \) and nursing pre-assessment pro-forma \( n=10 \). The majority thought the checks were the joint responsibility of the endoscopist and the nurse \( n=18 \) and following this the admission or recovery endoscopy nurse \( n=10 \).

Figure 2.3 and Table 2.2 illustrate which safety checks staff members thought were warranted in addition to current checks.

Figure 2.1. What pre-procedural checks are currently undertaken
Table 2.1. Component responses for ‘Other’ Safety Checks

<table>
<thead>
<tr>
<th>Other Safety Checks Breakdown</th>
<th>Frequency</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alcohol / smoking</td>
<td>1</td>
</tr>
<tr>
<td>Analgesia</td>
<td>1</td>
</tr>
<tr>
<td>Bowel cancer screening pre-assessment clinic</td>
<td>1</td>
</tr>
<tr>
<td>Biopsy samples</td>
<td>1</td>
</tr>
<tr>
<td>Creutzfeldt Jacob Disease (CJD) / Infectious risk</td>
<td>1</td>
</tr>
<tr>
<td>Correct staff for procedure</td>
<td>1</td>
</tr>
<tr>
<td>Glaucoma</td>
<td>1</td>
</tr>
<tr>
<td>Haemodynamic stability</td>
<td>1</td>
</tr>
<tr>
<td>Intravenous access</td>
<td>1</td>
</tr>
<tr>
<td>Metallic prosthesis</td>
<td>2</td>
</tr>
<tr>
<td>Nursing Observations</td>
<td>1</td>
</tr>
<tr>
<td>Previous investigations (Blood tests / imaging)</td>
<td>1</td>
</tr>
<tr>
<td>Prosthetic valve</td>
<td>1</td>
</tr>
<tr>
<td>Diathermy settings</td>
<td>1</td>
</tr>
</tbody>
</table>

15
Figure 2.2. Who is responsible for completing existing safety checks?

- Referring doctor
- General Practitioner
- Administration
- BCSP*
- Endoscopist
- Admission / Recovery Nurse
- Endoscopist / Nurse

*Bowel Cancer Screening Nurse Practitioner

Figure 2.3. Which safety checks in addition to current safety checks are required?

- Other
- Medical notes
- Intravenous access
- Equipment check
- Discharge plan
- Sedation contraindications
- Therapy contraindications
- Sedation
- Bowel preparation
- Correct procedure
- Medical / Drug history
- Correct patient
- Consent form signed
- Allergies
Table 2.2. Component responses for ‘Other’ additional Safety Checks

<table>
<thead>
<tr>
<th>Other Safety Checks Breakdown</th>
<th>Frequency</th>
</tr>
</thead>
<tbody>
<tr>
<td>Resuscitation Status</td>
<td>1</td>
</tr>
<tr>
<td>Anticoagulant drugs</td>
<td>1</td>
</tr>
<tr>
<td>Advanced consent process</td>
<td>1</td>
</tr>
<tr>
<td>Analgesia</td>
<td>1</td>
</tr>
<tr>
<td>Appropriate equipment</td>
<td>1</td>
</tr>
<tr>
<td>Blood tests</td>
<td>1</td>
</tr>
<tr>
<td>Communication between staff in rooms</td>
<td>1</td>
</tr>
<tr>
<td>Communication between endoscopist and nurse</td>
<td>1</td>
</tr>
<tr>
<td>Correct follow up according to unit guidance</td>
<td>1</td>
</tr>
<tr>
<td>Endoscopist ability</td>
<td>1</td>
</tr>
<tr>
<td>Endoscopist assessment of ASA score</td>
<td>1</td>
</tr>
<tr>
<td>Endoscopists’ ‘habits’</td>
<td>1</td>
</tr>
<tr>
<td>Indication</td>
<td>1</td>
</tr>
<tr>
<td>Intravenous drugs</td>
<td>1</td>
</tr>
<tr>
<td>List of equipment needed for each therapeutic procedure</td>
<td>1</td>
</tr>
<tr>
<td>Endoscopy list order</td>
<td>1</td>
</tr>
<tr>
<td>Medical status on day of procedure</td>
<td>1</td>
</tr>
<tr>
<td>Points on list</td>
<td>1</td>
</tr>
<tr>
<td>Permanent pacemaker</td>
<td>1</td>
</tr>
<tr>
<td>Reports from previous procedure</td>
<td>1</td>
</tr>
<tr>
<td><strong>Sum</strong></td>
<td><strong>20</strong></td>
</tr>
</tbody>
</table>

Teamwork Items

Nine respondents (2 surgical consultants, 1 medical consultant and 6 nurses) had heard of the WHO Surgical safety checklist and 20 had not. On questioning whether a safety checklist would be useful for endoscopy all 29 respondents thought it would be useful in emergency and therapeutic procedures and 26 / 29 respondents thought a checklist would be useful for elective procedures. When questioned if there was a consistent escalation point should a problem arise during a list, 13 respondents stated there was and this designated person was the nurse in charge (n=5), nurse in the room (n=4) a senior endoscopist (n=4) but not the unit manager (n=0). Lastly, respondents were asked the names of the staff members they had just completed a list with. Twenty-five respondents knew the names of all staff members in the
room, 2 respondents knew some of the names and 2 were unaware of any of their team members’ names.

Free text comments were analysed and the following qualitative themes deduced:

- Additional safety checks are not required if existing checks are conducted fully (R3, R7, R14)
- Escalation point depends on the problem (R3, R9, R20)
- What people state they check and what they actually check in practice differs (R7, R15, R19)
- Nursing staff are more likely to introduce themselves to the patient compared to endoscopists (R2, R10)

2.5.2 Prospective observational study of Patient Safety Incidents (PSIs) in Endoscopy

2.5.2.1 Demographic data and Study Participants

One hundred and forty endoscopic procedures were observed over 37 lists. Procedures included upper and lower GI endoscopy and were both diagnostic (n=92) and therapeutic (n=48) and conducted by medical, surgical and nurse endoscopists (Figure 2.4). Endoscopy lists were carried out by experts (n=25) defined as medical surgical and endoscopy nurse consultants and trainees (n=12), all other doctors of non-consultant grade i.e. gastroenterology and surgical registrars and endoscopy clinical fellows. The observed endoscopy lists were conducted by 22 different endoscopists from medical, surgical and nursing backgrounds (Figure 2.5). The study participants included the endoscopist, endoscopy nurses and the patient undergoing the procedure.
**Figure 2.4.** Endoscopy lists observed by speciality of the endoscopist

**Figure 2.5.** Endoscopy lists observed by speciality and expertise of the endoscopist
2.5.2.2 Incidence of PSIs

A total of 140 PSIs were identified (median 1.0 range 0-7 per procedure). Fifty-four (39%) PSIs were recorded within the 92 diagnostic cases and 86 (61%) within the 48 therapeutic cases. This represented 0.59 PSIs per procedure for diagnostic and 2.95 PSIs per procedure for therapeutic subtypes. Significantly more PSIs were observed in therapeutic endoscopy cases (p =<0.001) (Table 2.3).

Table 2.3. PSI Incidence according to diagnostic and therapeutic procedure subtype

<table>
<thead>
<tr>
<th>Procedure Subtype</th>
<th>Number of PSIs</th>
<th>Number of procedures</th>
<th>PSIs per procedure</th>
<th>Ratio Estimate (95% CI)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diagnostic</td>
<td>54</td>
<td>92</td>
<td>0.59</td>
<td>1</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Therapeutic</td>
<td>86</td>
<td>48</td>
<td>1.73</td>
<td>2.95 (2.09, 4.15)</td>
<td></td>
</tr>
</tbody>
</table>

Experts encountered a median of 2 PSIs per list (IQR 1,5) and trainees a median of 6 (IQR 2,8) p = 0.03. The median PSI per list and IQR for professional sub-groups of endoscopists was 2 (1,4) for medical endoscopists 2 (1,6) for nurse endoscopists and 6 (5,9) for surgical endoscopists p=0.009.

Five out of the 31 lists observed had no PSIs – these comprised 13 diagnostic procedures in total. Four out of five of these lists were performed by endoscopists who were consultants and the fifth a senior endoscopy fellow.

Twenty-one (15%) PSIs were categorised as severe and 12 (9%) had the potential to be never events. 40 (28%) of PSIs were classified as intermediate and 78 (56%) as minor (Figure 2.6). One PSI was an anticipated procedural complication of a haemorrhage requiring a repeat endoscopy under General Anaesthetic with a successful clinical outcome and was not classified within this system following expert consensus. This was the only PSI for which an incident form was submitted to the hospital reporting system by the clinical team.
2.5.2.3 Severe PSIs and Never Events

Twenty-one (15%) of the observed PSIs were categorised as severe and just over half of these (n=12) were also never events (Table 2.4). Severe errors fulfilling the never events criteria included patient misidentification and sub-optimal administration / monitoring of sedation.

In accordance with Reason’s model, severe PSIs were frequently associated with minor predecessor PSIs and this is detailed in an example of multiple PSIs observed in a single patient (Figure 2.7).

2.5.2.4 Intermediate and Minor PSIs

The majority of observed PSIs were categorised as intermediate and minor severity. Examples of intermediate PSIs included a sedated patient on a trolley with the side rails down, excess sedation† in an elderly patient with no reversal agent administered and omission of intravenous sedatives administered on the endoscopy report (documented in the nursing proforma). Minor PSIs included a nurse assistant not suitably trained in polypectomy assisting in a complex high risk case, endoscopist asking for ‘usual diathermy settings’ as

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* Defined according to BSG guidance of maintaining verbal contact with sedated patient throughout the period of conscious sedation. [BSG guidance link]
unfamiliar with equipment and the endoscopy report stating procedure performed by consultant (absent) instead of the trainee

**Figure 2.7.** ‘Swiss Cheese’ model illustrating the coalition of minor errors leading to significant Patient Safety Incidents (PSIs) in one observed case. (Image adapted from Reason\textsuperscript{18} and Runciman\textsuperscript{21})

**Table 2.4.** Severe PSIs and proportion of Never Events

<table>
<thead>
<tr>
<th>PSI Detail</th>
<th>Severity of PSI</th>
<th>Never Event Y/N</th>
<th>Frequency</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient misidentification resulting in incorrect procedure</td>
<td>3</td>
<td>Y</td>
<td>1</td>
</tr>
<tr>
<td>Sedation with no oxygen</td>
<td>3</td>
<td>Y</td>
<td>2</td>
</tr>
<tr>
<td>Sedation with no oxygen saturation monitor</td>
<td>3</td>
<td>Y</td>
<td>6</td>
</tr>
<tr>
<td>Sedated patient in corridor unmonitored</td>
<td>3</td>
<td>Y</td>
<td>2</td>
</tr>
<tr>
<td>Recovery in corridor unattended and prolonged as waiting for porter to transfer to ward. (No dedicated recovery and nurses in procedure room changing kit)</td>
<td>3</td>
<td>Y</td>
<td>1</td>
</tr>
<tr>
<td>Wrong drug administered – additional Midazolam instead of requested Pethidine</td>
<td>3</td>
<td>N</td>
<td>1</td>
</tr>
<tr>
<td>Wrong patient details on endoscopy report (similar surnames)</td>
<td>3</td>
<td>N</td>
<td>1</td>
</tr>
<tr>
<td>PSI Detail</td>
<td>Severity of PSI</td>
<td>Never Event Y/N</td>
<td>Frequency</td>
</tr>
<tr>
<td>---------------------------------------------------------------------------</td>
<td>-----------------</td>
<td>-----------------</td>
<td>-----------</td>
</tr>
<tr>
<td>Wrong details on patient report (incorrect patient details) picked up on ward</td>
<td>3</td>
<td>N</td>
<td>1</td>
</tr>
<tr>
<td>Inadequate supervision of trainee (supervisor largely absent due to dual commitments, present for one case, distracted, trainee out of depth)</td>
<td>3</td>
<td>N</td>
<td>4</td>
</tr>
<tr>
<td>Procedure performed by a trainee required a Consultant</td>
<td>3</td>
<td>N</td>
<td>2</td>
</tr>
<tr>
<td>Post-polypectomy haemorrhage requiring re-scope under GA and an overnight admission</td>
<td>*</td>
<td>N</td>
<td>1</td>
</tr>
</tbody>
</table>

* This PSI was not categorised within this scoring system, as it was a recognised complication of the procedure with a good clinical outcome.

### 2.5.2.5 Incidence of PSIs according to key themes

In addition to coding PSIs by severity thematic categorisation was also undertaken. PSIs were classified into 9 broad groups:

1. Oxygen monitoring
2. Distractors and time management
3. Non-technical skills and training
4. Documentation and reporting errors
5. Technical skills and equipment handling
6. Sedation, intravenous access and monitoring
7. Drug errors
8. Consent related issues
9. Histology and sampling errors.

The frequency and severity of PSIs within these categories is summarised in Figure 2.8. The theme with the greatest number of severe PSIs was oxygen monitoring (n=8) followed by non-technical skills and training issues (n=7).
2.5.2.6 Detailed analysis of PSI and educational strategies

A systems approach was adopted by using Vincent’s London Protocol\(^\text{19}\). This framework was used to dissect important and severe incidents by identifying care delivery problems within clinical context and contributory factors (defined in section 2.4.2.6). The following sections illustrate two examples where the error analysis framework was used and how educational strategies were tailored appropriately.

2.5.2.6.1 Patient misidentification and ‘wrong-site’ procedure

**Chronology of Events**

Two never events occurred during this patient’s procedure: a different patient to the one that was intended was in the procedure room and technically the wrong procedure was attempted (See Figure 2.6 for overview). The endoscopy nurse called the patient by her surname from the waiting area (patient A) but a different patient (patient B) with a similar sounding surname stood up and followed the nurse into the procedure room. There were
no further attempts to verify the complete patient details including the procedure and indication (patient B). The team in the room were under the assumption that they were doing a colonoscopy (patient A) when the patient in the room was booked and consented for a flexible sigmoidoscopy (patient B). Patient B was elderly, had a heart rate of 100 and received intravenous medication (midazolam, pethidine and buscopan) that would not normally be administered for a flexible sigmoidoscopy. The endoscopy team realised the patient misidentification and wrong site procedure errors when they came across solid stool in the descending colon and were not able to proceed with the intended ‘colonoscopy’. They questioned the patient on adequacy of bowel preparation and the patient explained she had not received full bowel preparation but an enema in the unit. The mismatch between the patient identity (patient B) and the medical notes in the room (patient A) was realised at this point. The procedure was then terminated after the patient’s recto-sigmoid bowel had been examined. Patient B did not have an escort with her and required an extended period of recovery whilst suitable arrangements were made to discharge her safely home.

**Care Delivery Problems (CDPs)**

In analysing this incident the CDPs identified included an inadequate initial patient identification check. This was coupled with sub-optimal review of the medical and nursing notes and sub-optimal safety practices around intravenous sedation use.

**Clinical Context**

These care delivery problems occurred in the context of this endoscopy list being conducted by a relatively junior trainee. The endoscopist was new to the department and despite attending the endoscopy induction, was not familiar with the usual unit practices and patient flow. There was variability amongst endoscopists and nurses as to whom will track the progress of the list and monitor patient flow (e.g. list order, cancellations, room swaps). Similarly there was variability as to which team member will call the patient from the waiting area. Furthermore, this list had started late due to a complex procedure over-running from the morning list and there was pressure on the afternoon team to ‘catch up’.
Contributory Factors

The contributory factors to the care delivery problems in this incident are summarised:

<table>
<thead>
<tr>
<th>Contributory Factor</th>
<th>Detail</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient Factors</td>
<td>Patient B elderly and hard of hearing mistook patient A’s surname as her own</td>
</tr>
<tr>
<td>Individual Factors</td>
<td>Inadequate patient identification by nurse collecting patient from waiting room, nurse in endoscopy room and endoscopist Sub-optimal review of patient’s vital signs, need for sedation and patient preferences</td>
</tr>
<tr>
<td>Task Factors</td>
<td>Lack of clear protocol on when, where and whom should conduct patient identification checks leading to variable practice. Failure to identify high resting heart rate, review blood pressure and consider need for drugs</td>
</tr>
<tr>
<td>Team Factors</td>
<td>Inadequate review of pre-procedure information (medical notes, consent form, patient risk factors, procedure, indications, escort etc.)</td>
</tr>
<tr>
<td>Work Environment</td>
<td>Late running of lists due to scheduling and nursing staff availability and consequent time pressure. Patients often move between lists to improve efficiency which can cause confusion if not clearly communicated Noisy waiting room area</td>
</tr>
<tr>
<td>Organisational</td>
<td>Financial resources</td>
</tr>
</tbody>
</table>

Outcomes

There was no actual significant harm to the patient as a result of these PSIs. Clinically there were no complications from the sedation or the procedure. The patient was informed that there had been an error in documentation in that the wrong medical notes were in the room.

The nurse in charge was informed at the end of the list and this PSI was then escalated to the Clinical Lead for Endoscopy. Following a review of the medical and nursing notes, the clinical lead tasked researcher (MM) to analyse the PSI in detail, organised a meeting with the trainee endoscopist to identify their concerns and provided appropriate clear feedback. The clinical lead also ensured the endoscopy nursing lead met with the nurse who called the patient initially from the waiting area. Appropriate feedback was provided and the importance of checking the full patient identification with the wristband highlighted. Additionally it was emphasised this was not a blame seeking exercise, and the initial identification error was not the only causative factor as further opportunities to verify the patient details were also overlooked.
The case was presented at the endoscopy users meeting (internal Governance) in an open and anonymised fashion to promote learning and not to blame individuals involved.

**Prolonged procedure**

A 60-year-old patient was referred for a tertiary opinion. Initial symptomatology included a change in bowel habit and endoscopic and histological evaluation confirmed a very large benign, tubulovillous adenoma situated in the ano-rectum. Subsequent discussions at the local colorectal multi-disciplinary meeting suggested the patient should undergo transanal endoscopic micro-surgery (TEMS) and failing that more extensive surgery in the form of an abdomino-perinal (AP) resection. The patient was quite concerned about having such extensive surgery for a benign lesion and sought a second opinion through his general practitioner. A tertiary colorectal surgical opinion was requested and the advice given was tertiary endoscopic assessment and evaluation of endoscopic resection should be considered.

**Chronology of Events**

A diagnostic flexible sigmoidoscopy was undertaken by an expert endoscopist who identified an 8cm LST-G‡ (Isp +IIa) with large nodules extending from the anal canal and occupying 2/3 of the bowel circumference. This lesion was thought to be benign and endoscopically resectable by endoscopic sub-mucosal dissection (ESD). It was advised that the MRI rectum and CT scans conducted locally should be reviewed in the tertiary colorectal MDT.

The therapeutic ESD was planned and started at 1345. Senior, experienced nurses were scheduled to be in the room and no further cases were booked on the list. At the end of the nursing shift, the procedure was on-going and an endoscopy clinical fellow, nurse endoscopist and a senior endoscopy nurse stepped in to assist. The procedure continued overnight and was terminated approximately 16 hours later at 0900 by the clinical lead for endoscopy. The lesion was 90% resected, and the patient was clinically stable though had required blood transfusions, fresh frozen plasma (FFP) and gelofusin overnight to maintain his blood pressure and haemoglobin. A senior endoscopist assessed the situation and advised the procedure should be stopped on clinical grounds (prolonged procedure time, patient discomfort, DVT risk and background of sleep apnoea requiring CPAP). It was advised surgical and anaesthetic opinion be sought and the patient booked for a General Anaesthetic.

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‡ LST-G: Laterally spreading tumour – Granular subtype
(GA) the following day to consider surgical resection. The patient was informed and agreed to this plan but preferred endoscopic to surgical resection.

The residual polyp was removed under general anaesthetic by ESD within 3 hours, 48 hours after the index procedure. The histology from the resection showed tubulovillous adenoma with low-grade dysplasia only. The patient made an uneventful recovery and was discharged the day after the completed resection.

The patient underwent follow up flexible sigmoidoscopy 3 months later with no signs of recurrence and a patent rectum with no narrowing of the lumen from scarring. The patient complained of some urge incontinence at this stage. A follow up colonoscopy scheduled 6 months later was also unremarkable and the patient regained good control of his symptoms having been referred to the biofeedback service following consultation in the colorectal clinic. The patient was discharged from the tertiary colorectal clinic and remains under endoscopic surveillance at a 3-yearly interval.

**Care Delivery Problems**

The main CDP in this incident is an unplanned prolonged endoscopic procedure. This was conducted in the endoscopy unit under conscious sedation with no anaesthetic input. Whilst the patient was monitored regularly by the assisting team and supportive measures taken (intravenous fluids and blood products) this was beyond normal protocol. Following the event, it became apparent the nursing team had concerns but did not adequately escalate these. The decision-making processes may well have been affected by fatigue and there was no overall escalation strategy (on call anaesthetic and surgical team) as the team felt the procedure was progressing adequately and the lead endoscopist did not anticipate the ongoing extensions in time required to resect the lesion.

**Clinical Context**

This incident is complex as the patient received the intended outcome (endoscopic resection under sedation) and avoided an invasive surgical resection. Despite the significant risks of endoscopic resection of such a large, villous lesion the patient remained clinically stable.

Following in-depth interview analyses with four main team members (lead endoscopist, endoscopy fellow, nurse endoscopist, assisting endoscopy nurse) an important influence expressed by all members was the patient’s clear preference to have endoscopic resection
over surgical intervention. Moreover, the patient’s observations remained stable and he was given the opportunity to pause and have a break but was happy for the resection to resume.

The unintended consequences from this PSI were that the clinical lead had to make arrangements to cancel / cover other scheduled cases for that morning as the team were not able to safely continue further endoscopy not having had a break for over 24 hours. This illustrates the negative ‘knock on effects’ of one PSI to the care of other patients.

**Contributory Factors**

The contributory factors to the care delivery problems in this incident are summarised:

<table>
<thead>
<tr>
<th>Contributory Factor</th>
<th>Detail</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Patient Factors</strong></td>
<td>Patient preference to avoid surgery&lt;br&gt;Large ano-rectal lesion presenting complex endoscopic management&lt;br&gt; Comorbidity of sleep apnoea requiring CPAP potentially an issue with prolonged unmonitored sedation</td>
</tr>
<tr>
<td><strong>Individual Factors</strong></td>
<td>Determination of endoscopist to complete procedure&lt;br&gt; Determination of experienced senior team to assist and support endoscopist&lt;br&gt; Technically challenging, stimulating and rewarding case&lt;br&gt; Prolonged procedure and fatigue likely to affect decision making and technical skill.&lt;br&gt; Single endoscopist conducting procedure overnight as specialised technique&lt;br&gt; Differences in endoscopy training mean prolonged ESD acceptable in endoscopists country of training</td>
</tr>
<tr>
<td><strong>Task Factors</strong></td>
<td>Highly complex, high risk challenging lesion&lt;br&gt; Significant cognitive and visual-motor work load&lt;br&gt; Important to assess for malignancy macroscopically&lt;br&gt; Endoscopist under-estimated true size of lesion and did not account for extra time required to deal with concomitant bleeding&lt;br&gt; Potentially high risk bleeding to be managed proactively&lt;br&gt; No clear unit policy on ESD procedures (No Plan ‘B’)</td>
</tr>
<tr>
<td><strong>Team Factors</strong></td>
<td>Collaborative supportive team-working&lt;br&gt; No questioning of lead endoscopists decision-making?&lt;br&gt; Possible deference to senior endoscopist?&lt;br&gt; Team fatigue and reduced situation awareness&lt;br&gt; Procedure continued overnight without communicating to other relevant teams (site manager, anaesthetist, surgeon, haematologist)</td>
</tr>
<tr>
<td><strong>Work Environment</strong></td>
<td>Not adequately staffed for overnight work and potentially problematic in context of an emergency developing.</td>
</tr>
</tbody>
</table>
Outcomes

This incident was reviewed by the endoscopy clinical lead who learned of the prolonged procedure coincidentally whilst arriving to conduct a scheduled list that morning. This individual provided a fresh pair of eyes on the clinical situation and was able to assess the range of risks to the patient, the team and the unit. Effective leadership enabled decisive actions to be taken and relevant communication with the patient, endoscopist and allied teams (anaesthetists, colorectal surgeons).

The incident was discussed at the internal endoscopy executive meeting and a unit protocol devised to give clear guidance on ESD planning and limitations. The clinical lead debriefed the endoscopist to encourage reflection on patient factors, decision-making and managing endoscopic risk.

This incident had gravitas, as it was a relatively unique incident that had not previously been encountered in the unit. Furthermore, there was no actual harm to the patient yet senior team members thought the patient had been put under undue risk to complete the resection endoscopically for a benign lesion. This also had a significant effect on the senior team involved in the procedure who felt they had acted in the patient’s best interest. An interview analysis was conducted with the core team conducting the procedure: Lead endoscopist (LE), endoscopy fellow (EF), nurse endoscopist (NE) and assisting endoscopy nurse (AN). Key themes from this interview are summarised.

- The patient was clinically stable throughout the procedure (LE, EF, NE)
- Appropriate clinical measures were taken i.e. fluids and blood products (LE, EF, NE)
- The patient was given the choice by the endoscopist§ to stop but was happy to proceed (EF, NE, AN)
- The lesion seemed to be near completion but was bigger than initially thought and took longer to deal with bleeding (LE)
- It is acceptable to take this long to do an ESD for a lesion of this size (LE)
- There was good will to support the endoscopist to achieve the resection hence we assisted out of hours (AN, NE)

§ Although the patient was not consented for a procedure of this duration under conscious sedation
There was heavy criticism in the morning despite the clinical situation being under control and the patient stable (LE, EF, NE)

The decision-making was appropriate and I would not change my actions in retrospect (EF)

2.6 Discussion

2.6.1 Questionnaire Study Summary

The questionnaire study findings showed full awareness of pre-procedural safety checks but wide variation in what constituted these checks. As a result there was overlap in responses when asked what pre-procedural checks are in place and which additional checks are required. The responsibility for conducting safety checks was most frequently cited to be the endoscopist and the nurse (18 responses). One third of responders were aware of the WHO surgical safety checklist but there was universal agreement that a similar checklist in endoscopy would be useful for emergency and therapeutic procedures. The majority of responders (90%) thought it would also be useful in elective endoscopic procedures. Fifty-five per cent of responders did not have a clear escalation point if a problem arose in the room. The 45% of responders who had a clear escalation point stated this would be the nurse in charge (5 responses), the nurse in the room assisting with the procedure (4 responses) or a senior endoscopist (4 responses). The majority of responders (86%) knew all the names of the team members they had just conducted a list with.

2.6.2 Patient Safety Incidents Summary

This study supports the premise that patient safety incidents occur frequently in endoscopy. The PSIs documented in this study are diverse. They constitute individual error, sub-optimal team performance, task related problems, resource constraints generating conflicting demands as well as individual and organisational attitudes towards risk and patient safety culture. This reinforces the need to adopt a systems approach when considering the causes and consequences of error.

Sub-group analyses showed there were almost three times as many PSIs in therapeutic cases compared to diagnostic and 75% (36/48) of therapeutic cases were completed by experts in this series. Overall however, PSIs were lower for experts compared to trainees. The number of PSIs per list was highest in the surgical group compared to medical and nurse endoscopists and may reflect training disparities, senior supervision or volume of procedures.
Twelve of the 22 severe errors fulfilled never events criteria although there was no significant clinical harm to the patients identified during the study. The majority of observed PSIs were categorised as minor and often there were no immediate consequences. Given that major patient safety incidents frequently arise from a series of minor errors, this is important to address if the emphasis is on error prevention. Additionally, avoiding minor PSIs enables teams to focus their time and attention on more significant issues such as technical performance, team leadership and managing unexpected complications.

Considering the frequency of PSIs across themes, oxygen-monitoring errors occurred most frequently with a similar proportion of mild, intermediate and severe PSIs within this group. This category also had the highest number of severe PSIs, highlighting that basic monitoring of oxygen saturations remains an under-utilised safety opportunity with further measures required to ensure adherence to established guidance on safe sedation and oxygen monitoring.

It is accepted that the focus for adverse events should shift from that of ‘reporting’ to ‘understanding’ the multifaceted reasons why an error occurred, ensuring accountability and how future error may be prevented. In depth analyses of significant errors with a validated error analysis framework identifies issues broadly and enables detail to be examined in clinical context. These analyses support influential learning opportunities for the individual, team, unit and wider hospital governance and by placing the error in the systems context, shifts the focus from individual blame.

2.6.3 Questionnaire Study Implications

The questionnaire findings indicate that there is wide variability amongst endoscopy users as to which pre-procedural endoscopy safety checks should be carried out. This reflects the variability in endoscopic practice and lack of clarity regarding a protocol for safety checks. Consequently, there was no clear consensus on whose responsibility it is to ensure these safety checks are adequately completed. In response to this endoscopy users agreed that an endoscopy safety checklist had a role. The majority of responders were not aware of a designated person to escalate problems arising in the room. Those that did have a clear escalation point varied in their responses as to whom this was and stated it was variable according to the problem. In an urgent situation there may not be sufficient time to gather this information and make appropriate decisions, and indeed this would be the role of the
designated individual who is not directly involved in the procedure itself. Interestingly, the majority of responders knew the names of their team members but tended not to use them whilst communicating / issuing instructions or making requests during the procedure. In summary, this questionnaire study illustrates that endoscopy users have variable opinions on what essential safety checks should be conducted. This may be due to individual variation in practice and an unclear unit policy. It should be acknowledged that the safety climate may have changed during the course of this study and therefore these findings may not accurately reflect current thinking. Appropriate endoscopy safety checks serve to identify and mitigate error and a clear strategy is required to ensure procedures are carried out safely and efficiently. The implications for the endoscopy team by missing an opportunity to standardise this process are increased cognitive load by managing consequent errors and inefficiency. The implication for patients of variable safety checks is that some patients are potentially exposed to avoidable error.

2.6.4 Patient Safety Incidents Study Implications

Whilst endoscopy safety and quality has undoubtedly improved for patients, avoidable error remains prevalent and under recognised. Unit policies and protocols relating to many of the observed PSIs were already in place at the time of the study but not necessarily adhered to (i.e. oxygenation pre-sedation and supervision of trainees). Whilst important for safety culture, the existence of safety protocols will not fully safeguard against PSIs unless coupled with other contemporaneous safety and teamwork educational measures.

The risks associated with therapeutic procedures should not be under-estimated and reflected appropriately in the consent process for the patient. Trainees encountered more PSIs and this has an impact on service provision, senior supervision and on-going training opportunities beyond independent practice. Unless there are regular and sustained feedback opportunities separate to ‘basic training’ low-level errors are perpetuated. This study shows that PSIs occur across medical, surgical and nurse endoscopists with a range of experience. Although PSIs occurred across specialties, this series showed a higher number of PSIs in surgical lists. This finding may reflect training disparities, senior supervision or volume of procedures conducted. Importantly, it emphasises that targeted training needs to encompass this broad group of endoscopists to improve quality and patient safety.
Considering the severe errors, 12 / 22 fulfilled the never events criteria at the time including patient misidentification and wrong site procedure (Figure 2.6) both occurring in a single procedure. There was no significant harm to the patient and critics will state that the patient had the left side of their colon imaged as intended and therefore this was not a ‘wrong site procedure’. However, these errors highlight the multiple systems failures in checking essential, critical patient information as a significant problem: There was no uniform standard for confirming the patient identity. This PSI would be perceived to be more consequential if a Percutaneous Endoscopic Gastrostomy (PEG) had been inserted instead of an Oesophago-Gastro Duodenoscopy (OGD) for example, yet the systemic latent failures whereby both these errors occur is the same.

Oxygen monitoring and associated sedation safety PSIs were prevalent within the severe category. Whilst sedation practices and guidance vary internationally with conscious and deep sedation options for certain patients and procedures\(^{24-26}\) there remains variability regarding administration and monitoring of sedation by a dedicated anaesthetist. Clearly this would enhance safety and sedation, but anaesthetic support is not universally available for all endoscopy in the UK and hence sedation selection, administration, titration and monitoring are key safety issues for the endoscopist to be aware of, even if allied team members are available to monitor this.

Non-technical skills and training related PSIs were the next most prevalent group followed by distractors and time management related PSIs. Endoscopy non-technical skills training although feasible\(^{27}\) (Chapter 5) and considered important\(^{28}\), is not yet explicitly formalised within existing training programmes, accreditation processes or quality assurance measures. This is increasingly recognised as an important component of high quality practice within screening colonoscopy for example\(^{29}\) and would be a mechanism to reduce PSIs related to non-technical skills and teamwork.

Interview analyses with team members’ involved in incidents provides a valuable insight into the evolution of error when coupled with error analysis tools. Additionally, this is a valuable opportunity to identify the personal and professional ramifications for the endoscopist and consider the effectiveness of coping mechanisms and further support in the form of mentorship for example. Research in surgery evaluating the impact of surgical complications on surgeons’ well-being suggest this is overlooked professionally and institutionally.\(^{30}\)
More important than defining the incidence of error, this study precipitated several actions to ensure that lessons were learnt. Clearly optimising patient management and responding to the patient (and their family)\textsuperscript{31} is key and more likely to occur when the PSI is considered to be severe (high immediacy and causality) or require further corrective action. Educating multi-disciplinary Endoscopy teams about the occurrence and future prevention of error is a key outcome of this study. It serves to raise awareness on error and risk management in endoscopy in a clinically relevant manner. Such approaches contribute to forming a safety culture, which in time may encourage endoscopy providers to speak up about error. This study illustrated wide variation in pre-procedural safety checks with consequent PSIs as routine checks were overlooked or not shared with the relevant team members. Escalation of these issues to the internal endoscopy governance meetings, bowel cancer screening unit quality assurance as well as the wider hospital governance process prioritised development of an endoscopy safety checklist.\textsuperscript{32} This intervention would ensure essential baseline checks are conducted by the endoscopy team in the room in conjunction with the patient.

2.6.5 Limitations

2.6.5.1 Questionnaire Study Limitations
The limitations of this study are that it was conducted in a single centre with a modest number of respondents. In addition, the safety checks that responders state they would conduct are not necessarily carried out in practice.

2.6.5.2 PSI Study Limitations
The limitations of this study include no long-term follow up data of patient outcomes with regard to morbidity, hospital re-attendance and mortality. Similarly, it is difficult to demonstrate causality between PSIs and negative patient outcomes due to a number of confounding factors. Also as this is a single centre experience it raises the question about the generalizability of the results to other procedures in other units. Furthermore the Hawthorne effect\textsuperscript{33} whereby subjects alter their behaviour in response to being observed may have influenced practice. If this was a significant and sustained effect, one may have expected a reduction in errors, as endoscopy teams may have been more careful in their practice knowing that they were being observed. It should also be noted that endoscopists categorised to the trainee sub-group represent a broad range of skill and experience from junior registrars to pre-consultant endoscopy fellows. Finally, the sub-group analyses for trainees, experts and
specialty should be interpreted in the context of limited numbers within each sub-group as the study was not sufficiently powered to examine these differences.

2.6.6 Future work

Future work should focus on understanding endoscopy users’ opinion on safety checks and endoscopy errors on a wider scale. This could be conducted as a nation-wide questionnaire study in alliance with existing endoscopy quality assurance mechanisms such as the Global Rating Scale (GRS) and the Joint Advisory Group for Endoscopy (JAG). Alternatively this could be disseminated through the British Society of Gastroenterology regional educational meetings. Further work could identify and understand opinions of endoscopy sub groups (trainees / consultants / physicians / surgeons / nurses) in order to unify the process for the entire team and ultimately the patient. Some would argue that gathering this information is unlikely to make an impact, as there is already an understanding that safety checks are variable and that a uniform standard of care across the board should be in place.

Understanding the incidence and type of PSIs on a larger scale will define the extent and the scale of the issue. In order to achieve this, the PSI study could be replicated in other units to provide a representative sample of endoscopy in the UK to identify common problems for endoscopy as well as unit specific ones enabling targeted self-improvement alongside existing GRS measures. Current work towards developing a National Endoscopy Database (NED)\textsuperscript{34} will enable prospective automated data collection from endoscopy reporting systems and likely to be a useful tool for collating and learning from adverse events. Replicating the study internationally would provide a large error database that can be scrutinised by professional bodies and measures implemented to improve endoscopy on a large scale.

Ultimately creating a national framework for reporting error that is deemed useful to clinical endoscopy teams will provide an accurate reflection of important safety issues within the changing face of endoscopy patients, techniques and services and should be developed within existing GRS and JAG quality assurance mechanisms.

This study has not examined the impact of error on endoscopists and endoscopy nurses, although this theme was identified during the interview analyses. This is an important aspect of quality assurance, as the negative effects of stress, fatigue and ‘burn-out’ associated with error\textsuperscript{35} can have an adverse effect on clinical performance\textsuperscript{36} aside from the personal distress.
Further work will address the question as to whether patient safety incidents and never events in endoscopy can be reduced by implementing a pre-procedural endoscopy safety checklist by unifying the team to conduct a standard set checks.

2.7 Conclusion

In conclusion, this chapter has identified patient safety issues in a tertiary endoscopy unit by means of two studies. Firstly, it was identified that endoscopy users opinion on safety checks and teamwork was highly variable with little consistency in approach. Secondly, patient safety incidents occur frequently in routine practice, and often remain ‘invisible’ to the system unless there is immediate high impact to the patient or the team. Whilst many of the observed errors were without immediate serious consequence, they represent latent failures and thus provide a golden opportunity to intervene proactively. Furthermore, patient safety incidents have ramifications beyond the patient and some consider ‘doctors to be the second victims of medical error’.

Managing error effectively is important for the patient, the endoscopy team, the unit and the organisation as a whole when considering efficiency.

The long-term goal should focus on accurate, relevant and transparent endoscopy patient safety incident reporting at an individual and unit level. From this a national database of PSIs could be collated and provide a mechanism to disseminate lessons learnt more widely, thereby further enhancing quality and patient safety in endoscopy. Helmreich summarizes the error troika, by stating the first aim is to avoid error, secondly to trap error and lastly to mitigate the consequences of error when they do occur. The next chapter presents a prospective observational study evaluating endoscopy teamwork to further contextualise patient safety incidents.
Chapter 3: Identifying and Measuring Factors Affecting Patient Safety in Routine Endoscopy Teams

3.1 Chapter Overview

The previous chapter illustrated the wide array of patient safety incidents that occur in routine endoscopic practice. Thematic analysis and qualitative data indicated that teamwork interactions were frequently implicated in the aetiology of error. This chapter explores these issues in greater detail by evaluating the endoscopist’s technical and non-technical performance in the context of teamwork and safety behaviours. This is achieved by prospective observations of endoscopy teams conducting an array of gastrointestinal endoscopic procedures. An introduction to teamwork and non-technical skills in endoscopy is presented followed by the study aims and methodology. The study findings are discussed and implications for future quality improvement in endoscopy outlined.

3.2 Introduction

3.2.1 Complexity of endoscopy

Endoscopy as a skill is a complex procedure and can become more complex due to the unpredictability of individual patients and endoscopy operator variability. This complexity is magnified when one considers the endoscopy team processes within a unit providing a service. Endoscopy service provision is challenging, and requires careful orchestration of individuals, multi-disciplinary teams and complex pathways to ensure the patient at the centre receives effective, compassionate and safe care.

3.2.2 Endoscopic non-technical skills – definitions and relevance

Non-technical skills are defined in Chapter 1 (section 1.4.3) as the inter-personal and cognitive skill set that complement and often enhance technical performance. Features of non-technical skills include communication skills, situation awareness**, leadership, followership, judgement, decision-making, planning, preparation and prioritisation, managing stress and fatigue effectively amongst other attributes. Non-technical skills are closely interconnected with teamwork. Furthermore, non-technical skills often feature highly in expert medical practice and form an important part of professionalism. Identification, ** Situation awareness refers to an individual’s perception and understanding of their dynamic environment. 1. Wright MC. Objective measures of situation awareness in a simulated medical environment. Quality and Safety in Health Care 2004; 13: i65-i71
measurement and training in non-technical skills has the potential to enhance patient care and this is considered specifically for gastrointestinal endoscopy.

Previous qualitative research\textsuperscript{2} adopted formalised scientific methodology under the theme of cognitive task analysis to identify key non-technical skills for endoscopy. This included a knowledge audit with expert focus groups, sorting and rating tasks, semi-structured interviews, critical incident analysis and thematic analysis to code for key non-technical skills and thus develop a taxonomy specific to endoscopy\textsuperscript{2}. From this an endoscopic non-technical skills rating tool was developed.\textsuperscript{3} This framework comprises four main categories (communication and teamwork, situation awareness, leadership, judgement and decision-making) and thirteen elements with exemplar behaviours. This tool enables objective evaluation of endoscopist’s non-technical skills within their teams (appendix 2.2).

### 3.2.3 Non-technical and technical skills

Non-technical and technical skills are often considered to be polar skill sets when in fact there is a complex interplay between the two. The ways these skills are considered in the literature and evaluated in practice reinforces this stance.\textsuperscript{4} Furthermore, it is important to consider the interaction between the two skill sets, as enhancing specific non-technical skills through training may positively enhance technical skills acquisition and development. The importance of the interdependence of these skill sets is often more pronounced in the crisis setting \textsuperscript{5} but likely to be relevant in routine procedures too for example in team situation awareness to avert a crisis. Studies in the surgical literature\textsuperscript{6,4} acknowledge this question but this is yet to be explored in detail in endoscopy.

### 3.2.4 The endoscopy team and patient centeredness

Chapter 1 illustrated how existing endoscopy quality assurance mechanisms are well developed for the individual endoscopist and the endoscopy unit through GRS databases and JAG accreditation measures. Team goals, task coordination, performance and feedback are less clearly developed and not currently assessed as part of the accreditation mechanisms. This study seeks to address this by focussing on teamwork qualities in the context of delivering patient centred care. Endoscopy patient safety is analysed in the context of teamwork, technical and non-technical skills as these three factors are key components of quality.
3.3 Aims

This study primarily aimed to systematically evaluate three main variables in the context of endoscopy teamwork:

a. Safety checks for endoscopic procedures
b. Technical skills of the endoscopist
c. Non-technical skills of the endoscopist

Secondary aims addressed the relationship of safety checks with technical and non-technical skill. Patient safety incidents were also evaluated in relation to the other variables.

3.4 Methods

3.4.1 Study Design

This was a prospective observational study in a single tertiary endoscopy unit (The Wolfson Unit for Endoscopy at St Mark’s Hospital). Convenience sampling was adopted with the aim of achieving a representative sample of endoscopists and routine gastrointestinal endoscopic procedures to adequately evaluate teamwork. This was a mixed methods study with qualitative and quantitative research methods employed.

3.4.2 Participants, procedures and setting

Study participants were principally endoscopists but also included the core endoscopy team and the patient undergoing the procedure. Endoscopists performing the procedures were experts and trainees, including medical gastroenterologists, colorectal surgeons and independent endoscopy nurse practitioners. Expert endoscopists (Group A) were defined as medical surgical and endoscopy nurse consultants. Trainee endoscopists (Group B) were defined as all other doctors of non-consultant grade: The trainee group comprised gastroenterology and surgical registrars and endoscopy clinical fellows within 2-6 years of completion of specialist training.

Elective (non-emergency) endoscopic procedures were observed and included a representative sample of endoscopy sub-types: Oesophagogastroduodenoscopy (OGD), colonoscopy (C), bowel cancer screening colonoscopy (BCSC), flexible sigmoidoscopy (FS) and endoscopic retrograde cholangio-pancreatography (ERCP) to strengthen sampling validity. Procedures included a mix of diagnostic and therapeutic cases: endoscopic mucosal
resection (EMR), endoscopic sub-mucosal dissection (ESD), stent insertion (SI) and variceal ligation (VL). Patient factors such as age and comorbidity were not analysed. This study was set in the Wolfson Endoscopy Unit and procedures were observed from within the endoscopy room or the radiology suite.

3.4.3 Skills and behaviour measurement

The endoscopic procedures were observed by gastroenterologists (AH and MM) trained in technical and non-technical skills assessment. Dual rating of 20% of endoscopy lists was undertaken where each assessor was blinded to the other’s ratings to determine inter-rater reliability. These individuals formed part of the clinical team and their presence in endoscopy rooms was thus commonplace. The endoscopy training room adjacent to the procedure room is equipped with a live audio-visual link. This facility displays multi-split views providing detailed information in the form of the endoscopic luminal view, endoscope position and configuration by 3D scope position guide and team views (Figure 3.1). The live link was adopted when two observers were completing assessments to minimise disruption in the procedure room. When a single observer was present, evaluations were undertaken from within the endoscopy room. Assessments were conducted for the principal or first endoscopist, defined as the endoscopist performing the majority of the procedure. The principal endoscopist needed to be defined when there were two endoscopists in the room, usually a senior trainer and a trainee. Validated rating tools were used to make three main assessments and these are described in the next section (see appendix 2.1 for an overview).
3.4.3.1 Technical Skill (DOPS)

The technical competency of the principal endoscopist was measured using a validated national competency framework ‘Directly Observed Procedural Skills’ (DOPS) assessment commonly used in the UK\(^7\) (appendix 2.3). Procedure-specific DOPS forms were used to cover the range of endoscopies observed in the study. Formative and summative DOPS assessment tools are available and the former was used in this study. A formative DOPS assessment entails an assessor observing the endoscopist performing a complete endoscopy and scoring technical performance within four domains:

1. Assessment, consent and communication
2. Safety and sedation
3. Endoscopic skills during procedure
4. Diagnostic and therapeutic ability.
Assessments are completed with pre-defined criteria and follow a 1-4 anchored scale:

1= Accepted standards not met
2= Some standards not yet met
3= Competent and safe throughout procedure
4= Highly skilled performance.

3.4.3.2 Non-Technical Skill (ENTS)
Non-technical skills were objectively evaluated by direct behavioural observation using the Endoscopic Non-Technical Skills (ENTS) framework described in section 3.2.2 (appendix 3.2). Observed behaviours during the procedure were coded into the four categories using the descriptor behaviours. The ENTS tool follows a 1-4 rating scale anchored as follows:

1= Poor: Performance endangered patient safety
2= Marginal: Performance indicated cause for concern
3= Acceptable: Performance was satisfactory
4= Good: Performance of a consistently high standard, enhancing patient safety

Endoscopic non-technical skills were evaluated for each procedure for the principal endoscopist. A tally of observable ENTS behaviours was recorded for multiple procedures over the course of a list. This was supplemented by qualitative observations. An ENTS score was assigned to each category (i.e. one each for communication and teamwork, situation awareness, leadership and judgment / decision-making) as observed throughout the procedures. An overall ENTS score for each endoscopist over the course of a list was calculated as the average of these four categorical ratings.

3.4.3.3 In room Safety Checks (SC)
The questionnaire study presented in chapter 1 focussed attention on the need for a standardised system of safety checks. Following this, essential standard safety checks (SC) were defined from an expert focus group (two senior endoscopists, a senior nurse and the unit manager). This process identified 14 safety checks including patient identification, allergies,
confirmation of procedure, indication and consent amongst others (appendix 3.4). Each of the 14 checks was scored by the assessors on a 4-point scale as follows:

1= No discernible attempt to perform the check
2= Performing a safety check without verbalization
3= Performing a safety check with verbalization
4= Performing a safety check and ‘cross checking’ with a colleague

A clinical example of how this scale translates in practice is provided in Table 3.1.

The safety checks were scored for the endoscopist completing the check with the team; either leading the checks or affirming team responses. An average safety check score was assigned to each list. Whilst there are some similarities between non-technical skills and safety checks, the two parameters were separate entities with clearly defined scales for the purposes of the study.

Table 3.1. Degrees of Safety Checks (SC).

<table>
<thead>
<tr>
<th>The four point safety check scale is illustrated with the example of checking intravenous drugs</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. No check of drug prior to administration</td>
</tr>
<tr>
<td>2. Checks drug independently with no verbalization to team prior to administration</td>
</tr>
<tr>
<td>3. Checks drug independently and verbalizes to team prior to administration</td>
</tr>
<tr>
<td>4. Cross checks drug name, dose and expiry date with another team member prior to administration</td>
</tr>
</tbody>
</table>

### 3.4.3.4 Patient Safety Incidents

In addition, any observed patient safety incidents (PSIs) were recorded according to the methodology described in chapter 2 (section 2.4.2.3-4). PSIs were defined as any safety issue that had the potential to, or directly adversely affected patient care. PSIs were defined as near misses, recognised procedural complications, adverse events and never events according to the Department of Health’s classification at the time of the study. PSIs were identified from the assessors’ qualitative notes and examination of the patient’s medical and nursing record.
The study period was extended to enable further PSIs observation and analysis. In addition to the procedures from 31 lists presented in this study, 7 additional lists were observed for further PSI data. The PSI data from all 37 lists is presented in chapter 2.

3.4.4 Ethical Approval

Ethical approval for this study was obtained from the National Research Ethics Service (NRES) Committee London, Reference 08/H0719/54. Informed consent to observe each endoscopy procedure was obtained from the patient and the endoscopist and assisting nurses conducting the procedure. Participation was voluntary and participants’ anonymity and patient confidentiality were maintained throughout. Endoscopy teams were informed that observations were being undertaken to evaluate team processes and safety in endoscopy. In the event of an adverse patient outcome, normal unit policies were adopted whereby the nurse in charge and the unit manager were informed and the incident reported to the hospital’s adverse event reporting system.10

3.4.5 Data analysis

Descriptive analyses included the number of diagnostic and therapeutic cases, procedure subtype, and the level of seniority of the endoscopist (expert or trainee). A weighted kappa statistic was used to determine inter-rater reliability for the ENTS assessments.

3.4.5.1 Experts and trainees

The ENTS and DOPS scores for trainees and experts were compared using the Mann Whitney U test. Safety checks for experts and trainees were compared using the between groups t-test.

3.4.5.2 Diagnostic and therapeutic procedures

The Mann Whitney U test was used to compare the incidence of PSIs in diagnostic and therapeutic cases. To compare the incidence of PSIs between experts and trainees, the percentage of diagnostic procedures between the two groups was compared using the unpaired t-test. To account for differences between the proportion of diagnostic and therapeutic cases, adjusted values were obtained using linear regression.
3.4.5.3 Medical, surgical and nurse endoscopist subgroups

In order to compare the three professional groups of endoscopists, the Kruskall Wallis test was used for comparison of non-technical skills (ENTS), technical skills (DOPS) and Patient Safety Incidents (PSIs) whilst analysis of variance was used for the safety checks (SC).

3.4.5.4 Correlational analysis

The association between technical skills (DOPS), non-technical skills (ENTS), safety checks (SC) and PSIs was determined by Spearman’s rho correlation coefficients. For all analyses significance was set at p<0.05.

3.5 Results

3.5.1 Demographics data

One hundred and thirteen procedures by 18 different endoscopists over 31 endoscopy lists were prospectively evaluated. Sixty-one per cent of endoscopists were male and procedures were distributed between medical (n=68), surgical (n=20) and nurse (n=25) endoscopists. Each endoscopist performed an average of 1.7 lists (range 1-4). Endoscopists’ lifetime experience was variable (minimum 2 maximum >20 years) with procedures by both experts (n=75) and trainees (n=38).

Procedures were both diagnostic (n=72) and therapeutic (n=41) and included esophagogastroduodenoscopy (n=25), colonoscopy (n=29), bowel cancer screening colonoscopy (n=16), flexible sigmoidoscopy (n=25), and endoscopic retrograde cholangiopancreatography (n=18).

3.5.2 Technical skills

Technical skills assessed by the DOPS tool ranged from 2-4 with a median score of 3 (competent and safe throughout procedure).

3.5.3 Non-Technical skill

Endoscopists’ non-technical skills scores showed variation (range 1 to 4) between endoscopists, with a median score of 3 (acceptable: satisfactory performance). Figure 3.2 illustrates examples of specific behaviours observed at both ends of the scale. All endoscopists with an ENTS score of 4 were experts.
Specific examples of ENTS ratings

<table>
<thead>
<tr>
<th>Good Endoscopic non-technical skills (ENTS=4)</th>
<th>Poor Endoscopic non-technical skills (ENTS=1)</th>
</tr>
</thead>
<tbody>
<tr>
<td>‘One of the patients had recently suffered an MI. The endoscopist reassured the patient and informed the team. The baseline blood pressure reading was checked and verbalized and the Clopidogrel stop date shared with the team’</td>
<td>‘The endoscopist was on-call and received multiple phone calls on his mobile which interrupted the list. The endoscopist attempted to curtail these conversations but was unable to. Consequently communication from the nurses was missed due to this dual commitment’.</td>
</tr>
<tr>
<td>☑ Communication and teamwork</td>
<td>☐ Focus and concentration</td>
</tr>
<tr>
<td>☑ Situation Awareness – Reviewing the situation and maintaining a shared understanding</td>
<td>☑ Maintaining standards</td>
</tr>
<tr>
<td>☑ Judgment and decision-making</td>
<td></td>
</tr>
</tbody>
</table>

**Figure 3.2.** Specific examples of endoscopic non-technical skills at both ends of the scale

### 3.5.4 In room Safety Checks

In total, 1539 opportunities to perform a safety check over 113 procedures were identified. The median safety-check score across procedures was 1 (no safety check performed) range 1-4. In 41% of safety check opportunities, no safety check was performed (Figure 3.3). The most frequently omitted safety checks were internal prosthesis (14%), team members’ names (12%), correct screen on endoscopy reporting software (11%), anticoagulants (10%) and allergies (10%). A level 4 safety check (cross checking with a colleague) was conducted in 8% of occasions.
Patient Safety Incidents (PSIs)

One hundred and six PSIs were observed (median 1.0 range 0-7 per procedure). Fifty-five PSIs occurred with Group B endoscopists (trainees) and 51 with Group A (experts). Sixteen of the PSIs occurred in a single list (comprising 4 procedures) where the trainee endoscopist received an ENTS score of 1. There were significantly more PSIs in therapeutic procedures (median PSIs / procedure 2.0) than diagnostic cases (median PSIs / procedure 0.2 $p \leq 0.001$) (Table 3.2). Trainees performed significantly more diagnostic cases than experts (Table 3.3). In unadjusted analyses there was no significant difference in PSI incidence between experts and trainees. Adjusted analyses for diagnostic / therapeutic case mix showed significantly more PSIs occurring with trainee endoscopists compared to experts (Table 3.4). That is, trainees had on average 0.9 PSIs per procedure higher than experts. Examples of observed PSIs included, inadequate monitoring with sedation, equipment failures and inaccurate report writing. In depth analysis of these (and additional) PSIs is presented in chapter 2.
Table 3.2. Comparison of Patient Safety Incidents in diagnostic and therapeutic procedures.

<table>
<thead>
<tr>
<th>Procedure type</th>
<th>Number of lists</th>
<th>Number of procedures</th>
<th>PSIs / procedure Median (IQR)</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diagnostic</td>
<td>26</td>
<td>34</td>
<td>0.2 (0.0, 1.0)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Therapeutic</td>
<td>24</td>
<td>72</td>
<td>2.0 (0.5, 2.8)</td>
<td></td>
</tr>
</tbody>
</table>

Table 3.3. Comparison of percentage diagnostic procedures for Group A endoscopists (experts) and Group B endoscopists (trainees).

<table>
<thead>
<tr>
<th>Endoscopist group</th>
<th>Number of lists</th>
<th>% Diagnostic procedures Mean (SD)</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>A (Experts)</td>
<td>21</td>
<td>49 (38)</td>
<td>0.04</td>
</tr>
<tr>
<td>B (Trainees)</td>
<td>10</td>
<td>77 (21)</td>
<td></td>
</tr>
</tbody>
</table>

Table 3.4. Comparison PSIs incidence between Group A endoscopists (experts) and Group B endoscopists (trainees) with adjustments for diagnostic / therapeutic case mix.

<table>
<thead>
<tr>
<th>Analysis</th>
<th>Endoscopist Group</th>
<th>PSIs / procedure Mean (SD)</th>
<th>Difference (*) Mean (95% CI)</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unadjusted</td>
<td>A (experts)</td>
<td>0.9 (1.0)</td>
<td>0</td>
<td>0.29</td>
</tr>
<tr>
<td></td>
<td>B (trainees)</td>
<td>1.4 (1.3)</td>
<td>0.5 (-0.4, 1.3)</td>
<td></td>
</tr>
<tr>
<td>Adjusted for</td>
<td>A (experts)</td>
<td>-</td>
<td>0</td>
<td>0.02</td>
</tr>
<tr>
<td>diagnostic/therapeutic cases</td>
<td>B (trainees)</td>
<td>-</td>
<td>0.9 (0.2, 1.7)</td>
<td></td>
</tr>
</tbody>
</table>

(* Differences reported as value for Group B minus value for Group A)

3.5.6 Inter-rater reliability

Eighteen out of 113 procedures across five lists were co-rated by the same two assessors to establish agreement in the scoring (reliability). The inter-rater reliability for the ENTS score was good with a weighted kappa score of 0.62 (95% CI 0.28-0.96). For the co-rated procedures 76% of ENTS scores were exactly the same for both raters. For the remaining 24% they differed by a single point only on the 4-point scale.
3.5.7 **Sub-group analyses: Experts and trainees**

Subgroup analyses were performed to compare Group A endoscopists (experts) and Group B endoscopists (trainees) with respect to ENTS, DOPS and SC scores (Table 3.5). This showed that ENTS and DOPS scores were significantly higher for experts compared to trainees, which provides validity evidence for these metrics (i.e. they are able to discriminate the performance of the two groups).

**Table 3.5.** Comparison of Endoscopic non-technical skills (ENTS), Technical skills (DOPS) and Safety checks (SC) scores in Group A endoscopists (experts) and Group B endoscopists (trainees).

<table>
<thead>
<tr>
<th>Skill Measure</th>
<th>Group A (expert) endoscopists’ lists n=21 (75 procedures)</th>
<th>Group B (trainee) endoscopists’ lists n=10 (38 procedures)</th>
<th>Statistical comparison</th>
</tr>
</thead>
<tbody>
<tr>
<td>Non-technical skill ENTS</td>
<td>Median 3, Range 2-4</td>
<td>Median 3, Range 1-3</td>
<td>Mann Whitney U p=0.03</td>
</tr>
<tr>
<td>Technical Skill DOPS</td>
<td>Median 4, Range 3-4</td>
<td>Median 3, Range 2-4</td>
<td>Mann Whitney U p=0.03</td>
</tr>
<tr>
<td>Safety Checks SC</td>
<td>Mean 2.04, SD 0.31</td>
<td>Mean 1.80, SD 0.30</td>
<td>t-test p=0.05</td>
</tr>
</tbody>
</table>

3.5.8 **Sub-group analyses: Medical, surgical and nurse endoscopists**

Comparisons between the professional sub-groups of endoscopists are presented (Table 3.6) There was no significant variation between the non-technical and safety checks scores. Technical skills scores (DOPS) were highest for nurse endoscopists (although n=3). Technical skills were lowest for surgical endoscopists with 43% receiving a DOPS rating of 2. Surgical endoscopists had a median of 6 PSIs per list compared to medical and nursing endoscopists who had a median of 2.
Table 3.6. Comparison of Endoscopic non-technical skills (ENTS), Technical skills (DOPS) and Safety checks (SC) between Medical, Surgical and Nurse endoscopists.

<table>
<thead>
<tr>
<th>Variable (score)</th>
<th>Medical n (%)</th>
<th>Surgical n (%)</th>
<th>Nurse n (%)</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>ENTS 1</td>
<td>0 (0%)</td>
<td>1 (11%)</td>
<td>0 (0%)</td>
<td>0.28</td>
</tr>
<tr>
<td>ENTS 2</td>
<td>6 (26%)</td>
<td>3 (33%)</td>
<td>1 (20%)</td>
<td></td>
</tr>
<tr>
<td>ENTS 3</td>
<td>14 (61%)</td>
<td>5 (56%)</td>
<td>3 (60%)</td>
<td></td>
</tr>
<tr>
<td>ENTS 4</td>
<td>3 (13%)</td>
<td>0 (0%)</td>
<td>1 (20%)</td>
<td></td>
</tr>
<tr>
<td>DOPS 2</td>
<td>0 (30%)</td>
<td>3 (43%)</td>
<td>0 (0%)</td>
<td>0.003</td>
</tr>
<tr>
<td>DOPS 3</td>
<td>8 (53%)</td>
<td>4 (57%)</td>
<td>0 (0%)</td>
<td></td>
</tr>
<tr>
<td>DOPS 4</td>
<td>7 (47%)</td>
<td>0 (0%)</td>
<td>3 (100%)</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Variable</th>
<th>Medical Mean (SD)</th>
<th>Surgical Mean (SD)</th>
<th>Nurse Mean (SD)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Safety Check</td>
<td>2.00 (0.32)</td>
<td>1.85 (0.33)</td>
<td>1.94 (0.41)</td>
<td>0.66</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Variable</th>
<th>Medical Median (IQR)</th>
<th>Surgical Median (IQR)</th>
<th>Nurse Median (IQR)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of PSIs / list</td>
<td>2 (1, 4)</td>
<td>6 (5, 9)</td>
<td>2 (1, 6)</td>
<td>0.009</td>
</tr>
</tbody>
</table>

3.5.9 Correlational relationships

The correlation coefficients for the four variables, technical skills (DOPS), endoscopic non-technical skills (ENTS), safety checks (SC) and patient safety incidents (PSIs), are summarised (Table 3.7). The safety check score and PSIs showed a significant negative correlation (rho=-0.39, p=0.03), indicating that a higher-rated safety check was associated with a lower number of PSIs (Figure 3.4). Similarly, there was a significant negative correlation between non-technical skill (ENTS) and PSIs (rho=-0.43 p=<0.02 such that better non-technical skills were associated with fewer PSIs (Figure 3.5). Non-technical skills (ENTS) and safety checks showed a significant positive association: (rho=0.80, p=<0.001) suggesting that the higher the ENTS scores the more likely a robust safety check was performed (Figure 3.6). A positive association was also found between technical skill (DOPS) and non-technical skill (ENTS) although this did not reach significance (rho=0.43, p=0.06) (Figure 3.7). No significant association was found between the degree of safety checks and technical skill (DOPS) (rho=0.21 p=0.38).
Table 3.7. Spearman’s rho correlations between non-technical skill (ENTs), technical skill (DOPS), safety checks (SCs) and PSI incidence

<table>
<thead>
<tr>
<th></th>
<th>Patient safety incident (n)</th>
<th>Safety checks (1 to 4 scale)</th>
<th>Technical skill DOPS (1-4 scale)</th>
<th>Non-technical skill, ENTS (1 to 4 scale)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient safety incident</td>
<td>1.00</td>
<td>-0.39*</td>
<td>-0.17</td>
<td>-0.43*</td>
</tr>
<tr>
<td>Safety checks</td>
<td></td>
<td>1.00</td>
<td>0.21</td>
<td>0.80**</td>
</tr>
<tr>
<td>Technical skill, DOPS</td>
<td></td>
<td></td>
<td>1.00</td>
<td>0.43^</td>
</tr>
<tr>
<td>Non-technical skill, ENTS</td>
<td></td>
<td></td>
<td></td>
<td>1.00</td>
</tr>
</tbody>
</table>

**p<0.001; *p<0.05; ^p=0.06

Figure 3.4. Correlation between Safety Check score and PSI
Figure 3.5. Correlation between ENTS scores and PSIs

Figure 3.6. Correlation between ENTS and Safety Checks scores
3.5.10 Qualitative themes

The assessment frameworks enabled objective scores on a four-point scale to be collated. These ratings were supplemented by qualitative observations. These were categorised by thematic analysis and the following key themes identified.

3.5.10.1 Sub teams

Both endoscopists and nurses initiated safety checks during cases but these often occurred in an unstructured fashion and varied between endoscopists and nurses, even within the same list. The actual safety checks undertaken, the professional performing the check and the time-point during the process where the check was completed were all highly variable. Endoscopists’ safety check repertoire and the quality of these checks varied according to other pressures on the list (e.g. time, complexity of cases, overbooking of list and patient factors) and were modified according to the experience of the other team members.

Professional divisions separating endoscopists and endoscopy nurses were commonly observed. The two groups would perform safety checks independently for the same patient in
parallel, and not communicate the outcomes, significance or consequences of these checks to the other within the endoscopy room. An example of this was observed during a bowel cancer-screening list where communication exchanges prior to the patient’s procedure occurred between three pairs of different individuals: medical endoscopists discussed strategies for polypectomy and anticoagulation, endoscopy nurses were discussing equipment availability and the specialist screening practitioner was discussing sedation options with the patient whilst training a junior colleague. These professional sub-teams did not communicate their own priorities with each other yet all three aspects were important for the patient.

For some lists it was noted that overall team unity was lacking and that the sub-teams often had differing priorities. This was often a source of tension for the team that affected the ways in which they interacted with each other.

3.5.10.2 Hierarchy and problem escalation

Professional hierarchies remain clearly delineated in endoscopy both within and between professional sub-groups. These professional divisions may not be of significance in routine situations but can negatively affect professionalism and hinder patient safety in the urgent setting. As illustrated in chapter 2 patient safety incidents rarely occur in isolation and frequently a single error creates other errors that in turn coalesce and lead on to a significant patient safety incident. Individuals or teams may identify these pre-cursor errors and thus potentially influence the error trajectory. However, situations in this study were observed where individuals were aware of sub-optimal practice or an erroneous decision, but weren’t sufficiently empowered to influence actions. An example of this was observed when an endoscopy team were conducting a list but had not previously worked with the endoscopist. A number of adverse factors were inherited by the team including overbooked cases, delayed list start time and endoscopist on call for emergencies. The endoscopist was not suitably trained to remove large polyps and made a decision to perform polypectomy inadequately in sub-optimal conditions (poor bowel preparation, looped scope and prolonged and incomplete insertion). The senior and experienced endoscopy nurses were aware early on in this ninety-minute procedure that the patient was in discomfort and the endoscopist out of his depth. They were supportive of the endoscopist and tried to assist (suggesting position change, and setting up the water pump to improve luminal views). There were subtle suggestions that the endoscopist could consider asking for help from a senior endoscopist. The endoscopist was concentrating hard and displaying frustration at the lack of progress. When the endoscopist...
eventually acknowledged the nurses’ concerns after the patient became increasingly distressed he was dismissive, defensive and critical. This example illustrates how the nursing team did not speak out loudly or early enough about valid concerns and when they did question the endoscopist they faced significant criticism. They did not feel suitably equipped to escalate the issue themselves although this would have been completely justified and in the patient’s best interest. This example also highlights the close interplay between technical and non-technical skill: Improved non-technical skills may have enabled this endoscopist to overcome some of the insufficiencies in technical skill; for example by listening and responding to the nursing team’s suggestions.

### 3.5.10.3 Training, supervision and specialities

Chapter 1 details the important role JAG has played in the unification of training and accreditation processes for endoscopists from diverse professional backgrounds. Despite this, variation in training and supervision across specialties is inevitable due to conflicting training demands (i.e. surgeons need to primarily train in surgical operations). Furthermore, different professional groups and individuals display differing attitude towards risk: For a surgeon performing high-risk surgery, endoscopy is likely to feature at the ‘safe’ end of their spectrum. This is exemplified by observations of a surgical registrar who stated, ‘we surgeons just push through loops unlike you medics…if there’s a hole I’ll just sort it out in theatre’.

### 3.5.10.4 Reactive, opportunistic and proactive problem solving

As described in the introduction to this chapter, endoscopy is a complex process and has to be balanced with resourcing, staffing and capacity issues whilst trying to manage demand and fulfil targets. Stressful working conditions can lead to low staff morale, who often already supersede their basic duties. Time pressures and difficult working environments mean that problems are often dealt with in a reactive manner. Even when team members are cognisant of latent failures in the system it is frequently not possible to implement an effective solution. Problem solving is thus often reactive (i.e. following a patient complaint) sometimes opportunistic (pre-assessment of higher risk patients) and sometimes proactive (motivated by quality assurance). This theme was illustrated in this study by the report of diathermy equipment failure. This was identified as an error and appropriately reported with clear instruction by the nurse in charge to label the equipment as faulty so it would not be used until repaired. Study observations undertaken in a different room with a different team on the following day identified the same faulty equipment in use and the error only identified when
the diathermy failed again during a second patient’s procedure. This is an example of a recurrent error that should have been captured and avoided for the second patient.

3.6 Discussion

3.6.1 Summary

This study shows variation in technical and non-technical skill in diverse GI endoscopic procedures conducted by a range of endoscopists. Important safety checks were often not seen to be conducted and when checks were performed they were frequently done independently without verification from an associated team member.

One hundred and six patient safety incidents (PSIs) were identified across experts and trainees and were significantly more likely to occur in therapeutic cases. Experts conducted more therapeutic cases and in adjusted analyses had fewer PSIs compared to trainees.

Sub-group analyses showed technical and non-technical skills were higher for experts. Examining the professional sub-groups, surgical endoscopists had lower technical skills scores compared to medical and nurse endoscopists.

Correlational analyses showed that more robust safety checks and well-developed non-technical skills were associated with fewer PSIs. Higher-level non-technical skills were also positively associated with more robust safety checks. Technical and non-technical skills showed some positive association although this did not reach statistical significance.

3.6.2 Implications of Study Findings

3.6.2.1 Technical skills

The technical skills median score was 3 equating to competent and safe performance throughout the procedure. Within the detail of the qualitative observations there was evidence to support the premise that technical skills training and performance could be improved. This was manifest in the surgical subgroup of endoscopists who may scope less frequently than the other groups and rotate through the department and thus not be ‘resident’ endoscopists. Practicing endoscopy independently often means the opportunities for supervision, feedback and development are curtailed and it is important to recognise this as an important feature of on-going practical skills development. The importance of technical skills performance should not be overlooked when considering safety and quality issues.
3.6.2.2 Non-technical skills

Endoscopic non-technical skills also showed wide variation, reflecting the full range of scores in the rating tool. An ENTS score of 3 indicating ‘satisfactory performance but could be improved’ occurred most frequently, but there were scores at the extremes of 1 and 4 illustrating the sensitivity of the rating tool and the significant differences in non-technical skills within a single unit. Endoscopists who received an ENTS score of 4 were always the most experienced. However, endoscopists who scored an ENTS of 1-2 were trainees as well as experts. There was good inter-rater reliability for the ENTS scores (although it is acknowledged that this is based on ENTS scores from a modest number of 18 procedures).

Importantly, endoscopists who were rated higher on non-technical skills scores were also more likely to perform better safety checks. This was a highly significant result and raises the question as to whether good non-technical skills ensue from performing structured high quality safety checks, or whether having a safety check ‘routine’ enhances endoscopists’ non-technical skills. It may be argued that the correlation between ENTS and safety checks is not surprising, as there is some degree of overlap. However, it should be noted that these are separate entities: one measuring safety-enhancing behaviour’s and the other whether or not checks were actually completed. The qualitative thematic analysis draws out the relevance and importance of non-technical skills by demonstrating communication failures, team priorities, professional hierarchies as well as error management issues. This concept is also supported by the PSI analyses presented in chapter 2 (section 2.5.2.6) where detailed error analysis reveals a catalogue of suboptimal processes in the background that commonly relate to non-technical skills.

3.6.2.3 Safety Checks

In this study, the ideal safety check of ‘cross checking’ with a colleague was only performed in 8% of instances and in 41% of instances no safety check was visibly or audibly undertaken. It should be noted that the safety checks evaluated were quite basic, including patient identification and a shortlist of essential safety checks derived by expert consensus. A possible explanation for the overall low level of safety checks could be an assumption that the check had already been completed by someone else (e.g. pre-admission nurse or referring clinician) and therefore it was not deemed essential to repeat the safety check in the endoscopy room. When this data is considered in conjunction with the questionnaire study presented in chapter 1 it is clear that endoscopy teams in this study had no clear, consistent
and methodical approach to carrying out safety checks pre-procedurally. This would manifest as erratic safety checks and translated to inefficient use of endoscopy time and sets the scene for avoidable error.

### 3.6.2.4 Patient Safety Incidents

PSIs occurred frequently and were more common in therapeutic compared to diagnostic procedures and more likely to occur with trainee as opposed to expert endoscopists. The number of observed errors is high, although there were no immediate, significant detrimental outcomes for patients in this study. Many of the observed incidents highlighted areas of weakness that could pose a potential threat to patient safety. Quantifying these incidents identifies the scale of the problem, contextualises error and identifies opportunities to proactively intervene preventing future errors translating into patient harm.

In this study a concentration of PSIs was found to occur in a list conducted by a surgical trainee with an ENTS score of 1. This is not surprising given the number of adverse features associated with this list. The consultant was unavailable for the list but the administrative staff had not been informed. Consequently, the trainee was unsupervised and the cases required the expertise of a consultant. In addition the trainee was relatively new to the department and there were extra cases added onto this list at short notice. Considering administrative issues, one of the complex patients had an OGD and colonoscopy requested and this was clearly indicated in the medical notes and the request form, but the former procedure was not booked in error, and also overlooked by the endoscopist.

Problems arose with confronting professional hierarchies and the nurses were unable to escalate the issues early enough although they tried to address the issues. There were many technical and non-technical issues relating to the endoscopist that impacted on teamwork and morale. Two different consultants assisted with difficult polypectomies but there was no overall continuity of supervision for the endoscopist. Senior review of the list by the clinical lead raised further issues with documentation as the consultant was listed as the endoscopist on the report although he was not present for this list and the trainee was not documented as performing these procedures. This has significant implications for accuracy and tracking endoscopists and procedures in the event of a delayed PSI. Reviewing this list in detail, it becomes clear how complex the ‘Swiss cheese’ of errors can be and although there was sub-optimal performance from the endoscopist this was compounded by teamwork factors, administrative processes and supervision issues.
3.6.2.5 Correlations

Importantly, endoscopists who were rated higher on non-technical skills scores were also more likely to perform better safety checks. This was a highly significant result and raises the question as to whether good non-technical skills ensue from performing structured high quality safety checks, or whether having a safety check ‘routine’ enhances endoscopists’ non-technical skills. It may be argued that the correlation between non-technical skills and safety checks is not surprising, as there is some degree of overlap. However, it should be noted that these are separate entities: one measuring safety-enhancing behaviours and the other whether or not checks were actually completed.

The analysis showed that higher safety scores were associated with a lower number of PSIs. This supports the premise that a standardised system of safety checks can enhance patient safety by reducing PSIs. There was a significant negative association between ENTS and PSIs. This suggests that poor non-technical skills may be instrumental in PSI occurrence, and targeted training in endoscopic non-technical skills may influence PSI occurrence.

There was no significant relationship between the quality of safety checks and the technical skill of the endoscopist, suggesting that safety checks are variable even with endoscopists of high technical proficiency. This is relevant from a patient safety perspective, as simple interventions to ensure baseline safety checks are carried out consistently for each patient (i.e. a simple checklist) are currently not uniformly in place across endoscopy units but likely to be beneficial. Further, we found a weak association between non-technical skills and technical performance. This could be explained by the fact that often the endoscopists scoring most highly on technical performance were also the most experienced and elements such as leadership, judgment, decision-making, delegation and list planning may be superior to those of trainees, whose focus may lie more with technical aspects of the procedure. This level of correlation between technical and non-technical aspects of endoscopists’ performance is consistent with a recent review of these skills in surgeons in the operating room 4.

3.6.2.6 Subgroup analyses

Comparing experts and trainees, the ENTS and DOPS scores were significantly higher for the more experienced group, which may be expected. This suggests that good non-technical skills may be acquired with years of experience. Although the mean safety check score was significantly higher for the more experienced endoscopists this difference is overall small in size and reinforces the point that safety checks are performed inconsistently even by expert
endoscopists. Interestingly, although the surgical endoscopists would have been familiar with the WHO Surgical Safety Checklist\textsuperscript{11} as it is mandated for use across all surgical procedures in the UK, they did not seem to ‘translate’ this behaviour into endoscopy.

### 3.6.3 Limitations

This study has limitations. Firstly, all observations were undertaken in a single centre with an overall modest sample size. Although multiple endoscopists and differing types of endoscopic procedures were evaluated, there remains uncertainty about the generalizability to procedures performed in other units. Similarly a wide range of procedures of varying complexity and risk were analysed. Patient factors such as age and comorbidity that may affect PSIs were not analysed. It is acknowledged that there is no long-term follow up of PSIs and an extended period of PSI observation may have highlighted significant clinical problems (such as delayed haemorrhage and perforation). It was not feasible to prospectively record this within this study. Limited conclusions can be made from the professional sub-group analyses as the numbers within each group (medical, surgical and nurse endoscopist) are small and the study was not designed to specifically look at this endpoint. The Hawthorne effect should be considered, whereby participants modify their behaviours in response to being observed. This is a limitation of all observational studies and notably this would perhaps have been expected to lead to an improvement in safety checking behaviours, possibly suggesting the bias had minimal impact. Other limitations include an overall small-scale study and small sample of cases for the reliability analyses (although our sample for reliability is similar to samples taken in other studies of non-technical skills)\textsuperscript{12,13}

### 3.6.4 Future Work

To corroborate the findings of this study further data should be collected from other endoscopy units both tertiary and non-tertiary. The process of making observations with scientific assessment tools is itself very informative and could be applied by individual units to self-assess their teams and provide evidence based feedback. Increasing the sample size of sub-groups of endoscopists will allow meaningful comparisons to be made and inform endoscopy units of how to tackle the discrepancies likely to exist between endoscopist groups. This in turn could focus safety, and quality improvements. A closer evaluation of the relationship between non-technical and technical skills may identify the non-technical skills most likely to affect patient harm through impact on technical performance. This would
inform non-technical skills training strategies by focussing on the specific skills most likely to exert influence on patient safety. To achieve a more global assessment of teamwork in endoscopy, the existing non-technical skills framework could be developed to capture ratings for the core team by developing descriptors for the endoscopist, supervisor and assisting nurses. Scientifically developing a usable tool that envelops key technical and non-technical skills assessment is likely to provide a more focussed assessment and could form part of the existing JAG accreditation process.

3.7 Conclusion

Scientific evaluation of endoscopic non-technical skills and safety checks as relevant factors in patient safety has not previously been reported. This study suggests that robust safety checks and non-technical skills are linked professional behaviours, which can play an important role in endoscopy patient safety. A minimum standard of technical skill has been widely accepted as a pre-requisite to safe independent endoscopic practice. In order to enhance the safety and quality of endoscopy further, non-technical skills should form part of the future training landscape.

This study provides the foundation for further research to design and implement an endoscopy safety checklist, similar to the WHO Surgical Safety Checklist and non-technical skills team training, to enhance safety and team performance in gastrointestinal endoscopy.
Chapter 4: Identifying and Measuring Factors Affecting Patient Safety in Emergency Endoscopy Teams

4.1 Chapter Overview

The previous two chapters have focussed on endoscopy errors and team performance in the routine setting. This chapter seeks to examine the safety and quality issues that impact patient care in the urgent and emergency setting. It is established that urgent and emergency endoscopic procedures pose differing challenges when compared to elective procedures. This chapter defines these issues by evaluating technical and non-technical aspects of team performance as well as the patient safety incidents encountered in the emergency setting. It is acknowledged that there is a spectrum of immediacy for these procedures (urgent – emergency) and the term ‘emergency’ will be used to encompass these patients with detail on definitions described in the methodology section. The introduction summarises the characteristics of emergency procedures and is followed by the aims and study methodology. The main findings are discussed in the context of improvements for endoscopy patients requiring urgent procedures.

4.2 Introduction

Emergency endoscopic procedures are more complex than routine ones with a greater number of variables to consider. Emergency endoscopy requires thoughtful decision making to weigh up the risks and benefits of the intervention for each individual patient.

4.2.1 Emergency endoscopy

Emergency endoscopic procedures are technically more challenging\(^1\) and often require therapeutic intervention compared to elective cases. One of the primary difficulties is defining urgent endoscopic cases requiring immediate intervention in comparison to those that can wait for a semi-elective slot within the next 24-48 hours. Whilst there are objective parameters to guide this decision, semi-urgent and emergency procedures are distributed along a spectrum and often experienced clinical judgement is required. Many patients referred for urgent endoscopy will present with acute upper gastrointestinal bleeding. Other indications include complications from previous endoscopic therapy e.g. post-polypectomy haemorrhage and stent insertion for malignant obstruction. Furthermore, patients may enter the pathway through acute medical or surgical admissions with variation in pre-procedural
optimisation and escalation for senior decision-making. Often this early section of the patient pathway is managed by non-endoscopists and patients need to be appropriately triaged both within and out of normal working hours.

4.2.2 Patient factors

Acute upper gastrointestinal haemorrhage is a common medical emergency with approximately 85,000 cases / year in the UK or the equivalent of one Gastrointestinal (GI) bleed every six minutes. Additionally, GI bleed hospital mortality rates have remained relatively static at 10% despite advances in endoscopy. These patients are often complex and critically unwell, with the potential to deteriorate irrespective of endoscopic intervention. Furthermore, the nature of patients presenting acutely is changing: The patient population is increasing in age with related comorbidities. The prevalence of ischaemic heart disease in an aging population is important as patients are treated with multiple antithrombotic agents. These increasingly include direct oral anticoagulants (DOACs) for which specific reversal agents are not available. These patients often require complex management decisions, as issues such as the ‘severity of bleeding, intensity of anticoagulation and thrombotic risk’ need to be carefully considered and appropriately discussed with the patient. Well validated clinical risk stratification scoring systems help identify those patients that need urgent intervention as well as those that may be suitable for early discharge and facilitate decision making to some extent.

4.2.3 Skills and expertise of the endoscopist

Most acute endoscopy services are staffed by independent endoscopists, either at consultant or specialist registrar grade if competent. However, dedicated training and assessment processes are less well developed for emergency endoscopic procedures. This is recognised by the profession as a gap in training and work is in progress to develop and disseminate dedicated assessment tools for emergency endoscopic procedures, which will also serve to inform training.

Whilst some skills are generic for routine and emergency procedures, there are specific skills unique to the emergency situation that need to be identified, trained and assessed to ensure adequate levels of competency. These skills clearly involve technical aspects such as achieving effective haemostasis but also cognitive skills directing judgement and decision-making, planning and prioritising, leadership and crisis management. In considering
cognitive skills, intuitive (instinctive) and analytical (systematic) decision-making models are well described (Table 4.1) with the former representing ‘mental short cuts’ and the latter a more scientific, rational evaluation of the data.\textsuperscript{8} Decision-making processes are important particularly in the emergency setting where the volume of decisions required and the potential for error is not insignificant.\textsuperscript{9} Considering the complexity of emergency endoscopy procedures and patients, there is no dedicated simulation training provided in the UK endoscopy curriculum to prepare for such cases. Most training therefore occurs in the acute setting with variable levels of supervision. Furthermore, emergency cases are encountered less frequently than elective diagnostic procedures and consequently there is a longer learning curve, posing challenges for complex skills acquisition and retention. There is a broad skill-set encompassing both technical and non-technical skills that needs to be more clearly defined, trained and assessed to ensure endoscopists performing these cases are well equipped.

Table 4.1. Crooksey’s Principle characteristics of Type 1 and Type 2 decision making processes\textsuperscript{8,10}

<table>
<thead>
<tr>
<th>Cognitive characteristics</th>
<th>Type 1 Heuristic Intuitive</th>
<th>Type 2 Systematic Analytical</th>
</tr>
</thead>
<tbody>
<tr>
<td>Computational principle</td>
<td>Associative</td>
<td>Rule based</td>
</tr>
<tr>
<td>Responsiveness</td>
<td>Passive</td>
<td>Active</td>
</tr>
<tr>
<td>Capacity</td>
<td>High</td>
<td>Limited</td>
</tr>
<tr>
<td>Cognitive awareness</td>
<td>Low</td>
<td>High</td>
</tr>
<tr>
<td>Automaticity</td>
<td>High</td>
<td>Low</td>
</tr>
<tr>
<td>Rate</td>
<td>Fast</td>
<td>Slow</td>
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<tr>
<td>Reliability</td>
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<tr>
<td>Errors</td>
<td>Common</td>
<td>Rare</td>
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<tr>
<td>Effort</td>
<td>Low</td>
<td>High</td>
</tr>
<tr>
<td>Emotional attachment</td>
<td>High</td>
<td>Low</td>
</tr>
<tr>
<td>Scientific rigour</td>
<td>Low</td>
<td>High</td>
</tr>
</tbody>
</table>

4.2.4 The emergency endoscopy team

The multitude of skills required for the endoscopist to acquire proficiency and develop expertise cannot be considered in isolation. The impact of the immediate and wider team in
the emergency setting is of critical importance. There is an interdependence between the endoscopist and the assisting nurses to understand the priorities for the procedure, proactively deal with potential obstacles and communicate clearly. This is greatly enhanced by the presence of trained endoscopy nurse assistants, although endoscopy nurse assistants are not a pre-requisite for an acute endoscopy service. Fire fighting technical equipment related issues for example, in the emergency setting is not only stressful and inefficient, but can divert the endoscopist’s attention resulting in cognitive overload and dual task interference\(^{11}\) setting the scene for subsequent errors. Apart from the assisting nurses, the wider team may also include anaesthetists, intensive care specialists and operating theatre staff amongst other key individuals (Figure 4.1) all of whom have a specific input, dependent upon clear communication and coordination of tasks to orchestrate the intervention.

Often these transient emergency ‘teams’ are collated at short notice, have variable membership, and may be subject to individual conflict secondary to competing demands. Additionally, procedures may need to be undertaken in unfamiliar environments such as Intensive Care, or the Operating Theatre and sometimes outside of routine working hours, adding to the complexity.

**Figure 4.1.** The wider multi-disciplinary endoscopy team
4.2.5 Service provision and Organisational challenges

The UK National Confidential Enquiry into Patient Outcomes and Death (NCEOPD) in 2004 scrutinised 30-day mortality, and highlighted several problems with emergency endoscopy. Few patients benefitted from effective pre-procedural optimisation in appropriate high dependency care settings. Linked to this, anaesthetists were rarely involved in pre-procedural management and these patients received large volume blood transfusions with all the associated risks.

This was corroborated by the acute upper GI bleeding (UGIB) audit conducted in the UK in 2007, which also highlighted significant inconsistencies and suboptimal service provision for patients presenting with UGIB. Variation exists on when urgent procedures are performed, equipment availability, endoscopy teams, procedure setting and access to senior supervision. Even when a patient is appropriately resuscitated and identified as requiring an urgent procedure, a designated ‘bleed slot’ may not be available as capacity is often fully utilised for pre-booked elective cases.

These influential studies have indicated that a re-structure of acute endoscopy services is needed which poses significant organisational challenges in the face of resource constraints. NICE guidance stipulates 24/7 provision of endoscopy services for acute care providers with access to a consultant gastroenterologist within 24 hours. The Upper GI Bleed Toolkit sets quality standards for providing acute endoscopy services safely by balancing local and regional specialist units and developing GI bleed networks.

Current NCEPOD guidance on gastrointestinal haemorrhage is outlined through 26 key recommendations. These recommendations state that acute GI bleed patients should only be admitted to hospitals with 24/7 endoscopy, interventional radiology GI bleed surgery and critical care facilities. It also advises against the traditional divisions of upper GI bleeding within the domain of the physician and lower GI bleeding the responsibility of the surgeon. Instead, a lead clinician is responsible for integrated care pathways for GI bleed and in the event of a major bleed should be informed within an hour of the diagnosis. These developments undoubtedly will raise the standard of care but thoughtful implementation plans need to be well communicated to the multidisciplinary team involved. In summary, to provide an effective acute endoscopy service, safe staffing levels with appropriately trained nurses and endoscopists need to be coordinated into safe and functional teams through clearly defined protocols and regional networks.
4.3 **Aims**

This study primarily aimed to systematically evaluate three main variables for teamwork in emergency endoscopy and routine elective cases:

a. Technical skills of the endoscopist

b. Non-technical skills of the endoscopist

c. Safety checks for endoscopic procedures

Secondary aims addressed the relationship of safety checks with technical and non-technical skill. Patient safety incidents were also evaluated in relation to the other variables.

4.4 **Methods**

4.4.1 **Study Design**

This was a prospective observational study in a single tertiary endoscopy unit (The Wolfson Unit for Endoscopy at St Mark’s Hospital). A comparative study was conducted to evaluate team performance in urgent and emergency (E) procedures with elective routine cases (R). Consecutive emergency / urgent endoscopy referrals during a two month period were evaluated and matched with an elective endoscopy. Live observations of procedures were conducted both in hours (IH) and outside (OOH) of normal working hours to capture a representative range of emergency and urgent procedures. This was a mixed methods study with qualitative and quantitative research methods.

4.4.2 **Participants, procedures and settings**

The details of the participants and setting for the endoscopy are considered for the two patient groups.

4.4.2.1 **Emergency procedures**

Emergency procedures were defined as those procedures that were deemed urgent enough to require endoscopic intervention within 24 hours after appropriate resuscitation and optimisation of the patient for endoscopic intervention. This was based on clinical judgement and risk stratification scoring systems by the referring clinician and the on call gastroenterologist / endoscopist. These included emergency procedures for example life threatening GI bleeding, as well as urgent procedures required due to complex comorbidity for example relating to urgent anticoagulation. The definition of emergency and urgent
endoscopy for the purposes of this study included all cases that were deemed urgent by both the referring clinician and the duty endoscopist verifying the appropriateness of the endoscopic intervention. Emergency procedures were ranked according to severity. This was achieved by using the Glasgow-Blatchford scale in conjunction with the setting of the procedure (Operating theatre [OR] > Intensive Care Unit [ICU] > Endoscopy department [E]), whether therapeutic intervention was required at endoscopy and clinical judgement based on information provided in the referral form and medical notes.

For emergency cases study participants were mainly endoscopists but also included the assisting nurses, the core endoscopy team and the patient undergoing the procedure. Endoscopists performing the emergency procedures were independent endoscopists on the emergency GI bleed rota, comprising registrar and consultant gastroenterologists. Assisting nurses included endoscopy trained nurses, site practitioners and theatre scrub nurses. The wider emergency endoscopy team included anaesthetists, operating theatre staff and intensive care teams.

The majority of urgent requests were for Oesophago-duodenoscopy (OGD) for suspected Upper GI Bleeding (UGIB). Other procedures included Flexible Sigmoidoscopy (FS) and Colonoscopy (C) for lower GI blood loss as well as colonic stent insertion for obstructing malignant disease.

Endoscopies were evaluated in the setting where they were conducted: the endoscopy department, intensive care unit or the operating theatre both in and out of hours across the two month period.

4.4.2.2 Routine procedures
Study participants were mainly the endoscopists but also included the wider endoscopy team as well as the patient. Endoscopists were registrar and consultant medical gastroenterologists as well as independent endoscopy nurse endoscopists. OGD, FS and C procedure sub-types were examined and these were conducted in the endoscopy suite during normal working hours.

4.4.3 Case selection
All emergency / urgent endoscopy requests within the two month observation period were included in the study. These cases were identified by various means. Study details were
communicated via e-mail at a Trust level to ensure all potential participants (endoscopy teams, emergency teams, anaesthetic teams, surgical teams and site practitioners) were informed of the study ahead of the data collection period. The study was presented at the endoscopy users meeting to ensure all gastroenterology registrars and consultants were adequately informed. In addition posters advertising the study were posted on the trust computers as a screensaver to further disseminate information.

The duty endoscopist and the on-call gastroenterology registrar, were asked to contact research registrar (MM) at the point an emergency / urgent referral was received. In addition research registrar (MM) contacted the endoscopy nurse in charge and the on call gastroenterology registrar on a daily basis for the two-month observation period to ensure all cases were captured.

Once an emergency / urgent case was identified and live observations of teamwork completed, a routine elective case was matched within the next 24 hours to enable comparisons. The emergency and elective cases were matched for procedure subtype (e.g. OGD) and the grade of the endoscopist (e.g. registrar) but not for patient demographics. Where practically permissible the same endoscopist was rated in the emergency and routine setting although this was not always possible due to the study time period.

4.4.4 Exclusion criteria

All urgent / emergency endoscopy referrals identified were evaluated for study suitability. Those cases where the patient was unable to consent to the observations of the endoscopy team were excluded.

4.4.5 Primary measures: Skills, behaviours and errors.

Both emergency and elective endoscopic procedures were observed by research registrar (MM) trained in technical and non-technical skills assessment. Inter-rater reliability was determined in a previous study evaluating teamwork in the routine setting (Chapter 3) and was not duplicated in the emergency setting due to practical constraints. All observations were conducted prospectively from within the procedure room. Assessments were conducted for the principal or first endoscopist, defined as the endoscopist performing the majority of the procedure. The principal endoscopist needed to be defined when there were two endoscopists in the room, usually a gastroenterology registrar and the on-call
gastroenterology consultant. Validated rating tools were used to make three main assessments and these are described in the next section (see appendix 3.1 for an overview of technical and non-technical skills assessment tools).

4.4.5.1 Technical Skill (DOPS)
The technical competency of the principal endoscopist was measured using a validated national competency framework ‘Directly Observed Procedural Skills’ (DOPS) assessment commonly used in the UK14 (appendix 3.3). Procedure-specific DOPS forms were used, although these were not specific to emergency endoscopy. A formative DOPS assessment was completed for each procedure and technical skill scored within four domains:

1. Assessment, consent and communication
2. Safety and sedation
3. Endoscopic skills during procedure
4. Diagnostic and therapeutic ability.

Assessments are completed with pre-defined criteria and follow a 1-4 anchored scale 15:

1= Accepted standards not met
2= Some standards not yet met
3= Competent and safe throughout procedure
4= Highly skilled performance.

4.4.5.2 Non-Technical Skill (ENTS)
Non-technical skills were objectively evaluated by direct behavioural observation using the Endoscopic Non-Technical Skills (ENTS) framework16 described in section 3.2.2 (appendix 3.2). Observed behaviours during the procedure were coded into four categories with anchored 1-4 rating scale:

- Communication and teamwork
- Situation awareness
- Leadership
Judgment and decision-making

1= Poor: Performance endangered patient safety

2= Marginal: Performance indicated cause for concern

3= Acceptable: Performance was satisfactory

4= Good: Performance of a consistently high standard, enhancing patient safety

The ENTS tool covers a range of safety behaviours but is not specific to emergency procedures. Endoscopic non-technical skills were evaluated for each procedure for the principal endoscopist. An ENTS score was assigned to each category as observed throughout the procedure and these ratings informed the overall ENTS score for the endoscopist. This was supplemented by qualitative observations both pre and post procedure where planning and preparation, seeking senior advice, communication, delegating tasks and assigning responsibility could be observed in preparing for an urgent case and also ensuring optimal post procedure management.

4.4.5.3 Safety Checks (SC)

As identified in Chapter 2 there was no set standard for pre-procedural safety checks in the unit. In chapter 3 similar safety check observations were conducted for routine elective procedures where 14 key items were rated on a 1-4 scale for robustness of safety check (section 3.4.3.3). By the time of this current study the unit procedure for conducting safety checks had been standardised by implementation of a 13-item endoscopy safety checklist (Chapter 5). Safety checks in this study were therefore assessed by the degree of completion of the checklist i.e. proportion of 13 items checked. The safety checks were scored for the endoscopist completing the check with the team during the checklist; either leading the checks or affirming team responses.

4.4.5.4 Patient Safety Incidents (PSI)

Observable patient safety incidents (PSI) were recorded according to the methodology described in chapter 2 (section 2.4.2.3-4). PSI were defined as any safety issue that had the potential to, or directly adversely affected patient care and were recorded pre, intra and post procedurally. PSI were defined as near misses, recognised procedural complications, adverse events and never events according to the Department of Health’s classification at the time of the study\textsuperscript{17}. PSI were identified from the assessor’s qualitative notes and examination of the
patient’s medical and nursing record. PSI were also considered in relation to the checklist i.e. those PSIs that occurred as a result of safety checks not being completed through the checklist and those near misses that were captured by the checklist. The clinical impact of the PSI was assessed during the immediate observation period and not extended beyond this.

4.4.6 Secondary Measures

In addition to the primary measures described above, additional data was collected and analysed. These included the completeness of the referral form (including calculation of the Glasgow Blatchford score where indicated) as well as the time taken to conduct the procedure from the point of referral. Procedures conducted within working hours (defined as between 0800 and 1800) and those occurring out of hours were analysed. Urgent and emergency procedures were stratified by ranking cases according to clinical severity and taking into account the procedure setting to see if there was a difference in performance according to case severity. Haemodynamic instability of the patient was recorded: This was defined as a systolic blood pressure (SBP) <90 and / or a heart rate (HR) >90. Senior support was recorded if the receiving registrar contacted the on-call consultant to be present during the procedure. Additionally, the number of clinical team members engaging in the checklist and also involved in the procedure was measured.

4.4.7 Ethical Considerations

Ethical approval for this study was obtained from the National Research Ethics Service (NRES) Committee London, Reference 08/H0719/54. Informed consent to observe each endoscopy procedure was obtained from the patient, the endoscopist, the assisting nurses and wider endoscopy team (e.g. anaesthetist) involved in conducting the procedure. Particular consideration was given to patients who may be so acutely unwell at presentation that their ability to give informed consent was affected. Although the patients were not the direct focus of the study (the endoscopist and team interactions were being assessed) such cases were excluded from the study.

For the endoscopists, participation was voluntary and participants’ anonymity and patient confidentiality were maintained throughout. Endoscopy teams were informed that observations were being undertaken to evaluate team processes and safety in endoscopy. In the event of an adverse patient outcome, normal unit policies were adopted whereby the site
practitioner, nurse in charge and the unit manager were informed and the incident reported to
the hospital’s adverse event reporting system.\textsuperscript{18}

4.4.8 Data analysis

Data analysis was conducted in two main parts. Firstly, overall analysis for the entire data set
(emergency and routine cases combined) and secondly comparative analysis between
emergency and routine cases. The statistical methods used for each are detailed below.

4.4.8.1 Combined emergency and routine cases

Overall analyses were conducted by using Spearman’s rank correlation as the majority of
measures were either ordinal in nature or had a skewed distribution.

4.4.8.2 Comparison between emergency and routine cases

Primary measures

Emergency and routine cases were individually matched and thus treated as paired data sets.
Variables measured on an ordinal scale or found to have skewed distributions were analysed
using the Wilcoxon matched-pairs test. Normally distributed continuous variables were
compared using the paired t-test.

Patient Safety Incidents relating to the checklist were summarised in percentage.

Secondary measures

The emergency case severity was assessed on an ordinal scale. The association between this
measure and the other variables was assessed for the emergency procedures by Spearman’s
rank correlation.

The time between the referral being made and the endoscopy being performed was expressed
as a median time in minutes due to the skewed distribution of data.

The number of clinical team members participating in the checklist and the number involved
in completing the procedure were compared. For each procedure the ratio of the number in
the procedure team to the checklist team was calculated. The one sample t test was used to
examine if this ratio was significantly different to 1, the value that would be obtained if all
the members conducting the procedure also contributed to the checklist. This analysis was
completed for elective cases and emergency cases separately as well as for the dataset
combined. A comparison was also made between emergency and elective cases using the paired t test.

Finally, procedures performed in-hours (IH) (0800-1800) and out of hours (OOH) were compared. Ordinal score variables and continuous variables found to have skewed distributions were compared between groups using the Mann-Whitney test. Normally distributed continuous variables were analysed using the unpaired t-test.

4.5 Results

4.5.1 Demographics and Study Participants

Forty-one emergency and 41 routine cases were analysed. These comprised 72 OGDs, 6 FS, 2 C and 2 OGD/FS as combined procedures. Emergency and routine procedures were conducted by 17 different endoscopists.

The emergency endoscopy request form was complete in 23/41 (56%), partially complete in 10/41 (24%) and not completed in 8/41 (20%) of cases. The complete GI bleed bundle (GIBB) document was not fully completed for any of the emergency cases. It was partially completed for 20/41 (49%), not completed for 15/41 (37%) and not applicable in 4/41 (10%). The medical records for 2/41 (5%) were not attainable. The Glasgow Blatchford score was completed in 25/41 (61%), was not calculated in 12/41 (29%) and not applicable in 4/41 (10%).

For 8/41 (20%) of emergency cases a senior consultant was present for the procedure. Seven of these were supervised IH and one procedure was technically OOH (1855) although the consultant was conducting a parallel evening list in the endoscopy unit and was asked to complete a DOPS assessment for the endoscopist.

The majority of procedures were conducted in the endoscopy unit (n=72) followed by the operating theatre (n=7) and the Intensive Care Unit (n=3). There were no patients scoped in the Emergency Department. Haemodynamic instability (SBP <90 / HR >90) was found in 9/41 (22%) of emergency cases. For the majority of patients 36/41 (88%) this was the index procedure of their current admission and for 5/41 (12%) it was the second procedure and therefore represented concern for on-going bleeding. With regards to the degree of blood loss 6/41 (15%) of patients had a haemoglobin level <8g/dl. The indications for the emergency procedure are summarised in Figure 4.2.
4.5.2 Combined Emergency and Routine Case Analysis

4.5.2.1 Technical and Non-Technical Skills
Across the dataset technical skills scores (DOPS) ranged from 2-4 with a modal score of 4. Non-technical skills (ENTS) ranged from 2-4 with a modal score of 3.

4.5.2.2 Safety Checks through the Checklist (SC)
The endoscopy safety checklist was not initiated in 5/41 (12%) of emergency procedures and was initiated but variably completed in the remainder of urgent and all routine cases. The mean time taken to complete the checklist was 58.4 seconds with a range of 16-164 seconds. Overall completion of the 13-item checklist was 46% - that is to say 493/1066 individual

Figure 4.2. Emergency Procedure Indications (as stated on request form)

Abbreviations
checks were completed. For emergency procedures 39% (210/533) checklist items were complete and for routine procedures this figure was 53% (283/533).

4.5.2.3 Patient Safety Incidents (PSI)
Two hundred and eighteen PSI were recorded with 188 observed in emergency procedures and 30 in routine cases. The range was 0-12 PSI per procedure. For 29 (13%) of the observed PSI, the error was captured and hence mitigated through the endoscopy checklist. For 93 of the observed PSI the error could have been captured by the endoscopy safety checklist if the appropriate check had been conducted. That is to say in 29 of the PSI the checklist was successful in absolving the error and 93 PSI could have been resolved had the checklist been adhered to. PSI in relation to the checklist are summarised in Figure 4.3. (The complete list of PSI can be found in the Appendix).

![Figure 4.3. Schema summarising Patient Safety Incidents in relation to the Endoscopy Safety Checklist](image)

**Figure 4.3.** Schema summarising Patient Safety Incidents in relation to the Endoscopy Safety Checklist

4.5.2.4 Correlational Analyses
Correlational analyses for the four main variables (technical skill, non-technical skill, safety checks and patient safety incidents) across all 82 cases are summarised in Table 4.2.
Table 4.2. Spearman’s Rank Correlational analysis for Skills and PSI across Routine and Emergency cases (n=82)

<table>
<thead>
<tr>
<th>Variable 1</th>
<th>Variable 2</th>
<th>Correlation Coefficient</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>ENTS</td>
<td>DOPS</td>
<td>0.43</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>ENTS</td>
<td>PSI</td>
<td>-0.54</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>ENTS</td>
<td>SC</td>
<td>0.42</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>DOPS</td>
<td>PSI</td>
<td>-0.51</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>DOPS</td>
<td>SC</td>
<td>0.40</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>PSI</td>
<td>SC</td>
<td>-0.55</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>


Highly significant associations were found between all pairs of variables. A higher non-technical score (ENTS) was associated with a higher technical score (DOPS) and greater completion of the endoscopy safety checklist (SC). Conversely, a higher non-technical skills score (ENTS) was inversely correlated with the number of PSI suggesting a better non-technical skills score was associated with fewer PSI.

The measure of technical skill (DOPS) was positively correlated with the degree of checklist completion (SC) and negatively correlated with PSI, suggesting greater technical skills were associated with fewer PSI.

Finally, the degree of completion of the endoscopy safety checklist (SC) was negatively correlated with the number of PSI indicating that fewer PSI occurred with greater checklist completion.

4.5.3 Emergency and Routine Case Comparative Analysis: Primary Measures

Comparisons were made between routine and emergency cases for the four main variables. These are summarised in Table 4.3. Technical (DOPS) and non-technical (ENTs) scores were treated as ordinal data rated on a 1-4 scale and the proportion of scores within these categories is presented. The degree of completion of the 13-item checklist represented normally distributed continuous variables and is summarised by the mean and standard deviation.
deviation. The number of PSI was non-normally distributed and summarised by the median and inter-quartile range.

Table 4.3. Comparison of Skills and PSI between Emergency and Routine cases.

<table>
<thead>
<tr>
<th>Skills Variable</th>
<th>Categorical score (1-4)</th>
<th>Routine n (%)</th>
<th>Emergency n (%)</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>ENTS</td>
<td>2</td>
<td>1 (2)</td>
<td>15 (37)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td></td>
<td>3</td>
<td>24 (59)</td>
<td>19 (46)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>4</td>
<td>16 (39)</td>
<td>7 (17)</td>
<td></td>
</tr>
<tr>
<td>DOPS</td>
<td>2</td>
<td>0 (0)</td>
<td>1 (2)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td></td>
<td>3</td>
<td>4 (10)</td>
<td>19 (46)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>4</td>
<td>37 (90)</td>
<td>21 (51)</td>
<td></td>
</tr>
<tr>
<td>SC Variable</td>
<td>n checklist items</td>
<td>Mean (SD)</td>
<td>Mean (SD)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td></td>
<td>completed (0-13)</td>
<td>6.9 (1.9)</td>
<td>5.1 (2.7)</td>
<td></td>
</tr>
<tr>
<td>PSI Variable</td>
<td>Median (IQR)</td>
<td></td>
<td></td>
<td>&lt;0.001</td>
</tr>
<tr>
<td></td>
<td>n PSI</td>
<td>0 (0,1)</td>
<td>4 (3,5)</td>
<td></td>
</tr>
</tbody>
</table>

The comparative analyses suggested a significant difference for all four main variables between routine and emergency cases. Both non-technical (ENTS) and technical (DOPS) skills scores were lower for emergency procedures compared to routine ones. Thirty-nine per cent of routine procedures received the highest ENTS score of 4 compared to only 17% in the emergency cases. Ninety per cent of routine cases had a high technical skill score of 4 compared to 50% in emergency procedures. The 13-point checklist was less complete in emergency cases with a mean of 5.1 checks completed compared to a mean of 6.9 for routine cases. Similarly, there was a greater number of PSI (median 4) observed in emergency procedures compared to routine cases (median 0).

4.5.4 Secondary Measures

In addition to the main data analyses described above, secondary measures are summarised in the next section.
4.5.4.1 Emergency Case Severity

The emergency cases were ranked according to clinical severity and correlational analyses conducted for the four main variables. There were no significant associations between case severity and primary variables and this is summarised in Table 4.4.

Table 4.4. Correlational Analysis between Case Severity and Primary Measures

<table>
<thead>
<tr>
<th>Variable</th>
<th>Correlation Coefficient between case severity &amp; primary measures</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>ENTS</td>
<td>0.00</td>
<td>0.98</td>
</tr>
<tr>
<td>DOPS</td>
<td>-0.13</td>
<td>0.42</td>
</tr>
<tr>
<td>SC</td>
<td>-0.19</td>
<td>0.23</td>
</tr>
<tr>
<td>PSI</td>
<td>0.14</td>
<td>0.37</td>
</tr>
</tbody>
</table>

4.5.4.2 Referral to Endoscopy lead time

The median time frame from the emergency / urgent referral being made to the endoscopy being carried out was 6.5 hours (IQR 4.1, 10.0 and range 0.9, 39.5). This included all urgent referrals including those that required further resuscitation prior to endoscopic intervention.

4.5.4.3 Procedure and Checklist Team Membership

Comparisons were made between the checklist and procedure team constituents. The minimum requirement for both is one endoscopist and two assisting nurses. The ratio of procedure : checklist team members is summarised in Table 4.5 and a comparison between emergency and elective cases is presented in Table 4.6.

Table 4.5. Comparison of relative numbers in checklist and procedure team members using the one sample t test.

<table>
<thead>
<tr>
<th>Procedure Subtype</th>
<th>Team membership Ratio: Procedure members n / Checklist members n (95% CI)</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Elective Procedures</td>
<td>1.11 (0.96, 1.26)</td>
<td>0.15</td>
</tr>
<tr>
<td>Emergency Procedures</td>
<td>1.70 (1.39, 2.02)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Elective and Emergency combined</td>
<td>1.40 (1.22, 1.58)</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>
Table 4.6. Comparison of Checklist and Procedure Team Members in Emergency and Elective cases using the paired t test.

<table>
<thead>
<tr>
<th>Procedure Subtype</th>
<th>Team n difference *</th>
<th>Group difference</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean (SD)</td>
<td>Mean (95% CI)</td>
<td></td>
</tr>
<tr>
<td>Elective</td>
<td>0.2 (0.5)</td>
<td>0</td>
<td>0.01</td>
</tr>
<tr>
<td>Emergency</td>
<td>1.1 (2.0)</td>
<td>0.9 (0.2, 1.7)</td>
<td></td>
</tr>
</tbody>
</table>

These results demonstrate a significant difference in the number of team members participating in the procedure and the checklist examining the combined data and the emergency sub-set but not for the elective cases. That is to say fewer people participated in the checklist compared to the actual procedure. For the combined data the procedure team had 40% more members than the checklist team and this difference increased to 70% when the emergency cases were considered separately.

When the two groups (emergency and elective) were compared the discrepancy between checklist and procedure team membership was more pronounced for the emergency data set.

4.5.4.4 Procedures conducted out of routine working hours

The majority of procedures were conducted within routine working hours (n=69 / 84%) and 13 (16%) procedures were completed outside routine hours. The primary measures were compared for these 2 groups. The skills variables were ordinal in nature and the percentages of scores in each category are presented. The number of checklist items completed was normally distributed continuous data and summarised by the mean and standard deviation measures. PSI were non-normally distributed and summarised by median and interquartile range. The findings are detailed in Table 4.7 with no significant differences for skills and errors for procedures conducted out of hours.

Table 4.7. Comparison of Skills and PSI measures for procedures within (IH) and outside (OOH) of routine working hours (defined as 0800-1800)

<table>
<thead>
<tr>
<th>Skills Variable</th>
<th>Categorical score (1-4)</th>
<th>IH n=69 n (%)</th>
<th>OOH n=13 n (%)</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>ENTS</td>
<td>2</td>
<td>12 (17)</td>
<td>4 (31)</td>
<td>0.66</td>
</tr>
<tr>
<td></td>
<td>3</td>
<td>38 (55)</td>
<td>5 (38)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>4</td>
<td>19 (28)</td>
<td>4 (31)</td>
<td></td>
</tr>
<tr>
<td>Skills Variable</td>
<td>Categorical score (1-4)</td>
<td>IH n=69 n (%)</td>
<td>OOH n=13 n (%)</td>
<td>p value</td>
</tr>
<tr>
<td>-----------------</td>
<td>-------------------------</td>
<td>--------------</td>
<td>----------------</td>
<td>---------</td>
</tr>
<tr>
<td>DOPS</td>
<td>2</td>
<td>1 (1)</td>
<td>0 (0)</td>
<td>0.46</td>
</tr>
<tr>
<td></td>
<td>3</td>
<td>18 (26)</td>
<td>5 (38)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>4</td>
<td>50 (72)</td>
<td>8 (62)</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Variable</th>
<th>Mean (SD)</th>
<th>Median (IQR)</th>
</tr>
</thead>
<tbody>
<tr>
<td>SC</td>
<td>6.1 (2.5)</td>
<td>2 (0,4)</td>
</tr>
<tr>
<td>PSI</td>
<td>5.3 (2.7)</td>
<td>3 (1,5)</td>
</tr>
</tbody>
</table>

4.5.5 Qualitative themes

In addition to the qualitative measures described above a significant amount of time was spent observing team interactions pre, intra and post procedurally enabling detailed qualitative assessments to be made. These were extracted from field notes and the major themes are detailed below.

4.5.5.1 Planning, coordination and organisation

The urgent and emergency procedures frequently required significant organisational skills and coordination amongst different individuals, teams and specialities. This was often observed to be very difficult to implement even when the endoscopist had good insight into the planning of tasks and processes required. In addition to planning for the index procedure the importance of contingency planning in the eventuality that the index intervention was not successful may have been considered by the endoscopist, but was rarely explicitly communicated with the wider teams involved.

Planning and preparation skills were frequently related to sub-optimal utilisation of the dedicated urgent endoscopy slot each weekday. This was set up to accommodate urgent procedures thus limiting impact on planned elective procedures. However there were limitations in the handover process from the night to day team for example and coordinating the endoscopist, nurses and the ward team to ensure the patient and staff were adequately prepared to carry out the procedure. Consequently, this early morning slot was often not used causing organisational challenges in accommodating the procedure later in the day with booked lists. In some cases this was not possible and the case was conducted out of hours with all the associated ramifications of limited staff and hospital services.
4.5.5.2  Endoscopic Procedures conducted out of hours

Due to organisational factors procedures were occasionally conducted out of hours, which in some instances could have been conducted in routine hours. A key threat to patient safety associated with this was the lack of availability of trained endoscopy nurses. In emergency cases where therapeutic intervention is often required the presence of a skilled endoscopy nurse assistant cannot be underestimated. Haemodynamically unstable patients or those requiring airway protection required a slot in emergency theatre, with significant additional planning and coordination. The endoscopist would have to compete with other specialties to acquire theatre space for their patient and complex decisions in prioritising patients had to be taken in conjunction with operating theatre coordinators and the on call Anaesthetist. Consequently the timing of the procedure could rarely be confirmed, and was often significantly delayed from the anticipated time resulting in the procedure taking place later into the shift with an increasingly fatigued on call team.

Cases conducted in the operating theatre and intensive care unit also represented the most critical patients often with the least experienced (in endoscopy) assistants e.g. site managers with other key responsibilities managing the entire hospital out of hours. Additionally, the duty gastroenterology registrar would have to make a definitive decision to call in a superior out of hours. This could be a complex decision and sometimes registrars were deterred from seeking senior advice or supervision due to the time of night.

4.5.5.3  Technical Factors

Aside from the important non-technical skills required to safely and effectively conduct emergency cases, technical issues were also more challenging in this setting. The endoscopic intervention itself was technically more difficult e.g. controlling haemorrhage with a combination of techniques and colonic stent insertion for a malignant stricture. Additionally, these technically challenging procedures were often being performed in sub-optimal conditions (e.g. out of the unit and out of hours without trained endoscopy nurses). As a result of this, technical issues relating to equipment availability, use, familiarity and problem solving were more pronounced. Although an emergency endoscopy stack was prepared and checked in the unit each day endoscopists had varying levels of familiarity with the contents of this stack and where to find key accessories. This led to errors and was inefficient in time critical situations where the endoscopy assistants were not trained to deal with these issues.
Furthermore, recurrent equipment related errors were observed, as the situation had not been adequately handed over and/or resolved the following day after the acute procedure.

4.5.5.4 Complex communication and decision making
Qualitative observations in conjunction with the non-technical skills rating tool highlighted the importance of complex communication skills. These would manifest not only during the procedure with key team members, but included critical discussions with patients and families pre-procedurally relating to risks, benefits, alternatives and resuscitation decisions. These were difficult communication issues but provided a critical foundation to adequately consenting patients, providing patient choice and managing expectations. In addition, difficult decisions presented themselves frequently for emergency cases requiring balanced judgement and weighted consideration of multiple pieces of information (patient wishes, comorbidity, likely outcome, unnecessary risks, resource availability, technical expertise allied specialist team availability etc.). In particular, it was often more difficult for endoscopists to cancel or defer a procedure even if they did not feel it was in the patient’s best interest. This was particularly pronounced when plans were already in place to initiate the procedure (e.g. by the day team), and this was the patient’s expectation. These decisions and communications were often taken in time-pressured situations and often by registrars as opposed to senior consultants. This is in contrast to the elective setting where second opinions can more readily be sought and complex communications can often be escalated to consultant level.

4.6 Discussion

4.6.1 Summary
This study is the first to prospectively evaluate technical and non-technical skills affecting patient safety in urgent and emergency endoscopy procedures. The majority of these procedures were OGDs for presumed upper GI bleeding and conducted in the endoscopy unit although cases in the operating theatre and intensive care constituted a quarter of the data set. Around a quarter of these patients were haemodynamically unstable representing the severe end of the clinical spectrum. Approximately half of the referral documentation was adequately completed when examining the medical documentation.

Across routine and emergency procedures, checklist completion was below 50% with completion rates being poorer for emergency procedures compared to routine ones. A
A significant number of PSI (n=218) were observed across procedures and the majority of these occurred in emergency procedures.

Correlational analyses showed significantly positive correlation between ENTS, DOPS and SC and negative correlation for PSI with ENTS DOPS and SC.

All skill measures ENTS, DOPS, SC as well as PSI were significantly poorer for emergency cases compared to routine ones.

4.6.2 Primary measures

The primary measures of this study evaluated whether technical and non-technical skills, safety checks and patient safety incidents differed between emergency and routine endoscopy. These results showed that emergency cases had significantly poorer measures compared to routine cases. That is to say despite a similar calibre of endoscopist, procedural technical scores were lower, non-technical skills were poorer, the safety checklist was less complete and a greater number of errors were recorded for emergency endoscopy procedures. This may reflect the complexity of the patients, the endoscopic intervention, the emergency nature of the situation as well as the organisational issues around coordinating such cases in the appropriate setting with adequate supervision.

4.6.2.1 Technical Skill

It is notable that these differences for emergency endoscopy were observed for independent endoscopists experienced enough to be selected for the emergency endoscopy rota. This implies the technical capabilities of the endoscopist were well established. Despite this, performance was diminished in the emergency context suggesting that the required non-technical skills in this setting may be adversely impacting technical performance. This is illustrated by the example of technical equipment related problems distracting the endoscopist from focussing on the procedure itself. Although anticipating and rectifying equipment related problems forms part of good situation awareness, there are opportunities prior to the procedure where these issues could have been addressed. Additionally, in the routine situation these issues could be delegated to trained endoscopy nurses or may have been obviated by the team in the first instance.
4.6.2.2 Non-Technical Skill

The range and importance of good non-technical skills in the emergency setting was significant. This may be because the emergency situation provided greater necessity for these skills to be utilised or because the absence of these skills had detrimental effects on patient.

This is illustrated by considering communication skills as a sub-set of non-technical skills. In the emergency setting the communications needed to be even more explicit and complete given the fact that the setting may be unusual and the team unfamiliar. Poor communication led to misunderstandings between sub-teams in the room i.e. theatre team and endoscopy team leading to errors in anticoagulation and fluid resuscitation.

In total 16 observations equated to the lowest ENTS score of 2 and all but one of these were emergency cases. The observed PSI in these procedures ranged from 2-12. The procedures with multiple PSI had sub-optimal non-technical skills in multiple domains. This was exemplified by a case conducted in the operating theatre, which is summarised in Table 4.8.

4.6.2.3 Safety checks

Coupled with poorer non-technical skill the endoscopy safety checklist was also less complete for emergency cases: Objectively, it was observed that fewer of the 13 component checks were completed. For the 5 cases in which the checklist was omitted, 3 of these procedures were performed in ITU (the other 2 in Endoscopy) where one could argue the importance of the checklist was paramount (patient severity and unfamiliar team and environment). Checklist omission not only contradicted unit policy at the time, but was also associated with additional errors such as inadequately documented consent, missing endoscopy equipment and erroneous patient identity labels on histology samples. In addition to this, the nature and quality of the checklist was different particularly with procedures conducted outside the endoscopy unit. There was an understanding of and expectation to complete a pre-procedural checklist in the operating theatre given theatre teams’ familiarity with the WHO surgical safety checklist. This however led to confusion as to whether the endoscopy checklist needed to be completed. Whilst there is some degree of overlap between the 2 checklists key endoscopy related checks were sometimes omitted when only the WHO checklist was undertaken. There were also practical issues in completing the checklist outside the unit (unclear of team members, checklist document unavailable etc.) and coupled with time pressures and a sense of urgency it was often justified by the team to skip the checklist rather than understanding it was even more necessary in this situation. The process in
Intensive Care was more variable with a wider array of people involved, unclear leadership roles and consequently greater opportunity for error. As the checklist was a relatively new intervention, teams sometimes lacked conviction in ensuring the checklist was properly completed and that all relevant specialties were engaged in the process. This is supported by the data showing that there were a greater number of team members involved in the procedure compared to the checklist.

Table 4.8. Illustration of multiple PSI and sub-optimal Non-Technical Skills in a single procedure

<table>
<thead>
<tr>
<th>PSI</th>
<th>Communication</th>
<th>Judgement Decision Making</th>
<th>Situation Awareness</th>
<th>Leadership</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient with Clostridium Difficille infection previously in theatre and inadequate deep clean of theatre environment</td>
<td>Documentation / Handover error</td>
<td>Surgical referrers insist on emergency colonoscopy, endoscopist disagrees but continues with procedure</td>
<td>Nurses query deep clean prior to following case but no definitive decision / action taken</td>
<td>Endoscopist has concerns about procedure suitability but did not escalate issue and continued with the procedure</td>
</tr>
<tr>
<td>No documented referral form</td>
<td>Nurses alert endoscopist no referral form, endoscopist distracted</td>
<td>Patient deemed too ill for CT angiogram yet prepared for colonoscopy</td>
<td></td>
<td>Endoscopist raises doubts about endoscopic procedures and management but ineffectual in changing decision to proceed to colonoscopy</td>
</tr>
<tr>
<td>No valid consent form (Blank consent 4 in medical notes)</td>
<td>Team unclear on consent process prior to theatre</td>
<td>No resolution on consent issue and team continue with procedure (passive decision)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sub-optimal preparation of equipment</td>
<td></td>
<td></td>
<td>Nurses aware bowel preparation sub-optimal but did not prepare foot pump in advance. One nurse had to return to endoscopy to collect equipment resulting in delays.</td>
<td></td>
</tr>
</tbody>
</table>
Confusion over patient’s clinical stability
Lactate misread on serial ABGs. Thought to be falling with resuscitation but was actually rising (Lactate 9 at time of endoscopy)
Distractions and multiple intra-speciality conversations.
Anaesthetist and endoscopist interchanging leadership roles

Confusion over patient’s anticoagulation status
Misinformation about timing of anticoagulant drugs and most recent INR result
Drug chart and latest blood tests not checked and shared with the team to resolve the confusion over anticoagulation status
Team dis-engaged by the start of the procedure
No clear overall leadership to unit endoscopy, theatre, anaesthetic and nursing teams

Abbreviations: ABG (Arterial Blood Gas) INR (International Normalised Ratio)

4.6.2.4 Patient Safety Incidents (PSI)
Significantly more errors were observed in emergency cases and these were negatively correlated with technical and non-technical skill and safety check completion. It could be inferred that a greater number of PSI were observed as a result of other skills being poorer, notably non-technical skills and checklist completion. Although there was no significant lasting harm to any of the patients from the endoscopy within the study time frame, it could be argued that emergency patients are less able to withstand the effects of error, particularly if the error was avoidable. This study clearly highlighted that errors could be avoided if the quality and processes around checklist completion for emergency cases were improved.

4.6.3 Secondary measures
Statistical analyses did not draw out any differences in the skills measured according to case severity, procedures outside of the endoscopy unit or those outside of normal working hours. This may have been because the sample size was small and the study was not specifically designed to address these secondary questions. Qualitative data suggested that there were many factors threatening patient safety through sub-optimal non-technical skills particularly for cases conducted in intensive care and the operating theatre. The majority of emergency procedures were conducted by registrars and consultant involvement when requested varied from communication over the phone to physically assisting with the procedure. This clearly involved a degree of individual judgement and decision making which the NCEPOD counters
by stipulating that all GI bleed patients should be referred to or discussed with the designated duty consultant within an hour of the diagnosis of a major bleed.²

Urgent procedures were accommodated in a timely manner with a median referral to procedure time of 6.5 hours. There were extreme cases of patients waiting >24h for a procedure and this was related to clinical reasons (patient stability) as well as organisational factors (accommodating a less urgent case during working hours).

4.6.4 Study Limitations

Although the two comparison groups were similar, the cases were not matched for patient demographics (e.g. age, gender and presence of comorbidity) due to the practicalities of rating within 24 hours of the matched emergency case. In a similar vein, it would be ideal to examine the same endoscopist in the emergency and routine setting – i.e. examine the same endoscopist longitudinally in both study situations. To diminish this effect, the same grade of endoscopists was matched for emergency and routine cases. Where a registrar endoscopist was not available for an elective OGD, a nurse endoscopist was observed as they performed a large majority of the elective work and had comparable experience. The majority of routine cases were diagnostic in nature whereas the emergency cases involved more therapeutic intervention. Ideally it would have been better to match diagnostic emergency cases with diagnostic routine ones and emergency therapeutic cases with routine therapeutic ones. This would have been feasible for the diagnostic pairs, but more challenging for therapeutic cases.

Furthermore, it is acknowledged that the technical skills rating tool used (DOPS)¹⁹ is not specifically designed for emergency procedures. Although a DOPS tool for emergency procedures has since been developed⁷, this tool was not available at the time of the study. The absolute numbers within the study are small, although these were emergency cases arising less frequently than elective scheduled cases. The study was not sufficiently powered to make robust conclusions for the secondary measures presented. Considering the patient safety incidents there was no follow up of patients beyond the immediate observation period to determine if significant harm had been encountered as a result of the error. In addition, PSI that were averted by the checklist were also included and it could be argued this represents an over-estimate of actual error. Importantly, this study did not evaluate patient outcome data to determine whether or not the observable errors translated to actual patient harm.
4.6.5 Future work

This study raises the question as to whether technical performance in emergency endoscopy could be enhanced by identifying, training and assessing non-technical skills a concept supported in the literature\(^{20} \textit{21}\). This in turn could impact avoidable error and possibly affect efficiency.

Further work to address these questions should include a multicentre larger scale study to corroborate these findings and to ensure they are not a phenomenon unique to the institution where the study was conducted. Additionally, development of a non-technical skills rating tool specific to emergency endoscopy would provide a more bespoke and in depth assessment of these skills.

Emergency endoscopy training requires further development to match the quality of training for elective cases. This should be developed to incorporate simulation training to better prepare registrars for emergency endoscopy clinical scenarios. This is well established in anaesthetics\(^{22}\) and surgery\(^{23}\) and should be translatable to endoscopy if simulation technology\(^{24}\) and team training concepts\(^{25}\) are combined. Once these training modalities are established through the existing infrastructure of JETS, further advantages such as managing stress during acute emergency endoscopy situations can be examined.

The concept of mental practice where cognitive rehearsal in a simulated setting can positively affect performance, is a well-established technique for professional sports players and has been shown to be of value in surgery.\(^{26} \textit{27}\) By addressing the effects of stress and performance\(^{28}\) early on in training the opportunity to develop non-technical skills in parallel to technical skills can be maximised. The advantages to patient safety are many fold, but primarily trainees (and patients) benefit from training and practicing techniques in a safe simulated setting ahead of being in ‘the driving seat’.

Various policy changes have already been translated to clinical practice, but further practical measures can be developed to mitigate the errors observed within this study. These include further training and development in the acute care bundle to ensure teamwork techniques such as effective checklist use, are implemented in practice. Additionally, standardisation of processes where possible e.g. re-evaluation of the design and organisation of contents within the emergency endoscopy stack should be considered. The effectiveness of collaborating with design, technology and engineering experts has been illustrated by the ‘Designing out
Medical Error” (DOME) project. Collaborative interdisciplinary research to enhance resuscitation trolleys and clinical work stations for example not only improve ergonomics but can impact patient safety by enhancing hand hygiene. Future collaborative projects with other professionals where the endoscopy environment and equipment related issues can be ameliorated may be a practical approach to overcoming some patient safety obstacles.

4.7 Conclusion

This study highlighted that performance in urgent and emergency endoscopy was significantly poorer compared to routine procedures and resulted in more patient safety incidents. Different technical and non-technical skills may be required for emergency endoscopy. In these complex higher-risk cases, poorer non-technical skills and suboptimal checklist completion may be negatively impacting technical performance in endoscopists who perform well in the routine setting. These offer targeted training opportunities and performance assessments to enhance safety and quality for this patient sub-group.
Chapter 5: Identifying and Measuring Factors Affecting Patient Safety in Colorectal Cancer Multidisciplinary Teams

5.1 Chapter Overview

Endoscopy patient pathways are closely interlinked with the colorectal cancer care pathway, with the cancer multidisciplinary team (MDT) meeting representing a confluence for decision making. The MDT plays an important role for patients prior to their endoscopic procedure as well as following an endoscopy with a suspected or confirmed cancer diagnosis. This chapter seeks to identify the safety and quality factors impacting the colorectal cancer MDT, given the focal point this process adopts for some endoscopy patients. Multi-disciplinary team working processes, decision making and errors are objectively evaluated and considered for key patient pathways to identify opportunities to enhance safety at both ends of the endoscopy patient pathway. The introduction contextualises the MDT for patient pathways, followed by the methodology for scientifically measuring the MDT process. The results are discussed with an emphasis on extending the quality assurance measures established within endoscopy to also include the colorectal cancer MDT.

5.2 Introduction

Cancer multidisciplinary team working and decision making is increasingly the preferred model for delivering cancer care. The link between endoscopy and the colorectal cancer MDT represents both a threat and an opportunity to enhance patient safety. Coordinating information, communication and decisions between teams of professionals adds complexity, with multiple defects in the system paving the way for medical error. Conversely, the MDT enables specialist peer review of diagnostic and patient management decisions to optimise and rationalise investigations for each individual patient, thus enhancing quality. The introductory chapter (section 1.5) outlined key endoscopy patient pathways dividing into bowel cancer screening, symptomatic patients, suspected cancer 2 week wait pathway and tertiary referrals. The interaction of patients from these streams with the MDT, both pre and post endoscopy, are important opportunities for enhancing endoscopy patient safety and quality.
5.2.1 Definition of Cancer Multidisciplinary Teams

A cancer multidisciplinary team (MDT) is defined as a, “group of people of different healthcare disciplines, which meets together at a given time (whether physically in one place, or by video teleconferencing) to discuss a patient and who are each able to contribute independently to the diagnostic and treatment decisions about the patient”. Multidisciplinary teams thus establish a means of coordinating patient information, communication and decision making between specialists to propose treatment options for patients. Despite the recommendations for cancer services to be organised around MDTs, the evidence base supporting their effectiveness remains questionable and the performance of MDTs is known to be highly variable. Nevertheless, MDTs remain the cornerstone of cancer care decision-making and treatment planning, and research and policy developments endorsed by The National Institute for Health and Clinical Excellence (NICE) have focussed on improving the effectiveness, quality and patient centeredness of MDTs.

5.2.2 Quality Assurance of Cancer Multi-Disciplinary Teams

Treating patients within cancer MDTs was mandated in the UK in 2004 following recommendations from the Manual for Cancer Services to streamline cancer services for patients on a national scale. This document sets out detailed measurable standards for planning and provision of cancer care to fulfil acceptable standards of care. Quality assurance of MDTs is set by the National Cancer ‘Peer Review’ Programme which seeks to evaluate MDTs compliance with the Manual for Cancer Services. Whilst this quality assurance framework provides a foundation, it does not specifically address the quality metrics of information, teamwork and decision-making within the MDT meeting itself, which is a crucial aspect.

5.2.3 Characteristics and Value of Cancer Multidisciplinary Teams

The MDT has many functions. Primarily it provides a forum for critical analysis of information and discussion of treatment options. This can involve interrogation of diagnostic data, seeking specialist opinion, proposing alternatives and collaborative decision making in order to reach consensus. The complexity of decision-making in defined clinical situations has been analysed and this complexity is compounded in cancer management given the myriad of diagnostic and treatment modalities available, and the number of professionals involved in delivering care. It is clear that MDTs make different decisions to individual
clinicians\textsuperscript{11} and this often arises from expert peer review of clinical information. The MDT plays a role in enhancing clinical decision-making by ‘implementing quality control mechanism for radiology and pathology and by increasing the internal consistency of decision-making’ by adherence to best guidance and dissemination of research.\textsuperscript{12} The educational value of MDTs is heavily implicated in this aspect, particularly considering that there is no dedicated training to equip doctors in good MDT practice. MDTs also play an important role in individualising patient management: By improving information relating to comorbidity and patient preference (over biomedical information) treatment decisions can be optimised with improved implementation.\textsuperscript{13} Implementation of MDT treatment decisions provides a barometer for effective MDT decision-making and highlights areas for improvement, often relating to patient centred information.\textsuperscript{14}

In addition to diagnostic pathways, MDTs provide recommendations for surveillance, survivorship and palliative care and represent an important link between primary and secondary care.\textsuperscript{5} In summary, decision support strategies and an appreciation of teamwork\textsuperscript{15} should be considered to enhance the ‘clinical, operational and governance aspects of cancer MDTs’.\textsuperscript{5}

5.2.4 Quality and Safety extended across the endoscopy pathway

Patients undergoing a bowel cancer screening colonoscopy undergo a procedure by an accredited colonoscopist with robust quality assurance measures for the procedure as well as the pre-assessment process. At the point a positive diagnosis of colorectal cancer is made, the patient is transferred to the symptomatic service, which does not have the equivalent quality assurance infrastructure. The opportunity to extend this quality assurance at the most critical point for the patient therefore rests with the quality of the information presented and the judgement and decision making at the MDT.

Additionally, a smaller number of patients entering the MDT via alternative routes may require an endoscopic intervention. The decision-making about the appropriateness of the endoscopic procedure for the patient, the technicalities of the intervention and patient preferences are key considerations for the MDT and decisions that may be undertaken without the required specialist endoscopist. The MDT thus plays a crucial role for ensuring the endoscopic procedure is ‘completed’ with high quality decision-making and ‘prepared’ appropriately. This is with the objective of maintaining patient safety (e.g. avoiding
unnecessary high risk endoscopic procedures) and continuing high quality care (e.g. accurate and complete endoscopy report writing equipping the MDT to make the best decision for the patient).

5.2.5 **Sub-optimal MDT processes impacting endoscopy patients**

Quality assurance processes in endoscopy ideally require a systematic process to receive and triage referrals for endoscopic procedures. This screening of referrals is completed by a combination of administrative and clinical team members and is dependent on complete and accurate information on the request form. This is frequently sub-optimal resulting in delays in patients being booked whilst the information is being sought, or in some cases patients being booked inappropriately (e.g. wrong procedure, inadequate pre-procedure consent, wrong endoscopist or insufficient allocation of procedure time). This process was raised at the unit’s endoscopy governance and attention drawn to the endoscopy referrals generated by the colorectal MDT. These requests frequently had a paucity of clinical information as they were often completed within the MDT by a surgical team-member who may not have all the required clinical information to hand and was unlikely to have assessed the patient themselves. Due to pressures to comply with cancer treatment targets, the requests were submitted directly from the MDT but with errors occurring down the line (e.g. request for colonic stent insertion without prior discussion with specialist endoscopist).

Similarly, the active involvement of the clinical lead for endoscopy in the colorectal cancer MDT identified quality issues relating to endoscopy coming to light within the MDT. Delays in patient management were identified due to sub-optimal endoscopy report documentation (e.g. distance of rectal cancer from anal verge omitted from endoscopy report, completion Computed Tomography Colonography (CTC) and staging imaging not requested after endoscopic diagnosis of malignancy, and unclear documentation on what was communicated to the patient about the probable diagnosis). These clinical issues manifesting in the MDT directly impacted endoscopy quality assurance and required further analysis.

5.3 **Aims**

The aims of this study are to prospectively assess the quality of information presented at the MDT and the quality of specialty contribution to the discussion. This was undertaken for patients presenting through the key pathways into the colorectal cancer MDT:
1. Bowel cancer screening (BCS)

2. Two-week wait patients (2WW)

3. Symptomatic patients (SYM)

4. Tertiary referrals (TER)

In addition, patient safety incidents (PSIs)†† identified through the colorectal MDT were evaluated. Secondarily, this study sought to determine if MDT performance could be enhanced following a series of quality improvement measures.

5.4 Methods

This study was conducted at St. Mark’s Hospital colorectal cancer MDT between 30/09/2011 – 07/08/2015. MDT team performance was evaluated in line with the systems approach to teamwork consisting of the ‘input-process-output’ model (see Introduction section 1.4.2) and considering technical and non-technical factors. Baseline observations were conducted which identified key patient safety and quality issues which were addressed by a series of training and quality improvement interventions, followed by re-evaluation of the MDT.

5.4.1 Ethical Considerations

This study fulfilled the criteria for a service evaluation and quality improvement intervention rather than a research study. The study design was submitted to the local Research and Development department and formal ethical approval was not indicated. All MDT team members were informed of the study via e-mail and informed at the MDT the week prior to observations commencing.

5.4.2 Development of MDT assessment tool

In order to scientifically evaluate the MDT in a reliable and valid fashion, a previously validated Urology cancer MDT rating tool (MDT-MODe) was examined and considered specifically for the colorectal cancer MDT meeting in the tertiary setting. Observational rating tools are based on observable behaviours displayed within the MDT with examples of

†† PSIs were defined in the same way as for Chapter 2 (Section 2.4.2.3) as any safety issue that had the potential to, or directly adversely affected patient care: PSIs with and without immediate consequences were included. Specifically, PSIs were defined as near misses, adverse events and never events according to the Department of Health’s classification at the time of the study.
optimal behaviour. Observed behaviours could thus be compared to exemplar behaviours defined within anchors. A five-point Likert scale was adopted to illustrate a range of anchors with a score of 5 representing the optimal behaviour and 1 the opposite of this. A score of 3 represents the midpoint of the scale or ‘average’ behaviour with scores of 2 and 4 allowing sufficient grading of observed behaviours. This structure is effectively used in other behavioural teamwork scoring systems\textsuperscript{19} and is consistent with the evaluations undertaken for endoscopic procedures in earlier chapters. As this approach had been effectively adopted by MDT-MODe for Urology, the key structure of this rating tool was maintained but important additions were made to suit the patient sub-types of the colorectal cancer MDT. This was achieved by two means: The principal observer (MM) conducted trial ratings in the colorectal cancer MDT with the original MDT-MODe tool, and expert consensus was sought.

5.4.2.1 Focus group and expert consensus
A focus group comprising representatives of core colorectal cancer MDT specialist members\textsuperscript{11} was conducted. The key objective was to enhance content validity of the assessment tool. The MDT-MODe rating tool was examined by each member and relevance to the colorectal MDT considered. In addition to the existing measures, further metrics were added to the tool based on expert opinion and recommendations from the trial ratings.

5.4.2.2 Modification of MDT rating tool
The following additions to the original MDT rating tool were made to enhance the tool for the colorectal cancer MDT:

- Availability of patient’s medical records at MDT (Y/N)
- Patient Safety Incidents identified in the MDT (Y/N and detail to enable categorisation and quality improvement)
- Time taken to discuss each individual patient
- Whether a patient was added on to the MDT during the meeting i.e. without prior preparation of medical notes and information (Y/N)
- Patient stage: A. Pre-treatment B. Post treatment

\textsuperscript{11} The main investigator (MM) chaired the focus group and lead consultants from colorectal surgery, radiology, histopathology, oncology and endoscopy were present. The colorectal cancer nurse specialist, colorectal cancer MDT coordinator and cancer services manager were also present.
- Patient sub-categorisation: BCS (Bowel cancer screening) 2WW (Two-week wait urgent pathway) SYM (Symptomatic patients) TER (Tertiary referral patients)
- Patient awareness of the potential / confirmed cancer diagnosis (Y/N/Unknown)
- Consideration of clinical trials (Y/N)
- Modifications to descriptors on 1-5 Likert scale with addition of definitions for points 2 and 4 on scale.

The revised tool (Appendix 5.1 and 5.2) was disseminated to the core members of the focus group and trialled by the principal raters in a CRC MDT prior to formal data collection.

5.4.3 Study Design

This study was a prospective observational longitudinal pre – post intervention study. Prospective observations of the colorectal cancer MDT were conducted in real time by two clinical observers ordinarily present at the colorectal cancer MDT (MM Endoscopy research fellow and RB Superintendent research radiographer). Observations were conducted at baseline to identify the key factors affecting provision of information to the MDT, team contribution to the discussion and PSIs. This data was analysed and a summary presented to the MDT enabling reflective practice on MDT performance. This led to a series of proposed quality improvement measures being formulated by the MDT and implemented in a stepwise fashion. The MDT was re-evaluated in the same method once the quality improvement measures (Section 5.6) were embedded in clinical practice. Comparisons were made between performance metrics pre and post intervention. The study design is summarised in Figure 5.1.

![Figure 5.1. Study Design Overview](image-url)
5.4.4 Participants, patients and settings

The main participants in this study were the core members of the colorectal cancer MDT. This included one or more members from the following specialities: colorectal surgery, radiology, pathology, oncology, endoscopy, liver surgery, oncology, cancer nurse specialist and the MDT coordinator. Additional team members that were included for some patients included bowel cancer screening specialist nurse practitioners and visiting clinicians from other specialties (e.g. general surgery and acute medicine). Although patient clinical information and management decisions were part of the study, patients themselves were not directly involved. The study was conducted at the weekly colorectal cancer MDT at St. Mark’s Hospital. This MDT evaluates patients from the local population as well as tertiary referrals nationally and internationally and included patient decisions from symptomatic, 2-week wait, screening and tertiary pathways including complex cancer. The MDT included suspected and confirmed rectal and colonic cancers as well as patients presenting with metastatic liver disease where the primary lesion was unknown. This MDT is not video linked with other centres.

5.4.5 Data collection

Live observations were conducted from the MDT meeting room by two independent raters. Data was recorded on a paper version of the MDT rating tool and was uploaded onto an excel spreadsheet after each meeting.

5.4.6 Data analysis

The following demographic data was recorded:

- Number of patient discussions
- Number of MDT meetings
- Presence of Core MDT members
- Proportion of patients pre and post treatment
- Proportion of patients added to MDT within meeting
- Decision outcome
- Clinical trial considered
5.4.7 Statistical Analysis

The statistical analyses conducted are summarised below.

5.4.7.1 Information, Team and Global scores

For each measured variable the data was non-normally distributed (tested using the Shapiro Wilk test which was significant for all variables). Mean and standard deviations are reported for the information and team discussion scores rated on a 1-5 scale respectively. This was completed for the component information and team member ratings as well as the merged score to achieve the global score. For completion the median and inter-quartile range is also presented.

5.4.7.2 Inter-rater reliability

Inter-rater reliability between the two observers was assessed by conducting an intraclass correlation coefficient (ICC) analysis on 52% (n=213) of the ratings conducted during the pre-intervention observation period (n=412). Similarly, ICC analysis was completed on 42% (n=98) of the post intervention sample.

5.4.7.3 Decision Outcome

The decision outcome from the MDT was recorded in one of three ways: Y (decision made) N (decision not made) and D (decision deferred). The breakdown of decision outcomes was recorded as a percentage and comparisons between pathways made using chi square analysis.

5.4.7.4 Correlational analysis

Correlational relationships were determined by Spearman’s rho to examine the availability of medical notes with global information score, global team discussion score, decision made and error incidence.

In addition, correlational analyses were performed for the time spent discussing a case, global information score, team discussion score, decision made and error incidence.

5.4.7.5 Pre and post intervention analysis

Comparisons of the component information and team contribution scores were made using the Man-Whitney test as the scores followed a 1-5 Likert scale. The global information and global team scores were continuous and normally distributed therefore the un-paired t test was used to make comparisons. Pre and post intervention analyses were performed for each patient pathway (BCS, 2WW, TER and SYM) as well as the overall patient population.
Comparisons of PSIs were made using the Mann-Whitney test and crosstabs were used to determine counts of errors pre and post intervention.

5.4.7.6 Patient pathways

The effect of patient pathway (BCS, 2WW, TER and SYM) on ratings (information, discussion and decision) was determined using the Kruskall Wallis test. Multiple comparisons between patient pathways and dependent measures (ratings) were conducted using the Mann Whitney test.

5.5 Patient Safety Incidents (PSIs)

Patient Safety Incidents identified within the MDT meeting were recorded for each patient quantitatively (number of PSIs per patient) and qualitatively by both the clinical evaluators. These PSIs were subsequently categorised by the two raters and a representative sample corroborated by expert consensus in the following ways:

5.5.1 Incidence of PSI in relation to the MDT meeting:
- Pre MDT (error occurred prior to meeting)
- Intra MDT (error occurred within the MDT meeting)
- Post MDT (error occurred following the MDT meeting)

5.5.2 Severity of the PSI based on actual or potential clinical impact

1. Mild
2. Moderate
3. Severe

5.5.3 Thematic analysis of PSIs

The two clinical evaluators grouped all of the PSIs into sub-categories and then grouped sub-categories into 8 major themes:

- MDT data input
- MDT team-working skills
Quality Improvement Interventions

Multiple sequential quality improvement measures were implemented over time. The approach was educational and collaborative incentivising teams to improve quality rather than mandating new processes (‘bottom up’ not ‘top down’). The key interventions are summarised below.

5.6.1 MDT education through self reflection

The MDT evaluations undertaken at baseline were presented to the core and wider MDT members. This consisted of a 30-minute power-point presentation summarising the key findings of the MDT characteristics, information and teamwork scores. In addition the number and type of patient safety incidents recorded were presented. This was followed by a facilitated discussion chaired by the clinical lead for endoscopy to galvanise expert opinion on whether these standards were sufficient and if not what further improvements would be desirable and practically achievable. (See Appendix 5.3 for feedback handout).

5.6.2 Minimum dataset

Following MDT expert opinion and PSI analysis, a major theme related to insufficient information to reach a patient management decision. This would manifest as absent clinical data (e.g. radiology and histology investigation results outstanding) as well as insufficient patient related information (e.g. comorbidity and fitness for surgical intervention) and impede optimal decision-making. To facilitate patient centred decision-making and to enhance efficiency of the MDT by preventing such cases being re-discussed the following week, a minimum data set for each patient was proposed. This was to be completed by the clinician at
the point of referral to the MDT co-ordinator to ensure there was a minimum standard of patient information and a clear question for the MDT to address.

This minimum dataset would populate the patient list and thus prevent duplication of work by the MDT coordinator. Furthermore, this would enable better organisation of the patient list by grouping post-operative patients together for example. A template of the data input process is presented in Appendix 5.4.

5.6.3 Leadership through effective Chairmanship

The roles and responsibilities of the chairperson were defined and agreed by the CRC MDT lead and the core members. These included:

- Review the MDT case load with the coordinator in advance of the meeting to ensure cases are appropriate for discussion that week
- Time management of discussion and decision making for each patient
- Ensuring minimum data-set for each patient reviewed
- Ensuring all relevant specialties have contributed to discussion
- Articulating MDT decision clearly and ensuring MDT outcome documentation adequate
- Managing conflict and reaching consensus

In addition, the chairperson was rotated by speciality to reflect the diversity of the core members. Each core specialty nominated 1-2 representative members keen to chair the meeting and a rota devised. At the end of each MDT meeting the chairperson would confirm the chairperson for the following week and this was to be circulated with the index MDT outcome document. This also enabled key communications to be conducted with the relevant chair ahead of the following meeting.

5.6.4 Documenting outcomes

The MDT management outcome was documented in paper format during the MDT with variable degrees of information, content accuracy and legibility (Appendix 5.5) This impeded accurate communication with the patient and primary care but also hindered completion of the national cancer data set requirements. In order to address this, key information e.g.
TNM§§ cancer stage, post-operative resection margins and the MDT outcome were documented in each patient’s electronic patient record, as decisions were made live during the meeting (Appendix 5.6). This enabled peer review of the documentation to ensure it accurately reflected the discussion and the decision reached. Additionally, all relevant clinical and administrative staff could access the MDT outcome without locating the patient’s paper record.

5.6.5 Awareness of MDT PSIs

By informing the MDT of the number and range of errors that were observed a broader appreciation of the impact of distractors and errors on the decision making process was highlighted. Team vigilance towards error was enhanced as team members actively fed back to the team at the beginning or end of an MDT.

5.6.6 Physical MDT environment

The structure of the MDT meeting room was not conducive to collaborative team discussion and decision-making. Surgical team members were seated at the main table with the patient records. All other MDT core members were seated in the periphery of the room. This was modified to ensure at least one representative from each of the core specialties were seated around the main table to facilitate chairing, audible team discussion and review of the MDT outcome documentation.

5.6.7 Feedback on performance

Further MDT education on performance metrics and sustainable improvement strategies was provided towards the end of the study by presentation of the data at the St. Mark’s Grand Round attended by the majority of the MDT specialties.

5.7 Results

In total 645 patient cases were evaluated over the course of 36 MDT meetings. Table 5.0 summarises the demographic data. Representatives from each core specialty *** were present for 32/36 meetings. In 4 MDT meetings core members (Liver Surgeon, Oncologist, Colorectal surgeon) were not present for a proportion of the patients discussed. The

§§ TNM cancer staging: Tumour Node Metastases

*** Core members defined as consultant representatives from: Colorectal Surgery, Oncology, Radiology, Histopathology, Endoscopy, Liver Surgery, Clinical Nurse Specialist and MDT Coordinator.
distribution of patients within each patient pathway is presented in Table 5.1 and Figures 5.2 and 5.3.

**Table 5.1.** CRC MDT meeting characteristics

<table>
<thead>
<tr>
<th>MDT meeting (n)</th>
<th>Patient (n)</th>
<th>A. Pre-Treatment</th>
<th>B. Post-Treatment</th>
<th>Patients added during meeting</th>
<th>Time per case (mins)*</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n</td>
<td>%</td>
<td>n</td>
<td>%</td>
<td>Mean</td>
</tr>
<tr>
<td>Pre-Intervention</td>
<td>27</td>
<td>412</td>
<td>216</td>
<td>52.4</td>
<td>196</td>
</tr>
<tr>
<td>Post-Intervention</td>
<td>9</td>
<td>233</td>
<td>108</td>
<td>46.4</td>
<td>125</td>
</tr>
<tr>
<td>Total</td>
<td>36</td>
<td>645</td>
<td>324</td>
<td>321</td>
<td>39</td>
</tr>
</tbody>
</table>

**Table 5.2.** Numbers of patients in each patient pathway

<table>
<thead>
<tr>
<th></th>
<th>BCS (n)</th>
<th>2WW (n)</th>
<th>TER (n)</th>
<th>SYM (n)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-Intervention</td>
<td>52</td>
<td>98</td>
<td>97</td>
<td>165</td>
</tr>
<tr>
<td>Post-Intervention</td>
<td>20</td>
<td>44</td>
<td>85</td>
<td>84</td>
</tr>
<tr>
<td>Total (n)</td>
<td>72</td>
<td>142</td>
<td>182</td>
<td>249</td>
</tr>
</tbody>
</table>
5.7.1 Reliability of evaluations

Inter-rater reliability was assessed by intraclass correlation coefficient (ICC) analysis on 52% (n=213) of the pre-intervention sample and 42% (n=98) of the post intervention sample. For the pre-intervention data, moderate to high reliability agreement was demonstrated for global
information (ICC = 0.76), global contribution (ICC=0.68), and a somewhat weaker reliability for decision made (ICC=0.46). Reliability measures for the post-intervention data were similar: information (ICC = 0.77), global contribution (ICC = 0.67) and decision made (ICC = 0.32).

5.7.2 Information and team contribution scores

The average ratings for the sub-components of information and team contribution are presented for pre and post intervention samples in Tables 5.2 to 5.3.

Table 5.3. Pre and post Intervention Information Scores

<table>
<thead>
<tr>
<th>Mean (SD)</th>
<th>History</th>
<th>Radiology</th>
<th>Pathology</th>
<th>Psychosocial</th>
<th>Comorbidity</th>
<th>Patient Views</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-intervention</td>
<td>2.71 (1.26)</td>
<td>3.82 (1.63)</td>
<td>2.66 (1.82)</td>
<td>1.47 (1.07)</td>
<td>1.76 (1.29)</td>
<td>1.37 (0.99)</td>
</tr>
<tr>
<td>Post-intervention</td>
<td>4.26 (1.04)</td>
<td>3.77 (1.74)</td>
<td>2.84 (1.92)</td>
<td>1.43 (1.07)</td>
<td>2.78 (1.69)</td>
<td>1.68 (1.30)</td>
</tr>
<tr>
<td>P value</td>
<td>&lt;0.001</td>
<td>0.74</td>
<td>0.16</td>
<td>0.30</td>
<td>&lt;0.001</td>
<td>0.001</td>
</tr>
</tbody>
</table>

Table 5.4. Pre and post Intervention Team Contribution Scores

<table>
<thead>
<tr>
<th>MDT Member</th>
<th>Pre-intervention Mean (SD)</th>
<th>Post-intervention Mean (SD)</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chairperson</td>
<td>2.87 (1.10)</td>
<td>4.03 (0.83)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Colorectal Surgeon</td>
<td>3.58 (1.27)</td>
<td>3.94 (1.46)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Endoscopist</td>
<td>1.56 (1.22)</td>
<td>2.67 (1.84)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Oncologist</td>
<td>2.31 (1.67)</td>
<td>1.99 (1.59)</td>
<td>0.006</td>
</tr>
<tr>
<td>Hepatopancreatobiliary Surgeon</td>
<td>1.29 (1.0)</td>
<td>1.10 (0.63)</td>
<td>0.007</td>
</tr>
<tr>
<td>Histopathologist</td>
<td>1.42 (1.11)</td>
<td>1.54 (1.24)</td>
<td>0.46</td>
</tr>
<tr>
<td>Radiologist</td>
<td>2.73 (1.67)</td>
<td>2.79 (1.79)</td>
<td>0.78</td>
</tr>
<tr>
<td>Cancer Nurse Specialist</td>
<td>1.42 (0.99)</td>
<td>1.58 (1.13)</td>
<td>0.07</td>
</tr>
<tr>
<td>MDT Co-ordinator</td>
<td>1.20 (0.69)</td>
<td>1.09 (0.44)</td>
<td>0.07</td>
</tr>
</tbody>
</table>
5.7.3 Patient pathway and global patient population analyses

The following tables present the average scores for the four patient sub-groups as well as the overall patient populations. Table 5.4 presents the mean and median values and the decision outcomes. Table 5.5 summarises the p values (derived from the mean values) for information and discussion scores, pre and post intervention for the same patient groups.
Table 5.5. Descriptive Statistics for Patient Pathways pre and post Intervention.

<table>
<thead>
<tr>
<th>Measure</th>
<th>Pre – Intervention</th>
<th></th>
<th></th>
<th></th>
<th></th>
<th>Post – Intervention</th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>BCS</td>
<td>2WW</td>
<td>TER</td>
<td>SYM</td>
<td>Overall</td>
<td>BCS</td>
<td>2WW</td>
<td>TER</td>
<td>SYM</td>
<td>Overall</td>
</tr>
<tr>
<td>Patients (n)</td>
<td>53</td>
<td>97</td>
<td>97</td>
<td>165</td>
<td>412</td>
<td>20</td>
<td>92</td>
<td>37</td>
<td>84</td>
<td>233</td>
</tr>
<tr>
<td>Information scores Mean (SD)</td>
<td>14.24 (4.17)</td>
<td>12.84 (3.96)</td>
<td>14.20 (3.76)</td>
<td>13.78 (3.58)</td>
<td>13.89 (3.84)</td>
<td>16.65 (4.49)</td>
<td>16.74 (4.28)</td>
<td>17.32 (4.59)</td>
<td>17.46 (3.56)</td>
<td>17.09 (4.1)</td>
</tr>
<tr>
<td>Team Discussion scores Mean (SD)</td>
<td>18.56 (4.11)</td>
<td>17.77 (4.69)</td>
<td>18.68 (3.60)</td>
<td>17.83 (4.11)</td>
<td>18.09 (4.11)</td>
<td>22.65 (6.06)</td>
<td>21.20 (5.86)</td>
<td>24.24 (4.97)</td>
<td>22.02 (6.42)</td>
<td>22.10 (6.01)</td>
</tr>
<tr>
<td>Information scores Median (IQR)</td>
<td>13 (5)</td>
<td>12 (5)</td>
<td>14 (6)</td>
<td>13 (6)</td>
<td>13.0 (5.0)</td>
<td>19 (7)</td>
<td>18 (6)</td>
<td>18 (5)</td>
<td>17.5 (5)</td>
<td>18.0 (6.0)</td>
</tr>
<tr>
<td>Team Discussion scores Median (IQR)</td>
<td>19 (7)</td>
<td>18 (6)</td>
<td>18 (5)</td>
<td>17.5 (5)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Decision outcome</td>
<td>Y 47</td>
<td>Y 75</td>
<td>Y 83</td>
<td>Y 131</td>
<td>Y 336</td>
<td>Y 18</td>
<td>Y 72</td>
<td>Y 34</td>
<td>Y 76</td>
<td></td>
</tr>
<tr>
<td></td>
<td>N 1</td>
<td>N 9</td>
<td>N 2</td>
<td>N 8</td>
<td>N 20</td>
<td>N 0</td>
<td>N 1</td>
<td>N 1</td>
<td>N 3</td>
<td></td>
</tr>
<tr>
<td></td>
<td>D 5</td>
<td>D 13</td>
<td>D 12</td>
<td>D 26</td>
<td>D 56</td>
<td>D 2</td>
<td>D 19</td>
<td>D 2</td>
<td>D 5</td>
<td></td>
</tr>
</tbody>
</table>

Yes / No / Deferred
Table 5.6. Comparison of pre and post intervention mean scores by sub-group and overall patient populations

<table>
<thead>
<tr>
<th>Measure</th>
<th>Pre – Intervention</th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>BCS</td>
<td>2WW</td>
<td>TER</td>
<td>SYM</td>
</tr>
<tr>
<td>Patients (n)</td>
<td></td>
<td>53</td>
<td>97</td>
<td>97</td>
<td>165</td>
</tr>
<tr>
<td>Information scores Mean (SD)</td>
<td>14.24 (4.17)</td>
<td>12.84 (3.96)</td>
<td>14.20 (3.76)</td>
<td>13.78 (3.58)</td>
<td>13.89 (3.84)</td>
</tr>
<tr>
<td>Team Discussion scores Mean (SD)</td>
<td>18.56 (4.11)</td>
<td>17.77 (4.69)</td>
<td>18.68 (3.60)</td>
<td>17.83 (4.11)</td>
<td>18.09 (4.11)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Measure</th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Post – Intervention</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>BCS</td>
<td>2WW</td>
<td>TER</td>
<td>SYM</td>
<td>Overall</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Patients (n)</td>
<td>20</td>
<td>92</td>
<td>37</td>
<td>84</td>
<td>233</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Information scores Mean (SD)</td>
<td>16.65 (4.49)</td>
<td>16.74 (4.28)</td>
<td>17.32 (4.59)</td>
<td>17.46 (3.56)</td>
<td>17.09 (4.1)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Team Discussion scores Mean (SD)</td>
<td>22.65 (6.06)</td>
<td>21.20 (5.86)</td>
<td>24.24 (4.97)</td>
<td>22.02 (6.42)</td>
<td>22.10 (6.01)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*p value (Information scores) | 0.07 | <0.001 | <0.001 | <0.001 | <0.001 |
*p value (Discussion scores) | 0.03 | 0.008 | <0.001 | <0.001 | <0.001 |
5.7.4  Patient Safety Incidents (PSIs)

Two hundred PSIs were identified pre-intervention and 81 post intervention, indicating a significant reduction in PSIs: $x^2(1) = 17.46$, p=0.001 (Cramer’s V effect size 0.17). The modal PSI per patient was 1 (range 1-3) see Table 5.7

Table 5.7.  Proportion of patients with one or more PSI recorded

<table>
<thead>
<tr>
<th>Number of PSI per patient</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>Total PSI (n)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-Intervention</td>
<td>132</td>
<td>54</td>
<td>14</td>
<td>200</td>
</tr>
<tr>
<td>Post-Intervention</td>
<td>67</td>
<td>11</td>
<td>3</td>
<td>81</td>
</tr>
<tr>
<td>Total PSI (n)</td>
<td>199</td>
<td>65</td>
<td>17</td>
<td>281</td>
</tr>
</tbody>
</table>

5.7.4.1  Patient Safety Incidents and patient pathways

The distribution of PSIs according to the four patient pathways is summarised in Table 5.8.

Table 5.8.  Number of PSIs per Patient Pathway

<table>
<thead>
<tr>
<th>BCS</th>
<th>2WW</th>
<th>TER</th>
<th>SYM</th>
<th>Total PSI (n)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-Intervention</td>
<td>25</td>
<td>50</td>
<td>45</td>
<td>80</td>
</tr>
<tr>
<td>Post-Intervention</td>
<td>14</td>
<td>9</td>
<td>30</td>
<td>28</td>
</tr>
<tr>
<td>Total PSI (n)</td>
<td>39</td>
<td>59</td>
<td>75</td>
<td>108</td>
</tr>
</tbody>
</table>

5.7.4.2  Patient Safety Incidents and temporal incidence

The distribution of PSIs occurring temporally across the MDT is summarised in Table 5.9 followed by examples of each category.
Table 5.9. Proportion of PSIs occurring pre, intra and post MDT meeting

<table>
<thead>
<tr>
<th></th>
<th>Pre MDT</th>
<th>Intra MDT</th>
<th>Post MDT</th>
<th>Total PSI (n)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n</td>
<td>%</td>
<td>n</td>
<td>%</td>
</tr>
<tr>
<td>Pre-Intervention</td>
<td>99</td>
<td>49.5</td>
<td>92</td>
<td>46.0</td>
</tr>
<tr>
<td>Post-Intervention</td>
<td>66</td>
<td>81.5</td>
<td>12</td>
<td>14.8</td>
</tr>
<tr>
<td>Total PSI (n)</td>
<td>165</td>
<td>104</td>
<td>12</td>
<td>281</td>
</tr>
</tbody>
</table>

Examples of PSIs across the MDT pathway:

- Pre MDT PSI: Inaccurate histological analysis due to inaccurate labelling of polyp specimens at endoscopy
- Intra MDT: Radiological images of a different patient (same surname) being presented to the patient being discussed
- Post MDT: Patient lost to follow up and subsequently developed liver metastases. Documentation from previous MDT outcome unclear on follow up recommendations.

5.7.4.3 Patient Safety Incident Severity

The categorisation of PSI by severity (defined as actual or potential clinical impact) is presented in Table 5.10 and Figures 5.4 and 5.5. Examples of PSIs categorised by severity are listed below.

Examples of PSIs according to severity:

- Mild PSI: MDT member who’s specialist opinion was required for optimal decision making was absent
- Moderate PSI: Non GI specialist radiologist reported images incorrectly. Identified and corrected by specialist GI radiologist in MDT with an addendum added to the original report.
- Severe PSI: Patient lost to follow up whilst being investigated by primary and secondary care. Complex cancer exacerbated by avoidable delays.
Table 5.10. Proportion of PSIs categorised by severity.

<table>
<thead>
<tr>
<th></th>
<th>1. Mild</th>
<th></th>
<th>2. Moderate</th>
<th></th>
<th>3. Severe</th>
<th></th>
<th>Total PSI (n)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n</td>
<td>%</td>
<td>n</td>
<td>%</td>
<td>n</td>
<td>%</td>
<td></td>
</tr>
<tr>
<td>Pre-Intervention</td>
<td>149</td>
<td>74.5</td>
<td>28</td>
<td>14.0</td>
<td>23</td>
<td>11.5</td>
<td>200</td>
</tr>
<tr>
<td>Post-Intervention</td>
<td>40</td>
<td>49.4</td>
<td>24</td>
<td>29.6</td>
<td>17</td>
<td>21.0</td>
<td>81</td>
</tr>
<tr>
<td>Total</td>
<td>189</td>
<td>52.0</td>
<td>52</td>
<td>29.6</td>
<td>40</td>
<td>21.0</td>
<td>281</td>
</tr>
</tbody>
</table>

Categorisation of PSI by Severity (Pre-Intervention)

- Mild: n=149 (74%)  
- Moderate: n=28 (14%)  
- Severe: n=23 (12%)

Figure 5.4. Pre-Intervention Patient Safety Incident severity categorisation
Figure 5.5. Post-Intervention Patient Safety Incident severity categorisation

5.7.4.4 Patient Safety Incident thematic categorisation

Qualitative analysis of the PSIs enabled thematic analysis to derive 8 major themes from 27 component themes. These themes are summarised in Table 5.11.

Table 5.11. Thematic categorisation of PSIs: Component and Major themes

<table>
<thead>
<tr>
<th>Major themes (n=8)</th>
<th>Component themes (n=27)</th>
</tr>
</thead>
<tbody>
<tr>
<td>MDT data input</td>
<td>Incorrect clinical data</td>
</tr>
<tr>
<td></td>
<td>Incorrect patient details</td>
</tr>
<tr>
<td></td>
<td>Missing data</td>
</tr>
<tr>
<td></td>
<td>Patient on incorrect cancer MDT</td>
</tr>
<tr>
<td></td>
<td>No specific question for MDT to address</td>
</tr>
<tr>
<td></td>
<td>Inappropriate recurrence of patient discussion on MDT</td>
</tr>
<tr>
<td></td>
<td>Inappropriate timing for MDT (i.e. insufficient data)</td>
</tr>
<tr>
<td></td>
<td>No suspected / confirmed cancer diagnosis</td>
</tr>
<tr>
<td>MDT team working</td>
<td>Time pressures impacting quality of discussion</td>
</tr>
<tr>
<td></td>
<td>Confusion secondary to changes in patient list order</td>
</tr>
<tr>
<td></td>
<td>Sub-optimal professional contribution to discussion / decision</td>
</tr>
<tr>
<td></td>
<td>Specialist knowledge required but not sought</td>
</tr>
<tr>
<td></td>
<td>Absent core member</td>
</tr>
<tr>
<td></td>
<td>Core member on phone</td>
</tr>
</tbody>
</table>
Major themes (n=8) | Component themes (n=27)  
--- | ---  
Hostility between core members  
Inaudible discussion / decision  
Multiple simultaneous discussions causing confusion  
Individual decision not MDT decision  
Failure to review all available data  
Specialty expertise | Sub-optimal professional performance  
(e.g. missed cancer at endoscopy / radiology)  
Documentation error | Documentation error of any type (clinical and administrative)  
MDT actions incomplete | Recommended outcome not completed  
Patient lost to follow up  
Miscommunication | Erroneous information given to patient  
Miscommunication between specialties  
Avoidable cancer pathway delay | Poor clinical planning  
Avoidable delay (investigations / procedures)  
Other | Other PSI not categorised in themes above  

All recorded PSIs were categorised to component themes (with more than one theme applicable to a single PSI). The distribution of the PSIs by major themes is presented in Table 5.12 and Figures 5.6 – 5.8.

**Table 5.12.** Thematic Incidence of Patient Safety Incidents

<table>
<thead>
<tr>
<th>Major themes</th>
<th>Pre-Intervention PSI n=200</th>
<th>Post-Intervention PSI n=81</th>
</tr>
</thead>
<tbody>
<tr>
<td>MDT data input</td>
<td>225</td>
<td>79</td>
</tr>
<tr>
<td>MDT team working</td>
<td>205</td>
<td>40</td>
</tr>
<tr>
<td>Specialty expertise</td>
<td>19</td>
<td>13</td>
</tr>
<tr>
<td>Documentation error</td>
<td>30</td>
<td>13</td>
</tr>
<tr>
<td>MDT actions incomplete</td>
<td>23</td>
<td>4</td>
</tr>
<tr>
<td>Miscommunication</td>
<td>33</td>
<td>23</td>
</tr>
<tr>
<td>Avoidable cancer pathway delay</td>
<td>24</td>
<td>74</td>
</tr>
<tr>
<td>Other</td>
<td>9</td>
<td>5</td>
</tr>
<tr>
<td>Total categorisations</td>
<td>568</td>
<td>251</td>
</tr>
</tbody>
</table>
**Figure 5.6.**  Thematic comparison of Patient Safety Incidents pre and post intervention

**Figure 5.7.**  Categorisation of pre-intervention Patient Safety Incidents by major themes
Discussion

The main findings of this study along with key limitations are presented. The clinical implications along with future work are also discussed.

5.8.1 Summary of Main Findings

This study illustrates that MDT performance as measured by provision of clinical information and team contribution to discussion as well as decision-making can be enhanced longitudinally by a series of modest quality improvement interventions. Considering the global assessments of information and team discussion, there was a significant improvement following the quality improvement intervention. The interventions were low cost, derived from the MDT core members themselves and disseminated to the wider team through multiple educational interventions. A sustained multi-stage improvement package was embedded into clinical practice over a long time frame and was also associated with a reduction in recorded PSIs.
5.8.1.1 Assessment of MDT Information and Team Contribution

5.8.1.1.1 Information

Considering the global assessments of information and team discussion, there was a significant improvement following the quality improvement intervention. Reviewing the global scores there was a mean increase of 2.7 points in the post intervention group. Consistent with other studies, this study shows that patient centred information (co-morbidity, psycho-social aspects and patient views) is less fully presented to the MDT compared to clinical information (radiology and histology investigation results). Following the quality improvement measures there was a significant improvement in patient history, comorbidity and patient views presented to the MDT. Psycho-social aspects of MDT decision-making had low scores and did not change following this intervention, suggesting further strategies need to be identified to ensure this information is adequately presented.

5.8.1.1.2 Team Contribution

Colorectal surgeons contributed most avidly to discussion and decision making with other team members (cancer nurse speciality and liver surgeon) having lower levels of contribution. This was in part due to their input not being required but also due to the observed team dynamics impeding inclusive discussion. Relevant team work factors and non-technical skills were presented to the MDT throughout the quality improvement intervention and opportunistically within the MDT meeting via the chairperson. The comparative analyses showed that the specialty contribution significantly improved for chairmanship, colorectal surgeon and endoscopist following quality improvement. More importantly, there was some improvement in the cancer nurse specialist contribution (although this did not quite reach statistical significance) as these individuals often had more patient centred information to inform the MDT discussion. Conversely, oncology, hepato-pancreatobiliary and MDT co-ordinator contribution decreased following the quality improvement. This suggests the educational measures had no impact on these groups or possibly that their contribution to the discussion was less relevant for the patients in the post intervention group accounting for their lower scores. Further work should identify methods of engaging these sub-specialties further: For example sporadic cases would require pancreato-biliary input and therefore streamlining these patients together at the beginning of the MDT would not only be more efficient but would focus the discussion and specialist contribution. It could be proposed that the oncologists take a more avid role in chairmanship to enhance their contribution given their experience in other cancer MDTs.
5.8.1.2 Characteristics of Key Patient Pathways

Anecdotally it has been observed that there is variability in the level of information and quality of discussion for patients presenting through the four key pathways. In this study, patients presenting to the MDT via the 2-week wait pathway had a paucity of clinical information. This was implicated by incomplete information on the referral form and no clinical team member having met the patient prior to the MDT (as many presented via the straight-to-test pathway), thus impacting the patient centeredness of the discussion. Patients within the BCS pathway had a high information score, which is reflected by the detailed pre-assessment these patients undergo by a specialist screening nurse practitioner (SSP) prior to the index colonoscopy. Optimising a minimum standard of essential patient information for the MDT for all patient groups is clearly a necessity. Team discussion scores were comparable across the pathways with tertiary and BCS patients having slightly higher scores. Importantly, patient information scores significantly improved for all the sub-groups following the intervention (except for BCS which was just under-significance but starting with a high pre-intervention score). Similarly the team contribution scores showed significant improvements for all four patient sub-groups indicating this intervention was well targeted to enhance MDT quality across a range of patient sub-groups.

5.8.1.3 Patient Safety Incidents (PSIs)

Within this study a significant reduction in Patient Safety Incidents occurred following the quality improvement intervention. Patient safety incidents showed high variability in themes and the MDT identified errors which were prevalent for all four patient pathways (BCS, 2WW, TER and SYM) and occurred across the cancer care pathway (i.e. pre, intra and post MDT). The majority of errors occurred before and during the MDT, with a smaller proportion occurring post MDT. Formal statistical analysis to compare errors between patient sub-groups was not conducted, as the sample size was insufficient to make meaningful comparisons. There appear to be more errors in the symptomatic patient sub-group although further work is required to investigate the differences between these groups.

The majority of PSIs were minor in nature but with many recurring errors identified, which helped inform the quality improvement interventions. There were a greater proportion of minor errors at baseline compared to the post intervention sample suggesting the intervention did not positively affect this aspect of MDT performance. It could be argued that PSI aetiology is multifactorial and may not be improved over the time span of this study but
requires additional dedicated interventions. Although formal analysis on the PSI subtype could not reliably be performed these results suggest that the nature of PSIs changed following the intervention with less data input (40-31%) and team-working (36-16%) PSIs recorded following the intervention. Interestingly a greater proportion of PSIs were categorised to ‘avoidable delays in the cancer care pathway’ post intervention indicating a shift to the process of care over teamwork factors.

5.8.2 Clinical Implications

This study shows that MDT processes can be enhanced by improving the content and quality of clinical information prior to the MDT as well as by focussing on inclusive patient discussion to ensure all relevant members make a contribution to decision making. This leads the way for more patient centred decision-making and prevents patient management decisions being unnecessarily deferred to the following week. This contributes to efficiency in the cancer care pathway and timely patient management. There are established processes for certain patient pathways that enhance information provision and practices can be applied to other patient groups to improve quality, although there will be resource implications. It is possible to prevent PSIs by improving MDT processes, which will enhance patient safety, although it is difficult to measure the clinical effect of this directly.

5.8.3 Limitations

This study has limitations, notably the absence of a control MDT group making it difficult to attribute the improvements in MDT performance to the quality improvement interventions implemented. Additionally, observations were undertaken in a single MDT of a specific tumour site raising the question about the generalizability of the results. The interpretation of silence in the MDT remains a challenge. In particular this rating tool assigned a low score to specialities for not contributing to the discussion even when their specific specialty input was not required (e.g. hepatopancreatobiliary surgeon received a score of 1 for patient discussion where no liver opinion was required). The patient safety incidents were defined in broad terms to enable minor and latent errors to also be captured. As there was no clinical follow up of patient outcomes beyond the MDT, the clinical relevance of the PSIs has not been determined within this study.
5.8.4 Future Work

Further work should focus on sustaining quality improvement within the MDT outside of the study setting. To make more detailed improvements in the MDT process, the subcomponent scores for information provision††† and for team member contribution‡‡‡ should be further interrogated to make more targeted interventions. It was notable that the psycho-social information did not really improve following the intervention and that the cancer specialist nurse scores showed only modest improvement. Furthermore, colorectal cancer MDT evaluation should be completed at other centres that provide a tertiary colorectal cancer and bowel cancer screening service to evaluate generalizability. Evaluating a larger sample size including the 4 patient sub-groups would help provide a more equitable cancer service for patients irrespective of the pathway they enter the MDT. Further analyses of the PSIs through error analysis tools such as the London Protocol may identify systems problems outside of the MDT that can be addressed to positively impact efficient time management across the cancer care pathway. By understanding the financial implications of improving the efficiency of the MDT pathway and thus the cancer pathway, managerial teams can be incentivised to make the necessary investments in MDT team working processes.

5.9 Conclusion

In conclusion, this is the first study to formally evaluate the performance of a tertiary centre colorectal cancer MDT including patients from all four pathways. This study shows that engaging MDT team members in quality improvement measures that they decide upon along side a dedicated training programme can significantly improve performance metrics over time and reduce error.

††† Information: History, radiology, pathology, psycho-social, co-morbidity and patient views
‡‡‡ Team contribution: Chairperson, colorectal surgeon, endoscopist, oncologist, liver surgeon, histopathologist, radiologist, cancer nurse specialist and MDT coordinator
Part B: Evaluating Solutions

The first part of this thesis sought to define the factors affecting patient safety and quality in endoscopy. The second part of this thesis evaluates specific interventions implemented in endoscopic practice to try and target the problems identified.
Chapter 6: Developing, Implementing and Evaluating an Endoscopy Team Training Intervention

6.1 Chapter Overview

Endoscopy training in the UK has dramatically changed since 2000 with the development of formalised training programmes and accreditation process led by JAG. This has been a crucial step for the widely accepted minimum standard for endoscopic technical skills development. The observational studies in Part A of this thesis identify enhanced non-technical skills as an important contributor to patient safety. To address this need, a formalised non-technical skills training intervention was designed, implemented and evaluated. In this chapter a brief introduction to training in endoscopy is presented, followed by the methodology by which this training intervention was implemented. The evaluation of the training intervention is presented followed by future developments.

6.2 Introduction

6.2.1 The emergence of high quality endoscopy training

The magnitude of discrepancies in endoscopy training and variability in performance was uncovered by Bowles et al in 2004. Despite the recommendation for trainees to receive close supervision for their first 100 procedures, Bowles’ data suggested that only 17% of trainees had received this. Participation in a formalised endoscopy training course was also low at 39.3%. Variability in colonoscopy completion rates between medical and surgical endoscopists was significant and probably influenced by differences in training, senior supervision and possibly patient case mix. This study concluded that, ‘training of high calibre early in the process, peer review and continuous audit were required to address the deficiencies. This precipitated many of the improvement measures led by JAG.

6.2.2 Concepts in Endoscopy Training

In understanding endoscopy training it maybe useful to reflect upon the definition of training and how it differs from learning. Learning can be defined as, ‘the activity or process of gaining knowledge or skill by studying, practicing, being taught or experiencing something’ Goldstein defines training as, ‘the acquisition of skills, concepts or attitudes that result in improved performance in an on the job situation’. Learning is an important component of training but the latter aims to improve performance in a specified task. Training therefore
supersedes learning as it focuses on implementation of knowledge and skills acquired. Traditionally, medical teaching practices were didactic and well suited to apprenticeship style training, which reinforced the polarised view of the expert and novice. Effective training for experienced health professionals however, needs to take into consideration the principles of adult learning theory where training should have meaning and relevance and actively engage and motivate the individuals involved. It is also important to have realistic objectives, act upon feedback obtained and reflect upon achievements and future goals.

Training is a variable process for individuals but the overall aim is to achieve competency, defined as the ‘minimum level of skill for safe and proficient task performance’. Competency is thought to be attained in steps (Figure 6.1) with unconscious competency reflecting the automation of experienced performance. However, reverting back to conscious competency is the gold standard enabling fine-tuning of skills towards excellent not just competent performance. Endoscopists who are consciously competent are often also skilled in training, as they possess the ability to articulate knowledge and skills and identify obstacles in a trainee’s performance during a training episode.

Training in endoscopy is a complex skill with cognitive, psychomotor and affective domains influencing performance. Effective performance in endoscopy clearly requires good knowledge and skill but can also be influenced by additional factors such as teamwork, stress management and fatigue and may well be enhanced by mental practice for example. Training the individual’s technical skill is a necessary starting point, but high-level performance will require training in non-technical and teamwork skills. Training for the individual is a necessary starting point but effective performance should also consider patient and team factors.
6.2.3 Training in Endoscopy for the Individual

Endoscopy training and accreditation in the UK is a well structured and transparent process led by the Joint Advisory Group (JAG) for Endoscopy for all gastrointestinal endoscopists regardless of their professional background. Individual endoscopy trainees and trainers have access to an on-line e portfolio to track experience, training goals assessments and feedback. This, in conjunction with training courses aimed at technical skills development, enable an individualised approach within a set framework for training.

In a similar notion, the GI endoscopy for nurses (GIN) programme provides updates on service development facilitating a structured approach to training, assessment and appraisal for endoscopy nurses. Although the infrastructure for endoscopist and nurse training are under the remit of JAG, there is no cross-over in training or assessment between the two groups. The context of training and the differing skill-sets for routine and emergency procedures for example, is also less well established. Access to simulation training remains ad hoc and is not universally available. Diagnostic and therapeutic skills training is well organised through JAG accredited courses with the aim of continuing training at an appropriate level at the base unit. Bowel cancer screening endoscopists undergo a rigorous accreditation process with the focus remaining on the endoscopist’s technical ability. Issues pertaining to endoscopy patient safety are interwoven in to existing training courses and will

Figure 6.1. Steps towards attaining competency
feature in routine training lists to some degree. There is no set curriculum around patient safety in endoscopy but some aspects feature alongside technical skills, for example in polypectomy training. Training, assessment and accreditation for endoscopy is clearly defined for the individual endoscopist and the individual nurse. However no formal combined professional endoscopy team training exists despite its importance for patient safety and quality.

6.3 Aims

- To develop, implement and evaluate a novel endoscopic patient safety and non-technical skills training intervention for multidisciplinary Bowel Cancer Screening (BCS) teams
- To improve Bowel Cancer Screening teams’ knowledge and attitudes towards patient safety specifically in gastrointestinal endoscopy.

6.4 Methods

6.4.1 Study Design

This was a pre-post intervention study where a set of measures was made at baseline and repeated immediately after the training. The study was devised in three main parts: development of training material, delivery of training and assessment of impact and overall evaluation (see sections 6.4.4-6.4.6)

6.4.2 Ethical considerations

This team training intervention was devised with the combined knowledge and expertise of the Wolfson Endoscopy Unit at St. Marks Hospital and the National Institute of Health Research (NIHR) Imperial Patient Safety Translational Research Centre (PSTRC). The faculty delivering the training consisted of two consultant gastroenterologists and a psychologist. The two gastroenterologists (AH and STG) are accredited BCS endoscopists with research experience in endoscopy training. The psychologist (NS) has international expertise in team performance and patient safety with experience in surgical team training. Participation within the training intervention for invitees was optional. Ethical approval was granted by NRES Committee London (08/H0719/54).

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The NIHR PSTRC was known as the Imperial College Centre for Patient Safety and Service Quality (CPSSQ) at the time of the study.
6.4.3 Recruitment of participants

Bowel cancer screening accreditation units across England were informed about the non-technical skills training intervention by the clinical lead (STG). Potential participants were informed via e-mail that this was a single day’s training to be delivered in London (UK) and invited to attend with a full Bowel Cancer screening team. This was defined as at least one BCS endoscopist, specialist screening practitioner (SSP), endoscopy nurses familiar with BCS endoscopy and ideally administrative staff (though this was not a pre-requisite given staff capacity issues). Four teams were selected based on confirmation of attendance of a complete screening team.

Participants were thus highly experienced teams, with screening endoscopists performing a minimum of 1000 screening procedures at baseline and at least 150 screening procedures annually thereafter. Specialist screening practitioners and endoscopy nurses were senior nurses at the higher end of the scale (band 6-8).

6.4.4 Development of training contents and assessments

There were two main elements to developing the training package. Firstly the training contents was defined and created and secondly appropriate assessment tools were devised to measure the effect of training.

6.4.4.1 Development of Training Contents

A comprehensive and reproducible training package was formulated by the expert faculty and researcher MM. A course leaflet and printed course manual were issued to all delegates. The manual included the course aims, evaluation materials, presentation slides, landmark publications and the Endoscopic Non-Technical Skills rating tool (chapter 3 appendix 3.2). These materials were created to facilitate dissemination of non-technical skills awareness with the wider endoscopy team at the base unit.

Expert faculty developed educational content suitable for a day’s training to include a mix of didactic and interactive training techniques. Specialty specific team training interventions as well as more generic approaches were reviewed to identify a suitable focus for endoscopy teams. Whilst broad patient safety principles were defined, this training was specifically designed for endoscopy teams (focussing on bowel cancer screening teams) and the content was thus appropriately specific. Real bowel cancer screening clinical examples were utilised
to illustrate the importance of human factors, patient safety incidents and non-technical skills for endoscopy patient safety (See appendix 6.1 for overview).

6.4.4.2 Development of Training Assessments
The assessment of training impact was considered within the traditional domains of knowledge, skill and attitude according to Bloom’s taxonomy.\(^5\) Delegate assessments were undertaken within two main domains: Knowledge of and attitude towards patient safety. Patient safety skills were not formally assessed within this training due to the training course design (classroom based and not work place based training). Delegates were encouraged to evaluate their own patient safety skills in routine clinical practice with an exercise outlined in the course manual (observations of a routine list and identification of safety enhancing and safety threatening behaviours using the ENTS tool). The development of the assessments is detailed below.

6.4.4.2.1 Patient Safety Knowledge
Knowledge was assessed by MCQs consisting of a single stem and a best of five response. The MCQs were written by the faculty and targeted to endoscopy patient safety with more general patient safety questions adapted from similar training within Surgery\(^9\). MCQs were selected from a sample of 30 questions that were piloted and validated prior to the training with a sample of medical students (n=5), endoscopy nurses (n=5), specialist screening practitioners (n=4) and bowel cancer screening endoscopists (n=2). The most discriminatory questions were selected.

6.4.4.2.2 Patient Safety Attitudes
Patient safety attitudes relevant to endoscopy and bowel cancer screening were assessed using a modified version of a validated questionnaire\(^11\) \(^12\). Safety attitudes were quantified on a 5-point scale (1=strongly disagree, 5=strongly agree) for each category within 6 sections (appendix 6.2).

6.4.5 Delivery of Training
The training was delivered in a single day at a central London location with endoscopy teams seated at round tables to facilitate open discussion. Teaching aids included an audio-visual projector for the slides, two flip boards for facilitated discussions and the course manual. Teaching methods employed took into account the professional skill mix and experience of the target audience: Information was imparted through short didactic lectures, interactive
small group exercises, facilitated discussions and video analysis of real endoscopy scenarios to identify non-technical skills as illustrated in the ENTS framework (chapter 3 Appendix 3.2). The training was video recorded to provide faculty the opportunity to reflect and adapt training for future training episodes. Two gastroenterology registrars were also present to assist delegates in completing online evaluations. The overall training format is illustrated (Figure 6.2) and described in detail in the following sections.

**Figure 6.2.** Overview of Training Format

6.4.6 **Pre and post Training Assessments**

The training intervention was evaluated according to Kirkpatrick’s framework \(^{13}\) considering reaction, learning, behaviour and results. The assessments comprised the patient safety knowledge MCQs and safety attitudes questionnaire described in 6.4.4.2. Delegates undertook both these assessments at two time points. Firstly baseline assessments were made after registration and before training commenced. The second set of assessments were
completed at the end of the training. All assessments were completed using an online survey tool. Respondents were randomly assigned a four-digit number so that paired responses could be analysed and anonymity preserved.

6.4.7 Training Evaluation and Expert focus group

A global training satisfaction evaluation was undertaken following the post training assessments. This evaluation focused on content, training material and faculty and reactions were captured using a 5-point Likert scale. Participants’ descriptive evaluations were also recorded following standard good training practice.

Finally, considering the range of delegate expertise from multiple units, we incorporated an expert focus group after the training, assessments and evaluations were all complete. This allowed us to broaden the expert opinion beyond a single centre and also to understand if there was an appetite to disseminate similar training to other endoscopy teams across the UK.

6.4.8 Data Analysis

Descriptive analyses were completed including the delegates’ age, gender and professional background. Patient safety knowledge and attitudes were measured pre and post-training. The paired t-test was used to determine differences in the percentage (%) of correct MCQ responses. Safety attitudes were assessed on a 5-point ordinal scale (1=strongly disagree, 5=strongly agree). The pre and post-course responses were analysed using Wilcoxon tests. Free text comments were analysed qualitatively and emerging themes in participants’ comments were tabulated\(^{14} \text{15}\)

6.5 Results

6.5.1 Demographic results

Four English Bowel Cancer Screening training centres performing large volume screening colonoscopy took part in the study. 23/25 (92%) of invitees, in teams of 6-8 participants, attended from 4 screening accreditation centres across England. Thirteen per-cent (n=3) were male and 87% (n=20) were female. The age of participants varied from age ranges 25-35 (13%), 35-45 (35%), 45-55 (39%) to >55 (13%). Table 6.1 summarises the professional subtypes. Specialist screening practitioners had 0-5 years (n=4), 5-10 years (n=2) and >10 years (n=1) of experience in specialist post. Endoscopy nurses were also experienced with 0-5 years (n=2) 5-10 years (n=3) and >10 years (n=3) years of experience as dedicated
endoscopy nurses. Endoscopy administrative staff included a senior endoscopy unit manager overseeing screening services.

Table 6.1. Participants’ demographics

<table>
<thead>
<tr>
<th>Participant specialty</th>
<th>n</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bowel Cancer Screening Endoscopist (BCSE)</td>
<td>6</td>
</tr>
<tr>
<td>Specialist screening practitioner (SSP)</td>
<td>6</td>
</tr>
<tr>
<td>Endoscopy nurse (EN)</td>
<td>8</td>
</tr>
<tr>
<td>Administrative staff (A)</td>
<td>3</td>
</tr>
</tbody>
</table>

6.5.2 Patient Safety Knowledge

There was a highly significant improvement in post course patient safety knowledge in the context of bowel cancer screening endoscopy (Table 6.2).

Table 6.2. Participants (n=23) patient safety knowledge assessment: Multiple Choice Question (MCQ) scores pre and post training

<table>
<thead>
<tr>
<th>Knowledge assessment</th>
<th>Pre-training Mean (SD)</th>
<th>Post-training Mean (SD)</th>
<th>Change Mean (95% CI)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Correct Multiple Choice Question responses</td>
<td>43% (16%)</td>
<td>55% (16%)</td>
<td>+12% (6-18)</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

6.5.3 Patient Safety Attitudes

Attitudes towards patient safety pre and post training intervention are illustrated in Table 6.3. A change in patient safety attitudes was observed for 12/41 (29%) of items assessed. A significant change in participants’ attitudes was found following the training in the areas of perceived patient safety knowledge and awareness (Table 6.3 categories A and B). There was no significant change in perceived influence on patient safety (C), attitudes towards error management (D), error management actions (E) or personal views following an error (F).
6.5.4 Global Course Evaluation

The overall feedback was positive: 91% of delegates strongly agreed/agreed that they were satisfied with the course. Both quantitative (Table 6.4) and qualitative (Table 6.5) measures indicate that the participants viewed the training intervention very favourably.

Table 6.3. Participants (n=23) patient safety attitudes pre and post training on a 5-point Likert scale (1= Strongly disagree, 5 = Strongly agree)

<table>
<thead>
<tr>
<th>Patient Safety Attitude</th>
<th>Pre-course Mean (SD)</th>
<th>Post-course Mean (SD)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>A. Perceived Patient Safety Knowledge</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Different types of medical error</td>
<td>3.3 (1.2)</td>
<td>4.2 (0.6)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Factors contributing to error</td>
<td>3.5 (1.0)</td>
<td>4.5 (0.5)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Factors influencing patient safety</td>
<td>4.0 (1.0)</td>
<td>4.5 (0.5)</td>
<td>0.04</td>
</tr>
<tr>
<td>Ways of speaking up about error</td>
<td>3.5 (1.1)</td>
<td>4.3 (0.6)</td>
<td>0.009</td>
</tr>
<tr>
<td>What should happen if an error occurs</td>
<td>3.6 (1.2)</td>
<td>4.3 (0.7)</td>
<td>0.01</td>
</tr>
<tr>
<td>How to report an error</td>
<td>3.8 (1.3)</td>
<td>4.3 (0.7)</td>
<td>0.11</td>
</tr>
<tr>
<td><strong>B. Perceived Patient Safety Awareness</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Able to identify situations leading to error</td>
<td>3.9 (0.6)</td>
<td>4.3 (0.5)</td>
<td>0.03</td>
</tr>
<tr>
<td>Able to take steps to ensure patient safety</td>
<td>4.0 (0.5)</td>
<td>4.1 (0.5)</td>
<td>0.45</td>
</tr>
<tr>
<td>Able to investigate errors to prevent re-occurrence</td>
<td>3.5 (0.8)</td>
<td>4.1 (0.6)</td>
<td>0.006</td>
</tr>
<tr>
<td>Understand the role of human factors in error prevention</td>
<td>4.0 (0.8)</td>
<td>4.5 (0.6)</td>
<td>0.01</td>
</tr>
<tr>
<td>Able to see potential for error and rectify it</td>
<td>3.8 (0.6)</td>
<td>4.0 (0.6)</td>
<td>0.09</td>
</tr>
<tr>
<td>Understand factors resulting in wrong site procedure</td>
<td>3.8 (0.8)</td>
<td>4.7 (0.5)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Able to prevent wrong site procedures</td>
<td>4.0 (0.7)</td>
<td>4.5 (0.6)</td>
<td>0.004</td>
</tr>
<tr>
<td>Understand factors behind drug errors</td>
<td>3.9 (0.8)</td>
<td>4.4 (0.6)</td>
<td>0.004</td>
</tr>
<tr>
<td>Able to prevent drug errors</td>
<td>3.9 (0.8)</td>
<td>4.4 (0.6)</td>
<td>0.002</td>
</tr>
<tr>
<td><strong>C. Perceived Influence on Patient Safety</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Easier to find someone to blame following an error</td>
<td>2.5 (1.2)</td>
<td>2.4 (1.0)</td>
<td>0.79</td>
</tr>
<tr>
<td>Confident addressing a colleague disregarding patient safety</td>
<td>3.9 (0.8)</td>
<td>4.3 (0.6)</td>
<td>0.07</td>
</tr>
<tr>
<td>Able to talk to a colleague who has made an error</td>
<td>3.7 (0.7)</td>
<td>4.0 (0.7)</td>
<td>0.06</td>
</tr>
<tr>
<td>Able to ensure safety is not compromised</td>
<td>3.5 (0.8)</td>
<td>3.9 (0.8)</td>
<td>0.10</td>
</tr>
<tr>
<td>Incident forms improve patient safety</td>
<td>4.0 (1.0)</td>
<td>4.0 (0.8)</td>
<td>0.59</td>
</tr>
<tr>
<td>Able to talk about my own errors</td>
<td>4.1 (0.5)</td>
<td>4.3 (0.5)</td>
<td>0.16</td>
</tr>
<tr>
<td><strong>D. Attitudes Towards Error Management</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Identifying incident causation contributes to patient safety</td>
<td>4.3 (0.6)</td>
<td>4.5 (0.5)</td>
<td>0.13</td>
</tr>
<tr>
<td>Patient Safety Attitude</td>
<td>Pre-course Mean (SD)</td>
<td>Post-course Mean (SD)</td>
<td>P-value</td>
</tr>
<tr>
<td>----------------------------------------------------------------------------------------</td>
<td>----------------------</td>
<td>------------------------</td>
<td>---------</td>
</tr>
<tr>
<td>Learning from my mistakes will prevent medical error</td>
<td>4.2 (0.8)</td>
<td>4.4 (0.6)</td>
<td>0.45</td>
</tr>
<tr>
<td>Dealing with errors is an important part of my job</td>
<td>4.5 (0.5)</td>
<td>4.5 (0.5)</td>
<td>1.00</td>
</tr>
<tr>
<td>Able to challenge practices that compromise patient safety</td>
<td>4.5 (0.5)</td>
<td>4.6 (0.6)</td>
<td>0.65</td>
</tr>
<tr>
<td>It is acceptable to be honest about mistakes in my workplace</td>
<td>4.5 (0.6)</td>
<td>4.4 (0.6)</td>
<td>0.48</td>
</tr>
<tr>
<td>Admitting error would lead to fair treatment by management</td>
<td>4.0 (0.7)</td>
<td>4.1 (0.6)</td>
<td>0.32</td>
</tr>
</tbody>
</table>

**E. Error Management Actions**

<table>
<thead>
<tr>
<th>Statement</th>
<th>Pre-course Mean (SD)</th>
<th>Post-course Mean (SD)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>I report errors in my workplace</td>
<td>4.4 (0.7)</td>
<td>4.5 (0.6)</td>
<td>0.76</td>
</tr>
<tr>
<td>I challenge patient safety complacency</td>
<td>4.2 (0.7)</td>
<td>4.4 (0.5)</td>
<td>0.24</td>
</tr>
<tr>
<td>I communicate safety expectations to my team</td>
<td>4.3 (0.6)</td>
<td>4.4 (0.5)</td>
<td>0.39</td>
</tr>
<tr>
<td>I support team members involved in an incident</td>
<td>4.5 (0.6)</td>
<td>4.7 (0.5)</td>
<td>0.10</td>
</tr>
<tr>
<td>I inform colleagues about errors they make</td>
<td>4.2 (0.6)</td>
<td>4.1 (0.6)</td>
<td>0.71</td>
</tr>
<tr>
<td>I intervene if a patient is exposed to harm</td>
<td>4.4 (0.7)</td>
<td>4.6 (0.5)</td>
<td>0.23</td>
</tr>
<tr>
<td>I actively learn from others’ mistakes</td>
<td>4.4 (0.6)</td>
<td>4.5 (0.5)</td>
<td>0.41</td>
</tr>
</tbody>
</table>

**F. Personal Views Following an Error**

<table>
<thead>
<tr>
<th>Statement</th>
<th>Pre-course Mean (SD)</th>
<th>Post-course Mean (SD)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Following an error I would feel afraid</td>
<td>3.1 (0.9)</td>
<td>3.1 (0.8)</td>
<td>1.00</td>
</tr>
<tr>
<td>Following an error I would feel ashamed</td>
<td>3.6 (0.9)</td>
<td>3.6 (1.0)</td>
<td>1.00</td>
</tr>
<tr>
<td>Following an error I would feel guilty</td>
<td>4.1 (0.7)</td>
<td>3.9 (0.8)</td>
<td>0.15</td>
</tr>
<tr>
<td>Following an error I would feel upset</td>
<td>4.5 (0.5)</td>
<td>4.3 (0.6)</td>
<td>0.24</td>
</tr>
<tr>
<td>I know whom to inform following an error</td>
<td>4.4 (0.7)</td>
<td>4.5 (0.6)</td>
<td>0.24</td>
</tr>
<tr>
<td>I know whom to escalate a problem to arising during a list</td>
<td>4.5 (0.7)</td>
<td>4.4 (0.7)</td>
<td>0.56</td>
</tr>
<tr>
<td>Able to request a debrief +/-support following a mistake I have made</td>
<td>4.1 (1.1)</td>
<td>4.2 (0.9)</td>
<td>0.94</td>
</tr>
</tbody>
</table>

**Highlighted stems = no significant change following training**

**Table 6.4.** Summary of quantitative course evaluation for 23 participants following the training intervention on a 5-point Likert scale (1 = Strongly disagree, 5 = Strongly agree).

<table>
<thead>
<tr>
<th>Course Evaluation</th>
<th>Statement</th>
<th>Mean (SD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Content</td>
<td>Improved my understanding of patient safety, human factors &amp; the systems approach to error</td>
<td>3.95 (0.72)</td>
</tr>
<tr>
<td></td>
<td>Improved my understanding of how to analyse an adverse event &amp; learn from error</td>
<td>4.14 (0.77)</td>
</tr>
<tr>
<td></td>
<td>Improved my understanding of solutions to prevent error</td>
<td>4.18 (0.66)</td>
</tr>
<tr>
<td></td>
<td>Enhanced my understanding of non-technical skills</td>
<td>4.32 (0.57)</td>
</tr>
</tbody>
</table>
## Table 6.5. Summary of qualitative course evaluation

<table>
<thead>
<tr>
<th>Free text comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>• ‘Highly relevant to day-to-day endoscopy practice’</td>
</tr>
<tr>
<td>• ‘ENTS is a no-brainer…need to educate others’ on the topic’</td>
</tr>
<tr>
<td>• ‘Video cases were really interesting and good interactive discussion’</td>
</tr>
<tr>
<td>• ‘Excellent faculty, and well organised with high quality handbook’</td>
</tr>
<tr>
<td>• ‘Highly important topic, training should be mandatory for all endoscopy teams’</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td><strong>Suggested Improvements</strong></td>
</tr>
<tr>
<td>• More clinical cases</td>
</tr>
<tr>
<td>• More adverse events analysis</td>
</tr>
<tr>
<td>• More time for video analysis</td>
</tr>
<tr>
<td>• Practical ENTS sessions in real teams</td>
</tr>
</tbody>
</table>

### 6.6 Discussion

#### 6.6.1 Summary

This is the first multi-disciplinary patient safety and non-technical skills training intervention targeted towards bowel screening endoscopy teams. The key findings of this study that training improved patient safety knowledge scores and some patient safety attitudes in expert teams after a single days training have future implications: Endoscopy patient safety training...
to multiple teams without special resources such as simulation is feasible. Importantly, expert endoscopy teams value non-technical skills training and believe this should be developed and disseminated.

**Strengths of study and strengths of training**

This endoscopy training approach is novel as participants were from diverse multidisciplinary expert teams with training focussed on the team as opposed to the individual. By using validated safety attitudes questionnaire and a robust evidence-based approach to course set-up and evaluation this training provides scientific credibility for wider dissemination.

### 6.6.2 Implications

Current endoscopy training for endoscopists and nurses is well established. Through the infrastructure of JAG and within the framework of the NHS there is a real opportunity to push endoscopy quality assurance by systematically educating endoscopists on non-technical skills. These skills have the potential to enhance technical skills facilitate teamwork and potentially mitigate error. The components of endoscopy quality assurance are individually well developed for endoscopist (JAG), nurses (GIN) and units (GRS) but could have a more meaningful impact if these elements were combined to target endoscopy teamwork.

Teamwork training has an important role in endoscopy. There are many benefits to training multi-disciplinary teams, such as promoting cohesive team working and breaking down inter-professional communication barriers. By adopting the approach of training the core team, it is more likely that improvement measures will be translated to patient care compared to limiting training to a single profession. The implications of this study from the main outcome measures are detailed below.

### 6.6.2.1 Patient Safety Knowledge Implications

This training intervention resulted in significant improvements in patient safety knowledge in highly experienced multi-disciplinary Bowel Cancer Screening teams. This highlights that experienced endoscopists and nurses working in screening training centres were able to improve their knowledge after just a single day’s training, despite there being a large volume of novel information to assimilate in a single day.
6.6.2.2 Patient Safety Attitudes Implications
Attitudes towards patient safety are complex and will be affected by multiple factors including personal experiences, attitudes towards risk and the safety culture within the individual’s workplace. Perceived patient safety knowledge and awareness both significantly improved, however influence on patient safety and attitudes towards error management did not change following the intervention. This finding may be explained by the fact that these are self-selected senior attendees with an interest in patient safety and teamwork skills. The baseline patient safety attitude scores were quite high and the training is therefore likely to have had less impact on attitude in these teams. This may also be explained by the fact that attitudes can be quite deeply embedded and less likely to be significantly changed after a single day’s training. This is corroborated by Arora et al’s study of safety skills training in surgical residents\(^9\) where similarly, there was no significant change in 4 out of the 6 safety attitude domains following training. Overall, this is a common finding in such training courses\(^9\)\(^{10}\)\(^{16}\)– some attitudes improve, and some remain unchanged. A one-day course alone cannot change deeply held attitudes about safety; typically these take longer to change and are associated with changes alongside the clinical workplace.

Nevertheless, the safety attitudes questionnaire responses revealed important areas to target for subsequent training: The highlighted stems in Table 3 show items in the attitudes questionnaire that did not significantly change following training. These areas could be targeted in future training courses for example by making explicit a ‘take home message’ of key patient safety actions the teams could implement in their own clinical practice.

6.6.2.3 Expert focus group
The expert focus group was broadly led within two main themes: future endoscopy team training and safety checklists to enhance team performance. Key qualitative themes arising from this are summarised below.

Team training dissemination
- Endoscopy is safer than Surgery so patient safety risks must be contextualised
- Need good ‘buy in’ form all team members
- Develop team training through existing JAG courses
- Live feedback on team performance by trained faculty desirable but resource intensive
● Develop to include endoscopy team simulation

Endoscopy safety checklist

● Engage teams in rationale and practicalities of how to undertake checklist
● Risk of ‘tick box’ exercise if teams not engaged
● Stop and pause prior to procedure
● ‘Any concerns’ at the end of the checklist is an open moment – allow all team members
● Checklist enables roles to be assigned to team members i.e. head end nurse
● Checklist facilitates cognitive synchronisation
● Teams should be encouraged to modify checklist after use
● Patients need to be involved in checklist
● Checklist should be completed at moment of ‘take-off’ and not outside room
● Use checklist to not do a test where patient safety may be compromised.
● Contextualise checklist with list briefings and de-briefings
● Guidance for checklist adoption needs to be considered to avoid ‘death by paperwork’
● Standardised checklist document promoted by NHS Bowel Cancer Screening will aid adoption
● Learn from WHO surgical checklist implementation and ensure teams are engaged early in process

6.6.3 Limitations

The limitations of this study are considered for the study design as well as the training intervention itself.

6.6.3.1 Study design limitations

The study small sample size was small in terms of absolute numbers, although this novel training intervention targeted 4 out of 10 bowel cancer screening training centres in England. Delivering interactive small group training and video analyses is not feasible for larger groups, and the educational strategy was not intended to be purely didactic.
There was inevitably also a degree of selection bias, with interested, motivated teams and those with the capacity to cancel clinical commitments more likely to attend. Participants therefore consisted of interested endoscopy leads already actively engaging in patient safety measures. It could be argued that any positive benefit may thus be attenuated, as the baseline appreciation of these issues was high in this select group. There are, however, also advantages to targeting motivated groups from the point of view of future implementation: trained interested experts can become ‘champions’ for this type of training and hence drive its implementation on a wider national scale.

Additionally, from a study design perspective, a control group for comparison purposes would have been desirable. As in other similar studies,9,10,16 however, we felt it was not feasible to obtain a closely matched group of experts willing to accurately complete the extensive MCQ and safety attitudes assessments without the incentive of training. This study was limited as there was insufficient data to support long-term retention of knowledge or skills acquired from the training. Further developments of our training intervention could include observational assessment (live or recorded) of a bowel cancer screening team conducting a colonoscopy, and rating the teamwork and non-technical skills pre and post training.

Furthermore, we cannot provide definitive evidence from this single study that teamwork training directly impacts adverse events in endoscopy. It is difficult to prove that training interventions of this type improve patient safety due to the relative rarity of severe adverse events, the complexity of medical error and the length of follow up required for such a study. It is, however, well accepted that team training can improve safety attitudes and behaviours and in the surgical arena a reduction in mortality has also been shown.17,18

6.6.3.2 Training intervention limitations

Multi-disciplinary team training is advantageous, but brings challenges to designing and implementing training suitable for all the professional sub-groups. One of the challenges is to ensure that the educational content is appropriate for the varied skill sets of the different professional groups. It is acknowledged that perception of patient safety varies by professional subgroup19 and these differences may be more difficult to address in a multi-disciplinary team training intervention. Whilst knowledge and attitudes were directly assessed, patient safety skills assessment was beyond the scope of this training. Furthermore, whilst a full day’s training offers the opportunity to cover the fundamentals of endoscopy
patient safety, it remains a ‘one-off’ teaching intervention with no guarantee that knowledge acquired will be retained or practically applied in each team’s respective endoscopy unit. Translating knowledge, skills and attitudes acquired during patient safety training to actual clinical practice is important but difficult to ascertain. To address one could utilise the endoscopic non-technical skills framework to assess safety behaviours in the workplace – this was beyond the scope of this training but can be done scientifically\textsuperscript{20}.

### 6.6.4 Future developments

Participants’ feedback included suggestions that team training should be mandatory for all endoscopy teams in order to improve patient safety, and that teamwork optimisation was a highly important but under-recognised theme. The video case analyses of endoscopy teams were well received and suggested course developments included endoscopy team simulations with structured feedback. Additionally, it was thought that the training intervention was highly relevant to day-to-day endoscopy practice and equally if not more important for non-bowel cancer screening endoscopy teams.

This initial training intervention demonstrates that training screening teams is feasible and perceived to be useful. It is therefore feasible to replicate this training for the remaining six screening training centres. This would enable a core faculty to be trained across England facilitating teamwork training to all to all endoscopists through JAG. By imparting patient safety and non-technical skills training to motivated leaders, the foundation has been laid to ‘train the trainers’. This would catalyse local team training and thus facilitate wider dissemination of endoscopy teamwork and patient safety issues. Research in the domain of surgical non-technical skills has shown a UK cross disciplinary consensus regarding the importance of training faculty to assess and de-brief non-technical skills performance\textsuperscript{20}.

Although screening teams participated in this study, this training is highly transferable to other sub-specialist endoscopy teams: emergency endoscopy, upper and lower gastrointestinal therapeutic endoscopy as well as surveillance procedures. It could also be readily adapted for prospective gastroenterology trainees, which would enable patient safety issues to be embedded at an earlier stage in training.

Future developments of the existing training could include extension of the training period to two days to incorporate a practical scenario utilising a simulated or real endoscopic procedure(s) on day two. Trained faculty would closely observe the endoscopy team in action
in diagnostic, therapeutic and emergency cases followed by a structured ‘de-brief’\textsuperscript{21} of the patient safety issues and relevant non-technical skills using the ENTS framework as a guide. Development of team simulation training for specific scenarios is the natural corollary for this training intervention. In considering endoscopy education, training sustainability has to be balanced with the time, resources and logistics of travel and loss of service provision involved in extending such patient safety training to its full potential. This should be considered on a national training level if we want to further extend and maintain quality assurance for endoscopy.

6.7 Conclusion

This study demonstrated it is feasible and valuable to deliver a comprehensive training package addressing endoscopic patient safety, non-technical skills and adverse event analysis using a multifactorial approach. Although similar human factors training has been developed for Anaesthetics and Surgery, this is novel in endoscopy and cancer screening. Given the importance of patient safety in the context of the asymptomatic screening population and expansion in screening services, team training should be developed and disseminated within training endoscopy units. Strategies to incorporate endoscopic non-technical skills and patient safety into routine endoscopy training for both trainees and accredited endoscopists should be explored and developed at a national and international level.
Chapter 7: Development, Implementation and Evaluation of an Endoscopy Safety Checklist

7.1 Chapter Overview

Chapter 6 outlined the importance of education and training to enhance teamwork, which underpins the effectiveness of all quality improvement interventions. This chapter builds upon the findings in chapters 2 and 3, which illustrated wide variability in safety checks and the frequent occurrence of avoidable error. In order to address some of the problems identified in Part A of this thesis, a safety checklist was devised as a mechanism to provide consistency to the safety check repertoire and to facilitate effective team working. The introduction contextualises the origins of safety checklists and their transition into healthcare, followed by the study aims and methods. The results are discussed with a focus on the practical considerations of disseminating endoscopy safety checklists more widely.

7.2 Introduction

7.2.1 Checklist origins

Safety checklists have their origin in aviation well renowned for its safety culture\(^1\). Designers of the technologically superior Boeing B-17 bomber plane were vying for a government contract for 2\(^{\text{nd}}\) World War fighter planes. The test flight resulted in a fatal explosive crash: The pilot forgot to release the elevator locks. The phrase, ‘too much plane for one man to fly’\(^2\) was coined by the media encapsulating the complexities of the human - technological interface. The B-17 model was re-presented to the US government with a mechanism to ensure such oversights would not re-occur, and this led to the creation of the aviation safety checklist. Currently, there is approximately one passenger fatality per 10 million flights\(^3\) \(^4\) compared to one iatrogenic patient death per 100 hospital admissions.\(^5\) Checklists alongside confidential incident reporting systems, crew resource management and a ‘no blame’ safety culture have built aviation’s safety legacy. Importantly similarities and differences between aviation and healthcare should be considered (Chapter 1, section 1.3.4) but safety lessons can be learnt from aviation and applied to Gastroenterology quality assurance\(^6\) and the safety checklist is a defined entity to start with.
7.2.2 What is a safety checklist?

Within the medical literature there is no uniform definition detailing exactly what a safety checklist is.\(^7\) The term ‘checklist’ is increasingly used in various hospital policies and means different things to different people. Safety checklists are distinct from protocols, algorithms and guidelines, which detail the steps within a procedure. A checklist has a specific design and function, which may not always be clearly understood by the end users. A checklist is a series of safety checks and actions to, ‘provide a means of reminding the crew, immediately prior to take off, that all items critical for safe flight have been accomplished’.\(^1\) Checklists compose a defined set of safety standards, in paper or electronic format, for the team to complete at set time points (e.g. before incision). Checklists provide a clear structure for safety critical steps to counter the effects of fatigue and stress on individual performance and to enable mutual supervision (cross checking) among team members. The roles and responsibilities of respective team members are defined facilitating team coordination and reinforcing the correct mind set and ‘attitude’ towards the procedure ahead.\(^1\) Checklists not only standardise safety checks they enhance teamwork by facilitating communication and unifying team members for the immediate task in hand.

7.2.3 How should a safety checklist be used?

There are various aspects to conducting a checklist effectively. Firstly it needs to be clear that the checklist is being undertaken with active engagement from all team members and effective leadership. The checklist can function as a ‘read and do’ check for example when confirming equipment is present and functioning.\(^8\) This approach is prescriptive and ensures each item is checked step by step. Alternatively, the ‘challenge – response’ approach uses the checklist as a back-up: The crew complete all the safety steps in advance and accuracy and completion are subsequently verified with the checklist, which also highlights any missed items. This approach has built in redundancy and works to mitigate the effects of human error.\(^1\) Adopting aspects of both of these methods is the checklist as an ‘aide memoire’ where it is used as a cognitive aid with structured prompts at key stages of the procedure. In practice a combination of these methods may be employed.\(^9\) The exact method is less important than the active involvement of the core team. Whilst accomplishing standardised checks in a thorough manner is the obvious purpose of the checklist, secondary gains of team cohesiveness through information exchange and alignment of goals, may well be more important for patient safety.


7.2.4  Checklists beyond Aviation

From their inception in aviation in the 1930s, checklists have been widely adopted in high-risk industries\[^{10,11}\] and considered by some, ‘another member of the crew’\[^{12}\] as opposed to a tick box exercise. In addition to aviation, the military, nuclear, oil and construction industries\[^{3}\] adhere to the concept of safety checklists and have adapted them to suit their individual tasks, teams and environments. Checklists have slowly been adopted in health care and key illustrative examples are summarised with their evidence in the following three sections.

7.2.4.1  Evidence for Checklists in Medicine

Many examples of medical checklists can be found in the literature\[^{13}\] and although there is variation in how effectively these tools are devised, implemented and used, they can lead to improved quality of patient care.\[^{14}\] Checklists have been devised to address wide ranging issues from withdrawal of life support\[^{15}\], interventional radiology\[^{16}\] intensive care handover processes\[^{17}\] cardiac catheterisation\[^{18}\] and bronchoscopy.\[^{19}\]

An important example of effective checklist use relates to central venous catheter safety. Catheter associated blood stream infections in intensive care patients occur frequently, are potentially lethal and incur significant cost considering the extra hospital bed days involved.\[^{20}\]

To address this, Pronovost et al\[^{21}\] conducted a collaborative cohort study to evaluate the effectiveness of adherence to evidence-based practices through a checklist intervention. Infection rates were measured before, during and 18 months after checklist implementation. The central venous catheter checklist was a concise, single sheet outlining key aseptic techniques, and to be used for each patient undergoing the intervention. Baseline observations prior to the intervention revealed that all the aseptic components outlined in the checklist were only fully completed in 62% of catheter insertions. The checklist was implemented in a considered manner with attention to interdisciplinary communication and teamwork.\[^{22}\] Importantly, nurses were given the authority to stop a procedure if a step in the checklist was omitted (32% of cases in the first month).\[^{23}\] Data from 103 units representing 375,757 catheter days showed a reduction in the median rate of infection per 1000 catheter days from 2.7 at baseline to 0 at 3 months following the checklist intervention.\[^{21}\] The reduction in infection rates was not observed in the control units. It was estimated that 43 catheter related infections were prevented, 8 deaths avoided and $1,945,922 additional costs per year avoided. This landmark study illustrated how evidence based interventions could be
effectively optimised through use of a checklist, and in turn lead to a significant and sustained reduction in infection rates.

7.2.4.2 Evidence for Checklists in Surgery

‘Although surgical care can prevent loss of life or limb, it is also associated with considerable risk of complication and death’.24 The operating theatre is a highly complex environment and also the commonest setting for medical error25. Although medical checklists originated in critical care, international attention was galvanised by the World Health Organisation (WHO) surgical safety checklist24 constituting part of the ‘Safe Surgery Saves Lives’ initiative.26 The checklist was derived following a detailed development process10 and tailored for surgical interventions yet applicable on a global scale. A concise nineteen-item checklist was devised targeting critical actions27 across three sections of an operation: Sign in (before anaesthesia), time out (before skin incision) and sign out (before leaving theatre). The checklist was implemented in eight countries with diverse socio-economic patient populations and was associated with a significant reduction in complications (11-7%) and mortality (1.5-0.8%). Importantly, its effectiveness and feasibility was also observed in emergency surgery addressing concerns that it would delay therapeutic intervention and thus put patients at increased risk.28 The WHO surgical checklist was successful due to strong leadership and an accompanying ‘manifesto’3 resultin in many institutions mandating its use, although practical challenges to implementation required considered attention.29 Unsurprisingly, the reduction in morbidity and mortality correlates with increased checklist compliance.27,30 which remains a focal point for quality improvement.31

These findings were corroborated by the Surgical Patient Safety System (SURPASS) checklist implemented in six hospitals in the Netherlands with high baseline safety standards. The Dutch checklist was a more comprehensive multi-disciplinary checklist tracking the surgical patient pathway from admission to discharge.32 Comparisons pre and post checklist implementation revealed a reduction in the total number of complications per 100 patients (27.3-16.7 95% CI) and a reduction in mortality (1.5-0.8%) with no change in outcomes in the five control hospitals.33 Despite these two major studies, a degree of scepticism prevails over surgical checklists34 35 36 and a large Canadian study found no reduction in complications, mortality or patient outcomes attributable to checklist implementation.37 This study raises questions around adherence and team training as well as the generalizability to ‘real world’ practice as opposed to ‘safety research’ settings. Nevertheless, a recent
systematic review on checklists concluded that ‘safety checklists appear to be effective tools for improving patient safety in medicine by strengthening compliance with guidelines, improving human factors, reducing errors and decreasing morbidity and mortality in some instances…with no negative effects on patient safety’.7

7.2.5 Strengths and Weaknesses of Checklists

It is clear that checklists have potential to reduce error and enhance safety. This is possible when they are well designed, thoughtfully implemented, easy to use, deemed to be effective by clinical teams and efficiently incorporated into existing pathways without disruption to patient flow. Checklists not only can improve safety by minimising error, but additional benefits include improved team communication and cohesion through aligned goals. These benefits however, rely on the team being fully engaged in the checklist process and understanding the rationale. If there is limited ‘buy in’ from front line staff, checklists run the risks of being misused (incomplete, rushed, conducted without key figures and dismissive responses29). Such checklists are unlikely to be useful and run the risk of potentially negatively affecting safety by engendering a false sense of security or disrupting teamwork if certain figures oppose checklist use. Effective checklists need clear leadership but they are not a panacea for medical error. It should also be noted that the research settings in which key checklist studies are evaluated, are confounded by strong leadership, dedicated team members and training initiatives and an organisational programme motivated towards safety and quality and hence the effectiveness of the checklist should be considered within this wider context.34

7.3 Aims

The aims of this study were two-fold: Firstly to design, implement and evaluate an endoscopy safety checklist. Secondly, to determine the effects of the checklist on performance and patient safety incidents. Performance pre and post checklist implementation was assessed by measuring and comparing the following variables:

a. Technical skills of the endoscopist

b. Non-technical skills of the endoscopist

c. Safety checks for endoscopic procedures

d. Patient Safety Incidents
7.4 Methods

7.4.1 Checklist development

Some trusts have mandated the use of the WHO surgical checklist for interventional procedures including endoscopy. Whilst there are clear benefits to streamlining safety checks, using a checklist that is not specific to the task, the team and the process is likely to be ineffective and inefficient. To counter this the endoscopy checklist was created, the components of which were defined considering the benefits of checklists beyond safety checks, team members’ attitudes, expert opinion, the unit requirements and the endoscopy patient safety incidents study (Chapter 2).

7.4.1.1 Defining checklist functions

In addition to confirming safety checks have been completed, checklists have important additional functions. They mark the beginning of the intervention separate to the preparatory stage and signal to the patient and the team that the procedure is underway. By confirming team members’ names and roles, team identity is clarified and this serves to facilitate subsequent team communications. This enhances teamwork processes (Chapter 1, section 1.4.2) by aligning agendas, strengthening team cohesion and diminishing hierarchy. The checklist enables team members and the patient to clarify issues at the last moment prior to the intervention. These checklist functions were considered when defining the checklist components.

7.4.1.2 Endoscopy Staff Attitudes to Safety Checks Questionnaire study

The findings of the safety attitudes questionnaire study (Chapter 2, section 2.5.1) helped inform the checklist components. The safety checks that had high numbers of responses (e.g. patient identification, consent and medical history) were incorporated in the checklist not only because they were key and consistent with the content of other checklists, but because they represented the local unit’s needs and helped engage users in subsequent checklist adoption.

7.4.1.3 Patient Safety Incidents Study

Chapter 2 also presented the range and frequency of patient safety incidents across endoscopic procedures. The observed errors were categorised into 9 themes and where possible these areas were addressed by the checklist. In addition the never events (patient
misidentification, wrong procedure) and severe errors (documentation errors, sedation, intravenous access, oxygenation and monitoring) were also built into the checklist.

7.4.1.4 **WHO Surgical Safety Checklist: Translating concept and adapting content**
The WHO surgical safety checklist was a model. The concept of the checklist being completed by the immediate team at set points during the procedure was translated to endoscopy and the content adapted for endoscopy. Furthermore, a proportion of endoscopy nurses and all of the surgical endoscopists were familiar with the surgical checklist from the operating theatre environment. Additionally, the lessons learnt from the WHO checklist deployment process were considered in the design and implementation of the endoscopy checklist to enhance uptake.

7.4.1.5 **Expert focus group**
Following this initial checklist development process, a provisional checklist was devised. This was reviewed with key senior endoscopy representatives including the unit manager, the endoscopy clinical lead, the endoscopy training lead, the Bowel Cancer Screening Programme manager and two senior endoscopy nurses. The content and order of the checklist was reviewed, discussed and revised. In addition practical considerations such as where the checklist was to be conducted (in the endoscopy room or at pre-admission), who would be responsible for leading the checklist (endoscopist or nurse), how this would be communicated to the patient, how many parts the checklist would be completed in (pre-admission, pre-procedure, post procedure) and whether the checklist should be paper based or electronic and incorporated into the endoscopy reporting software, were outlined with the advantages and disadvantages of various approaches for the patient, the team and the unit as a whole considered. The checklist was incorporated into specific patient care plans e.g. endoscopy in theatre under General Anaesthetic and Bowel Cancer Screening to ensure coverage was complete. This process further shaped the checklist. It was agreed that the checklist should form part of safe patient centred endoscopy and be a standard of best practice for all patients, but that its use was not *mandated* from the beginning to avoid barriers associated with an imposed implementation approach.38

7.4.1.6 **Checklist Feedback and Modification**
Following the expert focus group modifications, the checklist was disseminated to endoscopy users through a series of dedicated training sessions. The checklist rationale and practical use, was explained targeting key groups: endoscopy nurses, medical endoscopists, surgical
endoscopists, trainees, experts as well as administrative staff. These training sessions invited feedback from this broad group of endoscopy users and further modifications made. The checklist was printed and displayed in each endoscopy room. (See Appendix 7.1 for the checklist that was in use at the time of the study).

7.4.2 Checklist Patient Opinion Questionnaire Study

In seeking clinical team members’ opinion on the checklist, a concern was raised that the checklist may provoke anxiety in the patient and that performing further checks at the last moment might undermine the patients confidence in the endoscopist. This was addressed early on in the checklist roll out by completing a checklist patient opinion questionnaire study. A paper-based questionnaire composed of 20 questions with responses on a 1-7 scale: 1. Strongly disagree – 7. Strongly agree (see appendix 5.2) was adapted from similar work in Surgery.39. This was distributed with a letter explaining the questionnaire (Appendix 5.3) to 100 patients in endoscopy after their procedure had completed. These patients were asked to complete the questionnaire prior to discharge when the effects of any administered sedation were deemed negligible.

7.4.3 Checklist Implementation Strategy

Once the checklist had been finalised an implementation strategy was planned with a series of training interventions as an integral part of the process. Initial checklist communication was disseminated in the design phase where users were invited to give feedback on the content of the endoscopy checklist. Further training was directed at endoscopy sub-group users, nurses, endoscopists, bowel cancer screening teams and administrative staff. These training interventions were targeted to the audience and included presentation of evidence for checklists, video examples of endoscopy checklist scenarios (emergency endoscopy, routine endoscopy, motivated endoscopist, disengaged endoscopist etc.) how to practically conduct the checklist effectively and the pros and cons of using the checklist.

The checklist implementation was also presented at the GI Governance meeting to ensure the wider gastroenterology teams (Surgery, Radiology, IBD and Nutrition) were aware of the practice change. The endoscopy checklist was also presented to the Medical Director of the hospital as a quality improvement intervention, who subsequently mandated use of checklists for all interventional procedures in the Trust.
The checklist launch date was advertised in the preceding month through posters distributed across the Trust as well as a PowerPoint screensaver slide on the Trust NHS computers (Appendix 7. 5). The main researcher (MM) was based in the endoscopy unit for the initial launch week to provide further hands on training in the endoscopy room, to lead the checklist in some cases, provide feedback to individuals and teams and to field any problems that arose. Positive examples of where the checklist averted an error were noted and shared amongst the unit and between lists to demonstrate it’s effectiveness.

7.4.3.1 Further Checklist Feedback and Modification
As part of the training and implementation strategy of the checklist, endoscopy users were actively encouraged to provide critical feedback on the checklist. This was encouraged in a number of formats including directly reporting back by email to researcher MM, escalating issues to the nurse in charge and by posting anonymous comments in a feedback box placed in the unit for the first 2 months of implementation. The feedback was reviewed weekly by researcher MM and on a monthly basis for the first 3 months with the clinical lead and further modifications made longitudinally as checklist use became incorporated into daily practice. The checklist was also incorporated into the patient care pathways for endoscopy under General Anaesthesia and Bowel Cancer Screening. Additionally, an open discussion forum was conducted in the endoscopy nurse monthly training session after 2 months to review progress, discuss issues with the checklist and empower nurses to challenge sub-optimal checklist use similar to the strategy employed by Pronovost’s group21 40.

7.4.4 Checklist Evaluation Study Design
This was a prospective observational study in a single tertiary endoscopy unit. A mixed methods study with qualitative and quantitative research methods was employed adopting the methodology described in Chapter 3 (section 3.4). The number of cases was matched to the number of cases analysed in routine endoscopy teams prior to checklist implementation (Chapter 3).

7.4.4.1 Ethical Considerations
Ethical approval for this study was obtained from the National Research Ethics Service (NRES) Committee London, Reference 08/H0719/54. Informed consent to observe each endoscopy procedure was obtained from the patient and the endoscopist and assisting nurses conducting the procedure. Participation was voluntary and participants’ anonymity and
patient confidentiality were maintained throughout. Endoscopy teams were informed that observations were being undertaken to evaluate team processes and safety in endoscopy. In the event of an adverse patient outcome, normal unit policies were adopted whereby the nurse in charge and the unit manager were informed and the incident reported to the hospital’s adverse event reporting system.41

7.4.4.2 Participants, Procedures and Settings
Study participants were endoscopists, the core endoscopy team and the patient undergoing the procedure. Endoscopists performing the procedures were experts and trainees, including medical gastroenterologists, colorectal surgeons and independent endoscopy nurse practitioners. Expert endoscopists (Group A) were defined as medical surgical and endoscopy nurse consultants. Trainee endoscopists (Group B) were defined as all other doctors of non-consultant grade: The trainee group comprised gastroenterology and surgical registrars and endoscopy clinical fellows within 2-6 years of completion of specialist training.

Elective (non-emergency) outpatient and inpatient endoscopic procedures were observed and included a representative sample of endoscopy sub-types: Oesophagogastrroduodenoscopy (OGD), colonoscopy (C), bowel cancer screening colonoscopy (BCSC), flexible sigmoidoscopy (FS) and endoscopic retrograde cholangio-pancreatography (ERCP) to ensure sampling validity and a comparable case mix to the baseline study. Procedures included a mix of diagnostic and therapeutic cases: endoscopic mucosal resection (EMR), stent insertion (SI) and variceal ligation (VL). Patient factors such as age and comorbidity were not analysed. This study was set in the Wolfson Endoscopy Unit at St Mark’s Hospital and procedures were observed from within the endoscopy room or the radiology suite for ERCP.

7.4.4.3 Skills and Behaviours assessment (ENTS DOPS SC)
Assessments were undertaken by the same gastroenterologists observing the baseline procedures (AH and MM) trained in technical and non-technical skills assessment. Dual rating of 15% of endoscopy lists was undertaken where each assessor was blinded to the other’s ratings to determine inter-rater reliability. The assessors independently completed observations and were not involved in the endoscopic procedure. They were however, part of the regular clinical team, and their presence in endoscopy rooms was thus commonplace. The live audio-visual link with quad split views (Chapter 3, figure 3.1) in the adjacent endoscopy training room was adopted when two observers were completing assessments to minimise disruption in the procedure room. When a single observer was present, evaluations were
undertaken from within the endoscopy room. Assessments were conducted for the principal or first endoscopist, defined as the endoscopist performing the majority of the procedure. The principal endoscopist needed to be defined when there were two endoscopists in the room, usually a senior trainee and a trainer. The number of individuals (endoscopists and nurses) conducting the procedure and the checklist were recorded separately.

Validated rating tools were used to make three main assessments: Technical skill (DOPS), Non-technical skill (ENTS) and Safety Checks (SC) all on 1-4 scales previously described in Chapter 3 (3.4.3.1 – 3.4.3.3) and summarised in appendix 3.1. Ratings for each of these parameters were assigned at a procedure level, which subsequently informed the overall score assigned at the list level. The rating at the list level was used for statistical analyses. These assessments were consistent with the measures undertaken in the pre-checklist study. In addition to these measures, the checklist was evaluated in detail and this is described below (section 7.4.4.5). Sub-group analysis was also completed to evaluate Bowel Cancer Screening procedures compared to non-screening procedures.

7.4.4.4 Comparison of Skills and Behaviours Assessments Pre and Post Checklist
In order to evaluate the impact of the checklist, comparisons were made with the baseline observations made in the pre-checklist study presented in Chapter 3. The safety check scores, technical skills, non-technical skills and patient safety incidents were measured in the same manner pre and post checklist and comparisons between the ratings at the two time points made.

7.4.4.5 Checklist Measures
The safety checklist was broadly evaluated using quantitative and qualitative approaches. The number of team members present and engaged in the checklist was recorded and compared to the number of individuals conducting the procedure. The time taken to complete the ‘time out’ section of the checklist (i.e. the 10/13 items that constituted the safety checks prior to scope insertion) was timed in seconds. In addition to whether the checklist was initiated or not, the number of the component safety checks adequately completed was recorded. From this a percentage completion of the 13 checklist items was calculated. Qualitative assessments centred around documenting optimal checklist completion i.e. clearly demarcating the beginning of the checklist, ensuring all relevant team members were present and engaged, cross checking information with the patient and the medical documentation, seeking further information if questions were posed, listening and responding to information
adequately and ensuring there was a short pause at the end for team members and the patient to raise any final concerns.

7.4.4.6 Incidence of Patient Safety Incidents
In addition to checklist completion, technical skill, non-technical skill and patient safety incidents (PSI) were prospectively recorded. Consistent with chapters 2 and 3, PSIs were defined as any safety issue that had the potential to, or directly adversely affected patient care. PSIs were defined as near misses, recognised procedural complications, adverse events and never events according to the Department of Health’s classification at the time of the study\(^4\). PSIs were identified from the assessors’ qualitative notes and examination of the patient’s medical and nursing record. PSIs were observed for the period of time the patient was in the endoscopy suite and did not formally extend pre or post procedurally.

In addition to recording the number of PSI, they were subsequently categorised by theme and severity as per Chapter 2. In addition it was noted whether the PSI occurred as a result of sub-optimal checklist use or whether the PSI occurred despite effective checklist completion.

7.4.5 Longitudinal Evaluation of Checklist Compliance
The checklist implementation plan included a short term and long term approach given the recognised challenges in changing healthcare processes within established NHS structures. The endoscopy implementation plan was shaped following the lessons learnt from the WHO Surgical Safety Checklist where studies have demonstrated significant variation in its use and subsequent effectiveness.\(^3\) In order to inform on-going checklist feedback and training measures at a unit and hospital governance level, compliance with the checklist was measured. This was structured as a quality improvement evaluation with a series of Plan Do Study Act (PDSA) cycles.\(^4\) Compliance with the checklist was assessed 12 months following implementation by evaluating the medical documentation for presence of the checklist documentation and degree of completion. Checklist compliance was prospectively evaluated for consecutive endoscopic procedures conducted during a seven-day period across the Wolfson Unit. The medical documentation was examined for the following parameters:

- Section of checklist completed (Time out / Sign Out / Both)
- Degree of completion (fully complete, partially complete, incomplete)
- Time frame (AM / PM)
7.4.6 Wider Checklist Dissemination

The checklist was formally implemented and evaluated in the Wolfson Unit for Endoscopy at St. Mark’s Hospital, which is part of the London North West Hospitals (LNWH) NHS Trust. This entailed the principle researcher (MM) providing training to endoscopists and nurses, responding to queries via e-mail and at joint governance meetings and training a ‘checklist nurse champion’ to optimise checklist use.

7.4.7 Statistical Methods

The data analysis methods employed for each part of the study are detailed below.

7.4.7.1 Patient Opinion Questionnaire

The responses to each of the 20 questions corresponded a 1-7 scale (strongly agree to strongly disagree). The responses were further categorised into 3 broad groups:

- Disagree (1-2)
- Neither agree / disagree (3-5)
- Agree (6-7)

The first analysis calculated the percentage of patients in each of the three categories. Additionally confidence intervals for these percentages were calculated, using the exact binomial method. Additional analyses compared the responses to each question between gender, and between patients who had and had not previously had an endoscopy. The Mann-Whitney test was used for the comparisons due to the ordinal nature of responses. Statistical analyses were not performed to compare those patients who had and had not experienced a previous medical error due to the small number of patients.

7.4.7.2 Safety Skills and Behaviours Assessments

Technical skill (DOPS) and non-technical skill (ENTS) were rated on a 1-4 scale and treated as categorical data. The median score with the range was presented. The safety check (SC)
score was completed on a 1-4 scale for each of the 14 checks proposed prior to the checklist and calculated as an average score for the list. This data set was treated as continuous and the mean and range values presented. The SC score although superseded by the checklist score was completed to ensure consistent measures with the baseline pre-checklist study.

7.4.7.2.1 Comparison between Experts and Trainees
Firstly the characteristics of the lists of trainees and experts were compared. The total number of procedures per list was compared between groups, as was the number of diagnostic and therapeutic procedures. The case mix was compared by measuring the percentage of diagnostic procedures per list. All variables were compared between groups using the unpaired t-test.

Subsequently the outcome variables were compared between experts and trainees. The non-technical (ENTs) and technical (DOPS) scores were ordinal in nature, with each list falling into one of a relatively small number of categories. As a result of the ordinal nature of these variables, the Mann-Whitney test was used to compare between the two experience groups. The safety scores (SC) were continuous in nature, and an examination of the distribution of values suggested that they were approximately normally distributed, therefore the unpaired t-test was used to compare between groups.

7.4.7.2.2 Comparison between Bowel Cancer Screening (BCS) and Non-Screening procedures.
The same methods used to compare experts and trainees were also used to compare BCS procedures with non-BCS procedures. The procedure characteristics in the two groups were compared followed by comparisons between the technical and non-technical skills (Mann Whitney test) and the safety check score (unpaired t-test).

7.4.7.3 Checklist Completion
Checklist completion was assessed for each of the endoscopic procedures in the study. Thirteen component checks were completed in two sections: ‘Time out’ prior to scope insertion and ‘Sign out’ prior to the patient leaving the procedure room. The proportion of checklist items completed for each procedure was calculated as a percentage and an average computed for the list.
7.4.7.4 Evaluation of Patient Safety Incidents (PSIs)

Patient Safety Incidents were recorded and analysed for diagnostic and therapeutic cases. The recorded PSIs were grouped into 9 major themes and categorised according to severity: mild, intermediate and severe defined by the actual or potential impact of the incident to the patient and adherence to accepted best practice. Categorisation was agreed by expert consensus by the same methodology used to analyse PSIs described in Chapter 2 (section 2.4.2.5). In addition sub-group analyses were preformed to compare the incidence of PSIs in experts and trainees and bowel cancer screening lists and non-screening lists. The PSIs were categorised in relation to the endoscopy checklist: PSIs were categorised according to whether they could have been averted if the checklist had been optimally completed and whether the PSI would have occurred irrespective of the checklist.

7.4.7.4.1 Comparison of Patient Safety Incidents (PSIs) between Experts and Trainees

The number of PSIs was examined in two different ways. Firstly the number of PSIs per list was compared between the two groups. Additionally, the number of PSIs per procedure for each list was calculated by dividing the number of PSIs by the number of procedures for that list. The calculations were made for all procedures combined, and then separately for diagnostic and therapeutic procedures. Lists with no diagnostic or therapeutic cases respectively, were omitted from this analysis. The number of PSIs was found to follow a positively skewed distribution, and thus the Mann-Whitney test was used to compare between experts and trainees.

7.4.7.5 Checklist Compliance

The percentage of checklists fully completed was calculated pre and post checklist intervention. Factors affecting checklist completion were also noted and comparisons were made using the two tailed chi squared test.

7.4.7.6 Comparison pre and post checklist intervention

The methods of analysis were equivalent to those used to compare between expert and trainees in the post-checklist data: List characteristics for the two groups were compared in terms of diagnostic and therapeutic cases and measured variables compared using the unpaired t-test. An additional analysis compared the make-up of clinicians (experts or trainees) between groups using the Chi-square test.
7.5  Results

The results in this Chapter are presented starting with patient opinion evaluation, followed by the observational study evaluating safety behaviours, checklist evaluation, patient safety incident analysis, checklist compliance and comparison of skills behaviours pre and post checklist implementation.

7.5.1  Checklist Patient Opinion Questionnaire

One hundred patients were invited to complete the 20-point questionnaire with a 100% response rate. Responses were received from 57 female and 43 male patients. Three main analyses were performed for this dataset: Firstly, the percentage responses on the 1-7 scale were calculated into 3 main categories. Secondly, the results were analysed according to patient gender and lastly according to whether this was the index endoscopy or whether the patient had undergone a previous endoscopic procedure.

Table 7.1 summarises the percentage of responses in the three main categories, along with corresponding confidence intervals.

<table>
<thead>
<tr>
<th>Question</th>
<th>Disagree (1-2) % (95% CI)</th>
<th>Neither agree / disagree (3-5) % (95% CI)</th>
<th>Agree (6-7) % (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. I want the safety checklist to be used if I have an endoscopy in the future</td>
<td>2% (0-7%)</td>
<td>29% (20-39%)</td>
<td>69% (59-78%)</td>
</tr>
<tr>
<td>2. Hearing staff discussing anticipated problems before my endoscopy made me anxious</td>
<td>46% (36-56%)</td>
<td>48% (38-58%)</td>
<td>6% (2-13%)</td>
</tr>
<tr>
<td>3. I’m worried that busy staff won’t complete the checklist properly</td>
<td>49% (39-59%)</td>
<td>45% (35-55%)</td>
<td>6% (2-13%)</td>
</tr>
<tr>
<td>4. The checklist seemed like an unnecessary tick box exercise</td>
<td>65% (55-74%)</td>
<td>32% (23-42%)</td>
<td>3% (0-9%)</td>
</tr>
<tr>
<td>5. I found repeated checks irritating</td>
<td>70% (60-79%)</td>
<td>28% (19-38%)</td>
<td>2% (0-7%)</td>
</tr>
<tr>
<td>6. I assumed an endoscopy safety checklist like this had always been in place</td>
<td>10% (5-18%)</td>
<td>52% (42-63%)</td>
<td>37% (28-48%)</td>
</tr>
<tr>
<td>7. I trust endoscopy staff to take care of me without having to use the checklist</td>
<td>29% (20-39%)</td>
<td>63% (53-72%)</td>
<td>8% (4-15%)</td>
</tr>
<tr>
<td>Question</td>
<td>Disagree (1-2)</td>
<td>Neither agree / disagree (3-5)</td>
<td>Agree (6-7)</td>
</tr>
<tr>
<td>-------------------------------------------------------------------------</td>
<td>----------------</td>
<td>-------------------------------</td>
<td>-------------</td>
</tr>
<tr>
<td>8. Using the checklist made me feel safer</td>
<td>2% (0-7%)</td>
<td>34% (25-44%)</td>
<td>64% (54-73%)</td>
</tr>
<tr>
<td>9. I understand why I need to confirm my identity and the procedure I am having just before my endoscopy</td>
<td>0% (0-4%)</td>
<td>17% (10-26%)</td>
<td>83% (74-90%)</td>
</tr>
<tr>
<td>10. Errors during an endoscopy are less likely with the checklist</td>
<td>12% (6-20%)</td>
<td>40% (30-50%)</td>
<td>48% (38-58%)</td>
</tr>
<tr>
<td>11. The checklist undermines the competence of the endoscopy staff</td>
<td>55% (45-65%)</td>
<td>39% (29-49%)</td>
<td>6% (2-13%)</td>
</tr>
<tr>
<td>12. The checklist improved communication between staff in the endoscopy room</td>
<td>2% (0-7%)</td>
<td>45% (35-55%)</td>
<td>53% (43-63%)</td>
</tr>
<tr>
<td>13. I would like proof that the checklist was used for my endoscopy</td>
<td>50% (40-60%)</td>
<td>45% (35-55%)</td>
<td>5% (2-11%)</td>
</tr>
<tr>
<td>14. Checks repeated by the team actually doing my endoscopy, are preferable to relying on checks made by others</td>
<td>0% (0-4%)</td>
<td>50% (40-60%)</td>
<td>50% (40-60%)</td>
</tr>
<tr>
<td>15. I worry that I will come to unnecessary harm in hospital</td>
<td>46% (36-56%)</td>
<td>45% (35-55%)</td>
<td>9% (4-16%)</td>
</tr>
<tr>
<td>16. The voice of patients should be used to identify areas for improvement in patient safety</td>
<td>6% (2-13%)</td>
<td>73% (63-81%)</td>
<td>21% (13-30%)</td>
</tr>
<tr>
<td>17. It is best to leave decisions about patient safety to healthcare professionals</td>
<td>23% (15-32%)</td>
<td>67% (57-76%)</td>
<td>10% (5-18%)</td>
</tr>
<tr>
<td>18. Given the opportunity, I would like to be more involved in efforts to reduce patient harm</td>
<td>27% (19-37%)</td>
<td>66% (56-75%)</td>
<td>7% (3-14%)</td>
</tr>
<tr>
<td>19. I think I could help to reduce errors in my care by being more involved</td>
<td>31% (22-41%)</td>
<td>62% (52-72%)</td>
<td>7% (3-14%)</td>
</tr>
<tr>
<td>20. I have personally received care in the past that I felt was unsafe</td>
<td>87% (79-93%)</td>
<td>11% (6-19%)</td>
<td>2% (0-7%)</td>
</tr>
</tbody>
</table>

Categories with greater than 50% responses in the ‘agree’ and ‘disagree’ columns are highlighted. Further analyses sought to examine if there was a difference between patient responses by gender. Representation was roughly equal with 57 female and 43 male patients completing the questionnaire. The responses by gender are summarised in Table 7.2. The analysis was performed on the same 7-point scale but the data is presented in the three main categories previously described with the corresponding p value.
Table 7.2. Percentage of responses within three main categories by gender

<table>
<thead>
<tr>
<th>Question</th>
<th>Gender</th>
<th>Disagree</th>
<th>Neither</th>
<th>Agree</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. I want the safety checklist to be used if I have an endoscopy in the future</td>
<td>Female</td>
<td>1.8%</td>
<td>33.3%</td>
<td>64.9%</td>
<td>0.86</td>
</tr>
<tr>
<td></td>
<td>Male</td>
<td>2.3%</td>
<td>23.3%</td>
<td>74.4%</td>
<td></td>
</tr>
<tr>
<td>2. Hearing staff discussing anticipated problems before my endoscopy made me anxious</td>
<td>Female</td>
<td>47.4%</td>
<td>47.4%</td>
<td>5.3%</td>
<td>0.18</td>
</tr>
<tr>
<td></td>
<td>Male</td>
<td>44.2%</td>
<td>48.8%</td>
<td>7.0%</td>
<td></td>
</tr>
<tr>
<td>3. I’m worried that busy staff won’t complete the checklist properly</td>
<td>Female</td>
<td>54.4%</td>
<td>40.4%</td>
<td>5.3%</td>
<td>0.10</td>
</tr>
<tr>
<td></td>
<td>Male</td>
<td>41.9%</td>
<td>51.2%</td>
<td>7.0%</td>
<td></td>
</tr>
<tr>
<td>4. The checklist seemed like an unnecessary tick box exercise</td>
<td>Female</td>
<td>66.7%</td>
<td>31.6%</td>
<td>1.8%</td>
<td>0.83</td>
</tr>
<tr>
<td></td>
<td>Male</td>
<td>62.8%</td>
<td>32.6%</td>
<td>4.7%</td>
<td></td>
</tr>
<tr>
<td>5. I found repeated checks irritating</td>
<td>Female</td>
<td>75.4%</td>
<td>22.8%</td>
<td>1.8%</td>
<td>0.39</td>
</tr>
<tr>
<td></td>
<td>Male</td>
<td>62.8%</td>
<td>34.9%</td>
<td>2.3%</td>
<td></td>
</tr>
<tr>
<td>6. I assumed an endoscopy safety checklist like this had always been in place</td>
<td>Female</td>
<td>10.7%</td>
<td>48.2%</td>
<td>41.1%</td>
<td>0.28</td>
</tr>
<tr>
<td></td>
<td>Male</td>
<td>9.3%</td>
<td>58.1%</td>
<td>32.6%</td>
<td></td>
</tr>
<tr>
<td>7. I trust endoscopy staff to take care of me without having to use the checklist</td>
<td>Female</td>
<td>33.3%</td>
<td>61.4%</td>
<td>5.3%</td>
<td>0.77</td>
</tr>
<tr>
<td></td>
<td>Male</td>
<td>23.3%</td>
<td>65.1%</td>
<td>11.6%</td>
<td></td>
</tr>
<tr>
<td>8. Using the checklist made me feel safer</td>
<td>Female</td>
<td>1.8%</td>
<td>31.6%</td>
<td>66.7%</td>
<td>0.84</td>
</tr>
<tr>
<td></td>
<td>Male</td>
<td>2.3%</td>
<td>37.2%</td>
<td>60.5%</td>
<td></td>
</tr>
<tr>
<td>9. I understand why I need to confirm my identity and the procedure I am having just before my endoscopy</td>
<td>Female</td>
<td>0.0%</td>
<td>12.3%</td>
<td>87.7%</td>
<td>0.94</td>
</tr>
<tr>
<td></td>
<td>Male</td>
<td>0.0%</td>
<td>23.3%</td>
<td>76.7%</td>
<td></td>
</tr>
<tr>
<td>10. Errors during an endoscopy are less likely with the checklist</td>
<td>Female</td>
<td>8.8%</td>
<td>38.6%</td>
<td>52.6%</td>
<td>0.19</td>
</tr>
<tr>
<td></td>
<td>Male</td>
<td>16.3%</td>
<td>41.9%</td>
<td>41.9%</td>
<td></td>
</tr>
<tr>
<td>11. The checklist undermines the competence of the endoscopy staff</td>
<td>Female</td>
<td>61.4%</td>
<td>33.3%</td>
<td>5.3%</td>
<td>0.13</td>
</tr>
<tr>
<td></td>
<td>Male</td>
<td>46.5%</td>
<td>46.5%</td>
<td>7.0%</td>
<td></td>
</tr>
<tr>
<td>12. The checklist improved communication between staff in the endoscopy room</td>
<td>Female</td>
<td>0.0%</td>
<td>42.1%</td>
<td>57.9%</td>
<td>0.34</td>
</tr>
<tr>
<td></td>
<td>Male</td>
<td>4.7%</td>
<td>48.8%</td>
<td>46.5%</td>
<td></td>
</tr>
<tr>
<td>Question</td>
<td>Gender</td>
<td>Disagree</td>
<td>Neither</td>
<td>Agree</td>
<td>P-value</td>
</tr>
<tr>
<td>-------------------------------------------------------------------------</td>
<td>--------</td>
<td>----------</td>
<td>---------</td>
<td>-------</td>
<td>---------</td>
</tr>
<tr>
<td>13. I would like proof that the checklist was used for my endoscopy</td>
<td>Female</td>
<td>52.6%</td>
<td>40.4%</td>
<td>7.0%</td>
<td>0.70</td>
</tr>
<tr>
<td></td>
<td>Male</td>
<td>46.5%</td>
<td>51.2%</td>
<td>2.3%</td>
<td></td>
</tr>
<tr>
<td>14. Checks repeated by the team actually doing my endoscopy, are preferable to relying on checks made by others</td>
<td>Female</td>
<td>0.0%</td>
<td>49.1%</td>
<td>50.9%</td>
<td>0.85</td>
</tr>
<tr>
<td></td>
<td>Male</td>
<td>0.0%</td>
<td>51.2%</td>
<td>48.8%</td>
<td></td>
</tr>
<tr>
<td>15. I worry that I will come to unnecessary harm in hospital</td>
<td>Female</td>
<td>50.9%</td>
<td>42.1%</td>
<td>7.0%</td>
<td>0.05</td>
</tr>
<tr>
<td></td>
<td>Male</td>
<td>39.5%</td>
<td>48.8%</td>
<td>11.6%</td>
<td></td>
</tr>
<tr>
<td>16. The voice of patients should be used to identify areas for improvement in patient safety</td>
<td>Female</td>
<td>7%</td>
<td>68.4%</td>
<td>24.6%</td>
<td>0.66</td>
</tr>
<tr>
<td></td>
<td>Male</td>
<td>4.7%</td>
<td>79.1%</td>
<td>16.3%</td>
<td></td>
</tr>
<tr>
<td>17. It is best to leave decisions about patient safety to healthcare professionals</td>
<td>Female</td>
<td>26.3%</td>
<td>61.4%</td>
<td>12.3%</td>
<td>0.39</td>
</tr>
<tr>
<td></td>
<td>Male</td>
<td>18.6%</td>
<td>74.4%</td>
<td>7.0%</td>
<td></td>
</tr>
<tr>
<td>18. Given the opportunity, I would like to be more involved in efforts to reduce patient harm</td>
<td>Female</td>
<td>29.8%</td>
<td>63.2%</td>
<td>7.0%</td>
<td>0.65</td>
</tr>
<tr>
<td></td>
<td>Male</td>
<td>23.3%</td>
<td>69.8%</td>
<td>7.0%</td>
<td></td>
</tr>
<tr>
<td>19. I think I could help to reduce errors in my care by being more involved</td>
<td>Female</td>
<td>35.1%</td>
<td>57.9%</td>
<td>7.0%</td>
<td>0.11</td>
</tr>
<tr>
<td></td>
<td>Male</td>
<td>25.6%</td>
<td>67.4%</td>
<td>7.0%</td>
<td></td>
</tr>
<tr>
<td>20. I have personally received care in the past that I felt was unsafe</td>
<td>Female</td>
<td>89.5%</td>
<td>8.8%</td>
<td>1.8%</td>
<td>0.26</td>
</tr>
<tr>
<td></td>
<td>Male</td>
<td>83.7%</td>
<td>14%</td>
<td>2.3%</td>
<td></td>
</tr>
</tbody>
</table>

There was no strong evidence that the responses to any of the questions varied by gender. There was some evidence that the results to question 15,’ I worry that I will come to unnecessary harm in hospital’ varied between genders, although this was of borderline statistical significance. Male patients were slightly more likely to agree with this statement compared to females.

Finally, the data was examined according to whether this was the patient’s index endoscopy or whether they had undergone a prior procedure. Thirty-seven patients had undergone a previous gastrointestinal endoscopic procedure, 15 patients reported this was their first endoscopy and 48 patients did not respond to this question and thus were omitted from the analysis. These results are summarised in Table 7.3.
Table 7.3.  Percentage of responses within three main categories in relation to whether a previous endoscopy had been performed or not

<table>
<thead>
<tr>
<th>Question</th>
<th>Previous</th>
<th>Disagree</th>
<th>Neither</th>
<th>Agree</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. I want the safety checklist to be used if I have an endoscopy in the future</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>0.0%</td>
<td>20.0%</td>
<td>80.0%</td>
<td></td>
<td>0.31</td>
</tr>
<tr>
<td>Yes</td>
<td>2.7%</td>
<td>35.1%</td>
<td>62.2%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. Hearing staff discussing anticipated problems before my endoscopy made me anxious</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>66.7%</td>
<td>33.3%</td>
<td>0.0%</td>
<td></td>
<td>0.07</td>
</tr>
<tr>
<td>Yes</td>
<td>37.8%</td>
<td>54.1%</td>
<td>8.1%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3. I’m worried that busy staff won’t complete the checklist properly</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>46.7%</td>
<td>33.3%</td>
<td>20.0%</td>
<td></td>
<td>0.53</td>
</tr>
<tr>
<td>Yes</td>
<td>56.8%</td>
<td>40.5%</td>
<td>2.7%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4. The checklist seemed like an unnecessary tick box exercise</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>86.7%</td>
<td>13.3%</td>
<td>0.0%</td>
<td></td>
<td>0.07</td>
</tr>
<tr>
<td>Yes</td>
<td>45.9%</td>
<td>48.6%</td>
<td>5.4%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5. I found repeated checks irritating</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>100.0%</td>
<td>0.0%</td>
<td>0.0%</td>
<td></td>
<td><strong>0.004</strong></td>
</tr>
<tr>
<td>Yes</td>
<td>51.4%</td>
<td>45.9%</td>
<td>2.7%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>6. I assumed an endoscopy safety checklist like this had always been in place</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>26.7%</td>
<td>60%</td>
<td>13.3%</td>
<td></td>
<td><strong>0.008</strong></td>
</tr>
<tr>
<td>Yes</td>
<td>2.7%</td>
<td>48.6%</td>
<td>48.6%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>7. I trust endoscopy staff to take care of me without having to use the checklist</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>33.3%</td>
<td>60%</td>
<td>6.7%</td>
<td></td>
<td>0.20</td>
</tr>
<tr>
<td>Yes</td>
<td>27%</td>
<td>62.2%</td>
<td>10.8%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>8. Using the checklist made me feel safer</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>0.0%</td>
<td>13.3%</td>
<td>86.7%</td>
<td></td>
<td>0.13</td>
</tr>
<tr>
<td>Yes</td>
<td>2.7%</td>
<td>45.9%</td>
<td>51.4%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>9. I understand why I need to confirm my identity and the procedure I am having just before my endoscopy</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>0.0%</td>
<td>6.7%</td>
<td>93.3%</td>
<td></td>
<td><strong>0.04</strong></td>
</tr>
<tr>
<td>Yes</td>
<td>0.0%</td>
<td>24.3%</td>
<td>75.7%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>10. Errors during an endoscopy are less likely with the checklist</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>26.7%</td>
<td>26.7%</td>
<td>46.7%</td>
<td></td>
<td>0.93</td>
</tr>
<tr>
<td>Yes</td>
<td>13.5%</td>
<td>43.2%</td>
<td>43.2%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>11. The checklist undermines the competence of the endoscopy staff</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>86.7%</td>
<td>6.7%</td>
<td>6.7%</td>
<td></td>
<td><strong>0.01</strong></td>
</tr>
<tr>
<td>Yes</td>
<td>35.1%</td>
<td>56.8%</td>
<td>8.1%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>12. The checklist improved communication between staff in the endoscopy room</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>0.0%</td>
<td>33.3%</td>
<td>66.7%</td>
<td></td>
<td>0.05</td>
</tr>
<tr>
<td>Yes</td>
<td>2.7%</td>
<td>54.1%</td>
<td>43.2%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Question</td>
<td>Previous</td>
<td>Disagree</td>
<td>Neither</td>
<td>Agree</td>
<td>P-value</td>
</tr>
<tr>
<td>-------------------------------------------------------------------------</td>
<td>----------</td>
<td>----------</td>
<td>---------</td>
<td>-------</td>
<td>---------</td>
</tr>
<tr>
<td>13. I would like proof that the checklist was used for my endoscopy</td>
<td>No</td>
<td>73.3%</td>
<td>26.7%</td>
<td>0.0%</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td></td>
<td>Yes</td>
<td>32.4%</td>
<td>62.2%</td>
<td>5.4%</td>
<td></td>
</tr>
<tr>
<td>14. Checks repeated by the team actually doing my endoscopy are preferable to relying on checks made by others</td>
<td>No</td>
<td>0.0%</td>
<td>53.3%</td>
<td>46.7%</td>
<td>0.86</td>
</tr>
<tr>
<td></td>
<td>Yes</td>
<td>0.0%</td>
<td>48.6%</td>
<td>51.4%</td>
<td></td>
</tr>
<tr>
<td>15. I worry that I will come to unnecessary harm in hospital</td>
<td>No</td>
<td>93.3%</td>
<td>6.7%</td>
<td>0.0%</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td></td>
<td>Yes</td>
<td>29.7%</td>
<td>54.1%</td>
<td>16.2%</td>
<td></td>
</tr>
<tr>
<td>16. The voice of patients should be used to identify areas for improvement in patient safety</td>
<td>No</td>
<td>6.7%</td>
<td>66.7%</td>
<td>26.7%</td>
<td>0.68</td>
</tr>
<tr>
<td></td>
<td>Yes</td>
<td>2.7%</td>
<td>75.7%</td>
<td>21.6%</td>
<td></td>
</tr>
<tr>
<td>17. It is best to leave decisions about patient safety to healthcare professionals</td>
<td>No</td>
<td>26.7%</td>
<td>60%</td>
<td>13.3%</td>
<td>0.17</td>
</tr>
<tr>
<td></td>
<td>Yes</td>
<td>21.6%</td>
<td>62.2%</td>
<td>16.2%</td>
<td></td>
</tr>
<tr>
<td>18. Given the opportunity, I would like to be more involved in efforts to reduce patient harm</td>
<td>No</td>
<td>26.7%</td>
<td>60%</td>
<td>13.3%</td>
<td>0.08</td>
</tr>
<tr>
<td></td>
<td>Yes</td>
<td>13.5%</td>
<td>73%</td>
<td>13.5%</td>
<td></td>
</tr>
<tr>
<td>19. I think I could help to reduce errors in my care by being more involved</td>
<td>No</td>
<td>26.7%</td>
<td>66.7%</td>
<td>6.7%</td>
<td>0.32</td>
</tr>
<tr>
<td></td>
<td>Yes</td>
<td>18.9%</td>
<td>70.3%</td>
<td>10.8%</td>
<td></td>
</tr>
<tr>
<td>20. I have personally received care in the past that I felt was unsafe</td>
<td>No</td>
<td>100%</td>
<td>0.0%</td>
<td>0.0%</td>
<td>0.007</td>
</tr>
<tr>
<td></td>
<td>Yes</td>
<td>78.4%</td>
<td>16.2%</td>
<td>5.4%</td>
<td></td>
</tr>
</tbody>
</table>

This data indicates significant differences in 7 questions according to whether the patient had been exposed to a previous endoscopy. Those patients that had previously had an endoscopy were more likely to agree with the following statements:

- Q. 5: Repeated safety checks were irritating
- Q. 6: Assumption that a safety checklist was already in place
- Q. 11: The checklist undermines the staff competency
- Q. 13: Would like evidence the checklist was completed for their procedure
- Q. 15: Worry that I will come to unnecessary harm in hospital
Q. 20: Received unsafe care in the past

Conversely, patients who had previously undergone an endoscopy were less likely to agree with the following statement.

Q. 9: Understand need to confirm identity and procedure just before the endoscopy.

7.5.2 Observational Study Evaluating Safety Behaviours: Demographics and Study Participants

One hundred and forty-one procedures over 31 lists were observed. Five out of the 31 lists (15%) comprising 19 procedures were co-rated. Experts conducted 25 lists (108 procedures) and trainees 6 lists (33 procedures). Eight of the thirty-one observed lists were Bowel Cancer Screening (BCS) lists representing 25% of the cohort. The demographics of the endoscopists are illustrated in Figure 7.1. and 7.2.

Figure 7.1. Endoscopy lists by endoscopist grade
Figure 7.2. Endoscopy lists and procedures by endoscopist speciality

The demographics of the procedure subtypes in this study revealed 81 diagnostic and 60 therapeutic cases. Figure 7.3 illustrates the procedure by subtype.

Figure 7.3. Number of procedure subtypes
7.5.3 Skills and Behaviours assessment

Technical skill (DOPS), endoscopic non-technical skill (ENTS) and safety check scores (SC) were each assessed on 4 point scales. The median technical skills score was 4 (range 3-4). The median non-technical skills score was 3 (range 2-4). The mean safety check score was 2.77 (range 1.21 – 3.47).

7.5.3.1 Sub-group Analyses of Experts and Trainees

Experts performed 108 procedures over 25 lists and trainees 33 procedures over 6 lists. The characteristics of the two experience groups were identified in terms of procedure numbers and subtype and this data is presented in Table 7.4.

Table 7.4. Procedure Characteristics between Experts and Trainees

<table>
<thead>
<tr>
<th>Variable</th>
<th>Experts (List n=25) Mean (SD)</th>
<th>Trainees (List n=6) Mean (SD)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total procedure number</td>
<td>4.2 (1.6)</td>
<td>5.2 (1.6)</td>
<td>0.21</td>
</tr>
<tr>
<td>Diagnostic procedures</td>
<td>2.4 (2.0)</td>
<td>2.7 (1.4)</td>
<td>0.79</td>
</tr>
<tr>
<td>Therapeutic procedures</td>
<td>1.8 (1.4)</td>
<td>2.5 (0.5)</td>
<td>0.24</td>
</tr>
<tr>
<td>% Diagnostic procedures</td>
<td>53 (33)</td>
<td>49 (13)</td>
<td>0.79</td>
</tr>
</tbody>
</table>

The results indicate no significant differences between experts and trainees in terms of the total procedures performed and the procedure sub-type. Additionally the proportion of diagnostic procedure sub-type was comparable in both groups.

Further analyses compared the behaviours and skills assessments between trainees and experts and is presented in Table 7.5. The first part of the table gives the results for ENTS and DOPS, where the figures reported are the number and percentage of responses in each outcome category. The second part of the table gives the results for the safety score, where the mean and standard deviation in each group are reported.
Table 7.5. Comparison of Technical skill (DOPS), Non-Technical skill (ENTS) and Safety Check scores between Experts (Consultants) and Trainees (Registrars)

<table>
<thead>
<tr>
<th>Variable - Category</th>
<th>Experts n (%)</th>
<th>Trainees n (%)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>ENTS 1</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
<td>0.01</td>
</tr>
<tr>
<td>ENTS 2</td>
<td>2 (8%)</td>
<td>3 (50%)</td>
<td></td>
</tr>
<tr>
<td>ENTS 3</td>
<td>14 (56%)</td>
<td>3 (50%)</td>
<td></td>
</tr>
<tr>
<td>ENTS 4</td>
<td>9 (36%)</td>
<td>0 (0%)</td>
<td></td>
</tr>
<tr>
<td>DOPS 2</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
<td>0.95</td>
</tr>
<tr>
<td>DOPS 3</td>
<td>8 (32%)</td>
<td>2 (33%)</td>
<td></td>
</tr>
<tr>
<td>DOPS 4</td>
<td>17 (68%)</td>
<td>4 (67%)</td>
<td></td>
</tr>
<tr>
<td>Safety Check Score (SC)</td>
<td>2.85 (0.49)</td>
<td>2.47 (0.52)</td>
<td>0.11</td>
</tr>
</tbody>
</table>

The data in Table 7.5 illustrate a significant difference in Non-Technical skills (ENTS) between the two groups. The values were higher for experts, with 92% of experts scoring 3 or 4, compared to only 50% of trainees. There was no significant difference between the two experience groups for either the technical skill (DOPS) or safety check scores (SC).

7.5.3.2 Sub-group analyses of Bowel Cancer Screening (BCS) and non screening procedures

Five out of the thirty-one lists in this study were BCS lists equating to 19/141 procedures. The characteristics of the BCS and non-BCS procedures are displayed in Table 7.6

Table 7.6. Procedure Characteristics between BCS and non-BCS procedures

<table>
<thead>
<tr>
<th>Variable</th>
<th>Non-BCS (List n=23) Mean (SD)</th>
<th>BCS (List n=8) Mean (SD)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total procedure number</td>
<td>4.5 (1.7)</td>
<td>4.3 (1.3)</td>
<td>0.74</td>
</tr>
<tr>
<td>Diagnostic procedures</td>
<td>2.6 (1.9)</td>
<td>2.3 (1.6)</td>
<td>0.68</td>
</tr>
<tr>
<td>Therapeutic procedures</td>
<td>1.9 (1.3)</td>
<td>2.0 (1.4)</td>
<td>0.87</td>
</tr>
<tr>
<td>% Diagnostic procedures</td>
<td>53 (31)</td>
<td>51 (30)</td>
<td>0.89</td>
</tr>
</tbody>
</table>
The results suggest no differences between the two groups in terms of the total procedures performed, or the number of each procedure type. Additionally the proportion of diagnostic procedures was not found to vary significantly between the two groups.

Additional analyses compared the study outcomes between the BCS and non-BCS groups, and the analysis results are summarised in Table 7.7. The first part of the table gives the results for non-technical (ENTS) and technical (DOPS) scores, where the figures reported are the number and percentage of responses in each outcome category. The second part of the table gives the results for the safety score (SC), where the mean and standard deviation in each group is reported.

Table 7.7.  Comparison of Technical skill (DOPS), Non-Technical skill (ENTS) and safety check scores between BCS and non BCS groups

<table>
<thead>
<tr>
<th>Variable</th>
<th>Non-BCS N (%)</th>
<th>BCS N (%)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>ENTS 1</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
<td>0.01</td>
</tr>
<tr>
<td>ENTS 2</td>
<td>5 (22%)</td>
<td>0 (0%)</td>
<td></td>
</tr>
<tr>
<td>ENTS 3</td>
<td>14 (61%)</td>
<td>3 (37%)</td>
<td></td>
</tr>
<tr>
<td>ENTS 4</td>
<td>4 (17%)</td>
<td>5 (63%)</td>
<td></td>
</tr>
<tr>
<td>DOPS 2</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
<td>0.03</td>
</tr>
<tr>
<td>DOPS 3</td>
<td>10 (43%)</td>
<td>0 (0%)</td>
<td></td>
</tr>
<tr>
<td>DOPS 4</td>
<td>13 (57%)</td>
<td>10 (100%)</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Variable</th>
<th>Non-BCS Mean (SD)</th>
<th>BCS Mean (SD)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Safety Check Score (SC)</td>
<td>2.64 (0.51)</td>
<td>3.16 (0.27)</td>
<td>0.01</td>
</tr>
</tbody>
</table>

This analysis showed a significant difference in non-technical, technical and safety check scores between the two groups. The values for all measures were higher in the BCS group. For the ENTS score, almost two thirds (63%) of the BCS group scored 4, compared to only 17% of non-BCS group. All the BCS group scored 4 on the DOPS, compared only just over half of the non-BCS group. The mean safety score was 3.2 for the BCS group, compared to a mean score of 2.6 for the non-BCS group.
7.5.4  Quantitative Checklist assessment

The checklist was not undertaken in 2 procedures: An ERCP conducted by a consultant physician and a colonoscopy conducted by a consultant surgeon. In the remaining procedures, checklist completion was variable and summarised below.

7.5.4.1  Degree of checklist completion

None of the observed checklists were fully completed with all 13 parts of the Time Out and Sign Out effectively completed: In the remaining 139 procedures the checklist was partially completed. The percentage of the 13 items completed was calculated for each procedure with an average result calculated for the list. The range of checklist completion over the 31 lists was 19-90% with a mean score of 57%. Alternatively, considering there were 141 procedures in the study each with 13 safety checks opportunities through the checklist, 1059/1781 (61%) checklist items were completed. The BCS subgroup checklist completion ranged from 43-90% over 8 lists (mean score 67%).

7.5.4.2  Time taken to complete Checklist

The checklist ‘Time Out’ section (constituting 10/13 safety checks) prior to scope insertion was timed for each of the 139 procedures where the checklist was undertaken. The mean time to complete the checklist was 55 seconds (range 20-154 seconds).

7.5.5  Qualitative Checklist assessment

Key themes were drawn out from the qualitative observation notes and these are summarised:

7.5.5.1  Leadership

The quality of the checklist and the degree to which team members engaged with the process was more effective when the checklist was clearly led from the start. This was most apparent when the consultant endoscopist led the checklist or the Specialist Screening Practitioner (SSP) in bowel cancer screening cases. The most professionally conducted checklists involved and reassured the patient and exchanged key medical information without unnecessary jargon. This strong checklist leadership also validated the importance of the checklist to the team who contributed more pro-actively in these cases. Conversely, when the endoscopist was absent or disengaged from the checklist, the nursing team would persist with its completion but it was usually hurried and incomplete.
7.5.5.2 Compliance

The checklist was frequently incomplete and this was more pronounced in the ‘Sign Out’ section of the checklist post-procedure. In the majority of cases team members were passively non-compliant rather than actively resisting checklist use. There were a few cases where an attempt at initiating the checklist with the full team was unsuccessful and the nurse ticked the checks independently without conferring with the team. It may be that checklist completion was more actively resisted outside of the study setting and this behaviour was therefore not observed in this study. In these episodes where the checklist was treated as a ‘tick-box’ exercise, patient safety was jeopardised by instilling a false sense of security that safety checks had been completed and reducing team vigilance. This was apparent in two cases where the endoscopist was absent for the checklist but asked if it had been completed prior to the procedure but being unaware of the clinical aspects raised by the nurses during the checklist. In these situations, it may have been better for the checklist not to be attempted at all and the individuals revert back to their independent safety check practice.

7.5.5.3 Efficiency

Evaluating efficiency of patient flow was beyond the scope of this study but it was important to determine if the checklist was feasible in clinical practice. Measuring the time taken to conduct the checklist revealed it did not add significant time to each procedure and could be appropriately conducted in approximately a minute. Where the checklist took longer it was invariably picking up inconsistencies in clinical information, patient concerns or potential errors and hence the additional time was justified. Checklist efficiency and effectiveness are obviously dependent on the pre-admission process being well carried out (e.g. medical notes and referral availability and results of recent relevant investigations) thus safety measures prior to the checklist also need to be well organised.

7.5.6 Incidence of Patient Safety Incidents (PSIs)

In total 120 PSIs were recorded over the 141 procedures observed. Forty-three errors were detected in diagnostic procedures and 77 in therapeutic cases. Three out of 31 lists had no PSIs detected during the observation period. In the remaining lists, the number of PSIs over the list for a single endoscopist ranged from 1-32 with a mean 3.87 PSI per list. One PSI relating to faulty equipment recurred over two separate lists, as the error was identified but not rectified after the first incident. None of the observed PSIs in this study led to patients’
requiring inpatient admission to mitigate the error and there were no patient deaths relating to
the observed errors.

7.5.6.1 PSI Categorisation by Theme and Severity.
The observed PSIs were categorised according to 3 severity levels and agreed by expert consensus. The majority of errors (75%) were categorised as mild (Figure 7.4). The themes with the greatest proportion of severe errors were ‘oxygen monitoring’ (n=3) and ‘Sedation / IV access / Monitoring’ (n=3). The severe PSIs are listed in Table 7.9. There were no definitive never events recorded in this study although the ‘severe’ oxygen and monitoring related events had the potential to be never events.

Figure 7.4. PSI Categorisation by Severity

Table 7.8. Description of Severe PSIs

<table>
<thead>
<tr>
<th>Severe PSI</th>
<th>Theme</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sedated patient on trolley without oxygen or saturation monitor (awaiting transfer)</td>
<td>Oxygen Monitoring</td>
</tr>
<tr>
<td>Sedation without checking baseline saturations in patient &gt;70 years (n=2)</td>
<td></td>
</tr>
<tr>
<td>Sedated patient in corridor unmonitored for 30 minutes, with no nurse with a porter awaiting transfer</td>
<td>Sedation / IV access / Monitoring</td>
</tr>
<tr>
<td>Oxygen saturation probe falls off sedated patient, no alarm, not rectified for 15 minutes</td>
<td></td>
</tr>
</tbody>
</table>
PSIs were categorised according to the 9 major themes identified in Chapter 2. The breakdown of PSI according to theme and respective severity rating is presented in Figure 7.5.

![Post Checklist PSI categorisation by theme and severity](image_url)

**Figure 7.5.** PSI Categorisation by Theme and Severity

### 7.5.7 PSI Incidence in Expert and Trainee Endoscopists

In addition to the overall incidence of PSIs the data was examined to compare PSI incidence in experts and trainees taking into consideration the differences in diagnostic / therapeutic cases. These results are presented in Table 7.9.
Table 7.9. Comparison of Patient Safety Incidents (PSI) in Expert and Trainee Endoscopists

<table>
<thead>
<tr>
<th>Variable</th>
<th>Experts Median (IQR)</th>
<th>Trainees Median (IQR)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>PSIs / list</td>
<td>2 (1, 3)</td>
<td>2.5 (1, 6)</td>
<td>0.40</td>
</tr>
<tr>
<td>PSIs / procedure</td>
<td>0.3 (0.3, 1.0)</td>
<td>0.5 (0.2, 2.0)</td>
<td>0.74</td>
</tr>
<tr>
<td>Diagnostic PSIs / list *</td>
<td>1 (0, 1)</td>
<td>1 (0, 1)</td>
<td>0.66</td>
</tr>
<tr>
<td>Diagnostic PSIs / procedure *</td>
<td>0.2 (0.0, 0.5)</td>
<td>0.4 (0.0, 1.0)</td>
<td>0.33</td>
</tr>
<tr>
<td>Therapeutic PSIs / list **</td>
<td>2 (1, 2)</td>
<td>2 (1, 5)</td>
<td>0.57</td>
</tr>
<tr>
<td>Therapeutic PSIs / procedure **</td>
<td>1.0 (0.3, 2.0)</td>
<td>0.8 (0.3, 2.5)</td>
<td>0.75</td>
</tr>
</tbody>
</table>

* Omitting lists containing no diagnostic procedures

** Omitting lists containing no therapeutic procedures

There were no significant differences between PSIs observed in experts and trainees. This was the case when the data was examined for PSIs per list as well as PSIs per procedure. There was no difference between the two endoscopist sub-groups when diagnostic and therapeutic cases were analysed separately.

7.5.8 PSI Incidence in Bowel Cancer Screening (BCS) and Non-Screening Endoscopists

Comparisons of PSI incidence were also made for bowel cancer screening endoscopists and non – screening endoscopists. These results are presented in Table 7.10.

Table 7.10. Comparison of Patient Safety Incidents (PSI) in Expert and Trainee Endoscopists

<table>
<thead>
<tr>
<th>Variable</th>
<th>Non-BCS Median (IQR)</th>
<th>BCS Median (IQR)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>PSIs / list</td>
<td>2 (1, 6)</td>
<td>1.5 (0, 2)</td>
<td><strong>0.02</strong></td>
</tr>
<tr>
<td>PSIs / procedure</td>
<td>0.5 (0.3, 1.5)</td>
<td>0.3 (0.0, 0.6)</td>
<td>0.07</td>
</tr>
<tr>
<td>Diagnostic PSIs / list *</td>
<td>1 (0, 2)</td>
<td>0 (0, 0)</td>
<td><strong>0.01</strong></td>
</tr>
<tr>
<td>Diagnostic PSIs / procedure *</td>
<td>0.3 (0.0, 0.8)</td>
<td>0.0 (0.0, 0.0)</td>
<td><strong>0.01</strong></td>
</tr>
<tr>
<td>Therapeutic PSIs / list **</td>
<td>2 (1, 5)</td>
<td>1 (0, 2)</td>
<td>0.22</td>
</tr>
<tr>
<td>Therapeutic PSIs / procedure **</td>
<td>1.0 (0.3, 2.3)</td>
<td>0.5 (0.0, 1.0)</td>
<td>0.29</td>
</tr>
</tbody>
</table>

* Omitting lists containing no diagnostic procedures

** Omitting lists containing no therapeutic procedures
The total number of PSIs varied significantly between the two sub-groups of endoscopists, with fewer PSIs in the BCS group. For each list there was a median of 1.5 PSIs for the BCS group, compared to 2.0 for the non-BCS group. There was also some evidence that the number of PSIs per procedure also varied between groups, although this result was only of borderline statistical significance.

The number of PSIs (per list and per procedure) was lower in the BCS group when only the diagnostic procedures were examined. There was no significant difference in PSIs between BCS and non-screening endoscopists when therapeutic cases were analysed. The number of PSIs did not correlate with the number of checklist items completed (correlation coefficient -0.08 / p value 0.3) or the time taken to complete the checklist (correlation coefficient -0.01 p value 0.88).

7.5.8.1 Patient Safety Incidents in Relation to the Checklist

The observed PSI were analysed in relation to the checklist and this data is summarised in Figure 7.6. Over half of the observed PSIs were related to the checklist with the majority (86%) occurring as a result of the checklist being sub-optimally completed. In other words, 62/72 errors relating to the checklist could have been avoided if the checklist had been properly conducted by the team. In 10/72 (14%) instances the checklist was instrumental in averting an error – i.e. the checklist picked up the error so corrective action could be taken prior to the patient being affected by the ‘potential’ error.

![Figure 7.6. Schema summarising Patient Safety Incidents in relation to the Endoscopy Safety Checklist](image-url)
7.5.9 List of Compliance at 11 and 16 months following implementation.

Compliance with the checklist was measured 11 months after implementation and once the intervention was embedded in clinical practice. Compliance at the first time point is illustrated in Figure 7.5 and compared to compliance at 16 months (Figure 7.6) following a series of targeted educational strategies. One hundred and ninety-nine checklist documents were examined at baseline and 151 checklists were examined following the targeted interventions.

![Checklist compliance at 11 months](image)

**Figure 7.7.** Checklist compliance 11 months post implementation
The completion of ‘Time out’ and ‘Sign Out’ sections of the checklist were measured. In the pre-checklist data ‘Time out’ was completed in 178/199 (89%) cases compared to ‘Sign Out’ 116/199 (58%) cases. This increased in the post checklist data: ‘Time out’ 148/151 (98%) and ‘Sign Out’ 104/151 (69%) although the latter part of the checklist was still less likely to be completed.

These results show a greater proportion of fully completed checklists following the training interventions: Completed checklists constituted 53% of the sample and increased to 66% p=0.03. Similarly the proportion of blank checklists documents decreased from 10% to 2% =0.003.

### 7.5.9.1 Factors Affecting Checklist Compliance

Compliance with the checklist was measured for various factors and is illustrated for the two time points in Figure 7.7.
Figure 7.9. Factors affecting checklist compliance at 11 months (pre intervention) and 16 months (post intervention)
The baseline data at 11 months showed a morning schedule, consultant and nurse endoscopists as well as BCS cases were associated with greater checklist compliance. This data was analysed and guided subsequent training interventions which are summarised in Table 7.11.

### Table 7.11. Summary of Targeted Training Intervention to Enhance Checklist Compliance

- Checklist training incorporated into Endoscopy unit induction to ensure new Registrars trained
- Compliance data presented at Colorectal Governance meeting
- Posters displayed in endoscopy rooms as a reminder
- Nurse in charge set reminder for afternoon lists to complete checklist
- Bowel Cancer Screening teams shared merits of checklist with wider nursing team
- Checklist mandated by Medical Director

The post intervention data showed no difference in checklist compliance between morning and afternoon schedules and a greater compliance with procedures conducted by Registrars and Nurses. The factors affecting checklist compliance are summarised in Table 7.12.

### Table 7.12. Summary of Factors Affecting Checklist Compliance Pre and Post Targeted Training Interventions

<table>
<thead>
<tr>
<th>Factor</th>
<th>Pre-intervention (11 months)</th>
<th>Post-intervention (16 months)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Time of day</td>
<td>Greater compliance AM p&lt;0.05</td>
<td>Similar compliance AM:PM p=0.704</td>
</tr>
<tr>
<td>Grade Consultant</td>
<td>Greatest compliance consultants and nurses p&lt;0.001</td>
<td>Lowest compliance consultants compared to Nurses 0.021 Registrars p=0.0002</td>
</tr>
<tr>
<td>Registrar Nurse</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Patient sub-type</td>
<td>Greater compliance BCS p&lt;0.01</td>
<td>NA (sub-types insufficient to compare)</td>
</tr>
<tr>
<td>BCS / elective / urgent</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### 7.5.10 Comparison of safety and quality pre and post checklist

One hundred and thirteen procedures over 31 lists constituted baseline observations (Chapter 3) and these were compared with 141 procedures over 31 lists following checklist implementation. The two data sets were first examined to determine similarities in procedure sub-type and endoscopist subtype. The results are summarised in Table 7.13.
Table 7.13. Comparison of Procedure and Endoscopist Sub-types in pre and post checklist data sets.

<table>
<thead>
<tr>
<th>Variable</th>
<th>Pre Checklist (n=31)</th>
<th>Post Checklist (n=31)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean (SD)</td>
<td>Mean (SD)</td>
<td></td>
</tr>
<tr>
<td>Total procedure number</td>
<td>3.6 (1.9)</td>
<td>4.4 (1.6)</td>
<td>0.08</td>
</tr>
<tr>
<td>Diagnostic procedures</td>
<td>2.3 (2.0)</td>
<td>2.5 (1.8)</td>
<td>0.74</td>
</tr>
<tr>
<td>Therapeutic procedures</td>
<td>1.3 (1.0)</td>
<td>1.9 (1.3)</td>
<td><strong>0.03</strong></td>
</tr>
<tr>
<td>% Diagnostic procedures</td>
<td>58 (36)</td>
<td>52 (30)</td>
<td>0.47</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Endoscopist</th>
<th>Pre</th>
<th>Post</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Expert</td>
<td>21 (68%)</td>
<td>25 (81%)</td>
<td>0.25</td>
</tr>
<tr>
<td>Trainee</td>
<td>10 (32%)</td>
<td>6 (19%)</td>
<td></td>
</tr>
</tbody>
</table>

The results show no differences between experts and trainees in terms of the total number of procedures performed. The proportion of diagnostic procedures was also similar between the two data sets. However, the number of therapeutic procedures per list was found to be higher in the post checklist data.

7.5.11 Comparison of Non-Technical (ENTS), Technical (DOPS) and Safety Scores (SC) Pre and Post Checklist

Additional analyses compared the measured variables (ENTS, DOPS and SC) between the pre and post checklist groups. These analyses are summarised in the Table 7.14.

Table 7.14. Comparison of Non-Technical Skill (ENTS), Technical Skill (DOPS), Safety checks, and Patient Safety Incidents (PSIs) Pre and Post Checklist

<table>
<thead>
<tr>
<th>Variable</th>
<th>Pre Checklist</th>
<th>Post Checklist</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n (%)</td>
<td>n (%)</td>
<td></td>
</tr>
<tr>
<td>ENTS 1</td>
<td>1 (3%)</td>
<td>0 (0%)</td>
<td>0.08</td>
</tr>
<tr>
<td>ENTS 2</td>
<td>8 (26%)</td>
<td>5 (16%)</td>
<td></td>
</tr>
<tr>
<td>ENTS 3</td>
<td>18 (58%)</td>
<td>17 (55%)</td>
<td></td>
</tr>
<tr>
<td>ENTS 4</td>
<td>4 (13%)</td>
<td>9 (29%)</td>
<td></td>
</tr>
<tr>
<td>DOPS 2</td>
<td>2 (11%)</td>
<td>0 (0%)</td>
<td>0.05</td>
</tr>
<tr>
<td>DOPS 3</td>
<td>9 (47%)</td>
<td>10 (32%)</td>
<td></td>
</tr>
</tbody>
</table>
Variable | Pre Checklist | Post Checklist | p-value |
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>DOPS 4</td>
<td>8 (42%)</td>
<td>21 (68%)</td>
<td></td>
</tr>
</tbody>
</table>

Variable | Pre Mean (SD) | Post Mean (SD) | P-value |
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Safety Check (SC)</td>
<td>1.96 (0.32)</td>
<td>2.77 (0.51)</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

The analysis suggests some evidence of a difference in non-technical (ENTs) and technical skill (DOPS) scores between the two time points, although the results were of borderline statistical significance. Both non-technical and technical skills scores were higher in the post checklist data set compared to baseline. For non-technical skill 84% of the post checklist scores were 3 or 4, compared to only 71% of baseline scores. For technical skill, 68% of post checklist scores were 4 compared to 42% of baseline scores. Safety scores showed a significant increase post checklist, with a baseline mean score of 1.96 increasing to 2.77 post checklist (p=<0.001).

7.5.12 Comparison of Patient Safety Incidents (PSIs) Pre and Post Checklist

There were 139 PSI recorded in the baseline study and 160 post checklist implementation. Statistical analysis revealed no significant differences between the two data sets. The result held when examining both the number of PSIs per list and also per procedure. The lack of difference also held for both diagnostic and therapeutic procedures in addition to all procedures combined. (Table 7.15)

Table 7.15. Comparison of Patient Safety Incidents (PSIs) Pre and Post Checklist

<table>
<thead>
<tr>
<th>Variable</th>
<th>Pre Median (IQR)</th>
<th>Post Median (IQR)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>PSIs / list</td>
<td>2 (1, 5)</td>
<td>2 (1, 4)</td>
<td>0.89</td>
</tr>
<tr>
<td>PSIs / procedure</td>
<td>0.7 (0.2, 1.7)</td>
<td>0.4 (0.3, 1.0)</td>
<td>0.54</td>
</tr>
<tr>
<td>Diagnostic PSIs / list (*)</td>
<td>1 (0, 2)</td>
<td>1 (0, 1)</td>
<td>0.78</td>
</tr>
<tr>
<td>Diagnostic PSIs / procedure (*)&amp;</td>
<td>0.2 (0.0, 1.0)</td>
<td>0.3 (0.0, 0.5)</td>
<td>0.80</td>
</tr>
<tr>
<td>Therapeutic PSIs / list (**)</td>
<td>2 (1, 5)</td>
<td>2 (1, 3)</td>
<td>0.41</td>
</tr>
<tr>
<td>Therapeutic PSIs / procedure (**)</td>
<td>2.0 (0.5, 2.8)</td>
<td>1.0 (0.3, 2.0)</td>
<td>0.12</td>
</tr>
</tbody>
</table>

(*) Omitting lists containing no diagnostic procedures

(**) Omitting lists containing no therapeutic procedures
Considering the severity rating of PSIs, there were a greater number of mild PSIs post checklist and fewer severe PSIs. There were no never events in the post checklist PSIs whilst two were recorded pre-checklist (patient mis-identification and wrong site procedure).

![PSI Severity Pre and Post Checklist](image)

**Figure 7.10.** Comparison of Patient Safety Incidents (PSIs) by Severity Pre and Post Checklist

Examining the thematic categorisation of PSIs, some categories had fewer errors post checklist (e.g. Oxygen Monitoring, Sedation, Intravenous access and Monitoring) whilst other categories had more PSIs (e.g. Non-Technical skills and Training and Technical skill and Equipment). The comparison by PSI theme pre and post checklist is illustrated in Figure 7.9.
This study aimed to design, implement and evaluate in depth a bespoke safety checklist for gastrointestinal endoscopy. The checklist was analysed from the perspective of the patient as well as individual and team performance by measuring technical and non-technical skill and the quality of safety behaviours. The quality of checklist use was assessed and measures to enhance compliance across professionals explored. The effect of the checklist on patient safety incidents was examined and the results of these analyses disseminated to the wider department to raise awareness of teamwork factors. These measures were conducted with the aim of embedding sustainable safety practices and culture change in Endoscopy. The key findings from this chapter are summarised in the next section.
7.6.1 Summary

- Patient opinion of the checklist was favourable with patients agreeing that they understood the rationale for confirming their identity prior to the procedure and that they would want a checklist to be used for subsequent endoscopic examinations.

- Patients who had previously undergone endoscopy were more likely to assume that a checklist was already in place, worry about coming to harm in hospital and prefer documentation to confirm a checklist had been completed for their procedure.

- Comparing the performance of experts and trainees, experts had significantly higher non-technical skill scores but no differences were seen in technical and safety check scores.

- Bowel cancer screening procedures had significantly higher scores for non-technical, technical and safety check scores when compared to non-screening procedures.

- Checklist completion was highly variable with no checklists fully completed despite the mean time to conduct the checklist in this study being 55 seconds.

- One-hundred and twenty PSIs were recorded in the post checklist group with the majority (75%) being categorised as mild in severity, with ‘Non-Technical Skills and Training’ related errors being the most prevalent. There was no significant difference in PSI incidence between experts and trainees. Bowel cancer screening cases had significantly fewer PSIs compared to non-screening cases.

- Sixty per cent of PSIs were related to the checklist with the majority of these episodes (86%) occurring as the checklist was not completed appropriately. Had the checklist been completed these PSIs could have been averted.

- Full compliance with the checklist was low (53%) as measured 11 months after implementation, but was enhanced following dedicated training interventions to subgroups of endoscopists.

- Following checklist implementation there was a highly significant improvement in safety check scores. There was an indication of improved technical and non-technical scores although this was not of statistical significance.

- There was no significant change in PSI incidence following checklist implementation although there were fewer severe PSIs and no never events following the checklist.
7.6.2 **Implications**

This work has significant implications for clinical practice in this setting and more widely for endoscopic practice across the UK. The main points are summarised below.

7.6.2.1 **Patient Opinion**

Endoscopy patient opinion towards the concept of a safety checklist is favourable and is comparable to similar work in Surgery\textsuperscript{39}. This is relevant considering some of the obstacles encountered in implementing the checklist as senior figures argued that the checklist could undermine the patient’s confidence in the endoscopist. By formally evaluating patient opinion this view was not upheld and enabled checklist advocates to continue improving checklist practices.

7.6.2.2 **Endoscopist Sub-groups**

The checklist evaluation study provided evidence that sub-groups of endoscopists demonstrated superior skills in some aspects of performance. Experts had better non-technical skills compared to trainees despite technical skill scores being comparable overall. This supports the argument presented in Chapter 6 of enhancing endoscopy quality by identifying and training non-technical skills as part of the endoscopy training programme. Experts may develop these skills with time and experience but there is an opportunity to develop these skills more fully at an earlier stage of training to complement safe technical skills acquisition.

Similarly, screening endoscopists had superior performance globally as assessed for technical and non-technical skills as well as safety checks and PSI incidence. Whilst these individuals have demonstrated a high level of technical expertise through the screening accreditation process, there are other factors that may be implicated such as organisational factors (set numbers of procedures on screening lists, patient pre-assessment and experienced nursing team) and endoscopist motivation to perform to a high level driven by transparent recording of data through the national database. The differences in these sub-groups with superior performance are important to recognise with a view to identifying opportunities to disseminate enhanced performance in the symptomatic service too.

7.6.2.3 **Checklist Effects**

Despite the detailed checklist implementation strategy, the quality of checklist completion remained sub-optimal across the study. This highlights the challenges in changing behaviours
and implementing new practices in busy clinical environments and the need for both short
term and long term strategies. Despite the partial uptake of the checklist, there was still a
significant improvement in safety check scores. This resulted in a unified approach and
consistent policy for safety check protocols across the endoscopy unit, which is in contrast to
the highly variable approach to safety checks prior to the checklist detailed in Chapter 2.

There was no significant difference in performance metrics following the checklist although
there was a suggestion that technical and non-technical skills showed improvement with the
checklist. It maybe that the checklist was not fully embedded in clinical practice and hence
this effect was not demonstrated at this time-point. Also the checklist in isolation is unlikely
to impact non-technical skills performance and in reality needs to be coupled with non-
technical skills team training interventions across the unit.

The implementation of the checklist did not result in a reduction in Patient Safety Incidents
(PSIs) when absolute numbers were considered. The nature of the PSIs however was
modified favourably by the checklist with less severe error being recorded and evidence of
error capture and mitigation directly as a result of the checklist. This study clearly
demonstrates that there is an open opportunity to reduce the number of PSIs by improving
checklist compliance, which is a focus for future work.

7.6.3 Limitations

The limitations of the studies presented in this chapter are that they focus on a single
endoscopy site and therefore wider generalisations cannot be inferred. In addition the
Hawthorne Effect may be relevant as endoscopy teams were aware safety behaviours were
being observed and consequently may have modified their behaviour. The checklist being at
the beginning of the procedure may have been particularly affected, and therefore in wider
practice may be even less complete than indicated in this study. The effectiveness of the
checklist and its true impact was probably inadequately assessed in this study due to the low
compliance rates. As discussed in Chapter 2, Patient Safety Incidents were broad and did not
equate to direct patient harm. The large number of PSIs in this study may have been affected
by the researcher becoming more skilled at detecting PSIs in the post checklist phase having
understood the nature and range of PSIs in the pre-checklist study. It is accepted that it is
difficult to establish causality between checklists effects and patient outcomes and this is
acknowledged in wider checklist research. Finally, as acknowledged in other studies, rates of
medical error whilst an important metric in their own right are a relatively crude marker of safety and quality as the incidence of serious error remains relatively rare.

7.6.4 Future work

Future studies should focus on multi-centre checklist evaluation to promote a standard of care with the other two sites in the Trust conducting similar prospective observational studies analysing technical and non-technical skill as well as Patient Safety Incidents. The checklist developed as part of this study has been requested for use by 16 other Trusts who have expressed a view that the checklist was an important safety intervention, and often Trust management teams had advised that the WHO surgical checklist be used for endoscopy, which was deemed unsatisfactory by the clinical endoscopy teams.

Further targeted efforts to enhance optimal checklist use beyond compliance should be examined to ensure the full benefit of the checklist as a safety tool is gleaned. Systems factors should be continually reviewed as endoscopy processes and pathways change, to ensure the checklist remains easy to use: An example of this is incorporating the checklist into existing patient care plans to avoid additional loose pieces of paper. Further work should examine the merits of developing an electronic checklist linked to the endoscopy reporting software and thus the patient’s endoscopy report. Such developments may ‘encourage’ checklist completion for example by only enabling the scope to function once the checklist process was electronically complete. Additionally, such metrics if measured by endoscopy reporting software programmes could link in to the National Endoscopy Database.46

Although not the focus of this study, accountability for conducting the checklist appropriately should be clearly defined, as the checklist document is likely to be examined in the future investigations of errors in endoscopy as a medico-legal method of identifying adherence to safety practices.

Further work should examine the merits of developing endoscopy checklists for specific scenarios such as upper and lower GI endoscopy, ERCP, emergency endoscopy, gastrointestinal bleed endoscopy, variceal bleed, therapeutic interventions and screening procedures for example. These tailored endoscopy checklists may be more effective in addressing the specific safety issues relevant to these procedures but will only be effective once the concept of conducting a team checklist effectively is established in clinical practice. In addition, such tailored endoscopy checklists lend themselves to be incorporated into
specific GI care bundles, to enhance implementation of best clinical practice during the pre, intra and post endoscopy pathways.

Checklist compliance and optimisation measures should be embedded in a wider non-technical skills and team training programmes where it is emphasised that the checklist is a single tool to help reduce error and enhance safety but not a panacea for all endoscopy error. Checklists need to be bolstered by other measures such as team briefings, debriefings, handover processes and an attitude of learning from error to promote a culture of safety within endoscopy.

The endoscopy checklist represents a set standard for safety checks for endoscopy and should be a minimum standard of safety for endoscopy more widely. In order for the checklist to make a significant impact on patient safety, the checklist should be part of the quality standards laid out by the Joint Advisory Group and authorised by professional bodies such as the British Society of Gastroenterology with guidance on checklist implementation and training available to all endoscopy units in the UK.

### 7.7 Conclusion

In conclusion, a bespoke endoscopy checklist has been devised, implemented and evaluated in detail in a tertiary endoscopy referral centre and has been embedded into endoscopic practice. Patient opinion advocates checklist use and there is a perceived need for an endoscopy checklist from other units in the UK as it is practical and feasible. The checklist represents a shift towards further enhancing safety in endoscopy and has standardised pre-procedural checks without compromising efficiency. Although this study did not show a significant reduction in the number of Patient Safety Incidents, the observed errors appeared to be less severe. Enhancing checklist compliance should remain a long-term goal as the full impact of the checklist as a safety intervention may not have been realised early on in its implementation.
Chapter 8: Thesis Discussion

8.1 Chapter Outline

This chapter presents an overall discussion pertaining to the studies presented in this thesis. Firstly, the key problems addressed by this research are defined followed by a summary of the main findings. The aims of the thesis are considered and the limitations of the research studies addressed. The key implications of this research for endoscopy training, clinical practice and patient safety are discussed and future research summarised. The chapter concludes with my personal reflections on my research.

8.2 Defining the Problem

The concepts of patient safety and quality have been well defined for healthcare largely through seminal work in surgery, but a comprehensive, in-depth analysis specific to gastrointestinal endoscopy has not been undertaken. Whilst many important aspects particularly relating to endoscopy training and service delivery have been positively transformed through the Joint Advisory Group (JAG) and Global Rating Scale (GRS), a holistic approach to endoscopy safety and quality through error analysis, team work factors, non-technical skills, training objectives and service delivery has not previously been completed. Current professional training focuses on clinical knowledge and technical skills acquisition with implicit non-technical skills development through experience. Much has already been achieved through training and accreditation of individual endoscopists and endoscopy unit performance metrics, but a focus on non-technical skills and teamwork factors to bridge safety and quality has been missing. Existing research illustrates the variability in endoscopy practice but the significance, long term outcomes and effects on patients have not been fully examined. This is in part because endoscopy is generally considered to be a safe intervention, particularly in comparison to surgery where the scale of risk differs. If we are to fulfil the aspiration of significantly developing diagnostic, therapeutic, screening and emergency endoscopy services, then a reliable infrastructure for endoscopy safety and quality must be in place at a national level. The work in this thesis has examined these issues.

In this closing chapter I present an overview of the key research findings, review the study limitations and discuss the implications of this research for patient safety in endoscopy through clinical, organisational and patient focussed perspectives.
8.3 Summary of thesis findings

The overarching aims of this thesis presented in Chapter 1 were two-fold: Firstly, to identify and assess the patient safety issues in gastrointestinal endoscopy (Chapters 1-5) and secondly, to devise, implement and evaluate solutions to improve patient safety and quality in endoscopy (Chapters 6-7).

The studies in this thesis have evaluated, assessed and set out strategies to enhance non-technical skills and teamwork in endoscopy. In part A of this thesis, Chapter 1 contextualised patient safety and quality within healthcare and defined the relevance, importance and opportunities of this for endoscopy. In Chapter 2 endoscopy team members’ attitudes towards endoscopy safety were identified and the frequency, type and severity of patient safety incidents were prospectively evaluated in routine endoscopy. Live teamwork observations presented in Chapters 3 and 4 scientifically evaluated safety checks, technical and non-technical skills in endoscopy teams conducting elective and emergency procedures respectively, and delineated the relationship between patient safety incidents. Chapter 5 examined the extended endoscopy pathway by evaluating colorectal cancer MDT team working, decision-making and errors across key patient groups and implemented interventions to enhance quality.

In part B of this thesis specific interventions to enhance the safety and quality issues identified in part A were presented. Chapter 6 illustrates the feasibility and effectiveness of a multi-disciplinary team training intervention for experienced bowel cancer screening teams targeting non-technical skills, error analysis and enhanced team performance strategies. Finally in Chapter 7 an endoscopy safety checklist was devised, implemented into clinical practice and prospectively evaluated in detail to examine the effects on safety checks, patient safety incidents, technical and non-technical skills.

8.4 Fulfilling Aims

The overarching aim of this thesis was to identify and examine patient safety and quality issues that impact patients undergoing gastrointestinal endoscopy and to devise, implement and evaluate interventions to enhance safety and quality. In order to achieve this a number of secondary aims were addressed by the research studies:
**Secondary Aims**

1. Increase our understanding of patient safety incidents in endoscopy

   This aim was achieved specifically in Chapter 2 through prospective evaluation of patient safety incidents and detailed analysis of these errors to understand the aetiology, disseminate wider learning and inform preventative strategies. Furthermore, patient safety incidents were evaluated in the emergency endoscopy setting and compared to elective cases to further understand the different threats to patient safety (Chapter 4).

2. To determine the role of non-technical skills in endoscopy and educational strategies to enhance these skills (Chapters 3, 4 and 6)

   This was achieved by utilising a validated endoscopic non-technical skills tool to objectively evaluate endoscopists in their teams. Non-technical skills were considered in elective cases (Chapter 3) as well as emergency cases (Chapter 4) and the relationship between other performance measures (technical skill, safety checks and patient safety incidents) analysed. These studies indicated significant opportunities to improve patient safety by enhanced non-technical skills not only of the endoscopist but also the core team. A non-technical skills team training intervention was developed, implemented and evaluated for experienced bowel cancer screening teams (Chapter 6).

3. To identify differences in patient safety issues in elective and emergency endoscopy

   Prospective teamwork observations were conducted for emergency endoscopic procedures conducted within endoscopy as well as critical care and the operating theatre outside of working hours. Performance measures (safety checks, technical and non-technical skill) and patient safety incidents were analysed for these critical cases and compared to elective cases (Chapter 4).

4. To examine opportunities to enhance endoscopy safety and quality by evaluating colorectal cancer multi-disciplinary team working

   This was achieved by scientifically evaluating the MDT process and implementing staged improvement strategies augmented by MDT education and measuring their effectiveness (Chapter 5).
5. To develop an endoscopy safety checklist and implement into clinical practice (Chapter 7)

The Patient Safety Incident analyses (Chapter 2) and the teamwork observational studies (Chapters 3 and 4) highlighted the need for a consistent approach to pre-procedure safety checks. This objective was met by devising, implementing and evaluating the effectiveness of a tailored endoscopy checklist (Chapter 7).

8.5 Limitations

Inevitably, there are limitations to the research presented in this thesis. Specific limitations pertaining to each individual study are addressed in detail in the preceding chapters. This section details the general and specific limitations to the methodological research approaches adopted.

8.5.1 Evidence base

In formulating the studies within this thesis it was evident that there was a limited evidence base for endoscopy safety and quality when considered broadly. The published literature is generally procedure specific, has a narrow remit and the emphasis remains on severe but infrequent errors e.g. haemorrhage and perforation. Whilst valuable data pertaining to safety and quality can be scrutinised from the bowel cancer-screening programme, this level of accurate and detailed data on performance at a national level is not yet available for other forms of endoscopy. Consequently, inferences were made from the surgical literature where human factors and teamwork skills relating to performance and error have been more fully studied. It is acknowledged that these two areas are not interchangeable with many important differences in practice. Nevertheless, the principles of patient safety and teamwork identified and studied in other specialties were examined to provide a basis for this work. The studies within this thesis serve to provide preliminary research in endoscopy patient safety and quality upon which further work can be developed.

8.5.2 Sampling and Generalisability

The sample size for procedures observed is relatively small when considered in light of the study questions posed. In total, 336 endoscopic procedures, 541 patient safety incidents and 645 colorectal cancer MDT decisions were evaluated within the studies presented in this thesis. Whilst this is a significant number of observations given the time and resources
required to complete this, a larger sample size would have enabled more robust statistical conclusions to be drawn. Similarly, this research reflected the practice of a single institution limiting the generalizability of the results. The patient population served by this institution will have particular characteristics that may not be representative of patients receiving endoscopy and colorectal services at a national level. Moreover, this was a tertiary referral centre for endoscopy and colorectal surgery and thus will include a selected more complex patient group not necessarily representative of colorectal patients (and thus decision–making) presenting more widely. Furthermore there is a bias given the clinicians delivering such a tertiary service will have a more sub-specialist practice, which may not be comparable to clinicians in a non-referral centre.

### 8.5.3 Patient Involvement

The underlying theme of this research is improving patient safety and quality. This research is limited by a lack of in depth patient opinion for each area studied. Patient views were objectively collated in relation to the endoscopy safety checklist given the point raised about potential negative consequences for patients. This provided valuable data supporting the patient view on the checklist. However, patient involvement in the other studies was not possible (though desirable) due to resource and time limitations. Patient involvement in the analysis of endoscopy errors would have provided valuable information on the true impact of error from the patient’s perspective. In addition patient centred communication as measured by the non-technical skills rating tool in the routine and emergency endoscopy observational studies would have been supported by patient views on the effectiveness of communication across the procedure. This could be subsequently incorporated into non-technical skills training interventions. The colorectal MDT evaluation did not formally evaluate the actual impact of decision-making, investigations and treatment plans on patients along the cancer pathway, although this would have been insightful, particularly when analysing the patient centred information scores.

### 8.5.4 Observational assessments

Many of the studies adopted observational methods for data collection, which have associated limitations. Firstly the individuals and teams being observed were not blinded to the presence of an observer and hence their practice is likely to be modified to some degree knowing they were being observed. The Hawthorn effect may have skewed behaviours at the start of the
observations although teams appeared to be immersed in the procedures as the list progressed so the changes from routine practice are likely to be minimal. Additionally, observational methods require behaviours to be displayed and intentions communicated to ensure performance is firstly seen and then accurately interpreted. This is not always the case and therefore important thought processes may be overlooked in observational assessment. As a corollary the interpretation of silence remains controversial. At times of critical importance it could be argued that silence is necessary for concentration and ordered thought processes, whilst in other situations vital communication with the team could be compromised. By utilising rating tools in observational studies the process is objectified to some degree although judgement and interpretation by the observer will persist and may influence the data.

Some of the procedures observed were rapid (e.g. unsedated diagnostic OGD and post-operative MDT discussion). In these settings it is challenging to accurately rate the encounter given the number of variables being examined. Invariably there is a learning curve to observational assessments such that the assessors became more adept at making and recording the observations as the numbers of cases increased.

8.5.5 Observational rating tools

Validated rating tools for the endoscopy and MDT assessments provided a scientific approach to measuring teamwork. The reliability and validity of these assessments depend to a certain degree, upon the training in rating tool use and the ability of the raters making the assessments. For the endoscopy observations I was trained in using the ENTS rating tool by the clinician who devised the tool. The reliability ratings were also conducted with the same clinician and hence measures were in place to ensure the tool was employed correctly. However, although the reliability measures were reasonable, they do not indicate that the measures were necessarily valid and thus highlight a limitation of rating tools. Furthermore, the ENTS rating tool provides an assessment tool for the endoscopist and does not incorporate the core team. Some of these key teamwork interactions were captured in qualitative data around patient safety incidents but not always captured by the tool itself. Whilst all rating tools aim to provide an objective base for assessments, the raters understanding and interpretation of the team performance will invariably form part of the assessment and hence subjective views cannot completely be excluded.
8.5.6 Patient Safety Incidents and Analysis

Identification of patient safety incidents requires the error to be manifest in some way during the study observation period. The very nature and breadth of medical error means that error is not always immediately visible and hence the true incidence may have been under-estimated. On the other hand, the definition of error used was deliberately broad so it could be argued that minor inconsequential errors were included when in reality the impact to the individual patient was negligible on that occasion. The PSI analysis did not examine the impact of the errors identified on the patient in the short or long term, or to the organisation in terms of costs and efficiency of care. By examining the factors that may influence error incidence (such as checklist completion) it should be acknowledged that correlations do not equate to causation and various factors are likely to influence error incidence. Given the multi-factorial nature of error, the underlying systems factors were not fully addressed for all the types of errors observed and one could argue that the focus has been more on documenting the number and type of error rather than understanding the detailed nature of the error and hence preventing errors. This is an important piece of work that needs to be developed further but was not possible within the confines of this thesis.

8.5.7 Quality improvement interventions

The checklist implementation and the MDT study adopted quality improvement (QI) methodology. These were multi-stage interventions, which rely on the improvement measures to be reliably in place in order to measure a difference. Despite various educational strategies this is difficult to achieve fully and will invariably impact upon the outcome measure. However, quality improvement is a step-wise approach with the assimilation of changes in clinical practice likely to occur beyond the study time frame. Furthermore, the MDT interventional study did not adopt a control group to delineate whether the changes were attributable to the interventions themselves or not. Additionally, the length of time required to embed changes into clinical practice mean that there are likely to be other confounding factors alongside the planned interventions. This has implications for the generalizability of the quality improvement measures.
8.6 Implications for Endoscopy practice

The work undertaken in this thesis has presented a framework by which endoscopy practice can be positively improved. There are general measures and specific examples of practice change as a result of this work summarised in the following two sections.

8.6.1 General implications

This work can be distilled into three clear strategies to address patient safety and quality: Firstly, an understanding of and incorporation of error analysis into clinical practice will enhance learning from error that the endoscopy team believes is relevant to their practice. Secondly, enhanced team performance through dedicated team training measures can build upon the team’s effectiveness at delivering a high quality procedure and mitigating error. Thirdly, implementing an endoscopy safety checklist on a national level through the existing infrastructure of JAG is a practical step towards enhanced safety. These measures are realistic, feasible and relatively low cost but do require senior leadership to facilitate implementation. There are no significant negatives for these measures, except one must consider the time that may be taken away from service provision to implement such practice change. Data from such quality improvement measures would be a useful way of evaluating endoscopy practice globally and could form part of a national endoscopy database. By addressing the team aspects of performance through non-technical skills and a safety checklist, the opportunity to bridge the gap between quality measures for the individual endoscopist and the endoscopy unit as a whole, is possible. These changes in endoscopy practice define a set standard of care (i.e. checklist completion, debrief after errors and team training completion) that enhances safety and quality for endoscopy patients. Such quality assurance practice is likely to be transferable to other interventional procedures in angiography, bronchoscopy and interventional radiology for example.

8.6.2 Specific implications

The research evaluating safety and quality in emergency endoscopy highlighted key concerns and policy modifications were devised to enhance the quality assurance processes of emergency procedures. This was influenced by these study findings and was also part of broader governance measures occurring in parallel. In accordance with NICE guidance, a gastrointestinal bleed pathway was put into place to provide patients undergoing emergency endoscopy optimal care and to coordinate teamwork amongst various specialties. This
involved a GI bleed ‘care bundle’ clearly enabling risk stratification and outlining best practices not only during the procedure but pre and post intervention too. This care bundle ensures pre-procedure resuscitation is appropriate and clarifies pathways according to non-variceal, variceal and lower gastrointestinal blood loss as per Scottish Intercollegiate guidance 1 endorsed by the British Society of Gastroenterology 2 A further key policy change was the introduction of endoscopy nurse assistants on call with the endoscopists on a 24/7 rota. This change in policy provides the team with the correct skill-set to conduct the procedure, facilitates preparation of equipment and provides skilled assistance with the procedure, particularly important with therapeutic intervention. In addition to this, the acute GI care bundle provides clear parameters for when other specialists should be involved (e.g. anaesthetics and interventional radiology) thus facilitating escalation of care to the appropriate specialty and the appropriate seniority. These improvements helped to cement the endoscopy team for emergency cases particularly those cases requiring endoscopic intervention out of routine hours.

8.7 Implications for Training and assessment

Effective education and training provide the mechanism whereby endoscopy quality improvement is translated into practice. The science of human factors and the principles of good teamwork as a pre-requisite to performance are beginning to feature in undergraduate medical school curricula. This is an important step to ensure these principles are explicitly taught and backed by senior role models as an important clinical skill. The research presented in this thesis supports the idea that training in human factors and teamwork specific to endoscopy needs to be built into the specialty training programme and can be cemented prior to hands on skills training. This also may facilitate technical skills acquisition when the endoscopist is starting out on their training by providing them with strategies to problem solve, maximise their team utility and escalate risks and errors in a timely fashion. Individual training remains the starting point but the focus needs to evolve to team training to include the core team of endoscopists and nurses but also the wider team (anaesthetists, interventional radiology, ward teams, porters, administrative and managerial staff).

The assessment of performance at endoscopy is well established through the JETS system through DOPS competency assessments. Since the start of this research these assessments have been developed further to incorporate non-technical skills as part of the formative and summative assessment and will become more detailed for specific endoscopy scenarios in
both the elective and emergency settings. By developing a comprehensive training plan for safety and quality in endoscopy a longer-term investment is made towards an open culture of learning with less focus on blame. The delivery and assessment of specific non-technical skills training interventions for endoscopy teams should be incorporated into the existing GRS and JAG processes. For senior endoscopists these skills could be re-visited as part of the revalidation process.

8.8 Implications for Patient Safety

This work has influenced patient safety at the frontline of clinical care by changing practice. By providing a scientific foundation to safety and quality in endoscopy, this work has the potential to improve patient safety at a national level through policy change. By adopting a coalition of quality improvement into clinical practice one can maximise simple opportunities to enhance safety. It is accepted that medical error cannot be abolished, but predictable, recurrent errors can be tackled. This work provides a catalyst for the wider systems changes in healthcare institutions that are required. This requires backing from government health policy with suitable financial investment to see things through to fruition. Whilst this is a long-term aspiration, continuing to improve patient safety at a local level through each individual unit provides the stepping-stones for improved patient care. In conducting this research, it is clear that what matters to patients is also what matters to healthcare teams, although in reality there are obstacles to achieving what are aligned safety and quality goals.

8.9 Future Work

The detailed developments for each study are presented in the individual chapters. The work presented in this thesis sets the foundation to develop a robust and prospective national endoscopy data set for patient safety incidents. Endoscopy team training should be disseminated nationally through existing endoscopy training centres and form part of JAG accreditation. Further developments should focus on sub-team training and customised checklists for example relating to emergency endoscopy or specific interventions, such as ERCP and ESD. Effective use of the endoscopy safety checklist should be a goal for all patients and form part of best practice through professional bodies such as BSG, ACPGBI and JAG****.

**** BSG: British Society of Gastroenterology, ACPGBI: The Association of Coloproctology of Great Britain and Ireland, JAG: Joint Advisory Group for Endoscopy
8.10 Personal Reflections

The opportunity to conduct research with a direct application to patient safety in clinical medicine has been an academic, professional and personal privilege. I was fortunate to be in the right place at the right time to seize the opportunity and was given the benefit of the doubt by Adam and Siwan who agreed to supervise me after an interview to check ‘I had two eyes and one nose’. Adam has inspired and encouraged me to pick up where his thesis finished and planted the seeds for my research. Nick has brought a wealth of academic knowledge and scientific grounding to my work and opened my eyes to the world of patient safety. Although the focus of my research was not absolutely clear from the onset, with my supervisors’ backing, I have shaped this research into something I care passionately about and has become my long-term professional vocation that will continue beyond this thesis. I am deeply grateful for these opportunities and it has been a huge honour to work in the Wolfson Unit and Imperial College – my medical school and academic ‘home’.

Through my PhD I have acquired and refined a multitude of research skills including critical literature review, qualitative and quantitative research methodologies, seeking ethical approval, scientific writing, submitting abstracts, managing papers through submission revision, rejection and re-submission, presentation skills and communication of research through conferences, training endeavours and social media. Importantly for me I have indulged in the art of science by being able to think imaginatively and ambitiously and institute changes in clinical practice by connecting with people on the shop floor.

The breadth and depth of my research has allowed me to develop wider skills such as project management, prioritising tasks according to time and urgency along with galvanising teams of professionals in change management. I have had to understand and engage with a range of disciplines in healthcare including nursing, administrative, management, governance and service delivery committees to enable what I understand to be best clinical practice to be transmitted more robustly across an NHS trust. Collaborating with such an array of professionals including patients, nurses, managers, radiographers, radiologists, surgeons, oncologists, pathologists, psychologists, designers, technicians and statisticians has taught me to appreciate the value of diverse skill sets and never to send group e mails entitled ‘Dear all’.

Separate to the research, I have been educated and trained in allied areas that I would not have otherwise experienced at this stage in my career. I have had targeted, intensive and focused clinical and endoscopic training that has made me a better gastroenterologist. I have
had an insight into the practical and quality aspects of the national bowel cancer screening programme by observing bowel cancer screening colonoscopists and learnt the ‘Wolfson way’ of scoping, lesion recognition, therapeutic intervention, team management and patient communication. This has given me a template to aspire towards and in this vein I have completed my Flexible Sigmoidoscopy bowel cancer screening accreditation. Developing my practical skills as an endoscopist has highlighted how much fulfilment I gain from being a thinking proceduralist and the importance of rallying your team, the ritual like start to a procedure, managing the list effectively and most importantly speaking humanely to your patient. It has been a privilege to have completed research that contributes to endoscopy quality and safety considering that UK endoscopy has an international reputation for excellence, and I am motivated to contribute to this goal internationally.

My education in the emerging field of ‘colorectal medicine’ truly bridges colorectal surgery, endoscopy and gastroenterology and has been hugely valuable. This started out by regular attendance at the colorectal cancer MDT meeting where the subtleties of patient management are debated and addressed by experts and new scientific and technological developments are considered. I stepped up to be the endoscopy representative at the MDT and saw the importance of there being a reliable conduit between endoscopy and cancer care decision making. The sharp tongue, clinical acumen, wit and leadership on display every Friday morning from the Grand Round to the MDT meant there was never a dull moment. Being part of the fabric of St Mark’s for 5 years has enabled my research and learning opportunities to supersede the endoscopy department and I have been able to regularly assist in local training courses, a forte of St Marks. I have developed a network, which has enabled me to embed clinical and academic work by being part of a ‘permanent team’ as a Registrar, which has been rewarding.

Alongside this I have had the responsibility of being an Imperial College education fellow and taught both undergraduate and post-graduate medical students. My role as the trainee editor for Frontline Gastroenterology has required me to be a reviewer for papers submitted to the journal and has opened up the world of social media for dissemination of academic work and clinical practice and embracing the opportunity of a wider dialogue with patients and professionals alike.
My period of research has given me a grounded insight into academic life and inspired me to work hard to carve out and balance clinical, academic and family life and to fulfil these important roles.

I have had great fortune in having supervisors and mentors who have supported, encouraged, criticised and inspired me to ‘lean in’ and be the best doctor I can. Most importantly, my research period has helped uncover the most important aspects of my life as a doctor and a mother. My son Jai experienced a medical error in hospital as an unwell neonate at a time of uncertainty about his survival. I have experienced first hand the complexity and array of emotions and responsibilities as a doctor, a patient and a mother and the very fine line we walk every day when we go to work to help others. Overwhelmingly, the clearest observation at this time was the incredible dedication and hard work from most of the people who treated us. This personal experience highlights to me the importance of human error and a systems approach and remains a very personal motivation to continue this work in endoscopy. Despite this, Jai has flourished, learnt to spell ‘gastroenterologist’ at the age of 5, has polyp recognition skills thanks to Google images and enjoys calling his mother a ‘poo doctor’ at the school gates. My youngest son Ram now 3 accompanied me on call for the emergency observations at 32 weeks gestation and the nursing team were convinced this baby’s first word would be ‘checklist’. This work has only been possible due to the selfless support of my family, in particular my father for instilling his work ethic and my mother the incredible woman who taught me to put others’ first and ‘spin plates’ with style and a smile. I have met friends for life and had the privilege of being guided and inspired by my mentors, most particularly Siwan, who’s attention to detail, commitment to gastroenterology passion for education and exacting high standards are truly inspirational. I am grateful to my research mentors who have shaped my future career and inspired me to be the best clinical doctor, academic researcher and mother to my two wonderful boys Jai and Ram, to whom I dedicate this work.
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Chapter 8


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Appendix 1

Appendix 1.1

Endoscopy Questionnaire Date:

<table>
<thead>
<tr>
<th>Specialty</th>
<th>Title</th>
<th>Room #</th>
<th>AM/PM</th>
</tr>
</thead>
</table>

1. Are you aware of any pre-procedure checks undertaken prior to each patient undergoing an endoscopic procedure?
   (Please circle) Y N

2. What pre-procedure checks are currently undertaken, and who does them?

<table>
<thead>
<tr>
<th>Check</th>
<th>Responsible</th>
</tr>
</thead>
</table>

3. Are you aware of the WHO Surgical Safety Checklist?
   (Please circle) Y N

4. What additional checks do you think should always be performed, and by whom?

<table>
<thead>
<tr>
<th>Check</th>
<th>Responsible</th>
</tr>
</thead>
</table>

5. Would a safety checklist be useful prior to the following endoscopic procedures (please circle)?

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Y</th>
<th>N</th>
</tr>
</thead>
<tbody>
<tr>
<td>Elective procedures</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Emergency procedures</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Therapeutic procedures</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

276
6. Do you have a consistent escalation point if a problem arises during your endoscopy list?  
(Please circle) Y N  
If yes, who is your escalation point? (Please circle)  

a. Nurse in charge  
b. Nurse in room  
c. Unit Manager  
d. Senior endoscopist  
e. Other (state who):  

7. What are the names of the other staff in the room with you today?  

Additional Comments:
## Appendix 2

### Appendix 2.1 Summary of rating tools employed

<table>
<thead>
<tr>
<th>Tool</th>
<th>Technical</th>
<th>Non-Technical</th>
<th>Safety Checks</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Directly observed Procedural Skills: DOPS</td>
<td>Endoscopic Non-Technical Skills: ENTS</td>
<td>Basic Safety Checks: SC</td>
</tr>
<tr>
<td>Rating scale</td>
<td>1-4</td>
<td>1-4</td>
<td>1-4</td>
</tr>
</tbody>
</table>
Appendix 2.2  Framework for observing and rating endoscopic non-technical skills

Overview

<table>
<thead>
<tr>
<th>Communication &amp; Teamwork</th>
<th>Situation awareness</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exchanging information</td>
<td>Preparation</td>
</tr>
<tr>
<td>Maintaining a shared understanding</td>
<td>Continuous assessment</td>
</tr>
<tr>
<td>Maintaining a patient-centred</td>
<td>Problem recognition</td>
</tr>
<tr>
<td>approach</td>
<td>Focus</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Leadership</th>
<th>Judgement &amp; Decision Making</th>
</tr>
</thead>
<tbody>
<tr>
<td>Supporting others</td>
<td>Considering options</td>
</tr>
<tr>
<td>Maintaining standards</td>
<td>Making decisions</td>
</tr>
<tr>
<td>Dealing with problems</td>
<td>Reviewing the situation</td>
</tr>
</tbody>
</table>

Acknowledgement

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St Mark’s Hospital
Wortford Road
Harrow, Middlesex HA1 3UJ
Tel: +44 (0)208 223 4225
Fax: +44 (0)208 423 3558
Appendix 2.3  Technical skills measurement tool (DOPS)

<table>
<thead>
<tr>
<th>Criteria</th>
<th>Score</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Formative Colonoscopy &amp; FS DOPS Assessment Form - JAG approved</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Colonoscopist: ..................................</td>
<td>Date .....././.......</td>
<td>Trainer / Peer: ..................................</td>
</tr>
<tr>
<td>• Major criteria</td>
<td>o Minor criteria</td>
<td></td>
</tr>
<tr>
<td>Scale: 4</td>
<td>- Highly skilled performance</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>- Competent &amp; safe throughout procedure, no uncorrected errors</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>- Some standards not yet met, aspects to be improved, some errors uncorrected</td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>- Accepted standards not yet met, frequent errors uncorrected</td>
<td></td>
</tr>
<tr>
<td>N/A</td>
<td>- Not applicable</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Assessment, Consent, Communication</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Obtains informed consent using a structured approach</td>
</tr>
<tr>
<td>- Satisfactory procedural information</td>
</tr>
<tr>
<td>- Risk &amp; complications explained</td>
</tr>
<tr>
<td>- Co-morbidity</td>
</tr>
<tr>
<td>- Sedation</td>
</tr>
<tr>
<td>- Opportunity for questions</td>
</tr>
<tr>
<td>• Demonstrates respect for patient's views and modesty during the procedure</td>
</tr>
<tr>
<td>• Communicates clearly with patient throughout, including the results of the procedure with appropriate management and follow-up plan</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Safety &amp; sedation</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Safe and secure IV access</td>
</tr>
<tr>
<td>• Gives appropriate dose of analgesia and sedation and ensures adequate oxygenation and monitoring of patient</td>
</tr>
<tr>
<td>• Demonstrates good communication with the nursing staff, including dosages &amp; vital signs</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Endoscopic Skills during insertion &amp; withdrawal</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Checks endoscope function before intubation</td>
</tr>
<tr>
<td>• Performs PR</td>
</tr>
<tr>
<td>• Maintains luminal view / inserts in luminal direction</td>
</tr>
<tr>
<td>• Demonstrates awareness of patient's consciousness and pain during the procedure and takes appropriate action</td>
</tr>
<tr>
<td>• Uses torque steering</td>
</tr>
<tr>
<td>• Uses distension, suction &amp; lens washing appropriately</td>
</tr>
<tr>
<td>• Recognises &amp; logically resolves loop formation</td>
</tr>
<tr>
<td>• Uses position change and abdominal pressure to aid luminal views</td>
</tr>
<tr>
<td>• Completes procedure in reasonable time</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Diagnostic &amp; Therapeutic Ability</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Adequate mucosal visualisation</td>
</tr>
<tr>
<td>• Recognises caecal/rectal colon landmarks or incomplete examination</td>
</tr>
<tr>
<td>• Accurate identification &amp; management of pathology</td>
</tr>
<tr>
<td>• Uses diathermy and therapeutic techniques appropriately and safely</td>
</tr>
<tr>
<td>• Recognises &amp; manages complications appropriately</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Case difficulty</th>
</tr>
</thead>
<tbody>
<tr>
<td>Extremely easy</td>
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<td>1</td>
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Learning objectives for next case:
### Appendix 2.4  Safety Checks framework (SC)

<table>
<thead>
<tr>
<th>Safety Check</th>
<th>4 Verbalises and checks with other</th>
<th>3 Verbalises only</th>
<th>2 Check without verbalising</th>
<th>1 No attempt to check</th>
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<tbody>
<tr>
<td>Staff introductions</td>
<td></td>
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<td>Patient identification</td>
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<tr>
<td>Procedure</td>
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<td>Indication</td>
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<td>Allergies</td>
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<td>Comorbidity</td>
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<td>Anticoagulants</td>
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<tr>
<td>Correct patient on reporting software</td>
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<td>Internal prosthesis</td>
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<td>Correct endoscope</td>
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<td>Samples and labelling</td>
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<tr>
<td>Correct report</td>
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<tr>
<td>Endoscopy recall</td>
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<tr>
<td>Opiate register</td>
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Appendix 3

Appendix 3.1  Colorectal cancer MDT rating tool and criteria for ratings scales

Rating tool

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<thead>
<tr>
<th>No.</th>
<th>Med notes</th>
<th>Start Time</th>
<th>Extra on list Y/N</th>
<th>Point in Rx</th>
<th>Med Hx</th>
<th>Radiology</th>
<th>Histopath</th>
<th>Psych-Soc</th>
<th>CCo morbidity</th>
<th>Pt views</th>
<th>Pt know Ca</th>
<th>MDT Chair</th>
<th>GI Surgery</th>
<th>GI Physician</th>
<th>Oncology</th>
<th>Nurse</th>
<th>Radiology</th>
<th>Histopath</th>
<th>MDT Coordinator</th>
<th>Liver surgeon</th>
<th>Decision Y/N/D</th>
<th>Trial Y/N</th>
<th>AE / near miss Y/N</th>
<th>Outcome</th>
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<tr>
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</tr>
</tbody>
</table>

Prompt notes: Notable absences, Leaves early, info needed from other sites, wrong MDT, on list inappropriately
### Appendix 3.2  Criterion for rating tool

<table>
<thead>
<tr>
<th>History</th>
<th>5</th>
<th>Fluent, comprehensive case history</th>
<th>Psycho-social</th>
<th>5</th>
<th>Comprehensive first-hand knowledge of pts personal circumstances, social &amp; psychological issues</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>4</td>
<td>Good case history</td>
<td></td>
<td>4</td>
<td>good knowledge of personal circumstances, social &amp; psychological issues – from letter</td>
</tr>
<tr>
<td></td>
<td>3</td>
<td>Partial case history</td>
<td></td>
<td>3</td>
<td>Vague first-hand knowledge or good second-hand knowledge of personal circumstances, social &amp; psychological issues</td>
</tr>
<tr>
<td></td>
<td>2</td>
<td>Case history very short</td>
<td></td>
<td>2</td>
<td>Limited</td>
</tr>
<tr>
<td></td>
<td>1</td>
<td>No patient case history</td>
<td></td>
<td>1</td>
<td>No knowledge of personal circumstances, social &amp; psychological issues</td>
</tr>
<tr>
<td>X-ray</td>
<td>5</td>
<td>Radiological Images</td>
<td>Co-morbidity</td>
<td>5</td>
<td>Comprehensive first-hand knowledge of past medical history or performance status</td>
</tr>
<tr>
<td></td>
<td>4</td>
<td>Images, but not all relevant/seen</td>
<td></td>
<td>4</td>
<td>good knowledge of past medical history or performance status – from letter</td>
</tr>
<tr>
<td></td>
<td>3</td>
<td>Radiological info from report/account</td>
<td></td>
<td>3</td>
<td>Vague first-hand knowledge or good second-hand knowledge of past medical history or performance status</td>
</tr>
<tr>
<td></td>
<td>2</td>
<td>Some but partial info</td>
<td></td>
<td>2</td>
<td>Limited</td>
</tr>
<tr>
<td></td>
<td>1</td>
<td>No provision of radiological info</td>
<td></td>
<td>1</td>
<td>No knowledge of past medical history or performance status</td>
</tr>
<tr>
<td>Path</td>
<td>5</td>
<td>Full Histopathological info from Pathologist</td>
<td>Patients views</td>
<td>5</td>
<td>Comprehensive first-hand knowledge of pts wishes or opinions regarding treatment</td>
</tr>
<tr>
<td></td>
<td>4</td>
<td>Partial info but not prepared</td>
<td></td>
<td>4</td>
<td>good knowledge of pts wishes or opinions regarding treatment – from letter</td>
</tr>
<tr>
<td></td>
<td>3</td>
<td>Histopathological info from report/account</td>
<td></td>
<td>3</td>
<td>Vague first-hand knowledge or good second-hand knowledge of pts wishes or opinions regarding treatment</td>
</tr>
<tr>
<td></td>
<td>2</td>
<td>Some but partial info</td>
<td></td>
<td>2</td>
<td>Limited</td>
</tr>
<tr>
<td></td>
<td>1</td>
<td>No provision of Histopath. info</td>
<td></td>
<td>1</td>
<td>No knowledge of pts wishes or opinions regarding treatment</td>
</tr>
<tr>
<td>Chair</td>
<td>5</td>
<td>Good leadership enhanced team discus &amp; decision making incl every1</td>
<td>Members</td>
<td>5</td>
<td>Clear contribution regarding specialty relevant to pt management</td>
</tr>
<tr>
<td></td>
<td>4</td>
<td>Good leadership enhanced team discussion &amp; decision making</td>
<td></td>
<td>4</td>
<td>Clear contribution regarding specialty</td>
</tr>
<tr>
<td></td>
<td>3</td>
<td>Leadership neither enhanced or impeded team discussion &amp; decision making</td>
<td></td>
<td>3</td>
<td>Contribution inarticulate or vague</td>
</tr>
<tr>
<td></td>
<td>2</td>
<td>Passive Chair</td>
<td></td>
<td>2</td>
<td>Partial contribution</td>
</tr>
<tr>
<td></td>
<td>1</td>
<td>Poor/inadequate leadership impeded team discussion &amp; decision making</td>
<td></td>
<td>1</td>
<td>No contribution</td>
</tr>
<tr>
<td>Point</td>
<td></td>
<td>Pre treatment Ca known</td>
<td>Decision</td>
<td></td>
<td>Clear decision about treatment(s) to be offered</td>
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<tr>
<td>A</td>
<td>Y</td>
<td>Yes</td>
<td>Y</td>
<td>Clear decision about treatment(s) to be offered</td>
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</tr>
<tr>
<td>B</td>
<td>N</td>
<td>No</td>
<td>D</td>
<td>Decision to defer to next MDT</td>
<td></td>
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<tr>
<td></td>
<td>D</td>
<td>Don’t know</td>
<td>N</td>
<td>No decision / decision unclear</td>
<td></td>
</tr>
</tbody>
</table>

283
Appendix 3.3  MDT Feedback Material

Enhancing CRC Multi-Disciplinary Team Function

MDT OBSERVATIONS FEEDBACK
FACILITATED DISCUSSION
IMPROVEMENT ACTION PLAN

Systems Approach

Technical
Data
IT
Patient Factors
Pathway
Disease complexity
Preferences
Non-Technical
Communication
Judgement
Decision
Teamwork

MDT Skills
Clinical data assimilation
Listening & communication
Organisational
Conflict resolution
Chairmanship & Leadership
Presentation
Reaching consensus
Managing hierarchy
Time management

NCAT MDT-FIT

MDT OBSERVATIONS FEEDBACK

Aims
- Determine if team factors affect MDT quality
- Patient sub-types: Sym / 2WW / Ter / BCS
- Capture MDT Patient Safety Incidents (PSIs)*

Study Overview

Rating tool Development
Quality improvement
Team observations
Feedback / Education

Identified Actions

1. Education - clinical, administrative & management
2. Reflection - feedback - quarterly
3. Documenting outcomes - clinician led live typing, outcomes document circulated
4. CD - data quality and accessibility of information
5. Checklist - for MDT entry
6. Communication - referrals / *care / patient
7. Chairmanship - roles & responsibilities
8. Patient list order - subgroups

Objective Measures

Each MDT
- Start and end time
- Full attendance
- Distractions

Each patient
- Clinical data
- Case note availability
- Clarity of decision
- Professional input
- Discussion time
- Clinical trials
- Patient safety incidents*

CRC MDT rating tool

(*Qualitative methods)
Preliminary results

- Pre Rx 256 post Rx 296
  - 270/350 (77%) medical notes available
  - Mean time per patient discussion 6 min 4 sec
    (range 5-18 min)

Information scores

<table>
<thead>
<tr>
<th>Data</th>
<th>History</th>
<th>Radiol</th>
<th>Path</th>
<th>Prosta</th>
<th>Genit</th>
<th>Urine</th>
<th>Patient</th>
<th>Venes</th>
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</thead>
<tbody>
<tr>
<td>Mean score (SD)</td>
<td>3.1</td>
<td>4.0</td>
<td>3.3</td>
<td>2.2</td>
<td>2.2</td>
<td>4.0</td>
<td>2.4</td>
<td>2.6</td>
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</tbody>
</table>

Mean scores of quality of clinical data:
- 1 = no information
- 5 = clear relevant information presented to team

Team scores

<table>
<thead>
<tr>
<th>Member</th>
<th>Chief</th>
<th>OR</th>
<th>Nurse</th>
<th>Radiol</th>
<th>Surgeon</th>
<th>Path</th>
<th>Prosta</th>
<th>Genit</th>
<th>Urine</th>
<th>Patient</th>
<th>Venes</th>
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<td>3.4</td>
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<td>3.4</td>
<td>3.4</td>
</tr>
</tbody>
</table>

Mean scores of quality of professional input:
- 1 = no input
- 5 = clear relevant contribution

Outcomes

- ‘What’s the patient been told?’
  - MDT does not know what the patient knows

Outcome results

<table>
<thead>
<tr>
<th>Variable</th>
<th>Category</th>
<th>Sym</th>
<th>pWHR</th>
<th>Ter</th>
<th>BCS</th>
<th>p-value</th>
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<td>Decision</td>
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<td>2%</td>
<td>2%</td>
<td>5%</td>
<td>0.20</td>
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<td>3%</td>
<td>7%</td>
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Outcome results

<table>
<thead>
<tr>
<th>Variable</th>
<th>Category</th>
<th>Sym</th>
<th>pWHR</th>
<th>Ter</th>
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<td>7%</td>
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<td>0.20</td>
</tr>
<tr>
<td></td>
<td>Yes</td>
<td>5%</td>
<td>3%</td>
<td>7%</td>
<td>5%</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Don’t know</td>
<td>3%</td>
<td>12%</td>
<td>5%</td>
<td>5%</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Trial</td>
<td>No</td>
<td>4%</td>
<td>6%</td>
<td>5%</td>
<td>5%</td>
<td>0.69</td>
</tr>
<tr>
<td></td>
<td>Yes</td>
<td>5%</td>
<td>3%</td>
<td>7%</td>
<td>5%</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PSA</td>
<td>Yes</td>
<td>82%</td>
<td>71%</td>
<td>78%</td>
<td>84%</td>
<td>0.39</td>
</tr>
<tr>
<td></td>
<td>No</td>
<td>82%</td>
<td>71%</td>
<td>78%</td>
<td>84%</td>
<td></td>
</tr>
</tbody>
</table>

No statistical differences between patient subgroups
# Appendix 3.4  Colorectal cancer MDT minimum data input

St. Mark’s Hospital Colorectal Cancer Mdt Patient List (Template)

<table>
<thead>
<tr>
<th>Patient ID</th>
<th>Pathway</th>
<th>Referrer</th>
<th>Endoscopy</th>
<th>Histology</th>
<th>Radiology</th>
<th>Surgery</th>
<th>Clinical Question</th>
<th>Presentation Comorbidity</th>
<th>Management</th>
</tr>
</thead>
<tbody>
<tr>
<td>462xxxxx</td>
<td>SYM</td>
<td>RJK</td>
<td>NA</td>
<td>Moderately differentiated mucinous rectal adenocarcinoma</td>
<td>Post op CT 19.1.15</td>
<td>TME for rectal Ca at 10cm</td>
<td>Review post op CT</td>
<td>Well post op</td>
<td>OPA RJK</td>
</tr>
<tr>
<td>A******</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>04.11.1950</td>
<td>A****</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>64y</td>
<td>A*******</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>514xxxxx</td>
<td>BCS</td>
<td>Histol / SSP STG</td>
<td>Colonoscopy 22.1.15</td>
<td>Moderately differentiated adenocarcinoma in rectal polyp</td>
<td>MRI requested for 3.04.15</td>
<td>NA</td>
<td>Rectal polyp cancer ? complete excision</td>
<td>Iron deficiency anaemia</td>
<td>OPA 1J</td>
</tr>
<tr>
<td>F*****</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td><em>Pt does not know Ca dx</em></td>
</tr>
<tr>
<td>T***</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>02.06.1955</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>60y</td>
<td>T****</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>H15xxxxx</td>
<td>2WW Gen Gastro OF</td>
<td>Colonoscopy 30.1.15</td>
<td>Polyp Histology 30.01.15</td>
<td>CTC 8.1.15</td>
<td>NA</td>
<td>?Lower GI Ca causing anaemia</td>
<td>IP Byrd ward Anaemia, CIBH, Weight loss epigastric pain IHD AF warfarin DM COPD</td>
<td>Chase OGD from Ealing Care of Elderly review</td>
</tr>
</tbody>
</table>
Key

- Pathway: Patient route to MDT: 2 Week wait (2WW) / Symptomatic (SYM) / Tertiary referral (TER) / Bowel Cancer Screening (BCS) / Complex Cancer (CCC) / Post operative

- Referrer / Cons: Clarify who put patient on to MDT (Radiology / Another MDT / Registrar etc.) and who is the responsible consultant if already assigned – this may not be known at referral and may be assigned at the MDT itself

- Results section: Referrer and MDT Coordinator to populate date of relevant investigations requiring review for current MDT

- Patient factors: Question for MDT and relevant medical history to be clear from requester, management plan to be confirmed at MDT
Appendix 3.5  Example of Pre-Intervention MDT outcome documentation
Appendix 3.6  Example of Post-Intervention MDT outcome documentation. (Sequential MDT discussions for the same patient)

Pathway - MDT
MDT Date: 15/05/2015.
History: Rectal bleed, lower abdo pain. PMH HTN, DM. Mobile and fit.
Name of Referring Doctor: AA.
Bleep/Contact number: AA.
Clinician Responsible: A ANTONIOU.
Lower GI.

Pathway - MDT Discussion
Pre-Treatment
Diagnosis - Primary site: STI (RECTUM).
T-Category: T3.
N-Category: N0.
V-Category: V0.
MDT Management Plan: MRI CRM not threatened. CT awaited. Re-discuss post CT, if not mets then for primary surgery. RHK to see.

Pathway - MDT
MDT Date: 22/05/2015.
Reason for MDT: REVIEW CTVC 21/5/15 ONLY (as per mdt ins 15/5/15).
History: Change in bowel habit. Rectal bleeding. Rectal lesion biopsies: features highly suspicious of adenocarcinoma.
Name of Referring Doctor: aa.
Bleep/Contact number: aa.
Clinician Responsible: A ANTONIOU.
Lower GI.

Pathway - MDT Discussion
Pre-Treatment
Diagnosis - Primary site: STI (RECTUM).
T-Category: T3.
N-Category: N0.
M-Category: M0.
V-Category: V0.

Pathway - MDT
MDT Date: 26/06/2015.
History: Rectal tumour seen at flexi-sigmoidoscopy at 10-15 cm.
Name of Referring Doctor: AA.
Bleep/Contact number: AA.
Clinician Responsible: A ANTONIOU.
Lower GI.

Pathway - MDT Discussion
Pre-Treatment
T-Category: T3.
N-Category: N0.
M-Category: M0.
V-Category: V0.

Post-Treatment
Surgery Type: Laparotomy for post-operative haemorrhage.
Surgery Date: 19/06/2015.
T-Category: pT3.
N-Category: pN1.
M-Category: M0.
R-Category: R0.
V-Category: V0.
Appendix 4

Appendix 4.1  Training leaflet and contents overview

Faculty

Dr Sivan Thomas-Gibson
Consultant Endoscopist
The Wolfson Unit

Dr Nick Sevdalis
Academic Psychologist
CPSSQ Imperial College London

Dr Adam Haycock
Consultant Gastroenterologist
The Wolfson Unit

Venue

The Royal College of Physicians
Council Chamber Room
11 St. Andrews Place
Regent’s Place
London
NW1 4LE
020 38751049
www.rcofmediondon.ac.uk
5 CPD Points
All queries to:
m.matharoo@imperial.ac.uk

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NHS Bowel Cancer Screening Programme

Safe Endoscopy Teams in BCS: Human Factors & ENTS

6th February 2011

Welcome:
0930 – 1000 Registration & Coffee
Pre-course questionnaire
1015 – 1045 Introduction

1045 – 1130: Safety in Healthcare & Bowel Cancer Screening
Objectives:
- Understand the wider context of safety in Healthcare
- Recognise the varied ‘roles’ in BCS Endoscopy
- Safety in high-risk industries
What are Human Factors & Non-Technical Skills (NTS)?
How safe is BCS Endoscopy? – Common misperceptions
1130 – 1140 COFFEE

1140 – 1240: Endoscopic Non-Technical Skills
Objective:
- Describe the components of Endoscopic Non-Technical Skills (ENTS)
What are ENTS & how do they translate to Endoscopy?
- Defining ENTS
Complex BCS situations
ENTS rating tool
1240-1320 LUNCH

1320 – 1420: Adverse Event Analysis
Objective:
- How to promote open learning from adverse event analysis
BCS Adverse Event examples & current practice
- What are the merits of a ‘systems’ approach in AE analysis?
Near misses, SUIs & Never Events

1420 – 1530: Enhancing Team Performance
Objective:
- Use the ENTS framework to evaluate Human Factors in BCS
- Discuss interventions such as Checklists, Briefings & De-briefings to enhance team safety
- Videos of BCS teams in action
Interventions: Checklists, Briefings & De-briefings

1530 – 1600: Evaluation & Coffee
Post course questionnaire
Safety Observations Proforma
Cost Evaluation

1600-1645: Brainstorm
Future developments for ENTS training
1700 Close
Appendix 4.2

Multiple Choice Questions

1. Approximately what proportion of all hospital inpatients, suffer an adverse event during their care?
   a. 0.1%
   b. 1%
   c. 10%
   d. 30%
   e. 50%

2. What percentage of medical errors is thought to be preventable by optimal care?
   a. 5%
   b. 10%
   c. 15%
   d. 20%
   e. 25%

3. Which is a ‘systems approach’ to incident analysis?
   a. The London protocol
   b. The Process model
   c. The Medical model
   d. The Person model
   e. The Outcome protocol

4. Which statement is true?
   a. Most clinical errors are the result of carelessness
   b. Most clinical errors are the result of systems failures
   c. Most clinical errors are unavoidable
   d. Most errors are due to a lack of individual skill
   e. All of the above
5. Checklists have not been proven to improve safety in:
   a. Wrong site surgery
   b. Aviation
   c. Central line insertion
   d. Endoscopic sedation
   e. All of the above

6. A BCS Endoscopy Safety Checklist should be led by:
   a. The SSP
   b. The endoscopist
   c. The unit manager
   d. The endoscopy nurse
   e. Any of the above

7. According to the London Protocol:
   a. Adverse events have multiple determinants
   b. Adverse events should always be reported to a national body
   c. Adverse events are never due to individuals’ errors
   d. All adverse events should be considered ‘never events’
   e. All of the above

8. Checklists are typically used in high-risk industries:
   a. Instead of individual checks on operators
   b. Because teams are often dysfunctional
   c. Because the evidence base to support them within healthcare is robust
   d. As they are a cheaper alternative to team training
   e. As an adjunct to other team and safety interventions
9. Which is the ideal method to assess non-technical skills scientifically?
   a. Direct observation by a trained nurse
   b. Direct observation by two trained assessors who jointly agree on a single assessment
   c. Direct observation by two trained assessors blinded to each other’s assessments
   d. Direct observation in a simulated environment
   e. None of the above

10. Four of the following are ‘never events’, identify the odd one out:
    a. Patient mis-identification
    b. Failure to monitor oxygen saturations
    c. Overuse of sedative agents
    d. Use of a reversal agent
    e. Misplacement of NG tube

11. Which statement is true for BCS patients?
    a. The risk of perforation following polypectomy is 1:1000 cases
    b. Post-polypectomy bleeding occurs in 1:50 patients
    c. A patient is likely to suffer an adverse event from a BCS episode in 1:200 cases
    d. Intra-procedural bleeding following a polypectomy, is not classified as an adverse event
    e. Current data suggests 1:40 patients who are FOBT positive will have a polyp

12. Which statement would be classified as an adverse event (AE) in BCS patients?
    a. An event that prevents completion of the procedure due to any cause’
    b. Hypoxia (saturations <90%)
    c. Stricture caused by an EMR site
    d. Bleeding requiring transfusion is a major AE
    e. A perforation which resolves with conservative management does not require a Root Cause Analysis
       (Source: NHS BCSP QA guidelines Feb 2011)
13. Which statement is correct?

a. Root Cause Analysis is designed to find out who is to blame for an adverse event

b. A Serious Untoward Incident (SUI) has the potential to cause harm and/or is likely to attract media interest

c. The ‘Swiss Cheese’ model for systems errors is named after a physician called Dr Eh Manntal

d. The occurrence of a ‘never event’ leads to (temporary) suspension of whoever is to blame until a full investigation has been completed

e. Reporting of an adverse event in BCS must be done by the lead screening Endoscopist

14. Which statement is true?

a. The lifetime risk of bowel cancer in the background population is 1:50000

b. The risk of bowel cancer in an FOBT positive patient is 5%

c. The risk of death from elective surgery is greater than the risk of a post-polypectomy perforation

d. The risk of missed lesions is greater in the left side of the colon due to diverticular disease

e. The risk of interval cancer following BCS colonoscopy is about 5%

15. What is key for the ‘Systems’ view of safety?

a. An individual doctor’s technical (i.e. psychomotor) skills

b. A team’s ability to work well together

c. An individual’s skills, the level of team working and the clinical environment

d. A junior nurse’s skills to speak up when witnessing a potential risk to patient safety

e. All of the above
16. Identify the correct statement:
   a. BCS lists are the safest in endoscopy due to the technical proficiencies of the endoscopist
   b. Safety in the endoscopy suite is mainly the responsibility of the endoscopist
   c. A failure in non-technical skills usually underlies an adverse event
   d. Technical problems are the most common source of error in endoscopy
   e. It is not necessary to report a problem in endoscopy if no harm came to the patient.

17. In order to minimise errors relating to BCS colonoscopy surveillance intervals, current guidelines suggest:
   a. The SSP should assist in sample retrieval to ensure correct processing of histology
   b. Polyps removed but not retrieved should not be counted in the adenoma count
   c. Polyps left in situ should be counted in the adenoma count
   d. The SSP should ensure that all polyps are labelled correctly with the polyp type and excision method
   e. Surveillance intervals are best determined by the size of the lesion at Endoscopy, rather than Histology which may not be able to determine completeness of excision

18. Which of the following is true regarding Endoscopic Non-Technical skills evaluation.
   a. The ENTS framework is based on expert opinion
   b. The ENTS framework contains a complete list of non-technical skills behaviours relating to endoscopy
   c. The ENTS rating scale is based on safety concerns regarding observed behaviours
   d. Ratings using the ENTS tool should be made at either a category or element level
   e. Assessments using the ENTS tool are based on general impressions of skill and performance
19. Which of the following is not a category within the ENTS framework?
   a. Communication and teamwork
   b. Planning and preparation
   c. Situation awareness
   d. Leadership
   e. Judgement and decision-making

20. To use the ENTS framework most accurately for assessment, it is advised that:
   a. Users should start rating individuals summatively
   b. Trainees should not be given a copy of the handbook
   c. Feedback should focus on supporting skills development
   d. Overall assessment should be based on global impressions of performance
   e. Focus should be on observation and making contemporaneous notes is not recommended
# Appendix 4.3 Safety Attitude Questionnaire

## Section 1

Please circle the number that best describes your level of knowledge for each item:

<table>
<thead>
<tr>
<th>What is your level of knowledge regarding:</th>
<th>Low</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>High</th>
</tr>
</thead>
<tbody>
<tr>
<td>Different types of error?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>Factors contributing to error?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>Factors influencing patient safety?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>Ways of speaking up about error?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>What should happen if an error is made?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>How to report an error?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
</tbody>
</table>

## Section 2

Considering your awareness of issues relating to error, please circle the number that best describes your personal view for each statement:

<table>
<thead>
<tr>
<th></th>
<th>Strongly Disagree</th>
<th>Disagree</th>
<th>Neutral</th>
<th>Agree</th>
<th>Strongly Agree</th>
</tr>
</thead>
<tbody>
<tr>
<td>I can better identify situations which could potentially lead to errors</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>I know what steps to take to ensure patient safety and prevent adverse events / errors</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>If an error occurs, I know how to investigate the causes in order to prevent it from re-occurring</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>I understand the role of human factors in error prevention</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>If I see potential of an error in my workplace I will know how to prevent it</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>I understand the factors which may result in wrong site procedures (e.g. OGD instead of Colonoscopy)</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>I know how to prevent wrong site procedures</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>I understand the factors behind drug errors</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>I know how to prevent drug errors</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
</tbody>
</table>
Section 3
Considering your own ability to influence patient safety, please circle the number that best describes your personal view for each statement:

<table>
<thead>
<tr>
<th>Statement</th>
<th>Strongly Disagree</th>
<th>Disagree</th>
<th>Neutral</th>
<th>Agree</th>
<th>Strongly Agree</th>
</tr>
</thead>
<tbody>
<tr>
<td>It is easier to find someone to blame rather than focus on the causes of error</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>I am confident about speaking to someone who is showing a lack of concern for patient safety</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>I know how to talk to people who have made an error</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>I am always able to ensure that patient safety is not compromised</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>I believe that filling in reporting forms will help to improve patient safety</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>I am able to talk about my own errors</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
</tbody>
</table>

Section 4
Considering your personal beliefs with regards to patient safety, please circle the number that best describes your own view for each statement:

<table>
<thead>
<tr>
<th>Statement</th>
<th>Strongly Disagree</th>
<th>Disagree</th>
<th>Neutral</th>
<th>Agree</th>
<th>Strongly Agree</th>
</tr>
</thead>
<tbody>
<tr>
<td>By concentrating on the causes of incidents I can contribute to patient safety</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>If I keep learning from my mistakes, I can prevent incidents</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>Acknowledging and dealing with my errors is an important part of my job</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>It is appropriate to challenge practices that compromise patient safety, even if they are well established</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>Being open and honest about the mistakes I make is acceptable at my place of work</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>Admitting an error I had made would led to just and fair treatment by management</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
</tbody>
</table>
Section 5
Considering your intention regarding patient safety issues, please circle the number that best describes your personal view for each statement:

<table>
<thead>
<tr>
<th></th>
<th>Strongly Disagree</th>
<th>Disagree</th>
<th>Neutral</th>
<th>Agree</th>
<th>Strongly Agree</th>
</tr>
</thead>
<tbody>
<tr>
<td>I will report any errors I make at my place of work</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>I intend to challenge any complacency I notice with regard to patient safety issues</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>I intend to clearly communicate my safety expectations to members of my healthcare team(s)</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>I will support any members of my healthcare team who are involved in an accident</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>I plan to inform my colleagues about the errors they make</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>I will intervene whenever I think a patient may be exposed to harm</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>I plan to make a point of learning from the mistakes of others</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
</tbody>
</table>

Section 6
Please circle the number that best describes your feelings for each statement:

<table>
<thead>
<tr>
<th>If I made an error I would expect to feel</th>
<th>Strongly Disagree</th>
<th>Disagree</th>
<th>Neutral</th>
<th>Agree</th>
<th>Strongly Agree</th>
</tr>
</thead>
<tbody>
<tr>
<td>Afraid</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>Ashamed</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>Guilty</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>Upset</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>I know who to inform of an error I have made</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>I am able to request a de-brief +/- support following a mistake I have made</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>I know whom to escalate a problem to when it arises during my Endoscopy list</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>Telling others about an error I made would be:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Difficult</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>Easy</td>
</tr>
<tr>
<td>Worthless</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>Worthwhile</td>
</tr>
<tr>
<td>Unacceptable</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>Acceptable</td>
</tr>
<tr>
<td>Unhelpful</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>Helpful</td>
</tr>
</tbody>
</table>

MCQs: 1c 2e 3a 4b 5d 6e 7a 8e 9e 10d 11d 12c 13b 14e 15c 16e 17d 18e 19b 20c
Appendix 5

Appendix 5.1  Endoscopy Safety Checklist (version implemented at time of checklist study evaluation)

<table>
<thead>
<tr>
<th>Time Out</th>
<th>Team introduction</th>
<th>☐ Yes</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Patient ID</td>
<td>☐ Yes</td>
</tr>
<tr>
<td></td>
<td>Correct screen on reporting software</td>
<td>☐ Yes</td>
</tr>
<tr>
<td></td>
<td>Correct procedure</td>
<td>☐ Yes</td>
</tr>
<tr>
<td></td>
<td>Indication</td>
<td>☐ Yes</td>
</tr>
<tr>
<td></td>
<td>Consent</td>
<td>☐ Yes</td>
</tr>
<tr>
<td></td>
<td>Monitoring (IV access / O₂ sats)</td>
<td>☐ Yes</td>
</tr>
<tr>
<td></td>
<td>Allergies</td>
<td>☐ Yes ☐ No</td>
</tr>
<tr>
<td></td>
<td>Comorbidity</td>
<td>☐ Yes ☐ No</td>
</tr>
<tr>
<td></td>
<td>Anticoagulants</td>
<td>☐ Yes ☐ No</td>
</tr>
<tr>
<td></td>
<td>Correct scope &amp; kit</td>
<td>☐ Yes</td>
</tr>
<tr>
<td>Sign Out</td>
<td>Samples &amp; labelling</td>
<td>☐ Yes ☐ N/A</td>
</tr>
<tr>
<td>End of procedure</td>
<td>Accurate report</td>
<td>☐ Yes</td>
</tr>
<tr>
<td></td>
<td>Follow-Up</td>
<td>☐ Yes</td>
</tr>
</tbody>
</table>

Name (Dr / Nurse).................................Date & Time...............................Signature.................................
### Appendix 5.2 Patient Checklist Questionnaire

#### The Wolfson Unit for Endoscopy
Endoscopy Safety Checklist: Patient Questionnaire

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

To what extent do you agree or disagree that…?
Please tick one box only for each statement

<table>
<thead>
<tr>
<th>Question</th>
<th>Strongly disagree</th>
<th>Neither agree or disagree</th>
<th>Strongly agree</th>
</tr>
</thead>
<tbody>
<tr>
<td>Q1 I want the safety checklist to be used if I have an endoscopy in the future</td>
<td>1  2  3  4  5  6  7</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Q2 Hearing staff discussing anticipated problems before my endoscopy made me anxious</td>
<td>1  2  3  4  5  6  7</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Q3 I’m worried that busy staff won’t complete the checklist correctly</td>
<td>1  2  3  4  5  6  7</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Q4 The checklist seemed like an unnecessary tick box exercise</td>
<td>1  2  3  4  5  6  7</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Q5 I found repeated checks irritating</td>
<td>1  2  3  4  5  6  7</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Q6 I assumed an endoscopy safety checklist like this had always been in place</td>
<td>1  2  3  4  5  6  7</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Q7 I trust endoscopy staff to take care of me without having to use the checklist</td>
<td>1  2  3  4  5  6  7</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Q8 Using the checklist made me feel safer</td>
<td>1  2  3  4  5  6  7</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Q9 I understand why I need to confirm my identity and the procedure I am having just before my endoscopy</td>
<td>1  2  3  4  5  6  7</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Q10 Errors during an endoscopy are less likely with the checklist</td>
<td>1  2  3  4  5  6  7</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Q11 The checklist undermines the competence of the endoscopy staff</td>
<td>1  2  3  4  5  6  7</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Q12 The checklist improved communication between staff in the endoscopy room</td>
<td>1  2  3  4  5  6  7</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Q13 I would like proof that the checklist was used for my endoscopy</td>
<td>1  2  3  4  5  6  7</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Q14 Checks repeated by the team actually doing my endoscopy, are preferable to relying on checks made by others</td>
<td>1  2  3  4  5  6  7</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Please turn over
Appendix 5.3  Patient Checklist Questionnaire

Section 2. Patient Safety in Hospital

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

To what extent do you agree or disagree that...?
Please tick one box only for each statement

<table>
<thead>
<tr>
<th>Question</th>
<th>Statement</th>
<th>Strongly disagree</th>
<th>Neither agree or disagree</th>
<th>Strongly agree</th>
</tr>
</thead>
<tbody>
<tr>
<td>Q15</td>
<td>I worry that I will come to unnecessary harm in hospital</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>Q16</td>
<td>The voice of patients should be used to identify areas for improvement in patient safety</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>Q17</td>
<td>It is best to leave decisions about patient safety to healthcare professionals</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>Q18</td>
<td>Given the opportunity, I would like to be more involved in efforts to reduce patient harm</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>Q19</td>
<td>I think that I could help to reduce errors in my care by being more involved</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>Q20</td>
<td>I have personally received care in the past that I felt was unsafe</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
</tbody>
</table>

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

Sex: Male / Female  Age: _____  Occupation: _________  Ethnicity: _________

Reason for endoscopy: ___________________________ Gastroscopy / Colonoscopy / Both (please delete)

How many previous endoscopies have you had?: _____

Have you ever experienced an error whilst receiving care in a hospital?: Yes/No

If yes, what happened? ____________________________________________

_______________________________________________________________ Date: _________
Appendix 5.4 Patient Checklist Questionnaire Covering Letter

Dear Patient (________________),

Thankyou for attending the Wolfson Unit for your recent endoscopy test.

We are constantly seeking to improve the service for patients and would be grateful if you could take 10 minutes to complete the enclosed survey.

As part of the safety checks for patients, we have introduced an ‘endoscopy safety checklist’. This is a set of final checks (such as your name and any allergies to medicines) in the endoscopy room just before the procedure is about to start.

We appreciate that you will have already been asked some of this information before the checklist. The analogy for the checklist is a set of final checks – similar to the final safety checks a pilot makes before taking off on an aeroplane.

Thankyou very much for your participation, your views are highly important and will help improve our service.

Dr. Manmeet Matharoo
Endoscopy Fellow
Appendix 5.5  Visual aids to promote checklist

DO THE CHECKLIST

YOUR ENDOSCOPY SUITE NEEDS

YOU
Appendix 5.6   Visual aids to promote checklist
ENDOSCOPY SAFETY CHECKLIST

Launching at The Wolfson Unit for Endoscopy

Patient safety FIRST

• When? 18th April 2012
• Who? All Endoscopy team members
• Why? Checklists stop medical errors
• How? Final safety checks with team before each procedure

Contact Dr Manmeet Matharoo m.matharoo@imperial.ac.uk / ext 3025 for further information/ training/ feedback on checklist use.