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An independent evaluation of the NHS Modernisation Agency's 'Modernising Endoscopy Services' project using routinely collected, service-related endoscopy data.

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An independent evaluation of the NHS Modernisation Agency's *"Modernising Endoscopy Services"* project using routinely collected, service-related endoscopy data

by

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Submitted to the University of Wales in fulfilment of the requirements for the degree of Doctor of Philosophy

Swansea University

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SUMMARY

Aim: To independently evaluate the NHS Modernisation Agency's "Modernising Endoscopy Services" (MES) project using routinely collected, service-related endoscopy data.

Methods: A random selection of 10 sites who had participated in the MES project (called MES sites) were compared to a random selection of 10 sites who were unsuccessful applicants for the MES project but had indicated their intention to redesign independently (called Non-MES sites). Data on *Referral numbers, Number of patients waiting, Number of lost appointment slots* and *Activity* were collected from all 20 sites for eight specific time periods ranging from January 2003 to April 2006 to evaluate the endoscopy services of MES and Non-MES sites and to compare both site types at specific points in time using various statistical tests. *Activity* data were validated where appropriate using an equivalent HES dataset. Details of innovations introduced were collected to explore possible trends.

Results: Data were not routinely collected by endoscopy units. NHS Trust datasets were subsequently included to ensure a full dataset for analysis. The accuracy of the *Activity* data was successfully validated. There were relatively few statistically significant results to report. Consequently, this study found that the MES project did not significantly improve the endoscopy services of the MES sites over time. It also found that there was no significant difference between the MES sites and the Non-MES sites in the improvement of their endoscopy services over time and that the Non-MES sites appeared to implement changes that led to improvements to their services, although they were not statistically significant.

Conclusions: Data was not routinely collected by most NHS endoscopy units participating in this study. Based on the data analysed, the MES project did not appear to have significantly improved NHS endoscopy services over and above what could have been achieved independently with only the intention to redesign.

DECLARATIONS AND STATEMENTS

A. This work has not been previously accepted in substance for any degree and is not currently being concurrently submitted in candidature for any degree.

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B. This thesis has arisen as a result of my own investigations, except where otherwise stated. Where correction services have been used, the extent and nature of the correction is clearly marked in a footnote(s).
Other sources are acknowledged by footnotes giving explicit references. A bibliography is appended.

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C. I give my consent for this thesis, if accepted, to be available for photocopying and for inter-library loan, and for the title and summary to be made available to outside organisations.

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CONTENTS LIST

LIST OF TABLES

LIST OF FIGURES

PREFACE

The work submitted within this thesis was undertaken within the remit of the "EvaluatiNg Innovations in Gastroenterology by the NHS Modernisation Agency" (ENIGMA) study (SDO 46/2003) based at the Centre for Health Information, Research and Evaluation (CHIRAL) in the School of Medicine at Swansea University. The author and the work contained in this thesis were entirely funded by the ENIGMA study.

The work in this thesis was done in isolation from the main ENIGMA study. The author was solely responsible for the design, implementation, analysis and writing up of this research and there was no external input from any member of the ENIGMA study. The author was asked to contribute two chapters to the final report of the ENIGMA study based on the work in this thesis.

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Secondly, I would like to offer my gratitude to the principal investigator of the ENIGMA study, Professor John Williams, for allowing me to investigate this additional avenue of data collection and analysis on behalf of the ENIGMA study which also allowed me to pursue this postgraduate qualification. I would also like to thank Judy, Emma and Anne, my colleagues on the ENIGMA study for their moral support over the last three years and I would like to acknowledge the statistical advice provided by Dr Wai-Yee Cheung. Additionally, I would also like to thank Caroline Brooks at the Health Information Research Unit based in Swansea University for providing me access to the HES datasets used in this study.

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PUBLICATIONS AND PRESENTATIONS ARISING

Publications

1. **Thorne, K.**, Hutchings, H.A., Elwyn, G. 2008 *Evaluation of the Two Week Rule: A Systematic Literature Review* Gut 57 (S1):A110.

2. **Thorne, K.**, Hutchings, H.A., Elwyn, G. 2008 *Analysis of the impact of the MES project by the ENIGMA project using service-related endoscopy data* Gut 57 (S1):A111.

3. **Thorne, K.**, Hutchings, H.A., Elwyn, G. 2008 *Unmeasured improvement work: The lack of routinely collected, service-related data in NHS endoscopy units in England involved in "modernisation"* BMC Health Services Research 8:20.

4. **Thorne, K.**, Hutchings, H.A., Elwyn, G. 2006 *The effects of the Two-Week Rule on NHS colorectal cancer services: A systematic literature review* BMC Health Services Research 6: 43.

Presentations

1. **Thorne K**, Hutchings, H.A., Elwyn, G, Williams, J.G. Oral presentation *"Evaluation of the impact of the Modernising Endoscopy Services (MES) project using routinely collected, service-related endoscopy data"* to be presented at the **HSRN / NIHR SDO Joint Annual Conference** at the Manchester University Conference Centre 4th – 5th June 2008.

2. **Thorne K**, Hutchings, H.A., Elwyn, G, Williams J.G. poster presentation *"Analysis of the impact of the MES project by the ENIGMA project using service-related endoscopy data"* presented at the **British Society of Gastroenterology annual scientific meeting** at the International Conference Centre, Birmingham 10th – 13th March 2008.

3. **Thorne K**, Hutchings, H.A., Elwyn, G, Williams J.G. poster presentation *"Evaluation of the two-week rule: A systematic literature review"* presented at the **British Society of Gastroenterology annual scientific meeting** at the International Conference Centre, Birmingham 10th – 13th March 2008.

4. **Thorne, K.** 2007 Oral presentation *"The availability of routinely collected, service-related endoscopy data from NHS endoscopy units"* presented at the international conference **"Exploiting existing data for health research"**, held at St Andrews, Scotland 18th – 20th Sept 2007.

ABBREVIATIONS LIST

Abbreviation	Full term
12m PPQ	12 month Post Procedure Questionnaire
12m PRQ	12 month Post Referral Questionnaire
A&E	Accident and Emergency
AfC	Agenda for Change
ANOVA	Analysis of Variance
BPR	Business Process Reengineering
BQ	Baseline Questionnaire
BSG	British Society of Gastroenterology
CD	Crohn's disease
CHI	Commission for Health Improvement
CI	Confidence Interval
CNS	Clinical Nurse Specialist
CQI	Continuous Quality Improvement
CRC	Colorectal cancer
CSC	Cancer Services Collaborative
CSC-IP	Cancer Services Collaborative Improvement Partnership
CT	Computerised Tomography
DHA	District Health Authority
DNA	Did not attend
DH	Department of Health
DTC	Diagnostic and Treatment Centre
EDA	Exploratory Data Analysis
ENIGMA	Evaluating Innovations in Gastroenterology by the NHS Modernisation Agency
ENT	Ear, nose and throat
EQ-5D	EuroQol – 5D
ERCP	Endoscopic Retrograde Cholangiopancreatography
EUS	Endoscopic Ultrasound
FOBT	Faecal Occult Blood Test
FS	Flexible sigmoidoscopy
FT	Foundation Trust

Abbreviation	Full term
GDP	Gross Domestic Product
GERD	Gastroesophageal Reflux Disease
GESQ	Gastrointestinal Endoscopy Satisfaction Questionnaire
GI	Gastrointestinal
GP	General practitioner
GRS	Global Rating Scale
GSRQ	Gastrointestinal Symptom Rating Questionnaire
HA	Health Authority
HES	Hospital Episode Statistics
HIRU	Health Information Research Unit
IBD	Inflammatory Bowel Disease
IBS	Irritable Bowel Syndrome
ID	Identification
IHI	Institute of Health Improvement
IT	Information Technology
JAG	Joint Advisory Group on Gastrointestinal Endoscopy
LGE	Lower Gastrointestinal Endoscopy
MDT	Multi-disciplinary team
MES	Modernising Endoscopy Services
MESPT	MESPT
MeSH	Medical Subject Headings
MREC	Multi-centre Research Ethics Committee
NAO	National Audit Office
NBAP	National Booked Admissions Programme
NBCSP	NHS Bowel Cancer Screening Programme
NCEPOD	The National Confidential Enquiry into Patient Outcome and Death
NE	Nurse Endoscopist
NHS	National Health Service
NHSMA	NHS Modernisation Agency
NHS SDO	National Health Service Service Delivery and Organisation
NIHR SDO	National Institute of Health Research Service Delivery and Organisation
NPfIT	National Programme for Information Technology

Abbreviation	Full term
OA	Open access
OGD	Oesophago-gastro-duodenoscopy
ONS	Office of National Statistics
OPCS	Office for Population Censuses and Surveys
PAS	Patient Administration System
PbR	Payment by Results
PCG	Primary Care Group
PCT	Primary Care Trust
PDSA	Plan Do Study Act
PPQ	Post Procedure Questionnaire
PSG	Project Steering Group
PUD	Peptic ulcer disease
QoL	Quality of life
R&D	Research and Development
RCT	Randomised Controlled Trial
SDO	Service Delivery & Organisation
SF-36	Short Form - 36
SHA	Strategic Health Authority
Sig.	Significance
T	Time
TIS	Trust Information Services
TQM	Total quality management
TWR	Two-Week Rule
UC	Ulcerative colitis
UGE	Upper Gastrointestinal Endoscopy

1. INTRODUCTION

The National Health Service (NHS) is currently Britain's biggest single employer with over 1.3 million staff (The Information Centre, 2006), each with immensely varied skills and responsibilities encompassing a wide variety of medical, administrative and managerial disciplines in primary, secondary and tertiary healthcare. The highly complex networks that exist within the NHS are all interconnected and co-dependent. Few organisations in the world today provide so many different services on demand, free at the point of entry (NHS Modernisation Agency, 2003a).

Unfortunately, over time the NHS became a victim of the ever-increasing demands for free healthcare from a population that is not only growing exponentially, but that has an increasing proportion of elderly people within it – the Office of National Statistics (ONS) has predicted that men aged 65 years will live a further 16.9 years and women aged 65 years, a further 19.7 years (Office of National Statistics, 2008) and Help The Aged recently reported that the proportion of people in the UK population aged 85 years and over in February 2008 was almost one and a quarter million, and this was projected to double within 20 years (Help the Aged, 2008). This, coupled with the increasing number of people of all ages with chronic illnesses, has placed an escalating financial burden on NHS resources that has been further exacerbated by the expansion of technological possibilities and scientific knowledge offering better, but more expensive diagnoses and treatments for patients. This forced the NHS to push its financial boundaries to breaking point just to maintain the most basic services on a nationwide level and has led to many patients effectively paying twice for access to good health services, once via their taxes and a second time for private healthcare as they elect to hasten their treatment at an additional cost.

Patients have become far more knowledgeable about their health, their rights and the treatments available and now expect free care from the NHS to encompass access to expensive procedures whilst also receiving an efficient service to treat their conditions quickly. These factors, along with the rising costs of healthcare, an increasingly elderly population and an increase in the prevalence of chronic diseases, have meant that the NHS long ago reached the point where it could no longer function efficiently using its limited resources and traditional working practices, some of which date back to its inaugural years.

The original, founding principles of the NHS may have been appropriate at one time but today they reduce its adaptive capacity (Plamping, 1998). The system was originally designed to deal with acute illness and cannot adequately cope with the demands from today's society. The increased burden on NHS services is already evident in the field of diagnostics. Between 1996/7 and 2003/4, the number of diagnostic scans increased by almost four million (14%), with an increase of 47% in the proportion of CT (Computerised Tomography) scans (Lewis and Appleby, 2006).

Many policies have been introduced over the years by governments to improve public confidence in the NHS but the same problems still persist 60 years on regarding how best to organise and manage it, how to fund it adequately, how to balance the conflicting demands and expectations of patients, staff and taxpayers, and how to ensure finite resources were targeted where they were most needed. Previous attempts at NHS reform have most commonly been politically-led and designed to ensure greater value for money (Ferlie, 1997). Improvement has always been difficult because the NHS provides a vast range of services at no cost, it creates its own demand via referrals from its own primary and secondary care staff and it was enormously difficult to measure its output and productivity. Another preventative factor was the national variability of the provision of healthcare services. There were no clear instructions on best practice and guidelines (where available) were open to interpretation to suit local needs, so hospitals were left to develop their own ways of working in order to meet variable local demand and key government targets with minimal budgets (Klein, 2001).

Prior to 1997, the NHS lacked sufficient investment, national standards and incentives to improve its performance. It had old-fashioned demarcations between staff, barriers between services, was over-centralised and disempowered its patients. Reform fatigue had become a feature of healthcare systems and many changes had either, at best, not realised their full potential or at worst, simply failed, termed "dynamics without change" (Hunter, 2004). Many smaller reforms became absorbed into a system that was enormously resistant to change.

Following their election victory in 1997, the New Labour government responded to the demands of the population for improved access to NHS services to overcome its inertia and win back public confidence. Improvement initiatives gained momentum but unfortunately, a successful improvement culture could not be created overnight. It would require lots of hard work and commitment from dedicated staff going through the laborious process of analysing systems and

implementing better ways of working. There was also the additional pressure of searching for a financial "breakeven" during the redesign process (Black, 2002) to lower the amount of investment required and to aid sustainability.

The *NHS Plan* initiated unprecedented levels of investment accompanied by a stipulation that new resources were not to be used to provide more of the same, or else they would not succeed in truly transforming the NHS (Department of Health, 2000c). The challenge was to use the investment provided and the resources already available to achieve real benefits for patients by modernising NHS services using radical redesign strategies. This would prove difficult due to the complex nature of the NHS organisation. Past reforms had assumed that change would occur in a linear or planned manner but NHS staff would need to abandon linear models, accept its unpredictable nature and become flexible, creative and autonomous in their responses to overcoming problems (Plsek and Greenhalgh, 2001), meaning that change(s) could be as much unplanned as planned (Ferlie, 1997).

The *NHS Cancer Plan* pledged to reduce death rates from cancer by improving the referral route from their General Practitioner (GP) to NHS diagnostic services, by shortening the time taken from diagnosis to treatment and through population screening to increase the cancer diagnosis rate, especially for those at an earlier stage of cancer who would be more responsive to treatment (Department of Health, 2000b). These improvements were funded with an additional £570 million per annum and invoked the implementation of a major redesign programme for NHS diagnostic services for the diagnosis and treatment of patients with cancer.

The NHS Modernisation Agency (NHSMA) was established in 2001 in accordance with the *NHS Plan* (Department of Health, 2000c) to introduce a unique approach to the implementation of redesign initiatives in NHS diagnostic services. It promoted closer relationships between NHS staff and the NHSMA specialist redesign teams to promote innovative thinking, to understand redesign theory and to drive modernisation forward with a view to making changes successful, diffusible and sustainable. They incorporated the need for a fundamental understanding of how the current service worked before attempting to improve it and introduced tools and guides for NHS staff to follow as they embarked on redesign projects. They also realised the benefits of providing funding with the specific remit of facilitating pre-agreed redesign plans due to the competition experienced by NHS departments in securing unmarked funding from the corresponding NHS Trust and various other sources. The Service Improvement Team was just one of the seven teams that sat within the

umbrella of the NHSMA. Its primary function was to support the delivery of improved access to hospital services and to provide patients with certainty and choice. They were involved in a number of successful redesign projects. The one relevant to this thesis was the "Modernising Endoscopy Services" (MES) project.

Prompt and ready access to NHS endoscopy services was vital to improve the diagnosis and treatment of patients with a suspected gastrointestinal cancers in line with NHS Cancer Plan targets (Department of Health, 2000b). The MES project assisted 26 NHS endoscopy units across England with the modernisation of their service using data collection software, unmarked financial aid and continuous advice and support from the NHSMA during their 12 month redesign phase that ran from January to December 2003. The MES project advocated the collection of high quality data pertaining to demand, activity and capacity using their data collection software so that sites could identify problematic areas in their services and plan effective redesign initiatives aimed at solving the problems at source. Data were also analysed by the endoscopy unit staff to measure the impact of their modernisation plans over time and were uploaded to the MES Project Team (MESPT) on a monthly basis for independent analysis.

The NHSMA did their own internal evaluation of the MES project using the data collected and written feedback reports to assess each site's ability to meet key service-related targets set by the project. The key findings of that evaluation were published in a report (NHS Modernisation Agency, 2004e). However, the report was subjective and only focussed on case studies of good practice, rather than presenting an unbiased report on the success and more importantly, the failures (if any) of each site in relation to each individual target set by the MESPT. An independent, objective evaluation was required to determine the true impact of the MES project on NHS endoscopy services.

That challenge was taken up by the EvaluatiNg Innovations in Gastroenterology by the NHS Modernisation Agency (ENIGMA) study as part of an independent, mixed-methods evaluation of the MES project. The study was set up in September 2003 and ran for just over four and a half years. The ENIGMA study based its evaluation on comparing a random selection of 10 sites participating in the MES project (designated MES sites) with a random selection of sites that were unsuccessful in their bid for the MES project but that went on to redesign their endoscopy services independently (designated Non-MES sites). Their evaluation was primarily focussed on patient

quality of life (QoL) scores, with secondary outcome measures that included interviews with NHS staff and patients, GP questionnaires and health economics data analysis.

However, one important aspect of the MES project was missing from the ENIGMA study - an evaluation using service-related endoscopy data, namely demand, activity and capacity data. The author of this thesis was the quantitative researcher of the ENIGMA study and was keen to explore this further. She argued that it should have been the focal point of the main evaluation of the ENIGMA study, given that the MES project advocated the collection and analysis of high quality endoscopy data. With this in mind, she elected to perform an independent evaluation using data variables based on those collected by the data collection software used by the MES project in the same study sites as were recruited for the ENIGMA study.

The aims of this study were (1) to ascertain whether the MES project had improved endoscopy services significantly over time in the MES sites and whether any changes were sustained over time, (2) to ascertain whether the Non-MES sites who had modernised their services independently of the MES project has successfully improved their endoscopy services and (3) whether there was a significant difference in the endoscopy services of the MES sites and the Non-MES sites at any time.

This evaluation was based on a comparison of the MES sites and the Non-MES sites using the statistical analysis of service-related endoscopy data to determine firstly, whether there was any significant difference in the data within each Site type (MES or Non-MES) over time and secondly, to determine whether there were significant differences between MES sites and Non-MES sites at any point in time. The service-related data used encompassed the number of referrals received, the number of patients waiting for a specific period of time, the number of lost appointment slots and the number of procedures performed. All of these outcome measures were collected for eight specific time intervals over a period of 40 months between January 2003 and April 2006.

This evaluation also described the availability of these datasets, along with a descriptive summary of the innovations introduced by each site over time as secondary outcome measures. Data collected for this study were tested for their accuracy by comparing them to an equivalent dataset from Hospital Episode Statistics (HES). In doing so, any findings reported by this study could be done so with a degree of confidence.

Based on the findings of this evaluation, conclusions were drawn regarding the impact of the MES project on both MES and Non-MES sites and any other issues that came to light during the course of the study.

This thesis is structured to provide a generic background of all the information relevant to this study before focussing in more specifically on specific aspects of the study background. Chapter 2 gives a broad descriptive account of past reforms in the NHS with an overview of any early changes followed by a more in-depth look at NHS reforms in the last decade under the leadership of the New Labour government. Since the list of reforms issued since 1997 by both government and local healthcare organisations are vast, this thesis focuses more specifically on describing, but not critically analysing, the reforms that may have affected this study in some way. Chapter 3 introduces some of the redesign concepts used by the NHSMA in the MES project, providing both their theoretical bases and, where possible, examples of their application into the NHS setting in the past. The chapter ends by describing many of the problems encountered by NHS staff when trying to redesign their services followed by the principles of how the NHSMA taught NHS staff to overcome them.

Chapters 4 and 5 describe conditions of the gastrointestinal tract and how they are investigated using endoscopies. In doing so, they illustrate the level of demand on NHS endoscopy services due to the range of conditions that can be diagnosed and often treated using endoscopies, and how important the procedure is for identifying cancers of the gastrointestinal tract. Chapter 6 contains a systematic literature review to comprehensively describe the history of NHS endoscopy services modernisation since 1997. It encompasses many aspects of service delivery (demand, activity, waiting lists, etc) to set the MES project into context.

Chapters 7 and 8 describe the MES project and the ENIGMA study in more detail prior to a comprehensive description of this study which is set out in Chapter 9 which details the research question, hypotheses being tested and why this study was so important.

Chapter 10 describes and discusses the data collection process undertaken for this study, whilst Chapter 11 describes and discusses how the data was validated by statistical comparison using an equivalent HES dataset. Chapter 12 describes the exploratory data analyses performed on data received from each study site prior to their aggregation into MES and Non-MES groups. All statistical analyses performed to address the research hypotheses listed in Chapter 9 are

comprehensively described and discussed. Chapter 13 describes and discusses the past innovation histories of each site individually and according to MES and Non-MES grouping to ascertain whether there was any pattern in which types of innovations were introduced and when.

Chapter 14 provides an overall discussion of the work in this thesis, summarising and linking all results with the research hypotheses, discussing the strengths and weaknesses of the study design, discussing the results as a whole and comparing the results with other similar studies. The chapter closes with a discussion of the implications of the findings followed by the overall conclusions and recommendations arising.

2. PAST NHS REDESIGN INITIATIVES

NHS reforms have been ongoing for many years, as unanticipated demands have resulted in spiralling financial and organisational pressures that were not comprehensively addressed by any political party in power at the time. Many initiatives have unsuccessfully attempted to modernise the NHS to a point where the organisation was able to operate efficiently without detriment to patients' health.

This chapter will introduce some of the key NHS reforms implemented since the establishment of the NHS in 1948, with particular focus on reforms introduced in the last decade since the New Labour government came to power.

2.1 Background

The NHS was launched on the 5th July 1948 by Aneurin Bevan, the then Minister of Health for the Labour government, following the passing of the National Insurance Act 1946 to create the welfare state recommended by the Beveridge Report (Beveridge, 1942). It was set up as a single organisation based around 14 Regional Hospital Boards and brought hospital, GP and community-based services out of isolation to work together for the first time in a three-tiered structure. The aim of this ambitious undertaking was to provide safe, effective, dependable healthcare for people, removing the financial barriers to accessing healthcare. However, within three years of its investiture, the NHS was forced to introduce some modest fees as a result of unpredicted, spiralling running costs caused by an unanticipated increase in demand. Prescription charges and fees for dental treatment and glasses were introduced by Hugh Gaitskell, the Chancellor of the Exchequer at that time, prompting Bevan to resign in protest (Socialist Health Association, 1951).

A variety of independent reports criticised the structure and performance of the NHS during the 1960s; The Porritt Report (1962) criticised the structure of the NHS into three tiers and recommended unification; the Cogwheel Report (1967) proposed specialist groupings that would arrange clinical and administrative medical work more logically and the Salmon Report (1966) made recommendations for developing the senior nursing staff structure and the status of the

profession in hospital management. The NHS responded with many new proposals such as the Hospital Plan (National Health Service, 1962), the standardisation of medical records (Ministry of Health et al., 1965) and changes in staffing structures (Ministry of Health et al., 1961). Better management became a priority and professional divisions were created with the aim of grouping medical staff by speciality to arrange clinical and administrative work more logically. A new GP contract was introduced by the British Medical Association, initiating a new system of payment to GPs based on the number of patients registered, a basic practice allowance and fees for services. The advent of Information Technology (IT) saw the first steps in computerisation of administrative processes and clinical budgeting in the 1970s.

Margaret Thatcher's Conservative government came to power between 1979 and 1997. At this time, advancements in technology had resulted in more complex procedures becoming available on the NHS. The original 14 Regional Hospital Boards in England were replaced in 1982 by 192 District Health Authorities (DHAs) in an attempt to cut back bureaucracy and improve efficiency (Oliver, 2005). In 1984, the NHS introduced a system of hierarchical general management based on recommendations by the Griffiths report (1984), which highlighted the lack of a clearly defined general management structure as a weakness in the NHS and recommended that all levels should have a single general manager or chief executive (Oliver, 2005).

The 1990's saw the Thatcher-Major administration enforce radical changes to the foundations of the way the NHS worked with the introduction of the Patients' Charter (Department of Health, 1991) and the Internal Market. The Patients' Charter set out ten non-legally binding patients' rights to care and seven aspirations for national standards of care. Standards for the Charter were set using measures of the processes of healthcare, rather than clinical quality. Hospital league tables were developed to show how individual NHS Trusts met Charter standards. The standards imposed became built into the NHS reforms, providing a benchmark of performance by which hospitals were judged.

The concept of an Internal Market was introduced in *Working for Patients* (Department of Health, 1989), which passed into law as the NHS and Community Care Act 1990 (1990). On the 1st April 1991, in the face of huge resistance from healthcare professionals, the NHS began the most significant cultural shift since its inception as the tripartite structure of hospital, community and GP services was breached. The aim was to introduce some market incentives into a centrally planned, hierarchical system while maintaining universal and free access to health services. At the heart of

this reform was the devolution of financial control to DHAs and fundholding GPs, who were allocated funds for purchasing a defined set of elective services from "providers" including NHS Trusts, private sector organisations and other providers. The purchaser-provider split was meant to encourage competition between providers for contracts to boost their block grant allocated by the Department of Health (DH), thereby improving performance and service delivery and reducing costs as money followed patients. NHS Trusts were encouraged to merge to achieve economic gains by pooling resources, creating specialist teams, enlarging the organisation in response to challenges from purchasers and facilitating the sharing of good practice (Fulop et al., 2002).

Overall, the effects of the Internal Market were quite limited because the essential conditions for a market to operate were never completely fulfilled, so the reform did not improve NHS services as much as was theoretically possible (West, 1998, Mays and Pope, 2000). However, variations in prices existed between providers for seemingly similar services, regardless of the rules that effectively fixed prices at average cost (Propper and Soderlund, 1998). The Internal Market did not increase the choice for patients regarding procedures or provider (Le Grand, 1999), nor did it reduce the wait for "non-purchasable" treatments (Propper et al., 2000). Not all GPs joined the fundholding scheme and inequality in service provision arose, as patients of fundholding GPs were often able to obtain "purchasable" treatment more quickly than patients of non-fundholding GPs (Propper et al., 2000). There was little overall change for good or bad as a result of the reforms (Glennerster, 1998, Le Grand, 1999). Only modest improvements in healthcare were reported and these improvements were insufficient to justify their higher cost (Audit Commission, 1996).

The failure of the Internal Market to reform NHS services resulted in a crisis of confidence in the quality of care received by patients (Enthoven, 2000a). A 1996 survey of 1354 people reported that 56% thought that fundamental changes in the NHS were needed, whilst 41% expressed dissatisfaction with the services (Mossialos, 1997).

More comprehensive descriptions of the early reforms implemented during the history of the NHS are available from other authors (Rivett, 1998, Ham, 2004), whilst Ferlie has published a review on large-scale organisational and managerial change in healthcare that covers the 1980s and early 1990s which can be referred to for further detail (Ferlie, 1997).

2.2 NHS reform in the last decade (1997 to 2007)

The election of the New Labour government in May 1997 brought with it a radical approach to modernising NHS services. Pledging the abolition of the Internal Market and GP fundholding, they encouraged an environment of cooperation rather than competition. The White Paper *A First Class Service: Quality in the new NHS* laid out a 10-year programme of modernisation that focused on eliminating the national variability in standards of service delivery and placed more importance on the quality of healthcare, rather than playing a numbers game (Department of Health, 1998). It was the first time that patients' needs had played a significant role in NHS reforms but it was a principle that would be the focus of NHS modernisation throughout New Labours' time in power.

The White Paper *The New NHS. Modern. Dependable.* promised a new model for a new century, based on six key principles covering access to care, maximising efficiency and improving the quality of patient care (Department of Health, 1997). To facilitate NHS modernisation, two NHS regulators were established - the National Institute of Clinical Excellence (NICE) (Rodgers, 2002) (now the National Institute for Health and Clinical Excellence) and the Commission for Health Improvement (CHI) (now the Healthcare Commission) – to pursue better quality, efficiency and consistency throughout the NHS (Walshe, 2002, Oliver, 2005).

During New Labour's first term in office, the NHS was introduced to the concept of the electronic patient record (NHS Executive, 1998a), the National Booked Admissions Programme (NHS Executive, 2000, NHS Modernisation Agency, 2003c, The National Booking Team, 2004) and clinical governance (Department of Health, 1998). In 1999 the government replaced GP fundholding with the compulsory membership of GPs, community nurses and Family Health Services Authorities in England into 481 Primary Care Groups (PCGs). These groups were set up by 99 newly established Health Authorities (HAs) to delegate the responsibility for commissioning the majority of local hospital and community health services to the local PCG using a unified budget, in accordance with Section 31 of the Health Act 1999 (1999). Once a PCG had shown a systematic approach to monitoring and developing clinical standards within primary care, they were allowed to evolve into Primary Care Trusts (PCTs) with greater clinical and financial responsibilities, slowly replacing the executive regional offices of the NHS and HAs. PCTs held their own budget and deployed resources according to the needs of their community. In effect, fundholding became universalised, putting GPs in the driving seat in shaping local health services in the future (Department of Health, 1997) in the hope that it would result in the most radical

change in NHS history: a service driven from the bottom-up, reflecting local rather than national priorities.

As the NHS entered the new millennium, the government published *The NHS Plan: A plan for investment. A plan for reform* (Department of Health, 2000c). Its vision was to offer people fast and convenient care delivered to a consistently high standard and available when people required it, tailored to their individual needs. The government offered extra investments to coincide with the *NHS Plan*, taking NHS funding from 6% to 7.6% of the gross domestic product (GDP), equating to an increase from just under £50 billion to almost £70 billion over a four year period (Ferriman, 2000). This cash boost was earmarked to finance the modification of existing services, designing new services, building new "superhospitals", buying new equipment, establishing links with the private healthcare sector and improving conditions for both staff and patients. However, this additional funding came at a price - tougher standards for NHS organisations to achieve, including reducing unnecessary hospital admissions, providing the correct number of beds, reaching high standards of working, eliminating demarcations, introducing more flexibility into staff roles, adopting best practice and applying a more systematic approach to treating patients with chronic diseases.

> *"We would spend money if, but only if, we also changed the chronic system failures of the NHS. Money had to be accompanied by modernisation; investment, by reform"*
> Tony Blair, Foreword of the NHS Plan (Department of Health, 2000c)

Following their commitment to cut death rates from cancer in people under 75 years of age by at least a fifth by 2010, as set out in their White Paper *Saving Lives: Our Healthier Nation* (Department of Health, 1999), the government initiated the biggest ever programme to replace and update screening, diagnosis and treatments for cancer. They released the White Paper *The NHS Cancer Plan: A plan for investment. A plan for reform* in July 2000, pledging that no one should wait longer than one month from an urgent referral for suspected cancer to the beginning of treatment except for good clinical reasons or through patient choice (Department of Health, 2000b). The plan promised additional expenditure in cancer services but reiterated the importance of this investment being accompanied by massive organisation-wide reforms to produce successful and sustainable services.

Following their second successful election in 2001, New Labour built on past policies with *Shifting the Balance of Power* (Department of Health, 2001b), which described more radical changes

planned for both the organisational structure and the services provided by many NHS organisations. This was followed in June 2004 by the *NHS Improvement Plan* which, as well as describing the successes of past reforms in line with previous targets listed in past white papers, also highlighted many more policies to be implemented between 2005 and 2008 (Department of Health, 2004c). It stated that the next stage for the NHS was delivering more care, more quickly through investment and reform; offering people more personalised care and a greater degree of choice and finally, greater concentration on prevention rather than cure. The targets for NHS reforms since 1997, when New Labour came into power, that are relevant to this thesis are described in more detail below.

2.2.1 Changing the way the NHS was structured

April 2002 saw the evolution of the 99 HAs in England into 28 Strategic Health Authorities (SHAs), each covering an average population of 1.5 million people. All local NHS organisations became part of a single structure and were accountable to their respective SHA. Their main functions included supporting PCTs and NHS Trusts in delivering government targets locally, building capacity and supporting performance improvement across all their local health agencies. Each SHA produced a local delivery plan for their health community detailing the actions local health services would undertake to meet the needs of their patients and ensuring that each local PCT participated in a wide-ranging programme of improvement. In 2006, the number of SHAs was reorganised as part of a cost-cutting exercise, reducing the number to 10.

Foundation Trusts (FTs) were first introduced in *Delivering the NHS Plan: next steps on investment, next steps on reform* with the aim of devolving NHS services away from central government to allow local ownership and accountability and an ability to tailor services to best meet the needs of the local community (Department of Health, 2002d). Eligibility to become an FT arose from achieving three-star status in inspections (see later). FTs were controlled and run locally rather than nationally, with the maximum devolution of power to local GPs and health professionals to innovate locally with minimal intervention from Whitehall. They benefited from substantial financial, operational and managerial autonomy, and were free to develop their board and governance structures to ensure more effective involvement of patients, staff, the local community and other key stakeholders, whilst still treating NHS patients according to NHS principles. Devolution of control would inevitably lead to national variability, but supporters believed that a

varying quality of NHS services nationwide was inescapable within such an immense healthcare system and highly variable regional demands.

The concept of FTs was met with hostility by many politicians who feared they would run up huge debts as a result of their financial autonomy. There was also concern at the potential for creating a two-tier system whereby the best hospitals received more money, resulting in inequalities in patient care nationwide, although there is no evidence that this has happened to date (Lewis, 2005). A review of FTs by the Healthcare Commission commented that many of the concerns initially expressed about FTs did not manifest and that they had shown significant achievements during their first year of existence (Healthcare Commission, 2005b). The independent regulator "Monitor" gave 31 of 32 FTs a clean bill of health in their 2005 report, commenting that they had generated a £20 million surplus over nine months (O'Dowd, 2006). However, these viewpoints were contradicted by Lewis who reported little evidence of any major improvements in quality of care and no particular advantage to patients (Lewis, 2005). There is a deadline of December 2008 for all NHS Trusts to achieve FT status but Mooney recently reported that at the end of 2007, there were still approximately 140 Trusts who had not yet met the criteria and for those who would never be financially viable, the only options included merger or closer (Mooney, 2007).

NHS walk-in centres have been introduced across England to improve the accessibility of healthcare to patients both in terms of location (there are no location-based restrictions) and availability (to reduce the time taken off work to seek medical advice). They reduce the demand on primary care and also maximise the role of nurses to allow doctors to apply their skills more appropriately (Salisbury, 2003). However, there is also evidence to the contrary suggesting that NHS walk-in centres do not have a significant impact on GP workload (Hsu et al., 2003).

The NHSMA was the third regulatory body to be established by the government. Its aim was to help local clinicians and managers redesign local services around the needs and convenience of patients. It was established in April 2001 and was made up of key stakeholders, health professionals, patients, frontline managers and public representatives drawn from high-performing NHS organisations on secondment, with regional teams based in regional offices and working closely with regional NHS staff. The NHSMA operated across all sectors of the NHS - primary care, secondary care, mental health and ambulance trusts - abiding by the major principles of quality, patient safety, leadership and workforce development. The NHSMA disbanded at the end of March 2005, although most of its literature was available at an online legacy repository

(www.wise.nhs.uk) until recently. A statement on the ex-NHSMA website (www.modern.nhs.uk) in March 2005 reported that the NHSMA would *"continue to act as a catalyst for change within the NHS, helping administrators and staff to improve working conditions and care outcomes"*.

On 1st July 2005, the NHS Institute for Innovation and Improvement superseded the NHSMA, heralding a new era of improvement and change for the NHS in England. Established as a SHA and based on the campus of the University of Warwick, its mission was to support the NHS and its workforce in accelerating the delivery of world-class health and healthcare for patients and the public by encouraging innovation and developing capability at the frontline.

2.2.2 Increasing NHS funding

The three main goals of healthcare reform were improved access and quality and reduced costs, with the issue of cost (or more accurately, the rate of increase in costs) as the driving force (Eddy, 1993). Three quarters of all health expenditure was spent on NHS staff wages (Black, 2002). Upwards pressures on costs from new technologies and rising public expectations collided with downwards pressures from economic recession and political unwillingness to increase taxes (McKee et al., 1998). Health professionals struggled daily to maintain processes with limited resources. Most funding allocated to the NHS was marked for specific use and while this ensured that the investment was correctly targeted, it meant difficulties in securing unmarked funding for lower profile, non-target-related improvements due to competition.

There was a commonly held view that high quality care was expensive, but this failed to recognise that poor quality care also generated unnecessary costs through the underuse, overuse and misuse of services (Department of Health, 1998, McLoughlin and Leatherman, 2003) as the NHS continued to fail to provide treatments that worked, persisted in giving failing treatments, enforced delays and tolerated high levels of error (Smith, 2001).

The government invested nearly 7% of its GDP on the NHS during its first term in 1997. In 2000, they announced plans to increase this to 7.6% by 2004, putting the UK in line with the European average (Ferriman, 2000). The Wanless Review was commissioned to assess the resources required for the NHS to continue to meet its core objectives and it recommended large increases in NHS investment (Wanless, 2002). When NHS services did not improve as fast as the investment, the government pledged that healthcare spending would reach 9.4% of the GDP by 2008

(Department of Health, 2002b). However, there has been concern that the Wanless review was used by the government to justify, rather than inform its spending plans (Oliver, 2005).

The aim of Payment by Results (PbR) was to provide a transparent, rules-based system for paying NHS Trusts (Department of Health, 2002f). Each case (admission) was grouped into a healthcare resource group according to the treatment carried out and the clinical condition of the patient. Then a fixed tariff was assigned to each healthcare group based on the national average cost of treatment in NHS Trusts in England (Dixon, 2004). It rewarded efficiency, supported patient choice and diversity and encouraged activity for sustainable waiting time reductions as Trusts were being paid per case rather than the existing block contract basis (Dixon, 2004). Importantly, this system ensured a fair and consistent basis for hospital funding rather than being reliant principally on historic budgets and the negotiating skills of individual managers. Under these reforms all providers were paid for the activity they undertook, so PCTs commissioned the volume of activity required to deliver service priorities from a plurality of providers on the basis of a standard national price tariff, adjusted for regional variation in wages and other costs of service delivery. It was hoped that this incentive structure would encourage extra activity and for expensive providers to reduce their costs to the average, allowing more care to be purchased within existing budgets (Lewis and Appleby, 2006). PbR was gradually implemented by PCTs from 2002/3 with the national tariff in place within five years.

2.2.3 Increasing NHS capacity

Most buildings used by the majority of NHS sectors were ill-equipped to meet modern requirements and house new technologies whilst facilitating an improvement in service delivery. Most small, local hospitals were unable to support medical training, accreditation and governance issues, whilst the larger hospitals were unable to cope with the increasing demand for beds and services.

The NHS Plan instigated the building of more than 100 new, state of the art hospitals for large NHS Trusts by 2010, 500 new one-stop primary care centres and more than 3,000 modernised GP centres (Department of Health, 2000c). The old ward system was phased out in favour of intimate bays or rooms for those requiring overnight stays. New hospitals had an increased capacity with an extra 7,000 beds, reducing "bed-blocking" and waiting on trolleys in Accident and Emergency (A&E) departments. However, the timescale needed to realise these improvements meant that the benefits were not seen nationwide for a considerable time. Also, whilst new buildings were necessary, they did not themselves contribute much to "health gain" (Black, 2002).

Prior to the *NHS Plan*, only a few medical areas had partnerships with the private healthcare sector, and these were only short-term. Until recently, over 95% of interactions between a patient and doctor took place in the public sector (Smith, 2005). The policies of Frank Dobson, the Secretary of State for Health between 1997 and 1999, discouraged cooperation between the NHS and the private sector, a decision that was later reversed by Alan Milburn in 2000 when he signed a concordat with the private sector encouraging the NHS to buy spare capacity and make thousands of extra beds available to the NHS whilst keeping the patients within the NHS system (Department of Health, 2000a). The government believed that the use of private providers did not undermine the principles of the NHS if care was still free to patients (Timmins, 2005a). Private hospitals came to be seen by the New Labour government not as their nemesis, but as their saviour (Smith, 2005) as they increasingly provided 'pay as you go' schemes for NHS patients with fixed tariffs for common surgical procedures. This provided an element of competitiveness with public healthcare services to encourage innovation (Smith, 2005).

Long before 2000, the NHS was buying in between 60,000 to 80,000 procedures from private providers at a cost of around £100 million, approximately 40% or more above the average NHS cost for each operation it bought (Timmins, 2005b). Rather than continue this financial drain, the government created a network of Diagnostic and Treatment Centres (DTCs) in 2002 to provide safe, fast, pre-booked surgery and diagnostic tests for patients to meet targets for reducing NHS waiting lists, to increase capacity, to optimise service efficiency and to maximise patient satisfaction (Department of Health, 2002c). DTCs have traditionally focused on medical specialities which have the highest hospital waiting lists, such as orthopaedics and ophthalmology. Some DTCs were NHS-run whilst others were run by independent sector providers (Department of Health, 2005b), manned by overseas staff to reduce the poaching of NHS staff (Timmins, 2005b). In 2005, the DH reported that approximately one billion pounds worth of additional diagnostic scans would be procured from independent sector DTCs to bolster NHS capacity (Lewis and Appleby, 2006). The throughput of patients at these centres was eight times higher than in an NHS hospital (Andalo, 2005) because DTCs could focus on acute elective procedures in a purpose-built unit with emphasis on patient choice and convenience and were not affected by knock-on effects from other departments. By Dec 2004, more than 120,000 patients had been treated in DTCs (Andalo, 2005). To date, independently-run DTCs have had a much bigger effect on NHS waiting lists than can be accounted for by the number of procedures they perform (Timmins, 2005a).

2.2.4 Improving NHS information technology systems

NHS clinical information systems such as the Patient Administration System (PAS) and the computer hardware used in most hospitals were antiquated, inefficient and often not networked within the department, let alone the hospital or Trust. This caused an unnecessary amount of duplicated administrative work for both medical and clerical staff, repeatedly entering patient details on individual systems rather than being able to access and edit a patient's records from any remote terminal. Many tasks were done using paper-based methods because it was often easier and quicker, a practice stemming from the traditional working culture of the old NHS that was often "kept alive" by technophobes, or the lack of funding to upgrade inadequate computer equipment and software.

The successful reform of the NHS required a radical revamp of the current information technology (IT) situation in all sectors so that initiatives such as electronic booking and electronic patient records (NHS Executive, 1998a) could be implemented. The National Programme for Information Technology (NPfIT) was established in October 2002 to facilitate the NHS-wide reforms planned by the *NHS Plan* in line with the DH strategic documents *Information for Health* (NHS Executive, 1998a) and *Delivering 21st century IT support for the NHS* (Department of Health, 2002a). New IT systems for the NHS delivered services faster and more conveniently for patients. The government invested a total of £450 million to support GPs being connected to NHSnet by 2002, access to electronic personal medical records by 2004, electronic prescribing of medicines by 2004 and the electronic booking of patient appointments by 2005. Many IT systems were networked with automated diagnostic equipment in the laboratory, linking directly to the electronic patient record so results were immediately available. In April 2005, NHS Connecting for Health was formed as an agency of the DH to continue the delivery of the NPfIT. More details regarding this agency can be found at www.connectingforhealth.nhs.uk.

2.2.5 Increasing staff numbers

In the late 1990s, there was a shortage of people training to enter the NHS. Job prospects for other healthcare workers were not attractive, with low pay, long hours and inflexible working patterns. The *NHS Plan* intended to increase staff numbers by an additional 7,500 consultants, 2,000 GPs, 20,000 nurses and 6,500 therapists (Department of Health, 2000c). More places at medical schools were made available and healthcare workers were offered more attractive salaries

and flexible schedules. To cover the deficit in the short term, suitably qualified nursing staff from foreign developed countries were recruited.

The numbers of nurses increased from 256,000 in 1997 to 291,000 in 2002 but the numbers of GPs and consultants did not increased anywhere near as fast (Smith, 2003). The NHS Information Centre reported increases by 2006 in hospital-based medical staff of over 29,000, in nurses of over 73,000, in scientific and technical staff of over 40,000, in GPs of over 6,200 and in managerial staff of over 15,000 – an overall increase of 27% in the total number of NHS staff from 1996 to 2006 (The Information Centre, 2006).

Newly qualified health professionals were a significantly different workforce to that of decades ago, with women making up more than 50% of doctors qualifying and many of those in post under the age of 40 (Allen, 2000). This modern workforce required flexibility and the opportunity to train within and outside their profession if they were to remain dedicated. Consequently, plans to introduce more flexible working conditions, research schemes for medical staff and childcare support for all NHS employees were implemented.

2.2.6 Improving staff morale

The most valuable resources in the NHS were its dedicated staff, yet the majority were underpaid and felt undervalued for their level of skills and responsibilities, resulting in poor staff morale. Many disheartened staff had already left NHS employment, leaving departments understaffed and the remaining staff bearing additional loads. The recruitment of ex-NHS staff proved difficult, with many not wanting to re-enter the service due to bad past experiences and poor pay and conditions (BBC news, 1999). There lack-lustre implementation of the NPfIT programme also resulted in poor morale in NHS staff (Hendy et al., 2005). There were also problems with many highly skilled healthcare professionals consistently working below their level of expertise. Consequently, scarce resources were wasted, care was more expensive and boredom and frustration occurred.

Reforms meant that employees were rewarded for their dedication with improved pay and conditions. They also found their roles expanding as they were subsequently trained for and entrusted with increasing responsibilities. This allowed the highly skilled health professionals to delegate some of their more routine tasks to other suitably trained but lower-ranking staff, freeing up their time and expertise to be applied more effectively on difficult cases. Consequently, the

traditional demarcation that had existed between groups of professionals decreased as they voluntarily combined their efforts and cooperated to implement changes worthy of benefits in the form of financial rewards or an improved quality of working life.

The Agenda for Change (AfC) was introduced in December 2004 by the DH to improve the way NHS staff were paid, their career structures and the terms and conditions of their employment (Agenda for Change Project Team, 2004). It covered more than one million people, harmonising their pay scales and career progression arrangements across traditionally separate pay groups to ensure fair pay and a clearer system for career progression. For the first time staff were being paid on the basis of the jobs they were doing and the skills and knowledge they applied to these jobs. This reform was underpinned by a job evaluation scheme specifically designed for the NHS. More detail regarding AfC can be found at the NHS Employers website at www.nhsemployers.org/pay-conditions/agenda-for-change.cfm.

2.2.7 Improving the patient experience

With public opinion of the NHS running low, NHS services needed to be reshaped around the needs and preferences of its patients, their families and their carers to provide convenient care delivered to a consistently high standard, available when required, and tailored to individual needs. In principle, NHS organisations aimed to serve patients but in practice, they did not always put the patients' needs before the convenience of the organisation. Employers, payers and providers, rather than patients, primarily influenced the way the healthcare system functioned (Berry et al., 2003). The relationship between service providers and patients was previously too hierarchical and paternalistic. The NHS was designed to meet the needs of patients as defined by the professionals delivering the services rather than responding to the demands articulated by patients (Klein, 2001). The public's freedom was reduced by being forced to pay excessive taxation for the NHS (Bradshaw, 2003). However, the public could not tell whether they were getting value for money.

At the heart of the new reform plans was the stipulation that patients should be at the centre of any improvement culture. Patient choice and empowerment were major features of the redesigned NHS and by 2005, non-negotiable appointment dates were replaced by multiple choices. Patients were provided with better quality information about their procedures, leading to a reduction in the number of patients failing to attend their appointments (Hardy et al., 2001). Patients also indicated

their wish to see changes to normal working practices such as the introduction of "out of hours" or weekend clinics (Feeney et al., 2005, Douglas et al., 2005).

Patients were empowered with more information about looking after their own health, their local health services and being given the right to choose their GP based on published information about GP practices. NICE published "patient-friendly" versions of its clinical guidelines and NHS Direct was established in 1997 as a telephone helpline that later evolved into an additional web-based information source at www.nhsdirect.nhs.uk. Patients were also given the right to see their medical records in accordance with the Freedom of Information Act 2000 (2000).

The National Booked Admissions Programme (NBAP) let patients choose and pre-book the date of their appointment or admission. The programme helped NHS Trusts redesign their booking systems, and also worked with health communities to develop electronic booking. An in-house questionnaire-based evaluation of the fourth wave of the programme by the NHSMA found that day case targets had been achieved, there had been an increase in the number of call centres and a significant decrease in non-attendance and cancellation rates (The National Booking Team, 2004). Patients had more choice, flexibility, information, awareness and control, whilst staff morale also improved as an indirect consequence.

The "Choice at six months" programme was introduced on a phased basis from April 2004 and became fully operational in September 2004. It offered the choice of alternative providers to those patients waiting over six months for elective surgery in cases where it was faster to offer an alternative provider than it was to continue waiting for the original hospital. It aimed to offer patients certainty and also encouraged service improvement as public and private providers competed to provide these services (Smith, 2005) in accordance with PbR regulations. Lewis and Appleby commented on two pilots for patient choice of provider and reported that 62% and 57% of patients took the opportunity to select an alternative provider (Lewis and Appleby, 2006), although these figures appear to be hugely inflated when compared to official DH figures – the national average was 20.7% for the period April 2004 to March 2005, with some individual regions reporting figures ranging from 3.1% to 48.4% (Department of Health, 2005a) – and a report by Taylor et al commented that most patients still opted for their local hospital (Taylor et al., 2004).

The "Choice at point of referral" initiative officially superseded "Choice at six months" in December 2005 and meant that patients needing elective treatment were offered a choice of four or five

hospitals once their GP has decided that a referral was required (Department of Health, 2006a). The choice included NHS Trusts, FTs, DTCs or GPs with a special interest operating within primary care. This initiative was independently monitored by the National Audit Office (NAO) in 2005, who highlighted the need for an electronic booking system known as Choose and Book to be in place by the end of 2005 (National Audit Office, 2005). They also commented that the estimated cost of the scheme (£122 million) would lead to increased efficiencies worth an estimated £71 million to offset these costs.

The recent 2007 National Patient Choice Survey by the DH reported that 43% of approximately 62,000 patients surveyed recalled being offered a choice of hospital for their first outpatient appointment, 38% were aware before visiting their GP that they had a choice (Department of Health, 2007). A major contributing factor when choosing a hospital was location or transport considerations for 72% of patients, followed by the reputation of the hospital (22%), waiting times (22%), cleanliness (22%) and quality of care (17%). A higher proportion of patients selected an independent provider for their first outpatient appointment compared with the corresponding 2006 patient survey (62% Vs 43%) (Department of Health, 2006c). Unfortunately, the report did not extend to cover the proportion of patients selecting local hospitals when given a choice, although the proportion who stipulated location as a selection criterion suggests that many patients would have selected their local provider.

2.2.8 Improving the quality of NHS services

The inherent lack of communication between and within NHS departments and sectors often resulted in patient information not being shared, often resulting in the duplication of tests or more worryingly, a lack of tests. Patients often saw a number of health professionals during the course of their "journey", many of who may not have liaised with each another, so they end up asking the patient the same questions, causing unnecessary stress and extending the patients' journey time.

Another problem regarding the quality of care received by patients was that it had never been clearly defined who runs a hospital: managers or consultants (Probert et al., 1999). Neither has been willing to take responsibility for improving patient care in a proactive manner, with both professional groups preferring a reactive rather than a proactive role by simply responding to problems as they occurred instead of designing quality into the patient pathway.

NHS organisations have now been given higher national standards of quality as targets for achievement by the government as a way of improving the quality of service delivery by the NHS. It was hoped that there would also be an increase in productivity and a decrease in waiting lists and waiting times prior to treatment. Clinical governance was introduced into all parts of the NHS to facilitate this (Walshe et al., 2000). It was defined as "*a framework through which NHS organisations are accountable for continually improving the quality of their services and safeguarding high standards of care by creating an environment in which excellence in clinical care will flourish*" (Scally and Donaldson, 1998). Clinical governance was to be the main vehicle for continuously improving the quality of patient care and developing the capacity of the NHS in England to maintain high standards (including dealing with poor professional performance). It required the NHS to improve the quality of clinical care according to professional performance, resource use, risk assessment and patient satisfaction (Scally and Donaldson, 1998)

Strategies for the improvement of delivery of healthcare at a national level included evidence-based practice, clinical effectiveness, evidence-based clinical guidelines and audits (Rycroft-Malone et al., 2002). At the heart of a scientifically grounded theory for improving healthcare was the premise that quality is a system property and that what primarily determined the level of performance was the design of a healthcare system, not simply the will, native skill or attitude of the people who worked in that system (Berwick, 2003). Berwick wrote, "*Every system is perfectly designed to achieve exactly the results it gets*" which he has called the First Law of Improvement. To get a better result required changing the system (Berwick, 2003).

The NHS was never particularly stringent in enforcing the collection, analysis and dissemination of information. Instruments for identifying persistent failure regarding standards of care were old-fashioned and inadequate. Following the Internal Market reforms, the value of comparative data as a basis for purchasing decisions was realised and there was a drive to improve the collection of valuable data in the NHS (Goddard et al., 2000). New redesign strategies established by the NHSMA used healthcare-based guides and data collection software to allow the effective analysis of their current working practices to identify persistent problems so that they could target redesign resources towards solving the real cause of the problem. Process mapping also became a key feature of redesigning NHS services, encouraging health professionals to look from the patients' perspective at a specific process from start to finish to identify where problems or delays occurred in patient flow so that they could effectively focus their redesign efforts on that area (Locock, 2001).

The evaluation of NHS services using these methods became even more important with the introduction of assessments and inspections in NHS Trusts by government agencies to evaluate their overall performance against key targets and to help them to identify areas in need of improvement. The first report on performance ratings (also known as star ratings) was published in 2001 on Acute Trusts (Department of Health, 2001a) followed by a report on all NHS Trusts in 2002 (Department of Health, 2002e). CHI took over the inspections for 2002/03 and the Healthcare Commission in 2004.

Thresholds were set and NHS Trusts could achieve, under-achieve, or significantly under-achieve these targets. Taken together with the key target measures, the measures of clinical, staff and patient focus constituted a "balanced scorecard" approach, allowing a broad range of areas to be measured within a single methodology and all NHS Trusts performances were scored using a star rating system. Trusts with the highest levels of performance were awarded three stars and were eligible to become FTs whilst Trusts with the poorest levels of performance were awarded zero stars and were actively guided through improvement by NHSMA specialist redesign teams.

The performance rating system later came under fire for flawed inspection criteria using absolute rather than relative figures for some measures, consequently biasing results against the larger Trusts (Barker et al., 2004), for having a scoring system that did not take into account the quality of care, only measuring in absolutes of either achieving or not achieving targets (Gulland, 2002) and for not reflecting the quality of clinical care provided by hospitals (Rowan et al., 2004). It was also blamed by senior NHS staff for a number of detrimental effects on NHS services including reducing staff morale and distorting clinical priorities (Mannion et al., 2005). Consequently, the Healthcare Commission announced in November 2004 that the performance rating system was to be abandoned and that from April 2005, a "health check" for the NHS would be introduced that included spot inspections and unannounced visits and measured against core standards in seven areas set by the DH, developmental standards and new national and local targets (Healthcare Commission, 2005a).

2.2.9 Reducing waiting lists

The length and number of waiting lists have been a constant problem for a range of NHS services. Martin et al reported that there were substantial numbers of patients waiting more than six months for selected elective treatments, although these figures were limited to a small number of hospitals (Martin et al., 2003). They also reported that measures of capacity did not appear to be associated

with prolonged waiting. However, it appears that since 1999, there has been a sustained decline in the total number of patients waiting for a procedure in the NHS (Lewis and Appleby, 2006). The *NHS Improvement Plan* outlined new government targets for the NHS, including a maximum wait of eight weeks from referral to treatment for cancer patients by the end of 2005 and aimed to improve on that achievement to accomplish a maximum wait of 18 weeks from GP referral to the initiation of treatment in hospital for any patient by December 2008 (Department of Health, 2004c). To support this target, a website was established to facilitate the reduction of waiting lists in a variety of specialist fields (www.18weeks.nhs.uk/public/default.aspx). Despite considerable scepticism from many within and outside the NHS that previous waiting time targets would not and could not be met, they have been mostly achieved (Lewis and Appleby, 2006). This, along with a new understanding of waiting lists and their origins, makes the likelihood of achieving the 18 week target by the end of 2008 a real possibility for most NHS services.

2.2.10 Implementing new ways of working

Working in teams was promoted not only within departments but across departments in the creation of multi-disciplinary teams (MDTs) (Firth-Cozens, 1998). They were made up of a variety of health professionals with different roles from a range of interacting specialties and were responsible for patient care. The evolution of MDTs allowed the improvement of care of patients compared to individuals working in isolation (Carter et al., 2003). Referral to MDTs was essential to provide adequate support and clear information from the time of diagnosis throughout the care pathway (Broughton et al., 2004).

Collaborative programmes created specific improvements in healthcare for patients based on evidence-based principles for spreading best practice. They brought together groups of professionals from different healthcare organisations to work in a structured way to improve just one aspect of the quality of their services within a specified time period (Ovretveit et al., 2002). The collaborative methodology employed within the NHS originated from the work of the Institute of Healthcare Improvement (IHI) in the United States, who launched the "Breakthrough Series" of collaborative programmes (Institute for Healthcare Improvement, 2003) to support local teams to make 'breakthrough' improvements in quality for patients while reducing costs. The driving vision behind it was that sound science existed on the basis of which the costs and outcomes of current healthcare practices can be greatly improved, but that much of this science was unused in daily work. Collaboratives have become more widespread throughout the NHS, examples of which

include the primary healthcare collaborative (Smith, 2001), coronary heart disease collaborative (Coronary Heart Disease Collaborative, 2005) and cancer services collaborative (CSC) (Robert et al., 2003).

This chapter has summarised some of the many reforms that the NHS has undergone in the last decade to achieve significant improvement in line with government targets. To do this, it had to adopt a "modernisation mindset" which was made possible, in part, by the establishment of the NHSMA who educated healthcare professionals in various redesign theories and facilitated their application into various aspects of the NHS organisation. The origins of the main theories introduced to NHS services by the NHSMA are discussed in the next chapter.

3. ORGANISATIONAL REDESIGN

Organisational redesign can be initiated either by force in response to a pressure, political or otherwise, or by the free will of staff based on evidence of successes in similar fields. In the NHS, many valuable cultural traits already existed and were not to be changed, such as the principles of the NHS, a commitment to care, etc., but it was also important to identify any potential for improvement or if resistance was commonplace.

Redesign aimed to change a "process" – a collection of activities that takes one or more inputs to create an output that added value to the customer (Hammer and Champy, 1993). In the case of the NHS, this referred to any processes where a patient was directly the input and was directly on the receiving end (the output) (Probert et al., 1999). When applied to healthcare, the term "redesign" did not necessarily mean the change or reorganisation of a system. It required thinking from scratch to design the best process by which to achieve speedy and effective care from a patients' perspective, identifying where delays, unnecessary steps or the potential for error were built into the current process and then removing them to dramatically improve the quality of healthcare (Locock, 2003).

NHS redesign had to challenge the "organisational treadmill", questioning whether some working practices needed to be done at all and causing staff to reconsider their whole approach to improving the quality of their services. A key element of this thinking was to place the patients' perspective at the heart of understanding the purpose and value of NHS service delivery. What redesign theories offered were helpful ways to identify, analyse and reconceptualise many problems so that an effective course of action could be planned. It did not in itself provide a set of transferable solutions, and changes in both funding and the use of existing resources were necessary to support the redesigning of processes. Continuous evaluation and reflection with participants helped refine peoples' understanding of how to approach change in different circumstances and what might or might not be useful strategies to test out, helping to generate a "family of answers" rather than a single formula for success.

The problem with directly applying industry-based redesign methodologies was that they used jargon not commonly encountered within the healthcare setting and it was difficult for NHS staff to apply these redesign techniques to an organisation as complex as the NHS. The NHSMA played an important role in "interpreting" these methodologies for application within the NHS, and then actively guided both managerial and clinical staff on their use.

The NHSMA synthesised many industry-based redesign theories into one simple format for dissemination to NHS staff. These theories included Business Process Re-engineering (BPR) (Hammer and Champy, 1993), Total Quality Management (TQM) (also known as Continuous Quality Improvement or CQI) (Deming, 2000), Lean Thinking (Womack et al., 1990, Womack and Jones, 1996) and the Theory of Constraints (Goldratt, 1994, Goldratt, 1984). Each is described in more detail in Table 1. All advocated a "customer-centred" approach to redesign, examined whole processes rather than single tasks or departments and aimed for dramatic improvements in quality (Locock, 2001).

3.1   NHS reforms using industry-based redesign methodologies

The four redesign theories discussed in this thesis have been implemented within a number of NHS Trusts, although peer-reviewed publications citing examples of their application were limited. Each is discussed in more detail below.

3.1.1   Business Process Reengineering

There are many reports from authors who claim to have re-engineered but closer scrutiny of their methodology shows that they have used the terminology loosely and have not applied true BPR as described in Table 1.

Of those true BPR redesign studies published, the most infamous was implemented in Leicester Royal Infirmary in the 1990s. Its transformation was not to the extent and pace intended at the start of the initiative, but service efficiency had improved marginally faster than a peer group of the same status during this time (McNulty and Ferlie, 2002). Two external evaluations of this BPR project came to the same conclusion (Bowns and McNulty, 2000, Brennan et al., 2005), and also reported cash savings and that improvements had been sustained (Bowns and McNulty, 2000).

	Business Process Reengineering (BPR)	Total Quality Management (TQM)
Methodology	- Process mapping to identify the current process from the customers' perspective. - Start from scratch in deciding the best way to completely redesign the process from a customer-centred perspective. - Conduct a comprehensive pilot of the new design using meticulous measurements. - Monitor activity and the results of any action continuously.	- The "Plan; Do; Study; Act (PDSA)" cycle. ⇨ **Plan** - Identify and evaluate all causes of a problem. ⇨ **Do** – Change a process to eliminate the problem. ⇨ **Study** - Measure the effects of the change. ⇨ **Act** - Make the change permanent. - Monitor activity and the results of any action continuously.
Criteria required for successful introduction	- Decisions are made at the level where the work is carried out. - Preserving the trust of employees. - Extensive use of benchmarking. - An aggressive BPR performance target. - Strong emphasis on IT. - Reward positive behaviour. - BPR at the top of the corporate agenda.	- Organisation-wide philosophy of quality as everyone's business. - Eliminating numerical quotas. - Giving workers respect and feedback about how they are doing their jobs. - Reporting errors / defects without fear of blame. - Creating a culture of open questioning and constant learning. - Concentrating on prevention, not correction.
Advantages	- Has a dramatic potential for radical, high quality improvements within an organisation in a short space of time (~1 year).	- Does not require total upheaval. - Has achieved successful improvement in many defined project areas. - Professional and departmental barriers are broken down.
Disadvantages	- Causes dramatic reductions in staff. - Has a high (50-70%) failure rate. - Is violent and aggressive in sweeping aside existing practices. - Failure destroys morale and momentum. - Is often at odds with organisational values. - Cannot be achieved by simply fine-tuning or fixing a process. - It is not advisable to expend energy across too many BPR projects. - Is best applied to organisations that "have nothing to lose".	- Produces only slow, incremental improvements over many years. - Changes are usually on a relatively small scale. - Lack of immediate results can raise doubts as to whether the investment of time and money is justified. - Little evidence of any organisation-wide impact. - Does not advocate creating novel, innovative solutions. - Promotes single-loop learning rather than multi-loop learning. - Focuses on cost efficiency that could limit the capacity and opportunity for innovation.

(Cont'd...)

	Lean thinking	Theory of Constraints
Methodology	- Understanding what value is and what activities and resources are necessary to create that value - everything else is waste. - Process mapping to identify all steps in the value stream for each product, eliminating where possible those steps that do not create value. - Making value-creating steps occur in tight sequence so product flow is smoother. - Letting customers pull value from the next upstream activity. - Aims for perfect value with no waste.	- Identify the system's constraint. - Decide how to exploit the system's constraint, since it determines system throughput. - Subordinate everything else to the decision made in step 2. - Elevate the system's constraint. - If a constraint has been broken, go back to the start. Anything that increases throughput at a bottleneck, almost without regards to cost, adds value to the system.
Criteria required for successful introduction	- Short cycle times of design, production, and delivery. - Dedicated leaders at every level of the supply chain.	- Constant evaluation of the process to identify new bottlenecks.
Advantages	- A lean environment will have sufficient capacity to handle variations without introducing queues. - A control system with a short feedback loop is far more effective than a long feedback loop at maintaining control of a process.	- Very low failure rates. - 99% of organisational constraints in a company are policies or lack of and management can resolve them. - There will always be a bottleneck but it allows the decision as to where it is best managed. - It recognises that the whole is much more than the sum of its parts.
Disadvantages	- Must be sustained long-term for performance improvement. - It may be possible to identify a better pathway but it may not be clear how to resource it. - As products move from one department to another, gaps can develop, especially if each department has its own set of performance measures.	- Removing one bottleneck will inevitably result in another forming at another point. - The location of bottlenecks is not obvious so rigorous analysis is necessary.

Table 1: A description of the main four industry-based redesign strategies, BPR, TQM, Lean Thinking and the Theory of Constraints, applied to NHS redesign programmes by the NHSMA.

BPR has also been successfully applied to the fields of patient admissions and the dermatology diagnostic patient process (Probert et al., 1999), trauma wards (Leverment et al., 1998, Nicholson, 1995), surgery (Casaletto and Rajaratnam, 2004), pharmaceutical care (al-Shaqha and Zairi, 2000), A&E and orthopaedics (Nicholson, 1995). The reported impact of BPR included saving money (Probert et al., 1999), better patient care (Probert et al., 1999, al-Shaqha and Zairi, 2000), the restructuring of wards and improved admissions procedures (Leverment et al., 1998), the improved hospital documentation, the reduction of duplications and rich data sources (Nicholson, 1995) and a reduction in procedure time (Casaletto and Rajaratnam, 2004). However, one study reported that it was not well received by the relevant health professionals (Leverment et al., 1998).

3.1.2 Total Quality Management

The implementation of TQM in the NHS is more widespread, but less well reported than BPR due to its less invasive characteristics. The more commonly published TQM-related texts are concerned with the evaluation of TQM application by independent bodies. These reports all comment on the success of TQM at a generic level throughout NHS Trusts (Joss et al., 1994) or when applied to specific targets such as outpatient clinics (Hart, 1996), orthopaedics (Bate et al., 2002) and risk management (Scholefield, 2007). TQM successes include improvements in the proportion of patients seen within 30 minutes, a goal set out in the Patients' Charter (Hart, 1996), a decrease in mean length of stay for patients (Bate et al., 2002) and reduced risks in accordance with National Patient Safety Agency guidelines (Scholefield, 2007).

One DH-funded study evaluating the introduction of TQM at a sample of NHS Trusts (Joss et al., 1994) also led to the publication of a paper listing the clear factors that predict the successful implementation of TQM (Joss, 1994).

3.1.3 Lean thinking

The NHSMA published *The big referral wizard - a guide to systems management in healthcare* in September 2002 to introduce Lean Thinking to NHS staff (NHS Modernisation Agency Demand Management Group, 2002). Since then, Lean Thinking has been widely promoted by the NHS Institute for Innovation and Improvement as a method of improving turnaround times and reducing waste. Case studies on the application of Lean Thinking are available on their website (NHS Institute for Innovation and Improvement, 2008). The DH has also published literature to educate NHS staff on the benefits of Lean Thinking (Department of Health, 2006b).

Very little peer-reviewed literature has been published describing the impact of Lean Thinking on NHS services to date. The only relevant reference retrieved referred to its successful application of in a medical photography department within Cardiff and Vale NHS Trust (Crompton, 2005).

3.1.4 The Theory of Constraints

The Theory of Constraints was introduced to three departments – Neurosurgery, Eyes and the Ear, Nose and Throat (ENT) – at Radcliffe Infirmary in Oxford in 1997 to reduce waiting lists and improve patient throughput (Lubitsh et al., 2005). Successes were reported for Eyes and ENT but none for Neurosurgery, possibly due to the self-contained nature of Eyes and ENT departments and the fact that they were not subject to emergency referrals, whilst Neurosurgery was far more complex and relied on other diagnostic services.

Another study at the Oxford Radcliffe Hospitals NHS Trust focussed on the inability of their A&E services to meet the four hour turnaround targets because they were unable to move patients from one kind of care to the next (Goldratt, 2002). The implementation of the Theory of Constraints significantly improved their services as it led to the development of dynamic buffer management and treating the discharge practice as a complex, multi-project environment.

3.2 Problems with redesigning NHS services

The traditional working culture of an organisation may reflect what worked well in the past but equally, it may equally reflect a reluctance to change, either because of a lack of impetus or due to the fear of making things worse. The rules and regulations vital for safe and effective healthcare sometimes constrained redesign attempts. Some traditional working practices were based on rules that either no longer existed or were someone's personal interpretation of a guideline that remained unquestioned by management.

Healthcare workers operated in a fishbowl characterised by high expectations, deep personal commitment, and a low tolerance for error (Berwick, 2003). The weight of both political and public expectation made redesigning NHS services a difficult challenge. Most redesign strategies can work if managed effectively and given the necessary time, but they rarely live up to the dramatic claims made for them in the early stages of their promotion. Staff often became disheartened when evidence and benefits of successful change did not emerge in a short period of time, and keeping them motivated became more difficult.

Health professionals have no prior training in the design or management of radical changes needed to improve healthcare (Leach, 2001). Prior to the NHSMA, no clear advice or guidance had been published for inexperienced NHS management on how to effectively modernise NHS services to meet government targets efficiently and effectively on a nationwide level. Most redesign guides were targeted at redesign within the industrial sector and used complex jargon that health professionals were not familiar with. With no guidance on the best ways to redesign services, past attempts at reform were usually based on a safe, minor reorganisation of services as opposed to the radical, "starting from scratch" approach promoted by the NHSMA. Also, many changes were directed at solving one particular problem and did not address the process as a whole. Health professionals had been left to their own devices when it came to making the most of their resources to meet targets, resulting in a wide variety of working practices across the country and a two-fold difference in the cost of care between the best and the least efficient hospitals (Enthoven, 2000b).

Organisations do not change unless the people within them do (Killigrew, 2002). If NHS Plan targets were to be achieved, the number of staff actively involved in redesign needed to increase, but most were not keen to take on redesign challenges due to a history of unsuccessful reform causing low morale. Less than 15% of all NHS staff were actively involved in improvement activities prior to the publication of the NHS Plan (NHS Modernisation Agency, 2002a). There had been no personal or departmental incentives during past reform attempts, which led to a lack of ownership, failure of the redesign project and lack of motivation to support any future changes. Past improvements to strengthen management to increase efficiency created resentment amongst healthcare professionals who perceived it as a threat to their status and autonomy (Klein, 2001), believing that decision-making had become managerialised and hence, deprofessionalised (Ferlie, 1997). The improvement of healthcare required an increased emphasis on team working (Firth-Cozens, 1998), but the issue of professional trust also came to the foreground (Berwick, 2003). Professional demarcations between staff types needed to be tackled if team working was to result in effective modernisation.

Scepticism of redesign plans among key individuals (clinical and managerial alike) negatively affected the implementation of new practices and often manifested at the practical level as resistance. The causes of scepticism were complex and interconnected and included emotional, intellectual and organisational objections to change. The following reasons for scepticism towards

redesign have been identified (Leach, 2001, NHS Modernisation Agency, 2002a, Gollop et al., 2004):

- Bad presentation of information about the nature, purpose and significance of the redesign, leaving staff confused and unconvinced of the benefits.
- Perceiving that the redesign attempt has been politically inspired, or is a "top-down" management initiative.
- Believing that other competing priorities should take precedence.
- Believing that the change will not be beneficial to staff, patients or the organisation.
- Fearing that the change will be threatening to the individual's status and power.
- Dislike of the jargonistic language and theory associated with industry-based redesign initiatives.

On a positive note, scepticism can also highlight potential pitfalls, add an influx of energy to the change process, encourage searching for an alternative (and possibly superior) method and help to balance the pressure for change against the need for stability (NHS Modernisation Agency, 2002a).

A successful change can only truly be classified as such if it is capable of being naturally spread through the organisation and more importantly, sustained in the long term. However, the NHS has not been good at learning from itself in the past, with examples of good practice often not replicated in the same hospital, let alone the next town (Coombes, 2003). Successful reforms often exhibited an "Island of Improvement" effect, remaining confined to their department of origin and were often not applicable elsewhere, and/or an "Improvement Evaporation" effect if the reform was not continuously managed.

3.3 Overcoming the problems of redesigning the NHS

The principle underlying the new NHS reforms was "what counts is what works" (Goddard et al., 2000) i.e. retaining what works and discarding what doesn't. Healthcare systems cannot be reformed with single initiatives - multifaceted strategies are needed and even then, it needs to be acknowledged that some parts of the initiative may still fail (Smith, 2003).

The NHSMA introduced a unique approach to the implementation of redesign initiatives in the NHS. They promoted close relationships between NHS staff and their own specialist redesign teams to drive changes forward with a view to making them successful, sustainable and diffusible. They also incorporated the need for a fundamental understanding of how the current service worked before attempting to improve it and they introduced tools and guides for NHS staff to follow as they embarked on modernising their services. They also realised the benefits of providing some unmarked funding with the specific remit of facilitating pre-agreed redesign plans due to the difficulties faced by most units in securing this type of funding from NHS Trusts.

The NHSMA were guided by the Principles of Modernisation: Renewal – more modern buildings and facilities, new equipment and more staff; Redesign – services delivered in a radically different (but better) way; and Respect – a culture of mutual respect between politicians and the NHS, between different groups of staff in the service and between the NHS and the public (NHS Modernisation Agency, 2003a). In order to redesign healthcare services effectively, the NHSMA strongly advised seeing the whole of the patients' journey from the patients' perspective and giving frontline staff the time and the tools to tackle any problems. The complexities of applying any redesign strategy to the NHS were further confounded by the fact that there were often no suitably qualified individuals in post in the NHS to oversee their implementation. To address this, the NHSMA published guides geared towards both clinical and management professionals, as well as providing support and advice on demand.

Using the same successful evidence-based approaches applied to the industrial sector, the NHSMA blended the strengths of various redesign strategies whilst adapting them for use in NHS organisations. They combined the radical redesign concept and the value of "quick wins" from BPR with the incremental testing on a small scale using measurable data advocated by TQM, the process mapping techniques of Lean Thinking and the identification of constraints described by the Theory of Constraints.

Decisions on the leadership of a redesign project were made internally by NHS staff and not by the NHSMA, based on staff and resources available. Sometimes it was clinical professionals who assumed overall responsibility, while in other cases it was a management-based person with an interest in facilitating change, designated a "change agent". Both types of leader had advantageous qualities: clinical leads were well respected and better at connecting with and motivating their departmental staff, usually due to their common goal of improving the department,

whereas change agents tended to have more of the skills required to properly manage a redesign project, using more evidence-based ideas and being more conscious of the financial situation, impacts on other departments and other redesign projects within the hospital. No one position was better at leading redesign projects than the other – the best leader was usually the one with a strong belief that they could change anything they wanted (Smith, 2001).

Once a leader for the project was assigned, a redesign team was assembled consisting of both clinical and management staff from the frontline and all departmental staff were required to participate on some level. The redesign team had the day-to-day responsibility of setting up the project, implementing the changes and monitoring the results, whilst the leader posed as a "figurehead" for the project, acting as a catalyst for the redesign process and using their authority to overcome any barriers to change, political or financial.

Examination of the existing system was essential to identify problematic areas and then focus redesign efforts where they were most needed. It usually encompassed taking baseline (pre-redesign) measurements of demand, capacity and activity for a specific period of data collection at the 'raw' data level, to be analysed and evaluated by the redesign team. This would highlight any problems in the system. Many redesign tools and guides were available for performing this type of analysis but most were aimed at industrial organisations and many could not be applied to the NHS.

The NHSMA designed their own improvement guides (NHS Modernisation Agency, 2002d, NHS Modernisation Agency, 2002b, NHS Modernisation Agency, 2002c, NHS Modernisation Agency, 2002e, NHS Modernisation Agency, 2004b, NHS Modernisation Agency, 2004c, NHS Modernisation Agency, 2004a) and used data collection software called "Toolkits" designed specifically for use by inexperienced NHS staff for the examination of specific processes within areas of healthcare including endoscopy (NHS Modernisation Agency, 2003b) and radiology (NHS Modernisation Agency, 2003d).

Process mapping was implemented for analysing the patient journey during their time in the department. A specific process was selected and defined from starting point to finishing point and all members of staff within the department described the patient process from their perspective to allow a map of a patients' real journey to be drawn, ideally from the patient's perspective, and identifying all staff involved at each step and their roles. Timings of each step were necessary to

identify delays. Process mapping was a powerful tool for convincing staff to embrace change because it could successfully highlight unnecessary but engrained practices, the number of different staff a patient may see during their journey, any duplication in tasks, inadequate staffing levels and the inappropriate tasks being done by highly skilled professionals.

Once the baseline data collection and analysis was complete, and the problems were identified, the next step was to develop new ways of working that would solve those problems. The goal for redesign was based on what would be a "perfect" experience for patients. When all staff in the unit were involved in the redesign effort and asked for their opinions and ideas, it was thought that they would feel a sense of ownership of the changes and would be more motivated to help facilitate change.

It was vital that any successful modernisation initiatives were also sustainable, or else redesign efforts would have been wasted and staff morale would suffer. Changes also needed to be manageable but there had to be lateral thinking to look beyond existing processes to address the whole process. It was also important that the impact of the redesigns were measurable using consistent and accurate data in order to detect any positive or negative effects. The redesign team needed to consider all possible consequences of their redesign plans, both positive and negative, within and outside the department being redesigned. However, in complex and dynamic organisations such as the NHS, redesign plans could never anticipate everything.

Small scale testing of any redesign ideas was important to determine whether they had achieved the desired outcome, whether there were any unforeseen problems and whether they were financially and willingly sustainable for the foreseeable future. This was usually done using PDSA cycles taken from the Model for Improvement©, advocated by the IHI. Control charts monitored improvements by plotting data collected against theoretically achievable and sustainable targets. Small variations were acceptable, but if the data went beyond the upper or lower process control limits, action was necessary. Data collection could be used as evidence of successful improvements, helping to gain the interest and acceptance of staff as they saw demonstrable benefits, although it was unrealistic to assume a radical transformation overnight.

One specific aspect of NHS modernisation covered by the NHSMA was the modernisation of NHS endoscopy services in England. This focussed on the need to diagnose and treat patients with gastrointestinal (GI) complaints, especially those presenting with suspected GI cancers, in

56

accordance with the targets set by the *NHS Cancer Plan* (Department of Health, 2000b) and later on, the *NHS Improvement Plan* (Department of Health, 2004c). The next chapter explains the types of GI conditions that patients referred to an NHS endoscopy unit may be investigated for, as well as describing the way the service commonly operated.

4. CONDITIONS OF THE GASTROINTESTINAL TRACT

The human GI tract begins at the mouth and ends at the anus and is responsible for the intake and digestion of food, and the excretion of any remaining waste products. In a normal adult male, the GI tract is approximately 6.5 meters long and is split into the upper GI tract (mouth, pharynx, oesophagus, stomach and duodenum) and the lower GI tract (the small and large intestines, rectum and anus). The GI tract is prone to many acute and chronic health problems, both cancerous and non-cancerous. This chapter discusses the more commonly diagnosed disorders of the human GI tract in more detail.

4.1   Cancers of the GI tract

GI cancers usually begin as a benign growth known as an adenomatus polyp (or adenoma), that are formed as the result of uncontrolled cell division in the GI mucosal cells following damage to the cell nuclei. Some of these may later develop into adenocarcinomas – cancers of the GI mucosal tissues. The reason(s) for the development of a polyp into a malignant tumour are not known but may include diet, a genetic predisposition, age or DNA damage leading to abnormal apoptosis (programmed cell death). The organs of the GI tract possess a high capability of continuous tissue regeneration in response to acute or chronic disorders, largely maintained by a stable pool of peripheral stem cells that are tightly regulated in their proliferative capacity and give rise to a pool of highly proliferative progenitor cells (Neureiter et al., 2006). It is abnormalities with these cells that can lead to some GI cancers. The three most commonly occurring GI cancers in the UK are oesophageal cancer, stomach (or gastric) cancer and colorectal cancer (CRC). Each of these will be described in more detail below.

In oesophageal cancer, the lining of the oesophagus changes into either squamous cell carcinomas or adenocarcinomas, depending on their location. Approximately 74% of patients with oesophageal cancer present with dysphagia as the growing cancer obstructs the passage of food (Enzinger and Mayer, 2003), often leading to a significant amount of weight loss prior to diagnosis. Chest pain or retrosternal discomfort can occur in patients who have oesophageal spasm, again from irritation by the tumour. A larger tumour can erode the wall to the point where it causes

bleeding, noticed either when the patient vomits or with blackening of the stool. Oesophageal cancer is thought to be a multifactoral disease but may develop from oxidative damage caused by factors including smoking, alcohol and inflammation caused by conditions such as oesophagitis. All of these factors can increase cell turnover, possibly instigating the carcinogenic process (Enzinger and Mayer, 2003). McCabe and Dlamini have published a review of the molecular genetics and candidate genes thought to be associated with the development of oesophageal cancer (McCabe and Dlamini, 2005).

Stomach cancer, also known as gastric cancer, generally occurs when cells of the mucosa or submucosa (the lining of the stomach) grow uncontrollably and form adenocarcinomas. Studies suggest that genetic predisposition, alcohol, diet and smoking are part of a complex interaction that forms the cancer (Hohenberger and Gretschel, 2003, Catalano et al., 2005). Some gastric cancers have also been linked to *Helicobacter pylori (H. pylori)* infection during childhood (Hohenberger and Gretschel, 2003). Patients do not tend to be symptomatic at the early stage of the disease and at later stages the symptoms are often still non-specific and hard to diagnose (Catalano et al., 2005). The vast majority of patients present with vague complaints such as upper abdominal discomfort or indigestion, loss of appetite, occasional vomiting, flatulence, belching, or fullness (Catalano et al., 2005). Other symptoms such as vomiting blood or dysphagia are less common.

The majority of CRC tumours begin when normal tissue in the colon wall forms an adenomatous polyp, or pre-cancerous growth projecting from the colon wall. As the polyp grows into a tumour, it may bleed or obstruct the colon, causing symptoms including bleeding from the rectum visible in the stool or toilet after a bowel movement, a change in bowel habit, cramping pain in the abdomen, and iron deficiency anaemia (Majumdar et al., 1999, Hay, 2002). The incidence of CRC differs according to the region of the bowel (see Figure 1). CRC symptoms can vary according to whether the carcinoma is on the left or the right of the colon (Baig and Marks, 2000), but tend to include symptoms such as rectal bleeding, a change in bowel habit or a rectal mass. The cause of CRC is not known but there is evidence to suggest that diet, smoking and a genetic predisposition to the disease can greatly increase the relative risk for a person (Midgley and Kerr, 1999), as well as the age of the individual, with 95% of CRCs presenting in patients aged over 50 (Baig and Marks, 2000).
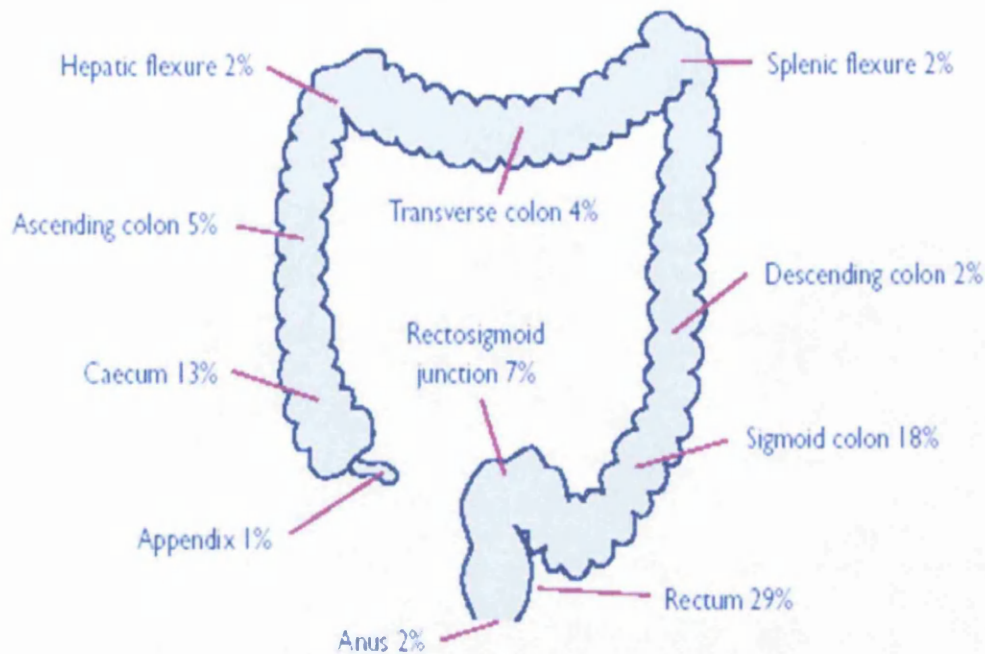
Figure 1: Percentage distribution of CRC cases by site within the large bowel, England 1997 to 2000.
Illustration taken from Cancer Research UK website at info.cancerresearchuk.org.

4.1.1 GI cancer incidence

There is an increase of between 1.4% and 2% per year in the number of people who will be diagnosed with a cancer because of better screening and diagnoses, and our ageing population (Department of Health, 2004b, Bosanquet and Sikora, 2004).

According to the ONS, the incidence of oesophageal cancer has increased since 1995 (see Figure 2). Cancer Research UK incidence reports ranked oesophageal cancer as the ninth most common cancer in 2004, accounting for 3% of all cancers diagnosed in 2003 (excluding non-melanoma skin cancer) (Cancer Research UK, 2008a). Table 2 gives the number of newly diagnosed cases of oesophageal cancer in the UK in 2002/04, along with an age-standardised incidence rate, split according to gender and country. Males had the highest incidence rate overall. When examined according to country, the incidence rate was highest in Scotland (17.9 for males and 7.4 for females) and lowest was in Northern Ireland (11.2 for males and 4.5 for females). A recent study by Moller *et al* estimated the number of oesophageal cancer cases to increase from 2001 to 2020 by 58% for males and 21% for females (Moller et al., 2007).
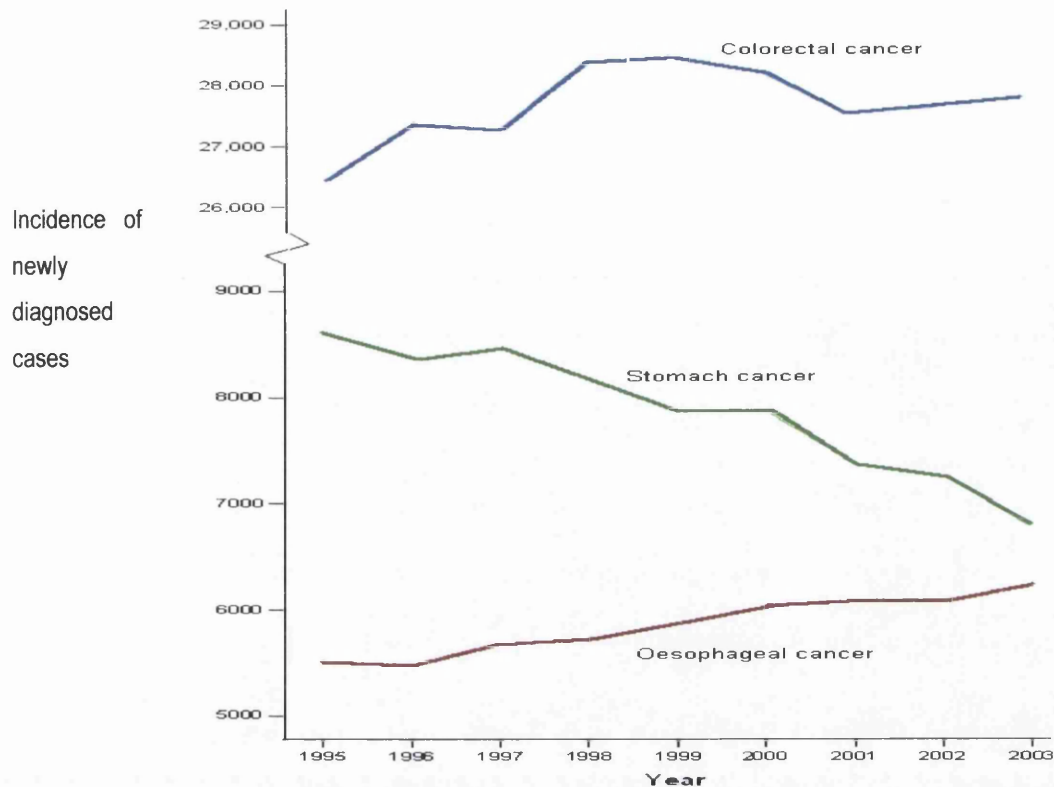
Figure 2: Incidence of newly registered cases of the three most common GI cancer types in England between 1995 and 2003. SOURCE: ONS (accessed Jan 2006).

Site description	Sex	UK		England		Wales		Scotland		N Ireland	
		No.	Rate	No.	Rate	No.	Rate	No.	Rate	No.	Rate
Oesophagus	M	4,817	14.0	3,953	13.7	257	13.9	515	17.9	92	11.2
(C15)	F	2,760	5.6	2,225	5.4	166	6.3	315	7.4	54	4.5
Stomach	M	5,422	15.3	4,408	14.8	345	18.2	521	18.0	148	17.5
(C16)	F	3,103	6.2	2,472	5.9	212	7.9	332	7.8	87	7.2
Colorectal	M	18,773	53.7	15,336	52.2	1,087	57.9	1,851	63.7	499	59.6
(C18-C20)	F	15,622	33.7	12,754	32.8	870	35.2	1,562	38.9	435	39.1

Table 2: Newly diagnosed cases of cancer and directly age-standardised[1] incidence rates per 100,000 population from GI cancers (according to ICD-10 codes). Selected sites by gender and country, UK, 2002-2004[2] ([1] Using the European standard population, [2] All numbers and rates in this table are calculated as three-year averages) SOURCE: ONS (accessed Sept 2007).

The incidence of stomach cancer has decreased over the last few years (see Figure 2). Cancer Research UK also reported that the incidence of stomach cancer fell from the sixth most common cancer to be diagnosed in 2000 to eighth in 2004 (excluding non-melanoma skin cancer) (Cancer Research UK, 2008a). Table 2 gives the number of newly diagnosed cases of stomach cancer in the UK in 2002-04, along with an age-standardised incidence rate, split according to gender and country. Males had the highest incidence rate overall. When examined according to country, the incidence rate was highest in Wales (18.2 for males and 7.9 for females) and lowest was in England (14.8 for males and 5.9 for females). Moller *et al* estimated that the number of stomach cancer cases will increase from 2001 to 2020 by 6% in males but that there will be a 7% decrease for females (Moller et al., 2007).

The incidence of CRC has risen and fallen over the last few years and is currently on the increase again (see Figure 2). Cancer Research UK also reported that in 2004, CRC incidence was ranked in third place, accounting for 13% of all cancers diagnosed that year (excluding non-melanoma skin cancer) (Cancer Research UK, 2008a). Table 2 gives the number of newly diagnosed cases of CRC in the UK in 2002-04, along with an age-standardised incidence rate, split according to gender and country. Males had the highest incidence rate overall. When examined according to country, the incidence rate was highest in Scotland (63.7) for males and in Northern Ireland (39.1) for females. The lowest was in England (52.2 for males and 32.8 for females). Moller *et al* estimated an increase from 2001 to 2020 in colon cancer cases by 32% for males and 12% for females and in rectal cancer cases by 52% for males and 35% for females (Moller et al., 2007).

4.1.2 GI cancer mortality rates

Cancer Research UK recently reported that oesophageal cancer was the fifth most common cause of cancer-related death in the UK in 2002 and 2003, accounting for 5% of all cancer-related deaths (Cancer Research UK, 2008b). Table 3 gives the number of deaths from oesophageal cancer in the UK in 2002-04, along with an age-standardised mortality rate, split according to gender and country. Males had the highest mortality rate overall. When examined according to country, the mortality rate was highest in Scotland (16.9 for males and 6.5 for females) and lowest was in Northern Ireland (12 for males and 4 for females).

Cancer Research UK also reported that stomach cancer was the seventh most common cause of cancer-related deaths in 2002 and 2003 (Cancer Research UK, 2008b). Table 3 gives the number of deaths from stomach cancer in the UK in 2002-04, along with an age-standardised mortality

rate, split according to gender and country. Males had the highest mortality rate overall and when examined according to country, the mortality rate was highest in Scotland (12.7) for males and in both Wales and Northern Ireland (5.5) for females. The lowest was in England (10 for males and 4.2 for females).

Cancer Research UK reported that CRC was the second most common cause of death by cancer in the UK in 2002 and 2003 (Cancer Research UK, 2008b). Table 3 gives the number of deaths from CRC in the UK in 2002-04, along with an age-standardised mortality rate, split according to gender and country. Males had the highest mortality rate overall. When examined according to country, the mortality rate was highest in Scotland (28.5 for males and 16.5 for females) and lowest was in England (23.1 for males and 14.1 for females).

Site description	Sex	UK		England		Wales		Scotland		N Ireland	
		N°.	Rate	N°.	Rate	N°.	Rate	N°.	Rate	N°.	Rate
Oesophagus	M	4,660	13.4	3,813	13.1	255	13.7	491	16.9	100	12.0
(C15)	F	2,617	5.1	2,124	4.9	153	5.6	289	6.5	51	4.0
Stomach	M	3,766	10.4	3,061	10.0	235	12.1	371	12.7	99	11.5
(C16)	F	2,322	4.4	1,863	4.2	154	5.5	234	5.2	71	5.5
Colorectal	M	8,496	23.9	6,932	23.1	498	26.1	839	28.5	228	27.2
(C18-C20)	F	7,412	14.4	6,087	14.1	407	14.5	724	16.5	194	16.2

Table 3: Deaths from cancer and directly age-standardised[1] mortality rates per 100,000 population from GI cancers (according to ICD-10 codes). Selected sites by gender and country, United Kingdom, 2002-2004[2] ([1] Using the European standard population, [2] All numbers and rates in this table are calculated as three-year averages) SOURCE: ONS (accessed Sept 2007).

4.1.3   GI cancer survival

The results of the Eurocare-3 study show that all three cancer types have a low one-year and five-year survival rate in the UK compared to the European average (see Figure 3) but recent data from ONS indicated that survival rates are gradually increasing, more so for cancers of the colon and rectum that for upper GI cancers (see Table 4) (Eurocare-3, 2006).
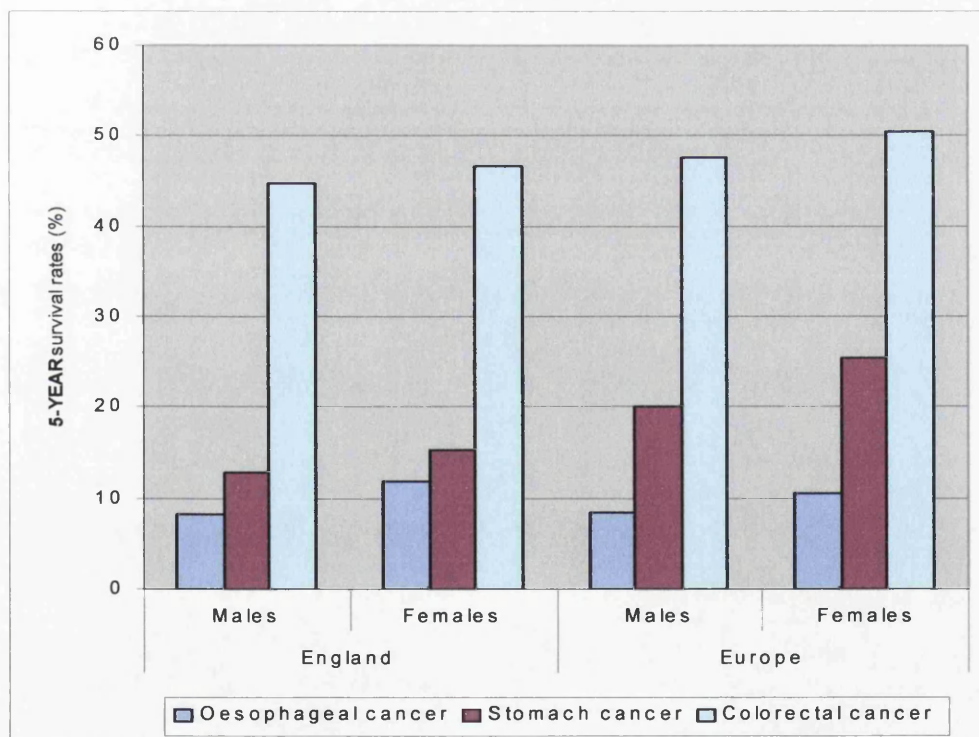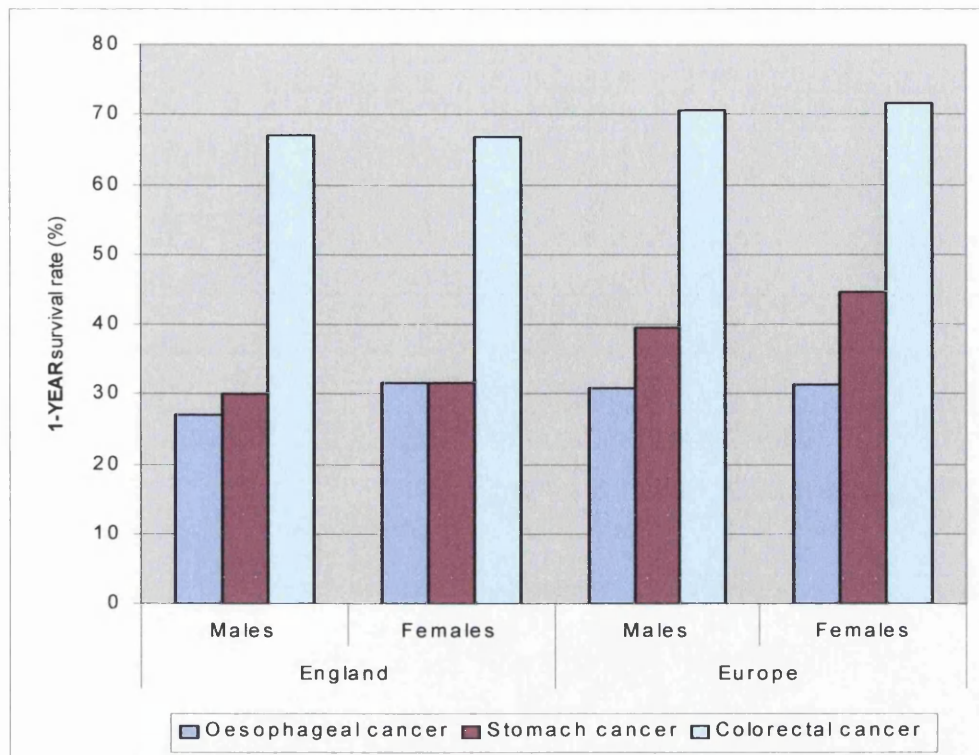
Figure 3: Age-standardised one-year and five-year survival rates (%) for oesophageal, stomach and colorectal cancer in England and Europe, of patients diagnosed between 1990-4, split by gender.

SOURCE: EUROCARE-3 study, 2005.

Cancer location	Gender	1991-95 †		1996-99 †		Total difference (1991 to 1999)
		N°. patients	Survival (%)	N°. patients	Survival (%)	
Oesophagus	M	14,644	5.6	12,814	6.9	+1.3
	F	9,928	8.3	8,219	8.2	-0.1
Stomach	M	25,793	10.0	19,555	12.6	+2.6
	F	14,608	12.4	10,618	14.7	+2.3
Colon	M	36,978	42.1	31,977	46.9	+4.8
	F	39,668	42.8	32,243	47.9	+5.1
Rectum	M	27,636	40.3	24,702	46.8	+6.5
	F	20,053	44.8	17,264	51.1	+6.3

Table 4: Five-year age-standardised relative survival (%) for adult patients from England and Wales diagnosed during 1991-95 and 1996-99, split by gender and cancer type. SOURCE: ONS 2005.

CRC patients who are diagnosed at an early stage have a much better prognosis than those who present with more extensive disease, as shown by the five year survival rates for CRC patients according to the stage of the tumour, as designated by modified version of the Duke's classification whereby A is an early stage tumour and D is a late stage tumour (Dukes, 1932). Campbell *et al* who reported that the proportion of patients surviving past five years is highest with earlier stage tumours (Stage A = 83%, B = 64%, C = 38% and D = 3%) (Campbell et al., 2001).

4.2 Non-cancerous conditions of the GI tract

Whilst cancerous conditions of the GI tract are more renowned, there are many other non-cancerous disorders of the GI tract that occur both acutely and/or chronically, in the general population far more frequently. The most common of these conditions are described in more detail below.

Dyspepsia is a heterogeneous disorder of as yet unknown aetiology (Chua, 2006). It consists of a variety of combinations of symptoms including abdominal pain or discomfort, bloating, nausea, heartburn and acid regurgitation. For those patients with the latter two symptoms, they are

commonly diagnosed with gastroesophageal reflux disease (see below) but for the many patients who do not have a definite cause for their symptoms, they are usually characterised as suffering from dyspepsia (Chua, 2006), although dyspepsia is not a diagnosis in itself (Arents et al., 2002). The condition occurs in between 19% and 41% of the Western population (Arents et al., 2002) and tends to be chronic but periods of remission are common. There is some evidence to suggest a role for the bacterium *H. pylori* as a causal agent for the disorder, but as yet, nothing conclusive.

H. pylori does play a significant role in the cause of peptic ulcer disease (PUD) (Arents et al., 2002, Chan and Leung, 2002). PUD occurs in the stomach and proximal duodenum and symptoms can include epigastric discomfort (specifically, pain relieved by food intake or antacids and pain that causes awakening at night or that occurs between meals), loss of appetite and weight loss (Ramakrishnan and Salinas, 2007). When *H. pylori* infection is diagnosed, the infection should be eradicated to alleviate symptoms.

Gastroesophageal reflux disease (GERD) is a chronic, relapsing condition suffered by approximately 40% of people in the Western world (Pettit, 2005). It is caused by a transient decrease in tension in the lower oesophageal sphincter that allows the gastric contents to leak into the oesophagus (Malfertheiner and Hallerback, 2005). In cases where this reflux is prolonged, the condition is considered abnormal and may cause oesophagitis (inflammation of the oesophagus) (Malfertheiner and Hallerback, 2005, Pettit, 2005). Patients classically present with symptoms such as heartburn, dysphagia, regurgitation, belching and chest pain (Hay, 2002, Prakash and Genreali, 2003). Risk factors for GERD include diet, alcohol, stress, pregnancy and some medications (Pettit, 2005).

In some patients GERD can develop into Barrett's oesophagus as the oesophageal mucosa develops into metaplastic columnar-specialised intestinal epithelium whereby the cells are abnormal but not yet cancerous (Malfertheiner and Hallerback, 2005, Flejou, 2005, Fitzgerald, 2005). A recent systematic review reported the cancer incidence from Barrett's oesophagus in the UK as 10 in 1000, although this reduced to 6 in 1000 for short segment Barrett's oesophagus (Thomas et al., 2007). Symptoms are similar to those of GERD but are longer in duration, earlier in onset and the complications seen in GERD are more common (Hay, 2002). Barrett's oesophagus is diagnosed in between 4% and 12.4% of patients with endoscopic examination for the symptoms of GERD or heartburn (British Society of Gastroenterology Working Party, 2005a, Fitzgerald, 2005) and is far more common in men than women (Spechler, 2003, Jeffery, 2005). The British Society

of Gastroenterology (BSG) have recommended biannual endoscopic surveillance for the early detection of any changes in the cells that may lead to cancer, since Barrett's oesophagus increases cancer risk anywhere between 10 - 150 fold (Jeffery, 2005, British Society of Gastroenterology Working Party, 2005a).

Inflammation is commonly caused by infection and can occur anywhere in the GI tract, manifesting as conditions including oesophagitis, gastritis and duodenitis and inflammatory bowel diseases (IBDs). The gut associated lymphoid tissue usually mediates all immune inflammatory processes, but occasionally the reaction is inappropriate. When it is not down-regulated, it can result in a contribution to the mucosal damage, as seen in IBDs including Ulcerative Colitis (UC) and Crohn's disease (CD) (Pathmakanthan and Hawkey, 2000, Griffiths, 2005, Beattie et al., 2006). UC presents in patients as chronic, bloody diarrhoea and depending upon the severity of the condition, can also cause pain and weight loss (Hay, 2002). The inflammation seen in UC is usually confined to the colonic mucosa. The annual incidence of UC in the UK is between five and eight cases per 100,000 population (Ghosh et al., 2000). Patients with CD commonly complain of pain, weight loss and diarrhoea (Hay, 2002). The condition can occur anywhere in the GI tract but is most common at the terminal ileum and/or colon (Head and Jurenka, 2004). The aetiology of CD remains unknown but it may be caused by genetic factors, diet, infective agents, smoking or stress (Metcalfe, 2002). A recent study has shown a continuing increase in the incidence of CD over time from 2.7 cases per million per year in 1931-1935 to 70 cases per million per year in 2001-2005, with a higher incidence in females than males (Gunesh et al., 2008).

Irritable bowel syndrome (IBS) is a complex, multifaceted condition broadly characterised by abdominal discomfort or pain in the setting of altered bowel function (Foxx-Orenstein, 2006) and can be caused by altered motility, visceral hypersensitivity, psychological factors and infection and usually occurs in young adulthood as a chronic condition (Hay, 2002). Patients experience abdominal pain or discomfort over a prolonged period of time associated with diarrhoea, constipation or both, and other problems with stool passage (Hay, 2002). The exact cause of IBS is unknown but it is believed to be multifactorial in origin. The symptoms are highly variable between patients and disease episode (Gilkin, 2005) but may be associated with increased stress which, in turn, affects the levels of stress-related hormones which may be responsible for an underlying predisposition to IBS (Foxx-Orenstein, 2006). Other potential factors include genetics, bacterial infections and food intolerance (Foxx-Orenstein, 2006). IBS is prevalent in approximately 10% - 15% of the UK population (Foxx-Orenstein, 2006) and is more prominent in females than

males (Spiller, 2004, Foxx-Orenstein, 2006). It is the most common of the functional GI disorders and constitutes approximately 3% of all primary care consultations in the UK (Spiller, 2004).

Haemorrhoids are a pathologic engorgement of the submucosal vascular plexus and can be located internally or externally (Tang et al., 2005). They are commonly classified into four types ranging from 1st degree (bleeding only) to 4th degree (permanent prolapse) (Hancock, 1992). Although they are often asymptomatic, haemorrhoids may cause bleeding and pain. They usually arise as a result of constipation and straining to pass hard stools and are a common side effect of pregnancy. They affect between 4% and 36.4% of the UK population (Nisar and Scholefield, 2003, Hardy et al., 2005). Endoscopy can help visualise the source of the internal haemorrhoids and a therapeutic procedure called "banding" may also take place during the examination to strangulate the haemorrhoids, causing them to become necrotic and slough away whilst the underlying tissue undergoes fixation by fibrotic wound healing (Nisar and Scholefield, 2003).

5. GASTROINTESTINAL ENDOSCOPY

Disorders of the GI tract are becoming more common in today's society. Factors such as diet, environment, and genetics can contribute towards many of the GI conditions described in Chapter 4. Patients presenting with these symptoms are often referred by their GP for a GI endoscopy, an examination that allows the direct visualisation of the extreme upper and lower ends of the GI tract through a natural body opening such as the throat or rectum using an instrument called an endoscope.

The word endoscopy is derived from the Greek words endo, meaning "within" and skopeo, "to look" (D'Silva, 1998). The endoscope was developed in 1806 by Philip Bozzini, but it wasn't until the 1930s that the first gastroscope was successfully used on a human subject (Shah, 2002, Sircus, 2003). Technological advancements led to the development of the flexible fibreoptic endoscope by Basil Hirschowitz in the 1950s (Shah, 2002). The introduction of wireless capsule endoscopy in more recent years has provided a new way of investigating the GI tract in its entirety. It involves the patient swallowing a capsule that contains fibreoptic bundles, video signals and power to allow a gastroenterologist to visualise regions of the small intestine not seen by traditional endoscopic techniques (Swain, 2003). It is not yet routinely available in all NHS endoscopy units.

The instrument shaft of a modern endoscope is composed of 20,000 to 40,000 specialised glass fibres, each approximately $10\mu m$ in diameter that allow the transmission of a light source with minimal distortion. The multiple fibre-optic images are integrated at the 2 - 3mm proximal eyepiece unit by a complex system of lenses. Within the instrument shaft are several "operating" channels designed for passage of optional devices such as biopsy forceps, polyp snare, cytology brush, cautery or laser devices, or a suction device. The channel also allows the transmission of air or water. At the head of the endoscope are two control devices that manoeuvre the instrument tip as it advances (Cotton and Williams, 1996). A camera or video recorder is often used during an endoscopic procedure to provide permanent records of internal organs, which may be used for later reference. Endoscope designs vary depending upon their purpose, with rigid endoscopes used for investigating short distances and flexible endoscopes with increased manoeuvrability used for more invasive procedures. Scope length varies, depending upon its intended target range.

An upper GI endoscopy (UGE) examines the first four feet of the GI tract to enable an accurate diagnosis of many conditions where the symptoms are visible on the lining of the oesophagus, stomach or duodenum. The colon and rectum make up the last few feet of the GI tract and are examinable using lower GI endoscopy (LGE), which can comfortably visualise the whole of the large intestine as far as the caecum (see Figure 4). The majority of GI complaints tend to occur within the limited range of an endoscope, with the 20 feet of unscopable small intestine only causing problems such as obscure GI bleeding in approximately 5% of patients (Lahoti and Fukami, 1999, Ali et al., 2004).
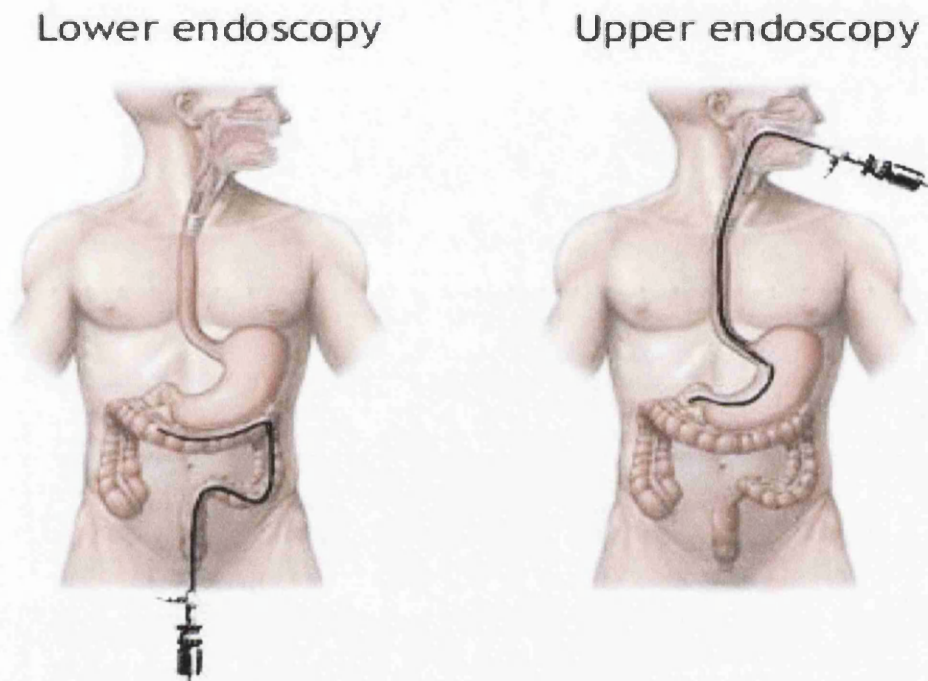
Figure 4: The human GI tract. This illustration was found using Google™ images (www.google.co.uk).

Endoscopy is credited with being able to identify the source of GI haemorrhaging in more than 90% of lesions, reducing the incidence of emergent surgeries and the overall mortality from acute upper GI bleeding (Vitale et al., 2005). It can also be used therapeutically to perform treatments or to take biopsies for diagnosis. Treatments can include controlled tissue destruction by photodymanic therapy, coagulation techniques and mucosal resection (Kuipers and Haringsma, 2005). Approximately 90% of acute GI bleeding occurring with peptic ulcers can also be treated at initial diagnosis (Vitale et al., 2005) and colonoscopic polypectomy (polyp removal) can reduce the incidence of CRC (Winawer et al., 1993).

It is likely that endoscopy will replace many surgical approaches in the management of many diseases over the next decade (Vitale et al., 2005), since it is a far less invasive procedure than open surgery, resulting in less scarring and a quicker recovery time. However, the appropriateness of its application needs to be balanced with the assessment and management of any potential complications in the patient (Kavic and Basson, 2001). Risks can include sedation (D'Silva, 1998, Kavic and Basson, 2001), cardiopulmonary problems (Shimamoto et al., 1999, Yazawa et al., 2000), perforation and haemorrhaging (Kavic and Basson, 2001) and patient distress (D'Silva, 1998). There is also a potential risk from incomplete decontamination of the endoscope (Gamble et al., 2007).

The increased versatility of modern endoscopy has also led to it replacing some radiological investigations. Recent studies have compared the effectiveness of endoscopic techniques with radiological ones in the identification of CRC and all concluded that colonoscopy had a superior sensitivity for polyps than barium enemas (Winawer et al., 2000, de Zwart et al., 2001, Smith and O'Dwyer, 2001, Menardo, 2004, Rockey et al., 2005). However, improvements in ultrasound technology has begun to redress this balance in the areas where GI endoscopy was largely blind (Hirschowitz, 2000).

5.1 Types of GI endoscopy

There are four main types of GI endoscopy performed routinely in NHS endoscopy units: Gastroscopies and oesophago-gastro-duodenoscopies (OGDs), which are both UGEs, and colonoscopies and sigmoidoscopies, which are both LGEs. All are discussed in more detail below.

5.1.1 Upper GI endoscopies

An OGD is a UGE procedure whereby a 120cm gastroscope is inserted via the mouth for a visual examination of the oesophagus, stomach, and duodenum, including the mucous membrane of the stomach from the top to the bottom. A gastroscopy uses the same equipment but involves the examination of the stomach only. The procedures can take between 10 - 15 minutes and localised sedation using a throat spray is optional. Gastroscopies account for approximately 70% of all investigations of the GI tract (D'Silva, 1998).

5.1.2 Lower GI endoscopies

Colonoscopies are one type of LGE procedure. At 160cm, the colonoscope is inserted via the anus to visualise the entire colon as far as the junction with the small intestine. The procedure can take between 15 - 60 minutes, depending upon the quality of the visualisation of the bowel, the location of the abnormality and the skill of the endoscopist. Discomfort during and after the procedure due to the insufflation of the bowel is common and sedation is highly recommended. Approximately 90% of polyps can be seen and removed during a colonoscopy (National Institute for Clinical Excellence, 2004b). It is an expensive procedure but is considered to be the "gold standard" for detecting small and pre-malignant lesions in the bowel.

Sigmoidoscopies are the other type of LGE and can be either rigid or flexible. Rigid sigmoidoscopy uses a short endoscope that examines only the rectum and usually takes approximately 10 minutes. Flexible sigmoidoscopy (FS) uses a 60cm long endoscope to examine the distal colon, which can take between 15 - 40 minutes. Approximately 70% of polyps can be seen and removed with FS (National Institute for Clinical Excellence, 2004b). However, FS is limited in its ability to examine the whole colon due to the length of the scope. Only the descending colon can be completely visualised, although two thirds of adenomas and cancers are located within the reach of a FS (Atkin et al., 1993). The presence of any abnormalities in the left side of the colon makes additional investigation necessary (Papagrigoriadis et al., 2004).

5.2   Complications of endoscopy

Complications can occur following an endoscopy whereby the patient has to be admitted to hospital within typically 30 days of their procedure for symptoms related to the condition that was investigated, or for other problems including angina or myocardial infarction, for observation or for pneumonia (Bowles et al., 2004). Complication rates for UGEs have been reported as high as 0.025% (Reed et al., 2004) whilst those for LGEs are far higher: colonoscopy at between 1.2% and 3% (Thomas-Gibson et al., 2002, Bowles et al., 2004) and for FS at 1.2% (Farraye et al., 2004).

Perforation rates for each procedure type have been reported as high as 4.5% for colonoscopy (Rembacken et al., 2000, Kavic and Basson, 2001, Gatto et al., 2003, Bowles et al., 2004, Rembacken, 2005). The perforation rate for FS is reportedly between 0.0001% and 0.00088% (Segnan et al., 2002, Gatto et al., 2003) and for UGEs it is approximately 0.02% to 0.2% (Kavic and Basson, 2001).

The National Confidential Enquiry into Patient Outcome and Death (NCEPOD) report into patient outcomes and death following endoscopy reported a mortality rate in 2002/03 for therapeutic UGEs as 5% (2,200 of 47,931 patients) and for LGEs (colonoscopy and FS combined) of <1% (102 of 40,378 patients) (National Confidential Enquiry into Patient Outcome and Death, 2004).

5.3 NHS GI endoscopy services

All UK NHS Trusts have at least one endoscopy unit to allow the investigation of GI symptoms. Referrals for GI endoscopy primarily originate from GPs within the primary care setting, or from medical staff via an outpatient clinic. Occasionally, secondary care referrals will also come from within the Trust for inpatients or for emergency cases via the A&E department.

Referral documentation originating from primary care varies according to the NHS Trust's protocols but in general, GPs complete referral proforma and/or letters of referral stating symptoms, patient history, the test required and the degree of urgency of the test (urgent, soon or routine). Some NHS Trusts operate a referral and appointment system from designated Trust-based appointment centres that allocate all diagnostic appointments, not just endoscopies, whilst others have the option for GPs to send referrals straight to the endoscopy unit. In some Trusts, referrals are validated by a consultant prior to entering the patient into the appointment system to ensure the referral is appropriate, based on the patient information on the referral. In 1999 a fast-track route was established specifically for patients presenting to their GP with symptoms indicative of a cancer, designated "Two-Week Rule" referrals. These referrals were faxed from GP practices direct to the endoscopy unit on a dedicated number and the patient was allocated an appointment to be seen at the hospital within two weeks of the referral (see Section 6.1.1 for more detail).

It is common practice that once a referral has been entered onto the system, the patient is sent a confirmation letter by the hospital and further correspondence by phone or letter that informs them of their appointment date if this was not available for inclusion in the confirmation letter. Information sheets and consent forms are posted prior to their appointment, along with bowel preparation when LGE is required. Complete evacuation of the GI tract is important for the visualisation of any abnormalities and patients are told to not eat for 12 hours prior to a UGE and 24 hours prior to an LGE. Some Trusts operate a system whereby the clerical staff phone patients who have reached the top of the waiting list to ensure that they still want their procedure as a way

of validating their waiting lists and in doing so, they are able to allocate a suitable appointment date over the phone.

GI endoscopies usually take place in the endoscopy unit but UGEs are more frequently occurring in specialist outpatient clinics in some Trusts. Most endoscopies are carried out by a skilled medical or nurse endoscopist as a day case procedure and unless there are complications, the patients are sent home the same day. On their arrival to the endoscopy unit, patients are greeted by staff who explain the procedure, take consent and give sedation where necessary. Once the endoscopist is ready and all equipment and supporting staff are present, the patient is taken into the procedure room. The time taken for procedures varies upon the type of examination, the ease of passing the scope and the added time taken for any therapeutic measures. Once the procedure has been successfully completed, the patient is taken to a recovery area while the sedation wears off. Once well, they are offered refreshments and assessed by nursing staff prior to discharge. The majority of procedures can yield a diagnosis immediately and this may be discussed with the patient during recovery. Where biopsies have been taken, results can take a few weeks.

5.4   Government targets for NHS GI endoscopy services

The *NHS Plan*, *NHS Cancer Plan* and later, the *NHS Improvement Plan* all advocated timely patient access to NHS services as being central to supporting the delivery of access targets. These targets included:

- Full booking by the end of 2005 (Department of Health, 2000c).
- Reducing the maximum wait for first routine outpatient appointment with a consultant from six months to three months by the end of 2005 (Department of Health, 2000c).
- A maximum two month wait from urgent GP referral to treatment for all cancers by the end of 2005 (Department of Health, 2000b).
- A maximum one month wait from diagnosis to treatment for all cancers by the end of 2005 (Department of Health, 2000b)
- A maximum 18 week wait from GP referral to treatment by the end of 2008 (Department of Health, 2004c).
- A choice of any providers for patients by the end of 2008 (Department of Health, 2004c).

To achieve these targets, major changes were needed to the most fundamental aspects of service delivery within NHS GI endoscopy units. These included changes in the way they managed their demand, waiting lists, capacity and activity. Since 1997, major changes have occurred within NHS endoscopy units, most of which have been politically driven and target-based, although some have been motivated by the desire to improve services by NHS staff. Some of these will be described in the following chapter.

6. MODERNISING NHS ENDOSCOPY SERVICES: A REVIEW OF THE LITERATURE

A comprehensive, systematic literature search was performed to retrieve all peer-reviewed publications that referred to any changes in service delivery implemented within NHS endoscopy services since 1997. This time point was chosen because it signified the introduction of the 10-year modernisation programme set out by the New Labour government when they came to power. The search criteria encompassed articles describing changes in the NHS endoscopy services in terms of demand, waiting lists, lost slots and activity, as a result of implementing any redesign initiatives. It also included the evaluation of any redesign initiatives by either the endoscopy unit itself or by an independent organisation.

Table 5 defines all inclusion and exclusion criteria applied to the literature search. The inclusion criteria were designed to include only those publications that were of immediate relevance to the research question being addressed by this thesis, namely the evaluation of modernisation within NHS endoscopy services in England, either as a consequence of being associated with the MES project or as a result of modernising independently, for political, target-driven or internal reasons.

Inclusion criteria	Exclusion criteria
1. NHS-based endoscopy	1. Endoscopy performed outside the NHS
2. Colonoscopy, FS, gastroscopy and OGD	2. All other types of endoscopy
3. GI disorders	3. Non-GI disorders & disorders of the liver / pancreas
4. Non-inherited GI conditions	4. Inherited GI conditions
5. Endoscopy in adults	5. Paediatric endoscopy
6. Peer-reviewed articles	6. Non-peer-reviewed articles / abstracts
7. Studies conducted from 1997 onwards	7. Studies conducted before 1997
8. Studies encompassing demand, waiting lists, cancellations and activity	8. Studies encompassing technological advances, cost effectiveness or patient satisfaction

Table 5: The inclusion and exclusion criteria of the literature search.

Only literature pertaining to studies initiated from 1997 onwards were included but where no study period was reported, a decision was made on its eligibility based on the date of acceptance for publication, the time span of the study, and any other relevant information. Since patient satisfaction and cost-effectiveness issues were major themes covered by the ENIGMA study (see Chapter 8) and did not fall within the remit of this study, they were not included in this literature review.

The primary literature search was performed using Entrez Pubmed (www.ncbi.nlm.nih.gov/sites/entrez?db=pubmed) based on a keyword search using the terms listed in Table 6 applied to the title and abstract of all entries. These same keywords were also used to locate any additional relevant literature from the Cochrane Library (www.cochrane.org/index.htm), Emerald Fulltext (www.emeraldinsight.com/Insight/menuNavigation.do?hdAction=InsightHome) and Centre for Reviews and Dissemination (www.york.ac.uk/inst/crd/index.htm).

An additional Medical Subject Headings (MeSH) terms search strategy was also used on Entrez Pubmed during the initial search phase but it did not reveal any additional items not already identified using the keyword search. It also failed to identify many important articles retrieved by the keyword search, possibly due to the ambiguous nature of the classification of the terminology used under the umbrella of NHS service redesign and so, was not used any further.

Independently published reports relating to NHS endoscopy services were later included as an additional source of information to increase the quality of the literature review with this sometimes non-peer-reviewed, but highly informative material. The old NHSMA website (last accessed Jan 2007) (www.wise.nhs.uk/cmswise/default/) and the National Library for Health (www.library.nhs.uk/Default.aspx) were searched for relevant reports using the same keyword searches as described in Table 6.

Where appropriate numerical data were retrieved in sufficient quantities, a meta-analysis was performed by aggregating common datasets from different sources and calculating a weighted average to determine a more relevant, overall picture of NHS endoscopy services.

In total, 154 publications were included in this literature review, the details of which are summarised in Appendix 16.1 (peer reviewed literature) and Appendix 16.2 (non-peer reviewed literature).

NHS	AND	Modernis*	OR	Demand	OR	Booking	OR	Staff
Gastroint*		Innovati*		Referr*		Appointment		Consultant
Gastroent*		Redesign*		Wait*		Guideline		Nurse
Endoscop*		Chang*		Activity		Clinic		Endoscopist
Cancer		Improve*		Capacity		Complication		GP
		Service delivery		Cancel*		Audit		Patient*
		Evaluat*		Attend*		Data		Train*
		Manag*		Screen*		Information		Consent
		Quality		TWR		Outpatient		Symptom*
		Measur*		Fast-track		Inpatient		Views
				Two-week		Day case		
				One-stop		Access		

Table 6: Keyword combinations used in the literature search strategy. The asterisk indicates where the truncated version of the word was used.

6.1 Changes affecting the demand on endoscopy services

Over the last 15 years the demand on NHS GI endoscopy units has gradually increased. In 1991/2, approximately 8.7% of patients attending a GP surgery had disorders of the GI tract, an increase by one fifth from 7.2% in 1981/2 and if this trend had continued, the figures for 2001/2 would have been 10.4% (Williams et al., 2007). In 1991/2 GI disorders accounted for one consultation for every five people in the population (Williams et al., 2007). Approximately 17% of finished consultant episodes in England had GI disease as the principal diagnosis and roughly 45% of these episodes were referred for endoscopic assessment (Williams et al., 2007).

As well as the demand from primary care for endoscopies to investigate GI diseases, NHS endoscopy services generated a proportion of their own demand typically from outpatient consultations. Between 38% and 40.3% of secondary care referrals were for surveillance patients who required regular follow-up appointments (Bowles et al., 2004, Shoaib et al., 2006), either to assess the progress of an abnormality or to check that there has been no regrowth following a polypectomy (polyp removal). Repeat procedures were necessary when cancellations occurred or when an endoscopy failed for any reason, which also increased demand on the unit. There was

also an element of "emergency demand" within NHS Trusts with no out-of-hours endoscopy service. A survey by Douglass *et al* reported 35 Trusts with no such service and discussed the implications of the average figure of 90.2 emergency endoscopies per 100,000 population per annum that were performed for upper GI bleeding, of which 26.7 were out-of-hours (Douglass et al., 2005).

There have been a number of initiatives, both government-led and Trust-led, that have affected the demand on NHS endoscopy services, some of which will be discussed at length in this chapter.

6.1.1 The Two-Week Rule

The Two-Week Rule (TWR) referral (NHS Executive, 1999) was introduced by the New Labour government to tackle the increasing problem of patients presenting to their GP with symptoms indicative of a cancer who, although urgently referred, did not get a hospital appointment in sufficient time as to significantly improve their health outcome. The aim of the TWR referral route was to reduce the number of cancer-related deaths by 20% in people under the age of 75 by 2010, thereby saving approximately 130,000 lives (Department of Health, 2000c). The scheme allowed GPs to "fast-track" these patients to shorten the length of time they waited for a diagnosis followed by potentially life saving treatment. TWR referrals were faxed to the endoscopy unit using a dedicated number and an appointment was made for the patient within two weeks. Only delays due to patient choice were acceptable reasons to over-run the two week target.

The *NHS Improvement Plan* claimed that nearly 99% of patients with a suspected cancer were being seen by a specialist within two weeks of an urgent GP referral compared to 63% in 1997 (Department of Health, 2004c). Peer-reviewed literature suggests that the actual number of TWR-referred patients seen within the two-week target ranges from 50% in 1998 (Raje et al., 2006) to 67% in 1999/2000 (Davies et al., 2007) to 96% in 2001 (Debnath et al., 2002, Barwick et al., 2004) and to 100% in 2004 (Stoker et al., 2005), although one 2006 study reported only 92% of patients being seen within two weeks (Rao, 2006).

Many studies have reported that the TWR has reduced the time from referral to diagnosis when compared to other referral routes (Walsh et al., 2002, Davies et al., 2002, Rao, 2006, Bevis et al., 2008). However, there was some evidence that it had not shortened the overall time to diagnosis or treatment due to lags before presentation to the GP and between outpatient appointment and procedure (Flashman et al., 2004).

79

GPs were given specific TWR referral guidelines to follow by the DH in 2000 (Department of Health, 2000d) that were later updated by NICE in 2005 (National Institute for Health and Clinical Excellence, 2005) for the appropriate, timely referral of patients with suspected cancers. This was done so that the TWR initiative was not overburdened to the detriment of other service users or NHS staff. It was hoped that by implementing TWR referral guidelines, more patients with a GI cancer would be diagnosed at an earlier stage of their disease. However, the TWR has placed a significant burden on the resources of most gastroenterology services in the NHS with little gain in identifying malignancies (Martin et al., 2002). A systematic review and meta-analysis of peer-reviewed studies published by the author of this thesis in 2006 reported that CRC was diagnosed in only 10.3% of those patients with lower GI tract symptoms referred using the TWR (Thorne et al., 2006). To justify a meta-analysis, only studies that were sufficiently comparable in the way that data were collected and reported were used. More evidence has since been published and the updated meta-analysis in this chapter now shows that the actual proportion of patients referred using the TWR who were eventually diagnosed with a GI cancer was 3.8% for UGEs and 9.1% for LGEs (see Table 7). This means that the pick-up rate for CRC detection via the TWR has actually decreased in recent years.

The table also showed that 30.1% of all CRC patients diagnosed in endoscopy units had been referred using the TWR route, implying that nearly 70% of CRC patients were referred by alternative routes including routine referrals and A&E. This figure is higher than the 24% figure originally published in 2006 (Thorne et al., 2006) using the literature available at that time. This indicates that more recent studies have found a larger proportion of CRC patients diagnosed using the TWR, suggesting that the TWR route may be becoming more effective over time.

The TWR guidelines were based on the assumption that patients with more advanced stages of the disease would exhibit specific alarm symptoms and that patients with "low risk" symptoms may be unnecessarily over-investigated, thereby increasing the demand on the service. The evidence presented here suggests that the guidelines are not sensitive enough, with many GI cancer patients not presenting with the required "high-risk" symptoms necessary to elicit the TWR referral route into secondary care. This is a major concern because it is patients exhibiting low risk symptoms who are at an earlier, more treatable stage of their disease, yet the guidelines are not sensitive enough to identify them.

Endoscopy type	Reference	Time period of study	TWR Nos.	Cancer pick-up rate (%)	Total No. of cancer cases diagnosed during that time period	% cancer cases referred via...		
						TWR	A&E	Other routes
UGEs	(Spahos et al., 2005)	Sept 98 - Sept 02	623	38 (6.1)	247	15		85
	(Kapoor et al., 2005)	Jul 00 - Feb 02	1852	70 (3.8)				
		Mar 02 - Feb 03	1785	52 (3)				
		Weighted average		**3.8**		**15**		
LGEs	(Bevis et al., 2008)	Oct 02 - Sept 04			193	50	27.5	22.5
	(Shaw et al., 2008)	Sept 05 - Sept 06	204	12 (5.9)				
	(Smith et al., 2007)	Jan 02 - Dec 04	2748	174 (6.3)	477	36.4		63.6
	(Rao, 2006)	Jun - Dec 03	319	14 (4.4)	40	35		65
	(Allgar et al., 2006)	Jan 01 - Dec 02	444	51 (11)	239	21		79
	(Stoker et al., 2005)	Mar - Jun 04	273	26 (9.5)				
	(Chohan et al., 2005)	Jul 00 - Dec 01	462	64 (13.8)	195	32.8	20	47.2
	(Maruthachalam et al., 2005)	Jan - Dec 03	630	51 (8.1)	234	21.8	10.6	67.6
	(Flashman et al., 2004)	Jul 00 - Jun 01	695	65 (9.4)	249	26.1	35.3	38.6
	(Barwick et al., 2004)	Jan - Aug 01	144	14 (10)	84	16.7	41.7	41.6
	(Trickett et al., 2004)	Nov 00 - Oct 01			147	20	29	51
	(Davies et al., 2004)	Nov 99 - Oct 00	697	87 (12.5)	208	41.8	58.2	
		Nov 00 - Oct 01	803	87 (10.8)	222	39.2	60.8	
		Nov 01 - Oct 02	794	83 (10.5)	205	40.5	59.5	
	(Eccersley et al., 2003)	Jun 00 - Mar 01	173	26 (15)	145	18	17	65
	(Walsh et al., 2002)	Aug - Oct 00	78	11 (14.1)	38	28.9		71.1
	(Mahon et al., 2002)	Sept 99 - Jul 00	115	18 (15.7)				
	(Kiran and Glass, 2002)	1998 - 2000 (2y)			232	21.8	28.9	78.2
	(Debnath et al., 2002)	Aug 00 - Jul 01	237	21 (8.9)	96			
		Weighted average		**9.1**		**30.1**		

Table 7: A meta-analysis of the literature pertaining to the effectiveness of the TWR on UGE and LGE referrals in terms of (1) cancer pick-up rate and (2) the proportion of patients with upper and lower GI cancers referred using the TWR.

81

The effect of the TWR on long term survival remains unknown (Walsh et al., 2002). Many studies have reported no significant difference in the stage of the disease in CRC patients referred via the TWR compared with other referral routes (Eccersley et al., 2003, Flashman et al., 2004, Chohan et al., 2005, Smith et al., 2007, Bevis et al., 2008). This finding was supported by a study by Kiran *et al* who reported that there was no relation between the duration of CRC symptoms and the stage at presentation (Kiran and Glass, 2002). This means that those patients with advanced stages of CRC do not necessarily become symptomatic at a particular time, so the TWR does not necessarily improve the survival of CRC patients but does reportedly reduce the number of patients presenting as emergency cases (Raje et al., 2006). Contrary to this, one study has shown that the TWR route has more CRC patients with Duke's classification stage D (late stage) tumours than any other route (TWR = 14, outpatient clinics = 8, A&E = 5) (Chohan et al., 2005). The embarrassing nature of CRC means that many symptomatic patients do not present to their GPs until the latter stages (Jiwa and Burr, 2002), which tend to be too advanced to confidently predict a good outcome for the patient. Another reason for late presentation was limited access to GP appointments (Jiwa and Burr, 2002).

Based on local data, Ward *et al* recently estimated the demand on endoscopy services from TWRs alone was approximately 65,000 per annum (Ward et al., 2006). To meet TWR targets, capacity needs to exceed mean demand by two patient slots per week for 99% success, or by one slot per week for 90% success (Thomas et al., 2001). The effect of the TWR on referral patterns is still debated, with some authors reporting increasing numbers of TWR referrals (Walsh et al., 2002, Stoker et al., 2005) whilst others report no significant rise (Debnath et al., 2002, Mahon et al., 2002).

In most hospitals, the TWR has a dedicated list to ensure NHS Trusts met the strict two-week target. This should, in theory, have a negative impact on all other aspects of the service, although no evidence of this has been found to date. Three studies reported a decline in the routine endoscopy waiting lists following the introduction of the TWR (Walsh et al., 2002, Spahos et al., 2005, Rao, 2006), possibly due to an increased awareness of the guidelines for patient referrals, the more efficient organisation of services or the introduction of nurse endoscopists to cope with increased demand (see later).

The response by GPs to the TWR has been generally positive, with 81% of GP reporting a perceived reduction in appointment waiting times and 86% reporting good communication with the hospital as a result of the initiative (Dodds et al., 2004).

6.1.2 Referral guidelines for GPs

Whilst it is widely acknowledged that referral for a diagnostic endoscopy has become the favoured method of diagnosing certain GI disorders, there was limited guidance for GPs to select which patient groups were most suitable for this procedure type and which needed to be referred urgently to prevent GPs referring their patients this way en masse.

The failure of GPs to refer patients in good time assigning the appropriate degree of urgency may have implications for timely diagnosis, especially in the case of GI cancers. Guidelines are more frequently being advocated to facilitate an appropriate plan of action resulting in the best care for the patient whilst trying to reduce the cost of that care where possible by avoiding the need for unnecessary investigations. However, they can also have a significant impact on the demand for various diagnostic services, as has been previously mentioned in the case of TWR referral guidelines.

Clinical decisions should be based on evidence-based medicine. This usually involves the identification and appraisal of high quality medical literature to make an informed decision about the treatment of a patient. In the case of patients with dyspepsia, GPs may take advice from a Cochrane review published in 2000 that recommended GPs recognise that endoscopy as an early investigation may not be cost-effective as a management strategy (Delaney et al., 2000). In the absence of high quality Randomised Controlled Trial (RCT) publications on specific clinical questions or established common practice, expert guidance is used.

Since 1997, there have been a number of government-backed guidelines published to facilitate appropriate, timely and cost-effective medical care to minimise error and provide uniformity of care and standardisation of treatment (Hodder et al., 2005a). Those relevant to NHS endoscopy services include the following:

- Investigation and management of suspected cancers of the upper GI tract (Department of Health, 2000d, Allum et al., 2002, National Institute for Health and Clinical Excellence, 2005).

- Investigation and management of suspected cancers of the lower GI tract (Department of Health, 2000d, Thompson, 2002, National Institute for Clinical Excellence, 2004b, National Institute for Health and Clinical Excellence, 2005).

- Investigation and management of dyspepsia presenting with acute GI bleeding (National Institute for Clinical Excellence, 2004a, Mason et al., 2005).

- Barrett's oesophagus (British Society of Gastroenterology Working Party, 2005a).

- IBDs (Carter et al., 2004).

- CRC screening in high risk groups (Cairns and Scholefield, 2002).

It has been widely acknowledged that the creation of guidelines to identify patients with GI cancers is essential to decrease the number of inappropriate referrals of patients with insignificant symptomatology via the TWR. Their accuracy is open to improvement, although it comes at a cost - increasing their sensitivity means losing the specificity, which will lead to an increase in the number of patients eligible to be referred, thereby increasing demand on endoscopy services and reducing timeliness, etc – the very things they were meant to enhance. Another confounding factor is that many serious conditions share the same symptomatology as benign disorders, many of which have a high incidence rate in the general population (Harinath et al., 2002). NICE reports have estimated that between 80% and 85% of CRC patients present with two or more of the symptoms stipulated by the DH TWR guidelines (National Institute for Clinical Excellence, 2004b), although the literature quotes this figure as between 35% and 94% (Mahon et al., 2002, Debnath et al., 2002, Flashman et al., 2004, Jiwa and Hamilton, 2004, Spahos et al., 2005, Chohan et al., 2005, Allgar et al., 2006, Bevis et al., 2008).

Many problems have been reported in the past with the inappropriate referral of patients for an endoscopy by their GP when their symptoms are not considered by published guidelines to be either appropriate or high-risk enough to warrant the procedure (Debnath et al., 2002, Dodds et al., 2004, Chohan et al., 2005, Pickard et al., 2007, Shaw et al., 2008). Reasons for inappropriate referrals included the fear of missing an important diagnosis, clinical uncertainty, patient pressure

and the long waiting times for routine referrals (Dodds et al., 2004). High levels of inappropriate referrals whereby patients are being over-investigated will have major implications with regards patient safety, service provision and cost to the NHS (Pickard et al., 2007).

Rigid application of guidelines can occasionally result in the routine referral of patients exhibiting low-risk symptoms listed in the guidelines who later develop a serious condition. In the case of the TWR guidelines for suspected CRC, between 10% and 15% of CRC patients will present with low-risk symptoms and will not qualify for the TWR referral (Thompson, 2002). The literature reported these figures as between 2% and 26.1% (Debnath et al., 2002, Eccersley et al., 2003, Flashman et al., 2004, Jiwa and Hamilton, 2004). A 2006 systematic literature review suggested that the actual figure is far higher, with an average of 52.4% of all CRC patients diagnosed at a given time originally being referred by a non-urgent, non-emergency route by their GP (Thorne et al., 2006). However, it could be that these patients presented with no significant alarm symptoms and so, may have been appropriately referred as routine. This begs the question, are the TWR guidelines working properly? Many authors argue that they are not sensitive enough (Harinath et al., 2002, Eccersley et al., 2003, Hodder et al., 2005a). Only one publication supported their effectiveness for selecting patients with cancer (Mahon et al., 2002). The number and length of the CRC guidelines from the DH have been criticised by GPs, as well as their accuracy, with many calling for a standardised protocol (Jiwa and Burr, 2002).

The erratic implementation of the guidelines was also a problem for healthcare professionals in secondary care, with 43 clinicians exhibiting a wide degree of variation in their assessment of 40 symptomatic colorectal referrals, with only 71.3% of CRC patients being correctly diagnosed and of those, only 47% were classified as urgent referrals (Hodder et al., 2005b). Four GPs were included in the test group and they, along with the 21 registrars scored highest in their ability to identify the CRC patients (82%). Surprisingly, the nine professor / consultant / associate specialist subjects only identified 51% of CRC patients (Hodder et al., 2005b).

A study providing clinical guidelines within a district general hospital showed that there was an extremely low adherence to the guidelines for upper GI bleeding (3%) and that this did not increase in the light of online guidelines being made available (Williams et al., 2004). Qualitative interviews

with the clinical staff indicated that the guidelines had been briefly consulted but not used in accordance with instructions.

6.1.3 GP referral practices

Jiwa et al identified problems in the referral documentation completed by GPs, with many missing relevant history and examination (Jiwa et al., 2002), as high as 97.5% in one study (Debnath et al., 2002). This may be because GPs are not formally trained in completing this type of paperwork or because they have limited consultation times with patients, so the referral is written once the patient has left (Jiwa and Burr, 2002). A qualitative study by Jiwa and Burr reported that GPs believed that consultants did not read the referral letter, but did acknowledge the need to be responsible for communicating with their colleagues (Jiwa and Burr, 2002). There was much confusion about what constituted an adequate referral letter (Jiwa and Burr, 2002), and the need for the standardisation of referral forms has been recognised (Dodds et al., 2004). When feedback was given to a selection of GPs about the quality and quantity of information they included on their referral letters, there was a significant improvement following the period of feedback (Jiwa et al., 2004).

There is often an absence of established clinical practices or RCT evidence due to health service delivery issues, funding and ethical issues. A poor evidence base for guidelines often presents itself as a reason for non-adherence by health professionals (Mandal et al., 2003). Other GPs commented that they found the guidelines for referring patients with a suspected cancer difficult to interpret and that they often felt pressure from patients for a quick referral (Dodds et al., 2004).

Referral proforma have been advocated for all NHS Trusts by NICE, along with a central referral system for the rapid and efficient referral of patients to the designated diagnostic service (National Institute for Clinical Excellence, 2004b). Faxable referral proforma for suspected CRC patients have been successfully introduced and in one Trust, the aim was to eventually replace it with Email referrals (UK NHS Cancer Services Collaborative, 2004).

One study has reported the successful introduction of referral assessment, with GPs obtaining feedback on dyspepsia referrals based on their adherence to the NICE dyspepsia guidelines.

Mean adherence rates of GPs referring to all three study sites rose by 20% to 75% (95% Confidence Interval (CI) 13.6% to 26.4%, p < 0.001). The adherence rate of the hospital doctors was 70% at baseline but did not follow the same trend as a result of the intervention. The referral assessment also resulted in a decrease in gastroscopy referrals from GP by 3.2 per week (p = 0.065) and by 10 per week from hospital doctors (p < 0.001), and significantly decreased the referral-to-procedure interval for gastroscopy (52.1 days Vs. 39.4 days, p < 0.001) (Elwyn et al., 2007).

6.1.4 Open access referrals

Open access (OA) referrals have been in operation since the 1970s (Marshall, 1998) but have become more commonly used in NHS endoscopy units in the last few years. In most NHS Trusts, GPs can now refer patients for an endoscopy using OA (also called direct access) referral services. This entails the GP making a referral for a specific endoscopic procedure directly to the endoscopy unit, with the GP maintaining overall management of the patients condition (Dougall et al., 2000) and avoids the involvement of the consultant. Barrison et al highlighted the quality criteria essential in any OA service (Barrison et al., 2001).

Whilst MacKenzie et al reported that OAs have not resulted in an increase in the number of investigations being booked (MacKenzie et al., 2003), Paterson et al reported a 32% increase in endoscopy workload following the introduction of an OA route (Paterson et al., 2006). OAs have successfully contributed to a significant reduction in the waiting time from referral to procedure and diagnosis (Verma and Giaffer, 2001, Maruthachalam et al., 2005). MacKenzie et al found that OAs were equally effective at diagnosing cases of CRC as consultant-led services (63.6% consultant Vs. 61.8% OA, p = 0.558) (MacKenzie et al., 2003), whilst Verma and Giaffer reported a significantly better diagnostic yield for OAs compared with hospital-initiated endoscopies (44% OAs Vs. 29% Hospital, p = 0.01). OAs have also been reported to be more effective at diagnosing earlier stage gastric cancer than conventional routes (Stephens et al., 2005), a finding contradicted by Paterson et al who found that there was no improvement of disease stage at diagnosis using the OA route (Paterson et al., 2006).

OAs are highly acceptable to patients (Maruthachalam et al., 2005), although GPs have been reported to prefer one-stop dyspepsia clinics as opposed to an OA clinic (Rutter et al., 1998). OA can be successfully applied to follow-up referrals for the outpatient follow-up of IBD patients (Williams et al., 2000). A qualitative evaluation of this system showed GP preference towards the service as opposed to the routine follow-up service (Cheung et al., 2002).

6.1.5 Alternatives to endoscopy

The "test and treat" initiative advocated in the NICE guidelines (National Institute for Clinical Excellence, 2004a) uses *H. pylori* testing on young patients with dyspepsia as a replacement for endoscopy and has been proposed to reduce the demand for endoscopy by up to 74% (Shaw et al., 2006).

6.1.6 CRC screening

Most CRCs result from malignant changes in polyps that developed at least a decade earlier (National Institute for Clinical Excellence, 2004b). Following the success of a trial by the UK CRC Screening Pilot Group (UK CRC Screening Pilot Evaluation Team, 2003, UK Colorectal Cancer Screening Pilot Group, 2004), the NHS Bowel Cancer Screening Programme (NBCSP) was initiated in England in April 2006. This dramatically increased the demand on NHS endoscopy services, as people aged between 60 and 69 years of age were invited to participate in biannual CRC screening. They were posted a Faecal Occult Blood Test (FOBT) kit to their home to test for the presence of blood in their stool. Positive FOBTs resulted in an invitation to a follow-up to have a colonoscopy at an endoscopy unit. More details of the NBCSP can be found on their dedicated website at www.cancerscreening.nhs.uk/bowel/.

The first round of the pilot study reported that the uptake for screening was 58.5% and that the number of positive tests from FOBTs increased the demand for colonoscopy by 1.5% (4116 of 478250 subjects screened), of which 81.5% of FOBT-positive subjects attended (UK Colorectal Cancer Screening Pilot Group, 2004). Ward *et al* calculated that this increase, if applied to all age groups, would result in a total increase of 69% in annual endoscopy investigations in the UK (Ward et al., 2006). However, Price *et al* argued that the pilot report was an under-estimate of the real demand and showed that colonoscopy activity following the CRC screening study actually

increased by 31% in Scotland and 21% in England due to FOBT-positive patients (Price et al., 2005).

The second round of screening by the pilot study was performed two years later. Uptake was significantly lower than in the first round (51.9% vs. 58.5%, p < 0.001), but there was a significantly higher number of positive FOBTs (1.77%) (Weller et al., 2007). The cancer detection rates were lower in the second round than the first round (0.94 per 1000 vs. 1.35 per 1000, p = 0.02).

The impact of the NBCSP has not been well documented, but Goodyear *et al* reported the effect of FOBT screening for CRC on emergency admissions in Coventry and North Warwickshire and concluded that since the pilot in 1999, there was a significant decline in emergency CRC workload with a marked improvement in 30 day mortality and decreased stoma formation (Goodyear et al., 2008). West *et al* reported an improvement in the standards of NHS endoscopy services in terms of patient experience, safety and improved practice (West et al., 2007). However, Thompson *et al* described the impact of screening for those subjects not at high risk of CRC, highlighting that for the UK population, the lifetime risk of death from CRC was approximately 1:50 and that more than 98% of the population would not benefit from CRC screening (Thompson et al., 2006). They also commented that the screening programme may be prone to bias whereby only healthy subjects tend to volunteer for screening and the problem associated with aggressive CRCs tending to have a shorter history which means that they are less likely to be identified during screening.

The DH allocated approximately £19 million per annum to fund the additional costs of diagnostic investigation as part of the NBCSP but the real costs of the FOBT alone have been estimated to be closer to £28 million (Ward et al., 2006), leaving the endoscopy units with inadequate funding to meet the anticipated increase in demand from patients with suspected bowel cancer.

6.1.7 Implementing new ways of predicting GI disorders in patients

Selvachandran *et al* developed a novel and successful system to predict whether patients with colorectal symptoms had CRC using a questionnaire completed by patients based on their history which was scored by a senior colorectal surgeon and proved to be more accurate than the GP referral letter at predicting patients with CRC (Selvachandran et al., 2002). This system was

independently evaluated by Hodder *et al* and was proven to have a sensitivity of 96.8% compared to the 80.1% from the guidelines (Hodder et al., 2005a).

Studies have been performed in NHS endoscopy units with the intention of informing guidelines on how to increase their sensitivity without losing their specificity, as well as decreasing the cost of endoscopy by reducing the number of inappropriate referrals. In a study by Mathew *et al*, approximately one fifth of patients who had an FS to investigate a rectal bleed were aged under 45 but the incidence of CRC in those patients was zero (Mathew et al., 2004). The authors went on to recommend that new guidelines should consider the age of patients. Kapoor *et al* used the DH upper GI cancer guidelines to identify high-risk cancer patients referred using a rapid access service, and then calculated the predictive value of the alarm features (Kapoor et al., 2005). From this, they restricted the guidelines to identify 99% of cancer patients with a specificity of 30.5%, compared with the 3.8% originally identified. When the redefined guidelines were applied to a validation cohort, they identified 92.3% of cancer patients and proposed a theoretical reduction in urgent workload by one third with the formal application of their revised guidelines.

A short dyspepsia questionnaire administered by a nurse in both primary and secondary care settings was found to be a valid, reliable tool for measuring the presence and severity of dyspepsia in patients (Moayyedi et al., 1998). When the questionnaire was compared to the GP assessment of the patient, it was found to have a sensitivity of 80% and a specificity of 79%.

Robertson *et al* tried to determine which characteristics of rectal bleeding were predictive of CRC from a sample of 604 patients referred to an OA FS clinic who completed a questionnaire, 22 (3.6%) of which were later diagnosed with CRC (Robertson et al., 2006). The most significant predictors were age ($\geq$ 70 years) (odds ratios = 8.2, 95% CI 2.1 to 31.8) and having blood mixed with the stool (age adjusted odds ratios = 3.8, 95% CI 1.4 to 10.5 respectively). However, the authors concluded that as an isolated symptom it held insufficient diagnostic value to be useful in general practice.

Haemorrhoids are a common problem but many patients are further investigated by LGE to rule out the possibility of CRC, whereby rectal bleeding is a significant predictor. When Tang *et al* studied

the impact of a new management strategy for patients with haemorrhoids they found that careful assessment at presentation meant that there was no requirement for LGE as no CRCs were missed (Tang et al., 2005).

6.2   Changes affecting the waiting lists of endoscopy services

Waiting times have always been and probably always will be a sticking point for most NHS services. Over time, the demand for an endoscopy has increased exponentially due to many of the reasons described above, amongst others, but the capacity of the units in terms of resources and space has remained static in most cases. Whilst there has been a marked reduction in waiting list numbers in some NHS Trusts as a result of the innovations that will be described in this chapter, they will never completely disappear because demand will almost always exceed activity, especially as the life expectancy of the population increases and as screening programmes are implemented.

Clinical decisions regarding whether to refer a patient, at what point to operate, etc., are crucial in determining success or failure in reducing waiting times (Lewis and Appleby, 2006). There is currently a far wider understanding of ways to tackle waiting times such as streamlining systems and the application of admission criteria to patients (Lewis and Appleby, 2006). Most endoscopy units try to operate at maximum efficiency with allocated resources most of the time. Even so, the demand placed on endoscopy units mean that some referrals are placed on a waiting list, usually the non-urgent ones. Waiting lists in the endoscopy unit can be split into active and planned: the active waiting list includes patients recently referred for the first time for an endoscopy whilst the planned waiting list contains mostly surveillance patients who are seen on an annual or biannual basis.

A retrospective survey of waiting times experienced by 13,454 cancer patients showed that waiting times for urgent appointments were significantly less than those for non-urgent appointments - median time in days to first outpatient appointment for CRC was 13 days for urgent and 27 days for non-urgent; for stomach cancer was 10 days for urgent and 27 days for non-urgent; and for oesophageal cancer was 11 days for urgent and 24 days for non-urgent (Spurgeon et al., 2000). It

91

also highlighted the need for a clear referral code relating to the degree of urgency based on these differences in waiting times.

Tactics for managing waiting lists have included the delaying of non-urgent patients in the hope that they will get better or go elsewhere, as well as the overbooking of patients because there is a good chance that patients who have waited a long time will not attend, and finally, the ring-fencing of capacity in the belief that they can predict the demand from urgent patients (Silvester et al., 2004). Instead, recent advice from the NHSMA has been to manage the bottlenecks and to reduce the variation in capacity (Silvester et al., 2004).

Long waiting lists are common for LGE procedures because they take longer to perform. UGEs can be completed within 15 minutes whilst LGEs can take up to 60 minutes, depending upon the location of the abnormality, the completeness of bowel evacuation and the need for therapeutic measures (e.g. biopsy). This means that far more UGEs can be done in a session than LGEs, resulting in a short UGE waiting list and a long LGE waiting list. There are also implications involved when allocating procedures to different staff types. Far more nurse endoscopists (see Section 6.4.2) are qualified to do UGEs than LGEs, whilst only a few skilled endoscopists are capable of performing certain therapeutic procedures. There is also a variation in working practices whereby some can complete a list in significantly less time than others. As a result, the efficient endoscopists tend to have lower numbers on their waiting lists whilst the slower ones will have an increasing backlog. Whilst communal waiting lists have been advocated by the NHSMA (NHS Modernisation Agency, 2004e) and the BSG (British Society of Gastroenterology, 2006a), this has resulted in a resistance to pooling waiting lists by the efficient endoscopists. The pooling of endoscopy waiting lists was advocated by the Belfry Plan and also included patients waiting for radiological procedures in the pooling (Richards, 2004) and has been successfully introduced in many endoscopy units as part of the MES project (NHS Modernisation Agency, 2004e).

The 2005 cancer waiting times targets stated that all patient with a suspected upper or lower GI cancer would be treated in secondary care within 31 days of diagnosis and also issued a target for a maximum 62 days from urgent GP referral to treatment (Department of Health, 2004b). The Belfry Plan was written following a meeting by various health professionals to improve on existing

cancer waiting times to meet the 2005 targets (Richards, 2004). The Plan advocated the need to review existing pathways, make sure referrals are appropriate, and to consider referrals of patients for investigation without the need for a consultation first. As of June 2004, the 31 day target was being met in 87% of CRC patients and 95% of upper GI cancer patients, but the 62 day target was only being met in 53.5% of CRC patients and 70% of upper GI patients (Richards, 2004).

Some Trusts have successfully implemented waiting list strategies that involve periodic waiting list validation, whereby those patients no longer requiring a procedure are taken off the list. Approximately one quarter of colonoscopy surveillance referrals are inappropriate (Cairns and Scholefield, 2002) and by applying recent CRC surveillance guidelines, one hospital was able to reduce their colonoscopy waiting lists by 76% by either rebooking patients for a later date (42%) or cancelling their appointment completely (34%) (Shoaib et al., 2006). This resulted in a reduction in urgent and routine waiting times as well as potentially saving the cancer network an estimated £1 million per annum.

The NBAP facilitated faster access to services and reducing waiting times, resulting in a decrease in DNAs from 5.6% in 1999 to 3.2% in 2000, and in patient cancellations from 12.8% to 11.9% for the same period (Kipping et al., 2000). This was attributed to the fact that most patients were allocated appointment dates rather than being kept on a long waiting list with no impending date.

An independent evaluation of three colorectal projects within the Cancer Services Collaborative (see Section 6.5.1) by Robert *et al* reported a non-significant decrease in the median waiting time from 64.5 days to 57 days – an 11.6% reduction (Robert et al., 2003).

The MES project used a variety of methods including waiting list validation, primary targeted lists and agreed follow up protocols to reduce active waiting lists in 22 endoscopy units by 27% over a 10 month period (NHS Modernisation Agency, 2004e). Individual sites commented on reductions in waiting lists attributed to validation, partial booking, guidelines, partial pooling and nurse endoscopists (NHS Modernisation Agency, 2004e). Unfortunately, the planned waiting list was not so successfully reduced but the NHSMA attributed this mainly to the nature of this type of follow-up.

93

A report by the Kings Fund for the DH highlighted five important factors for sustaining reductions in waiting times: Understanding the whole system, sustaining action over time, keeping up the work, coping with unexpected shocks and clinical ownership and involvement (Appleby et al., 2005). However, they were unable to attribute any magnitude of effect to each.

A "straight to test" strategy is currently being employed whereby the patient is referred directly for an endoscopic investigation and does not first see a specialist for an opinion. This cuts down the number of outpatient appointments and shortens the length of time patients wait for an endoscopy but relies on accurate referral information and a clear history (Richards, 2004).

6.3   Changes affecting lost slots in endoscopy services

The Patient's Charter clearly states that patients have a responsibility to attend outpatient appointments or to notify the hospital if they are unable to do so (Department of Health, 1991). However, the failure of patients to attend appointments is on the increase (Spinks, 2003). Patients who do not attend (DNA) or cancel too late are a huge problem for endoscopy units which carefully allocate slots on lists to best suit the medical needs of the patient and the availability of the necessary resources, which end up wasted. Reasons for not attending include forgetting about their appointment, forgetting to cancel it, symptoms resolving by the time their appointment date arrives, clerical errors and fear (Murdock et al., 2002). Some NHS Trusts offer patients who DNA a second appointment, negatively affecting the waiting lists.

One hospital attempted to reduce their colonoscopy DNA rate by introducing a system whereby a nurse specialist provided a patient study group with additional verbal information regarding the procedure two weeks prior to their appointment (Spinks, 2003). However, they were unable to show a significant difference between the study group and the control group who received only written information, but the study only used 19 patients and commented that the control group DNA rate of 10% was below their usual 35%.

The implementation of a nationwide booking system and a telephone reminder system has decreased the number of patients who DNA'd (Hardy et al., 2001, Dockery et al., 2001, Lee, 2003,

Tayal et al., 2006). However, in one study a reminder system resulted in no change to DNA rates, from 9.9% to 9.8% during a six month period (Bateson, 2004). The study also reported an overall increase from 1997 to 2002 in DNA rates from 7.8% to 10.3%.

In some cases it is the hospital that is forced to cancel a list when there are insufficient resources such as staff, facilities or equipment. Consultants are now required to cancel fixed lists to attend acute emergency duties and the lost sessions are difficult to backfill (British Society of Gastroenterology Working Party, 2005b). Endoscopy units need sufficient numbers of appropriately trained staff to safely tend for the patient, in accordance with JAG regulations (Joint Advisory Group on Gastrointestinal Endoscopy, 2004).

Many Trusts have introduced DNA policies to reduce the number of slots left empty by those patients either cancelling late or who DNA (NHS Modernisation Agency, 2004e). This involved strategies to fill empty slots following late cancellations with patients on the waiting list who had indicated that they were available at short notice. Many Trusts also referred patients who DNA'd back to their GP instead of rebooking them. By introducing annual leave policies, some Trusts have placed a minimum limit of six weeks notice for staff to book their annual leave so that those scheduling the endoscopy lists know who will be available at any given time. In this way, staff shortages could be anticipated and planned for to a degree.

The MES project reported a significant reduction in DNA rates in participating sites, with 71% of sites having DNAs of less than 5% and no sites with DNAs more than 10% by the project close (NHS Modernisation Agency, 2004e). Reasons for the reductions included reducing waits, introducing booking systems, implementing a DNA policy and rewriting patient literature in "plain English".

6.4 Changes affecting activity in endoscopy services

HES data showed that for 2000/01, approximately 9.5% of surgical procedures in England were performed on the GI tract, of which 73% were endoscopies (Williams et al., 2007), whilst a 2004

survey by the NAO reported increases in the number of FS and colonoscopies between 1995/6 and 2000/1 of 85% and 65% respectively (National Audit Office, 2004).

The NICE website (www.nice.org.uk/page.aspx?o=352025) currently states that the benchmark UGE rate should be 0.75% per year, or 750 endoscopies per 100,000 population and includes all diagnostic and follow-up endoscopies. Areas with a relatively elderly population, or a population with other risk factors, might be expected to have a slightly higher rate.

The activity in an endoscopy unit is greatly dependent on the potential capacity of the unit in terms of the availability of resources. Even though there is a theoretical maximum output that can be achieved by the unit, it is almost never reached in practice due to limited resource availability, problems with patient attendance and the actual time taken to examine patients resulting in bottlenecks in patient flow through the unit. The NCEPOD report highlighted that of 263 hospitals included in the survey, approximately 7% had only one endoscopy room (National Confidential Enquiry into Patient Outcome and Death, 2004).

Many changes have been implemented in NHS endoscopy units to improve their activity that included changes to staff types and roles and also changes to working practices. Details of these are given below.

6.4.1 Developing endoscopy staff roles

Patient access is restricted by a shortage of trained personnel (UK NHS Cancer Services Collaborative, 2004). *The NHS Cancer Plan and the new NHS* reported a 72% workforce expansion in the field of gastroenterology between 1999 and 2004 (Department of Health, 2004b). The number of GI consultants in England and Wales increased from 335 in 1993 to 725 in 2004, a 216% increase overall (Williams et al., 2007).

The European Working Time Directive from the Council of Europe (93/104/EC) was introduced into the NHS in 2004 and enforced a maximum 48 hour working week (NHS Executive, 1998b). This reduction in the hours of training grade doctors and led to the gradual disappearance of on-call rotas in favour of a more structured arrangement (Barrison et al., 2001). Specific out-of-hours

services have been established in many NHS Trusts to manage emergency cases in need of endoscopy in accordance with the basic requirements of an emergency endoscopy service (Barrison et al., 2001). There is evidence of dissatisfaction in the medical profession with the arrangements (Morris-Stiff et al., 2005). The DH published guidelines to advise on how best to cope with the reduced staff availability of doctors in training (Department of Health, 2004a).

GI endoscopy could fall under the umbrella of the medical directorate, the surgical directorate or both, depending on the Trust, resulting in inefficient administration systems (National Audit Office, 2004). The BSG recommended the need for medical gastroenterologists and GI surgeons to integrate and cooperate to provide the best care for patients with GI disorders (British Society of Gastroenterology, 2006a).

6.4.2 Nurse specialists in endoscopy

Demand for endoscopy often outstrips the capacity for medical endoscopists to provide the service within a reasonable time scale (Barrison et al., 2001). Following recommendations by the BSG (British Society of Gastroenterology Working Party, 2005b, British Society of Gastroenterology, 2006a), many nurses employed within endoscopy units have now progressed to become nurse endoscopists (NEs). They currently undergo rigorous training to reach set standards before qualifying to practice on patients and are trained to a greater level than doctors to work to guidelines and protocols (British Society of Gastroenterology Working Party, 2005b). Most clinicians have recognised the importance of the NE in reducing waiting lists but some have voiced a preference for their roles to be purely diagnostic (Pathmakanthan et al., 2001).

A recent tally of NEs in the UK reported 312 in post, 268 of which were in England (Williams et al., 2007). A 2004 survey of UK endoscopy units by Douglass et al reported that there were 149 NEs in post in 96 JAG-registered units, of which 32% did UGEs, 55% did LGEs and 20% did both (Douglass et al., 2004). Larger units tended to have more NEs and approximately 92% of them had their own dedicated lists. They contributed to a significant proportion of the unit's workload, performing 30.7% ± 6.7% of UGEs and 74% ± 6.3% of all FS procedures (Douglass et al., 2004). However, only a small number of NEs performed colonoscopies. The NCEPOD report highlighted that of 263 hospitals included in the survey, approximately 76% used a NE for at least one session

a week. However, of these, 17% did just one session, meaning that they did not maintain their competence (National Confidential Enquiry into Patient Outcome and Death, 2004).

NEs have now become an established feature in NHS endoscopy units, with 64% of units having at least one NE in post in 2004 (Douglass et al., 2004). The quality of endoscopy performed by NEs is high, with 99% of LGEs counted as successful (Duthie et al., 1998, Goodfellow et al., 2003). Evaluations of NEs show that they can perform with up to 99% sensitivity when compared to alternative methods of diagnosing CRC such as barium enema, and even detected anomalies not seen using radiological methods in 18% of patients (Goodfellow et al., 2003). No complications due to the performance of a NE have been reported to date (Goodfellow et al., 2003, Smale et al., 2003) and they have been shown to perform UGEs as safely as medical endoscopists (Smale et al., 2003).

Two RCTs comparing the effectiveness of endoscopy performed by nurses with medical endoscopists concluded that there was no statistically significant difference in their clinical effectiveness in diagnostic endoscopy for upper GI procedures only (Meaden et al., 2006) and for both upper and lower GI procedures (Williams et al., 2006). Meaden *et al* also reported that the NEs took significantly longer to perform the procedure (8.1 mins Vs. 4.6 mins, p < 0.001), whilst Williams *et al* found that the NEs were significantly more thorough in exploring the upper GI tract and that patients were significantly more satisfied with the endoscopy when done by an NE than a medical endoscopist (Williams et al., 2006).

There is much evidence indicating the benefits of nurse-led care in terms of diagnosing problems and improved patient satisfaction (Goodfellow et al., 2003, Jeffery, 2005, Mason, 2005, Pearson, 2005). Nurses have been proven to be more effective than endoscopists at assessing pain in patients whilst undergoing endoscopy (Ramakrishnan et al., 2004).

The advanced skills of nurses have led to the establishment of nurse-led clinics and dedicated nurse-run endoscopy lists (Loftus and Weston, 2001, Douglass et al., 2004) to facilitate medically qualified specialists undertaking more complicated, specialist investigations. They were also far

98

more flexible in their ability to fill in at short notice when consultants were called away for acute emergency duties (British Society of Gastroenterology Working Party, 2005b).

The multifaceted role of the Clinical Nurse Specialist (CNS) in the area of GI medicine has been described in detail (Hands, 2004). They have been allocated nurse-led clinics to investigate and/or manage patients with dyspepsia (Carter et al., 2004, Mason, 2005, Anagnostopoulos et al., 2006), IBD (Pearson, 2005), Barrett's oesophagus (Jeffery, 2005, Hall, 2006), and those patients with co-morbidities such as iron deficiency anaemia (Griffiths, 2002) as well as one-stop clinics (Goodfellow et al., 2003), TWR referral clinics (Maruthachalam et al., 2005, Smith et al., 2007) and endoscopy clinics set in primary care (Maruthachalam et al., 2006). A review of the work by the CSC reported one nurse-led "change of bowel habit" service saved 98 years worth of patients waiting in just one year (UK NHS Cancer Services Collaborative, 2004).

GI specialist nurses have recently been charged with the responsibility of ensuring that patients referred for endoscopies are fit enough for not only the procedure but also, in the case of LGEs, the bowel preparation (Maruthachalam et al., 2005, Stoker et al., 2005). This is usually done via a telephone pre-assessment and not only reduces the chances of the patient cancelling the appointment through ill health, but is also a source of comfort to the patient as they get to ask questions about the procedure and allay their anxiety. This role is most commonly applied to the TWR referral system within the endoscopy unit to ensure the Trust can meet the two-week target (Stoker et al., 2005).

There is also evidence that nurse practitioners can be successful in the dissemination and implementation of guidelines and the running primary care-based clinics (Chan, 2004). In some cases, the nurse is able to triage the patient based on their comments to ensure that they have been referred to the most appropriate pathway and investigation, which is particularly beneficial to both patient and endoscopy unit when the triaging results in a less complicated procedure e.g. FS replacing a colonoscopy (Stoker et al., 2005).

6.4.3 Improving the quality of endoscopies

The quality of an endoscopy is typically measured according to how successful the endoscopist has been at visualising the furthest required point. A "complete" colonoscopy means visualising the caecum or terminal ileum (Bowles et al., 2004). Following the publication of the NCEPOD report (National Confidential Enquiry into Patient Outcome and Death, 2004), many endoscopy units have evaluated the quality of their colonoscopies to determine whether their completion rates compared favourably with the national target of 90% set by the BSG. Reasons for excluding an uncompleted procedure to produce an adjusted completion rate included the abortion of the procedure due to patient discomfort, uncontrolled looping of the bowel, poor bowel preparation, diverticulosis and adequate delineation of subtotal colitis (Bowles et al., 2004). Adjusted completion rates range from 86% to 94% for hospitals as a whole (Ball et al., 2004, Fasih et al., 2004, Gorard and McIntyre, 2004), with individual endoscopist rates ranging from 74% to 97% (Fasih et al., 2004, Gorard and McIntyre, 2004), although the study by Gorard and McIntyre included trainees in the evaluation. A multi-centre study using 68 endoscopy units reported adjusted completion rate of only 80.4% (Bowles et al., 2004). For those sites participating in the NBSCP pilot, the completion rate reached 89.9% (UK Colorectal Cancer Screening Pilot Group, 2004). Only 19.1% of endoscopy units achieved the recommended 90% completion rate. When comparing adjusted completion rates according to the age of the patient, Karajeh *et al* found that there was a similar completion rate in those patients aged under 65 to those aged 65 and over (88.1% Vs. 87.6%, p = 0.18) (Karajeh et al., 2006).

The training of endoscopy, both doctor and nurse-led, has varied nationwide over the past decade, with many independent, successful training programmes in operation (Duthie et al., 1998). However, some endoscopists have not until recently attended a formal training course (Bowles et al., 2004). The endoscopy training project, funded by the DH, was implemented in 2001 at the Royal College of Surgeons and by March 2004, 797 participants had undertaken training in UGEs and LGEs (Keen, 2004). All endoscopists (nurses and doctors) now have to be trained in accordance with recommendations by JAG before they are permitted to practice on patients. It was hoped that this would reduce the variation in working practices across the UK and would improve the quality of expertise to allow the endoscopist to be more productive and to improve the patients' experience. As well as allowing endoscopy services to meet government targets, the

training of more endoscopists would also relieve the demand when the NBCSP was implemented (Keen, 2004). The use of simulators in training NEs was identified as a safe and necessary method of skill acquisition by a qualitative study using two inexperienced NEs (McGrath et al., 2003). The process of accreditation for endoscopy units is currently underway by JAG (Williams et al., 2007).

Endoscopy, as with any invasive procedure that is accompanied by sedation, comes with risks of complications, as described in Chapter 5. In 2006, the BSG published guidelines to advise endoscopy staff how best to manage patients deemed to be at high-risk of complications including cardio-pulmonary problems, infection, bleeding and perforation (British Society of Gastroenterology, 2006b). The NCEPOD report looked into the causes of patient death within 30 days of a GI endoscopy between Apr 2002 and Mar 2003 and found that of those patients who died, 91% presented as emergency cases and 95% had a co-existing medical condition (National Confidential Enquiry into Patient Outcome and Death, 2004).

The Global Rating Scale (GRS) was developed by Dr Roland Valori, a consultant gastroenterologist at Gloucester Royal Hospital and the national clinical lead for the 18 week endoscopy programme to provide an indication of how a patient will experience having an endoscopy in an endoscopy unit. It contained 12 items reflecting two dimensions: Clinical quality and Quality of patient experience to be completed biannually by participating endoscopy units (Williams et al., 2007). Although the web-based tool was voluntary, it has been estimated to have been used by more than 90% of endoscopy units in England (Williams et al., 2007). It has not been independently evaluated to date so no comments can be made on its impact on NHS endoscopy services, although endoscopists speak of the GRS in a favourable manner.

6.4.4 "Non-medical" endoscopists

The term "non-medical" is a term that is conventionally used in this field and refers to those endoscopists who are not traditionally set in secondary care (GP endoscopists) and also to those NHS staff in secondary care who are not qualified gastroenterologists (radiologists, healthcare assistants) but who have been trained to perform endoscopy.

Primary care-based endoscopy has been introduced in some NHS Trusts to address the increasing imbalance between demand for endoscopies and the capacity of medical endoscopists (Barrison et al., 2001). In 2004, there were 30 endoscopy units based in primary care (National Audit Office, 2004). A study commissioned by the Primary Care Society for Gastroenterology in 27 sites concluded that the use of endoscopy by GPs in primary care was safe (only one fatality in 36455 cases), resulted in shorter waiting times for both urgently and routinely referred patients and had very high levels of patient satisfaction (98% very good or excellent overall) (Primary Care Society for Gastroenterology, Galloway et al., 2002). They commented that it should be considered as an alternative referral source to hospital endoscopy units where available and when hospital waiting lists were extensive.

Swarbrick *et al* reported the engagement of other non-medical endoscopists including radiographers and staff who originated as non-health care personnel who have been educated to degree standard as endoscopists, although these non-medical endoscopists are few in number (British Society of Gastroenterology Working Party, 2005b).

6.4.5   Specialist clinics

Endoscopy services have evolved since 1997 and now incorporate specialist clinics including Barretts specialist clinics (Anagnostopoulos et al., 2006), one-stop dyspepsia clinics (Rutter et al., 1998, Melleney and Willoughby, 2002), one-stop colorectal clinics (Jones et al., 2001, Goodfellow et al., 2003, Badger et al., 2005, Agaba et al., 2006), nurse-led primary care-based clinics (Maruthachalam et al., 2006) and one-stop TWR clinics (Smith et al., 2007).

One-stop clinics cover a range of GI complaints and have been hugely successful in reducing the patient journey to just one hospital visit and improving the communication and management of patients (Melleney and Willoughby, 2002). They usually involve the patient being assessed by a clinician and the investigation required is then carried out by the same clinician or suitably trained NE the same day, often in the same appointment. Patient satisfaction with one-stop clinics are high (83%), especially for the benefits of being treated the same day (Melleney and Willoughby, 2002) and the median waiting time for these clinics tends to be shorter than the routine waiting time (11 days Vs 16.5 weeks respectively) (Melleney and Willoughby, 2002). Jones *et al* reported that

they also reduced the number of patients waiting for LGEs from 119 to 63 over a period of six months (Jones et al., 2001).

Two studies have reported the success of "paper clinics" (Porrett and Lunniss, 2004, Rao, 2006). These clinics involved health professionals meeting to discuss cases and arrange the appropriate follow up treatment of specific patients as opposed to the traditional method of following up all patients in outpatient clinics as a matter of course. This innovation led to a significant proportion (31% for Porrett and Lunniss; 81% for Rao) of patients being discharged because they had no need for a follow-up outpatient appointment, which subsequently led to the increased availability of outpatient appointments.

Anagnostopoulos *et al* reported the impact of a Barrett's specialist clinic gave a more structured approach to the management of patients with Barrett's oesophagus and recommended the establishment of these specialist clinics throughout the UK, along with the need for local guidelines (Anagnostopoulos et al., 2006).

Another recent development has been the introduction of nurse-led endoscopy clinics in the primary care setting. Maruthachalam *et al* studied the effectiveness of a NE performing FS on 100 patients in a GP practice in 2004 and found that the clinic resulted in a reduction of the waiting times from referral to procedure and diagnosis of CRC and also generated additional capacity for endoscopy in secondary care (Maruthachalam et al., 2006).

Evening clinics have been introduced to increase the activity of endoscopy units in response to increased demand. Jones *et al* reported their experiences running a weekly evening one-stop colorectal clinic from 6pm to 9:30pm to investigate their impact on waiting times and patient experience. They found that the number of patients waiting fell during the study period and rose again when the study ended (Jones et al., 2001).

6.4.6 Endoscopy equipment

Endoscopy services require a minimum of six gastroscopes, four colonoscopes, two flexible sigmoidoscopies and three side viewing duodenoscopies, as well as accessories, cleaning and

disinfection equipment (Barrison et al., 2001). Recovery beds are essential to allow the passage of patients out of the endoscopy room and increase patient flow whilst still maintaining quality of care for the patient until they feel ready to leave. Barrison *et al* recommend a minimum of eight to ten trolley beds and an equal number of reclining chairs with adequate monitoring equipment (Barrison et al., 2001).

Lack of functional equipment is another problem for endoscopy activity levels (UK NHS Cancer Services Collaborative, 2004). Given the invasive nature of the endoscope, there are strict protocols regarding their sterilisation. Any endoscopes that do not meet this standard have to be re-sterilised in accordance with BSG standards (British Society of Gastroenterology Working Party Report, 2005). This can take time and usually results in at least one procedure being cancelled. The quality of the endoscope can also cause problems during the procedure, as old endoscopes are more difficult to use, with a higher failure rate. Failures are also common when the GI tract has not been properly evacuated following the inadequate application of bowel preparation, and the mismatching of skilled staff to the appropriate procedure type (Ball et al., 2004).

6.5   Changes affecting all aspects of NHS endoscopy services

6.5.1   The Cancer Services Collaborative Improvement Partnership

The Cancer Services Collaborative Improvement Partnership (CSC-IP) was a national NHS-funded programme designed to drive improvements in the way cancer services were delivered to patients. It did this by providing a practical approach to support local clinical teams to look at their own services and make significant improvements for patients by redesigning the way that care is delivered. Phase1 piloted this approach for breast, lung, bowel, ovarian and prostate cancer with nine out 34 cancer networks in November 1999. Phase 2 commenced in April 2001 and was rolled out to all 34 cancer networks in England. Phase 3, started in April 2003, with service improvement being embedded at cancer network level. Work has expanded across all tumour areas in line with local cancer priorities, with continued national and local clinical leadership. An article by Kelly reported a local experience of the CSC-IP and how the programme brought ideas and tools that were fundamental to identifying problematic areas in their services (Kelly, 2002). Griffiths and Turner have published further information on the role of the CSC-IP (Griffiths and Turner, 2004).

Phase 1 of the CSC was independently evaluated by the Health Services Management Centre at Birmingham University. Participants considered it to be a success as it led to a modernisation drive to improve every aspect of NHS cancer services (Robert et al., 2003). Of the six key levers for change identified by participants, the two most common were the adoption of the patient perspective via process mapping and having dedicated project management time.

6.5.2 Multi-Disciplinary Teams

Multi-disciplinary Teams (MDTs) were set up to more effectively manage the care of all patients with CRC (National Institute for Clinical Excellence, 2004b). They were made up of a variety of health professionals from different specialties with a common interest in cancer patients and would meet periodically to discuss specific patient cases (UK NHS Cancer Services Collaborative, 2004, National Institute for Clinical Excellence, 2004b). NICE guidance reports have emphasised the need for MDTs to continue improving the overall experience of cancer patients due to improved communication leading to better continuity and co-ordination of care (National Institute for Clinical Excellence, 2004b). A BSG report also advocated their use in patient care (British Society of Gastroenterology, 2006a).

A survey of all 183 cancer networks found that 90% had MDTs in operation, although 62% admitted experiencing running problems and 32% did not have a dedicated MDT clerk (Kelly et al., 2003). Of the 150 MDTs in existence at the time, 64% had carried out a patient mapping process, 64% of which were successful. There has been an increase in the number of NHS Trusts with CRC MDTs from 40% in 2002 to 71% in 2006 (Soukop et al., 2007).

Colorectal MDTS have beneficial effects on patient care, training and morale (Sharma et al., 2007). However, in two studies evaluating the decision making at MDT meetings, between 10% and 15% of decisions were not implemented, mostly due to co-morbid health issues and patient choice (Blazeby et al., 2006, Wood et al., 2008). A lack of communication between MDT coordinators and both primary care and patients has also been reported (Soukop et al., 2007). Another negative aspect of MDTs that featured in the literature was that MDT attendance was not built into job plans of colorectal surgeons or nurse specialists (Sharma et al., 2007).

6.5.3 Analysis of working practices

There is a growing evidence base from endoscopy units reporting on audits performed on their services due to the increasing frequency of inspections and reports required by the government. They have been performed to investigate the management of Barrett's oesophagus patients (Jeffery, 2005) and to evaluate the effectiveness of nurse-led dyspepsia clinics (Mason, 2005), the quality of endoscopy within the unit (Thomas-Gibson et al., 2002, Fasih et al., 2004) and cancer waiting times (Lewis et al., 2005). Audits have been successfully introduced into many aspects of endoscopy services (Ball et al., 2004, Parmar and Mayberry, 2005, Davies et al., 2007) although NCEPOD reported that approximately 42% of their study sites did not hold audit meetings in their endoscopy department (National Confidential Enquiry into Patient Outcome and Death, 2004).

The collection of referral, activity and waiting list data highlight discrepancies between the demand and supply of NHS services. However, there is evidence to suggest that this data is not routinely collected by NHS endoscopy units (Thorne et al., 2008). Of a selection of 19 NHS endoscopy units in England, nine of which participated in the MES project, only eight sites collected and submitted any data and only three of these were MES project sites. Even for these eight sites, the datasets were not comprehensive enough to include all four measures requested: referral numbers, number of patients waiting, activity and lost appointment slots (Thorne et al., 2008).

Most endoscopists collect some aspect of clinical data corresponding to the quality of their expertise, although significantly more physicians and registrars collected data (87% and 95%) than surgeons (40%, $p < 0.001$) (Hearnshaw et al., 2007). When surveyed to establish the acceptability of distributing quality-related data, most commonly the colonoscopy completion rates, there was a high degree of resistance, with most endoscopists considering the publication of their outcome data as "fairly unacceptable / not very useful" (Hearnshaw et al., 2007).

When an independent evaluation of the CSC was performed in 2000, it came up against significant constraints as a result of poor patient-level data availability that restricted its ability to confidently evaluate the service quantitatively (Robert et al., 2003). Williams *et al* published a review commissioned by the BSG of the evidence relating to gastroenterology services in the UK in 2007 where they commented on the lack of high quality health technology assessment and evaluation in

the service (Williams et al., 2007). This issue of poor research and evaluation was also picked up in a 2006 BSG report, which went on to recommend the systematic introduction of good research or evaluation relating to initiatives in service delivery (British Society of Gastroenterology, 2006a).

6.5.4 New ways of working

Endoscopy units have attempted to improve the quality of the patient experience by improving the quality of the information given about their endoscopy and the consent process. Postal information and consent has been widely praised during anonymous patient evaluations with between 87.9% and 92.2% reporting the information supplied to be appropriate and useful (Shepherd et al., 2000, Sidhu et al., 2006). One of these studies reported the successful implementation of UGE postal consent, with 93.1% of patients signing the consent booklet and either returning it by post (55.1%) or in person when they attended the appointment (44.9%) (Shepherd et al., 2000).

A multi-centre RCT tested the implementation of patient-oriented self management using IBD patients and found that it significantly reduced hospital visits (difference = -1.04 (95% CI -1.43 to -0.65, $p < 0.001$) whilst maintaining the same degree of quality of life without evidence of anxiety about the intervention (Kennedy et al., 2004). The test group also reported a greater confidence in being able to cope with their condition. The BSG later published a report advocating the introduction of assisted self management by patients (British Society of Gastroenterology, 2006a).

7. THE "MODERNISING ENDOSCOPY SERVICES" PROJECT

The NHSMA set up the MES project to improve NHS endoscopy services in line with the targets specified in the *NHS Cancer Plan* (Department of Health, 2000b). It initiated a culture of redesign, process mapping and rigorous data capture so that endoscopy staff better understood what was happening to the patient during their journey through the unit. It also allowed them to focus redesign efforts where they were most needed. The aim of the MES project was for its participating sites to achieve the following targets (NHS Modernisation Agency, 2003b):

- No patient to wait over three months.
- Increase in effective use of capacity.
- DNAs below 2%.
- Cancellations below 5%.
- Implementation of partial followed by full booking.
- No suspected cancer patient to wait more than 31 days from GP referral to diagnosis.
- Four patient-led changes.
- Locally derived measures.

The team maintained close links with nominated endoscopy staff to facilitate the modernisation process, to explain the project requirements and to provide help and advice wherever necessary to help sites meet these targets.

7.1 The MES Toolkit

The MES Toolkit was a Microsoft Excel-based macro that allowed the input of specific counts of service-related data from the endoscopy unit on a daily or weekly basis, depending on the data type. Once data entry was complete, the software allowed the graphic visualisation of data trends

over time to help staff understand their services. The MES Toolkit was extremely rigorous in its data capture requests, insisting on accurate completion of the following counts and timings recorded in minutes on a daily basis and in some cases, per session (morning or afternoon):

- timings of patient entry and exits from procedure rooms (minutes)
- room turnover times (measured in minutes)
- referral numbers and types (measured as counts)
- activity (measured in minutes)
- potential capacity (measured in minutes)
- cancellations & DNAs (measured in minutes)
- endoscopist details (entered as text)
- waiting list data (measured in minutes and counts)
- failure rates (measured in minutes)

The MES Toolkit aggregated these data variables to produce total Demand, total Activity, total Capacity, total Number of patients waiting and total Lost slots in order to assess endoscopy services. These measures were defined as follows:

- Demand = Referral numbers multiplied by the time taken per procedure requested (measured in minutes).
- Activity = Actual procedure times (measured in minutes)
- Capacity = Total time available for the session based on endoscopist, room and kit availability (measured in minutes)
- Number of patients waiting = Number of patients on the active and planned waiting list (measured as counts)
- Lost slots = Number of over-runs, under-runs, late starts, cancellations, DNAs and failed procedures (measured in minutes).

The MES Toolkit was primarily issued as an Excel file in CD format, accompanied by a user manual (NHS Modernisation Agency, 2003b), and was sent to all sites participating in the MES project for compulsory use. Later in the study, the CD version was replaced by a web-based MES

Toolkit, designated the "Webtool". This version was later revised to make it more user-friendly prior to its national roll-out to all endoscopy units in the UK in 2005.

7.2   The MES project

Phase 1 of the MES project began in January 2002 with 12 endoscopy units using the MES Toolkit and £10,000 to fund the collection of baseline capacity and demand data for three months to identify any relevant issues for service redesign. Following this, they were asked to draft a proposal of redesign initiatives that targeted the areas highlighted by the data collection process as being in need of improvement. Of these 12, only eight were funded by the NHSMA to implement their proposed redesign efforts over the following 12 months.

The MES project identified a number of key issues during the first six months that were common to most sites: Identifying strategic support & clinical leadership, understanding the current service by mapping and analysing patient processes, seeing the service through patient's eyes, being clear about actual demand and actual capacity, understanding existing backlog, using activity records to identify trends over time and promoting new ways of working. These issues formed the framework for the revised MES Toolkit, making it a template for undertaking a demand and capacity audit and a valuable resource for project leads, clinicians and managers seeking ways of effectively improving their endoscopy service.

Phase 2 of the MES project began with all NHS endoscopy units in England being invited to apply to participate in the project by submitting a bid containing a detailed description of their services and proposals for change in Spring 2002. Of the 99 that applied, only 29 were chosen to participate in the preliminary stages of the project based on the scoring of a number of criteria by a panel of adjudicators. Sites selected were "*sites that we felt would benefit from the funding and improve their service*" (personal communication with Liz Allen – MES project lead), and not because of any proven modernisation successes that may have artificially improved the effect of the MES project.

In September 2002, a three month pilot study was initiated in these 29 sites to determine whether they could meet the needs of the project. The sites were allocated £10,000 to facilitate the collection and analysis of data using the MES Toolkit for three months. Only 26 of the 29 sites were invited by the NHSMA to continue with their proposed redesign plans and were allocated a further £30,000 to fund them. Once onboard, these sites were encouraged to attend both national and local events to learn about and disseminate examples of good practice and service redesign to other MES participants.

Of the 70 sites that were unsuccessful in their application to participate in the MES project, all were offered access to the MES Toolkit and training in its use by the NHSMA if they wished to initiate their own redesign efforts, but no funding was attached and help was only available on request, with no monthly upload of data necessary.

During the course of Phase 2, the NHSMA designed and issued their own improvement leaders' guides to help NHS staff find their way through the redesign process including Process Mapping, Analysis and Redesign (NHS Modernisation Agency, 2002d), Matching Capacity and Demand (NHS Modernisation Agency, 2002b), Measurement for Improvement (NHS Modernisation Agency, 2002c), Sustainability and Spread (NHS Modernisation Agency, 2002e), Redesigning Roles (NHS Modernisation Agency, 2004b), Working in Systems (NHS Modernisation Agency, 2004c) and Building and Nurturing an Improvement Culture (NHS Modernisation Agency, 2004a).

7.3 Outcomes of the MES project

A final report of the results of the sites involved in Phase 1 and 2 was published by the NHSMA in February and December 2004 respectively (NHS Modernisation Agency, 2004d, NHS Modernisation Agency, 2004e). The reports concluded that the MES project was a success and described examples of the initial problems identified by the sites. These included extensive waiting lists, high levels of DNAs and cancellations, problems in achieving full booking and poor patient experiences within the units. These problems were reportedly overcome following a better understanding of exactly what was happening in the unit in terms of demand, activity and waiting lists. New ways of working were described in case studies and included the pooling and the

111

validation of waiting lists, implementing DNA policies, rewriting patient information in "plain English", and employing and training NEs. Many sites commented that they were able to secure more external funding with business cases that used data collected by the MES Toolkit, an unforeseen benefit of the software.

In 2004, the NHSMA also published a report containing their list of "top 20 tips" for NHS endoscopy units to take onboard when trying to redesign their services (NHS Modernisation Agency, 2005) and included the following issues: Leadership, empowering staff, communication, patient involvement, process mapping, identifying and removing constraints, validating and pooling waiting lists, analysing demand and capacity data, strategies to tackle lost appointment slots and redesigning roles.

According to the NHSMA's in-house report, the second wave of the MES project was an outright success in terms of successful modification of endoscopy units (NHS Modernisation Agency, 2004e). However, compulsory data collection was terminated in December 2003 so the datasets were too limited to sufficiently determine the full extent of any impact on endoscopy services long term and whether any improvements were sustained long term. Also, their evaluation did not take into consideration the impact of modernisation on the patient journey from the patients' perspective, a major feature of the *NHS Plan*. Finally, there was no comparison with Non-MES endoscopy units to measure the impact of the project as a whole and to assess whether all endoscopy units were improving, not just the MES project sites.

With so many unanswered questions and potentially biased or inaccurate statements in the final MES reports, it was important that the MES project was independently evaluated. This task was undertaken by an independent research group who designed a mixed methods study in order to independently evaluate the MES project using quantitative, qualitative and health economics data analysis and by comparing the MES sites to a set of sites that had not participated in the MES project. This study will be discussed in more detail in the next chapter.

8. THE "EVALUATING INNOVATIONS IN GASTROENTEROLOGY BY THE NHS MODERNISATION AGENCY" (ENIGMA) STUDY

The National Institute for Health Research Service Delivery and Organisation (NIHR SDO) programme (formally known as the NHS Service Delivery and Organisation (NHS SDO)) was established to produce and promote the use of research evidence about how the organisation and delivery of services can be improved to increase the quality of patient care, ensure better strategic outcomes and contribute to improved public health. In 2003, the NHS SDO funded the EvaluatiNg Innovations in Gastroenterology by the NHS Modernisation Agency (ENIGMA) study (SDO/46/2003) to perform an independent evaluation of the MES project using mixed methods (quantitative and qualitative methodology) and also by introducing a control group of sites that had not participated in the MES project for comparative purposes. The NHSMA also contributed a small portion of funds for the study.

The project was based at the Centre for Health Information, Research and Evaluation (CHIRAL) at Swansea University and collaborator sites included Bangor University and the University of Glamorgan. The study team consisted of one quantitative researcher (KT), one qualitative researcher and one health economics researcher. Two secretarial assistants were employed to manage mail and input data. The study team reported monthly to the project steering group (PSG) made up of stakeholders including a consultant gastroenterologist, the quantitative, qualitative and health economics leads and the MES project lead.

The ENIGMA study commenced in September 2003 and started recruiting sites in October 2003. Ethical approval from the Multi-Centre Research Ethics Committee (MREC) for Wales was granted in November 2003 and Local Research Ethics Committees for all study sites were given written notification of the study, as directed by the MREC. The approval of the Research and Development (R&D) departments in all the NHS Trusts involved in the study took between one day

and 103 days, depending on the procedures in place at each Trust (Elwyn et al., 2005). Researchers held honorary contracts for all study sites prior to commencement of the first wave of patient recruitment in all 20 sites in April 2004.

8.1 Background

In brief, 99 endoscopy units in England submitted applications to participate in the MES project. Of these, 29 were successful in securing initial funding to analyse their services and prepare a redesign plan. Only 26 of these sites went on to fully participate in the next 12 months of the MES project – the redesign implementation phase. The ENIGMA study randomly selected ten MES study sites from these 26 sites by interval choice using an assigned random number after ranking sites according to bed numbers to ensure stratification by size. A reserve list of replacement sites was selected by allocation of one before and one after systematic interval sampling.

Of the 70 sites that were not successful in their application, 27 had indicated to the NHSMA that they were still interested in redesigning their services and expressed interest in attending MES Toolkit workshops and other NHSMA-led redesign workshops. The ENIGMA study randomly selected ten Non-MES study sites from these 27 in the same way as described above. Figure 5 better illustrates the recruitment of sites in this study. A reserve list of replacement sites was selected by allocation of one before and one after systematic interval sampling.

The 20 ENIGMA study sites were invited by letter to participate in the study and were each offered £5,000 as an incentive to participate and to cover costs. All endoscopy units were visited in person to introduce the study, agree the key contact person and assess the current method of service delivery within the unit.

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          ┌─────────────────────────┐
          │  99 endoscopy units who applied  │
          │      for the MES project          │
          └─────────────────────────┘
              /                    \
   ┌──────────────┐          ┌──────────────────┐
   │ 29 sites selected │          │ 70 sites unsuccessful │
   └──────────────┘          └──────────────────┘
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│ 3 sites │ │ 26 sites with │  │ 27 sites indicating a │ │ 43 sites with no │
│ dropped │ │ full funding  │  │  wish to redesign     │ │ wish to redesign │
└────────┘ └──────────┘  │   independently       │ │  independently    │
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       ┌────────────────┐  ┌────────────────┐
       │ 10 sites selected by │  │ 10 sites selected by │
       │  the ENIGMA study    │  │  the ENIGMA study    │
       │     (MES sites)       │  │   (Non-MES sites)     │
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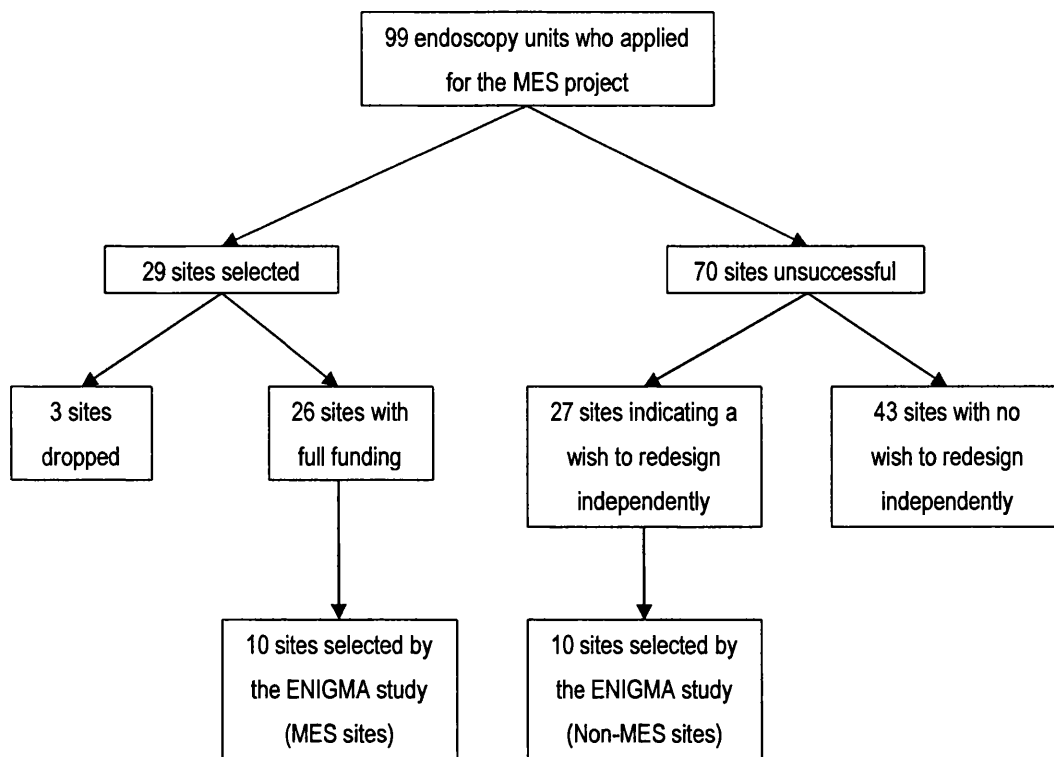
Figure 5: Flowchart to indicate the selection of MES and Non-MES sites by the ENIGMA study.

8.2 Aims and objectives

The aims of the ENIGMA study, as written in the final proposal to the NHS SDO were:

1. To evaluate, both quantitatively and qualitatively, innovative models of delivery and organisation of gastroenterology services in general, and endoscopy services in particular, initiated and co-ordinated by the MES project.

2. To compare the accessibility and acceptability to patients and professionals of the resulting models of service delivery and organisation with those of other new models.

3. To compare the effectiveness and cost-effectiveness of the resulting models in improving outcomes assessed by patients and professionals with those of other new models.

The objectives of the ENIGMA study were:

1. To describe new models of service delivery designed to improve the assessment and management of patients with new and continuing GI disorders. While many of these models will arise in experimental sites directly from the MES project, others will arise in control sites, either indirectly from the MES or independently of the MES. While some will focus narrowly on endoscopy services, others will cover gastroenterology services in general.

2. To estimate for both experimental and control models of service delivery:
   a. Accessibility and other measures of the quality of the process of care.
   b. Acceptability to patients and professionals and their perception of the value of these models.
   c. Outcome as assessed by patients and professionals.
   d. Resources consumed by NHS, patients and society in general.
   e. Effects on other aspects of the NHS.
   f. To develop methods to evaluate complex heterogeneous interventions designed with a common purpose.

8.3 The mixed-methods approach

The ENIGMA study used a variety of methodologies to evaluate the MES project from a secondary and primary care perspective using both quantitative and qualitative techniques. Each is discussed below in more detail.

8.3.1 Patient quality of life scores

The primary outcome of the ENIGMA study was to measure the effect of innovations implemented at each study site on patient QoL scores at three points in time: at the time of the patients' referral using the Baseline Questionnaire (BQ), immediately after their procedure using the Post Procedure Questionnaire (PPQ) and 12 months after the procedure using the 12 month Post Procedure Questionnaire (12m PPQ). If a procedure had not taken place within one year of referral, a 12 month Post Referral Questionnaire (12m PRQ) was sent.

116

Each of these study questionnaires contained the following sub-sections: the Medical Outcomes Study or Short Form 36 (SF-36 v2) questionnaire (www.sf-36.org), the Euroqol-5D (EQ-5D) questionnaire (www.euroqol.org) and the GI Symptom Rating Questionnaire (GSRQ) (Williams et al., 2006). A fourth questionnaire, the GI Endoscopy Satisfaction Questionnaire (GESQ) (Williams et al., 2006), was included in the PPQ only.

Patient QoL scores were collected from the questionnaires of all consenting patients from five waves of patient recruitment (Spring and Autumn 2004, Spring and Autumn 2005 and Spring 2006). The questionnaires were scanned using a Canon DR5020 scanner and the scores were downloaded into SPSS™ v13 (Lead Technologies Inc. 2004, USA) for statistical analysis.

8.3.2 The analysis of endoscopy unit data

Each endoscopy unit was contacted to determine whether they could provide some basic demand, activity and waiting list data. For those sites able to collect the data, forms requesting data for the five calendar months coinciding with the five waves of patient recruitment were posted to endoscopy units immediately following those months. A reminder form was sent by email if there was no response after one month. Retrospective data were also requested for the calendar months of January 03, June 03, and December 03, to coincide with the start, middle and end of the MES project.

The ENIGMA data collection form asked for the following counts for a specific calendar month, split by procedure type (FS, colonoscopy and OGD/Gastroscopy), and by degree of urgency (urgent or non-urgent).

1. The number of patients waiting more than 13 weeks for their endoscopy.
2. The % DNA rate.
3. The average time from GP referral to procedure.
4. The number of referrals made to the unit.

8.3.3 A survey of the views of health professionals

A longitudinal, qualitative evaluation was undertaken to gain some personal insight into the structures, processes and outcomes of the planned innovations and how they changed and developed over time. One consultant and one change agent from each of the participating sites, were interviewed face-to-face during Summer 2004 and Summer 2006 using semi-structured interviews that discussed their endoscopy unit's redesign efforts. If the same person was no longer in post when the second interview was due, a suitable replacement was found.

A focus group was also arranged in Spring 2006 with endoscopy specialists from hospitals that did not apply for the MES project. These sites were deemed to be completely independent of the MES project. The focus group was made up of five consultants and one nurse specialist and they were asked to contribute their opinions on themes relating to barriers and facilitators to change within their own endoscopy units.

8.3.4 A survey of patient views

Two patients per site, one urgently referred and the other non-urgently referred, were interviewed following their procedure. This was done on two separate occasions, one using Wave 2 patients recruited in Autumn 04 and the other using Wave 5 patients recruited in Spring 06. The interviewees were asked about their views on their referral to the endoscopy unit. The interviews were done over the telephone using semi-structured interviews and were recorded with the patients' consent.

8.3.5 The health economics evaluation

A health economics questionnaire (Williams et al., 2006) was also included in all study questionnaires to determine how often patients had used any health services in the last three months, what medication they were taking, and the prescribed dosage.

The health economics evaluation also estimated the NHS cost of each model of service delivery by identifying the NHS resources consumed by patients. Resources were valued in monetary terms using standard methods to derive a cost per patient referred. Cost utility analysis was performed using the EQ-5D from all three questionnaires and the incremental cost per quality adjusted life

year was estimated by comparing changes in EQ-5D scores with NHS costs. Cost effectiveness analysis was performed by comparing total societal costs with changes in the GSRQ score. The health economics researcher also conduct interviews at all sites in winter 2004 to discuss the costs involved in the endoscopy service and in any redesign initiatives employed at each site.

8.3.6 Capturing GP views using GP questionnaires

All GPs with patients in the study were sent a questionnaire at the end of Wave 5 asking for their perception of the impact of the changes that had occurred in the endoscopy unit participating in the study. The questionnaire asked GPs to complete a "yes/no" tick box to indicate whether they perceived that specific changes had occurred during the last two years, accompanied by a three-point Likert rating scale to reflect their opinion on the impact of the change ranging from better to worse. GPs were also invited to make specific comments for qualitative analysis.

9. THE RESEARCH QUESTION

This chapter will discuss the reasons why this research study was conducted, given that the ENIGMA study already existed. It will also discuss in detail the research questions being addressed, the hypotheses being tested and the basis for those hypotheses. The outcome measures used to address the research question are described in detail. The chapter closes with the definitive aims and objectives of this study.

9.1 Why was this research study necessary?

The final reports from the NHSMA concluded that the MES project was successful in facilitating the improvement of service delivery within participating endoscopy units and presented many case studies as evidence (NHS Modernisation Agency, 2004d, NHS Modernisation Agency, 2004e). The positive nature of these reports could have a profound effect on the way NHS endoscopy services, and possibly NHS services as a whole, modernise in the future by heralding the investiture of data collection software, improvement guides and process mapping techniques in partnership with the allocation of some financial backing to support redesign plans and achieve improvements in service delivery under the supervision of an organisation with redesign expertise.

However, it is important to recognise that the way these reports were analysed brings into question their internal and external validity – there may have been bias in the way data was collected and / or analysed, and the results were not easily applicable to all NHS endoscopy units. The reports were written by the MESPT and were based on prospectively collected data submitted by each study site for the sole purpose of the project. Also, the sites received financial rewards for their participation, providing a potential for bias in the data they reported.

It was important to independently evaluate the MES project to examine the occurrence and impact of any potential bias in the NHSMA reports prior to this modernisation project being rolled out

nationally for NHS endoscopy services or adapted for other NHS diagnostic services. The best way to do this was to compare the MES sites with a set of Non-MES sites, as described in Chapter 8, to determine whether there were any real differences between both site types in terms of their ability to successfully redesign their endoscopy services that could be directly attributable to the MES project.

The basis of the evaluation by the ENIGMA study focussed primarily on differences between MES and Non-MES sites from a patient-centred perspective by analysing patient QoL scores at three separate time points during the patient journey. They also examined the effect of the MES project on health professionals from primary and secondary care using questionnaires and interviews respectively, along with an evaluation of the cost efficiency of the service using health economics techniques. One smaller aspect of the ENIGMA study not planned for in the original proposal was the collection and analysis of service-related endoscopy data. Even though they later added this facet to the study, data were not completed in sufficient quantity or quality for any high quality analysis, leaving the option of only descriptive results for the final report. Since the author of this thesis viewed this aspect of the evaluation to be of high importance, she proposed an additional study within the remit of the ENIGMA study that involved a more comprehensive data collection and analysis study as a more appropriate method of evaluating the MES project.

Based on the findings of the literature review in Chapter 6, there was a clear gap in the field on independent research evaluating the modernisation of NHS endoscopy services in any way. The ENIGMA study will provide answers to the question of how effective the MES project was but it will be primarily from the perspective of patients and health professionals. What this research study offered was an independent evaluation of the MES and Non-MES sites using data that was routinely collected by endoscopy units and corresponded to various aspects of service delivery. The outcome measures included as service-related datasets will be described later in this chapter. It was felt that this type of data analysis would provide a more relevant and accurate picture of the effect(s) of improvement in terms of both the quality of data collected and the analysis of the data over time within and between MES and Non-MES sites.

It was felt that this study design would be a far better tool with which to evaluate the MES project because it would use completely unbiased, retrospectively collected data from endoscopy units. It would not be subject to recall bias in any way, which was a major limitation of the ENIGMA study, which relied upon the memories of patients and health professionals upon which to base their evaluations. It was also similar in many ways to the evaluation of the services of MES sites by the MESPT using the MES Toolkit, making the results of this study more comparable with the NHSMA's MES project report (NHS Modernisation Agency, 2004e)

9.2 The research question

This study was designed as a longitudinal, observational study to independently evaluate whether the recent modernisation drive in NHS endoscopy units in England participating in the MES project (the MES sites) had resulted in any significant changes to the delivery of their endoscopy services when compared to NHS endoscopy units in England who were not successful in their application to participate in the MES project but had indicated their intention to modernise their services independently (the Non-MES sites). For the purpose of this study, the term modernisation was defined as any changes, both new ways of working and doing more of the same, implemented with a view to improving the service.

This study was designed primarily to analyse routinely collected, service-related endoscopy data from each individual site to identify trends in data over time. Data were aggregated according to Site type into an MES group and a Non-MES group to explore any within-group data trends, to determine whether there were any significant differences between the MES and Non-MES group datasets and to determine whether any improvements in both groups were sustained. The specific outcome measures taken from the service-related endoscopy datasets are discussed later in this chapter.

Other facets of this study involved ascertaining the availability of routine data from each study site. Additionally, the data submitted for this study would require validation using an appropriate gold standard, namely the HES datasets. Finally, a descriptive comparison of the types of innovations introduced and the times of their first implementation would be made for MES and Non-MES sites

to identify whether the MES project had significantly influenced the modernisation plans employed by each of the study sites.

9.3   The background to the research question

The MES project advocated the need to collect high quality service-related endoscopy data to identify problematic areas in service delivery for a targeted redesign plan. They taught that to improve a service, one must first understand it in terms of what is input and what is output. The project also highlighted the need for measuring the impact of any improvement plans by collecting baseline and follow-up data over a specific period of time to analyse for significant changes over time. The MES sites were provided with data collection software for compulsory completion of service-related endoscopy unit data and unlimited advice and support during their 12 month redesign period. Consequently, the MES sites would have collected high quality service-related data during the course of the MES project that was uploaded to the MESPT for analysis that was also available to them for their own purposes. The MES sites also had access to £30,000 to fund the redesign plans that the NHSMA had approved over a period of 12 months.

The Non-MES sites in this study received no funding from the NHSMA and whilst they were offered access to the MES Toolkit and training, it was not compulsory. They were not obliged to complete the MES Toolkit in a rigorous manner because the data were not uploaded to the MESPT. It was up to the endoscopy staff themselves to accurately collect, input and analyse data to identify problem areas in the service to target for redesign.

9.4   The hypotheses being tested

The aims and objectives of this study were to test the hypotheses formulated below and come to a conclusion regarding the effectiveness of the MES project on NHS endoscopy services in England in terms of its immediate effect on MES sites, and its sustainability over time. This study would also determine the effect of modernising independently using the Non-MES sites. Finally, it would compare the MES and Non-MES sites to ascertain whether their services were significantly different at any point in time.

To measure how endoscopy services had changed over time, five outcome measures defined as "service-related data" variables were selected: Number of referrals (*Referral numbers*), Number of patients waiting more than three months (*Wait >3m*), Total number of patients waiting at a specific point in time (*Snapshot*), Number of lost appointment slots (*Lost slots*) and Number of procedures performed (*Activity*). These outcome measures are discussed in more detail later in this chapter. Using these outcome measures, this study would test the following hypotheses:

Hypothesis 1 - The MES sites would have a better system of routine data collection implemented than the Non-MES sites.

It was hypothesised that since the MES sites had to implement a rigorous data collection regime to complete the MES Toolkit in accordance with MES project guidelines they would have a better system for routinely collecting service-related data which would have been embedded during 2003 and maintained following the close of the MES project. It was also hypothesised that the Non-MES sites would collect rudimentary data (or possibly no data) in a more haphazard manner and that they would not be as proficient in the appropriate analysis of data to identify problematic areas in the delivery of their services. The null hypothesis was that there was no difference between the MES and Non-MES sites in their data collection practices.

Hypothesis 2 - The MES project would significantly improve various aspects of the endoscopy services of the MES sites.

It was hypothesised that over time the MES sites would show statistically significant changes in their services, namely increases in *Activity* mirrored by decreases in the *N° patients waiting* and *Lost slots*, irrespective of any changes in *Referral numbers*, as these were some of the targets set by the MESPT to be addressed in the redesign plans of the MES sites. It was also postulated that these improvements would not only be sustained but that we would see evidence of further improvement over time as a result of the embedding of a "modernisation culture" established within these sites by the MES project. This "ideal model" was proposed here as the gold standard that all MES sites should, in theory, have achieved over time. The model is better illustrated in Figure 6, indicating the proposed ideal changes to the endoscopy services of MES sites, both during the project and beyond. The null hypothesis was that there was no statistically significant change in any aspect of the service-related data from MES sites over time.
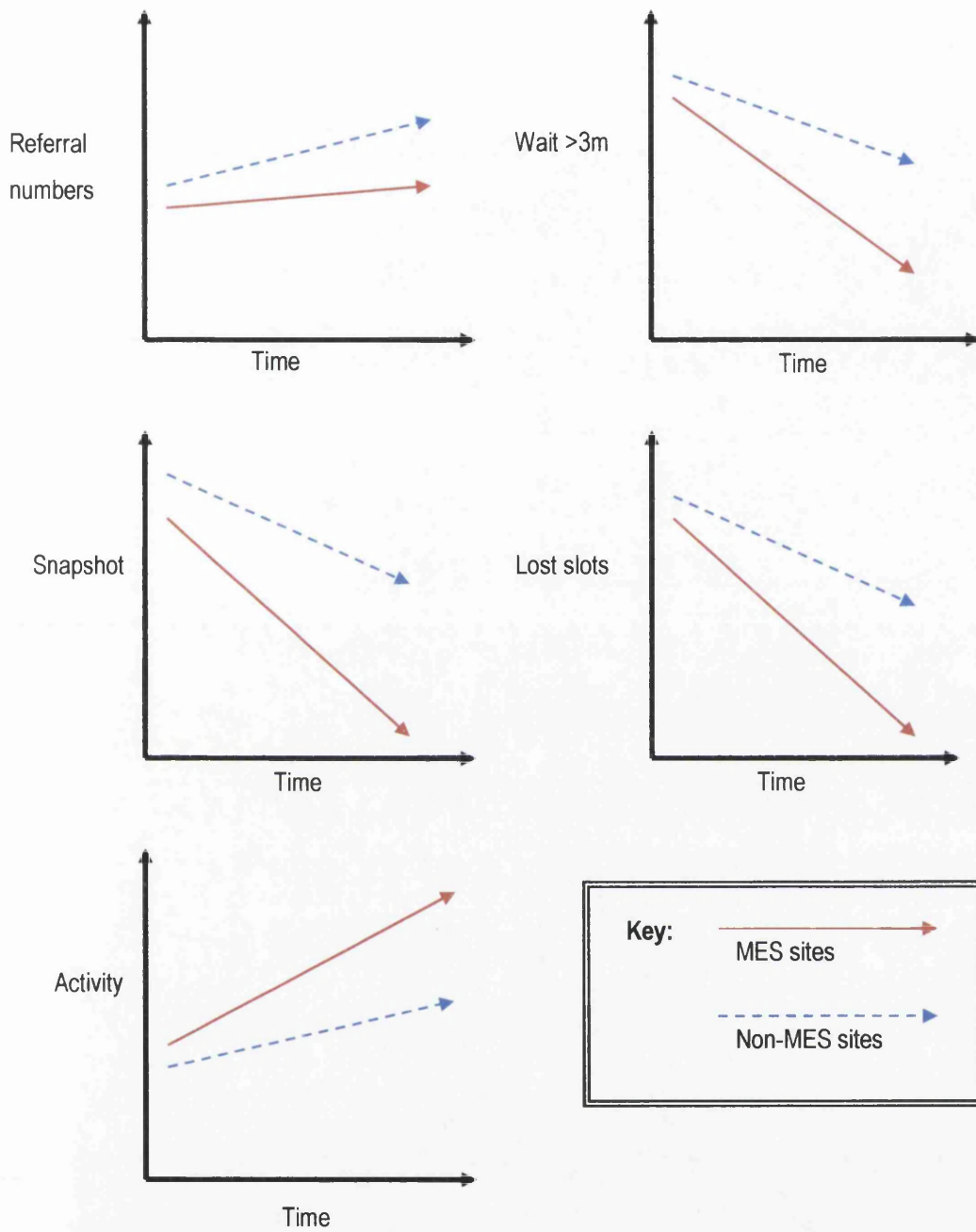
Figure 6: Illustration of the hypothesised changes in service-related data using five outcome measures (*Referral numbers, Wait >3m, Snapshot, № lost slots* and *Activity*) over time for MES and Non-MES sites.

Hypothesis 3 - The Non-MES sites would not have significantly improved their services, although some changes would be inevitable due to the natural evolution of their services and their intention to redesign independently.

It was hypothesised that the endoscopy services of the Non-MES sites would also show evidence of service improvement due both to their intention to modernise and to the "natural evolution" of their services over time as a consequence of other independent improvement programmes such as the NBAP. However, any improvements identified would not have been large enough to be statistically significant. The proposed model of the change in Non-MES site endoscopy services over time is illustrated in Figure 6. The null hypothesis was that there was no change whatsoever in any aspect of the service-related data from Non-MES sites over time.

Hypothesis 4 - There would be a significant difference in the endoscopy services of the MES group and Non-MES group that would increase over time.

It was hypothesised that the degree of improvement in the services of the MES sites, as measured by the five outcome measures stated in this chapter, would have been significantly different to the degree of improvement (or otherwise) in the services of the Non-MES sites. It was also hypothesised that over time, the differences between the MES and Non-MES sites would increase significantly. These hypotheses are also illustrated in Figure 6. The null hypothesis was that there was no significant difference between the MES and Non-MES sites in their service-related data at any point in time.

Hypothesis 5 - The MES sites would have introduced more innovations during the study period than the Non-MES sites.

Whilst both MES and Non-MES sites would have implemented a number of redesign initiatives during the course of this study, it was hypothesised that the MES sites would have introduced more innovations compared to the Non-MES sites due to the earlier implementation of redesign plans and the close guidance, support and advice provided by the MESPT. The null hypothesis was that there was no difference between the MES and Non-MES sites regarding the number of innovations introduced.

9.5　Study outcome measures

The outcome measures used for this study were based on some aspects of the service-related endoscopy data collected by the MES Toolkit from the MES sites. It was thought that if the MES project advocated the collection and analysis of demand, activity and capacity data using this software on a routine basis, then this evaluation should also be based on as many of the principles of the MES Toolkit as was feasible to collect retrospectively.

Since the ENIGMA study did not originally plan this type of data collection, this study was restricted to requesting data that was routinely collected by the endoscopy units and was unable to finance any retrospective data collection for more detailed data that were not routinely collected. One advantage to this was that it was able to get a clear picture of the nature of the data collection practices of each site. Unfortunately, capacity measures such as staff numbers and resource availability were not routinely collected or easily retrievable by NHS endoscopy units.

The analysis of the service-related endoscopy data were confined to the three most commonly requested endoscopies, namely UGEs, FS and colonoscopy. For the purpose of this study, the UGE category included both gastroscopies and OGDs because some study sites grouped both procedures into "Uppers" whilst others discriminated between the two in their data. From these three procedure types, "*total procedures*" data would be calculated and included as a feature of the analysis as well as examining the data split according to individual procedure types (designated *split procedures* data). The reason for this was to identify whether there were any changes in any of the five outcome measures that were specifically attributable to a particular procedure which would have been hidden when analysing *total procedures* data. For example, the referral guidelines for dyspepsia (National Institute for Clinical Excellence, 2004a) advocated the use of diagnostic UGEs, which may have resulted in an increase in UGE *No. patients waiting* and *Activity* that may have been obscured in the *total procedures* data analysis.

A more detailed description of each outcome measure follows, along with the time periods of data collection. All subsequent references to the outcome measures in this thesis will refer to them according to the titles given below, each of which will be italicised from this point for easier identification.

9.5.1 Referral numbers

This was the number of referrals received by the endoscopy unit for diagnostic and therapeutic UGE, FS and colonoscopy procedures made to the endoscopy unit during a specified time period. We requested that data be split where possible into referral types, including daycases (outpatients), TWR referrals, inpatients, follow-ups and emergencies.

9.5.2 Number of patients waiting more than three months (Wait >3m)

This study requested the number of patients waiting for diagnostic and therapeutic UGE, FS and colonoscopy procedures on the active waiting list for more than one month, three months, six months and 12 months during a specified time period. Of these, it was the number of patients waiting more than three months (designated *Wait >3m*) that was selected as the main waiting list target measure for all subsequent analyses because it was a government target that all NHS patients in England should be seen within 13 weeks of a referral by their GP.

9.5.3 Total number of patients waiting (Snapshot)

The total number of patients waiting on the active waiting list for diagnostic and therapeutic UGE, FS and colonoscopy procedures at a specific point each month during a specified time period, irrespective of how long they had been waiting, was also requested (designated "*Snapshot*").

9.5.4 Lost appointment slots (Lost slots)

This was the total number of individual diagnostic and therapeutic endoscopy appointment slots "lost" due to patient DNAs and cancellations by both hospital and patient during a specified time period. This dataset was not requested split by procedure type as the datasets were not routinely compiled in this way.

9.5.5 Number of procedures performed (Activity)

This was the total number of diagnostic and therapeutic UGE, FS and colonoscopy procedures performed within the endoscopy unit by endoscopy staff during a specified time period. The request did not include any procedures done within an outpatient clinic or theatre unless they were done within the remit of the endoscopy unit.

9.6 Time periods of data collection

All data were requested for specific calendar months to get a better idea of the performance of the service over a long period of time. A total of eight separate months were chosen by the ENIGMA study, due to their intention to combine this data with their own analyses for their final report. The months falling in 2003 corresponded to the start, middle and end of the MES project, whilst all other months related to the first five waves of patient recruitment within the ENIGMA study. Where these specific dates were not available, data were accepted if within one month.

This thesis refers to each month according to the corresponding time (T) value, indicated in brackets: January 2003 **(T0)**, June 2003 **(T1)**, December 2003 **(T2)**, April 2004 **(T3)**, November 2004 **(T4)**, April 2005 **(T5)**, October 2005 **(T6)** and April 2006 **(T7)**. The T0 data were to be used as a baseline measurement against which all subsequent data would be compared. Where T0 data were not available, the closest time points with data were used instead. Data were retrospectively requested in two phases, the first to cover T0 to T4 and the second to cover T5 to T7.

9.7 Study aims and objectives

To summarise, the aims of this study were:
   a) To make an independent assessment of the impact of the MES project based on the comparative analysis of service-related endoscopy data from MES and Non-MES sites.
   b) To determine whether any changes in service-related endoscopy data from both MES and Non-MES sites were sustained over time.
   c) To comment on the type and extent of innovations implemented as part of the modernisation agendas of the MES and Non-MES sites.

This would be achieved by fulfilling the following objectives:
   a) To collect routinely collected, service-related endoscopy data from 10 MES and 10 Non-MES study sites.
   b) To determine whether there were any significant positive changes in service-related endoscopy data in the MES sites and the Non-MES sites over time.

c) To explore whether there were any significant differences in service-related endoscopy data from both MES and Non-MES sites at specific points in time.

d) To measure the extent of any changes (in terms of time) in service-related endoscopy data from both MES and Non-MES sites.

e) To describe the types of innovations implemented in both MES sites and Non-MES sites over time and comment on the "innovativeness" of each site based on the types of innovations introduced and when they were first implemented.

To address these aims and objectives in a logical manner, the remainder of this thesis was split into individual chapters that would cover the availability of data (Chapter 10), the validation of data (Chapter 11), the analysis of data (Chapter 12), and a description of the innovations introduced (Chapter 13). Each of these chapters would be structured with a Methods, Results and Discussion section. An overall discussion of the study as a whole, including its strengths and weaknesses, would be located in Chapter 14, along with a discussion of the results of this study in context, the conclusions of the study and any recommendations arising.

10.   THE DATA COLLECTION PROCESS

The principal aim of this study was to ascertain whether the MES project had any significant impact on participating sites by comparing specific NHS endoscopy datasets from MES sites with those sites who modernised independently. To do this, the study aimed to analyse routinely collected, service-related endoscopy data from each study site. For the purpose of this thesis, the term "routine" refers to data already collected and used by the endoscopy unit and not retrieved for the sole purpose of a research study. This chapter describes the data collection process and the datasets received. It also describes how the datasets from each source were assessed for compatibility and comparability, prior to the aggregation of the data to form the final dataset used in all subsequent analyses. A focussed discussion on the availability (or lack thereof) of routinely collected, service-related endoscopy data from the endoscopy units closes the chapter.

10.1 Methods

10.1.1 Hospital recruitment

This study used the same endoscopy units that were randomly selected by the ENIGMA study, as described in Chapter 8.

10.1.2 Details of the data requested

The data request consisted of counts for the five study outcome measures previously discussed in Chapter 9, namely *Referral numbers, Wait >3m, Snapshot, Nº Lost slots* and *Activity.* Where possible, counts were split according to the three most commonly performed procedure types – UGEs, FS and colonoscopies – for all queries except for *Lost slots,* which were not generally collected according to procedure type. Where the sites were unable to split data by procedure type, the total number was accepted but it was noted that this figure would also contain unspecified endoscopic procedures, albeit in low numbers, making the data less comparable. All five outcome

measures were retrospectively requested for the eight calendar months discussed in Chapter 9, labelled T0 to T7.

10.1.2.1 The endoscopy unit data request

All participating endoscopy units were approached by phone or email in January 2005 to provide copies, either electronic or hard copy, of any service-related endoscopy data that had been routinely collected. The purpose of the data request was twofold: firstly to find out what type of datasets were collected by the endoscopy unit, if any, and secondly to provide datasets at their rawest (and probably its truest) levels, free from manipulation or misinterpretation by NHS Trust information departments. It was suggested that any other relevant data were also submitted. Units sending in-house datasets were asked to provide detailed descriptions of the data and any definitions used to make sure datasets were suitable for analysis. The initial data request in January 2005 retrospectively collected data pertaining to T0 to T4. Follow-up datasets to cover T5 to T7 were retrospectively requested in June 2006. The deadline for final data collection was January 2007.

Routinely collected data were specified for four reasons: (1) The ENIGMA sites had not agreed to collect any service-related data for this study as it was not part of the ENIGMA study's original remit, (2) the retrospective nature of the data request, (3) the fact that no financial incentive was made available to the units to fund the manual retrieval of these datasets if they were not routinely available, and (4) it would indicate what type of data were considered to be important enough to be collected by the endoscopy units.

Following the submission of all endoscopy unit datasets, Mann-Whitney U tests were used to determine whether there was a significant difference in the time taken by the endoscopy units of MES and Non-MES sites to return their datasets. Statistical tests were done using SPSS version 13 (Lead Technologies Inc, USA). A p-value of ≤ 0.05 was considered to be statistically significant.

10.1.2.2 The NHS Trust Information Services endoscopy data request

To ensure that this study had complete datasets for each time period and each outcome measure, equivalent datasets were also requested from the corresponding Trust Information Services (TIS)

departments of each study site's NHS Trust. In April 2005, the TIS managers of all 20 study sites were contacted by letter to ask whether they would be prepared to release copies of any service-related data that they routinely collected corresponding to the endoscopy unit of the hospital involved in ENIGMA within the Trust. Where no response to the original data collection request was received after six weeks, a second letter was sent. This time, the letter was addressed to a specific person in the TIS department identified by a contact based at HES. Where no response was received to the second letter, efforts were made to communicate with the person by email and telephone on a minimum of five separate occasions before the request was abandoned. Where other Trust sources of data were identified by the ENIGMA contact, such as IT departments, the named contact was approached by Email or phone in the same way. The initial data request in April 2005 retrospectively collected data pertaining to T0 to T4. Follow-up datasets to cover T5 to T7 were retrospectively requested in June 2006. The deadline for final data collection was January 2007.

Since TIS datasets were likely to be extensive if collected at the patient-level, the TIS contacts were also offered the option of a data collection proforma for completion designated the *TIS form*. The proforma was designed as an Excel-based spreadsheet that consisted of four pages requesting data on *Referral numbers* (Form A), *N° patients waiting* (Form B), *N° Lost slots* (Form C) and *Activity* (Form D) respectively, with the sub-variables described in Chapter 9 incorporated within the form (see Appendix 16.3). The *TIS form* was accompanied by a comprehensive instruction sheet to ensure its completion was accurate, comparable and related only to the hospital specified, not the Trust as a whole. The instructions also asked for the data request to be completed using the Office for Population Censuses and Surveys-4 (OPCS-4) coding system used by HES:

- Endoscopic operations on the oesophagus (G16 to G19) using OGD or gastroscopy.
- Endoscopic operations on the upper GI tract (G43 to G45) using OGD or gastroscopy.
- Endoscopic operations on the colon using colonoscopy (H20 to H22).
- Endoscopic operations on lower bowel using FS (H23 to H25).

TIS departments sending their own in-house datasets were asked to provide a detailed description of the data types and definitions used to ensure they were comparable with *TIS form* datasets. The *TIS form* was piloted in one study site endoscopy unit prior to being sent to those TIS contacts requesting a proforma.

Following the submission of all endoscopy datasets from the TIS contact, Mann-Whitney U tests were used to determine whether there was a significant difference in the time taken by the TIS departments of both MES and Non-MES sites to return their datasets. Statistical tests were done using SPSS version 13 (Lead Technologies Inc, USA). A p-value of ≤ 0.05 was considered to be statistically significant.

10.1.2.3 Endoscopy data from the ENIGMA study

As previously mentioned in Chapter 8, the ENIGMA study requested the retrospective completion of a rudimentary ENIGMA data collection form by each site with the datasets corresponding to the same time points as used in this study (T0 to T7). These datasets were available for this study, if necessary.

10.1.3 Assessment of endoscopy data collected

All data received were assessed following discussions with site contacts (endoscopy unit and/or TIS contacts), using the definitions provided and by using observational comparisons to determine their accuracy and comparability with other datasets. The *TIS form* was used as a proforma for the extraction of in-house, routinely collected data provided by both endoscopy units and the Trust to structure comparable datasets. The exclusion criteria described below were imposed following the first data request (T0 to T4) and where data were not suitable, it was not requested for T5 to T7. More suitable replacement datasets were requested wherever possible.

During the data extraction process, datasets were assessed for its compliance to strict specifications and in accordance with the instruction sheet accompanying the *TIS Form*. Data were excluded whenever they did not conform to the request in either content or output style (e.g. Trust-wide data, planned and active waiting list data combined, percentages, etc). Data were also excluded when not split according to procedure type because it was likely to include additional

endoscopic procedures, albeit small, artificially inflating the *total procedures* figures, thereby making the dataset inaccurate for comparison.

10.1.4 Validation of endoscopy data collected

Where data were extracted from routinely collected, in-house data to complete the *TIS forms*, it was validated by selecting approximately 20% of the datasets by randomly selecting site numbers and *TIS forms* using SPSS version 13 software (Lead Technologies Inc, USA) and re-completing them based on the original data. Any discrepancies resulted in the appropriate corrections being made and another 20% of the data being validated until no errors occurred.

Following this, all data from the verified *TIS forms* were input into SPSS. Data entry was validated by selecting 20% of the data in the file for re-entry. Any discrepancies resulted in the appropriate corrections being made and another 20% of the data being validated until no errors occurred.

10.2 Results

10.2.1 Hospital recruitment

All hospitals originally participating in the ENIGMA study were allocated unique identification (ID) numbers from one to 20 according to the order in which they agreed to participate in the ENIGMA study. The same numbers have been used in this thesis and they appear in brackets wherever reference is made to a specific site. A description of each study site according to its Site ID can be found in Table 8.

During the early stages of the ENIGMA study the PSG agreed to withdraw two study sites, one MES site (18) and one Non-MES site (10), because they were unable to comply with the strict patient recruitment criteria. These sites were not replaced because the ENIGMA study had already begun. The Non-MES site indicated that they were willing to participate in this study whilst the MES site chose to withdraw from all active participation. This meant that for this study, there were only 19 endoscopy units actively participating in service-related data collection. The withdrawn MES site was not contacted for this study, and data were only requested from the TIS department for that site.

Site ID	Site type	Unit type † (at first visit)	Population served by the Trust	N°. hospital beds*	N°. endoscopy rooms in unit in ...	
					2003	2006
1	MES	1, 4	250,000	547	2	2
2	Non-MES	1, 4	500,000	1100	2	2
3	Non-MES	1, 3	300,000	357	2	2
4	MES	1, 4	500,000	512	2	2
5	Non-MES	2, 4	500,000	520	2	2
6	MES	1, 4	183,000	396	1	2
7	MES	1, 3	250,000	413	2	2
8	MES	1, 4	1,500,000	1048	2	2
9	Non-MES	2, 3	265,000	968	2	2
10	Non-MES	1, 4	600,000	610	4	4
11	MES	1, 3	400,000	203	2	2
12	Non-MES	2, 4	300,000	450	1	2
13	MES	2, 3	500,000	519	3	4
14	Non-MES	1, 4	640,000	368	1	2
15	Non-MES	1, 4	350,000	430	3	3
16	MES	1, 4	138,500	320	2	2
17	Non-MES	1, 3	750,000	650	3	3
18	MES	1, 4	350,000	720	3	3
19	MES	2, 4	157,000	453	2	2
20	Non-MES	1, 3	550,000	427	3	3

Table 8: Description of each endoscopy unit in the study.

* The number of beds was taken from the ENIGMA study and was the basis of the sampling strategy that selected those 20 sites. †Key: 1 = self-contained; 2 = part of another specialty; 3 = modern/new unit; 4 = older/original unit.

10.2.2 The availability of service-related endoscopy data

10.2.2.1 Endoscopy unit service-related endoscopy data

Only eight of the 19 endoscopy units were able to provide copies of any service-related data for any of the time periods requested, of which three were MES sites and five were Non-MES sites. The data submitted by these eight sites consisted of seven Excel files (5, 7, 10, 12, 17 and 19), two internal written reports (10 and 19) and two Excel-based MES Toolkit files (1, 2).

Whilst one of the MES Toolkit files had been submitted by a Non-MES site, it was confirmed that they had legitimately secured a copy from the NHSMA but were not required to complete or submit any of their data to the NHSMA. Closer examination of the dataset confirmed that they were only interested in completing specific aspects of the MES Toolkit as some tabs were left blank.

One of these sites (1) agreed to pilot the *TIS form* by searching their PAS to extract the relevant data. The subsequent richness of the data on the form meant that it was far superior to the original dataset - a printout of part of the MES Toolkit for January 2003 only – and so, it was used in preference to the original, routinely collected data in order to have a more complete dataset for this site covering all eight time periods.

Of the remaining 11 sites, two submitted the *TIS forms* originally sent to the TIS contact because they had liaised with them for their completion but returned it themselves (4 and 6) and so, were classified as "mixed source" datasets. A further two sites claimed that they collected their own data but they refused to submitted copies for this study due to excessive staff workloads (9 and 15). The remaining seven reported that they did not routinely collect any service-related data within the unit and relied on their liaison at the TIS to extract and compile data whenever necessary (3, 8, 11, 13, 14, 16 and 20). When asked for copies of data collated following these requests, they had either not been kept or they were not relevant to this data request. In sites with no data, this was documented and no further requests were made unless, during the course of the ENIGMA study, they mentioned the intention to initiate data collection.

Of the eight sites providing routinely collected, service-related endoscopy data, not all of the outcome measures were collected. When examining the data more closely, the Non-MES sites

137

provided data for more outcome measures than the MES sites. When looking at all five outcome measures in this study, one MES site provided all five data types (1), whilst the other two were only able to provide one (7 and 19). One Non-MES site provided four data types (2), two provided three (5 and 12), one provided two (17) and only one provided just one data type (10). A breakdown of whether data for each outcome measure was provided by each endoscopy unit is illustrated in Table 9.

Table 10 shows the median time in weeks taken for the endoscopy units to return data in response to the first data request (T0 to T4), which varied for each site from zero to 38 weeks (median = 3). This figure did not include the two occasions when forms had been jointly completed by the endoscopy unit and TIS department in Sites 4 and 6. There were no significant differences in the response times of MES and Non-MES sites ($p > 0.05$, Mann-Whitney).

This study was designed on the basis that all NHS endoscopy units, especially the MES sites, would routinely collect some degree of service-related endoscopy data that would be available to this study for independent analysis. However, this soon proved to be untrue, with a number of sites reporting that they did not routinely collect any service-related endoscopy data.

Site ID	Site type	Referral Numbers	Wait >3m	Snapshot	Lost slots	Activity	Earliest time period with data
1	MES	Yes	Yes	Yes	Yes	Yes	Jan 2003
7	MES	No	No	Yes	No	No	Jan 2003
19	MES	No	No	No	No	Yes	Jan 2003
2	Non-MES	Yes	Yes	Yes	Yes	No	Dec 2003
5	Non-MES	Yes	No	No	Yes	Yes	Apr 2004
10	Non-MES	No	No	Yes	No	No	Apr 2004
12	Non-MES	Yes	No	Yes	No	Yes	Dec 2003
17	Non-MES	Yes	No	No	No	Yes	Dec 2003

Table 9: Description of outcome measures provided by the eight endoscopy units submitting routinely collected, service-related data for this study.

Site ID	Site type	Time (weeks) taken by...	
		Endoscopy unit	Trust
1	MES	35	No data submitted
2	Non-MES	3	12
3	Non-MES	No data submitted	31
4	MES	66	
5	Non-MES	3	10
6	MES	52	
7	MES	3	No data submitted
8	MES	No data submitted	67
9	Non-MES	No data submitted	4
10	Non-MES	1	5
11	MES	0	32
12	Non-MES	1	8
13	MES	No data submitted	19
14	Non-MES	No data submitted	24
15	Non-MES	No data submitted	22
16	MES	No data submitted	46
17	Non-MES	3	22
18	MES	Not requested	3
19	MES	38	3
20	Non-MES	No data submitted	46
Median (range)		3 (0 to 38)	22 (3 to 67)

Table 10: Description of the time taken in weeks to receive data pertaining to T0 to T4 from the endoscopy units and the corresponding Trusts of MES and Non-MES sites. Data from Sites 4 and 6 were completed jointly by the endoscopy unit and Trust. Data from Site 18 was not requested from the endoscopy unit.

With this in mind, the methodology of the study was altered to capture sufficient data from as few sources as possible to reduce the variation in data and allow a tentative comparison, so long as any conclusions would bear in mind the different sources of data making up the datasets being analysed. For this reason, the corresponding TIS departments of each study site were contacted to provide the same data as were requested from the endoscopy units.

10.2.2.2NHS TIS department service-related endoscopy data

Of the 20 TIS departments contacted to provide data files, responses were received from 19, including one IT department (3). One contact (7) did not respond to any attempts to get in touch with them by email, phone or letter. Eleven Trusts were able to send electronic copies of their data or reports (1, 2, 5, 9, 10, 12, 14, 16, 17, 18 and 19), while six sites completed the *TIS forms* and returned them electronically or by post (3, 8, 11, 13, 15 and 20). Another two TIS contacts liaised closely with the endoscopy unit for *TIS form* completion but the forms were submitted ultimately by the endoscopy unit so they were included as endoscopy unit data sources (4 and 6).

One TIS contact (12) submitted the same file as was submitted by the corresponding endoscopy unit, whilst another TIS contact (1) submitted a report but advised this author to consult with the corresponding endoscopy unit, commenting that they deferred to the endoscopy staff for accurate data collection from PAS.

Table 10 also shows the median time in weeks taken for the TIS contacts to return the service-related endoscopy data in response to the first data request (T0 to T4), which varied for each site from three to 67 weeks (median = 22). This figure did not include the two occasions when forms had been jointly completed in Sites 4 and 6. There were no significant differences in the response times of MES and Non-MES sites ($p > 0.05$, Mann-Whitney).

10.2.2.3 ENIGMA study endoscopy data

The ENIGMA study's retrospective data collection forms were available for this study. Fourteen of the 19 ENIGMA sites returned forms to correspond to one time point between T0 and T7 (1, 2, 3, 4, 6, 7, 8, 11, 12, 13, 14, 16, 17 and 20). A further two indicated early on that data were not routinely collected and they were not pursued any further during the ENIGMA study (5 and 10). Three sites reported that they collected data but did not complete the forms due to time and resource constraints (9, 15 and 19).

Of the 14 sites with forms, five stopped returning them for T6 and T7 (4, 6, 7, 8 and 14) and a further three did not return the final form corresponding to T7 only (2, 13 and 16). This may have been because sites had been asked to submit their routine datasets at this time and did not wish to

continue with completing the forms as well. Completed forms were not of particularly high quality, with many sites unable to split data by procedure type or degree of urgency. They also found it extremely difficult to complete the average time from GP referral to procedure.

Once this study had been acknowledged by the PSG to be of superior design to the rudimentary data collections forms drafted by the ENIGMA study, they were happy for the sites to "drop out" of completing their forms in favour of this study.

10.2.3 Categorisation of datasets

Based on discussions with site contacts (endoscopy unit and/or TIS contacts), the definitions provided and the observational comparisons, it was decided that data from endoscopy units would be used in preference to Trust-held datasets because some TIS contacts had commented that they were often unable to discriminate between endoscopies performed within and outside the endoscopy unit. There were also issues with a few TIS datasets concerning a change in coding practices for endoscopies, making their data less accurate when analysing for trends over time, although there was no published evidence of this occurring. TIS data were only used in the complete absence of any routinely collected endoscopy unit data and where possible, it was ensured that the data submitted was the same as the data sent to the endoscopy unit.

In all, four types of data were available from three sources for this study. Each was ranked according to its accuracy based on discussions with various endoscopy unit and Trust personnel. Whilst data completed by the endoscopy unit was considered to be most accurate by all questioned, the ENIGMA data collection forms were not completed very rigorously and as a consequence, they were not used unless all other data sources were exhausted.

The final data rankings used for this thesis were:

1. Routinely collected in-house endoscopy unit data.
2. *TIS forms* completed by the Trust.
3. Routinely collected Trust in-house data.
4. ENIGMA data collection forms.

Where possible, the same data source was used for all four *TIS forms* to allow consistency and enhance comparability. Data sources were allowed to vary between *TIS forms* where necessary, but not within the *TIS forms* or else data it would not be feasible to analyse the data over time.

10.2.4 Exclusion of datasets

Data were excluded because they did not conform to the request made, either in format or in the specification for it to be split according to procedure type. In one site (15), data were only available from the TIS and those datasets were all subsequently excluded because there was doubt cast upon their accuracy because they included a number of zeros. The TIS contact commented on changes in coding practices over the time period requested that, in her opinion, made the dataset unsuitable for analysis over time.

Referral numbers data were also excluded from Sites 14 and 19 because the data were not split according to referral type (14) or procedure type (19). *N° patients waiting* data were excluded from Sites 5, 11, 13 and 17. One site did not split their waiting list data according to procedure type (5), one site provided waiting list data but it was recorded in minutes rather than counts (17), and two sites submitted waiting list datasets that included both their active and planned waiting lists (11 and 13). *Lost slots* data were excluded from Sites 14, 16, 17 and 19 because two sites did not include hospital cancellations (14 and 16), one site did not include patient cancellations (17) and one site submitted only DNA counts (19). *Activity* data were excluded from Sites 7 and 14 because neither had split their data according to procedure type.

10.2.5 Formation of final datasets

The final datasets used for analyses in this study used a mixture of endoscopy unit data, Trust data and ENIGMA data. Table 11 shows the breakdown of the best sources of each dataset provided, and which datasets were subsequently excluded to produce the final dataset used by this study split according to Site ID, time and outcome measure. The numbers within the table corresponded to the best source of that data item, as described in the key. Grey-shaded cells highlight those datasets that were later excluded. Black cells indicated that no data were available from any source.

Table 11: Description of sources of data for the final dataset split according to site ID, site type (M = MES; NM = Non-MES), time point and data type based on TIS form completion (A = Referral numbers; B = Waiting lists; C = Lost slots and D = Activity).

Site		Jan-03 (T0)				Jun-03 (T1)				Dec-03 (T2)				Apr-04 (T3)				Nov-04 (T4)				Apr-05 (T5)				Oct-05 (T6)				Apr-06 (T7)			
		TIS Forms				TIS Forms				TIS Forms				TIS Forms				TIS Forms				TIS Forms				TIS Forms				TIS Forms			
ID	type	A	B	C	D	A	B	C	D	A	B	C	D	A	B	C	D	A	B	C	D	A	B	C	D	A	B	C	D	A	B	C	D
1	M																																
2	NM																																
3	NM																																
4	M																																
5	NM																																
6	M																																
7	M																																
8	M																																
9	NM																																
10	NM																																
11	M																																
12	NM																																
13	M																																
14	NM																																
15	NM																																
16	MI																																
17	NM																																
18	M																																
19	M																																
20	NM																																

Table key: 1 = Endoscopy unit in-house data; 2 = Trust-completed *TIS forms*; 3 = Trust in-house data; 4 = Endoscopy unit and Trust jointly-completed *TIS forms* (mixed source); 5 = ENIGMA data collection forms. The **grey-shaded** cells indicate that the data were excluded and the **black** cells indicate that no data were available from any source.

143

10.3 Discussion

It appears that data were not routinely collected by NHS endoscopy units. Only four of the nine MES sites approached submitted any routinely collected, service-related data, and one of those was only for one time period in 2003 (1). This lack of data availability was surprising, considering the MES project based its redesign principles on the collection and analysis of accurate, measurable service-related data for the analysis and evaluation of endoscopy service pre- and post-modernisation. It also advocated the routine collection of this data by the endoscopy units themselves using data collection software, in preference to liaising with TIS departments. The author expected, at the very least, to obtain data for all three time periods in 2003 if nothing else, but even this was beyond the scope of the MES sites.

It was clear that the key issue of the importance of high quality data collection and analysis advocated by the MES project was not taken on board by many MES sites. This may be explained by the fact that datasets were uploaded to the MESPT on a monthly basis and even though the staff attended MES Toolkit training sessions, they may not have understood how to analyse and understand the data at the ground level and may not have realised its true potential.

Informal discussions with some MES site contacts during the data collection phase highlighted the difficulties they experienced in collecting, using and extracting any meaningful datasets from the MES Toolkit. Since the data collection process was so labour-intensive, sites may have found it impossible to maintain this level of data acquisition in accordance with the strict deadlines imposed by the MESPT whilst also inputting data into a second database that was more appropriate for their purposes so the MES Toolkit would have taken priority. Many contacts from the MES sites also expressed their frustrations at having to collect such detailed datasets when, in their minds, they were able to analyse their services equally well with less complex, easier to collect data. However, this study showed that even the less complex service-related data was not routinely collected by the MES sites. They also commented on the fact that they had used some of the MES funding to pay for a data entry clerk to input data and when the funding ended, so did the data collection.

Problems with data collection and uploading to the MESPT were further exacerbated with the change from the Excel-based version to the web-based version (the MES Webtool) mid-way through the MES project. They commented that they were less able to manipulate their data for

144

their own purposes than before and viewed the Webtool as even more disadvantageous when compared to the Excel- based MES Toolkit.

Even with all the negative comments from sites regarding the data collection process, all MES sites agreed that some form of data collection was necessary and acknowledged the value of the MES Toolkit, not so much as a data collection tool but as an instigator for their own in-house data collection ideas. Unfortunately, this study suggests that routine data collection processes did not flourish in the same way that they were spoken about, although the reasons for this were unknown. Consequently, the definition of routinely collected data used in this study had to be adapted to encompass the use of the TIS datasets which, whilst routinely collected within their department, did not strictly adhere to the original definition of routine stated in the opening paragraph of this chapter. Instead, routinely collected data would encompass data routinely collected by the endoscopy unit and data collected by the Trust prior to it being manipulated for export into HES via central returns. It would not include HES datasets.

Another surprising aspect of this study was that half the Non-MES sites had initiated their own, in-house data collection protocols, although these were instigated during the latter part of 2003 or early 2004. The Non-MES sites were all aware of the MES project because they had originally applied to take part but had been rejected. They were offered the opportunity to be trained in the use of the MES Toolkit, if they so desired but only one Non-MES site took advantage of this opportunity (2) and used the Excel-based version of the MES Toolkit to collect some elements of endoscopy service-related data on a monthly basis. As a result, they were able to provide data for most outcome measures for all of the time periods requested by this study.

It is possible that the messages of accurate data collection advocated by the MES project were disseminated to these sites and they began their own data collection procedures, albeit later on. The raw datasets provided by the Non-MES sites covered more of the outcome measures requested than those of the MES sites. It is feasible that having access to view and use the MES Toolkit, they took on board the idea of data collection but did so in a rudimentary manner with basic counts of the relevant aspects of the service collected in Excel software and as a result, were more motivated to capture these simpler datasets over a prolonged period.

It was concerning to hear from some TIS personnel about the degree of potential coding ambiguities in their own endoscopy datasets, although there was no published evidence retrieved

in the field of endoscopy to support this. For the sites that relied on Trust-held data, it is questionable whether the data they were being given was truly accurate. However, it was not part of the remit of this study to investigate how aware the endoscopy staff were of the quality of their data, although it was evident that Trust data were used by the units in the absence of anything else, irrespective of its potential inaccuracies.

The need for good quality, routinely collected data in the NHS has been widely acknowledged based on independent assessment of current data collection practices (Benneyan et al., 2003, Audit Commission, 2002, Audit Commission, 2004, Thorne et al., 2008). However, there is currently no national impetus to collect routine data in NHS endoscopy services, even in light of the MES project report that described significant improvements in the services of MES sites based, in part, on high quality data collection and analysis (NHS Modernisation Agency, 2004e).

With increasing demands on NHS endoscopy services from initiatives including TWR referrals and the NBCSP, it is difficult to understand how NHS endoscopy services hope to become more efficient if they do not understand how they work and where underlying problems may exist in order to target any redesign plans effectively. This may explain why the service is only able to achieve TWR targets at the expense of the routine waiting list (Thorne et al., 2006). Even the most basic understanding of the demand, capacity and activity within the endoscopy unit can identify seasonal effects, underused resources and potential problems for further investigation, as well as providing an essential baseline measurement against which to measure the impact of any change(s) to the service. It can also provide an invaluable source of evidence when submitting bids for funding, all of which make the effort of establishing even a basic data collection regime worthwhile.

A possible lack of business experience in some NHS managers may go some way towards explaining the ineffective working practices of many NHS services, not just endoscopy, as many NHS managers may not be properly trained in the redesign concepts covered in Chapter 3, all of which advocate data collection and analysis as the basis for improving a process. Even though the NHSMA was established to bridge the gap between redesign theory and its practical implementation in the NHS, the message of continuous data collection and analysis did not appear to be fully understood and embraced by the MES sites used in this study. The Audit Commission have recently published a report aimed at public services to improve the quality of their data (Audit Commission, 2007). If this could be used as a framework for the NHS to initiate an improved data collection strategy, the quality of NHS services may improve in line with its datasets.

11.   VALIDATION OF THE STUDY DATA

Since the data compiled for this study was retrieved from up to three separate data sources (the endoscopy unit, the TIS department associated with each study site and the ENIGMA study), it was necessary to validate the final study datasets to ensure that any significant findings could be reported with confidence. HES is the national statistical data warehouse for England of the care provided by NHS hospitals and for NHS hospital patients treated elsewhere. Whilst tailor-made data requests can be made at a cost, there are also freely available datasets online at www.hesonline.org.uk/.

HES data has been used in many health services research studies in NHS trusts in England associated with GI disorders (Pollock and Vickers, 1998b, Pollock and Vickers, 1998a, Kang et al., 2003, Parry et al., 2004, Al-Sarira et al., 2007) although there was only one reported case to date of its use in investigating NHS endoscopy services (Williams and Mann, 2002). Given its wide application for the measurement of NHS management patterns, HES datasets were considered to be the most appropriate and best available datasets against which to validate the data submitted by each site for this study. Details of the validation process and the results of the comparison are presented and discussed in this chapter.

11.1 Methods

Since HES data was most commonly collected at the Trust-level and not at hospital-level, it contained data combined from each endoscopy unit within a Trust. It was not appropriate to include all 20 study sites in a comparative analysis, since all study sites had submitted data corresponding to one endoscopy unit and not for the Trust as a whole and so, where there were two or more endoscopy units within a Trust, the study data for that site could not be compared with the corresponding HES data. Only those sites that were the only endoscopy unit within their Trust were eligible for comparison. Of the 20 sites in this study, eight were the only endoscopy unit in the Trust and of these there were equal proportions of MES (6, 16, 18 and 19) and Non-MES (2, 3, 9 and 12) sites.

The most complete dataset collected by this study that was comparable with a HES dataset was for *Activity*. Details of the source of the *Activity* data for each of the eight study sites can be found in Chapter 10, whilst the actual data can be found in Appendices 16.5 – 16.8.

A request was submitted to the Health Information Research Unit (HIRU) based at Swansea University for HES *Activity* data split according to procedure type using OPCS-4 codes G16-G19, G43-G45 and H20-H25 for the following time periods: Jan 03, Jun 03, Dec 03, Apr 04, Nov 04, Apr 05, Oct 05 and Apr 06.

Where both "HES data" and "Study data" were available, the differences between the two datasets were calculated using Formula A to determine the *Difference* and Formula B to determine the *% Difference* between them.

Formula A: $Difference = HESdata - STUDYdata$

Formula B: $\%Difference = \dfrac{HESdata - STUDYdata}{STUDYdata}$

The datasets were compared using independent samples t-tests to identify whether there were any statistically significant differences between them at each time point. Both datasets were compared in their entirety before the data were split according to Site type, Time (T0 to T7) and procedure type (UGEs, FS and colonoscopy). Statistical tests were done using SPSS version 13 (Lead Technologies Inc, USA). A p-value of ≤ 0.05 was considered to be statistically significant.

11.2 Results

HIRU were able to provide all HES datasets requested at a cost of £315 which was paid for the by ENIGMA study. The data is available in Appendix 16.4. The results of applying Formulae A and B to the datasets are shown in Table 12 for the MES sites and Table 13 for the Non-MES sites. Any *% Difference* values $\geq \pm 50\%$ are illustrated in bold. A negative *% Difference* indicated that the HES data was lower than the Study data and vice versa.

Site ID	Procedure type	T0 Diff	T0 % Diff	T1 Diff	T1 % Diff	T2 Diff	T2 % Diff	T3 Diff	T3 % Diff	T4 Diff	T4 % Diff	T5 Diff	T5 % Diff	T6 Diff	T6 % Diff	T7 Diff	T7 % Diff
6	UGEs	9	4	71	**61**	0	0	-2	-1	-5	-3	-2	-1	16	8	-12	-9
6	Colonoscopy	-7	-15	3	5	-3	-5	0	0	1	2	1	1	0	0	4	8
6	FS	7	11	6	13	3	5	1	3	2	4	8	8	-9	-14	-22	-34
16	UGEs	-31	**-52**	-101	**-80**	-101	**-73**	-143	**-85**	-146	**-85**						
16	Colonoscopy	-140	**-93**	-338	**-95**	-342	**-96**	-350	**-96**	-316	**-96**						
16	FS	4	**400**	-9	**-75**	6	**200**	-1	-9	-24	**-83**						
18	UGEs	-290	**-85**	-351	**-89**	-272	**-84**	-291	**-85**	-358	**-90**	-334	**-87**	-319	**-89**	-137	**-71**
18	Colonoscopy	-278	**-95**	-334	**-94**	-354	**-94**	-334	**-92**	-334	**-92**	-403	**-92**	-474	**-96**	-213	**-93**
18	FS	-44	**-90**	-60	**-92**	-21	**-91**	-13	**-81**	3	**300**	-7	**-70**	-6	**-55**	2	**100**
19	UGEs	21	11	6	3	9	5	110	**169**	14	6	24	12				
19	Colonoscopy	4	11	2	4	6	14	-45	**-53**	0	0	15	23				
19	FS	11	9	5	4	6	8	-122	**-58**	10	10	16	21				

Table 12: *Difference (Diff)* and *% Difference (% Diff)* between HES data and Study data for the four eligible MES sites. Shaded areas indicate that Study data was not available for comparison with the HES data.

% Difference values in bold illustrate ≥ ± 50%.

149

Site ID	Procedure type	T0 Diff	T0 % Diff	T1 Diff	T1 % Diff	T2 Diff	T2 % Diff	T3 Diff	T3 % Diff	T4 Diff	T4 % Diff	T5 Diff	T5 % Diff	T6 Diff	T6 % Diff	T7 Diff	T7 % Diff
2	UGEs	53	15	89	23	41	11	55	15	38	10	58	16				
2	Colonoscopy	38	39	35	37	37	34	36	46	52	**59**	25	21				
2	FS	15	42	25	**89**	11	37	0	0	18	30	4	7				
3	UGEs	22	7	19	7	22	7	27	9	21	7	22	8	24	9	96	**54**
3	Colonoscopy	18	33	16	18	19	34	17	26	27	32	21	25	21	21	26	43
3	FS	1	4	2	6	3	7	0	0	9	20	2	5	5	11	10	33
9	UGEs	128	44	99	30	120	42	-129	**-51**	-115	-49	-119	-48	-106	-44	110	**57**
9	Colonoscopy	47	42	42	39	57	**65**	-51	**-61**	-35	-41	-63	**-71**	-31	-39	45	**56**
9	FS	4	**80**	10	**333**	10	**91**	6	**86**	-1	-8	-6	-38	9	**69**	27	**169**
12	UGEs					57	**66**	64	49	53	48	36	32	45	34		
12	Colonoscopy					-13	-11	0	0	7	6	17	17	-8	-6		
12	FS					17	39	7	13	10	11	8	12	17	31		

Table 13: *Difference (Diff)* and *% Difference (% Diff)* between HES data and Study data for the four eligible Non-MES sites.

% Difference values in bold illustrate ≥ ± 50%. Shaded areas indicate that Study data was not available for comparison with the HES data.

150

It was clear from Table 12 that Sites 16 and 18 had HES data that were a gross under-estimate of the Study data, with *% Difference* between the HES data and Study data reaching as high as - 96%. When the actual *Difference* values are examined for these two sites, it is clear that for procedure 3 (FS) the counts are low anyway which explains why the *% Difference* was large. However, when looking at each procedure type, the actual *Difference* values are also high, indicating a true large *% Difference* between the two datasets.

Closer examination of the HES data from Sites 16 and 18 revealed extremely low counts for UGEs and colonoscopies for all time points requested when compared to the Study data (see Table 14), so low as to cause serious concerns regarding their accuracy. Further interrogation of the HES database in collaboration with a HIRU data analyst revealed that the data was correct and was not the fault of any incorrect queries. It became apparent that it was the number of daycases being reported that was problematic, with Site 16 reporting three endoscopy daycases in total for 2003/04 and six for 2005/06, whilst Site 18 reported 21 endoscopy daycases in total for 2003/04 and 30 daycases for 2005/06. The reason for this discrepancy was not obvious, since the Study data from these two sites had both come from the Trust.

Site ID	Data source	Procedure type	T0	T1	T2	T3	T4	T5	T6	T7
16	HES	UGEs	29	25	37	26	25	22	34	19
		Colonoscopy	10	16	16	14	14	21	25	13
	Study	UGEs	60	126	138	169	171			
		Colonoscopy	150	354	358	364	330			
18	HES	UGEs	50	43	51	53	42	48	38	55
		Colonoscopy	15	23	22	29	28	33	20	17
	Study	UGEs	340	394	323	344	400	382	357	192
		Colonoscopy	293	357	376	363	362	436	494	230

Table 14: Comparison of HES data and Study data for Sites 16 and 18 for UGEs and colonoscopy.

When the TIS contacts were questioned about the anomalies in the datasets they reported that it used to be Trust policy to record their endoscopies as outpatient procedures, not daycases. This meant that they were not reported to HES, since the HES database did not require the compulsory inclusion of outpatient procedures until more recently.

The first stage of the analysis using independent samples t-tests were done using the datasets from all eight sites, since the reason for the analysis was to determine whether there were significant differences between the HES data and the Study data overall. However, it was also important for the sites with the two anomalous HES datasets to be excluded from subsequent analyses and for it to be repeated using just six site's datasets, only two of which would be MES sites.

11.2.1 Preliminary analysis

When examining the two sets of eight datasets as a whole, there was a significant difference (T = 2.41, p = 0.017) between the HES data (mean = 110.6) and the Study data (mean = 141.25). When this was further investigated by splitting the data according to Site type, this was only true for the MES group (HES mean = 69.89, Study mean = 155.21, T = 5.21, p < 0.001). There were no significant differences between the HES data and the Study data at each time point (T0 to T7) but there was a significant difference for the reporting of colonoscopies (HES mean = 73.09, Study mean = 141.96, T = 3.851, p < 0.001).

11.2.2 Final adjusted analysis

Following the exclusion of the data from Sites 16 and 18 from the analysis, there was no significant difference between the HES data (mean = 138.56) and the Study data (mean = 120.22) when all data points from all sites were combined (T = -1.398, p = 0.163). When the analysis was split according to Site type, there was no significant difference between HES data and Study data for the MES sites (HES mean = 113.95, Study mean = 106.6, T = -0.521, p = 0.603), or the Non-MES sites (HES mean = 151.32, Study mean = 127.28, T = -1.308, p = 0.193).

There was also no significant difference in HES data and Study data when the analysis was split by Time (T0 to T7). However, when the analysis was split by procedure type, there was a significant

difference between HES data and Study data for FS (HES mean = 51.61, Study mean = 67.12, T = -2.05, p = 0.044). When this was further investigated by splitting the data into Site type and procedure type, the significant difference was from Non-MES sites (HES mean = 55.81, Study mean = 34.81, T = -3.579, p = 0.001). It may be that the low values reported for FS from sites may have affected the statistical tests.

11.3 Discussion

There was a large significant difference between the HES data and the Study data from the eight endoscopy units. Further analysis indicated that the difference was isolated to the MES sites. Sites 16 and 18 had a significant impact on the comparison of HES and Study data due to the gross under-estimation of data from the corresponding HES datasets. When these two sites were excluded from the analysis, there was no longer any significant difference between HES data and Study data. This was also true when data were split by Site type and Time, but splitting the data by procedure type indicated that there was a significant difference in the reporting of FS between HES data and Study data, in particular for Non-MES sites.

The similarity of the data (following the exclusion of the two anomalous datasets) was to be expected, given that half of the data sources used in the Study dataset originated from the TIS department (Sites 2, 3 and 9) and of these, all were Non-MES sites. The other three data sources were from the endoscopy unit, with two submitting routinely collected data (12 and 19) whilst the other site's data came from the ENIGMA data collection forms (6).

In most cases, the mean Study data were lower than the mean HES data, as reflected by the positive % *Difference* values. This may be because the HES data were more rigorous in its data requests and the routinely collected datasets from the endoscopy units may not have included as many counts. It is also possible that the restriction in the OPCS codes given to the TIS contacts for the Study data request may have missed a particular aspect of *Activity* that was captured in the HES data. Alternatively, the HIRU request may not have been refined enough to block some of the procedures not included in the Study data request.

Only a partial validation of the Study data was possible as only the Activity dataset could be compared with the HES data. Consequently, only the Activity data could be confidently analysed, although it was hoped that the other datasets would be equally accurate, given the identical source of those datasets.

However, it also brings into perspective the need to be vigilant when using HES data for evaluating endoscopic procedures in NHS Trusts, since some Trusts did not record them as day cases but rather as outpatient procedures. Researchers intending to use HES data to examine the nature of NHS endoscopy services retrospectively should clarify with each Trust how they reported their endoscopy data to HES to ensure the HES dataset provides an accurate count. This, along with the more rigorous guidelines for Trusts concerning the completion of their data returns to HES means that this problem should not arise as often using current datasets but caution should be used when using older datasets, as was the case in this study.

12. THE EVALUATION OF ENDOSCOPY SERVICES USING ROUTINELY COLLECTED, SERVICE-RELATED ENDOSCOPY DATA

The primary aim of this study was to ascertain whether the MES project had any significant impact on participating sites by comparing specific endoscopy service-related datasets from MES sites with those sites who modernised independently at eight separate time points between January 2003 and April 2006. The study also aimed to examine the sustainability of any changes in data over time.

This chapter discusses how five outcome measures - *Referral numbers, Wait >3m, Snapshot, Lost slots* and *Activity* - were analysed to address the aims and objectives of this thesis and answer the research question conclusively. The chapter opens with a comprehensive description of the finalised datasets, followed by the data analysis section. A "within-groups" analysis determined whether there were any changes in data from the MES group and from the Non-MES group separately over time, whilst a "between-groups" analysis identified any significant differences between MES and Non-MES groups at each time point for each outcome measure. The chapter closes with a focussed discussion of the results.

12.1 Methods

12.1.1 Exploratory data analysis of data from both MES sites and Non-MES sites

Once the final dataset had been formed and validated in SPSS, the next step was to calculate the *total procedures* data from the sum of the data provided for all three procedure types.

Exploratory data analysis (EDA) was performed using SPSS on the *total procedures* data calculated for each individual study site to identify any outlying data points and to explore any site-

level data trends at individual time points. This involved plotting the data from each site on a line graph according to Site type and outcome measure. The MES and Non-MES group means were also plotted for reference and any sites with data deviating from the corresponding group mean were described in the text.

The data from each site was also analysed by comparing *Demand* and *Activity* to determine the *Variance* (defined as *Activity* minus *Demand*) within each site to identify whether there were any backlogs in the service due to *Demand* exceeding *Activity*, which would be illustrated by negative *Variance* values. For the purpose of this study, the *Demand* variable was defined as *Referral numbers*, the only outcome measure capable of indicating the "active" *Demand* on the service. The combination of either *Wait >3m* or *Snapshot* data with *Referral numbers* to produce an overall *Demand* value was not feasible because there were too many sites with these outcome measures missing.

12.1.2 Exploratory data analysis of data from the MES group and Non-MES group

All data from MES sites were aggregated to form a MES group dataset. The same was done for the Non-MES sites to create a Non-MES group dataset.

Due to the lack of data for many early and late time periods, it was also necessary to aggregate the data from individual time periods according to the corresponding year (2003, 2004, 2005 and 2006) for further analysis to improve the accuracy of the data. Since there was only one time period for 2006 and this had missing data for many sites, the data for 2005 and 2006 was merged to become 2005/06.

Graphical EDA using graphs with error bars indicating the 95% CI and stacked bar graphs were used to describe *total procedures* and *split procedures* data for the MES and Non-MES groups to identify outlying data points and to examine data trends at individual time points and for data aggregated according to year.

156

12.1.3 Correlation of outcome measures in the MES and Non-MES groups

Correlation was used to determine whether there were any significant linear relationships between any of the five outcome measures within both the MES and Non-MES groups and if so, to identify the strength and direction of the association. Spearman's correlation was chosen as the best test due to low sample numbers and the non-normal distribution of the data highlighted in previous EDA, since this test was based on ranked data rather than the actual data. This analysis was done for each Site type using only *total procedures* data for data aggregated according to year.

12.1.4 Two-way Analysis of Variance

A two-way analysis of variance (ANOVA), also known as a mixed between-within groups ANOVA, was performed using SPSS to determine the impact of Site type and Time using data aggregated according to year (2003, 2004 and 2005/06) on each outcome measure using both *total procedures* and *split procedures* data. A p-value ≤ 0.05 was considered to be statistically significant.

This test was able to concurrently perform a between-groups analysis to compare data from the MES and Non-MES groups whilst also comparing changes in data over Time within each Site type using within-group, repeated measures analysis. The test would also identify any significant interaction effects between Site type and Time whereby the rate or degree of change in data in one Site type was significantly different to the rate or degree of change of the data in the other Site type. As well as its significant p-value, a significant interaction effect could be illustrated graphically whereby the two lines plotted for the means of each Site type are non-parallel.

By using a two-way ANOVA, we reduce the number of statistical tests being done. This is vital, since evidence shows that a test with a p-value of 0.05 has a one in 20 chance of occurring by chance, so the more tests done, the more likely the possibility of a Type 1 error where we falsely reject the null hypothesis that states no significant difference (Bland and Altman, 1995). Ideally, a non-parametric equivalent to the two-way ANOVA would have been used, given the low sample numbers involved and its non-normal data distribution, but on seeking statistical advice from a statistics consultant, the author was advised that it was not within the capabilities of the statistical software (SPSS v13) to facilitate this type of analysis. Instead, the Friedman test was used to

investigate any significant differences in data within MES and Non-MES sites over time as this was the non-parametric equivalent to the repeated measures ANOVA.

In all cases, where Mauchly's test of sphericity was not significant (p > 0.05), the "sphericity assumed" p-value displayed by SPSS was used. A significant p-value led to using the "Greenhouse-Geisser" p-value instead, since it is more conservative in nature and is suitable for smaller sample sizes. Any significant differences in Time were investigated *a posteriori* using post hoc methods. Where a significant difference was found for Site type, no post hoc analysis was necessary, since there were only two categories being tested.

12.2 Results

12.2.1 Description of MES and Non-MES site datasets

In the case of *total procedures* data, *Referral numbers* were available for nine MES sites and seven Non-MES sites. *Wait >3m* data were available for six MES sites and four Non-MES sites. *Snapshot* data were available for four MES sites and five Non-MES sites. *Lost slots* data were available for five MES sites and four Non-MES sites. *Activity* data were available for nine MES sites and eight Non-MES sites.

Availability of the *Split procedures* data were identical, since it was calculated from the data for all three procedure types. The actual datasets used for this study can be found in Appendices 16.5 – 16.8, split according to *total procedures* data and *split procedures* data, namely FS, colonoscopy and UGE datasets respectively.

12.2.2 EDA for data from MES sites and Non-MES sites

The following section describes the data trends over time for each outcome measure from each study site, split according to Site type. Data are represented graphically according to Site type using *total procedures* data at individual time points, with individual sites' data plotted using different coloured lines. The MES group mean and the Non-MES group mean were also included in each corresponding graph for comparative purposes. The MES site and Non-MES site graphs did not have matching scales because the data were better illustrated this way and also, because

158

they were not meant for comparative purposes at this point. This issue will be dealt with later in the chapter.

Referral numbers for MES sites and Non-MES sites are plotted in Figures 7 and 8 respectively. The data trends of both MES sites and Non-MES sites appeared to be highly variable over time, although the variability of the MES group mean was less than the Non-MES group mean. Many sites deviated from the corresponding group means, particularly Site 18 (MES) and Site 17 (Non-MES). When examining the data from the earliest to the latest available individual time points, two MES sites (1 and 13) and two Non-MES sites (5 and 12) showed increases in *Referral numbers* over time, whilst seven MES sites (4, 6, 7, 8, 11, 16 and 18) and five Non-MES sites (2, 3, 9, 17 and 20) showed decreases in *Referral numbers* over time.

Wait >3m data for MES and Non-MES sites are plotted in Figures 9 and 10 respectively. Data were limited, especially from Non-MES sites. The trends of both the MES and Non-MES sites appeared to be fairly constant over time, with the exception of two MES sites (4 and 18) and one Non-MES site (14), which dramatically deviated from the Non-MES group mean after T2, causing the group mean to rise unexpectedly. When examining the data from the earliest to the latest available time points, one MES site (18) and one Non-MES site (14) showed increases in *Wait >3m* over time, whilst four MES sites (4, 6, 7, 8 and 19) and three Non-MES sites (2, 3 and 20) showed decreases. One MES site's data remained unchanged (6).

Snapshot for MES and Non-MES sites are plotted in Figures 11 and 12 respectively. Data were extremely limited from both Site types. The trends of both Site types were highly variable over time. The MES group mean was not representative of any of the individual sites, although none seemed to deviate far from the mean to any extent, whilst the Non-MES group mean showed a similar trend to many of its constituent sites. Site 9 showed extensive deviation from the Non-MES group mean after T1 as it was double the mean value. When examining the data from the earliest to the latest available time points, one MES site (18) and four Non-MES sites (9, 10, 11 and 12) showed increases in *Snapshot* over time, whilst three MES sites (1, 8 and 19) and one Non-MES site (2) showed decreases.

159
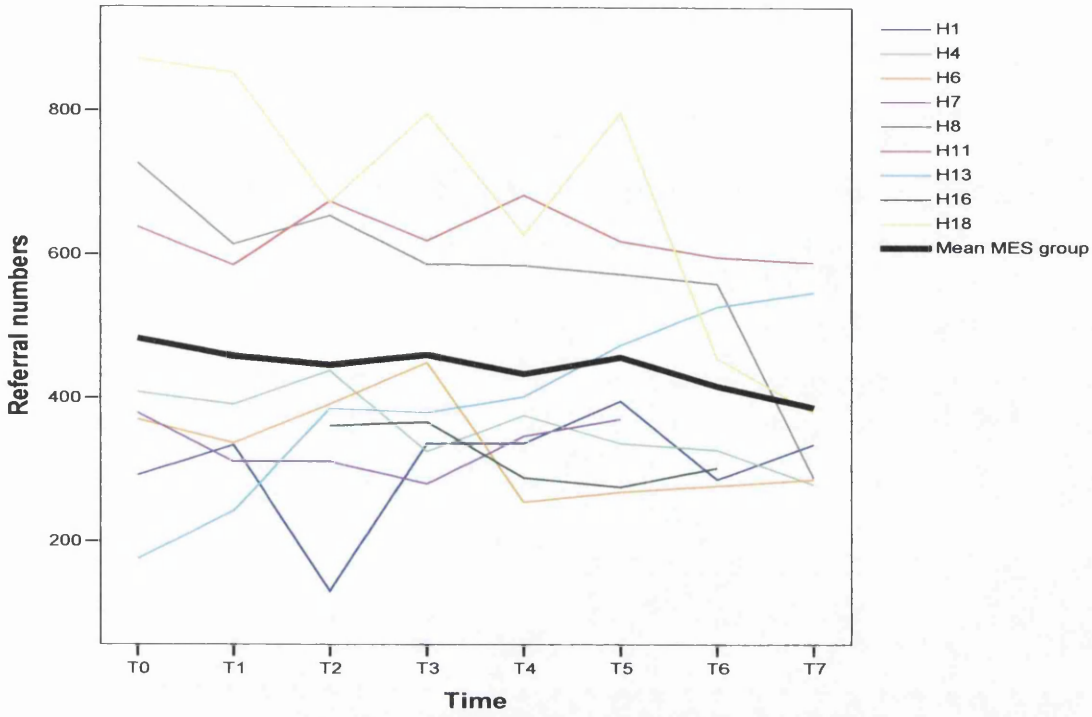
Figure 7: *Total procedures Referral numbers* for each MES site and the MES group mean.
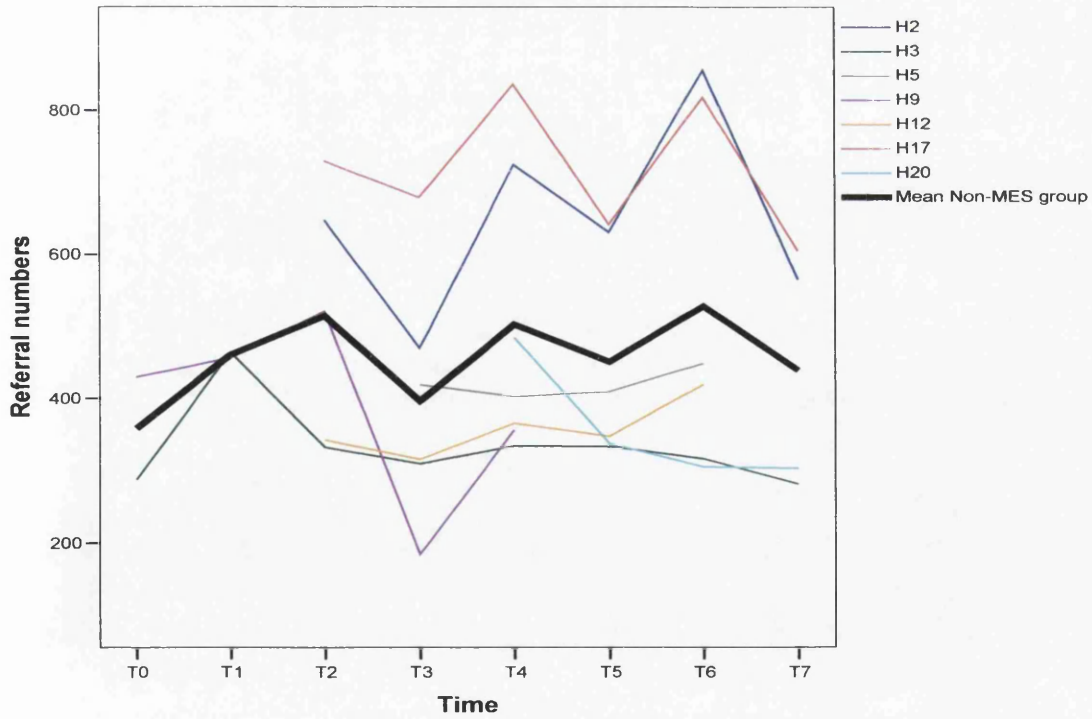
Figure 8: *Total procedures Referral numbers* for each Non-MES site and the Non-MES group mean.
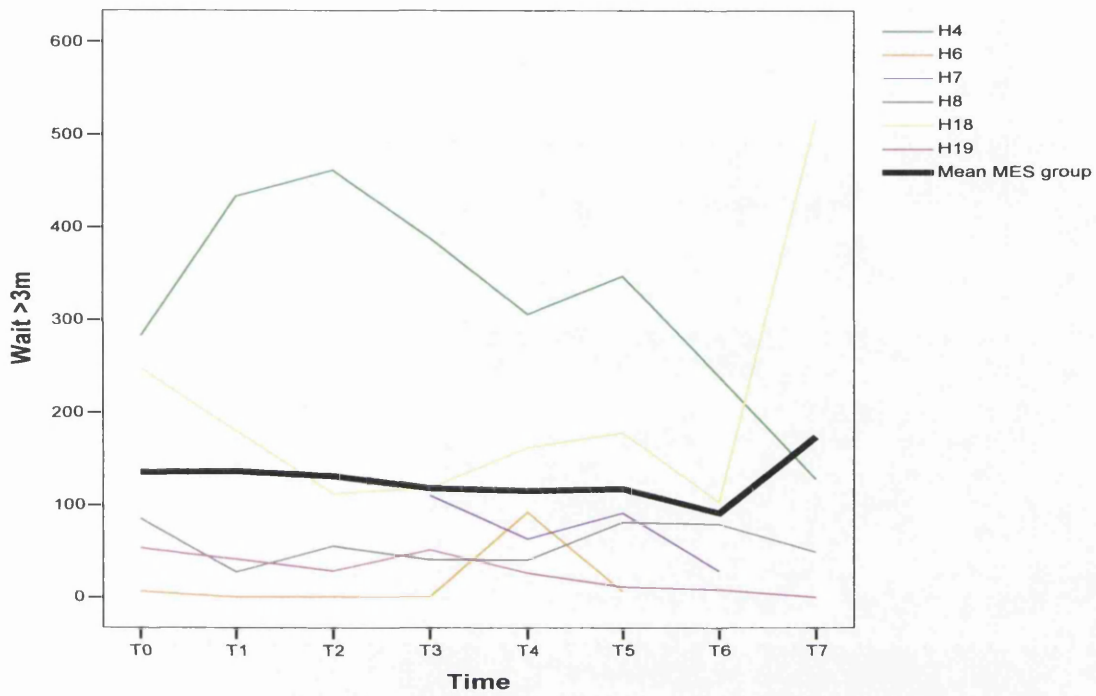
Figure 9: *Total procedures Wait >3m* for each MES site and the MES group mean.
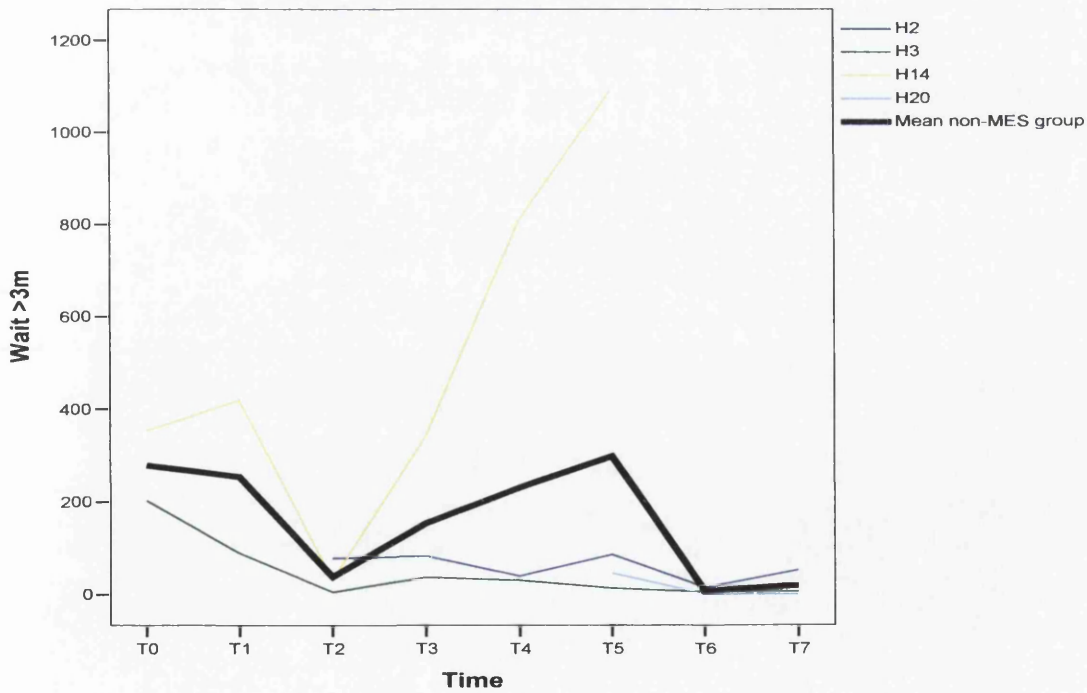
Figure 10: *Total procedures Wait >3m* for each Non-MES site and the Non-MES group mean.

161
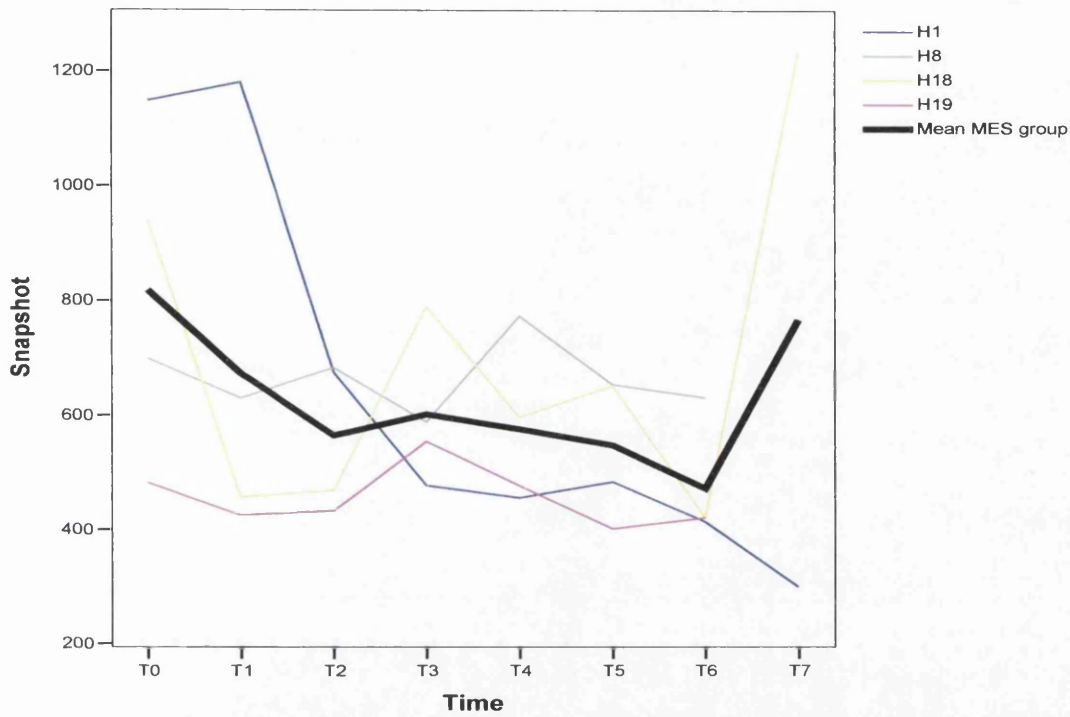
Figure 11: *Total procedures Snapshot* for each MES site and the MES group mean.
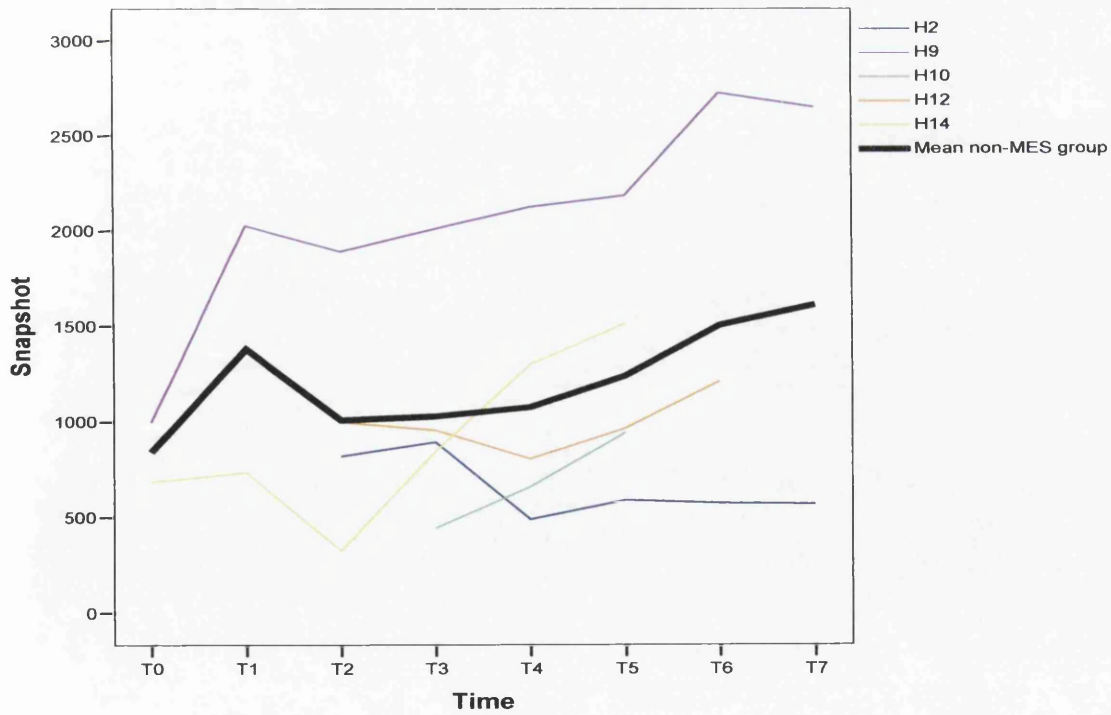
Figure 12: *Total procedures Snapshot* for each Non-MES site and the Non-MES group mean.

Lost slots for MES and Non-MES sites are plotted in Figures 13 and 14 respectively. Data were limited from both Site types. The data trends of both MES sites and Non-MES sites appeared to be fairly constant over time, as reflected in the corresponding group means. Site 18 was generally double that of the MES group mean and the same trend was seen for Site 9 compared to the Non-MES group mean from T2 onwards. When examining the data from the earliest to the latest available time points, no MES sites showed increases in *Lost slots* whilst two Non-MES sites did (2 and 5). All five MES sites (1, 6, 11, 13 and 18) showed decreases in their *Lost slots* over time compared with only two Non-MES sites (3 and 9).

Activity for MES and Non-MES sites are plotted in Figures 15 and 16 respectively. Data were available from the majority of sites. The trends of both MES and Non-MES sites appeared to be fairly constant over time, as reflected in the corresponding group means. Site 18 deviated from the MES group mean, whilst Site 17 appeared to deviate from the Non-MES group mean although the degree of difference for both compared to the group means was actually quite small in terms of actual numbers. When examining the data from the earliest to the latest available time points, two MES sites (16 and 19) and four Non-MES sites (2, 12, 17 and 20) showed increases in *Activity*, whilst seven MES sites (1, 4, 6, 8, 11, 13 and 18) and four Non-MES sites (3, 5, 9 and 10) showed decreases.

As well as a graphical illustration of the data trends in each site over time, the actual changes in data were calculated using *total procedures* data for each individual study site to determine whether it had increased, decreased or remained relatively constant from the earliest time point to the latest time point with data submitted by that site. The calculation was done using data from individual time points and data aggregated by year to cover the difference in the corresponding months (T0 to T7) and the mean values for the corresponding years (2003 to 2005/06), to ensure there was no obvious difference in the two time scales. The findings of this analysis are summarised in Table 15 with the actual difference in the data illustrated numerically, along with arrows to illustrate the direction of the differences as an increase or decrease.
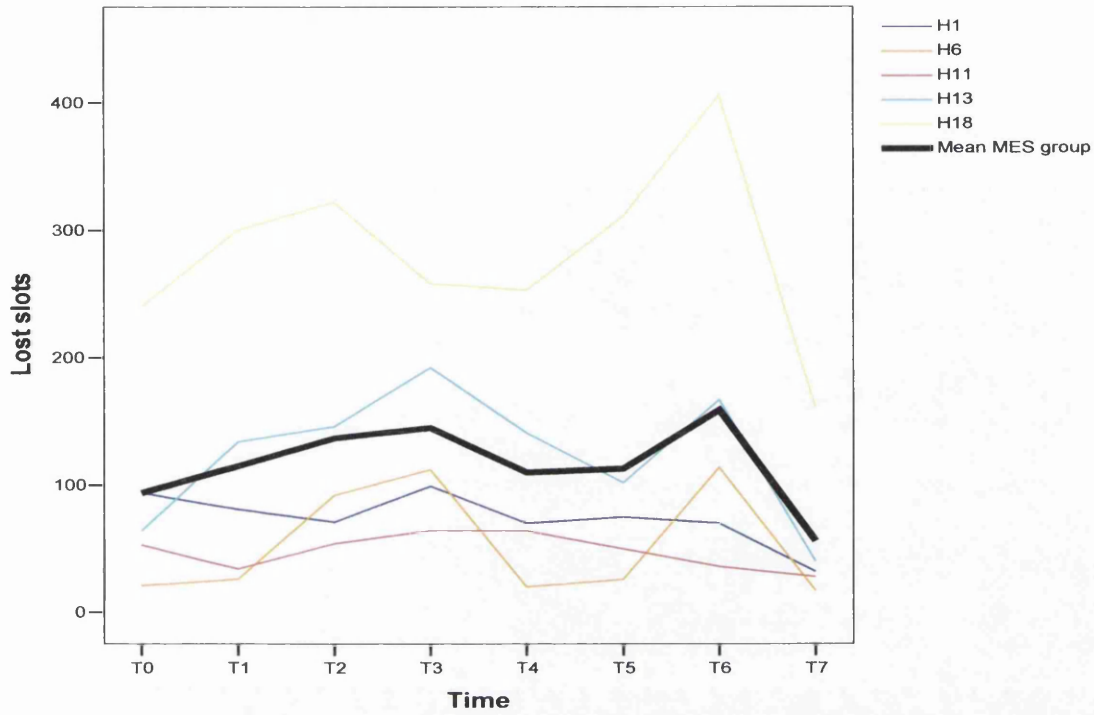
Figure 13: *Total procedures Lost slots* for each MES site and the MES group mean.
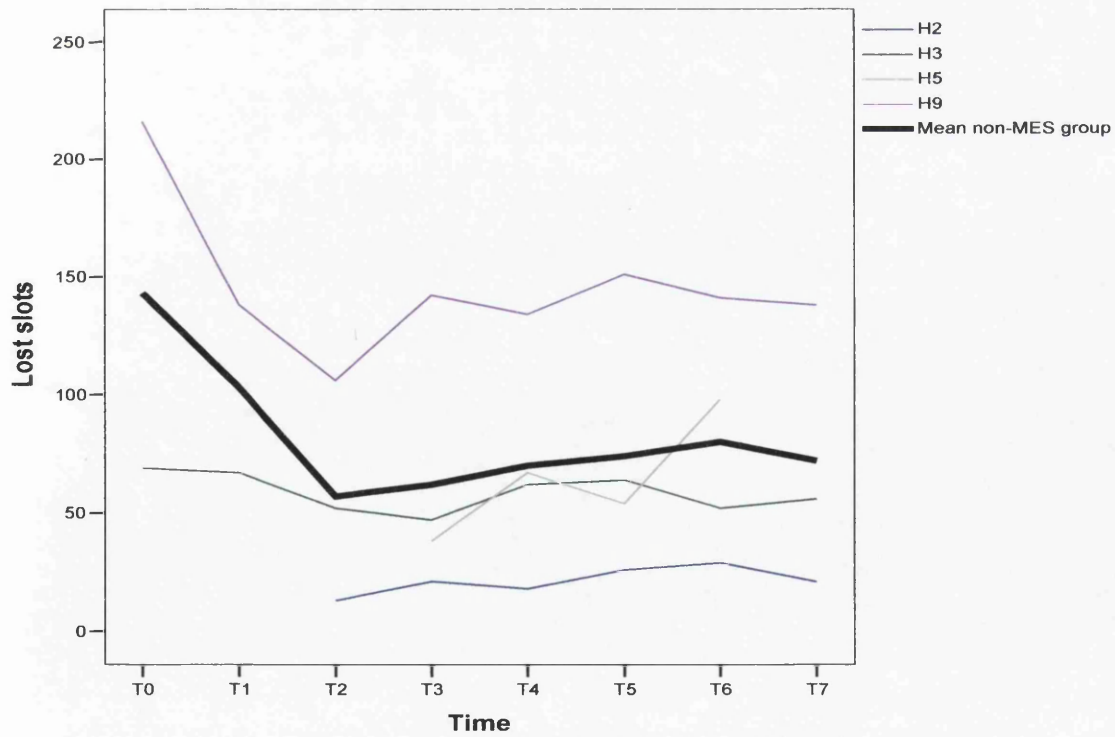
Figure 14: *Total procedures Lost slots* for each Non-MES site and the Non-MES group mean.
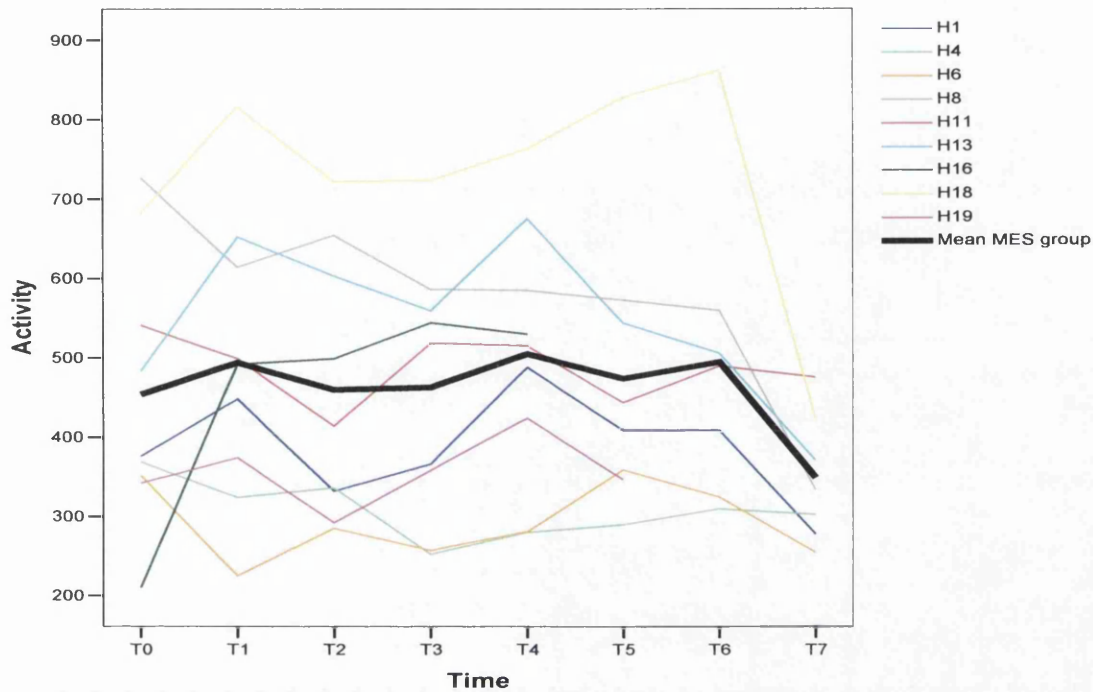
Figure 15: *Total procedures Activity* for each MES site and the MES group mean.
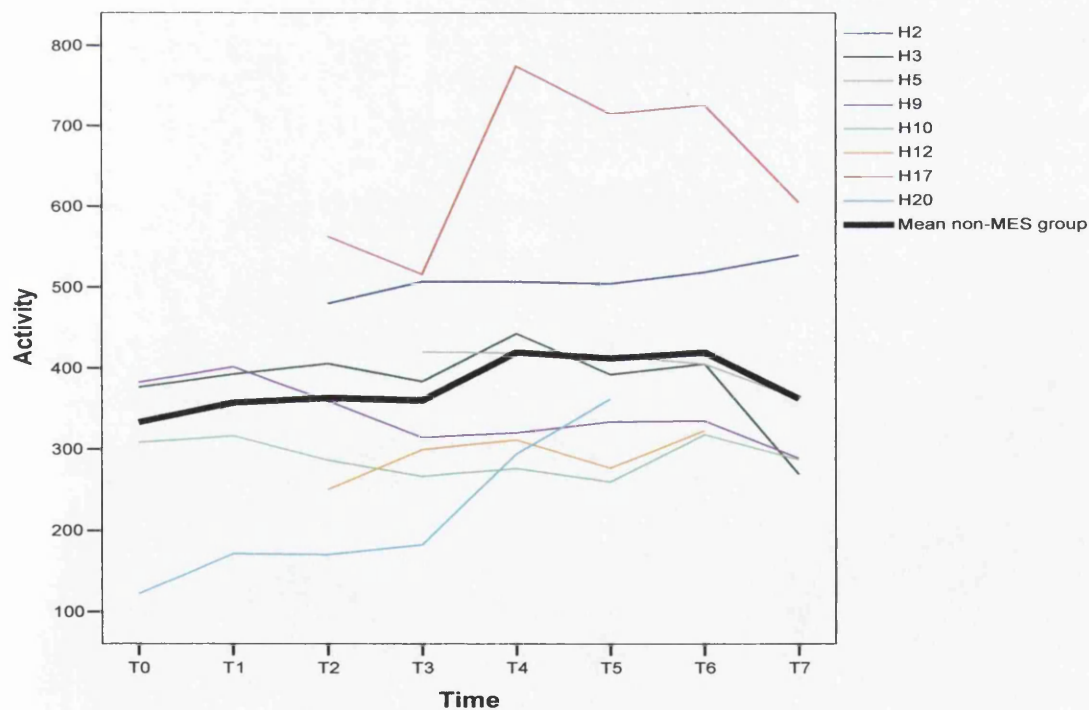
Figure 16: *Total procedures Activity* for each Non-MES site and the Non-MES group mean.

Site ID	Site type	Time Period	Referral numbers	Wait >3m	Snapshot	Lost slots	Activity
1	MES	T0 - T7	↑ (44)	No data	↓ (848)	↓ (62)	↓ (98)
		2003 - 2005/06	↑ (88)		↓ (602)	↓ (23)	↓ (20)
2	Non-MES	T0 - T7	↓ (83)	↓ (25)	↓ (251)	↑ (8)	↑ (60)
		2003 - 2005/06	↑ (36)	↓ (27)	↓ (242)	↑ (12)	↑ (42)
3	Non-MES	T0 - T7	↓ (6)	↓ (196)	No data	↓ (13)	↓ (107)
		2003 - 2005/06	↓ (51)	↓ (90)		↓ (5)	↓ (36)
4	MES	T0 - T7	↓ (128)	↓ (154)	No data	No data	↓ (66)
		2003 - 2005/06	↓ (97)	↓ (154)			↓ (42)
5	Non-MES	T0 - T7	↑ (30)	No data	No data	↑ (60)	↓ (57)
		2003 - 2005/06	No 2003 data			No 2003 data	No 2003 data
6	MES	T0 - T7	↓ (83)	No change	No data	↓ (4)	↓ (97)
		2003 - 2005/06	↓ (88)	↑ (4)		↑ (6)	↑ (26)
7	MES	T0 - T7	↓ (8)	↓ (82)	No data	No data	No data
		2003 - 2005/06	↑ (37)	No 2003 data			
8	MES	T0 - T7	↓ (438)	↓ (36)	↓ (68)	No data	↓ (393)
		2003 - 2005/06	↓ (191)	↑ (14)	↓ (28)		↓ (176)
9	Non-MES	T0 - T7	↓ (73)	No data	↑ (1653)	↓ (78)	↓ (93)
		2003 - 2005/06	No 2005/06 data		↑ (882)	↓ (10)	↓ (61)
10	Non-MES	T0 - T7	No data	No data	↑ (500)	No data	↓ (21)
		2003 - 2005/06			No 2003 data		↓ (15)
11	MES	T0 - T7	↓ (49)	No data	No data	↓ (25)	↓ (65)
		2003 - 2005/06	↓ (31)			↓ (9)	↓ (15)
12	Non-MES	T0 - T7	↑ (77)	No data	↑ (212)	No data	↑ (73)
		2003 - 2005/06	↑ (41)		↑ (90)		↑ (50)
13	MES	T0 - T7	↑ (373)	No data	No data	↓ (24)	↓ (112)
		2003 - 2005/06	↑ (249)			↓ (12)	↓ (106)
14	Non-MES	T0 - T7	No data	↑ (737)	↑ (826)	No data	No data
		2003 - 2005/06		↑ (823)	↑ (930)		
15	Non-MES	T0 - T7	No data	No data	No data	No data	No data
		2003 - 2005/06					
16	MES	T0 - T7	↓ (58)	No data	No data	No data	↑ (320)
		2003 - 2005/06	↓ (72)				No 2005/06 data
17	Non-MES	T0 - T7	↓ (125)	No data	No data	No data	↑ (42)
		2003 - 2005/06	↓ (41)				↑ (119)
18	MES	T0 - T7	↓ (492)	↑ (269)	↑ (293)	↓ (79)	↓ (258)
		2003 - 2005/06	↓ (254)	↑ (86)	↑ (147)	↑ (5)	↓ (35)
19	MES	T0 - T7	No data	↓ (53)	↓ (61)	No data	↑ (5)
		2003 - 2005/06		↓ (34)	↓ (35)		↑ (11)
20	Non-MES	T0 - T7	↓ (181)	↓ (45)	No data	No data	↑ (240)
		2003 - 2005/06	No 2003 data	No 2003 data			↑ (208)

Table 15: Summary of the trend of data for *Referral numbers, Wait >3m, Snapshot, Lost slots* and *Activity* over time. Data illustrates the difference in counts for each outcome measure from (i) T0 to T7 (or the closest time point with data) and (ii) 2003 to 2005/06. **Key**: ↑ = increase in counts; ↓ = decrease in counts. The number within the brackets signified the actual difference in counts.

166

Further evaluation of the service in each site compared *Demand* with *Activity* to produce a *Variance* (defined as *Activity* minus *Demand*) plot for each site over time. The results for each site are plotted in Figure 17 for the MES sites and Figure 18 for the Non-MES sites. Full data (namely *Referral numbers* and *Activity*) was only available for eight MES sites and seven Non-MES sites to calculate *Variance* over time and of these, only one MES site had missing start or end point *Variance* data (16) compared with six Non-MES sites (2, 5, 9, 12, 17 and 20).

Overall the MES sites seemed to have more positive *Variance* values than negative, indicating that *Activity* exceeded *Referral numbers* at those times, whilst the Non-MES sites seemed to display the opposite, with more negative *Variance* than positive at specific points in time, indicating that *Referral numbers* exceeded *Activity*. The MES sites tended to have positive *Variance* values that ranged further from zero than those of the Non-MES sites, as indicated by the scales used on each graph. They also showed far more variability over time than those of the Non-MES sites.

Four MES sites had the majority of their data as positive values (1, 13, 16 and 18) and one had its *Demand* exactly matching its *Activity* for T0 to T6 (8). Of those MES sites with negative *Variance* at the earlier time points, three showed a change in the data into positive *Variance* values over time (4, 6 and 18), whilst two showed the occurrence of a backlog indicated by increasingly negative *Variance* over time (11 and 13). Only three Non-MES sites showed any improvement in their *Variance* values over time (2, 9, 17 and 20) although the difference was extremely small for one (9). The remaining three showed the occurrence of a backlog shown by negative *Variance* over time (3, 5 and 12).

12.2.3 EDA of the MES group and Non-MES group data

The mean values of each outcome measure at each individual time point and for data aggregated by year were tabulated for MES and Non-MES groups using *total procedures* data (see Table 16) and *split procedures* data (see Tables 17 and 18). Trends for each mean data variable were discussed according to *total procedures* data and then *split procedures* data, according to the timescale used (individual time points or data aggregated by year).

167
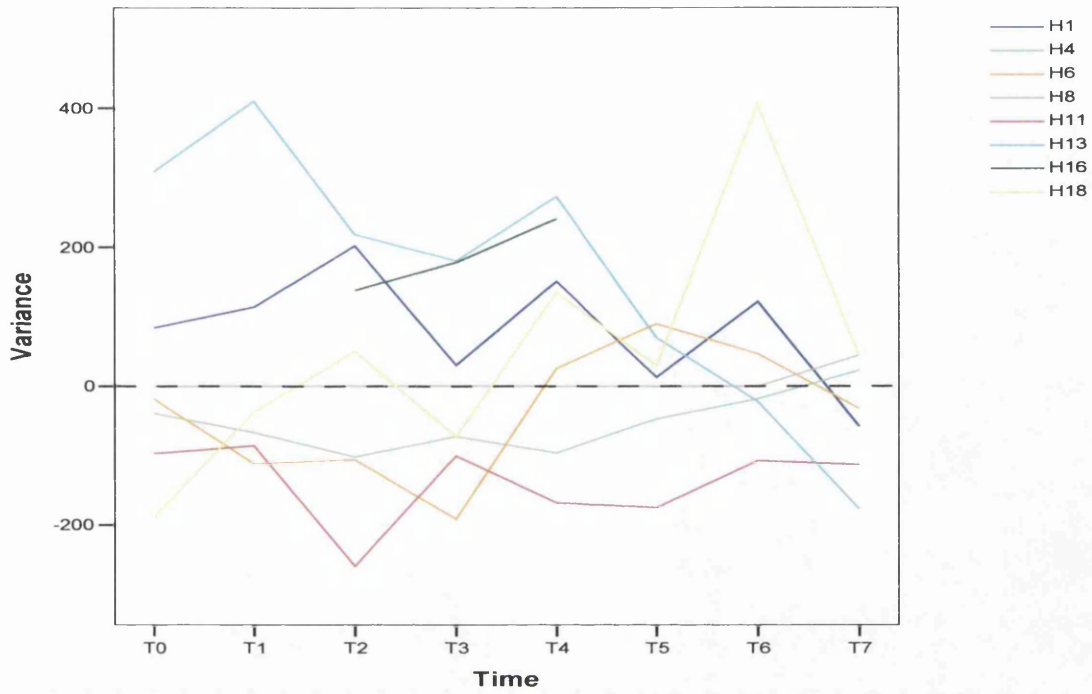
Figure 17: Variance within each MES site.
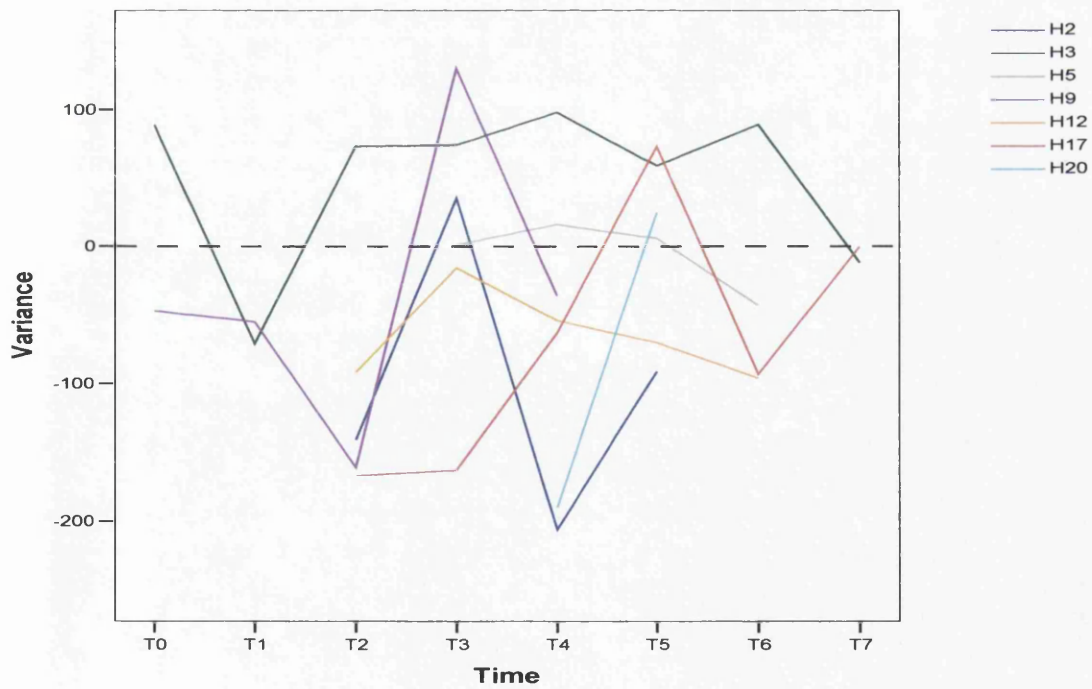
Figure 18: Variance within each Non-MES site.

Site type	Time	Time	Outcome measure				
			Referral Nos (n)	Wait >3m (n)	Snapshot (n)	Lost slots (n)	Activity (n)
MES	Individual time points	T0	483 ± 238 (8)	135 ± 123 (5)	818 ± 289 (4)	94 ± 86 (5)	454 ± 170 (9)
		T1	458 ± 207 (8)	136 ± 180 (5)	673 ± 350 (4)	115 ± 112 (5)	494 ± 181 (9)
		T2	446 ± 187 (9)	131 ± 189 (5)	565 ± 133 (4)	137 ± 109 (5)	460 ± 166 (9)
		T3	460 ± 172 (9)	118 ± 140 (6)	602 ± 133 (4)	145 ± 79 (5)	463 ± 162 (9)
		T4	434 ± 157 (9)	115 ± 105 (6)	576 ± 145 (4)	110 ± 91 (5)	505 ± 162 (9)
		T5	457 ± 177 (9)	119 ± 128 (6)	548 ± 126 (4)	113 ± 114 (5)	474 ± 173 (8)
		T6	417 ± 133 (8)	91 ± 91 (5)	472 ± 106 (4)	159 ± 147 (5)	495 ± 187 (7)
		T7	387 ± 129 (7)	174 ± 235 (4)	767 ± 660 (2)	56 ± 60 (5)	349 ± 80 (7)
	Data by year	2003	462 ± 202 (25)	134 ± 154 (15)	685 ± 270 (12)	116 ± 97 (15)	469 ± 167 (27)
		2004	447 ± 160 (18)	116 ± 118 (12)	589 ± 130 (8)	127 ± 82 (10)	484 ± 159 (18)
		2005/06	423 ± 147 (24)	124 ± 145 (15)	561 ± 266 (10)	109 ± 113 (15)	441 ± 161 (22)
Non-MES	Individual time points	T0	358 ± 100 (2)	278 ± 107 (2)	840 ± 219 (2)	143 ± 104 (2)	333 ± 133 (5)
		T1	460 ± 5 (2)	253 ± 233 (2)	1379 ± 913 (2)	103 ± 50 (2)	357 ± 124 (5)
		T2	514 ± 178 (5)	37 ± 37 (2)	1007 ± 653 (4)	57 ± 47 (3)	363 ± 140 (7)
		T3	396 ± 170 (6)	153 ± 164 (3)	1026 ± 584 (5)	62 ± 54 (4)	360 ± 117 (8)
		T4	502 ± 198 (7)	230 ± 385 (4)	1073 ± 659 (5)	70 ± 48 (4)	419 ± 166 (8)
		T5	450 ± 147 (6)	297 ± 530 (4)	1237 ± 623 (5)	74 ± 54 (4)	412 ± 150 (8)
		T6	527 ± 247 (6)	6 ± 7 (3)	1501 ± 1105 (3)	80 ± 50 (4)	419 ± 155 (6)
		T7	438 ± 170 (4)	19 ± 29 (3)	1608 ± 1472 (2)	72 ± 60 (3)	362 ± 140 (5)
	Data by year	2003	467 ± 147 (9)	167 ± 163 (7)	1058 ± 594 (8)	94 ± 67 (7)	352 ± 126 (17)
		2004	453 ± 186 (13)	197 ± 291 (7)	1049 ± 588 (10)	66 ± 48 (8)	390 ± 142 (16)
		2005/06	476 ± 187 (16)	127 ± 340 (10)	1390 ± 844 (10)	75 ± 49 (11)	401 ± 143 (19)

Table 16: Mean values with standard deviations of each outcome measure for *total procedures* data at individual time points and according to year for the MES and the Non-MES group.

Procedure type	Time	Time	Outcome measure			
			Referral Nos (n)	Wait >3m (n)	Snapshot (n)	Activity (n)
Flexible sigmoidoscopy	Individual time points	T0	79 ± 59 (8)	22 ± 29 (5)	150 ± 107 (4)	77 ± 56 (9)
		T1	72 ± 41 (8)	16 ± 25 (5)	136 ± 92 (4)	82 ± 61 (9)
		T2	72 ± 57 (9)	20 ± 25 (5)	129 ± 112 (4)	68 ± 63 (9)
		T3	76 ± 45 (9)	17 ± 13 (6)	124 ± 110 (4)	76 ± 67 (9)
		T4	74 ± 53 (9)	14 ± 14 (6)	139 ± 155 (4)	73 ± 55 (9)
		T5	79 ± 54 (9)	11 ± 11 (6)	101 ± 92 (4)	80 ± 53 (8)
		T6	86 ± 57 (8)	9 ± 10 (5)	104 ± 105 (4)	77 ± 53 (7)
		T7	79 ± 61 (7)	12 ± 10 (4)	20 ± 13 (7)	66 ± 45 (7)
	Data by year	2003	75 ± 51 (25)	19 ± 25 (15)	138 ± 95 (12)	75 ± 58 (27)
		2004	75 ± 47 (18)	15 ± 13 (12)	131 ± 124 (8)	74 ± 60 (18)
		2005/06	81 ± 55 (24)	11 ± 10 (15)	86 ± 88 (10)	75 ± 48 (22)
Colonoscopy	Individual time points	T0	121 ± 93 (8)	69 ± 93 (5)	255 ± 192 (4)	117 ± 77 (9)
		T1	144 ± 150 (8)	74 ± 91 (5)	220 ± 173 (4)	153 ± 118 (9)
		T2	121 ± 83 (9)	53 ± 66 (5)	184 ± 118 (4)	143 ± 129 (9)
		T3	129 ± 102 (9)	47 ± 55 (6)	220 ± 129 (4)	146 ± 125 (9)
		T4	139 ± 92 (9)	57 ± 60 (6)	162 ± 56 (4)	163 ± 108 (9)
		T5	145 ± 97 (9)	61 ± 70 (6)	161 ± 79 (4)	140 ± 121 (8)
		T6	119 ± 60 (8)	51 ± 53 (5)	149 ± 52 (4)	150 ± 154 (7)
		T7	105 ± 36 (7)	69 ± 86 (4)	246 ± 160 (2)	102 ± 64 (7)
	Data by year	2003	128 ± 107 (25)	65 ± 79 (15)	219 ± 152 (12)	138 ± 107 (27)
		2004	134 ± 94 (18)	52 ± 55 (12)	191 ± 97 (8)	155 ± 114 (18)
		2005/06	125 ± 70 (24)	60 ± 65 (15)	173 ± 86 (10)	131 ± 155 (22)
UGEs	Individual time points	T0	283 ± 130 (8)	44 ± 61 (5)	413 ± 175 (4)	259 ± 105 (9)
		T1	242 ± 82 (8)	46 ± 86 (5)	318 ± 229 (4)	259 ± 101 (9)
		T2	253 ± 115 (9)	59 ± 108 (5)	252 ± 47 (4)	249 ± 82 (9)
		T3	254 ± 102 (9)	55 ± 84 (6)	258 ± 86 (4)	241 ± 106 (9)
		T4	220 ± 94 (9)	44 ± 45 (6)	275 ± 74 (4)	269 ± 87 (9)
		T5	234 ± 113 (9)	47 ± 70 (6)	286 ± 85 (4)	254 ± 73 (8)
		T6	213 ± 98 (8)	31 ± 40 (5)	220 ± 55 (4)	268 ± 68 (7)
		T7	203 ± 67 (7)	93 ± 153 (4)	502 ± 514 (2)	180 ± 37 (7)

(... Cont'd)

Procedure type	Time	Time	Outcome measure			
			Referral Nᵒs (n)	Wait >3m (n)	Snapshot (n)	Activity (n)
UGEs	Data by year	2003	259 ± 107 (25)	50 ± 81 (15)	328 ± 167 (12)	256 ± 93 (27)
		2004	237 ± 97 (18)	49 ± 65 (12)	266 ± 75 (8)	255 ± 95 (18)
		2005/06	218 ± 93 (24)	54 ± 89 (15)	303 ± 212 (10)	235 ± 71 (22)

Table 17: Mean values with standard deviations of each outcome measure for FS, Colonoscopy and UGE procedures at each at individual time points and according to year for the MES group.

Procedure type	Time	Time	Outcome measure			
			Referral Nᵒs (n)	Wait >3m (n)	Snapshot (n)	Activity (n)
Flexible sigmoidoscopy	Individual time points	T0	9 ± 4 (2)	17 ± 2 (2)	15 ± 16 (2)	28 ± 22 (5)
		T1	24 ± 28 (2)	9 ± 6 (2)	17 ± 4 (2)	33 ± 24 (5)
		T2	56 ± 56 (5)	1 ± 2 (3)	61 ± 62 (4)	48 ± 36 (7)
		T3	73 ± 63 (6)	5 ± 5 (3)	225 ± 342 (5)	59 ± 41 (8)
		T4	98 ± 71 (7)	9 ± 14 (4)	75 ± 34 (5)	69 ± 58 (8)
		T5	97 ± 65 (6)	19 ± 23 (4)	89 ± 44 (5)	65 ± 53 (8)
		T6	100 ± 53 (6)	2 ± 3 (3)	118 ± 41 (3)	77 ± 60 (6)
		T7	81 ± 69 (4)	5 ± 9 (3)	72 ± 3 (2)	76 ± 70 (5)
	Data by year	2003	38 ± 46 (9)	8 ± 8 (7)	38 ± 48 (8)	38 ± 29 (17)
		2004	86 ± 66 (13)	7 ± 11 (7)	150 ± 243 (10)	64 ± 49 (16)
		2005/06	94 ± 58 (16)	10 ± 16 (10)	94 ± 39 (10)	72 ± 57 (19)

171

(...Cont'd)

Procedure type	Time	Time	Outcome measure			
			Referral Nᵒs (n)	Wait >3m (n)	Snapshot (n)	Activity (n)
Colonoscopy	Individual time points	T0	91 ± 9 (2)	199 ± 116 (2)	549 ± 135 (2)	66 ± 25 (5)
		T1	146 ± 5 (2)	211 ± 204 (2)	794 ± 361 (2)	76 ± 19 (5)
		T2	148 ± 39 (5)	24 ± 20 (3)	474 ± 404 (4)	87 ± 38 (7)
		T3	109 ± 39 (5)	95 ± 92 (3)	250 ± 178 (5)	80 ± 32 (8)
		T4	133 ± 53 (7)	139 ± 233 (4)	527 ± 451 (5)	101 ± 53 (8)
		T5	120 ± 58 (6)	179 ± 334 (4)	573 ± 424 (5)	121 ± 80 (8)
		T6	155 ± 98 (6)	4 ± 5 (3)	654 ± 516 (3)	112 ± 67 (6)
		T7	116 ± 54 (4)	12 ± 18 (3)	740 ± 722 (2)	89 ± 48 (5)
	Data by year	2003	135 ± 37 (9)	127 ± 137 (7)	573 ± 333 (8)	78 ± 30 (17)
		2004	122 ± 47 (13)	120 ± 175 (7)	388 ± 355 (10)	90 ± 44 (16)
		2005/06	132 ± 73 (16)	76 ± 213 (10)	631 ± 449 (10)	110 ± 66 (19)
UGEs	Individual time points	T0	259 ± 96 (2)	62 ± 7 (2)	277 ± 100 (2)	240 ± 110 (5)
		T1	291 ± 18 (2)	33 ± 24 (2)	568 ± 556 (2)	248 ± 122 (5)
		T2	310 ± 121 (5)	12 ± 16 (3)	472 ± 270 (4)	228 ± 113 (7)
		T3	214 ± 100 (6)	53 ± 71 (3)	551 ± 344 (5)	221 ± 94 (8)
		T4	270 ± 113 (7)	83 ± 139 (4)	471 ± 244 (5)	250 ± 98 (8)
		T5	233 ± 86 (6)	99 ± 192 (4)	575 ± 238 (5)	226 ± 94 (8)
		T6	272 ± 140 (6)	1 ± 2 (3)	729 ± 593 (3)	230 ± 59 (6)
		T7	242 ± 86 (4)	2 ± 2 (3)	796 ± 747 (2)	197 ± 33 (5)
	Data by year	2003	294 ± 95 (9)	32 ± 26 (7)	447 ± 299 (8)	237 ± 107 (17)
		2004	244 ± 107 (3)	70 ± 107 (7)	511 ± 284 (10)	236 ± 94 (16)
		2005/06	250 ± 104 (16)	41 ± 122 (10)	665 ± 418 (10)	220 ± 70 (19)

Table 18: Mean values with standard deviations of each outcome measure for FS, Colonoscopy and UGE procedures at each at individual time points and according to year for the Non-MES group.

Additonally, the group mean for each outcome measure was plotted graphically according to Site type and time scale used, using error bars marking the 95% CI for the mean *total procedures* data and stacked bar graphs for the mean *split procedures* data using UGEs, FS and colonoscopy data.

12.2.3.1 Referral numbers

The mean *total procedures Referral number* trend for the MES group fell from 483 to 387 between T0 and T7 whilst the Non-MES group mean increased from 358 at T0 to 438 at T7 (see Figure 19). The Non-MES group mean showed more variability over time than the MES group mean. There were missing data for T0 in the Non-MES group, resulting in a larger 95% CI for that time point. When data were aggregated by year, the MES group mean decreased from 462 at 2003 to 423 at 2005/06 (see Figure 20). The Non-MES group mean showed a minor dip in *Referral numbers* for 2004 but overall, there was a slight increase from 467 at 2003 to 476 at 2005/06.

When the data were split by procedure type, the MES group means for FS and colonoscopy were relatively constant from T0 to T7 (see Figure 21) and 2003 to 2005/06 (see Figure 22) and only small decreases were seen in UGEs over time. Data for all three procedure types for the Non-MES group were more variable over time for T0 to T7 and 2003 to 2005/06, with increasing numbers of FS and decreasing numbers of UGEs whilst colonoscopy remained relatively stable.

12.2.3.2 Wait >3m

The mean *total procedures Wait >3m* data showed an overall increase from 135 at T0 to 174 at T7 (see Figure 23) due to a similar sharp increase in Site 18 data. The Non-MES group mean showed an overall decrease from 278 at T0 to 19 at T7, with the rise at T5 greatly influenced by Site 14 data. Missing data from the Non-MES sites contributed to larger 95% CIs than seen for the MES group. When data were aggregated by year, the MES group mean showed a slight decrease from 134 at 2003 to 124 at 2005/06. The Non-MES group mean showed a peak for 2004 but overall, it slightly decreased from 167 at 2003 to 127 at 2005/06 (see Figure 24).

When data were split by procedure type, the MES group mean for each procedure were relatively unchanged until T7, when there was an increase in UGEs (see Figure 25), although the aggregation of data meant that this increase was not seen in the 2005/06 dataset (see Figure 26).

173
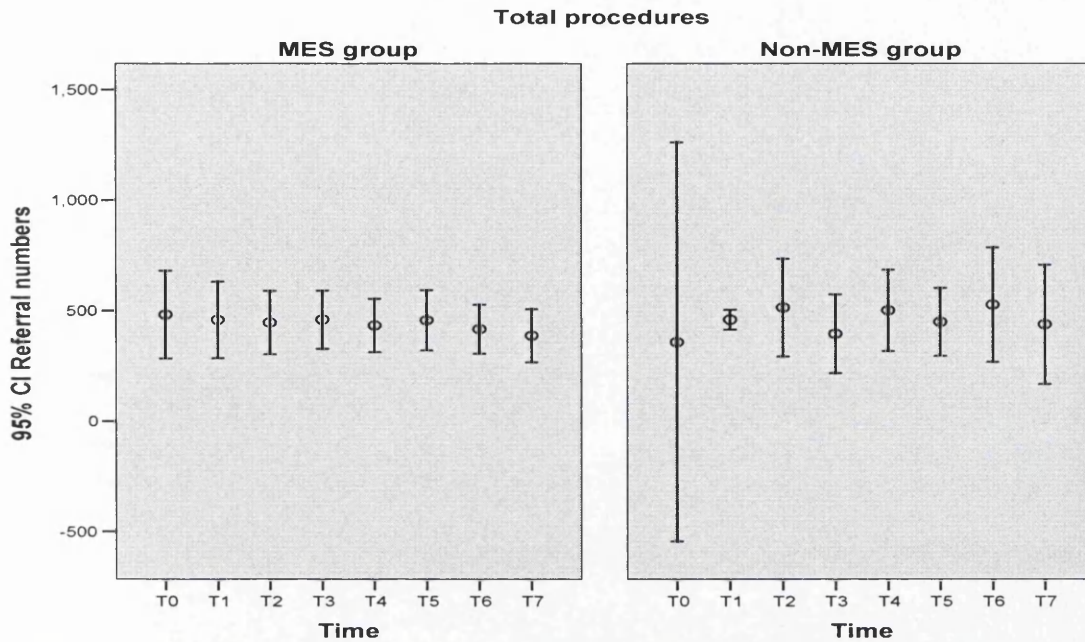
Figure 19: Mean *total procedures Referral numbers* for the MES and Non-MES group datasets for individual time points (T0 to T7) with error bars (95% CI).
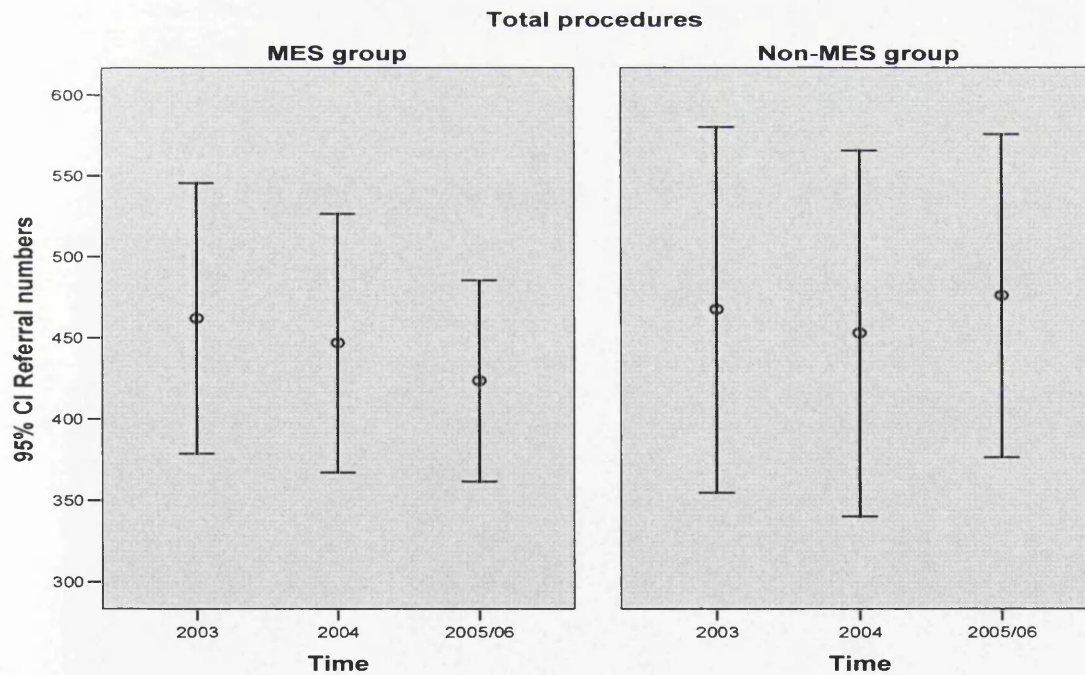
Figure 20: Mean *total procedures Referral numbers* for the MES and Non-MES group datasets for data, aggregated by year (2003, 2004 and 2005/06) with error bars (95% CI).
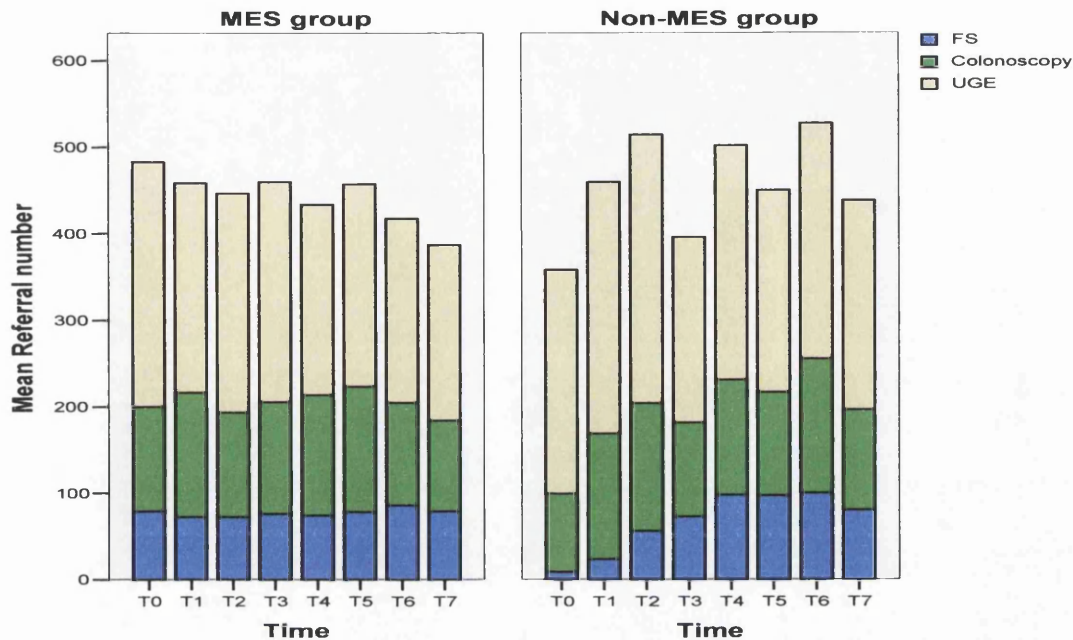
Figure 21: Mean *split procedures Referral numbers* for the MES and Non-MES group datasets for individual time points (T0 to T7).
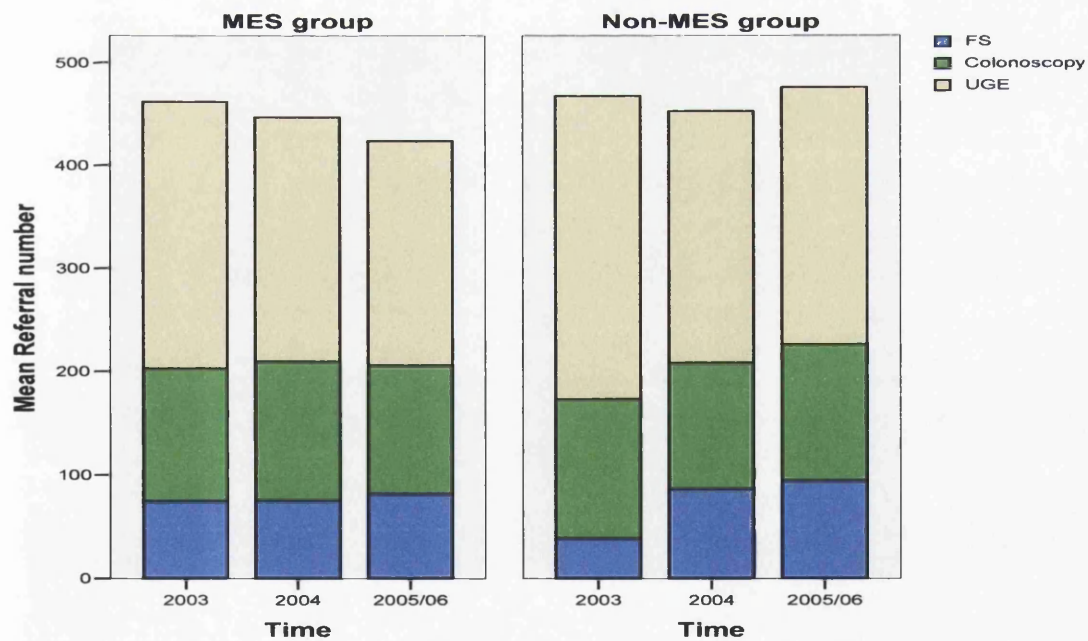
Figure 22: Mean *split procedures Referral numbers* for the MES and Non-MES group datasets for data, aggregated by year (2003, 2004 and 2005/06).

175
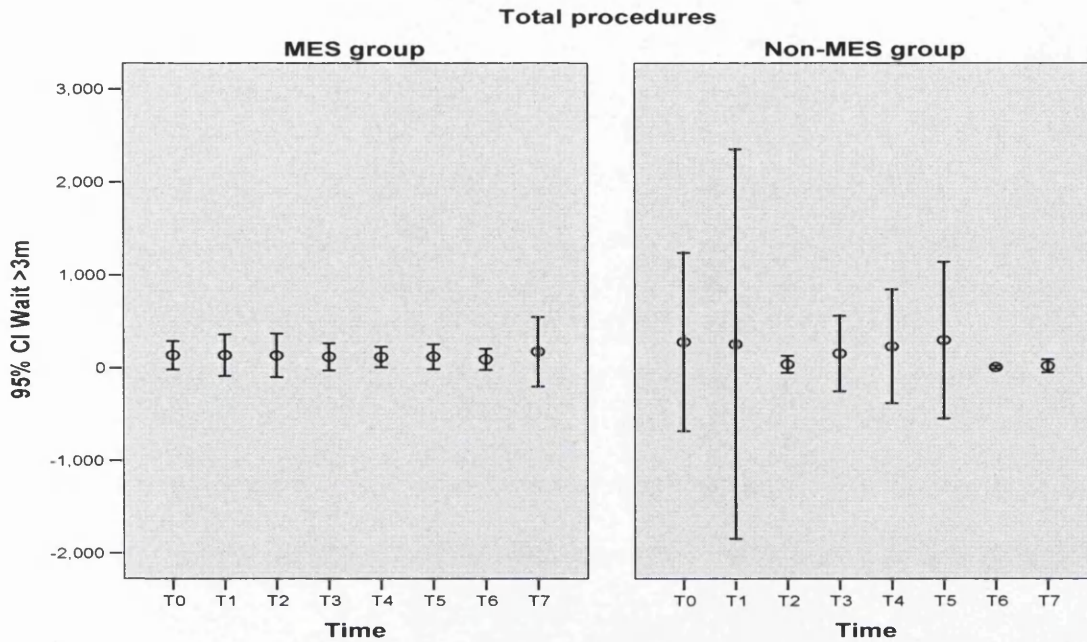
Figure 23: Mean *total procedures Wait >3m* for the MES and Non-MES group datasets for individual time points (T0 to T7) with error bars (95% CI).
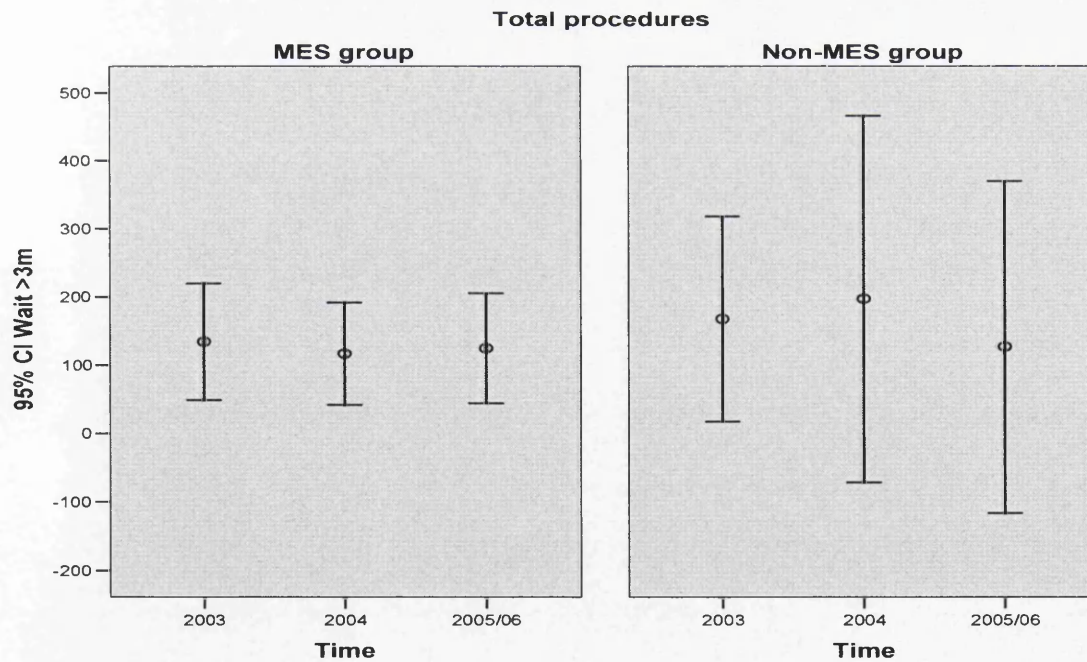
Figure 24: Mean *total procedures Wait >3m* for the MES and Non-MES group datasets for data, aggregated according to year (2003, 2004 and 2005/06) with error bars (95% CI).
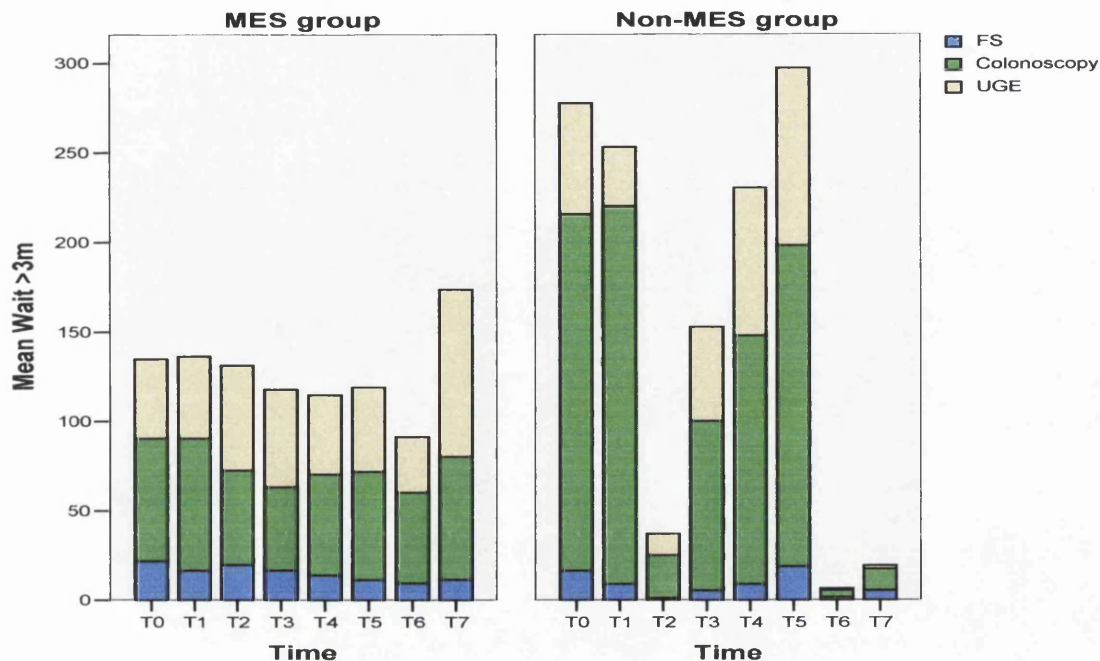
Figure 25: Mean *split procedures Wait >3m* for the MES and Non-MES group datasets for individual time points (T0 to T7).
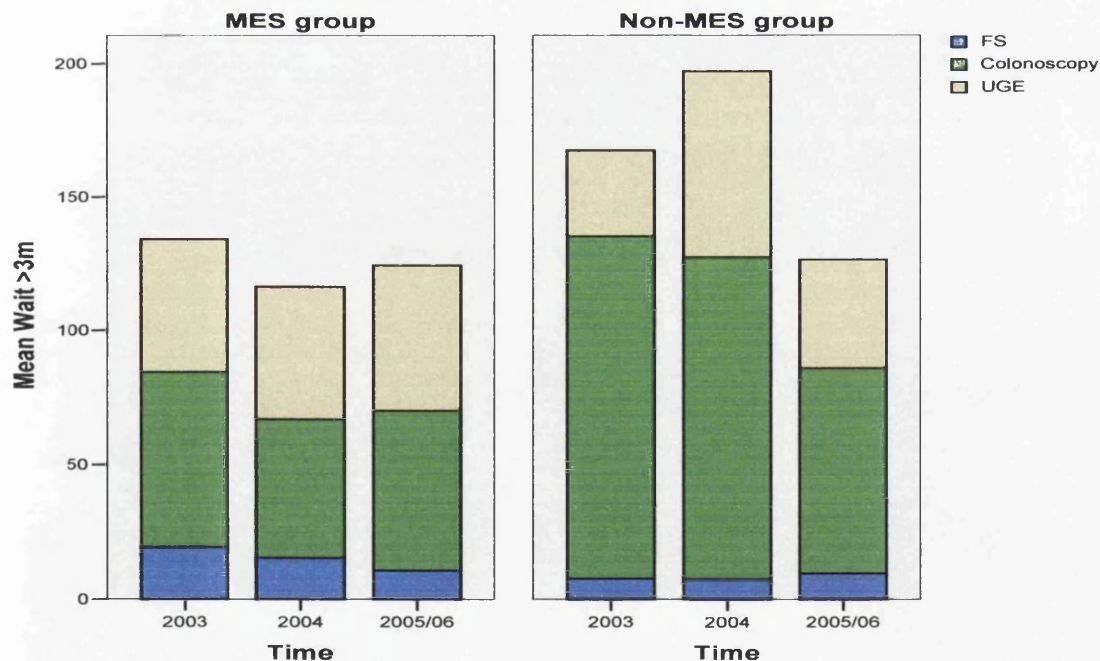
Figure 26: Mean *split procedures Wait >3m* for the MES and Non-MES group datasets for data, aggregated by year (2003, 2004 and 2005/06).

Data for all three procedures for the Non-MES group was highly variable over time for T0 to T7, especially for colonoscopy figures. This variability was less obvious when data was aggregated according to year, although colonoscopy and UGE figures showed a decreasing trend over time due to the influence of the extremely low figures reported in T2, T6 and T7 which affected the 2003 and 2005/06 data. FS figures were low and remained so throughout.

12.2.3.3 Snapshot

The mean *total procedures Snapshot* data for the MES group fell from 818 at T0 to 767 at T7, whilst the Non-MES group mean increased from 840 at T0 to 1608 at T7 (see Figure 27). Both the MES and the Non-MES group mean showed constant trends over time, although the extremely large 95% CI for the Non-MES group at T7 meant that the scales used for these plots were large enough that they may have obscured any real trends in the data. The aggregated data for the MES group mean decreased from 685 at 2003 to 561 at 2005/06 and the Non-MES group mean increased from 1058 at 2003 to 1390 at 2005/06 (see Figure 28).

When data were split by procedure type, the MES group means for each procedure decreased from T0 to T6 but increased in T7 for UGEs and colonoscopy but not for FS (see Figure 29). When data was aggregated by year, this was not visible in the 2005/06 bar (see Figure 30). Data for all three procedures for the Non-MES group were more variable over time for T0 to T7 and 2003 to 2005/06, with no obvious pattern emerging in either timescale.

12.2.3.4 Lost slots

The mean *total procedures Lost slots* trend for the MES group fell from 94 at T0 to 56 at T7, whilst the Non-MES group mean showed an overall decrease from 143 at T0 to 72 at T7 (see Figure 31). Both the MES and the Non-MES group mean showed remarkably constant trends over time that were also highly comparable, although the extremely large 95% CI for the Non-MES group at T1 meant that the scales used for these plots were large enough that they may have obscured any details in the trends. When data were aggregated by year, the MES group mean showed a slight decrease from 116 at 2003 to 109 at 2005/06 and the Non-MES group mean showed a decrease from 94 at 2003 to 75 at 2005/06 (see Figure 32). *Lost slots* data were not split by procedure type so no further analysis was possible.

178
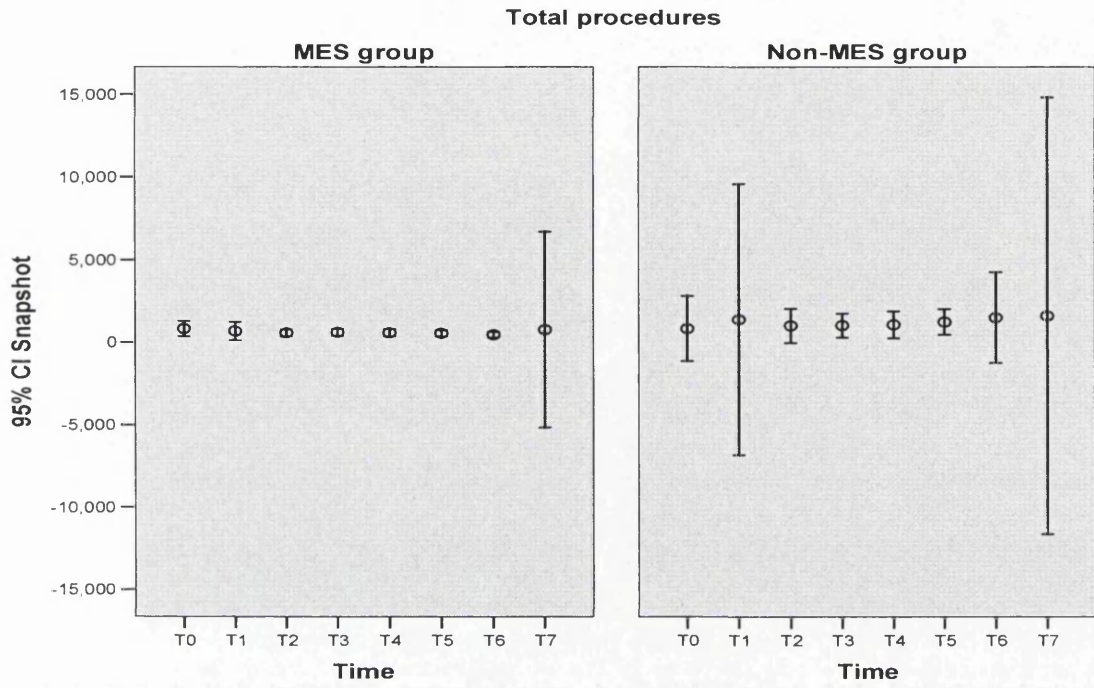
Figure 27: Mean *total procedures Snapshot* for the MES and Non-MES group datasets for individual time points (T0 to T7) with error bars (95% CI).
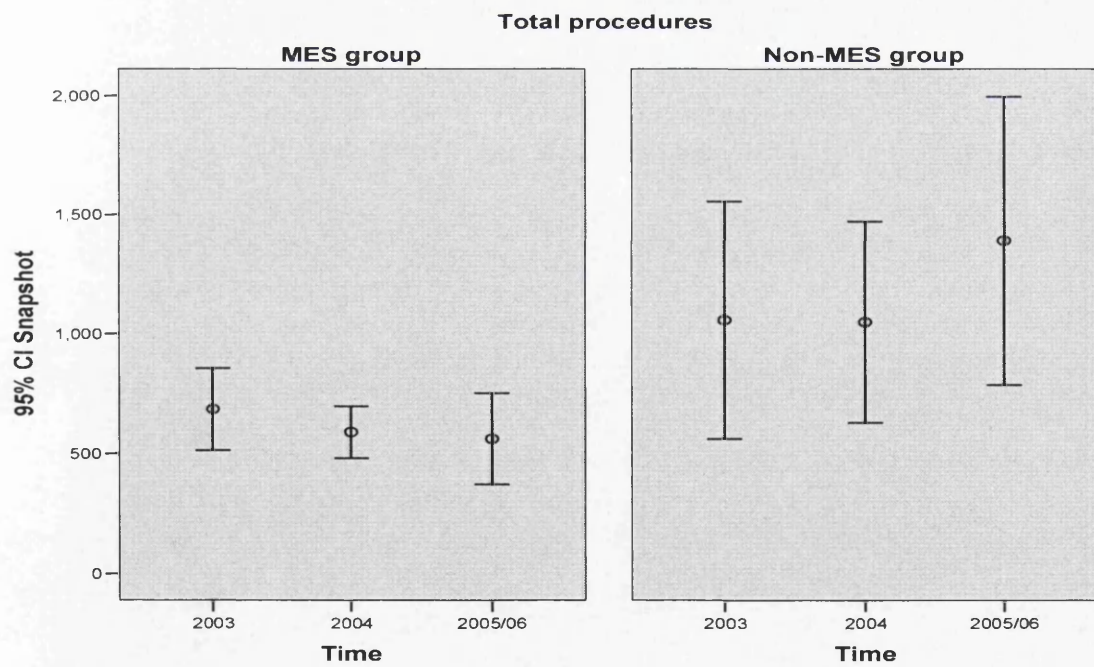
Figure 28: Mean *total procedures Snapshot* for the MES and Non-MES group datasets for data, aggregated according to year (2003, 2004 and 2005/06) with error bars (95% CI).

179
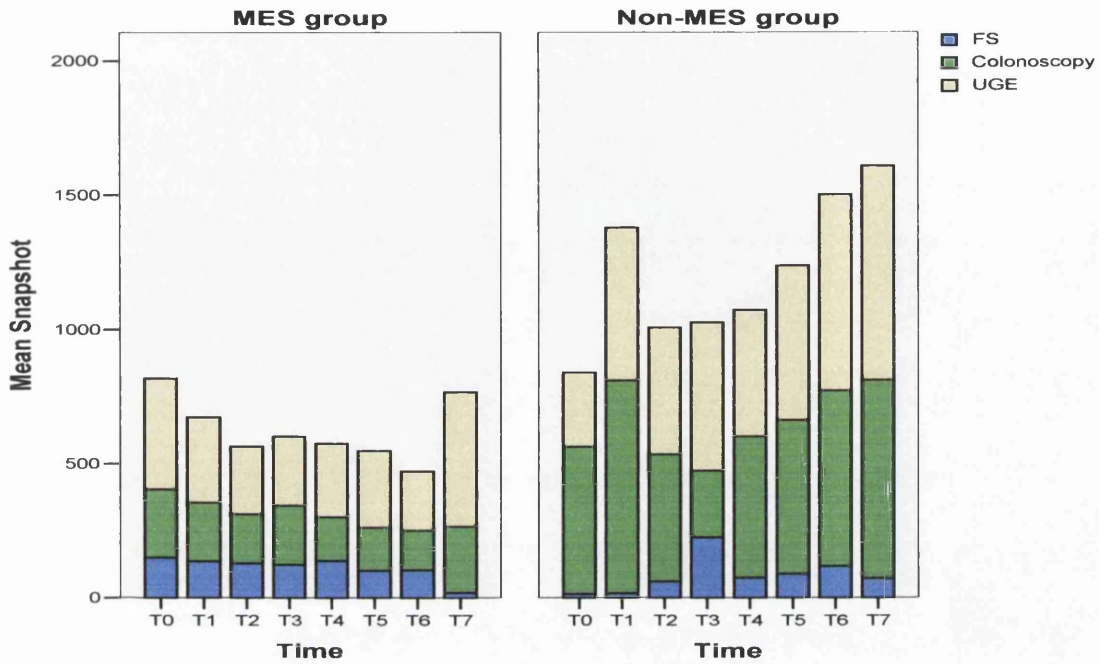
Figure 29: Mean *split procedures Snapshot* for the MES and Non-MES group datasets for individual time points (T0 to T7).
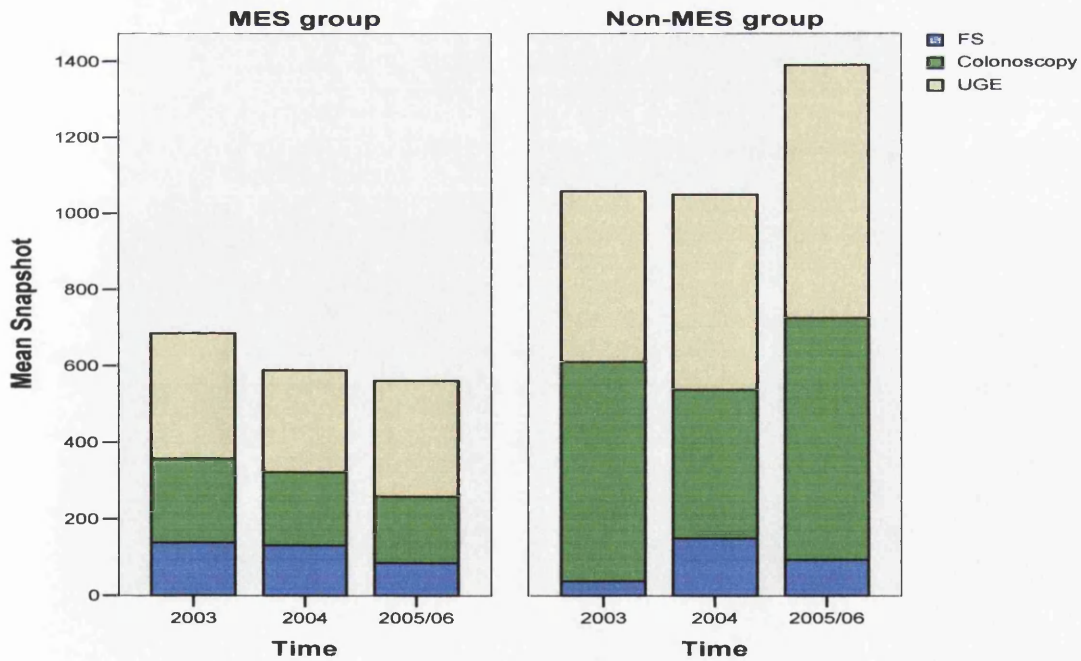
Figure 30: Mean *split procedures Snapshot* for the MES and Non-MES group datasets for data, aggregated according to year (2003, 2004 and 2005/06).
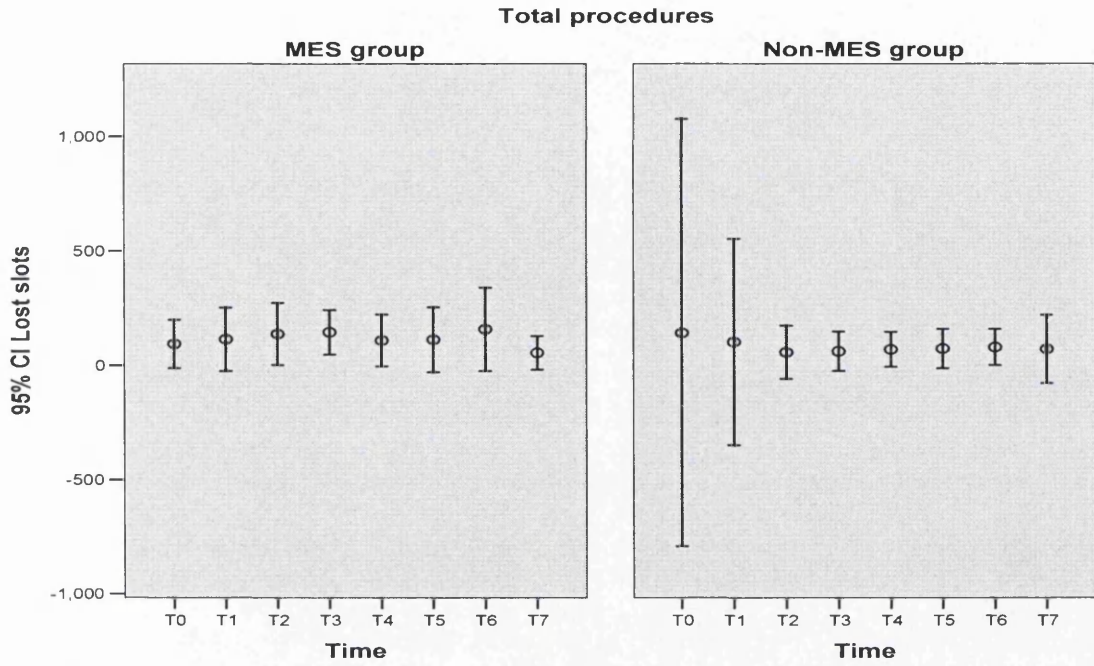
Figure 31: Mean *total procedures Lost slots* for the MES and Non-MES group datasets for individual time points (T0 to T7) with error bars (95% CI).
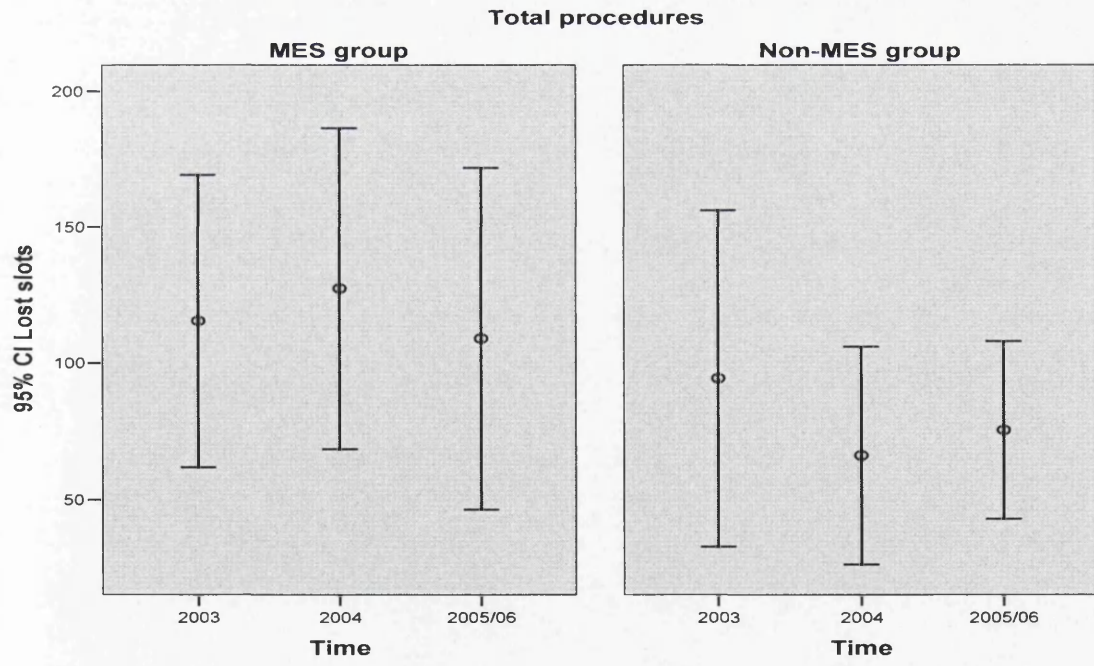
Figure 32: Mean *total procedures Lost slots* for the MES and Non-MES group datasets data, aggregated according to year (2003, 2004 and 2005/06) with error bars (95% CI).

12.2.3.5Activity

The mean *total procedures Activity* trend for the MES group fell from 454 at T0 to 349 at T7, whilst the Non-MES group mean increased from 333 at T0 to 362 at T7 (see Figure 33). Both the MES and the Non-MES group mean showed small variations in data over time, which were exaggerated in the graph due to the smaller scales used as a result of smaller 95% CI values for both Site types. When data were aggregated by year, the MES group mean showed a decrease from 469 at 2003 to 441 at 2005/06 and the Non-MES group mean showed an increase from 352 at 2003 to 401 at 2005/06 (see Figure 34).

When data were split by procedure type, the MES group data for all three procedure types remained relatively constant over time for T0 to T6 with only a decrease in UGEs and colonoscopy in T7 (see Figure 35). The aggregated data was less varied over time, although a minor decrease in UGEs for 2005/06 was evident (see Figure 36). The Non-MES group means for each procedure showed gradual increases over time from T0 to T6 with a slight decrease in T7 for UGEs and colonoscopy although this was not evident in the 2005/06 bar.

12.2.4 Correlation

Significant relationships between combinations of each outcome measure were identified using Spearman's correlation (*rho*). Only significant results were discussed in detail ($p \leq 0.05$). Correlation values between 0.5 and 1 were considered to be strong relationships, whilst those between 0.3 and 0.49 were of medium strength and those between 0.1 and 0.29 were considered to be only weakly related.

Significant positive correlation indicated that an increase in one variable was associated with an increase in the other variable, although the result would not indicate which variable was the causative one (if either – a third confounding variable may have a causative effect on both variables being correlated), whilst significant negative correlation indicated that an increase in one variable was associated with a decrease in the other. Again, the results would not explain which variable was the causative one.
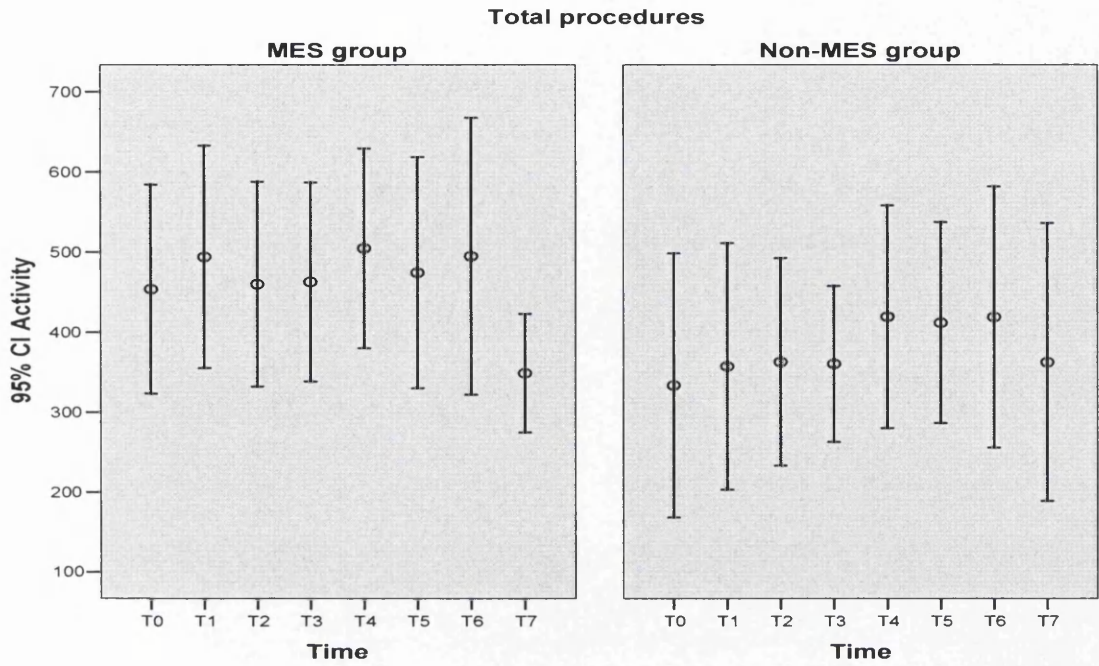
Figure 33: Mean *total procedures Activity* for the MES and Non-MES group datasets for individual time points (T0 to T7) with error bars (95% CI).
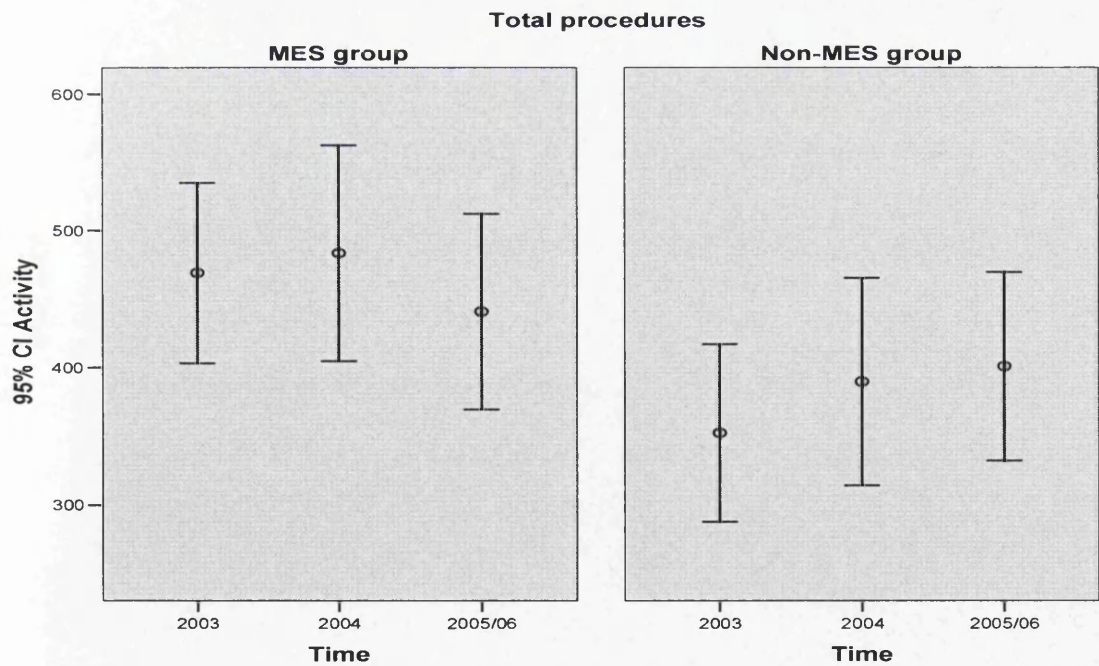
Figure 34: Mean *total procedures Activity* for the MES and Non-MES group datasets for data, aggregated according to time (2003, 2004 and 2005/06) with error bars (95% CI).
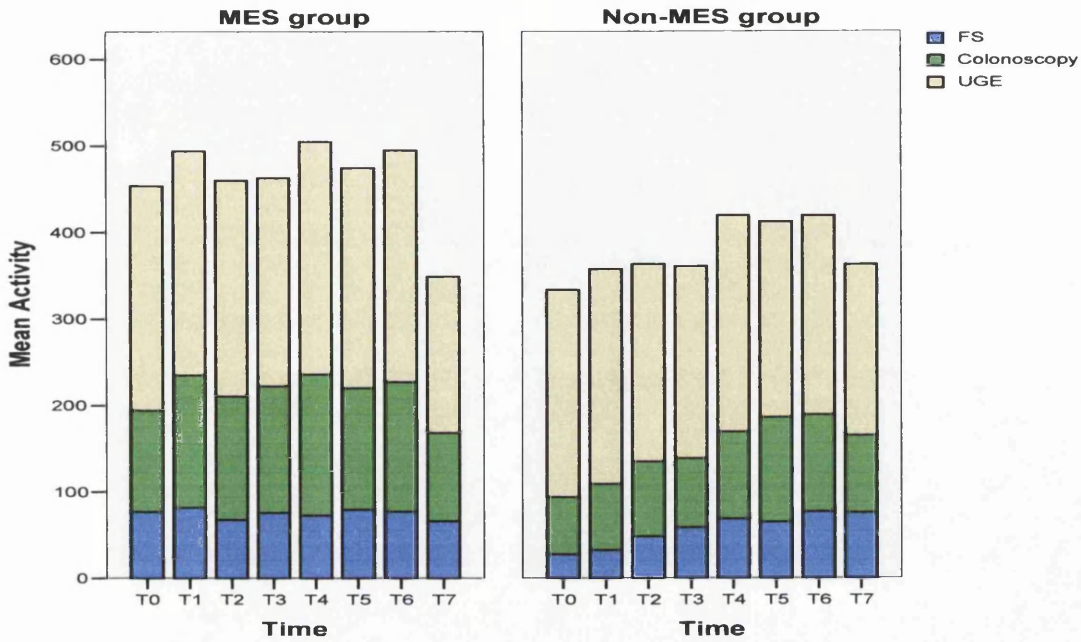
Figure 35: Mean *split procedures Activity* for the MES and Non-MES group datasets for individual time points (T0 to T7).
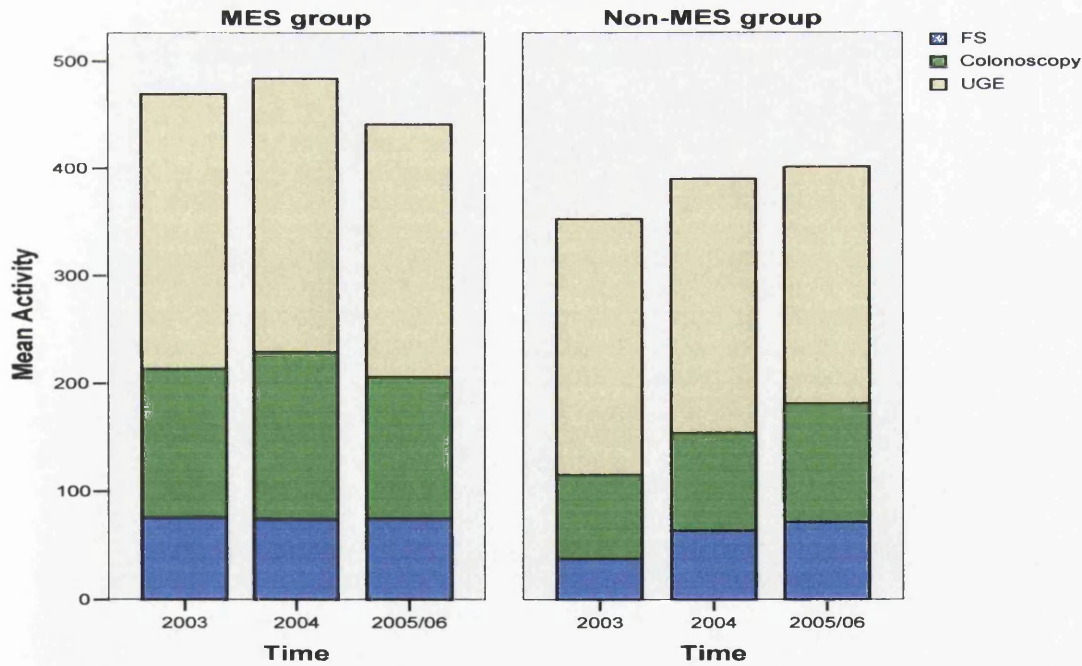
Figure 36: Mean *split procedures Activity* for the MES and Non-MES group datasets for data, aggregated according to time (2003, 2004 and 2005/06).

For the MES group, there was strong positive correlation between *Referral numbers* and *Activity* for 2003 (p = 0.006), 2004 (p = 0.02) and 2005/06 (p < 0.001) that grew in strength over time, indicating a successful and sustained response to any increased demand by increasing *Activity* (see Table 19). *Lost slots* and *Activity* also showed strong positive correlation for 2003 (p = 0.006), 2004 (p = 0.03) and 2005/06 (p = 0.009), although the strength of the relationship decreased slightly over time, indicating that either the sites increased their *Activity* in response to an increasing *Lost slots* rate, or an increase in *Activity* may have increased the incidence of *Lost slots*. There were no other significant linear relationships identified for the other combinations of outcome measures.

Site type	Variable 1	Variable 2	Sample N°.	Year	Correlation Coefficient (rho)	P-value
MES	Referral numbers	Activity	22	2003	0.569	0.006
	Lost slots	Activity	15	2003	0.675	0.006
	Referral numbers	Activity	16	2004	0.574	0.02
	Lost slots	Activity	10	2004	0.681	0.03
	Referral numbers	Activity	21	2005/06	0.725	<0.001
	Lost slots	Activity	15	2005/06	0.649	0.009
Non-MES	Referral numbers	Lost slots	8	2004	-0.786	0.021
	Referral numbers	Activity	13	2004	0.61	0.027
	Lost slots	Activity	8	2004	-0.881	0.004
	Referral numbers	Activity	12	2005/06	0.799	0.002

Table 19: Table of all significant (p ≤ 0.05) relationships between *total procedures* data aggregated according to year for *Referral numbers, Lost slots* and *Activity* from MES and Non-MES group datasets using Spearman's correlation coefficient (*rho*).

For the Non-MES group, *Referral numbers* and *Lost slots* data for 2004 showed strong negative correlation, with increasing *Referral numbers* being significantly associated with low numbers of *Lost slots* (p = 0.021), indicating that for that point in time, these sites appeared to have successfully reduced their *Lost slots* whilst also coping with increasing *Referral numbers* (see Table 19). However, this result was obtained from relatively low sample numbers (n = 8)

and may not be a true representation of the service in Non-MES sites for this time period. Data for 2003 and 2005/06 was not significant (p = 0.589 and 0.16 respectively), indicating that this change in services was not originally in place but was also not successfully maintained. There was a strong positive correlation between *Referral numbers* and *Activity* for 2004 (p = 0.027) and 2005/06 (p = 0.002), but not 2003 (p = 0.17), indicating that after a slow start the Non-MES group were also able to match *Referral numbers* with *Activity*. *Lost slots* and *Activity* showed a strong negative correlation for 2004 (p = 0.004), whereby increased *Lost slots* were significantly associated with decreased *Activity*. This was not the case for 2003 or 2005/06 (p = 0.148 and 0.066 respectively). This may be explained by the fact that *Activity* is counted as the number of completed procedures and as the number of *Lost slots* increases, the number of procedures completed decreases proportionally. Again, low sample numbers (n = 8) may have affected the results in Non-MES sites for this time period. There were no other significant linear relationships identified for the other combinations of outcome measures.

12.2.5 Two-way Analysis of Variance

When using a two-way ANOVA to analyse the *total procedures* data, there were no statistically significant between-groups or within-groups effects for *Referral numbers, Wait >3m, Snapshot, Lost slots* or *Activity*. This meant that whilst the data for these outcome measures did change over time, it did not change to a point where the difference became statistically significant in either Site type. The results also showed that any changes in *Referral numbers, Wait >3m, Snapshot, Lost slots* or *Activity* in the MES sites were mirrored by similar changes in the Non-MES sites, resulting in no significant differences between Site types at any specific point in time for any outcome measure.

However, the *Activity* dataset did show a significant interaction effect (F (2, 26) = 3.594, p = 0.042), indicating that there was a significant difference in the rate of the changes in the *Activity* data over time in the MES and Non-MES groups (see Table 20). Closer examination of the data indicated that the significant interaction effect was attributable to a decrease in MES group *Activity* over time corresponding with an increase in Non-MES group *Activity* over time. This can be visualised using a means plot whereby the lines for each Site type over time are not significantly parallel (see Figure 37).

186

Outcome measure	Procedure type	MES group means for 2003, 2004 and 2005/06	Non-MES group means for 2003, 2004 and 2005/06	Within-subject effects (F ratio, sig.)	Between-subject effects (F ratio, sig.)	Interaction effects (F ratio, sig.)
Referral numbers	FS	72.9, 75.2, 79.5 (n = 9)	67.8, 89.9, 92.8 (n = 4)	2.12, 0.169	0.059, 0.813	0.94, 0.365
	Colonoscopy	127.3, 134.4, 126 (n = 9)	141.2, 143.3, 163.1 (n = 4)	0.347, 0.58	0.201, 0.663	0.733, 0.417
	UGEs	254.1, 236.9, 209 (n = 9)	310.7, 271.8, 260.1 (n = 4)	5.151, **0.03**	0.646, 0.439	0.284, 0.67
	Total procedures	454.3, 446.6, 414.5 (n = 9)	519.7, 505, 516 (n = 4)	0.28, 0.64	0.586, 0.46	0.317, 0.617
Wait >3m	FS	19.3, 15.7, 9.7 (n = 5)	6.7, 8.7, 15.8 (n = 3)	0.016, 0.984	0.246, 0.638	2.296, 0.143
	Colonoscopy	65.2, 58.5, 55.6 (n = 5)	108.9, 138.5, 236 (n = 3)	0.965, 0.367	1.004, 0.355	1.247, 0.308
	UGEs	49.6, 48.1, 51.9 (n = 5)	31.8, 75.2, 131 (n = 3)	0.992, 0.362	0.226, 0.651	0.896, 0.385
	Total procedures	134.1, 122.3, 117.2 (n = 5)	147.3, 222.3, 382.8 (n = 3)	0.994, 0.36	0.594, 0.47	1.29, 0.3
Snapshot	FS	138.2, 131.4, 101 (n = 4)	61.5, 65.1, 82.3 (n = 4)	0.313, 0.737	0.826, 0.399	4.428, **0.036**
	Colonoscopy	219.4, 191.3, 161.1 (n = 4)	490.4, 594.4, 692.2 (n = 4)	0.931, 0.421	4.351, 0.082	3.06, 0.084
	UGEs	327.6, 266.3, 293.6 (n = 4)	455.8, 515.1, 647.4 (n = 4)	0.812, 0.467	3.23, 0.122	1.235, 0.325
	Total procedures	685.2, 588.9, 555.6 (n = 4)	1007.7, 1174.5, 1422.5 (n = 4)	0.733, 0.435	3.757, 0.101	2.461, 0.163
Lost slots	Total procedures	115.5, 127.3, 109 (n = 5)	76.3, 70.7, 75.3 (n = 3)	0.313, 0.737	0.469, 0.519	0.965, 0.409
Activity	FS	84.3, 73.2, 74.9 (n = 8)	46.1, 58.1, 57.5 (n = 7)	0.019, 0.981	0.899, 0.36	3.14, 0.06
	Colonoscopy	119.1, 129.6, 125.6 (n = 8)	88.1, 94.8, 129.6 (n = 7)	2.928, 0.103	0.255, 0.622	2.259, 0.151
	UGEs	274.2, 274.2, 232.4 (n = 8)	228.4, 232.6, 219.4 (n = 7)	5.249, **0.012**	0.586, 0.458	1.789, 0.187
	Total procedures	477.6, 476.9, 433 (n = 8)	360.1, 384.8, 403.8 (n = 7)	0.348, 0.71	1.106, 0.312	3.594, **0.042**

Table 20: Results of the two-way ANOVA for all five outcome measures using *total procedures* and *split procedures* data. All significant values are highlighted in bold.

187
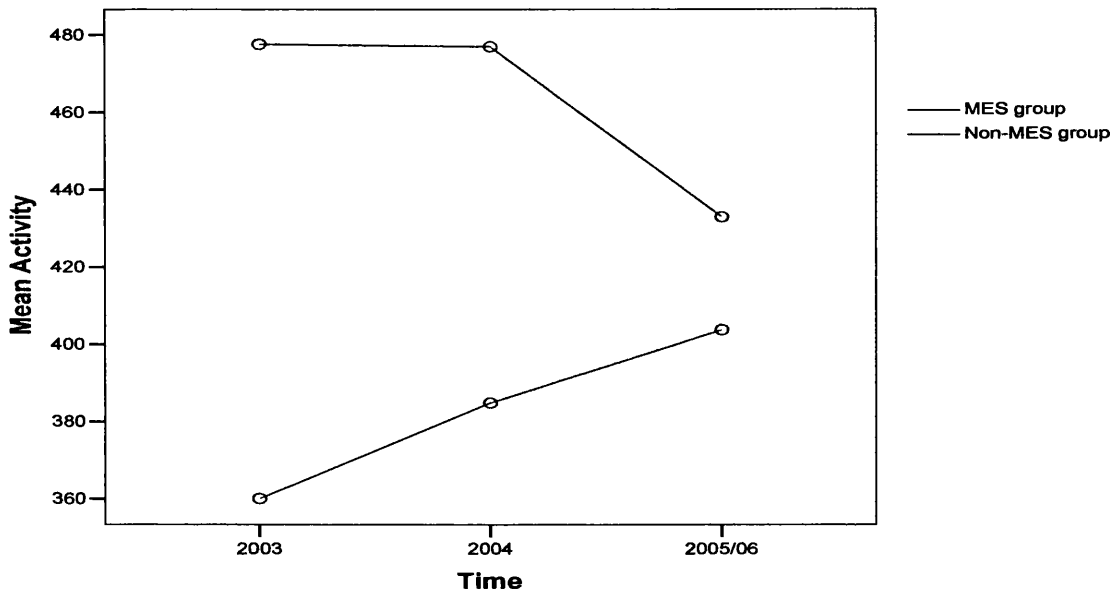
Figure 37: Mean *Activity* in MES and Non-MES groups using *total procedures* data.

When data were split by procedure type, there were no significant between-groups effects for any of the five outcome measures (see Table 20). The only significant within-group results were for UGEs over time for *Referral numbers* (F (1, 11) = 5.15, p = 0.03) and for *Activity* (F (1, 13) = 5.25, p = 0.012), indicating that those two outcome measures changed significantly over the three time periods analysed within the MES and Non-MES groups.

Post hoc analysis revealed that there was a significant difference between the UGE *Referral numbers* data for 2003 and 2004 (p = 0.05) and between the UGE *Activity* data for 2004 and 2005/06 (p = 0.019). Further analysis split according to Site type using the Friedman test revealed that there were significant differences in the Non-MES group *Referral numbers* over time (n = 4, df = 2, χ^2 = 6, p = 0.05), but not for the MES group *Referral numbers* (n = 9, df = 2, χ^2 = 4.67, p = 0.097). Friedman tests also revealed significant differences in the UGE *Activity* data for the MES group (n = 8, df = 2, χ^2 = 7, p = 0.03) but not for the Non-MES group (n = 7, df = 2, χ^2 = 2, p = 0.368). On closer examination of the raw data, the mean *Referral numbers* data from the four sites constituting the Non-MES group significantly decreased from 310.7 in 2003 to 260.1 in 2005/06

188

and the mean *Activity* data from the eight sites constituting the MES group significantly decreased from 274.2 in 2003 to 232.4 in 2005/06.

The only significant interaction effect found for *split procedures* data was associated with FS *Snapshot* data (F (1, 6) = 4.43, p = 0.036), indicating that there was a significant difference in the rate of change in the FS *Snapshot* data over time in the MES and Non-MES groups, as highlighted by Figure 38.
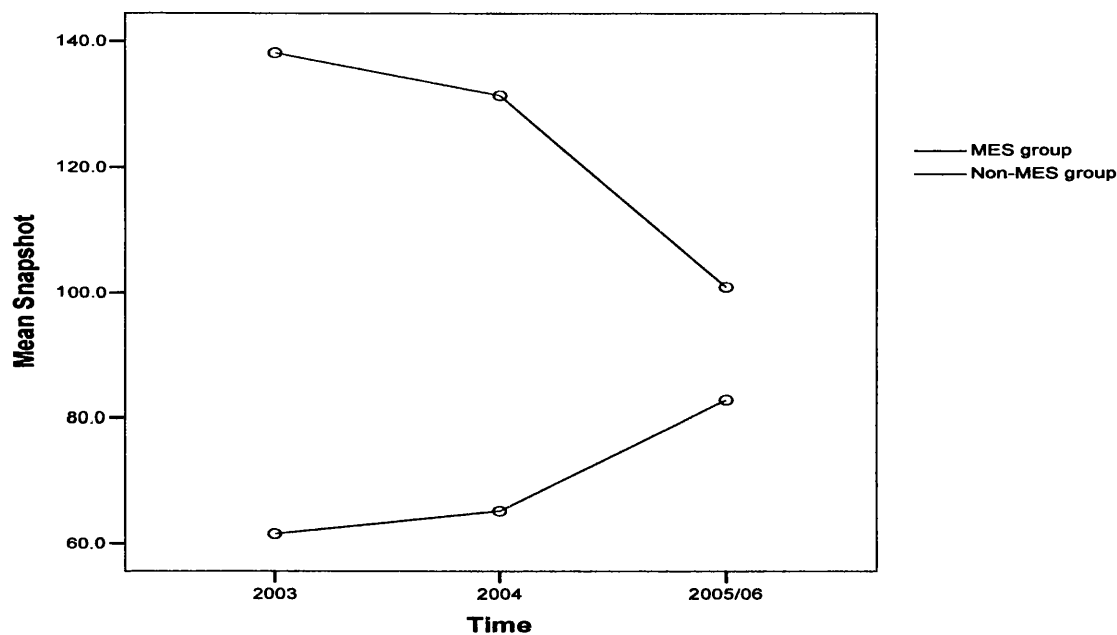
Figure 38: Mean FS *Snapshot* in MES and Non-MES groups using *split procedures* data

12.3 Discussion

The measurement and evaluation of NHS services is essential to ensure that a process is running optimally and to guarantee that there is no alternative way of doing things that would be even more efficient. The most effective way to evaluate NHS services is to look at different aspects of demand, capacity and activity and determine how well matched they are. This was one of the main principles of the MES Toolkit, using these measures to assess the performance of endoscopy services within MES sites during the MES project. The evaluation method used in this thesis was

based on the MES Toolkit, measuring changes within each study site in *Referral numbers, Wait >3m, Snapshot, Lost slots* and *Activity* over time.

This study has shown that there was a high degree of variability in the services of the 20 endoscopy units participating in this study over time for all five outcome measures, especially from the Non-MES sites. However, both the MES and Non-MES group means were more stable over time, although they were associated with large 95% CIs for some time points which was attributed to low sample numbers for those time points and the fact that these types of data are liable to be highly varied between sites. It was also feasible that the group means may have been affected by one or two rogue sites who did not perform in the same way as the majority of the sites in that group. Unfortunately, with such low sample numbers there was no way to control for it. Since the MES sites and non-MES sites were all geographically widespread, the data trends seen in this study were not likely to have been due to regional effects.

Variance analyses found that the MES sites tended to have more efficient services than the Non-MES sites as they were more efficient at balancing *Demand* with *Activity*. This may be attributed primarily to the fact that the MES Toolkit would have calculated this value and consequently, these sites may have been more able to react to sudden increases in *Demand*. However, when we examine the *Variance* data from the Non-MES sites, it is clear that the values are smaller than those seen in the MES sites, although many more sites have negative *Variance* values suggestive of a less efficient service and rising backlogs. However, when examining the *Variance* data for both Site types in a comparative manner, we must remember that the trend for *Referral numbers* differed in each Site type, with the MES group mean indicating slight decreases in *Referral numbers* over time whilst the Non-MES group mean indicated slight increases over time.

Referral numbers decreased over time in the MES group, but were more variable in the Non-MES group. This may be explained by the MES sites taking a more proactive approach to managing the demand on their services, as advised by the MESPT. Examples of this management included validation of referrals, introducing new referral pathways and most importantly, the introduction of partial and full booking – a MES project target. The implementation of partial and full booking for patients gave them the choice of appointment dates (and later evolved into the Choose and Book initiative – see Chapter 2) and may have affected the demand for MES sites more than the Non-MES sites. Another major contributor to changing the demand on NHS endoscopy services in both MES and Non-MES sites has been the implementation of guidelines to allow healthcare

professionals to correctly refer their patients (see Chapter 6). This should have reduced the number of inappropriate referrals to NHS endoscopy units, thereby reducing the demand on endoscopy services. Interestingly, the number of UGE referrals being made decreased in both Site types over time, possibly as a result of improved guidance regarding the referral of dyspepsia patients by NICE (National Institute for Clinical Excellence, 2004a).

The *Wait >3m* data remained relatively stable over time in MES sites, but was slightly higher and more variable in Non-MES sites. However, both Site types showed decreases in *Wait >3m* over time, as was expected given that it was a target stipulated in the *NHS Plan* (Department of Health, 2000c). There were differences in the proportion of patients waiting for a colonoscopy between the MES group and the Non-MES group, although this decreased over time as the Non-MES sites reduced the number of patients waiting for this procedure more than three months.

The trend for *Snapshot* data differed significantly between the MES and Non-MES group, with the MES group *Snapshot* decreasing over time whilst the Non-MES group *Snapshot* increased over time to become more than double of the MES group. This difference may be due to initiatives advocated by the MESPT that the MES sites successfully, including waiting list validation and pooling. The Non-MES sites may not have had this advice and so, their waiting lists did not improve. The need to meet the three month target may have been another confounding factor for the Non-MES sites as they were forced to reclassify and then reorganise their patients onto a routine waiting list so that only "eligible" patients were given priority to be seen within three months. This theory is supported by looking at the number of patients waiting for a colonoscopy over time. The *Wait >3m* data in the Non-MES sites showed a marked decrease over time. When we look at the colonoscopy *Snapshot* data over time we see that it has increased. It is highly likely that many colonoscopy patients were moved onto another waiting list not affected by the three month target.

Lost slots were lower in the Non-MES group than in the MES group and both showed differing trends: the MES group data showed a peak whereas the Non-MES group data showed a trough. The actual data also indicated that the mean MES *Lost slots* was consistently higher than the mean Non-MES *Lost slots* indicating that the Non-MES sites were better at reducing their *Lost slots* over time. This finding casts some doubt on the validity of the findings of the MES report which stated that during 2003, 71% of their 26 sites reduced their DNAs to less than 5%. These findings also show that any improvements in their DNA rates were subsequently not sustained over time. The reasons for this are unknown. However, it is difficult to compare the "% DNA rates" quoted by the MES report with the actual figures reported here – we can only judge the data trend

and comment that the increase makes it possible that the MES report is incorrect. It is also feasible that the 29% of MES sites who did not reduce their DNAs to less than 5% during the MES project were all represented in the 10 MES sites used in this study. If this was the case, then the MES final report is more likely to be correct.

It was interesting that the Non-MES group reduced their DNAs over time without any MES project support. Perhaps with less financial backing to implement changes, they sought to get the most out of their redesign initiatives and if DNAs and cancellations were a huge problem for these sites, they may have focussed on them in the hope that improving them would indirectly benefit their waiting lists as less people would be rebooked. However, this side effect was not evident in this analysis, probably because the number of appointments saved would have been a tiny proportion of the *Snapshot* dataset.

The *Activity* in the MES group decreased over time whilst the Non-MES group *Activity* increased, although the MES group *Activity* was far higher than that of the Non-MES group to begin with. The MESPT provided endless advice and support to allow MES sites to identify their potential capacity and increase their throughput accordingly. The introduction of NEs into NHS endoscopy units would have increased *Activity* in both Site types to a degree, depending upon when they were employed and the extent of their skills. It is feasible that the decrease seen in the MES sites may have been attributable to the introduction of nurse-led clinics as outpatient consultations which would not have been recorded in this dataset, although there is no reason why this new way of working would not have been introduced in the Non-MES sites too. When looking at the *split procedures Activity* data, it paints a clearer picture. The *Activity* in the MES sites for all three procedure types remains relatively constant, with only a minor drop in UGEs for 2005/06 whilst the Non-MES sites show an increase in colonoscopies that approaches that seen in the MES sites. It is possible that in an attempt to cope with their increasing waiting lists (as shown by the *Snapshot* data), the Non-MES sites successfully increased the number of colonoscopy procedures being performed. It is also possible that the increase in *Activity* is in part due to a decrease in *Lost slots* by the Non-MES sites, as described earlier. With less appointments lost, more procedures were being recorded as completed which may have contributed to the increase in the colonoscopy *Activity* figures.

There was a statistically significant, strong, positive correlation between *Referral numbers* and *Activity* over time in both the MES and the Non-MES group, indicating a successful and sustained

response to any increases in referrals in both Site types by increasing *Activity*. *Lost slots* and *Activity* in the MES group also showed a significant, strong, positive correlation over time, indicating that either these sites increased their *Activity* in response to an increasing *Lost slots* rate, or an increase in *Activity* may have increased the incidence of *Lost slots* proportionally. *Lost slots* and *Activity* in the Non-MES group showed a significant, strong, negative correlation at only one time point. This may be explained by the fact that *Activity* is counted as the number of completed procedures and as the number of *Lost slots* increases, the number of procedures completed decreases proportionally. Low sample numbers (n = 8) may have affected the results in Non-MES sites for this time period.

A two-way ANOVA using *total procedures* data showed that there were no significant differences in the data for any of the five outcome measures over time within both Site types. There was also no significant difference between the MES and Non-MES group data for any of the five outcome measures. The only significant interaction effect was for *Activity*, indicating that there was a significant difference in the rate of change in the *Activity* data over time in both Site types. This was illustrated graphically with decreases in MES group *Activity* mirrored by increases in Non-MES group *Activity* over time. This result highlights an interesting finding that was contrary to the original hypothesis that the MES sites would increase their *Activity* levels. The proposed explanation discussed earlier regarding the possibility of outpatient procedures accounting for *Activity* that was not recorded in this study could partly explain this significant difference. Another contributory reason could be the fact that the Non-MES sites had obviously made a degree of improvement in their services that, when compared to the MES sites, resulted in the significant interaction effect found.

When data were split according to procedure types, more significant differences were found. For UGEs, there was a significant within-groups effect for *Referral numbers* and *Activity*, indicating that the data differed significantly over time within the MES and Non-MES groups for these two outcome measures. Post hoc analysis found that the Non-MES group had the significant difference in UGE *Referral numbers* data over time as the number of referrals decreased significantly from 2003 to 2004, whilst the MES group were the source of the significant result for UGE *Activity* as the number of procedures performed decreased from 2004 to 2005/06.

There was one significant interaction effect whereby the changes in FS *Snapshot* data were significantly different over time for both Site types. When the data were illustrated graphically,

there was an obvious downwards trend in MES group data over time that was significantly different to the upwards trend in data seen from the Non-MES group data over time.

It is plausible that the number of comparisons made as part of a two-way ANOVA increases the chances of a statistically significant result occurring by chance. Setting the p-value at 0.05 meant that there was a 1 in 20 chance of a test being statistically significant when it was in fact not i.e. a type 1 error. When examining the proportion of significant tests in relation to the number of statistical tests performed in this type of multivariate analysis, there were approximately 51 individual tests being done (repeated measures and between site measures for five outcome measures according to *total procedures* and *split procedures* datasets – see Table 20), of which four were statistically significant (7.8%). Since this is close to the 5% figure we would expect to see given the number of tests being done, it is possible that there was only one truly significant two-way ANOVA result, with the remainder due to chance alone due to the p-value being set at ≤ 0.05. Unfortunately, if this were true, it would not be possible to ascertain which of the four results was likely to be true by simply looking at the raw data. However, since there were no obviously incorrect significant results, the findings reported by this study will assume that all four significant results are in fact true.

Therefore, the findings of this study are that overall, there were very few statistically significant changes in the five outcome measures tested within both MES and Non-MES groups, and the MES and Non-MES groups were not significantly different at any point in time because any changes in the services of the MES sites were mirrored by equivalent changes in the services of the Non-MES sites.

13.   PAST INNOVATIONS WITHIN STUDY SITES

As part of this evaluation it was important to ascertain exactly which innovations each site had implemented to ascertain whether there were any key factors in terms of the number or type of innovations introduced that were associated with the MES sites that may have been attributable to the MES project, or for the Non-MES sites that could be attributed to their independent redesign strategies. To achieve this, a list of all the innovations implemented by each site during three specific time periods was collected to provide a description of innovations introduced by each site for descriptive purposes and to allocate a score to represent how innovative each site had been.

13.1 Methods

13.1.1 Questionnaire design and allocation

A list of innovations occurring in the study sites since 2000 was compiled based on the first round of qualitative interviews performed within the 19 participating ENIGMA endoscopy units with clinicians and change agents (see Chapter 8). An "Innovations Form" (see Appendix 16.9) was designed, asking respondents to tick "Yes" or "No" to whether they had implemented each innovation listed and to tick one box under the Timeframe column ("2000/02", "2003" or "2004/05") to indicate when it was first implemented. A section was added at the end for the addition of innovations not listed on the form and for any comments.

The form was piloted at Singleton Hospital in Swansea before being sent to the ENIGMA contact of all endoscopy units except Site 18 (which had withdrawn from any active participation in the ENIGMA study) during July 2005. Where a response had not been received after eight weeks, a reminder letter and form was sent.

The form was later revised with an additional 2006 column and resent to the original respondents in May 2006 to update the entries as far as April 2006 (T7). A third reminder and revised form was sent to sites who had not returned an Innovations Form at that time.

195

13.1.2 Analysis plan

A description of the most commonly implemented innovations was drafted according to Site type. An independent samples t-test was used to determine whether there were any significant differences in the number of innovations implemented by MES and Non-MES sites.

Each innovation listed on the Innovation Form was scored according to whether it had been implemented or not. The scoring system was also devised to reflect any proactive redesign plans in each site by scoring innovations implemented earlier in the Timeframe more highly. Innovations implemented in 2000/02 scored "3", innovations implemented during 2003 scored "2" and innovations implemented during 2004/06 scored "1". Where the "Yes" column had been ticked but no specific Timeframe was indicated, no score was given. Any additional innovations added by respondents were either integrated into the existing framework or were included as an additional innovation in the list. Each site was given a score for each Timeframe and a total score that was used to assign a rank (1 to 19) to all study sites, irrespective of Site type.

13.2 Results

Of the 19 endoscopy units sent the Innovations Form, all returned it completed for 2005 and only two did not return the updated form with 2006 scores, both of which were MES sites (1 and 16). These forms were included in the analysis irrespective of the 2006 missing data, since any missing data would probably not have scored highly and therefore would probably not have had a significant impact on the final scores. Of the additional comments entered by respondents, all could be reclassified as one of the innovations already listed.

13.2.2 Innovations introduced – a descriptive summary

Of the innovations listed on the questionnaire, all were implemented by a minimum of two sites in each group out of a maximum of nine for the MES sites and 10 for the Non-MES sites. Table 21 illustrates how many MES and Non-MES sites implemented each innovation, irrespective of when they were implemented.

When the data in Table 21 was examined according to the innovation category, there were more innovations implemented by Non-MES sites than MES sites for all categories except for "Alteration of roles" and "New nurse responsibilities". Close examination of the raw data revealed that the Non-MES group implemented more innovations in total than the MES group (445 Vs. 394).

Innovation category	Innovation type	Site type	
		MES (n = 9)	Non-MES (n = 10)
New / additional staff	Nurse endoscopists	8	9
	GP endoscopists	3	6
	Consultants	6	10
	Link / escort nurses	4	3
	Health care assistants	5	7
	Receptionist / other clerical staff	5	8
	New management / leadership	6	5
	Data collection staff	3	3
	TOTAL	**40**	**51**
Alteration of roles	Changing roles of medical staff	3	2
	Changing roles of clerical staff	6	7
	Clerical duties taken from nurses	6	5
	TOTAL	**15**	**14**
New nurse responsibilities	Nurse led clinic(s)	5	6
	Nurse led consent	7	4
	Nurses performing cannulations	8	7
	PEG nurses	8	4
	Training nurses to be nurse endoscopists	6	9
	TOTAL	**34**	**30**
New working practices	New referral procedure(s) into the unit	6	9
	Validation of referrals	7	8
	New guideline(s) / protocols	7	9
	Triage of emergency patients	6	6
	Pre-assessment clinics	4	2
	DNA strategies	6	8
	Cancellation strategies	6	8
	"6-week notice period for leave" policy	9	9
	New procedure(s) performed	7	8
	One-stop clinics / dedicated training lists	6	7
	TOTAL	**64**	**74**
Increasing activity	Extra slots for emergency bleeds, etc	7	7
	Scheduling extra list(s) (Mon to Fri)	6	9
	Increasing the length of the working day	4	4
	Weekend / out of hours working	6	4
	TOTAL	**23**	**24**
Waiting list management	Validation of waiting lists	8	9
	Pooling waiting lists	7	8
	Waiting list initiative sessions	4	8
	TOTAL	**19**	**25**
Booking	Open access booking	5	5
	Full booking	6	8
	Partial booking	9	9
	TOTAL	**20**	**22**

(Cont'd...)

Innovation category	Innovation type	Site type	
		MES (n = 9)	Non-MES (n = 10)
Structural changes	New hospital / unit	4	5
	Structural alterations to current unit	5	4
	Increasing capacity in recovery area	3	5
	Centralising admin in one place	4	6
	Moving some endoscopy externally	3	4
	Refurbishment of reception / endoscopy suite	7	4
	TOTAL	**26**	**28**
Analysis of working practices	New / improved in-house data collection	5	9
	Demand and capacity studies	9	9
	Audits	9	10
	Process mapping	7	8
	Patient surveys	8	10
	TOTAL	**38**	**46**
Patient experience	New information leaflets for patients	8	9
	Improving patient privacy & dignity	6	8
	Home bowel preps	8	10
	Improving experience of inpatients	6	6
	Improving experience of diabetic patients	7	8
	Improving experience of patients with other comorbidities	6	3
	TOTAL	**41**	**44**
Staff experience	Staff training / development	7	8
	"Protected time" for staff to meet / train	5	5
	Surveying staff on changes wanted	5	7
	New / improved staffroom	6	4
	Endoscopy groups / staff meetings	6	10
	Improving staff communication	6	9
	TOTAL	**35**	**43**
Miscellaneous	New medical equipment	8	10
	New IT equipment / software	7	8
	Raising the profile of endoscopy	7	6
	Advice or help from within the Trust	6	9
	Advice or help from external agencies	4	6
	Open days for hospital staff / patients	7	5
	TOTAL	**39**	**44**
	Total score	**394**	**445**

Table 21: The number of MES and Non-MES sites implementing any of the 65 innovations listed between 2000 and 2006.

However, there were only nine MES sites compared to 10 Non-MES sites, so when the average number of innovations implemented in the MES and Non-MES group was calculated, the result showed that the MES sites, on average, implemented more innovations than the Non-MES sites (MES group = 91.7 ± 37.1; Non-MES group = 81.3 ± 19) although the difference was not statistically significant (T = 0.78, p = 0.446).

All nine MES sites had implemented a six week notice period for leave policy, partial booking, demand and capacity studies and audits, whilst all 10 Non-MES sites had implemented the following: additional consultants, audits, patient surveys, home bowel preparations, endoscopy groups / staff meetings and new medical equipment.

When data were assessed to determine the largest difference in counts (three or more) between the MES and Non-MES groups, the results showed that there were four examples where the MES group implemented more of the following innovations than the Non-MES group: Nurse-led consent (7:4), PEG nurses (8:4), refurbished their reception / endoscopy suite (7:4) and improving the experience of patients with other co-morbidities (6:3). However, there were 11 instances where the Non-MES group implemented more innovations than the MES group: additional GP endoscopists (6:3) additional consultants (10:6), additional receptionist / clerical staff (8:5), training nurses to be NEs (9:6), new referral procedure(s) (9:6), scheduling extra lists (9:6), waiting list initiative sessions (8:4), in-house data collection (9:5), endoscopy groups / staff meetings (10:6), improving staff communication (9:6) and advice or help from within the Trust (9:6).

13.2.3 Examination of innovation scores

All sites were scored as previously described and all scores and ranks are described for each MES and Non-MES site in Table 22. The distribution of the Site types were evenly spaced throughout the ranks, with an MES site as the top scoring site and the highest position for a Non-MES site at third place. However, the lowest two ranks were also MES sites.

Of the 19 sites returning a completed form, 13 had their highest score corresponding to 2000/02. This was to be expected, since the scoring framework rewarded a more proactive approach to modernisation (pre-MES project innovations) more highly. Of these, seven were MES sites (1, 4, 7, 11, 13, 16 and 19) with scores ranging from 27 to 129, whilst the other six were Non-MES sites (2, 5, 9, 15, 17 and 20), with scores ranging from 30 to 84.

Site ID	Site type	Timeframe			Total score	Rank
		2000/02	2003	2004/06		
19	MES	129	6	14	149	1
4	MES	111	20	7	138	2
15	Non-MES	84	18	10	112	3
20	Non-MES	90	8	11	109	4
7	MES	48	30	29	107	5
13	MES	66	22	12	100	6
12	Non-MES	18	42	33	93	7
11	MES	66	18	7	91	8
10	Non-MES	24	36	22	82	9
17	Non-MES	45	26	10	81	10 =
6	MES	3	50	28	81	10 =
5	Non-MES	42	16	21	79	12
9	Non-MES	45	18	12	75	13
16	MES	36	30	6	72	14
14	Non-MES	18	4	44	66	15
2	Non-MES	30	12	20	62	16
3	Non-MES	6	18	30	54	17
1	MES	27	12	12	51	18
8	MES	9	16	11	36	19
18	MES	No form sent				

Table 22: A breakdown of the Innovation Form scores for each Timeframe and the Total Innovation scores achieved by each MES and Non-MES site, listed according to rank.

The remaining six sites had their highest scores in either 2003 (6, 8, 10 and 12) or 2004/06 (3 and 14). Of these, two were MES sites (6 and 8) and the remaining four were Non-MES sites (3, 10, 12 and 14). The 2003 scores ranged from 16 to 50 for the MES sites and from 36 to 42 for the Non-MES sites whilst the 2004/06 scores ranged from 30 to 44 for the Non-MES sites (no MES sites scored more highly for 2004/06).

13.3 Discussion

Whilst there were more innovations implemented by MES sites than by Non-MES sites, the difference was not statistically significant. This suggests that either the Non-MES sites were equally active in their redesign projects or the MES sites did not introduce any more innovations as would have been introduced "naturally". Given that the Non-MES sites cited their intention to redesign irrespective of their exclusion from the MES project, the first explanation is most likely.

When examining which of the innovations all nine MES sites had implemented, the only one that was also implemented in all 10 Non-MES sites was audits. Closer examination of the types of innovations implemented by all MES sites revealed that they were closely tied in with the targets allocated and the advice given by the MESPT. Of those innovations implemented by the Non-MES sites, two were considered not to be innovations *per se* as they may have happened irrespective of any modernisation plans due to the evolution of the service – additional consultants and new medical equipment. However, the other innovations were considered to be new ways of working.

When exploring the difference in MES and Non-MES sites in terms of the number implementing each innovation type, there were 11 innovations that were implemented in higher numbers by the Non-MES sites than the MES sites compared with only four innovations that were implemented in higher numbers by the MES sites than the Non-MES sites. This was surprising, since some of these innovations were considered to be expensive, although it is feasible that staff increases were funded by the Trust and would have happened anyway, irrespective of any modernisation drive (or lack thereof) occurring within the units. It is interesting that more Non-MES sites were keen to introduce or enhance methods of communication, both internal and external, than the MES sites. They also appeared to be more amenable to data collection than the MES sites, a finding supported in Chapter 10 of this thesis.

It was originally thought that the financial implications of implementing innovations may have reduced the number of innovations introduced by the Non-MES sites compared to the MES sites as some would have had significant budget implications (additional staff and new equipment). Whilst partial funding for Non-MES sites may have been secured from other sources (e.g. charitable donations, business plans), the majority of sites would not have had a large amount of money with which to implement changes. They also would not have had the same level of access to advice from the MESPT during 2003 regarding how best to analyse and modernise their

services. Many changes implemented by the MES sites were very simple and were cost-neutral and involved only changing the way a process was done, usually by reducing the number of resources or by transferring the responsibility of a process to a qualified but less expensive member of staff, freeing up the more specialist staff to provide their expertise more effectively. However, the same point can be made for the Non-MES sites, possibly because they had no additional MES funding and needed to find inexpensive solutions to improving their services.

It is clear from the forms submitted for this study that many of the Non-MES sites were equally as proactive in their attempts to modernise their endoscopy services as those sites chosen to be MES project sites by the NHSMA. Discussions with NHSMA personnel via the ENIGMA study confirmed that the sites were chosen based on their application form and were not chosen as either good sites who would inevitably do well in the project, or poor sites who would show significant differences in their services that would be attributed to the MES project, thereby artificially overestimating the impact of the MES project. The analysis of the Innovation Forms confirms that the MES and Non-MES sites did not appear to be extremely different in their pre-MES project redesign plans.

The ranking of the sites based on their scores revealed that MES sites held the two top and bottom spaces on the one to 19 scale. Overall, there were marginally more MES sites than Non-MES sites populating the top ten spaces. This result suggests that these MES sites were more proactive in their modernisation programmes, implementing changes at an earlier point in time than the Non-MES sites which would have been reflected in their scores in earlier Timeframes.

There were two interesting points for discussion based on the Innovation Forms completed by the sites. The first was that only four of the MES sites (4, 7, 13 and 19) had ticked the box indicating that they had "help or advice from external agencies". This meant that five MES sites did not acknowledge the role of the MES project in their modernisation programmes. The second was that five MES sites and nine Non-MES sites had ticked the box indicating that they had "new / improved in-house data collection", a finding not reflected in the collection of routine data for this study. These two findings suggest that the results of this aspect of the study may not be entirely accurate, although one would expect any bias in a form of this type to be in the opposite direction, with sites ticking too many boxes instead of too few. However, the findings reported here do not constitute a major part of the study as this investigation was done as a secondary outcome measure only.

14.   OVERALL DISCUSSION

A focussed discussion of the results of this thesis has already been presented in the corresponding chapters (10 to 13). This discussion chapter will summarise all the results reported in this thesis and will link these results with the hypotheses listed in Chapter 9 to determine whether they were proven to be true or false. This will be followed by a broader discussion of the results of the study as a whole and how they link with each other. The strengths and weaknesses of all aspects of the study will be explored in detail and the study design and results will be put into context using comparable literature from the field of health services research. The implications of this study will be discussed and conclusions will be drawn from the results of this study on whether the MES project had a favourable impact on the modernisation of NHS endoscopy services. The thesis ends by drawing conclusions based on the results reported and making recommendations on how to improve NHS endoscopy services, how to improve the MES project for future use, how to improve this study design for application to the evaluation of NHS services in general and how future research might be conducted to further investigate some of the findings reported by this study.

14.1 Summary of results

This thesis independently evaluated the MES project by analysing and comparing the endoscopy services of 10 MES sites and 10 non-MES sites. All 20 sites were examined individually and grouped according to Site type using routinely collected, service-related data pertaining to eight calendar months ranging from Jan 2003 to Apr 2006. This thesis reported the following 11 findings:

1. *Service-related endoscopy data was not routinely collected by most of the NHS endoscopy units in this study.*

The design of this study was based on the assumption that most endoscopy units collected basic service-related endoscopy data on a routine basis, especially the MES sites. This assumption was based on discussions with all study sites as part of the ENIGMA study. However, only eight endoscopy units submitted any routinely collected data for this study. Only one had collected all of

the five outcome measures requested but data only corresponded to one month out of the eight requested. Consequently, Trust-held data was requested as a second source of data to fill in the gaps or else no analyses would have been possible. It was thought that as the Trust data was used by those endoscopy units who did not routinely collect their own service-related data, it would be feasible to use it as a supplementary source of data for this study.

2. *HES data did not hold completely accurate Activity data for all study sites to use for validation purposes.*

HES data was used to validate the data analysed in this study. Data for two sites were grossly underestimated in the HES dataset. The reason for this was the HES datasets did not include endoscopies as daycases for the time periods requested. Instead, they were classified as outpatient procedures and as such, they were not included in the HES dataset as it was not a compulsory field at that time. As a consequence, the data from these two sites was excluded from the validation process.

Comparing the six remaining sites revealed no significant differences between their HES data and Study data when data were combined, or when split by either Site type or Time. However, when split according to procedure type, there was a significant difference between HES data and Study data for FS, specifically for the data from Non-MES sites. However, the actual FS figures were relatively small, which may have affected this analysis. Based on these findings, it was possible to state that the data collected and analysed for this study were likely to be accurate and all results could be reported with a high degree of confidence.

3. *Data trends were highly variable over time in individual sites and to a lesser extent in the MES and Non-MES groups.*

EDA showed that the data from some sites showed large variations over time, irrespective of whether they were MES or Non-MES sites. The same was true when the MES group and Non-MES group datasets were examined in the same way, although the variation was to a lesser degree than for the individual sites. To adjust for this, all datasets were aggregated according to corresponding years to produce a mean value for that time period and this mean value would be used in subsequent analyses as a more reliable measure of service-related data.

4. *Some outcome measures showed significant correlation within the MES and non-MES groups.*

For the MES group, there was strong positive correlation between *Referral numbers* and *Activity* that grew in strength over time, indicating a successful and sustained response to any increased demand by increasing *Activity*. *Lost slots* and *Activity* also showed strong positive correlation, although the strength of the relationship decreased slightly over time, indicating that either the sites increased their *Activity* in response to an increasing *Lost slots* rate, or an increase in *Activity* may have increased the incidence of *Lost slots* proportionally.

For the Non-MES group, *Referral numbers* and *Lost slots* data for 2004 showed strong negative correlation, indicating that for that point in time, these sites appeared to have successfully reduced their *Lost slots* whilst also coping with increasing *Referral numbers*. Data for 2003 and 2005/06 were not significant, indicating that this change in services was not originally in place and was also not successfully maintained. There was a strong positive correlation between *Referral numbers* and *Activity* for 2004 and 2005/06, indicating that after a slow start the Non-MES group were also able to match *Referral numbers* with *Activity*. *Lost slots* and *Activity* showed a strong negative correlation for 2004, whereby increased *Lost slots* were significantly associated with decreased *Activity*. This may be explained by the fact that *Activity* is counted as the number of completed procedures and as the number of *Lost slots* increases, the number of procedures completed decreases proportionally.

5. ***There were no significant differences in total procedures data over time for any of the five outcome measures within either the MES group or the Non-MES group.***

This study found that although changes did occur in the *total procedures* data for *Referral numbers, Wait >3m, Snapshot, Lost slots* or *Activity*, they did not result in a significant difference in the data over time within the MES group or the Non-MES group when data were aggregated according to year. This indicated that whilst endoscopy services may have changed, and in many cases improved, the degree of change over time was not statistically significant.

6. ***When data was split by procedure type, the only significant difference in outcome measures over time was in UGE Referral numbers and Activity.***

When the data was split according to procedure type and reanalysed, the only significant within-group differences in data over time were for UGE *Referral numbers* and *Activity*, indicating that these data changed significantly over the three time periods analysed within the MES and Non-MES groups. Post hoc analysis revealed that the significant differences were between the UGE

Referral numbers data for 2003 and 2004 for the Non-MES group only and between the UGE *Activity* data for 2004 and 2005/06 for the MES group only.

7. ***There were no significant differences between the MES group and the Non-MES group for any of the five outcome measures using either total procedures data or split procedures data.***

This study found that changes to service-related data had occurred in both MES and Non-MES groups, but there was no significant difference in their *Referral numbers, Wait >3m, Snapshot, Lost slots* or *Activity* at any point in time when using either *total procedures* data or *split procedures* data aggregated according to year. This indicated that the MES group's involvement in the MES project had not resulted in any changes in the service that were significantly different to any changes occurring in the Non-MES group who had redesigned their services independently.

8. ***The only significant interaction effects were for Activity using total procedures data and for FS Snapshot data.***

There was a significant interaction effect for the *Activity* dataset, indicating that there was a significant difference in the degree and direction of the *Activity* data over time in the MES group when compared with that of the Non-MES group. Closer examination of the data showed that the decrease in *Activity* in the MES group over time was mirrored by an increase in the Non-MES group.

There was also a significant interaction effect associated with FS *Snapshot* data, indicating that there was a significant difference in the changes in the *Snapshot* data over time between the MES and Non-MES groups. Closer examination of the data showed that the FS *Snapshot* decreased in the MES group over time whilst it increased in the Non-MES group over time. No other statistically significant effects were observed.

9. ***There was no significant difference in the number of innovations implemented by MES sites and the Non-MES sites.***

When each site was asked to complete a questionnaire asking which innovations had been implemented, the results indicated that there was no statistically significant different in the number of innovations implemented by MES sites and Non-MES sites.

10. *Different types of innovations had been implemented by the MES group compared with the Non-MES group.*

All nine MES sites had implemented the following: a six week notice period for leave policy, partial booking, demand and capacity studies and audits, whilst all 10 Non-MES sites had implemented the following: additional consultants, audits, patient surveys, home bowel preparations, endoscopy groups / staff meetings and new medical equipment.

14.2 Linking the results to the research hypotheses

Based on these results, the author was able to address the research hypotheses listed in Chapter 9 as follows:

Hypothesis 1 - The MES sites would have a better system of routine data collection implemented than the Non-MES sites.

The availability of routinely collected, service-related endoscopy unit data was poorer from MES sites than from Non-MES sites, with only three MES sites submitting at least one item of routinely collected data compared with five Non-MES sites. This meant that it was not possible to accept the research hypothesis that the MES sites were better at routinely collecting data. However, it was also not appropriate to accept the null hypothesis that there was no difference in the data collection practices of these sites because there clearly was. Instead, an alternative research hypothesis stating that Non-MES sites were better at routinely collecting service-related data was formed and accepted.

Hypothesis 2 - The MES project significantly improved various aspects of the endoscopy services of the MES sites.

The data submitted from the MES sites indicated that there was no statistically significant improvement in any aspects of their services over time and so, rather than accepting the research hypothesis, the null hypothesis that stated that there was no significant change in endoscopy services over time was accepted instead.

Hypothesis 3 - The Non-MES sites would not have significantly improved their services, although some changes would be inevitable due to the natural evolution of their services and their notification to the NHSMA of their intention to redesign independently.

The data submitted from the Non-MES sites indicated that whilst some aspects of their services improved over time, the improvement was not statistically significant and so, the research hypothesis was accepted.

Hypothesis 4 - There would be a significant difference in the endoscopy services of the MES group and Non-MES group.

Based on the data received from the MES and Non-MES groups, there were no significant differences between MES and Non-MES groups for any of the five outcome measures at any point in time. Consequently, the null hypothesis that stated that there was no significant difference in the services of MES and Non-MES sites was accepted.

Hypothesis 5 - The MES sites would have introduced more innovations during the study period than the Non-MES sites.

This study found that there was no significant difference in the number of innovations introduced by the MES and Non-MES group and so, the research hypothesis was rejected and the null hypothesis that stated no difference between the Site types was accepted.

14.3   Strengths of the study

This study had a number of strengths that can be attributed to the author's study design that will be discussed in this section. The strengths arising as a consequence of being affiliated with the ENIGMA study are also discussed.

14.3.1 The originality of the study

One of the main strengths of this study was its originality. To date, no other study has attempted to collect and analyse routinely collected, service-related NHS endoscopy data to independently evaluate the impact of any modernisation project initiated by a high-level organisation such as the NHSMA under the direction of the local government. Literature searches performed to date were unable to retrieve any comparable studies. Whilst the ENIGMA study also evaluated the MES project, the aims and objectives differed as the primary focus of their evaluation was patient-centred using patient questionnaires and interviews, closely followed by the viewpoints of the health professionals involved with endoscopy services from primary and secondary care.

This study is also original in its innovative methods for the compilation of routinely collected, service-related endoscopy data from multiple hospitals and NHS Trusts. It is also unique in that it provides a caveat of the many pitfalls in the availability and analysability of this type of data not previously addressed in the literature until now (Thorne et al., 2008).

This study was also unique in its analysis of service-related endoscopy data. There were only a small number of published studies that analysed service-related endoscopy data. No studies had requested retrospective, routinely collected, service-related endoscopy data from more than one NHS endoscopy unit. Two studies were identified that used retrospectively collected endoscopy service-related data from individual NHS hospitals using data that was compiled deliberately for those studies and not routinely collected (Mulcahy et al., 2001, National Confidential Enquiry into Patient Outcome and Death, 2004). Other studies using endoscopy service-related data collected it prospectively using a specific format (Elwyn et al., 2007, Davies et al., 2007).

14.3.2 The design of the study

This study was designed with strict exclusion criteria applied to the routinely collected, service-related datasets from all sites and sources to minimise potential methodological and outcome biases and confounding to increase the internal validity of the study, which would have impacted on the results of the evaluation. The design of the study aimed to maximise its generalisability – the degree to which the results of the study hold true for situations other than those pertaining to the study (external validity). The outcome measures were datasets that are commonly available to NHS endoscopy units on request from the Trust or as a result of their own data collection regimes.

This study used a similar method of demand and capacity analysis to identify trends in outcome measures for each study site as the MES Toolkit. This was done firstly to substantiate or disprove the original findings by the MES project final reports for the MES sites and secondly, to determine whether this type of data collection was suitable for all NHS endoscopy units based on the service-related endoscopy data provided by Non-MES sites for this study.

The outcome measures requested covered most aspects of NHS endoscopy services and their potential problems, including high numbers of *Referral numbers*, *N° patients waiting* and *Lost slots* together with low *Activity*. The need for a *Capacity* measure was also identified early on in the design phase but the measure was not routinely collected by endoscopy units. It was specified

that all data were further split according to procedure type to ensure any changes in service delivery that were specific to a particular endoscopy type (e.g. increased demand for colonoscopy) were identified and not hidden within the *total procedures* data.

Whilst it is entirely possible that someone in each unit held data that were not submitted to this study due to our external presence, time pressures, workload, etc. Every effort was made to obtain data from these units and the author was confident that all potential avenues of routinely collected, service-related data were explored.

The validation technique used to compare the study data with an equivalent HES dataset allowed some degree of confidence in the use of the data in these analyses. It meant that the study could not be overly criticised for the decision to use two data sources when faced with the obstacle of no data for many sites.

Data were aggregated according to specific time periods (corresponding years) to increase sample numbers, to make the mean values more accurate and to make statistical testing more credible. EDA, correlation, independent samples t-tests and two-way ANOVAs were used appropriately to explore the relationships within and between the MES and Non-MES sites. All datasets were tabulated and graphically illustrated to better illustrate the trends over time within and between Site types.

The list of innovations was taken from the face to face interviews with 38 NHS endoscopy staff previously conducted by the author of this thesis and a qualitative researcher as part of the ENIGMA study. It was considered to be as comprehensive as possible to as to act as a memory aid for the person completing it. The Timeframes used were few in number to encourage its completion whilst the length of the Timeframes were extensive (one to two years) to allow sufficient accuracy in applying the correct Timeframe to the date the innovation was first implemented, given the retrospective nature of this data request and its reliance on temporal recall.

14.3.3 The affiliation with the ENIGMA study

The ENIGMA study randomly selected their MES and Non-MES sites from larger groups of 26 MES project sites and 27 Non-MES project sites. The selection by interval choice following ranking by bed number ensured that there was no selection bias for the choice of study sites. There was

no selection bias by the MES project in its selection of MES project sites as they claimed that each site had been selected by a panel based on the application form submitted. The selection of the Non-MES sites from which the sample was taken was based on those sites who had explicitly indicated their intention to modernise their services irrespective of their failure to participate in the MES project to ensure a true evaluation of the impact of the MES project on modernisation.

Some of the service-related data collected and analysed by this study came originally form the ENIGMA study. Whilst this study could have proceeded without the input of the ENIGMA data collection forms, its use did enhance this study.

The qualitative interviews conducted by the ENIGMA study led to the design of the Innovation form. It is possible that without the interviews to use as a guide for the list of innovations to act as a memory aid, the data for this part of the study may have been less accurate.

14.4 Weaknesses of the study

This study also had a number of weaknesses, some of which were attributable to the research design and some to external factors, but most of which were due to its operation within the boundaries of the ENIGMA study.

14.4.1 The design of the study

The primary objective of this study was to compare changes in *Referral numbers, Wait >3m, Snapshot, Lost slots* and *Activity* over time, based on the assumption that all endoscopy units would collect some or all of these data variables in a user-friendly format that could be used in this study. This was later proved to be untrue, with many sites unable to provide even the most basic level of service-related data (Thorne et al., 2008), possibly because they did not feel the need to collect it or because it was readily available from the Trust on request, or because they were unable to collect it due to the nature of their clinical information systems, since NHS databases were not built to help clinical research (Pilote and Tager, 2002), only to record and store patient details and notes.

Strict exclusion criteria may have ensured the highest degree of accuracy in the final dataset but also contributed to low sample numbers following the exclusion of incompatible or incomparable data from certain sites, which may have affected the group means for individual time points.

There were problems with missing data for specific time points in many sites, irrespective of data source. Data were often missing for the early time points in Non-MES sites because many sites had not initiated a data collection programme, whilst end point data were missing in many sites, irrespective of Site type due to a drop off in response rates. This was not surprising, since the endoscopy units and Trusts were providing data with no financial remuneration. This may have resulted in less than accurate means for the MES and Non-MES groups for early and late time points when compared to the middle time points where higher sample numbers provided a more realistic mean value for the group. The accuracy of the datasets were improved to a degree by aggregating them.

Another problem with data accuracy was the different terminology used between sites. An example of this was the classification of UGEs in endoscopy units, with some discriminating between OGDs and gastroscopies whilst others did not. This led to the amalgamation of all UGEs into one category.

Where some endoscopies were done as an outpatient procedure, it may have resulted in a difference in endoscopy service data from the Trust and the corresponding endoscopy unit. The Trust may have included outpatient endoscopies in their dataset because they were unable to determine the location of the procedure whereas the endoscopy unit would only count procedures within their own department. A few TIS contacts indicated that their data may have potentially included endoscopy procedures not done within the endoscopy unit and that the coding framework did not identify these procedures, artificially inflating the values provided.

Discussions with endoscopy staff prior to the data request meant that one outcome measure not available – *Capacity*. This would have incorporated a number of sub-variables: the number of endoscopy rooms, the number of slots per session, staff availability and equipment availability. It was made clear by the endoscopy staff that this variable was extremely difficult to collect prospectively and that a retrospective data request for *Capacity* was not likely to be of sufficient quality as to be useful in the evaluation.

212

The problem with the data collected by the Innovation Form was that it was collected retrospectively and was potentially exposed to recall bias by the individual completing it, both in terms of the innovation ticked and the Timeframe allocated. There was also the danger that the form was completed by more than one person where specialist knowledge was required, or if that person was not in post as far back as 2000. Every effort was made to convey the importance of the accurate completion of the Innovation Forms with innovations that had been introduced, irrespective of whether or not they worked, and when they were first implemented. Also, the updating of the forms for 2006 may have resulted in the inclusion of some planned but not yet implemented innovations. Fortunately, the low scoring of that category would mean that the impact of this effect should have been minimal. The potentially bias nature of this data meant that it did not feature too prominently in the analysis of services and was used primarily in a descriptive manner to identify those sites that were proactively modernising prior to the MES project, and to describe the most commonly introduced innovations in the MES and Non-MES groups.

14.4.2 The affiliation with the ENIGMA study

T0 (January 03) was used in this study as the baseline time from which all redesign programmes were implemented in the MES sites because it signified the true start of the MES project following the three month pilot whereby the sites had already analysed their services and had submitted redesign plans for approval by the NHSMA. However, the true baseline time point for an accurate evaluation should have begun in January 2002 to explore the data for any temporal trends prior to the MES project beginning so that "natural" cyclic changes in service delivery data would not be incorrectly attributed to the project. There was no way of controlling for any temporal trend bias within the remit of the ENIGMA study and there was not enough time or goodwill from study sites to collect enough pre-2003 data points to allow the exploration of any underlying seasonal or cyclical trends in data to allow a true estimate prior to the implementation of any modernisation agenda.

A true baseline data time point for the Non-MES sites was impossible because there was no defined period of modernisation – each would have begun their redesign programmes at different time points. It was also difficult to define periods of modernisation in many Non-MES sites, since all were operating independently of any common project target. They tended to introduce small changes sporadically as opposed to planning a modernisation programme for implementation during a given time period, making estimates of dates problematic.

These two problems with "baseline" effects would inevitably impact on the comparison of the MES and Non-MES groups overall, given that they may not experience the same secular trends or sudden changes due to the implementation of innovations. Also, the rate of progress of the Non-MES sites would have varied according to the type of redesign planned, resources available and staff involved.

This study was restricted to just eight time points for data collection so the initiation of a redesign programme may have fallen immediately after one of the time periods of data collection for this study. This would leave a number of months before the next period of data collection for any changes in the delivery of their services to be identified. The time intervals between datasets should have been greatly reduced. Ideally, monthly datasets should have been requested from each site to allow a more detailed analysis of the data over time using time series analysis. Unfortunately, the data request for this study was not a feature of the ENIGMA study when they agreed to participate and so, this could not feasibly be done without the risk of sites withdrawing.

The intervals separating the eight time periods actually used were not equally spaced and ideally would have been six months apart. The ENIGMA study specified their preference for the collection of any service-related endoscopy data to correlate with the same time periods as their patient QoL scores, a request which this author was obliged to adhere to – hence the choice of T3 to T7 time periods.

The 2003 time periods for the data collected (T0, T1 and T2) were selected to signify the start, middle and end of the MES project. There was a possibility that T2 data were affected by the seasonal variation common with Christmas period. However, a recent study by Auslander *et al* concluded that endoscopic procedures and diagnoses were not affected by seasonal variation (Auslander et al., 2006).

This study was obliged to use the same 20 study sites as were used in the ENIGMA study. Consequently, there may have been a degree of "size effect" from the endoscopy units participating in the study, since some Trusts had only one endoscopy unit and these would handle larger volumes of patients than those Trusts with two or more endoscopy units at various locations. This would have affected the group means for each outcome measure. However, since the ENIGMA study recruited a random selection of sites based on bed number from both the 26 MES

and 27 Non-MES sites, we would expect a similar proportion of these sites to be in each group so their size should not have affected the overall study results.

Since the ENIGMA study was partially funded by the NHSMA and had the MES project lead on its PSG there was, in theory, a possibility of funding bias that may have influenced not only the ENIGMA study but also this study. However, during the course of the ENIGMA study, the MES project lead did not contribute to the design or analysis plan of this study, or the ENIGMA study. As such, this study was untouched by the possibility of funding bias.

Finally, the study was unable to determine the extent to which the modernisation of endoscopy services in each site would have taken place as a result of the natural evolution of the service with no NHSMA interaction because there were no suitable control sites enrolled into the ENIGMA study and it was beyond the remit of this study to include any due to funding and time restrictions.

14.4.3 The impact of external factors

Other weaknesses of this study were due to external factors outside the control of both the author and the ENIGMA study and are discussed below in more detail.

Some study sites moved into new premises or units during the course of the study. This meant that modernisation programmes in these sites were deliberately temporarily suspended or in some cases not initiated until the relocation had taken place. It also meant that many sites had their operational capacity and activity dramatically altered and this may have affected the data from these sites. This study was unable to compensate for any potential impact this may have had.

Other important confounding factors were the introduction of external modernisation plans such as the NBAP and the TWR initiative, both of which were instigated to facilitate improvement within endoscopy services but not within the remit of the MES project. Initiatives such as these made it difficult to disentangle forced changes arising from external pressures from the "planned" modernisation of the MES project in the MES sites.

The introduction of the GRS (see Chapter 6) in Spring 2005 heralded a new drive to improve services following the completion of a web-based tool that asked endoscopy staff to voluntarily rate various aspects of their service on a twice yearly basis under two broad headings: Clinical quality

and Quality of patient experience. It is highly likely that, given the exceptional uptake of the GRS by NHS endoscopy units (according to the GRS website at www.grs.nhs.uk, 203 of 207 units in England completed the scale for Oct 2007), it has facilitated many changes in these endoscopy units that cannot be disentangled from the long-term impact of the MES project.

14.5 Discussion of results of the study as a whole

Based on the data collected and analysed for this study, the endoscopy services of the MES sites did not improve significantly over time. There could be any number of reasons for this, including a lack of ongoing, high quality data collection, a lack of ongoing external funding and support from the NHSMA, internal and external pressures to meet targets impacting on services and the introduction of unsustainable innovations. It is feasible that whilst the MES sites implemented numerous successful innovations during 2003 the evolution of the service following new politically-driven and locally-driven targets may have diluted the effect of past reforms under the MES project whilst also reducing the time and resources available to implement any further redesign plans. It is also possible that, given the strict nature and intensity of the MES project, many sites were experiencing "reform exhaustion" and felt unwilling to proceed with either the planning or the implementation of any further modernisation programmes once the MES project ended.

Another factor may have been the loss of the "change agent" in the MES sites after 2003. The MESPT stipulated that a change agent had to be designated to lead and facilitate the project and these people played a significant role in the management of modernisation during the MES project. However, during the course of the ENIGMA study it became apparent that many of these people had been reappointed to other departments within the Trust to act as modernisation managers based on their success with the MES project. For those who were originally endoscopy unit staff, the close of the project meant the end of their project management role and they quickly resumed their original duties, although they would do so with the experience of the project to bring to bear when necessary. This key fact brings to attention the fact that sustained leadership is equally as important as good leadership in any modernisation programme.

It was not so surprising that the Non-MES sites did not significantly improve their services, since they had no external support or funding during 2003 but were expected to address many of the same external and internal pressures that were imposed on the MES sites. Their intention to

modernise following their rejection from the MES project should have led to them implementing at least some minor improvements resulting in a small but statistically insignificant change to their services. However, the MES project may have acted as a catalyst in these sites, prompting them to think about modernising their services based on the original bid submitted to the NHSMA.

The lack of unmarked funding may have led to smaller changes to the service but should have caused Non-MES sites to think about implementing cost-neutral innovations. However, it would have taken a great deal of initiative from the people managing the modernisation programme in the Non-MES sites to locate and interpret the NHSMA literature to be applied to their own services. It was also clear from the ENIGMA study that there were more consultants than unit managers assuming a role equivalent of the change agent in the Non-MES sites and whilst they probably had a more explicit understanding of the way the service ran, they may not have had the time or project management skills to use the NHSMA literature to great effect.

It is plausible that the messages relayed to the MES sites from the MESPT may have been further disseminated between health professionals from MES and Non-MES sites at national gastroenterology-related events and conferences. Also, the literature published by the NHSMA was widely and freely available to all NHS endoscopy units, irrespective of whether they participated in the MES project or not. As a consequence, it was reasonable to anticipate that the Non-MES sites would have redesigned their service, but at a later date than the MES sites and possibly at a more fundamental level. However, the high 2000/02 innovation scores from many Non-MES sites indicated that the Non-MES sites secured their own resources for redesign plans prior to the MES project. This may go some way to explaining why this study was unable to report any significant differences in the service-related data from the MES and Non-MES groups.

It is of great importance to note that whilst this study has reported no statistically significant differences both within each Site type over time and between both Site types, that does not mean that the services did not make clinically significant improvements. It may be that, for example, a 5% increase in *Activity* over time is not statistically significant but to the endoscopy staff it could be clinically significant as it may mean an increase in throughput in their services and may also indirectly result in a reduction in waiting lists. However, since all MES and Non-MES sites would have had different service characteristics, it would have been inappropriate for this study to propose an ideal figure of what was considered to be a clinically significant improvement in each outcome measure against which to compare all study sites.

The lack of availability of data was a major problem for this study as it was designed on the basis of this data being available following discussions with ENIGMA contacts. Consequently, alternative data sources had to be sought to replace missing datasets if the study was to continue. The corresponding NHS Trusts held a wealth of information that were suitable, in principle, for this study, although they could have led to potential inaccuracies in the final dataset due to the additional and potentially incomparable sources of data. However, the alternative was to only analyse the endoscopy unit data which would not have produced any reliable results given the low sample numbers involved.

Whilst the use of Trust-held data was agreed for this study, these additional datasets were treated with caution. There have been a number of publications highlighting deficiencies in NHS Trust-based clinical information systems over the years (Whates et al., 1982, Gibson and Bridgman, 1998, Sherrard, 1999, Ballaro et al., 2000, Ola et al., 2001, Khwaja et al., 2002), although none refer to inaccuracies in gastroenterology-based datasets. Discussions were held with both the endoscopy unit contact and TIS contact to ensure the datasets received were suitable and accurate in terms of items requested and the format in which they were submitted.

It was likely that the waiting list data that were "routinely collected" by the endoscopy units and submitted as such to this study were actually data sent to them by their TIS department. This brings the issue of data ownership to the forefront. Whilst the NHSMA advocates the routine collection of service-related data for all NHS endoscopy units, it is usually the Trust that provides this dataset to most endoscopy units on a regular basis to ensure that they are meeting targets. It is possible that proactive endoscopy unit staff will create their own queries to interrogate their clinical information systems regarding waiting lists but this was not considered to be routine practice for most sites.

When the data were plotted as part of an EDA exercise, the high degree of variability of the data for many of the outcome measures within and between sites over time gave cause for concern. This may have been attributable to the different data sources used in this study. To assure the accuracy of the datasets received, they were compared with a nationally-held dataset from HES. The validation process found that the datasets used in the analyses were comparable with the equivalent HES datasets in most cases and therefore, could be analysed with confidence.

This study has shown that when using routinely collected endoscopy service-related data it is important to validate it against a comparable dataset. In the case of *Activity* data, the HES dataset was the most suitable. However, there are a number of publications that warn about the accuracy of HES data (Williams and Mann, 2002, Croft and Williams, 2005). The discrepancies commonly originate from coding errors by NHS Trusts (Ballaro et al., 2000, Khwaja et al., 2002). The validation process highlighted deficiencies in the HES dataset in terms of the reporting of endoscopies as either day cases or outpatient procedures during those time periods. HES needed to issue stricter guidelines regarding the completion of their data requests by Trusts to ensure they all used the same terminology, as defined by national guidelines and to ensure that they were not manipulated in any way by the Trust in a bid to secure more funding via the PbR scheme, or to meet national waiting list targets. HES now provide the opportunity to complete their datasets with this level of detail, but in the past it was not compulsory and since not all sites had been forthcoming with the appropriate data in the past, retrospective analyses over a long period of time could be problematic.

Given the potential for inaccurate data from both HES and the Trust, it is advisable that future health services research should attempt to use routinely collected data directly from the relevant NHS departments as they are more likely to hold the most accurate dataset. However, this brings problems in itself if the specialty being studied does not routinely collect any service-related data. There is also the problem of making routine datasets comparable when more than one site is being studied as their terminology can differ. If these obstacles can be overcome by first ensuring that relevant data is available retrospectively and secondly, that each dataset can be retrieved using a rigorous set of definitions to ensure accurate comparability, then the quantitative analyses should be based on data of the highest possible quality.

One major point of concern was the lack of uptake of the MES Toolkit after the MES project had ended. The routinely collected datasets did not feature this data collection software tool for any of the MES sites during 2004 or 2005/06 and none of the nine MES sites in the ENIGMA study had opted to continue using it after the MES project ended, although most commented that they would take on board the message of high quality data collection and create their own versions of the MES Toolkit which they would operate internally. However, based on the availability of data illustrated by this study it would seem that their intentions were not followed through to fruition.

One MES site's Innovation Form claimed to have collected routine data but this was not reflected by this study. However, closer examination of the raw data revealed an even more complex picture, with many sites who provided routinely collected data for this study not indicating so on their Innovation Forms, whilst other sites claimed that they did routine data collection when this study indicated otherwise.

By matching the data collected for different sections of this study, the data collection practices of most sites could be compared using the Innovation Forms (see Chapter 13) and the actual availability of data (see Chapter 10). Five MES sites (4, 7, 11, 13 and 19) and nine Non-MES sites (2, 3, 5, 10, 12, 14, 15, 17 and 20) had ticked the box on the Innovation Form indicating that they had "new / improved in-house data collection" and of those five MES sites claiming to collect in-house data, at least one source of data had been secured from all five prior to exclusion criteria being applied. However, of the nine Non-MES sites who claimed to collect data, data had only been secured from five sites (2, 5, 10, 12 and 17), although one additional site had commented on the existence of data but not submitted it to this study due to time constraints (15). This brings into question the validity of the Innovation Forms as a good source of evidence in this study. It is interesting that the difference in the data collection habits of the MES and Non-MES sites reported in Chapter 10 are also reflected here, with nine Non-MES sites reporting the initiation of in-house data collection compared with only five MES sites.

The validity of the information on the Innovation Forms was also identified as inaccurate when examining the number of MES sites acknowledging the NHSMA's role in the "help or advice from external agencies" row. Only four of the MES sites (4, 7, 13 and 19) had ticked that box. It brings into question whether the forms were given the due care and attention desired by the study when thinking about each innovation listed. It is also possible that the forms were completed by someone who was not in post in 2003 and was unaware of the MES project.

One issue arising from this study was the fact that the evaluation in the Non-MES sites was not likely to be typical of the natural evolution of endoscopy services over time, given that they were motivated to modernise. Both this study and the ENIGMA study were only able to ascertain the impact of the MES project on those sites who applied to participate, some of which were successful and others were not. A comparison of the MES sites with the Non-MES sites does not address how sites would have modernised their services completely independently of the MES project. This third group of sites could have provided a real insight into the benefits of the MES project by

acting as a Control group to illustrate the natural evolution of the service without NHSMA interference.

The design of this study using retrospective, routinely collected data meant that it was not possible to define modernisation as introducing innovative ways of working, since there was no way for the data being analysed to disentangle and identify such effects. Instead, the study defined modernisation as the introduction of a change to the service with a view to improving it. This meant that the study captured the impact of both innovative changes and those changes that were basically doing more of the same and as such, not truly innovative changes. In the same respect, it was also impossible to decipher those changes implemented as a result of the MES project (in the MES sites only) and those implemented as a consequence of other government-instigated redesign initiatives such as booking and waiting list initiatives, the introduction of DTCs and the TWR to name a few. Therefore, any conclusions drawn from this study had to be mindful of the potential confounding effects discussed here.

Whilst all five measures used were considered to be good measures of service efficiency and were also used by the MES Toolkit, it is entirely feasible that they were not the optimum outcome measures for performing an evaluation of the MES project. There was no capacity measure against which to measure the ability of a unit to increase their activity and reduce their waiting lists by exploring staff, room and equipment availability. This additional outcome measure would have allowed a more complex examination of the services of each site and allowed a level of predictability that would have allowed sites to forward plan their service usage to optimum effect and would have allowed this study to explore the more complex relationships between supply and demand for NHS endoscopy services over time. Unfortunately, capacity variables are not routinely collected by either endoscopy unit staff or the Trust in any analysable format. This issue needs to be addressed for a more complete service overview.

14.6 Results in context

Following the discussion of the results reported in this study, it was necessary to place them into context by comparing them with similar research. Since this study was completely original in both its research question and design, there was no truly comparable peer-reviewed literature against which to compare this study. Therefore, this discussion will focus on comparing the results with (1)

221

non-peer reviewed evaluations of the MES project and (2) the independent evaluation of other NHSMA-led modernisation programmes.

14.6.1 The evaluation of the MES project

This study is completely original in its evaluation of NHS endoscopy services using service-related endoscopy data and comparing sites who had participated in the MES project with those who had indicated their intention to modernise independently. Since the final report of the ENIGMA study had not been completed at the time of this thesis being submitted, the only literature available that can be closely compared with this study would be the NHSMA's final report of the MES project (NHS Modernisation Agency, 2004e). More specific details of the findings of the ENIGMA study are due to be published by the NIHR SDO in summer 2008.

The MESPT final report described improvements in the services of the MES sites participating in the project with regards their planned and active waiting lists, their DNA rates, the introduction of booking systems, patient-led changes, new ways of working and self assessment. Each of these were illustrated with a selection of case studies reported by the sites themselves. However, independent statistical analyses by this study using routinely collected, service-related data showed no significant improvement in any aspects of service delivery over time in 10 of the MES sites in the MES project. On the other hand, when compared to the Non-MES group, the MES group data were significantly lower than that of the Non-MES group for *Snapshot* data following the MES project close, and for *Activity* data at the earlier stages of the evaluation. There may be a number of reasons for the different findings reported by the MESPT and this study, each of which are discussed below:

- The MES project had different datasets for their analyses. Whilst this study opted to analyse retrospective, routinely collected data from both NHS endoscopy units and the corresponding Trusts, the MESPT used the prospectively completed, high quality MES Toolkit data and reports completed by endoscopy staff.
- The MESPT analyses were based on data collected on a monthly basis from January to December 2003, whereas this study analysed data collected at approximately six monthly intervals from January 2003 to April 2006, a substantially longer period of time with longer intervals between datasets, and aggregated them according to year for analysis.

- This MES report had 26 sites on which to base their findings and highlight examples of good practice whereas this study looked at a random selection of 10 of those 26 MES sites grouped into one MES group.

- The improvement in services was based on clinically significant targets allocated by the MESPT whereas this study evaluated endoscopy services according to whether the data changed over time to a point where it became statistically significant.

Based on these facts, it was felt that whilst the content of MESPT report on the second wave of the MES project was correct based on the analysis of their data, it only corresponded to a relatively small window in NHS endoscopy services modernisation during 2003. There was no follow-up report by the MESPT to fully explore the impact of the project in the 26 MES sites following its close. As a result, the MES report could be considered misleading as it failed to ascertain the sustainability of the innovations that the project had helped to introduce and it did not make any comparisons with sites who did not participate in the MES project. It was also biased in its reporting of the impact of the MES project, only illustrating examples of success and good practice.

14.6.2 The independent evaluation of NHSMA-directed modernisation projects

Other NHSMA modernisation projects have been implemented in the last decade, many of which have been independently evaluated. This section will discuss how well the findings of this study compare with the results of those other evaluations.

The independent evaluation of the NBAP by the Health Services Management Centre at Birmingham University reported that these systems can be implemented in the NHS and that there had been real progress in day case bookings, with reductions in the number of patients with no appointment date as well as the number who fail to attend appointments. Inpatient and primary care booking systems were under development. The 24 pilot sites in the study showed increased access and convenience for patients when compared to Trusts not participating in the pilot (Kipping et al., 2000).

The independent evaluation of the CSC was commissioned by the DH and was based on patient flow (time from referral to treatment) and access to services (Robert et al., 2003). The only GI cancer service included in the evaluation was for CRCs. Whilst the study was mixed methods, using qualitative interviews to arrive at many of its conclusions, it also had a substantial

quantitative element using patient-level data on booking and waiting times to be completed retrospectively by the hospital on data collection forms. However, there were clear indications in the report that even this level of data was not readily available for a large proportion of projects examined and subsequent analyses were restricted to those sites able to provide the appropriate datasets. They reported that 29% of CRC patients had been affected by the CSC programme and that in three individual colorectal projects there was a decrease in the median waiting times from 64.5 days to 57 days, a non-significant reduction of 11.6%. They also reported the implementation of full booking in seven of 11 sites. The study concluded that the CSC was a success in the view of the participants themselves but it also acknowledged that it was the beginning of a much longer term process.

The NHSMA commissioned an independent evaluation of the CSC-IP using an appreciative inquiry method (Reed and Turner, 2005). The study used this organisational development technique to explore the skills and strategies employed by CSC staff to facilitate development. The study reported many interesting findings: traditional line management strategies did not work due to the CSC's structure; resistance to the messages of the CSC were resisted at the outset, but decreased over time; CSC staff had to function as both "coaches" and "ambassadors"; people had to be "encouraged" to learn from any information presented and finally, perseverance and consistency were essential attributes for CSC staff. Unfortunately, no evaluation of the effectiveness of the CSC was reported by this study.

14.7 Implications of the findings of this study

14.7.1 Implications for the NHSMA

Unfortunately, the NHSMA disbanded in March 2005, making this evaluation of the MES project less applicable to today's NHS endoscopy services. However, there are still numerous important messages that have been derived from this evaluation in terms of NHS modernisation strategies and the importance of sustaining improvements in endoscopy units. It found that the MES project did not significantly improve service delivery in MES sites above and beyond what could have been achieved independently of the MES project with only the intention to redesign. This finding should, in theory, have had a major impact on the NHSMA had they still been in operation today. This study presents evidence to challenge to the value of the NHSMA's approach to modernising NHS services and should have forced a major reappraisal of their modernisation strategies. More

specifically, it should have led to a major change in the way they introduced compulsory, stringent data collection regimes.

Expanding of the issue of poor data collection, this study found that none of the MES sites continued to use the MES Toolkit following the close of the MES project. The data collection aspect was a significant portion of the redesign message advocated by the MESPT that allowed sites to evaluate their services pre- and post-redesign, but that message did not have the intended impact on MES sites. There is a clear message here for all externally-led modernisation agendas – no matter how good the concept, there is no guarantee that it will remain in use once it becomes voluntary. This means that future modernisation programmes will need to consider not only how they encourage NHS services to redesign and improve their services, but how they will sustain the importance of the key messages and the prolonged use of any ideas or tools after the projects close. It is vital that they recognise many external and internal pressures placed on NHS staff and that they are taken into account when designing and implementing data collection practices if they are to be sustained long-term. In the case of the MES Toolkit, its complexity and rigorousness actually added to the workload of the endoscopy staff and so, was never likely to be sustained long term for that reason. New modernisation concepts need to be time- or resource-savers, adapted for more practical use and easily embeddable into everyday use in the service so that it takes more effort to withdraw it from use than to keep it in use. Without the promise of sustainability, every modernisation agenda is set to fail before it has begun.

14.7.1 Implications for NHS endoscopy units

This study provides an invaluable resource for NHS endoscopy staff wishing to modernise their services as it gives clear messages on the necessity for routine data collection practices to be instigated and maintained if services are to be measured, monitored and evaluated over time. It also provides a comprehensive list of innovations implemented by NHS endoscopy units to use for ideas on how to change a process, many of which were cost-neutral and only involved a change of working practices.

The lack of routinely collected, service-related data from this selection of 20 NHS endoscopy units highlighted the inadequacies in the NHS as a whole to proactively evaluate and manage services from within those departments. This is because the NHS as a whole is not rigorously managed by data. There are numerous audits and improvement projects that occur within the NHS but they are

sporadic and isolated. The NHS needs to adopt an ethos of data collection and analysis throughout the organisation, across primary, secondary and tertiary care boundaries for the whole of the UK if it hopes to make and sustain any improvements in its delivery of care to patients. Staff should be trained in the importance of data collection and analysis in its application to improve service delivery and patient satisfaction to motivate them to accept a data collection regime as part of their daily tasks. This issue cannot be overstated as it is one of the keys to initiating change in the NHS. This would take time, investment, training and better IT provision but the end result should be a vastly improved service which would probably cost less to run in the longer term.

Perhaps the government should consider taking a business-like approach to improving NHS services and place greater importance on the findings of data analyses when introducing new policies and targets. They also need to realise that setting NHS targets does not facilitate data collection - it only encourages the manipulation of data to best meet the needs of the department.

It is feasible that the compulsory collection and analysis of rudimentary service-related data such as demand, activity and capacity would lead to an improvement in NHS endoscopy services, and maybe NHS services as a whole, as they are forced to collate the data and use it to measure their services themselves instead of waiting for a third party to highlight bottlenecks and problematic areas. This would allow NHS services to be proactive in process monitoring and would provide a good evidence base for building business plans for funding improvements. It is clear from this study that even the most basic datasets are of high enough quality to perform rudimentary data analysis – staff only need to be taught how to perform and interpret it effectively to examine their services.

14.7.3 Implications for external researchers

Finally, this study provides two warnings for external researchers intending to use routinely collected, service-related endoscopy data to analyse NHS endoscopy services. The first relates to the availability of this type of data, since not all endoscopy units collect service-related data routinely and even when they do, it is not necessarily easy to compare them as different definitions may be used nationwide. Prospective data collection may be more advisable to improve availability and accuracy but prevents any historical analyses. Alternatively, the clinical information system could be interrogated by endoscopy staff, probably at a cost.

The second warning relates to the reliability of older HES *Activity* datasets, which were shown in this study to be flawed in two sites due to the terminology applied to their endoscopies by the Trust, with both classifying them as outpatient procedures which were not recorded in their returns to HES for the time periods used in this study.

The findings of this study highlighted the importance of independent evaluations to provide clear, unbiased conclusions using a high quality study designs and sound research experience. It placed the impact of the MES project in a more realistic light by describing the services of the MES sites *in vivo* using unbiased data that were analysed using the appropriate statistical tests. This thesis fully illustrated different aspects of service delivery relating to all 20 study sites where available for any interested parties to examine the data trends over time to make their own decisions about whether these sites were truly successful in clinical terms, as well as in statistical terms.

This study also brought into the research setting a group of sites that had not participated in the MES project to evaluate their attempts at service redesign over the same time period and in doing so, provided a more realistic picture of what was achieved by the MES project and what was achieved independently. In doing this, it was able to give a clear message that even though some endoscopy units were not part of the MES project they still made clear improvements to their services over time, a message that may serve to sufficiently motivate endoscopy staff to improve their services.

14.8 Conclusions

With NHS endoscopy services facing their biggest challenge yet with increasing demand from new referral guidelines and cancer screening programmes, it is vital that the true impact of modernisation be reported so that any important findings can be used as a building block with which to further improve services. With this in mind it was crucial that the MES project was independently evaluated to determine whether it provided any significant advantage to those participating sites over and above what could have been achieved with only the intention to modernise. This study has reported a number of findings that can be drawn together to formulate the final conclusions regarding the impact of the MES project on NHS endoscopy services.

1. **Endoscopy data is not routinely collected and analysed by endoscopy unit staff.**

There was a noticeable lack of service-related endoscopy data being routinely collected by the NHS endoscopy units in this study since 2003. This could be because firstly, it is not compulsory for endoscopy units to collect service-related data and secondly, many units did not see the benefits of collecting the data for analysing their services. Participation in the MES project did not encourage the MES sites in this study to maintain a high standard of data collection. In fact, the Non-MES sites appeared to be more willing to routinely collect data. Fortunately, data were widely available for this study from TIS contacts but there were instances where their accuracy was questionable and was later excluded.

2. **The MES project did not have a significant impact on the endoscopy services of MES sites.**

The results of this study indicate that whilst the MES project may have improved the endoscopy services of the MES sites in this study, it did not do so in sufficient quantities as to produce a statistically significant difference in *Referral numbers*, the *Number of patients waiting more than three months*, the *Total number of patients waiting*, the *Number of lost appointment slots* or *Activity* over time. Equally, the endoscopy services of the Non-MES sites in this study also improved, although it was not sufficient to produce a statistically significant difference in data over time. However, they improved their services to a point where some areas of improvement seemed to be on a par with those seen in the MES sites, resulting in no significant difference between MES and Non-MES groups for any outcome measure. There was also no significant difference in the number of innovations introduced by MES and Non-MES sites between 2000 and 2006. This implied that the MES project did not significantly improve the endoscopy services of MES sites over and above what could have been achieved independently, so long as the intention to modernise was present.

3. **HES Activity data were not accurate for all sites.**

When using HES to validate the use of two data sources in the study datasets used in the analyses reported in this thesis, it was proven to be incorrect in two sites due to imprecision from the Trusts in their reporting of endoscopies as outpatient procedures as opposed to day cases. This resulted in the HES datasets grossly underestimating the *Activity* in those two sites.

14.9 Recommendations

Based on the conclusions of this thesis, the following recommendations are being made:

1. **The compulsory collection and analysis of rudimentary service-related data in all NHS endoscopy units.**

Based on the data availability reported by this study (Thorne et al., 2008), the first recommendation would be for all NHS endoscopy units to record basic demand, capacity and activity data themselves and to avoid relying on the Trust to provide them with information. The routine data provided by endoscopy units for this study was not complicated or deemed difficult to collect by those submitting it and it was considered to be of utmost importance by those sites for the unit to run efficiently and effectively, and to implement a strategic modernisation plan with targets identified by the data.

This study showed that basic demand and activity data can be used to effectively plot and analyse services over time to allow NHS endoscopy staff to monitor their services, identify problems and evaluate the impact of modernisation. Where possible, capacity data should be collected and analysed. All data should be split according to procedure type to identify any anomalies obscured by aggregating the data into a "total procedures" dataset. It would also be invaluable if the data variables collected could be further split into their constituent data types. For example, the number of lost appointment slots should be split according to the reasons for these lost slots, including patient DNAs, patient cancellations and hospital cancellations to get a clearer picture of where the problems lie and how effectively they are being managed.

Further to this, the compulsory training of selected NHS endoscopy staff in the accurate collection and analysis of service-related data is also essential to help them better understand the beneficial applications of high quality data and to ensure that they use it properly to analyse the service and evaluate changes to the service over time.

These recommendations can also be extended to all NHS services, not just endoscopy. The fundamental principles of the importance of data collection and analysis to monitor processes are well used in all successful businesses, but not by the NHS. Perhaps it is time for NHS management to shift their attention towards implementing a culture of process evaluation within each NHS department and to make more use of the data sent to HES internally.

2. **The standardisation of data collection processes in Trusts using a proforma.**

The TIS data used in this study differed in their structure and content. Whilst most were kept in Excel files, some kept patient-level data whilst others logged daily or weekly counts. The

definitions and abbreviations used between Trusts differed, making it difficult to make a quick visual comparison of datasets. Data received were often riddled with abbreviations that were often unique to that site and were not explained until they were discussed with the TIS contact. All data had to be "translated" into a common phraseology to make them comparable. In some cases the data had to be excluded due to comparability issues.

A few Trust contacts indicated that their data may have potentially included endoscopy procedures not done within the endoscopy unit and that their coding framework did not identify these procedures, artificially inflating the values provided. The reclassification and standardisation of endoscopy coding practices for all Trusts as part of the standardisation of data collection processes would be ideal so that all types of endoscopy in all locations, not just the endoscopy unit could be identified. It is also important that any changes to coding are traceable so that any retrospective analysis of data over time would be feasible.

A nationwide proforma for all NHS Trusts would rectify the geographic inconsistencies within data, accompanied by strict instructions for its correct use with no possibility of misinterpretation of the quality or quantity of data variables needed. It would require regular updating and ideally, would be accessible to external parties to facilitate research studies, both NHS-based and externally-based, thereby supporting the quality of evidence available on which to base any clinical decisions.

3. Changes to NHS modernisation programmes.

Since the MES Toolkit was considered by most MES sites to be extremely complicated to complete, both in terms of data collection and input, a more basic data collection tool should be developed for distribution to all NHS endoscopy units to facilitate service modernisation. The tool would require less rigorous data collection and all data would be in counts instead of timings, a far easier measurement to collect. This would also facilitate the collection of data in one format from all sites if used as a proforma, as recommended earlier.

It is also advisable to abandon any financial remuneration as it appears from this study that it does not provide any direct improvement in service delivery. The Non-MES sites were able to improve their services in line with the MES sites and they did so without the £30,000 provided by the NHSMA. By removing funding, a modernisation programme will indirectly promote the need to make changes to the service sustainable long-term.

14.10 An ideal study design

Given a dedicated budget, adequate resources and complete autonomy from any other study, any further evaluation of the modernisation of NHS endoscopy services (or indeed any NHS modernisation strategy) should include the following changes to the design used in this study:

- The selection of a wider range of study sites with a proven record of high quality service-related data collection by the corresponding endoscopy unit.

- The inclusion of a further two groups who had not applied to participate in the MES project to act as true control groups. One of these would have indicated their intention to modernise whilst the other would not have any intention of initiating redesign plans. In this way, we would be able to ascertain the impact of the natural evolution of the services over time due to external factors (e.g. government targets, cancer screening programmes) and internal impetus to improve services driven from within the unit by endoscopy staff. This would mean four study groups: 1) sites who successfully bid to participate in the MES project – the MES sites, 2) sites who were not successful in their MES project bid but who intended to modernise anyway – the Non-MES sites, 3) sites who did not bid to participate in the MES project but intended to modernise - the first Control group and 4) sites who did not bid to participate in the MES project and did not intend to modernise – the second Control group.

- The inclusion of a *Capacity* variable in the outcome measures would have greatly expanded the ability of this study to analyse data to ascertain whether units were operating at full capacity. It was a useful variable in the MES Toolkit and any future evaluations of NHS services should aim to capture and analyse it wherever possible.

- Monthly data collection intervals should be enforced to allow time series analysis within each site. This would give a better idea of short-term changes in data to allow the study to more easily identify the impact of any modernisation plans.
- Extending the time period of the study to a pre-baseline period would be ideal for the study to identify any underlying secular or temporal trends in the data prior to the study phase.

These can be controlled for during the analysis phase so that findings are not inadvertently attributed to what is actually a natural, cyclic or seasonal occurrence.

- Financial compensation for study sites would facilitate more comprehensive, prospective data collection whereby forms similar to the TIS forms used in this study are completed by endoscopy staff.

- Assuming that better data will be available as a result of some of the recommendations above, more rigorous statistical analyses would be feasible, for example, Time Series Analysis.

- Completion of the Innovation Form by verbal communication, either face to face or by phone rather than sending it by post may elicit a more accurately completed form as people could be asked to provide clarification regarding dates.

14.11 Recommendations for future research

Whilst it is clear that this study had a number of shortcomings, to repeat it with the improved study design outlined above would only waste resources answering a question that is actually no longer relevant, since the NHSMA and its modernisation programmes have largely dissipated over the last few years, making any further work in this field already out of date. It is more important that we address the three key issues highlighted by this study, namely the issue of NHS data collection, NHS modernisation and the use of HES data in research.

The importance of high quality data collection and analysis has been a recurrent theme in this thesis. It would be interesting to determine the current state of play in terms of the type and quality of data routinely collected within NHS endoscopy units nationwide, not just in the 20 units sampled here. From this, evidence could be presented in the hope of changing data collection policies for not only endoscopy services but for NHS services overall.

Since the GRS has succeeded the MES project in attempting to improve the standard of NHS endoscopy services, it would be interesting to independently evaluate the impact of the GRS on NHS endoscopy units, especially since it has had a wider uptake and so, more units would be

available for sampling. The services of these units could be monitored and analysed over time using facets of the ideal study design discussed above to determine whether the GRS has significantly improved endoscopy services.

Another avenue for future research would be to further investigate the reliability of the HES dataset. This study has highlighted the potential for inaccurate data to be recorded on the HES Activity dataset by Trusts and it is important that the true extent of these inaccuracies are explored and documented to make researchers aware of the reliability of these datasets prior to applying them to their work. This could be done by collecting and comparing equivalent activity datasets from both the endoscopy unit and corresponding Trusts in England. An additional feature of this would be to perform the same comparison using Welsh endoscopy units and Trusts and comparing their data with the Patient Episodes Database Wales and with Scottish endoscopy units using the Scottish Morbidity Records database.

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16.   APPENDICES

16.1   A table describing the peer reviewed literature featured in Chapter 6.

16.2   A table describing the non-peer reviewed literature featured in Chapter 6.

16.3   The *TIS form* proforma.

16.4   HES *Activity* data in Sites 2, 3, 6, 9, 12, 16, 18 and 19, split according to procedure type and time period.

16.5   *Total procedures* data submitted by highest ranking source for each site.

16.6   Data submitted from highest ranking source for FS procedures only.

16.7   Data submitted from highest ranking source for Colonoscopy procedures only.

16.8   Data submitted from highest ranking source for UGE procedures only.

16.9   Innovation form proforma.

16.1 Table describing the peer reviewed literature featured in Chapter 6.

Nº	First author	Year	Title
1	AGABA, A. E.	2006	One stop rectal bleeding clinic: the Coventry experience.
2	ALLGAR, V. L.	2006	Urgent GP referrals for suspected lung, colorectal, prostate and ovarian cancer.
3	ANAGNOSTOPOULOS, G. K.	2006	Barrett's esophagus specialist clinic: what difference can it make?
4	BADGER, S. A.	2005	The effectiveness of flexible sigmoidoscopy as the primary method for investigating colorectal symptoms in low-risk patients.
5	BALL, J. E.	2004	Quality improvement programme to achieve acceptable colonoscopy completion rates: prospective before and after study.
6	BARWICK, T. W.	2004	The two week referral for colorectal cancer: a retrospective analysis.
7	BATESON, M. C.	2004	Non-attendance at clinic: cycles of audit of a consultant based gastroenterology outpatient department.
8	BEVIS, P. M.	2008	The association between referral source and stage of disease in patients with colorectal cancer.
9	BLAZEBY, J.M.	2006	Analysis of clinical decision-making in multi-disciplinary cancer teams.
10	BOWLES, C. J.	2004	A prospective study of colonoscopy practice in the UK today: are we adequately prepared for national colorectal cancer screening tomorrow?
11	BROTHERSTONE, H.	2006	The impact of illustrations on public understanding of the aim of cancer screening.
12	CHAN, D.	2004	An emerging role for the upper GI nurse practitioner in primary and acute care.
13	CHEUNG, W. Y.	2002	Shared care in gastroenterology: GPs' views of open access to out-patient follow-up for patients with inflammatory bowel disease.
14	CHOHAN, D. P. K.	2005	How has the "two-week wait" rule affected the presentation of colorectal cancer?
15	DAVIES, E.	2007	Using clinical audit, qualitative data from patients and feedback from general practitioners to decrease delay in the referral

250

			of suspected colorectal cancer.
16	DAVIES, R. J.	2004	Reduction in the proportion of patients with colorectal cancer presenting as an emergency following the introduction of fast-track flexible sigmoidoscopy: a three-year prospective observational study.
17		2002	A prospective study to assess the implementation of a fast-track system to meet the two-week target for colorectal cancer in Somerset.
18	DEBNATH, D.	2002	Guidelines, compliance, and effectiveness: a 12 months' audit in an acute district general healthcare trust on the two week rule for suspected colorectal cancer.
19	DELANEY, B.	2000	Initial management strategies for dyspepsia.
20	DOCKERY, F.	2001	The effect of reminder calls in reducing non-attendance rates at care of the elderly clinics.
21	DODDS, W.	2004	Implementing the 2-week wait rule for cancer referral in the UK: general practitioners' views and practices.
22	DOUGALL, A.	2000	Rethinking patient satisfaction: patient experiences of an open access flexible sigmoidoscopy service.
23	DOUGLASS, A.	2004	The nurse endoscopist's contribution to service delivery.
24		2005	National survey of UK emergency endoscopy units.
25	DUTHIE, G. S.	1998	A UK training programme for nurse practitioner flexible sigmoidoscopy and a prospective evaluation of the practice of the first UK trained nurse flexible sigmoidoscopist.
26	ECCERSLEY, A. J.	2003	Referral guidelines for colorectal cancer–do they work?
27	ELWYN, G.	2007	Influencing referral practice using feedback of adherence to NICE guidelines: a quality improvement report for dyspepsia.
28	FASIH, T.	2004	Prospective audit of quality of colonoscopy in a surgical coloproctology unit.
29	FLASHMAN, K.	2004	The Department of Health's "two week standard" for bowel cancer: is it working?
30	GALLOWAY, J. M.	2002	Endoscopy in primary care–a survey of current practice.
31	GOODFELLOW, P. B.	2003	Nurse endoscopy in a district general hospital.

251

32	GOODYEAR, S.J.	2008	The effects of population-based faecal occult blood test screening upon emergency colorectal cancer admissions in Coventry and north Warwickshire.
33	GORARD, D. A.	2004	Completion rate to caecum as a quality measure of colonoscopy in a district general hospital.
34	GRIFFITHS, C.	2004	United Kingdom National Health Service. Cancer Services Collaborative "Improvement Partnership". Redesign of cancer services: A national approach.
35	GRIFFITHS, H.	2002	Iron-deficiency anaemia: developing a nurse-led integrated care pathway.
36	HALL, V.	2006	Developing a nurse driven Barrett's oesophagus clinic.
37	HANDS, E.	2004	Developing site-specific nurses for upper GI cancer.
38	HARDY, K.J.	2001	Information given to patients before appointments and its effects on non-attendance rate.
39	HARINATH, G.	2002	The effectiveness of new criteria for colorectal fast track clinics.
40	HART, A. R.	2003	An industry based approach to colorectal cancer screening in an asymptomatic population.
41	HEARNSHAW, S. A.	2007	Endoscopists attitudes on the publication of quality data for endoscopic procedures: a cross-sectional survey.
42	HODDER, R. J.	2005	Pitfalls in the construction of cancer guidelines demonstrated by the analyses of colorectal referrals.
43		2005	Variations in the evaluation of colorectal cancer risk.
44	JEFFERY, A.	2005	Barrett's oesophagus: using audit to investigate practice in endoscopy.
45	JIWA, M.	2002	& BURR, J. - GP letter writing in colorectal cancer: a qualitative study.
46		2002	Et al - Quality of information on referrals to colorectal surgeons: towards consensus.
47		2004	& HAMILTON, W. - Referral of suspected colorectal cancer: have guidelines made a difference?
48		2004	Et al - Referral letters to colorectal surgeons: the impact of peer-mediated feedback.
49	JONES, L. S.	2001	Experience with a one-stop colorectal clinic.
50	KAPOOR, N.	2005	Predictive value of alarm features in a rapid access upper gastrointestinal cancer service.

252

51	KARAJEH, M. A.	2006	Colonoscopy in elderly people is a safe procedure with a high diagnostic yield: a prospective comparative study of 2000 patients.
52	KEEN, A.	2004	Endoscopy: Why training for all is important.
53	KELLY, M.J.	2002	The Cancer Collaborative Services Project.
54		2003	A snapshot of MDT working and patient mapping in the UK colorectal cancer centres in 2002.
55	KENNEDY, A. P.	2004	A randomised controlled trial to assess the effectiveness and cost of a patient orientated self management approach to chronic inflammatory bowel disease.
56	KIRAN, P. R.	2002	Duration of symptoms and spread of colorectal cancer: a short history does not mean early disease.
57	LEE, C.S.	2003	Telephone reminders to reduce non-attendance rate for endoscopy.
58	LEWIS, R.	2005	A systematic review of cancer waiting time audits.
59		2006	Can the English NHS meet the 18-week waiting list target?
60	LOFTUS, L.A.	2001	The development of nurse-led clinics in cancer care.
61	MACKENZIE, S.	2003	Randomized clinical trial comparing consultant-led or open access investigation for large bowel symptoms.
62	MAHON, C. C.	2002	Preliminary evaluation of United Kingdom National Referral Guidelines for lower gastrointestinal tract cancer.
63	MANDAL, A.	2003	Current practice in surveillance strategy for patients with Barrett's oesophagus in the UK.
64	MARSHALL, J.B.	1998	Open access endoscopy in Britain: a service in evolution.
65	MARTIN, J. P.	2002	Referral patterns to a district general hospital gastroenterology outpatient clinic: implications for the 'two-week target'.
66	MARUTHACHALAM, K.	2005	Evolution of the two-week rule pathway–direct access colonoscopy vs outpatient appointments: one year's experience and patient satisfaction survey.
67		2006	Nurse led flexible sigmoidoscopy in primary care–the first thousand patients.
68	MASON, I.	2005	Audit of a newly established nurse-led dyspepsia triage clinic.

69	MASON, J. M.	2005	Managing dyspepsia without alarm signs in primary care: new national guidance for England and Wales.
70	MATHEW, J.	2004	Audit on flexible sigmoidoscopy for rectal bleeding in a district general hospital: are we over-loading the resources?
71	MCGRATH, A.	2003	Experiences of nurse specialist training in flexible sigmoidoscopy.
72	MEADEN, C.	2006	A randomised controlled trail comparing the accuracy of general diagnostic upper gastrointestinal endoscopy performed by nurse or medical endoscopists.
73	MELLENEY, E. M.	2002	Audit of a nurse endoscopist based one stop dyspepsia clinic.
74	MOAYYEDI, P.	1998	The Leeds Dyspepsia Questionnaire: A valid tool for measuring the presence and severity of dyspepsia.
75	MORRIS-STIFF, G.J.	2005	The European Working Time Directive: One for all and all for one?
76	MURDOCK, A.	2002	Why do patients not keep their appointments? Prospective study in a gastroenterology outpatient clinic.
77	PARMAR, V. N.	2005	An audit of informed consent in gastroscopy: investigation of a hospital's informed consent procedure in endoscopy by assessing current practice.
78	PATERSON, H.M.	2006	Impact of open-access endoscopy on detection of early oesophageal and gastric cancer 1994 – 2003: population-based study.
79	PATHMAKANTHAN, S.	2001	Nurse endoscopists in United Kingdom health care: a survey of prevalence, skills and attitudes.
80	PEARSON, C.	2005	A nurse-led IBD service in a district general hospital.
81	PICKARD, M.	2006	Follow up of patients with coiorectal polyps: are the BSG guidelines being adhered to?
82	PORRETT, T. R.	2004	'Paper Clinics'- a model for improving delivery of outpatient colorectal services.
83	PRICE, J.	2005	Impact of UK Colorectal Cancer Screening Pilot on hospital diagnostic services.
84	RAJE, D.	2006	Changing trends in the management of colorectal cancers and its impact on cancer waiting times.
85	RAMAKRISHNAN, S.	2004	Assessment of patient pain at colonoscopy: are nurses better than endoscopists?
86	RAO, G. N.	2006	Reducing surgical outpatient waiting is not the solution to meeting the 2005 colorectal cancer target.

254

87	ROBERTSON, R.	2006	Predicting colorectal cancer risk in patients with rectal bleeding.
88	RUTTER, M. D.	1998	The one-stop dyspepsia clinic--an alternative to open-access endoscopy for patients with dyspepsia.
89	SELVACHANDRAN, S. N.	2002	Prediction of colorectal cancer by a patient consultation questionnaire and scoring system: a prospective study.
90	SHARMA, A.	2007	Colorectal MDTs: the team's perspective.
91	SHAW, A.G.	2008	Referral of patients with iron deficiency anaemia under the lower gastrointestinal two-week wait rule.
92	SHAW, I. S.	2006	Limited impact on endoscopy demand from a primary care based 'test and treat' dyspepsia management strategy: the results of a randomised controlled trial.
93	SHEPHERD, H. A.	2000	Postal consent for upper gastrointestinal endoscopy.
94	SHOAIB, A.	2006	Why wait for a colonoscopy? An easy cure.
95	SIDHU, R.	2006	Patient feedback on helpfulness of postal information packs regarding informed consent for endoscopic procedures.
	SILVESTER, K.	2004	Reducing waiting times in the NHS: is lack of capacity the problem.
96	SMALE, S.	2003	Upper gastrointestinal endoscopy performed by nurses: scope for the future?
97	SMITH, R. A.	2007	Outcomes in 2748 patients referred to a colorectal two-week rule clinic.
98	SOUKOP, M.	2006	Results of a survey of the role of multidisciplinary team coordinators for colorectal cancer in England and Wales.
99	SPAHOS, T.	2005	Endoscopy waiting times and impact of the two week wait scheme on diagnosis and outcome of upper gastrointestinal cancer.
100	SPINKS, C.	2003	Can written information and verbal consultation reduce non-attendance for colonoscopy procedures?
101	SPURGEON, P.	2000	Waiting times for cancer patients in England after general practitioners' referrals: retrospective national survey.
102	STEPHENS, M.R.	2005	Prognostic significance of alarm symptoms in patients with gastric cancer.
103	STOKER, E.	2005	Achieving the lower GI two-week rule.
104	TANG, T.	2005	An approach to haemorrhoids.

105	TAYAL, S.C.	2006	Reducing waiting times for GU medicine appointments: the impact of a new appointment system.
106	THOMAS-GIBSON, S.	2002	Colonoscopy at a combined district general hospital and specialist endoscopy unit: lessons from 505 consecutive examinations.
107	THOMAS, S. J.	2001	How much surplus capacity is required to maintain low waiting times?
108	THOMPSON, M. R	2006	Effective Screening for Bowel Cancer: A United Kingdom Perspective.
109	THORNE, K.	2008	Unmeasured improvement work: The lack of routinely collected, service-related data in endoscopy units.
110		2006	The effects of the Two-Week Rule on NHS colorectal cancer diagnostic services: a systematic literature review.
111	TRICKETT, J. P.	2004	A study on the routes of referral for patients with colorectal cancer and its affect on the time to surgery and pathological stage.
112	UK COLORECTAL CANCER SCREENING PILOT GROUP	2004	Results of the first round of a demonstration pilot of screening for colorectal cancer in the United Kingdom.
113	UK NHS CANCER SERVICES COLLABORATIVE	2004	United Kingdom National Health Service, Cancer Services Collaborative "Improvement Partnership", redesign of cancer services - a national approach.
114	VERMA, S.	2001	Open-access versus hospital-initiated flexible sigmoidoscopy: a comparative audit of efficiency.
115	WALSH, S.	2002	The fourteen-day rule and colorectal cancer.
116	WARD, N.	2006	Fast track referrals for colorectal cancer: the impact of the faecal occult blood test screening programme.
117	WELLER, D.	2007	The UK colorectal cancer screening pilot: results of the second round of screening in England.
118	WEST, N.J.	2007	The NHS Bowel Cancer Screening Programme – a realistic approach with additional benefits.
119	WILLIAMS, J. G.	2007	Gastroenterology services in the UK. The burden of disease, and the organisation and delivery of services for gastrointestinal and liver disorders: a review of the evidence.

120	2006	What are the clinical outcome and cost-effectiveness of endoscopy undertaken by nurses when compared with doctors? A Multi-Institution Nurse Endoscopy Trial (MINuET).
121	2004	Clinical guidelines online: do they improve compliance?
122	2000	Open access follow up for inflammatory bowel disease: pragmatic randomised trial and cost effectiveness study.
123	WOOD, J.J.	2008	An evaluation of treatment decisions at a colorectal cancer multi-disciplinary team.

16.2 Table describing the non-peer reviewed literature featured in Chapter 6.

Nº	First author	Year	Title
1	ALLUM, W. H.	2002	Guidelines for the management of oesophageal and gastric cancer.
2	APPLEBY, J.	2005	Sustaining reductions in waiting times: Identifying successful strategies
3	BARRISON, I.G.	2001	Provision of Endoscopy Related Services in District General Hospitals.
4	BRITISH SOCIETY OF	2006	Care of Patients with Gastrointestinal Disorders in the United Kingdom.
5	GASTROENTEROLOGY	2006	Complications of gastrointestinal endoscopy.
6	BRITISH SOCIETY OF	2005	Guidelines for the diagnosis and management of Barrett's columnar-lined oesophagus.
7	GASTROENTEROLOGY WORKING PARTY	2005	Non-medical endoscopists.
8	CAIRNS, S.	2002	Guidelines for colorectal cancer screening in high risk groups.
9	CARTER, M. J.	2004	Guidelines for the management of inflammatory bowel disease in adults.
10	DEPARTMENT OF HEALTH	1991	The Patient's Charter.
11		2000	The NHS Plan.
12		2000	Referral guidelines for suspected cancer.
13		2004	A compendium of solutions to implementing the Working Time Directive for doctors in training from August 2004.
14		2004	The NHS Cancer Plan and the new NHS: Providing a patient-centred service.
15		2004	The NHS Improvement Plan.
16	JOINT ADVISORY GROUP ON GASTROINTESTINAL	2004	Guidelines for the training, appraisal and assessment of trainees in gastrointestinal endoscopy

	ENDOSCOPY		
17	KIPPING, R.	2000	Booking patients for hospital care: a progress report
18	NATIONAL AUDIT OFFICE	2004	Tackling cancer in England: saving more lives.
19	NATIONAL CONFIDENTIAL ENQUIRY INTO PATIENT OUTCOME AND DEATH	2004	Scoping our practice. National Confidential Enquiry into Patient Outcome and Death.
20	NATIONAL INSTITUTE FOR (HEALTH &) CLINICAL EXCELLENCE	2004	Dyspepsia: Management of dyspepsia in adults in primary care (Clinical Guideline 17).
21		2004	Guidance on Cancer Services: Improving outcomes in colorectal cancers.
22		2005	Referral guidelines for suspected cancer (Clinical guideline 27).
23	NHS EXECUTIVE	1998	Working time regulations
24		1999	Cancer waiting times: Achieving the two week target (HSC 1999/205).
25	NHS MODERNISATION AGENCY	2004	National Endoscopy Programme: Report from the second wave.
26	PRIMARY CARE SOCIETY FOR GASTROENTEROLOGY	2001	Endoscopy in primary care.
27	RICHARDS, M.	2004	The Belfry Plan
28	ROBERT, G.	2003	Modernising cancer services: an evaluation of phase I of the Cancer Services Collaborative
29	THOMPSON, M. R	2002	ACPGBI Referral guidelines for colorectal cancer.
30	UK CRC SCREENING PILOT EVALUATION TEAM	2003	Evaluation of the UK Colorectal Cancer Screening Pilot. Final Report.
31	WELLER, D.	2007	The English colorectal cancer screening pilot: results of the second round of screening in England

16.3 The TIS Form proforma

FORM A: Number of referrals received for endoscopy

Month requested	Referral type	FLEXIBLE SIGMOIDOSCOPY	COLONOSCOPY	GASTROSCOPY / OGD	TOTAL
MM/YY	Day case / outpatient				
	2 week (cancer)				
	Inpatient				
	Follow-up (surveillance)				
	Emergency				
	Total				

FORM B: Waiting list information

Month requested	No. patients waiting for...	FLEXIBLE SIGMOIDOSCOPY	COLONOSCOPY	GASTROSCOPY / OGD	TOTAL
MM/YY	> 1 month				
	> 3 months				
	> 6 months				
	> 12 months				
	Total				

260

FORM C: Cancellations / DNAs

Month requested	Reason for lost slot	Number lost
MM/YY	Patient cancellation	
	Patient DNA'd	
	Hospital Cancellation	
	Total	

FORM D: Number of endoscopies performed

Month requested	FLEXIBLE SIGMOIDOSCOPY	COLONOSCOPY	GASTROSCOPY / OGD	TOTAL
MM/YY				

MM/YY = Month/Year

261

16.4 HES *Activity* data in Sites 2, 3, 6, 9, 12, 16, 18 and 19, split according to procedure type and time period.

Site ID	Site type	Procedure type	Time							
			T0	T1	T2	T3	T4	T5	T6	T7
6	MES	UGE	247	188	168	188	167	176	210	127
6	MES	Colonoscopy	41	63	58	35	62	76	67	56
6	MES	FS	73	54	59	33	50	114	55	42
6	MES	Total procedures	361	305	285	256	279	366	332	225
16	MES	UGE	29	25	37	26	25	22	34	19
16	MES	Colonoscopy	10	16	16	14	14	21	25	13
16	MES	FS	4	3	9	10	5	4	6	7
16	MES	Total procedures	43	44	62	50	44	47	65	39
18	MES	UGE	50	43	51	53	42	48	38	55
18	MES	Colonoscopy	15	23	22	29	28	33	20	17
18	MES	FS	5	5	2	3	4	3	5	4
18	MES	Total procedures	70	71	75	85	74	84	63	76
19	MES	UGE	205	219	187	175	253	228	234	207
19	MES	Colonoscopy	41	48	49	40	87	80	74	73
19	MES	FS	132	120	77	87	108	94	107	87
19	MES	Total procedures	378	387	313	302	448	402	415	367
2	Non-MES	UGE	399	472	408	425	408	425	412	379
2	Non-MES	Colonoscopy	135	130	146	115	140	142	170	179
2	Non-MES	FS	51	53	41	55	78	59	75	74
2	Non-MES	Total procedures	585	655	595	595	626	626	657	632
3	Non-MES	UGE	318	289	327	313	334	292	285	275
3	Non-MES	Colonoscopy	73	107	75	82	111	106	120	86
3	Non-MES	FS	26	33	47	32	54	39	50	40
3	Non-MES	Total procedures	417	429	449	427	499	437	455	401
9	Non-MES	UGE	422	425	405	122	122	128	137	303
9	Non-MES	Colonoscopy	158	151	145	33	51	26	48	125
9	Non-MES	FS	9	13	21	13	12	10	22	43
9	Non-MES	Total procedures	589	589	571	168	185	164	207	471
12	Non-MES	UGE	199	186	143	194	164	150	178	147
12	Non-MES	Colonoscopy	109	105	107	113	119	115	128	122
12	Non-MES	FS	65	64	61	63	98	73	71	61
12	Non-MES	Total procedures	373	355	311	370	381	338	377	330

16.5 Total *procedures* data submitted by highest ranking source for each site.

Data variable	Time	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20
Referrals	T0	292		287	408		370	379	727	429		638		175	268	5			872	507	
	T1	334		463	391		337	311	614	456		585		242	251	1			853	555	
	T2	130	647	332	438		391	311	654	520		674	342	385	198	52	361	729	672	534	
	T3	336	469	309	325	418	449	280	586	184		619	315	379	260	88	366	678	796	494	
	T4	337	724	344	376	402	255	347	585	356		683	365	402	273	60	289	836	628	599	484
	T5	396	630	333	337	409	269	371	573			619	347	474	218	257	276	641	798	565	337
	T6	287	856	316	328	448	278		560			597	419	528			303	818	456	582	305
	T7	336	564	281	280		287		289			589		548				604	380		303
Wait >3m	T0			202	282	39	6		85			1043		1586	353	3			248	53	
	T1			88	433	172	0		27			808		1117	418	7			180	41	
	T2		77	4	461	60	0		55			889		1010	30	4			112	28	
	T3		82	36	388	56	0	110	40			1020		1113	340	3			118	51	
	T4		39	30	306	65	92	63	40			1063		1143	807	24			162	26	45
	T5		85	13	347	15	6	91	81			1265		1070	1090	6			178	11	0
	T6		14	5	239	26		28	79			2109		1080					103	8	0
	T7		52	6	128				49					1787					517	0	0
Snapshot	T0	1148							699	995					685				941	482	
	T1	1180							630	2024					733				457	425	
	T2	675	818			97			683	1889			996		324			27900	469	433	
	T3	477	890			97			588	2006	440		952		840			39540	789	554	
	T4	456	487			165			773	2122	657		803		1296			38085	597	477	
	T5	484	588			25			654	2183	940		963		1511			47295	652	402	

Hospital ID

263

(...Cont'd)

Data variable	Time	Hospital ID																			
		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20
Snapshot	T6	414	572			43			631	2723			1208					38085	421	421	
	T7	300	567							2648									1234		
Lost slots	T0	94		69			21			216		53		64	64	1	104				
	T1	81		67			26			138		34		134	63	6	244		300	29	
	T2	71	13	52			92			106		54		146	29	2	203	75	322	26	
	T3	99	21	47		38	112			142		64		192	33	121	232	82	258	21	
	T4	70	18	62		67	20			134		64		141	46	136	203	121	253	34	
	T5	75	26	64		54	26			151		50		102	40	135		97	311	26	
	T6	70	29	52		98	114			141		36		167				84	406	52	
	T7	32	21	56			17			138		28		40				65	161		
Activity	T0	376	479	376	369		352	473	727	382	308	541		483	203	111	210		682	342	122
	T1	448	506	392	324		225	298	614	401	316	499		652	267	88	492		816	374	171
	T2	332	506	405	336		285	408	654	359	286	414	250	603	130	80	499	562	722	292	170
	T3	366	504	383	252	419	257	412	586	314	266	518	299	559	186	248	544	515	723	358	182
	T4	488	518	442	280	418	281	458	585	320	276	515	311	675	208	301	530	773	763	424	294
	T5	409	539	392	290	415	359	449	573	334	260	444	277	544	157	397		714	828	347	362
	T6	409		405	310	405	325	430	560	335	318	490	323	506				725	862		
	T7	278		269	303	362	255	331	334	289	287	476		371				604	424		

Cells shaded in grey indicate datasets subsequently excluded due to irregularities.

16.6 Data submitted from highest ranking source for FS procedures only.

Variable	Time															Hospital ID					
		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20
Referrals	T0	7		12	53		72	121	188	6		97		14		0			81		
	T1	28		43	66		76	91	147	4		94		17		0			60		
	T2	6	44	33	49		69	97	193	6		97	45	82		0	52	153	7		
	T3	18	45	32	34	115	99	87	144	3		113	66	94		1	81	177	14		151
	T4	18	76	30	41	119	53	114	153	16		120	73	116		0	54	220	1		73
	T5	10	58	40	53	128	80	96	169			113	68	130		10	45	216	11		67
	T6	17	76	46	67	137	74		170			110	86	135			57	188	12		
	T7	20	49	28	48		68		113			167		136				182	2		63
Wait >3m	T0			18	40		0		65			29		252	15	0			0	4	
	T1			5	60		0		9			18		87	13	0			0	13	
	T2		3	0	62		0	24	20			45		97	0	0			2	14	
	T3		10	0	36		0	3	13			49		120	6	0			7	20	
	T4		3	3	38		16	3	19			76		110	30	0			4	4	0
	T5		50	2	14		2	16	29			105		119	23	0			4	2	0
	T6		5	0	20			3	20			426		124					0	4	0
	T7		16	0	17				22					152					7	0	0
Snapshot	T0	57							297	3					26				87	160	
	T1	65							260	14					20				66	151	
	T2	84	72						272	19			144		8			4665	7	152	
	T3	51	80						243	27	49		128		34			7230	13	189	
	T4	47	64						352	34	122		95		59			7695	6	150	
	T5	57	60						221	96	155		94		39			8760	7	119	
	T6	42	89						238	101			165					9105	2	132	
	T7	29	70							74									10		

(Cont'd...)

(...Cont'd)

Activity																			
T0	35	36	25	55		66		188	4	60	61		117	9	0		49	121	13
T1	43	28	31	45		48		147	3	71	58	44	203	16	12		65	115	30
T2	36	30	44	42	106	56		193	11	60	35	56	150	5	3	121	23	71	28
T3	54	55	32	32	100	32		144	7	54	72	88	111	10	11	132	16	85	29
T4	65	60	45	31	131	48		153	11	48	68	65	161	9	29	188	1	98	9
T5	51	55	37	36	106	106		169	15	48	56	54	131	17		160	10	78	11
T6	61		45	50	106	64		170	13	61	58		128			182	11		
T7	29		30	46	110	64	97	129	16	41	87		106			182	2		

Cells shaded in grey indicate datasets subsequently excluded due to irregularities.

16.7 Data submitted from highest ranking source for Colonoscopy procedures only.

Variable	Time									Hospital ID											
		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20
Referrals	T0	62		84	104		76	65	110	97		137		72					342		
	T1	73		142	108		89	88	113	149		140		35					507		
	T2	21	149	94	148		79	83	100	187		120	127	103			113	182	323		
	T3	71	125	75	92	57	115	68	86	102		108	127	97			132	165	396		
	T4	86	194	104	145	71	50	107	119	93		154	143	118		11	105	214	371		114
	T5	97	196	88	94	43	94	143	114			108	154	149		80	107	156	397		80
	T6	64	262	84	90	71	84		94			100	176	146			131	278	250		61
	T7	88	155	73	86		73		63			137		147				170	142		65
Wait >3m	T0			117	90		0		13			944		708	281	3			223	17	
	T1			67	174		0		11			714		432	355	7			174	11	
	T2		44	4	148		0		20			764		465	24	4			96	1	
	T3		53	31	133		0	18	17			884		478	200	3			98	14	
	T4		36	23	135		40	16	6			884		578	488	1			129	13	8
	T5		33	4	145		4	42	17			1082		628	680	1			153	3	0
	T6		9	2	123			25	15			1259		719					90	1	0
	T7		33	3	74				13					1299					188	0	0
Snapshot	T0	478							123	644					453				350	68	
	T1	458							120	1049					538				233	67	
	T2	354	302						131	1070			350		175			12450	164	87	
	T3	242	296						123	1146	107		368		451			16740	394	122	
	T4	186	205						110	1221	140		337		731			19350	230	123	
	T5	179	260						105	1160	189		383		875			25800	265	94	
	T6	191	239						97	1232			491					21870	195	111	
	T7	133	229							1250									359		

267

(Cont'd....)

(...Cont'd)

Activity																				
T0	81	97	55	99		48		110	88	51	153		85		21	150		293	37	40
T1	88	95	91	96		60		113	76	47	126		139		23	354		357	46	73
T2	63	109	56	83		61		100	74	40	91	120	111		21	358	145	376	43	63
T3	96	79	65	67	56	35		86	59	48	120	113	102		80	364	140	363	65	78
T4	131	88	84	86	61	61		119	74	40	141	112	152		103	330	210	362	87	137
T5	110	117	85	97	58	75		114	88	34	104	98	122		182		232	436	65	253
T6	126		99	80	75	67		94	79	48	120	136	66				235	494		
T7	62		60	82	85	52	103	67	80	50	142		80				170	230		

Cells shaded in grey indicate datasets subsequently excluded due to irregularities.

16.8 Data submitted from highest ranking source for UGE procedures only.

Variable	Time	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20
Referrals	T0	223		191	251		222	193	429	326		404		89		1			449		
	T1	233		278	217		172	132	354	303		351		190		0			286		
	T2	103	454	205	241		243	131	361	327		457	170	200		48	196	394	342		
	T3	247	299	202	199	246	235	125	356	79		398	122	188		80	153	336	386		
	T4	233	454	210	190	212	152	126	313	247		409	149	168		49	130	402	256		219
	T5	289	376	205	190	238	95	132	290			398	125	195		167	124	269	390		184
	T6	206	518	186	171	240	121		296			387	157	247			115	352	194		177
	T7	228	360	180	146		146		113			285		265				252	236		175
Wait >3m	T0			67	152		6	7	7			70		626	57	0			25	32	
	T1			16	199		0	7	7			76		598	50	0			6	17	
	T2		30	0	251		0		15			80		448	6	0			14	13	
	T3		19	5	219		0	68	10			87		515	134	0			13	17	37
	T4		0	4	133		36	44	15			103		455	289	23			29	9	
	T5		2	7	188		0	33	35			78		323	387	5			21	6	0
	T6		0	3	96			0	44			424		237					13	3	0
	T7		3	3	37				14					336					322	0	0
Snapshot	T0	613							279	348					206				504	254	
	T1	657							250	961					175				158	207	
	T2	237	444						280	800			502		141				298	194	
	T3	184	514						222	834	284		456		355			10765	382	243	
	T4	223	218						311	867	395		371		506			15570	361	204	
	T5	248	268						328	927	596		486		597			11040	380	189	
	T6	181	244						296	1390			552					12735	224	178	
	T7	138	268							1324								7110	865		

(Cont'd...)

(…Cont'd)

Activity																			
T0	260	346	296	215		238		429	290	197	327		281	**81**	60		340	184	69
T1	317	383	270	183		117		354	322	198	315		310	**49**	126		394	213	68
T2	233	367	305	211		168		361	274	186	288	86	342	**54**	138	296	323	178	79
T3	216	370	286	153	257	190		356	248	164	326	130	346	**158**	169	243	344	209	75
T4	292	370	313	163	257	172		313	235	188	306	111	362	**189**	171	375	400	239	148
T5	248	367	270	157	226	178		290	231	178	284	114	291	**198**		322	382	204	98
T6	222		261	180	224	194		296	243	209	312	133	312			308	357		
T7	187		179	175	167	139	131	138	193	196	247		185			252	192		

Cells shaded in grey indicate datasets subsequently excluded due to irregularities.

270

16.9 Innovation form proforma

Instruction sheet for the completion of the
ENIGMA Innovations Form

Please follow the instructions below to complete the Innovations Form.

1. Indicate which of the innovations listed have taken place at the **[NAME]** endoscopy unit by ticking either the "Yes" or "No" column.
2. Indicate the approximate year when the innovation took place by ticking the "**2000 – 2002**" column, the "**2003**" column or the "**2004 – 2005**" column.
3. If any innovations that have taken place in your department are not listed, please list these in the blank table on page 4.
4. Where relevant, please complete the "Comments" section on page 4 quoting the reference number of the innovation and any additional information. Continue on a separate sheet if necessary.

Notes:

Some changes may be applicable to more than one category of innovations listed. Please tick as many as apply and make a note in the Comments section.

Where changes have occurred that were **not** part of the endoscopy unit's modernisation plans, we would still like to know about them if they impacted on the endoscopy services. Please include them when completing the form and make notes in the comments section.

If you have any queries on the completion of the Innovations Form, please contact Kym Thorne on 01792 602062.

(Cont'd…)

(…Cont'd)

List of innovations	Implemented?		Timeframe		
	Yes	No	"2000 – 2002"	"2003"	"2004 - 2005"
NEW / ADDITIONAL STAFF:					
1. Nurse endoscopists					
2. GP endoscopists					
3. Consultants					
4. Link / escort nurses					
5. Health care assistants					
6. Receptionist / other clerical staff					
7. New management / leadership					
8. Data collection staff					
ALTERATIONS OF STAFF ROLES:					
9. Changing roles of medical staff					
10. Changing roles of clerical staff					
11. Clerical duties taken from nurses					
NEW NURSE RESPONSIBILITIES:					
12. Nurse led clinic(s)					
13. Nurse led consent					
14. Nurses performing cannulations					
15. PEG nurses					
16. Training nurses to be nurse endoscopists					
NEW WORKING PRACTICES:					
17. New referral procedure(s) into the unit					
18. Validation of referrals					
19. New guideline(s) / protocols					
20. Triage of emergency patients					
21. Pre-assessment clinics					
22. DNA strategies					
23. Cancellation strategies					
24. "6-week notice period for leave" policy					
25. New procedure(s) performed					
26. Introducing dedicated training list(s)					

(Cont'd…)

List of innovations	Implemented?		Timeframe		
	Yes	No	"2000 – 2002"	"2003"	"2004 - 2005"
INCREASING ACTIVITY:					
27. Extra slots for emergency bleeds, etc					
28. Scheduling extra list(s) (Mon → Fri)					
29. Increasing the length of the working day					
30. Weekend / out of hours working					
WAITING LIST MANAGEMENT:					
31. Validation of waiting lists					
32. Pooling waiting lists					
33. Waiting list initiative sessions					
CHANGES IN BOOKING PATIENTS APPOINTMENTS:					
34. Open access booking					
35. Full booking					
36. Partial booking					
STRUCTURAL CHANGES TO THE UNIT:					
37. New hospital / unit					
38. Structural alterations to current unit					
39. Increasing capacity in recovery area					
40. Centralising admin in one place					
41. Moving some endoscopy externally					
42. Refurbishment of reception / endoscopy suite					
ANALYSIS OF WORKING PRACTICES:					
43. New / improved in-house data collection					
44. Demand and capacity studies					
45. Audits					
46. Process mapping					
47. Patient surveys					
IMPROVING THE PATIENTS' EXPERIENCE:					
48. New information leaflets for patients					
49. Improving patient privacy & dignity					
50. Home bowel preps					
51. Improving experience of inpatients					

(Cont'd...)

(...Cont'd)

List of innovations	Implemented?		Timeframe		
	Yes	No	"2000 – 2002"	"2003"	"2004 - 2005"
52. Improving experience of diabetic patients					
53. Improving experience of patients with other comorbidities					
IMPROVING STAFF EXPERIENCE:					
54. Staff training / development					
55. "Protected time" for staff to meet / train					
56. Surveying staff on changes wanted					
57. New / improved staffroom					
58. Endoscopy groups / staff meetings					
59. Improving staff communication					
MISCELLANEOUS CHANGES:					
60. New medical equipment					
61. New IT equipment / software					
62. Raising the profile of endoscopy					
63. Advice or help from within the Trust					
64. Advice or help from external agencies					
65. Open days for hospital staff / patients					
OTHER INNOVATIONS NOT INCLUDED IN THE LIST:					
66.					
67.					
68.					
69.					
70.					

Comments