Evaluating innovations in the delivery and organisation of gastroenterology services initiated directly or indirectly by the Modernising Endoscopy Services programme of the NHS Modernisation Agency: (ENIGMA)

Report for the National Co-ordinating Centre for NHS Service Delivery and Organisation R&D (NCCSDO)

November 2008

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Foreword

This report describes a four year study of the effects of an important modernisation initiative on patients, endoscopy services and the wider NHS. Methodologically it breaks new ground in the evaluation of delivery of services, applying a quasi-experimental approach in the context of mixed methods to evaluate a diffuse intervention, and integrating the results to paint a cohesive picture of the impact of change, and the facilitators and barriers to progress. It demonstrates that such an evaluation is possible, and we would like to acknowledge the courage of the SDO Programme in commissioning such a large and complex project.

On page 11 there is an impersonal list of people and organisations that have helped us. The task was huge and the list does not do justice to the volume of effort. I and the ENIGMA team pay tribute to the support and collaboration we have received. We would also like to thank the 3818 patients who completed questionnaires and gave us their views. Without this support the study this report would not have been possible.

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Abbreviations list

Abbreviation	Full term
12m PPQ	12 month Post Procedure Questionnaire
12m PRQ	12 month Post Referral Questionnaire
ANOVA	Analysis of Variance
BPR	Business Process Reengineering
BQ	Baseline Questionnaire
BSG	British Society of Gastroenterology
CD	Crohn's disease
CI	Confidence Interval
CNS	Clinical Nurse Specialist
CRC	Colorectal cancer
CT	Computerised Tomography
DNA	Did not attend
DoH	Department of Health
DOU	Degree of urgency
EDA	Exploratory Data Analysis
ENIGMA	Evaluating Innovations in Gastroenterology by the NHS Modernisation Agency
EQ-5D	EuroQol – 5D (QoL Questionnaire)
ERCP	Endoscopic Retrograde Cholangiopancreatography
EUS	Endoscopic Ultrasound
FOBT	Faecal Occult Blood Test
FS	Flexible sigmoidoscopy
FT	Foundation Trust
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
HRQoL	Health-related Quality of Life
IBD	Inflammatory Bowel Disease
IBS	Irritable Bowel Syndrome
ICC	Intraclass Correlation Coefficient
ID	Identification
IHI	Institute of Health Improvement
IT	Information Technology
JAG	Joint Advisory Group on Gastrointestinal Endoscopy
LGE	Lower Gastrointestinal Endoscopy
LREC	Local Research Ethics Committee
MDT	Multidisciplinary Team
MES*	Modernising Endoscopy Services
MeSH	Medical Subject Headings
MESPT	MES programme Team
MLM	Multilevel Model
MRC	Medical Research Council

MREC	Multi-centre Research Ethics Committee
NBCSP*	NHS Bowel Cancer Screening Programme
NE	Nurse Endoscopist
NHS	National Health Service
NHS SDO	National Health Service Service Delivery and Organisation
NHSMA*	NHS Modernisation Agency
NICE	National Institute for Clinical Excellence
NIHR SDO	National Institute for Health Research Service Delivery and Organisation R&D Programme
NPfIT	National Programme for Information Technology
OA	Open access
OGD	Oesophageal-gastro-duodenoscopy
OPCS	Office for Population Censuses and Surveys
PAS	Patient Administration System
PPQ	Post Procedure Questionnaire
PSG	Project Steering Group
R&D	Research and Development
RCT	Randomised Controlled Trial
SDO	Service Delivery & Organisation
SF-36	Short Form – 36 (QoL Questionnaire)
Sig.	Significance
T	Time
TIS	Trust Information Services
TWR	Two Week Rule
UGE	Upper Gastrointestinal Endoscopy
UK	United Kingdom
y	Years

* Also included in Glossary

Glossary

Activity	The number of procedures performed by the endoscopy unit
Change	Referred to as changes to layout, equipment, management structures and working procedures within the units. In this context they were positive, neutral or negative. 'Changes' had sometimes been used interchangeably or together with 'Innovations', generally referring to anything that has been implemented or changed within the service.
Cluster randomised trial (CRT)	An epidemiological experiment in which clusters of participants (e.g. all those receiving an endoscopy in a specific hospital) are allocated at random between the experimental intervention and the control intervention. This may be the best research design to evaluate whether a cluster-wide intervention is effective (Last 2001).
Control sites	The Control sites had unsuccessfully applied to participate in the MES programme but had noted an intention to redesign their services independently.
Endoscopist	A skilled person who is qualified to perform endoscopies. Endoscopists can be clinicians / consultants, nurses or GPs with special interests.
Gastrointestinal endoscopy	A procedure whereby a fibre optic camera is inserted into a natural orifice with the purpose of visualising the gastrointestinal tract.
Global Rating Scale (GRS)*	A web-based assessment tool that makes a series of statements requiring a yes or no answer. From the answers it automatically calculates the GRS scores, which provide a summary view of your service. It enables units to assess how well they provide a patient-centred service.
Hospital Episode Statistics (HES)*	The national statistical data warehouse for England of the care provided by NHS hospitals and for NHS hospital patients treated elsewhere. HES is the data source for a wide range of healthcare analysis for the NHS, Government and many other organisations and individuals
Improvement	A change to services that makes things better in structure, process or outcome.
Innovation	A change to the way services were run as part of a redesign programme that could be positive, neutral or negative in outcome.
Innovations form	Forms completed by endoscopy staff to describe the

	types of innovations introduced into their services at specific time points.
Intervention sites	The Intervention sites had successfully applied to participate in the MES programme and redesigned their services over a period of 12 months beginning Jan 2003.
Key Person	Someone who had led or played a key role in modernising an endoscopy unit.
Lost slots	The number of lost appointment slots due to DNAs or cancellations by the patient or the hospital.
Modernisation	Adopting new ways of doing things.
Modernising Endoscopy Services (MES)	The MES programme was set up by the NHSMA in 2002 to facilitate the redesign of 26 endoscopy units in England during 2003.
NHS Bowel Cancer Screening Programme	Bowel cancer screening aims to detect bowel cancer at an early stage (in people with no symptoms), when treatment is more likely to be effective. The NHS Bowel Cancer Screening Programme is now being rolled out nationally and will achieve nationwide coverage by 2009.
NHS Breast Screening Programme	The NHS Breast Screening Programme provides free breast screening every three years for all women in the UK aged 50 and over. Around one-and-a-half million women are screened in the UK each year.
NHS Modernisation Agency (NHSMA)	Established in April 2001, but closed in March 2005, the NHS Modernisation Agency was designed to support the NHS and its partners in modernising services and improving outcomes for patients. The Agency focused on four areas: improving access, increasing local support, raising standards of care, and capturing and sharing knowledge widely.
Process data	The term applied to service-related measures including Referral numbers, Wait >3m, Snapshot, Lost slots and Activity.
Quasi-experiment	An epidemiological study in which the investigators lack full control over the allocation of interventions but conduct the study as if it were a randomised controlled trial or a cluster randomised trial (Last 2001)**.**
Randomised controlled trial (RCT)	An epidemiological experiment in which individual participants are allocated at random between an intervention group receiving the experimental intervention and a control group receiving an alternative intervention. Under most circumstances this is the best research design to evaluate whether an intervention is effective (Last 2001).
Referral numbers	The number of referrals for an upper or lower GI endoscopy made to the endoscopy unit.

Snapshot	The total number of patients waiting at a specific point in time, irrespective of how long they waited.
Wait >3m	The number of patients waiting more than three months for an endoscopy.

* Also included in the list of abbreviations

The Report

1 Introduction

This project started in 2003, at a time when the NHS was changing in response to political, social and economic pressures. As with many other secondary care diagnostic services, referrals for endoscopy were increasing, and waiting lists lengthened. There was a heavy demand for rapid access to diagnostic facilities for patients with symptoms that raise the possibility of gastrointestinal cancer (oesophagus, stomach, pancreas, colon and rectum), which are commoner than in any other organ system and most need endoscopy of the upper or lower gut for diagnosis. Endoscopy also has a major role in the diagnosis and treatment of benign disease. As a result gastroenterology units were having increasing difficulty maintaining appropriate, timely assessment of all patients.

In response to these pressures, gastroenterology services in general and gastrointestinal (GI) endoscopy in particular, were starting to modernise. Many improvement initiatives have been implemented as a result of the NHS Plan (Department of Health 2000(b)), NHS Cancer Plan (Department of Health 2000(a)) and NHS Improvement Plan (Department of Health 2004), all of which specify the need for service modernisation to be patient-centred, and for patients to be seen within strict timeframes. For example, all patients with a suspected GI cancer must be seen in the secondary care setting within a maximum of 14 days following referral from their GP. Since 2001 NHS gastroenterology services have also had to implement full and partial booking (NHS Modernisation Agency 2003).

In 2002, the NHS Modernisation Agency (NHSMA) had embarked on a Modernising Endoscopy Services (MES) programme to support the modernisation of NHS endoscopy services in England to facilitate target attainment in terms of waiting times, booking and patient satisfaction. The MES programme had a number of aims and objectives to achieve in order to modernise and improve NHS endoscopy services in England [Ref NHSMA report of 2nd wave 2004]. These were:

- To redesign endoscopy services with the patient at its centre.
- To demonstrate that improvements can be made by a systematic approach to service redesign.
- To implement booking and choice.
- To identify examples of good practice to help other teams redesign their service.
- To demonstrate that Modernising Endoscopy Services – A Practical Guide to Redesign (MES) could work for a wider and more diverse range of endoscopy units and truly supported day-to-day service management.

Specific programme targets were listed as follows :

- No patient to wait over 3 months
- Increase in effective use of capacity

- DNAs below 2%
- Cancellations below 5%
- Booking implemented – full
- Booking implemented - partial
- No cancer patient to wait more than 31 days from GP referral to diagnosis
- 4 patient led changes
- Locally derived measures

The MES programme encouraged and supported detailed analysis of demand and supply in 169 collaborating endoscopy departments, and gave £10,000 to twenty-nine selected pilot sites to help them use a MES Toolkit™ to analyse their endoscopy services over the last three months of 2002, together with training and support from the MES itself. The Toolkit™ used the principles of service improvement and redesign to enable pilot sites to assess current services in response to seven 'challenges' (Investing for Health). These were as follows:

Challenge 1: Inequalities Widening
Challenge 2: Variable Quality & Safety
Challenge 3: Complex Services Difficult to Navigate
Challenge 4: Lack of Public Confidence in Services
Challenge 5: Lack of Upstream Investment
Challenge 6: Buying things that don't work
Challenge 7: Costs Increasing Faster than Income

Of those pilot sites which used the Toolkit™, twenty-six successfully applied for further funding of £30,000 to support redesign of their services over the calendar year 2003 in response to the eighth and final 'challenge' – that of promoting new ways of working.

The 70 unsuccessful sites which received no funding were eligible to use the Toolkit™ outside the remit of the MES programme. They were also able to attend a one-day training course in the autumn of 2002 and thereafter receive support in kind from the NHSMA.

The ENIGMA project set out to evaluate the impact of the NHSMA's MES programme on services, patients and professionals. We selected 10 sites which received funding to modernise (Intervention sites), and 10 Control sites that did not receive funding, but had access to support from the MES programme. We focussed our research on these 20 sites and followed them over five waves from April 2004 to April 2006. We also sought views from sites in England and Wales who had no engagement with the MES programme.

It should be noted that further policies emerged after the start of the ENIGMA study, in particular the introduction of the Global Rating Scale (Valori 2005) in 2005 and the Bowel Cancer Screening programme in 2007 (Weller, Moss, Butler, Campbell and Coleman 2006), both of which have added to the burden of modernising endoscopy services. We will discuss the impact of these in chapter 11.

1.1 Aims of the research

We set out to:

1. Evaluate innovations in service delivery and organisation initiated by the MES programme of the NHS Modernisation Agency.

2. Compare the accessibility and acceptability of the resulting models of service delivery with other new models.

3. Compare effectiveness and cost-effectiveness in improving outcomes assessed by patients and professionals.

1.2 Objectives

As we embarked on this multi-faceted study of complex innovations and changes introduced haphazardly in 20 sites over a period of years, with or without financial support from the MES programme, we found it necessary to refine our objectives set out in the original protocol (see Appendix 1), as follows:

1. To describe new models of service delivery designed to improve the endoscopic assessment of patients with new and continuing gastrointestinal (GI) disorders (chapter 3);

2. To compare the impact on patient outcome in those sites which received MES funding, with those that did not (chapter 4);

3. To evaluate changes in endoscopic activity and compare those sites which received MES funding, with those that did not (chapter 5);

4. To compare resources consumed by the NHS and by patients, and the impact on patient outcomes in those sites which received MES funding, with those that did not (chapter 6);

5. To assess the views of patients on the changes they experienced, and compare those sites which received MES funding, with those that did not (chapter 7);

6. To assess the views of professionals working in endoscopy units, on drivers and facilitators of change, and compare these views of professionals at sites which received MES funding, with those that did not (chapters 8 and 9);

7. To assess the views of general practitioners on the impact of change and compare those referring to sites which received MES funding, with those that did not (chapter 10);

8. To assess the value of our approach to the evaluation of ill-defined and heterogeneous change in the NHS (discussed in chapters 2 and 11).

1.3 Methods of evaluation

We used a mixed method approach, comprising:

1. Interviews with study sites, and a questionnaire, to document their innovation history;

2. A quasi-experimental design to measure impact on patient outcomes over two years;

3. Analysis of data from study sites to assess the impact of change on endoscopy activity;

4. Health economics to determine the costs of modernisation and patients' use of other NHS resources and assess these against the impact of modernisation on patient health status;

5. A qualitative approach to obtain the views of patients and professionals, using questionnaires, interviews and focus groups.

These methods are summarised in chapter 2, and described in detail in chapters 3-10. In order to simplify the presentation of the effects we looked for and the methods we used, we have also developed a 'matrix' approach, which is described at the end of chapter 2. It is then used again to summarise the results in chapter 11.

The refinement of our objectives reflected a pragmatic approach to the complexity of the NHS environment in which we were working and the changes we were seeking to evaluate. Thus we added an analysis of endoscopic activity data (which was not in our original proposal – see Appendix 1) and also included focus groups with representatives of Welsh sites entirely independent of the NHSMA, as well as five English sites who did not access MES support in any way. We worked in collaboration with the NHSMA until it was disbanded in 2005. At that time the MES programme changed and began to focus more on quality of services than endoscopic activity. The catalyst for change became the development and introduction of the Global Rating Scale (GRS), which our project did not seek to evaluate, but which clearly began to have a major impact towards the end of our study. We discuss this further in chapter 11.

In summary, this report is set out as follows:

2 Overview of methods

This chapter discusses the philosophy of our approach before summarising the methods we used to collect and analyse quantitative, qualitative and health economic data separately. A more detailed description of method is provided within the subsequent chapters.

2.1 Philosophy

Evaluation Framework

Evaluative health research in health and health care can be perceived as a continuum with individual clinical treatments at one end and health policy at the other. Interventions at the clinical end are increasingly being evaluated by Randomised Controlled Trials (RCTs) while policy evaluations tend to eschew experimental designs and adopt more context-dependent approaches such as "realistic evaluation" (Pawson and Tilley 1997) and the mixed methods used to evaluate total fundholding (Goodwin, Mays, McLeod, Malbon and Raftery 1998). The ENIGMA project lies between the two ends of this continuum.

In recent years, however, there have been efforts to apply the rigour of the RCT to clinical interventions that are more complex than single treatments such as drugs. The term 'complex intervention' describes an intervention made up of separate elements where it is difficult to tease out the 'active ingredients'. They can include interventions in the form of organisational or service modifications (i.e. SDO research) as well as those at the level of the individual patients (Medical Research Council 2000). The Medical Research Council's (MRC) framework for the design and evaluation of complex interventions includes a definitive RCT as phase 3 of the development and evaluation process, while recognising that modifications are likely to be required due to the complex nature of these interventions (Campbell, Fitzpatrick, Haines, Kinmonth, Sandercock, Spiegelhalter et al. 2000).

More recently, one of the authors has developed PHAIME – a manual for evaluating "area wide interventions" (Westley and Russell 2008). These are arguably even more difficult to evaluate than 'complex interventions', for three main reasons. First it is more difficult to achieve consensus about the nature of an intervention across independent areas than across collegial teams. Second it is more difficult to randomise individual areas for the purpose of rigorous evaluation than individual patients. Thirdly the Cluster Randomised Trial (CRT), which randomises areas, is even more difficult to implement rigorously than the RCT, which randomises patients. So, while Westley and Russell (2008) recommend using CRTs where feasible, they recognise that modification is often necessary to take account of the political circumstances in which area wide interventions are implemented. These often prevent the random allocation of treatments and lead to a quasi-experimental approach that opportunistically treats the political allocation of interventions 'as if' it were random.

In these terms ENIGMA has treated the modernisation of endoscopy services as an 'area-wide intervention'. It meets the definition of a complex intervention since modernisation includes many elements, some of which will be more 'active' than others in improving patient outcomes. Though

endoscopy services are hospital-based, they are intended to affect care throughout the catchment area of a hospital and are thus area-wide. Though we accept modernisation as a policy initiative, we have adopted a quasi-experimental approach by extending experimental methods to an unusual application.

Extending rigorous evaluation principles to new applications is consistent with the way in which research guidance is often introduced with strict requirements which are later relaxed. For example the RCT principles originally applied to fastidious (i.e. strictly controlled) trials were later extended to pragmatic studies; and the CONSORT statement (Moher, Schulz and Altman 2001) which was initially intended for trials with individual patient randomisation, was later extended to CRT trials. By describing how such extensions were applied in the ENIGMA study, we shall identify where this has proved difficult and offer guidance for future research. The following sections outline the issues which complicate this extension.

Defining the intervention

ENIGMA is evaluating an intervention which involved the extra financial and non-financial support provided by the NHS Modernisation Agency (NHSMA) to selected hospital sites to assist them in modernising their endoscopy services through the Modernisation Endoscopy Services project. During the period of study, however, all parts of the National Health Service (NHS) were operating in a climate where modernisation was an explicit overarching philosophy of the Department of Health (DoH). Moreover, it was evident that many sites had started the process of modernising before the MES programme began and the extent to which endoscopy services were already 'modern' varied between sites. The intervention was thus intended to be a catalyst to the modernisation activities that all NHS sites were, to one extent or another, already undergoing or being planned.

Design of the Intervention

The MRC framework on complex interventions encompasses design as well as evaluation issues, arguing that problems in evaluating complex interventions often arise because "researchers have not fully defined and developed the intervention" (Campbell, Fitzpatrick, Haines, Kinmonth, Sandercock, Spiegelhalter et al. 2000). It advocates a pre-clinical phase to ensure that the intervention is grounded in theory and a modelling phase to ensure that the intervention includes the relevant components – although it will be evaluated as a whole intervention.

The implication is that the intervention will be evaluated by the same people who are responsible for its design and development. While this may be reasonable in certain cases, there will clearly be circumstances where the two elements of the framework cannot be undertaken by the same teams. In these circumstances an ideal model would have separate design and evaluation teams but with good channels of communication between them and each taking independent decisions.

While the NHSMA was in a position to take forward the MES programme at a rapid pace, the evaluation team were constrained by the slower processes involved in designing the evaluation and then applying for and securing funding. By the time the latter was achieved the intervention was already being introduced which meant that the opportunity to establish communications with the NHSMA with regard to the early phases of the MRC framework were lost.

Identifying the start date for the intervention

The start date for intervention was taken as the first day that sites implemented their 12 month re-design programme – 1st January 2003. It was always anticipated, however, that many sites in the Intervention arm of the study would inevitably find it difficult to disentangle the modernisation efforts that were catalysed by the intervention from those that were already planned or taking place anyway. Thus, while a specific start date for the intervention can be identified, its catalysing features inevitably introduce complications not seen with the evaluation of many other complex Service Delivery & Organisation (SDO) interventions such as stroke clinics.

Selection of Intervention and Control sites

A quasi-experimental design was necessary *inter alia* because it was not possible to randomly allocate hospitals to Intervention or Control groups. The sampling frame was made up of all ninety-nine hospitals which had applied to take part in the second phase of the MES programme. Of these, twenty-six of the twenty-nine who piloted the Toolkit™ were chosen by the MA to receive the intervention leaving seventy which were not. Selection of Intervention and Control sites for the evaluation thus had to be made from within the already chosen groups rather than by random allocation. (Details of selection and recruitment of study sites are given in section 2.2).

This meant that allocation to Intervention and Control arms of the study was subject to the effects of the earlier NHSMA selection which raises the possibility that outcomes could be influenced by confounding factors which could not be controlled for. For example, if the NHSMA selected those sites that they felt were most likely to successfully modernise, then the end results could be due at least in part to the NHSMA's ability to predict the 'winners' as opposed, or in addition to, the effects of the intervention. The mixed-method approach taken in the ENIGMA study attempts to gain an understanding of these effects through its qualitative enquiries.

Pre-intervention preparation

A potential complicating factor was the fact that all participating sites had applied for phase 2 MES support. This meant that from the outset each had declared an interest in modernising its endoscopy service and had already gone through an in-house inspection of their services with a view to preparing the relevant documentation and supporting evidence. While it could be argued that this resulted in sites not being representative of all endoscopy services in England, such 'preparation for modernisation' was regarded here as analogous to the way that patients in a clinical trial will be worked up in the same way to the point where the clinician determines that they are suitable candidates for randomisation.

Table 1 illustrates the similarities and the differences between the Intervention and the Control sites based on their involvement or lack thereof in the MES programme.

Table 1. MES-related activities in Intervention and Control sites

Intervention	Controls
Application for MES programme developed	Application for MES programme developed
Advice and guidance from NHSMA and MES programme lead	Advice and guidance from NHSMA and MES programme lead
Access to Improvement Guides on NHSMA website	Access to Improvement Guides on NHSMA website
Compulsory Toolkit™ use and training	Optional Toolkit™ use and training
£30,000 from the MES programme to fund pre-approved redesign plans	No MES programme funding available
Focussed redesign plans based on pilot data collection and redesign plan	Ad hoc redesign plans
Strict data collection regime	No compulsory MES-directed data collection regime
Buddy events to disseminate and learn good practice from other MES programme sites	No formal environment to disseminate or learn good practice
Site visits by MES personnel for problem solving	No face to face contact with MES personnel
NHSMA one day conferences	No invitation to NHSMA conferences

In a further attempt to address this issue, it had originally been intended to include a third study group of genuinely independent sites (i.e. non-MES applicants) identified through the British Society of Gastroenterology (BSG), to act as a more 'pure' Control group while bearing in mind the climate of modernisation that was in place at the time. In the event these were not included within the experimental design as not enough sites could be identified. However, we did not drop this concept as a source of data and instead focus groups were held with representatives of non-participating BSG sites from both England and Wales which are reported in chapter 9.

Defining modernisation

Though the MES programme aimed to modernise endoscopy services, the NHSMA did not provide a precise definition of the term 'modernisation' or specify what was to be considered a modernisation activity or investment. Nevertheless this study has used the term 'modernisation' because that was the term used by the NHSMA and partly because unlike related terms such as 'improvement', it carries fewer connotations i.e. it is possible to assess whether or not modernisation led to an improved service.

2.2 Hospital recruitment

The twenty-six sites selected by the NHSMA for the MES programme were ranked by bed numbers and ten were selected using an assigned random number. These sites were designated "Intervention" sites. Replacements for sites declining to participate were selected by allocation of one before and one after systematic interval sampling.

Of the seventy sites that were unsuccessful in their application for the MES programme (but who were offered access to the data collection Toolkit™ software along with training and support to encourage their own data

collection), twenty-seven sites had indicated their intention to redesign independently of the NHSMA. Ten of these sites were selected using the same method as for the Intervention sites, as were the replacement sites. These sites were designated "Control" sites.

The 20 randomly selected sites were invited by letter to participate in the study and were offered £5,000 as an incentive to participate and to cover postage and other costs. Two researchers visited ten endoscopy units each in order to introduce the study, agree the key contact person and assess the current method of service delivery within the unit. Following an agreement to participate, an appropriate method of distributing the patient recruitment packs was agreed by each site.

Of the 20 sites originally consenting to take part in the study, one Intervention site withdrew prior to the study beginning, citing excessive workloads and was replaced by the first site on the Intervention replacement list. None of the original Control sites withdrew prior to the study commencing.

To ensure anonymity, all 20 sites were given a unique identification number that will be presented within brackets throughout the report when referring to a particular site in order to preserve anonymity. A more detailed description of each site is shown in Table 2.

After the first wave of patient recruitment, two sites, one Intervention and one Control, were withdrawn from the study after full agreement of the Project Steering Group (PSG) because they were unable to comply with the strict patient recruitment criteria. These sites were not replaced because the study had already begun. The Control site indicated that they were willing to participate in all other aspects of the study while the Intervention site chose to withdraw completely.

Table 2. Characteristics of participating endoscopy units

Site ID	Site status	Site type	Unit type † (at first visit)	Population served by the Trust	Nº. hospital beds	Nº. endoscopy rooms in unit in …	
						2003	2006
8	Full participation	Intervention	1, 4	1,500,000	1048	2	2
18	Withdrew completely	Intervention	1, 4	350,000	720	3	3
1	Full participation	Intervention	1, 4	250,000	547	2	2
13	Full participation	Intervention	2, 3	500,000	519	3	4
4	Full participation	Intervention	1, 4	500,000	512	2	2
19	Full participation	Intervention	2, 4	157,000	453	2	2
7	Full participation	Intervention	1, 3	250,000	413	2	2
6	Full participation	Intervention	1, 4	183,000	396	1	2
16	Full participation	Intervention	1, 4	138,500	320	2	2
11	Full participation	Intervention	1, 3	400,000	203	2	2
2	Full participation	Control	1, 4	500,000	1100	2	2
9	Full participation	Control	2, 3	265,000	968	2	2
17	Full participation	Control	1, 3	750,000	650	3	3
10	Excluded from patient recruitment	Control	1, 4	600,000	610	4	4
5	Full participation	Control	2, 4	500,000	520	2	2
12	Full participation	Control	2, 4	300,000	450	1	2
15	Full participation	Control	1, 4	350,000	430	3	3
20	Full participation	Control	1, 3	550,000	427	3	3
14	Full participation	Control	1, 4	640,000	368	1	2
3	Full participation	Control	1, 3	300,000	357	2	2

†Key: 1 = self-contained; 2 = part of another specialty; 3 = modern/new unit; 4 = older/original unit.

2.3 Innovation history of participating sites

Qualitative interviews were used to compile the innovation history of each participating site, supplemented by subsequent completion of an innovation form by each site.

2.4 Patient outcomes and waiting times

Patient outcomes data were obtained by postal questionnaires (see Appendices 3-6), in five waves over two years. In each of the five waves of the study, a total of 100 sequential patients at each site who had been newly referred by their GP or via an outpatient clinic for either upper or lower GI endoscopies were invited to complete health related quality of life (HRQoL) questionnaires on three occasions: at baseline (Baseline Questionnaire - BQ), after the planned procedure (Post Procedure Questionnaire – PPQ) and 12 months after the procedure (12 month Post Procedure Questionnaires - 12m PPQ). If the patient had not been sent an appointment for a procedure by 12 months they were sent a 12 month Post Referral Questionnaire (12m PRQ). Recruitment of patients took place in April and November 2004, April and October 2005 and April 2006.

The primary outcome measure was GSRQ (Williams, Russell, Durai, Cheung, Farrin, Bloor et al. 2006). Secondary outcome measures were the Short Form 36 (SF-36) (www.sf-36.org); EQ-5D (EuroQol Group) and GESQ (Williams, Russell, Durai, Cheung, Farrin, Bloor et al. 2006).

The data variables collected at BQ were:

- Patient refusal or non-response.
- Patient demographic details (age, gender, degree of urgency (DOU), procedure type, waiting time).
- GSRQ, SF-36, EQ5D, patient comments.

Repeat GSRQ, SF-36, EQ5D and patient comments were collected PPQ and 12 months after procedure data collection. The GESQ was collected post procedure only.

The waiting times for patients were compared for Intervention and Control sites at each wave of recruitment. Additionally a literature review was conducted to determine the impact of the two-week rule (TWR) for referral (Thorne, Hutchings and Elwyn 2006).

2.5 Endoscopy process data analysis

Endoscopy process data were collected from all 20 Intervention and Control sites to evaluate the impact of the MES programme on five outcome measures including Referral numbers, Number of patients waiting more than three months, Total number of patients waiting, Lost appointment slots and Activity over time. These five measures were compared between Intervention and Control sites at specific points in time. We also explored the availability of these data from all 20 endoscopy units and validated the data collected based on a comparative analysis using Hospital Episode Statistics (HES) data.

2.6 Health economics

This study is evaluating an intervention which involved extra financial and non-financial support by the NHSMA to selected hospital sites to assist them in modernising their endoscopy services. Given the underlying climate of modernisation which prevailed during the period of the study, the economics of ENIGMA can be seen more generally as being concerned with the costs and effects of modernising endoscopy services and the extent to which the intervention acted as a catalyst toward modernisation.

The economics component of ENIGMA addressed the following five questions;

1. What has been the cost of modernisation in each of the ENIGMA sites?

2. Did modernisation costs differ between Intervention and Control sites?

3. Was there a difference in other NHS resource use between Intervention site patients and Control site patients?

4. Was there a difference in time off work between patients in Intervention and Control sites?

5. Was there a difference in health outcomes (as measured by EQ-5D) between Intervention and Control site patients?

6. If results are non-dominant, what are the extra costs (+ or -) per Quality Adjusted Life Year (QALY) and per unit of GSRQ of Intervention versus Control site patients?

2.6.1 Health economics interviews

Two semi-structured interviews were held one year apart with key personnel at each study site to identify the resources which had been deployed to facilitate modernisation of the endoscopy service. Identified incremental resources were classified as investments which produce a flow of benefits over time, one off activities and recurring revenue costs. These were valued using standard methods. Marginal costs per patient were derived by dividing the total cost of modernisation at each site by its endoscopy Activity.

2.6.2 Health economics questionnaire

NHS resource use data and patients time off work were obtained from patients via the BQ, PPQ and 12M PPQ. These data were multiplied by unit costs to assess primary care, secondary care, drug and total NHS costs. Costs were adjusted to account for baseline effects, group effects, and variations in length of time between baseline and subsequent questionnaires. Bootstrapping methods were applied to account for skewed cost data. Patients reported time off work was also examined.

2.7 Patient views

Telephone interviews were undertaken with consenting patients referred either as urgent or non-urgent, to the nine Intervention and nine Control sites, to elicit responses on their experience of the referral process to enable an understanding of their views of the accessibility and accessibility of service provision. Semi-structured interviews took place after the second and fifth waves of patient recruitment. The interviews were recorded and transcribed and analysed using content analysis.

2.8 Professional views at study sites

Semi-structured interviews were undertaken with clinicians and key people based in the 10 Intervention and 10 Control sites, who had played a role in modernising endoscopy units, To enable an understanding of the impact of the MES programme, the interviews aimed to capture the views of clinicians and key people on innovations in service organisation and delivery, clarifying their perceptions of the accessibility and acceptability of the innovations and exploring how each unit functioned to consider what innovations had been made or were planned. A second round of interviews was conducted two years later, with the same clinicians and key people to clarify what had taken place in the intervening two years and capture changes in the perceptions of participants. The interviews were recorded and transcribed and analysed using thematic content analysis.

2.9 Professional views at non-study sites

2.9.1 Recruitment and sample

We were unable to identify enough study sites to be an independent group. Instead, we ran focus groups in England and Wales. Focus group participants were accessed through the British Society of Gastroenterology's (BSG) list of all registered gastroenterologists in the UK. Key figures in gastroenterology, including surgeons, physicians, nurse managers and nurse leaders were sent details of the study asking those who were committed to genuinely independent redesign of their gastroenterology services, to contribute to the study by taking part in a qualitative focus group.

2.9.2 Method

Following written consent of participants, each focus group followed a similar procedure, lasted approximately one hour and was tape recorded and transcribed. Focus groups were facilitated by the ENIGMA qualitative research lead (FR) and one of the two senior research officers working on the qualitative elements of the study (AS, GJ). In each case an observer was present to take notes, manage the tape recording equipment and discuss their overall impression of the focus group with the facilitator at the end of the session. The focus groups were facilitated according to a pre-designed interview schedule. The same schedule was used for all focus groups with the Welsh groups having one additional question regarding the NHSMA's support for English units in terms of the impact of the NHSMA work on English units and impressions of the rate and extent of modernisation across England and Wales. The interview schedule was devised in keeping with the

research literature and to respond to the study aims and objectives and other qualitative datasets – patient and professional interviews. Consequently, the interview schedule concentrated on issues relating to: staffing, funding, impact, extent and rate of change and changes undertaken across units.

The focus groups encouraged all participants to have an equal say in discussions and many questions were directed to each participant in turn. In recognition of their contribution, on the day of the focus group, participants were reimbursed for their time.

2.10 GP views at study sites

All GPs with patients in the study were sent a questionnaire at the end of Wave 5 asking for their perceptions of the impact of the changes that had occurred in the endoscopy unit participating in the study. The questionnaire asked GPs to complete "yes or no" 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 as either better, neither better nor worse, or worse. GPs were also invited to make specific comments for qualitative analysis.

2.11 The evaluation of the effects of modernisation using the Method for Aggregating the Reporting of Interventions in Complex Studies (MATRICS)

In view of the complexity of this study we developed a matrix approach to summarising the effects we were seeing, the methods used and the findings. The first two layers of this matrix are shown in Tables 3 and 4 (layer 1 – effects sought and layer 2 – methods used). Each effect is numbered and cross referenced to the appropriate method(s) using this number. The resultant alpha-numeric code is then cross referenced to the findings in layer three, which are summarised in Table 71 (a, b and c) in chapter 11. We have designated this approach MATRICS (Method for Aggregating The Reporting of Interventions in Complex Studies).

Table 3. Effects[1] that were sought (MATRICS layer 1)

Effects on patients	Effects on endoscopy services	Effects on the rest of the NHS and society
1 - Patient Quality of Life **[B,D]**	**6** - Cost of modernisation **[H]**	**14** – Patients' time off work **[I]**
2 - Total health benefit **[C]**	**7** – Service performance **[A]**	
3 - Patient experience of referral process **[E]**	**8** – Organisation, function and process of service delivery **[E, F, G, J]**	
4 – Patient satisfaction with endoscopy **[L]**	**9 –** Accessibility to services **[E, F, K]**	
5 – Waiting times **[E, M]**	**10 –** Appropriateness and acceptability of services **[F, G, K]**	
	11 – Reliability and availability of routinely collected process data **[A]**	
	12 – Patient use of drugs **[I]**	
	13 – Patient use of primary and secondary care resources **[I]**	

[1]Outcomes defined specifically for each perspective, according to Aims and Objectives.

Table 4. Methods used (MATRICS layer 2)

Code	Method
A [7, 11]	Process data analysis
B [1]	Analysis of SF36 scores
C [2]	Analysis of EQ-5D scores
D [1]	Analysis of GSRQ scores
E [3, 5, 8, 10]	Semi-structured patient interviews
F[8, 9, 10]	Interviews with professionals and key people
G[8, 10]	Focus groups
H [6]	Health economic site visits
I [12, 13, 14]	Health economic patient reported resource use
J [8]	Innovations form
K [9, 10]	GP questionnaire
L [4]	GESQ (patient satisfaction questionnaire)
M [5]	Analysis of time difference between referral and procedure

2.12 Ethics

Ethical approval from the Multi-Centre Research Ethics Committee (MREC) for Wales (reference number 03/09/74) was received in November 2003 and Local Research Ethics Committees (LRECs) of the corresponding study sites were informed of the study accordingly. The Research and Development (R&D) departments in all the NHS Trusts involved in the study each granted approval prior to the commencement of the study. Both researchers obtained honorary contracts from all 20 Trusts.

The time taken for R&D approval varied in each site, with a minimum of one day and a maximum of 150 days (Elwyn, Seagrove, Thorne and Cheung 2005).

3 The innovation histories of study sites

3.1 Executive summary

This part of the evaluation sought to identify which innovations each site had implemented and to compare the number of innovations introduced by Intervention and Control sites. The innovations documented in this chapter include any changes made to the way the service was run, whether they were completely new ways of working, or simply "doing more of the same", so long as the change was made with a view to improving the service or the patient experience.

An Innovations Form with a comprehensive list of possible innovations was sent to all endoscopy units, and that asked them to indicate whether they had introduced any of the changes and if so, when they first implemented them (2000/02, 2003 or 2004/06) to indicate which were introduced prior to, during and after the MES programme. Each site was given a score to reflect any proactive modernisation plans with innovations introduced in 2000/02 scoring most highly and those introduced in 2004/06 scoring lowest. Mean scores were analysed using two-way Analysis of Variance (ANOVA) to determine whether there was any significant difference in their scores over time and between Site types (Intervention and Control).

Nineteen of 20 sites completed the form. Results indicated that on average, the Intervention sites had implemented more innovations than the Control sites although the difference was not statistically significant. Two-way ANOVA indicated that the scores differed significantly over time within Intervention sites but not in Control sites. Scores did not significantly differ between site types at any of the three time points tested.

3.2 Methods

3.2.1 Questionnaire design and allocation

A list of innovations occurring in the study sites since 2000 was compiled by the researcher in the course of the first round of qualitative interviews with clinicians and key people working in the 19 participating endoscopy units (see chapter 8). From this data, an "Innovations Form" (see Appendix 2) 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 Hospital 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 revised with an additional 2006 column and resent to the original respondents in May 2006 to update the entries as far as April 2006. A third reminder and revised form was sent to sites who had not returned an Innovations Form at that time.

3.2.2 Analysis plan

A description of the most commonly implemented innovations was drawn up 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 Intervention and Control sites.

Each innovation listed on the Innovation Form was scored according to whether it had been implemented or not and if so, when. The scoring system was 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"; 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 where appropriate or were included as an additional innovation.

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. The scores from the three Timeframes were analysed using a two-way Analysis of Variance (ANOVA) to determine whether there was any significant difference between Site type and between Timeframes and whether there was a significant interaction effect. P-values ≥ 0.05 were considered to be statistically significant.

3.3 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 Intervention sites (1 and 16). These forms were included in the analysis irrespective of the 2006 missing data, since any missing data would 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.

3.3.1 Innovations introduced – a descriptive summary

Of the innovations listed on the questionnaire, all were implemented by a minimum of two sites in each Site type out of a maximum of nine for the Intervention sites and 10 for the Control sites. Table 5 illustrates how many Intervention and Control sites implemented each innovation, split according to when they were first implemented.

There was no significant difference between the Intervention and Control sites with regard to the overall number (mean 91.7 ± 37.1 vs 81.3 ± 19, p = 0.446) or in the types of innovation introduced.

**Table 5. The number of Intervention and Control sites implementing any of the 65 innov
2006.**

Innovation category	Innovation type	Number of Intervention and Co innovations d			
		Intervention (n = 9)			
		2000/02	2003	2004/06	20
New / additional staff	Nurse endoscopists	4	2	1	
	GP endoscopists	1	1	0	
	Consultants	2	1	2	
	Link / escort nurses	2	0	2	
	Health care assistants	2	1	1	
	Receptionist / other clerical staff	2	1	1	
	New management / leadership	3	0	2	
	Data collection staff	1	0	1	
Alteration of roles	Changing roles of medical staff	0	1	1	
	Changing roles of clerical staff	1	2	2	
	Clerical duties taken from nurses	1	2	2	
New nurse responsibilities	Nurse led clinic(s)	2	0	3	
	Nurse led consent	3	1	2	
	Nurses performing cannulations	4	1	2	
	PEG nurses	4	1	2	
	Training nurses to be nurse endoscopists	2	2	1	
New working practices	New referral procedure(s) into the unit	2	0	3	
	Validation of referrals	2	2	2	
	New guideline(s) / protocols	1	3	2	
	Triage of emergency patients	2	0	3	
	Pre-assessment clinics	1	1	1	
	DNA strategies	2	2	1	
	Cancellation strategies	2	2	1	
	"6-week notice period for leave" policy	3	2	3	
	New procedure(s) performed	3	2	1	

	One-stop clinics / dedicated training lists	1	0	4	
Increasing activity	Extra slots for emergency bleeds, etc	1	0	4	
	Scheduling extra list(s) (Mon to Fri)	0	0	5	
	Increasing the length of the working day	0	0	4	
	Weekend / out of hours working	2	2	2	
Waiting list management	Validation of waiting lists	2	1	4	
	Pooling waiting lists	3	1	2	
	Waiting list initiative sessions	1	1	1	
Booking	Open access booking	2	0	2	
	Full booking	2	1	2	
	Partial booking	2	4	2	
Structural changes	New hospital / unit	1	1	1	
	Structural alterations to current unit	1	2	1	
	Increasing capacity in recovery area	0	1	1	
	Centralising admin in one place	1	2	0	
	Moving some endoscopy externally	1	1	1	
	Refurbishment of reception / endoscopy suite	2	3	1	
Analysis of working practices	New / improved in-house data collection	1	3	0	
	Demand and capacity studies	3	3	2	
	Audits	5	1	2	
	Process mapping	2	4	0	
	Patient surveys	4	2	1	
Patient experience	New information leaflets for patients	3	2	2	
	Improving patient privacy & dignity	1	3	1	
	Home bowel preps	5	1	1	
	Improving experience of inpatients	1	1	3	
	Improving experience of diabetic patients	1	1	4	
	Improving experience of patients with other comorbidities	1	0	4	
Staff experience	Staff training / development	4	2	0	
	"Protected time" for staff to meet / train	1	1	2	
	Surveying staff on changes wanted	0	2	2	

	New / improved staffroom	2	3	0	
	Endoscopy groups / staff meetings	3	1	1	
	Improving staff communication	2	2	1	
Miscellaneous	New medical equipment	3	2	2	
	New IT equipment / software	1	3	2	
	Raising the profile of endoscopy	0	4	2	
	Advice or help from within the Trust	1	3	1	
	Advice or help from external agencies	1	2	0	
	Open days for hospital staff / patients	3	3	0	

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

3.3.2 Analysis of innovation scores

All sites were scored as previously described. All scores and ranks are described for each Intervention and Control site in Table 5. The distribution of the Site types were fairly evenly spaced throughout the ranks, with an Intervention site as the top scoring site and the highest position for a Control site at third place. However, the lowest two ranks were also Intervention 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 programme innovations) more highly. Of these, seven were Intervention sites (1, 4, 7, 11, 13, 16 and 19) with scores ranging from 27 to 129, while the other six were Control sites (2, 5, 9, 15, 17 and 20), with scores ranging from 30 to 84.

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 Intervention sites (6 and 8) and the remaining four were Control sites (3, 10, 12 and 14). The 2003 scores ranged from 16 to 50 for the Intervention sites and from 36 to 42 for the Control sites while the 2004/06 scores ranged from 30 to 44 for the Control sites (no Intervention sites scored more highly for 2004/06).

When the scores for each Timeframe for both Site types were analysed using two-way ANOVA (see Table 6), there was no significant difference between Intervention and Control groups but there was a significant difference in the scores within each site at each Timeframe ($F(1, 17) = 8.031$, $p = 0.008$). Post hoc analysis within each Site type found that the significant difference for Intervention sites was between 2000/02 Vs. 2003 ($p = 0.048$) and 2000/02 Vs 2004/06 ($p = 0.009$), but not between 2003 Vs 2004/06 ($p = 1$). There were no significant differences in scores for Control sites over time.

Table 6. A breakdown of the Innovation Form scores for each Timeframe and the Total Innovation scores achieved by each Intervention and Control site, listed according to rank.

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

Table 7. Illustration of the results of the two-way ANOVA for the innovation scores from Intervention and Control groups. Significant values are highlighted in bold.

Intervention group means for 2000/02, 2003, 2004/06	Control group means for 2000/02, 2003, 2004/06	Within-subject effects (F ratio, sig.)	Between-subject effects (F ratio, sig.)	Interaction effects (F ratio, sig.)
55, 22.7, 14 (n = 9)	40.2, 19.8, 21.3 (n = 10)	8.031, **0.008**	0.608, 0.446	0.918, 0.365

3.4 Discussion

The most striking conclusion from these data was that there was no difference between the Intervention and Control sites in the level of innovation they achieved, though it is clear that for both groups the greatest innovation activity occurred early in the study timeframe.

While not statistically significant there were however on average more innovations implemented by Intervention sites than by Control sites

suggesting that the MES programme may have encouraged the implementation of more innovations not only during the course of the project but after the project had ended.

Closer examination of the types of innovations implemented by all nine Intervention sites - six week notice period for leave policy, partial booking, demand and capacity studies and audits - revealed that they were closely tied in with the targets allocated and the advice given by the MES programme team (MESPT), as described in chapter 1. The only innovation to be implemented by all nine Intervention sites and all 10 Control sites was audit. Of those innovations implemented by the Control 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 Intervention and Control sites in terms of the number implementing each innovation type, there were 11 innovations that were implemented in higher numbers by the Control sites than the Intervention sites. Conversely only four innovations were implemented in higher numbers by the Intervention sites than the Control sites. This was surprising, since some of these innovations were considered by the researcher to be expensive, although it is feasible that the increases in staff 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 Control sites were keen to introduce or enhance methods of communication, both internal and external, than the Intervention sites. They also appeared to be more amenable to data collection than the Intervention sites, a finding borne out in chapter 5 of this report. This issue is discussed more comprehensively in that chapter.

The financial implications of implementing innovations may have reduced the number of innovations introduced by the Control sites. Some would have had significant budget implications (additional staff and new equipment) and while funding in Control sites may have been secured from other sources (e.g. charitable donations, business plans), the majority would not have had a large amount of money with which to implement changes. They also would not have had the same access to advice from the MESPT regarding how best to analyse and modernise their services. Many changes implemented by the Intervention 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 Control 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 Control sites were equally as proactive in their attempts to modernise their endoscopy services as those sites chosen to be MES programme 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 programme, thereby artificially overestimating the impact of the MES programme. The analysis of the Innovation Forms confirms that the Intervention and Control sites did not

appear to be extremely different in their pre-MES programme redesign plans.

The ranking of the sites based on their scores revealed that Intervention sites held the two top and bottom spaces on the one to 19 scale. Overall, there were marginally more Intervention sites than Control sites populating the top ten spaces. This was not surprising, considering that the Intervention group implemented more innovations on average than the Control group. This result suggests that these Intervention sites were more proactive in their modernisation programmes, implementing changes at an earlier point in time than the Control sites which would have been reflected in their scores in earlier Timeframes.

The analysis of the innovation scores from each site grouped according to Site type identified a significant difference in the innovation scores of both Site types over the three Timeframes analysed due to a large decrease in the scores from 2000/02 to 2004/06. Post hoc analysis confirmed a statistically significant difference between 2000/02 and both 2003 and 2004/06. This implies that most sites were proactive in their modernisation initiatives, but that over time the number of new innovations introduced declined. This may have been due to the fact that the researcher only scored the innovation when it was first implemented so the innovation would not have been scored for the subsequent Timeframes if the innovation had been re-introduced as either a repeated or an improved version of the innovation. This finding would also have been affected by the nature of the scoring system, which gave a higher rating to those sites implementing innovations earlier on.

When the innovation forms were returned, only four of the Intervention sites (4, 7, 13 and 19) had ticked the box indicating that they had "help or advice from external agencies". This meant that five Intervention sites did not acknowledge the role of the MES programme in their modernisation programmes. Five Intervention sites and nine Control 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. Both of these issues are discussed in more detail in Chapter 5.

4 Patient outcomes and waiting times

4.1 Executive summary

4.1.1 Objectives

To assess the effect of modernisation implemented at each study site on patients Health-related Quality of Life (HRQoL) and waiting time.

4.1.2 Methods

We used a quasi-experimental design. Patients aged over 18 years referred for a upper gastrointestinal endoscopy (UGE) (gastroscopy or oesophago-gastro-duodenoscopy) flexible sigmoidoscopy (FS) or colonoscopy for the investigation of GI symptoms were recruited from 18 study sites in five waves from April 2004 until April 2006. In each wave patient HRQoL scores were assessed 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). The questionnaire process was piloted in October 2003. Patient waiting times were calculated by comparing the date the PPQ was completed with the date of referral from the study register.

4.1.3 Statistical analysis

Analysis of Variance (ANOVA) was conducted to determine whether there were any significant differences between the HRQoL scores reported by patients having a UGE, FS or colonoscopy. Differences in HRQoL scores over time were assessed by Repeated Measures ANOVA. Multilevel modelling was conducted to determine if there were any significant differences between the Control and Intervention sites with respect to the GSRQ (Gastrointestinal Symptom Rating Questionnaire), the two Short Form 36 (SF-36) summary measures (the Physical Component Summary (PCS) and the Mental Component Summary (MCS)) and the GESQ (Gastrointestinal Endoscopy Satisfaction Questionnaire). One way between-groups analysis of covariance comparisons were conducted to determine if there were any significant differences between the Control and Intervention sites with respect to the Euroqol-5D (EQ-5D). Independent samples t-tests were used to determine whether there were any differences between the Intervention and Control sites in waiting time.

4.1.4 Results

9154 patients were assessed for eligibility, 7974 were invited, and 3818 consented to take part. Non-respondent analysis showed some differences in age and procedure types between the consenters and the non-consenters. Data were adjusted to take account of these differences in analysis of patient outcomes. There was a significant improvement in both disease specific (GSRQ) and generic (SF-36) and (EQ-5D) HRQoL following all types

of endoscopy procedure. There was no difference between the Intervention and Control groups in any of the HRQoL measures. Intervention patients waited on average seven days less than the Control patients for their Endoscopy procedure, but this was not translated into improvements in patient outcomes. There was no overall change in waiting times between April 2004 and January 2007.

4.2 Objectives

The primary objective of this part of the study was to assess the effect of innovations implemented at each study site on patient HRQoL and waiting times, taking into account factors which might also have an impact (gender, age, type of procedure, degree of urgency (DOU), time at follow-up and study site). The effect of the MES programme on patient waiting times was also assessed.

4.3 Methods

Patient HRQoL scores were assessed at three points in time: at the time of the patients' referral using the BQ, immediately after their procedure using the PPQ and 12 months after the procedure using the 12m PPQ. If a procedure had not taken place within one year of referral, a 12 month Post Referral Questionnaire (12m PRQ) was sent.

Each of the study questionnaires contained the following sub-sections: the Medical Outcomes Study (SF-36 v2) questionnaire (purchased from www.sf-36.org/), the EQ-5D questionnaire (located at www.euroqol.org) and the GSRQ (Williams, Russell, Durai, Cheung, Farrin, Bloor et al. 2006). A fourth questionnaire, the GESQ (Williams, Russell, Durai, Cheung, Farrin, Bloor et al. 2006), was included in the PPQ. In addition to completion of the quantitative HRQoL sections, patients were also given the option to make comments regarding specific aspects of their treatment.

Patient HRQoL scores were collected from the questionnaires of all consenting patients from five waves of recruitment. The questionnaires were scanned using a Canon DR5020 scanner and the scores were downloaded into SPSS™ v13.0 (Lead Technologies Inc. 2004, USA) for analysis. Individual HRQoL sub-scale scores for each of the scales were calculated according to the developer's guidelines. The effect of study sites were analysed with SPSS and confirmed with MLwiN v2.0 (Rasbash, Steele, Browne and Prosser 2004).

Patient waiting times were calculated by comparing the date the PPQ was completed with the date of referral from the study register.

4.3.1 Participating patients

Only those patients over the age of 18 years who were referred for a UGE (gastroscopy or Oesophageal-Gastro-Duodenoscopy (OGD)) or Lower Gastrointestinal Endoscopy (LGE) (Flexible sigmoidoscopy or colonoscopy) for the investigation of GI symptoms and did not exhibit any of the exclusion criteria (outlined in Section 2.4) were considered for the study.

Following the withdrawal of two sites from the patient recruitment aspect of the study, a total of 9,000 patients were invited to take part. Units were limited to recruiting a maximum of 20 patients per day to ensure a fair allocation of patient types throughout a week.

Exclusion criteria for patients were issued to all staff responsible for allocating the study questionnaire packs, which were:

1. Patients aged under 18y
2. Patients with a learning disability
3. Patients who are severely ill or have a terminal illness
4. Patients in emergency situations
5. Patients with a mental illness
6. Prisoners or young offenders
7. Patients already participating in a research study
8. Patients who were undergoing repeat or surveillance procedures
9. Patients who do not speak English

On receipt of the referral documentation, the endoscopy staff posted the study questionnaire packs to the home address of eligible patients, and completed a study register with the patients' contact and referral details. The register was updated and returned to the study team on a regular basis.

Patients wishing to participate in the study were asked to complete a BQ at home and sign the consent form before returning it to the study team using the Freepost envelope provided. Patients refusing to participate were asked to return the blank BQ and in doing so, were not contacted again.

A system of reminders was set up to encourage patients to complete the BQ. If a patient did not return the BQ within two weeks of the hospital sending it, the study team sent a reminder letter and a second, identically numbered BQ, using the information provided by the study register. A reminder telephone call was made a minimum of two weeks after the reminder letter was sent. A postcard was sent as a final reminder when no contact was made by phone, or if contact was made but the questionnaire was not still returned after a further two weeks. Following the reminders, if a patient still did not respond, they were designated "non-responders" and were not pursued any further. Reminders were not sent to patients whose appointment date had passed.

Patient outcomes were measured at the time of patient referral, immediately after procedure and 12 months after procedure using the generic health questionnaires SF-36 Version 2 and EQ-5D, and a GI symptom-specific questionnaire called the GRSQ. The PPQ contained an additional questionnaire called the GESQ. This was a patient satisfaction questionnaire that addressed how the patient rated the hospital, skills of the team, pain and discomfort and information received before and after their procedure.

These questionnaires were used to obtain patients' HRQoL scores, use of NHS resources including drugs and time off work (reported in Chapter 6). The HRQoL sections elicited patients' assessment of their health status for both GI-specific conditions and general health at the time of referral, immediately after the procedure, and one year after the procedure. All three questionnaires were completed by the patient at home. The format of all questionnaires was designed in-house using TELEform™ version 10 (Teleform Enterprise 2003, USA) and professionally printed by Zenith Media (Cardiff, Wales).

The first pack to be sent contained the BQ previously described. The second pack contained the PPQ which was sent to patients by the study team once they had had their procedure. The last pack contained the 12M PPQ and was sent by the study team a year after their procedure date (see Figure 1).

Additional questionnaire packs were sent to patients who had not had their procedures more than 12 months and 24 months after their referral date. These contained the 12 month Post Referral Questionnaire (12M PRQ) and in some cases, the 24 month Post Referral Questionnaire (24M PRQ). Once the patient had attended their procedure, they were sent the second pack containing the PPQ (see Figure 2).

Figure 1. Allocation of all study questionnaires when the patient has their appointment within 12 months of being referred.

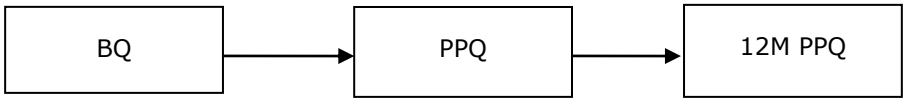
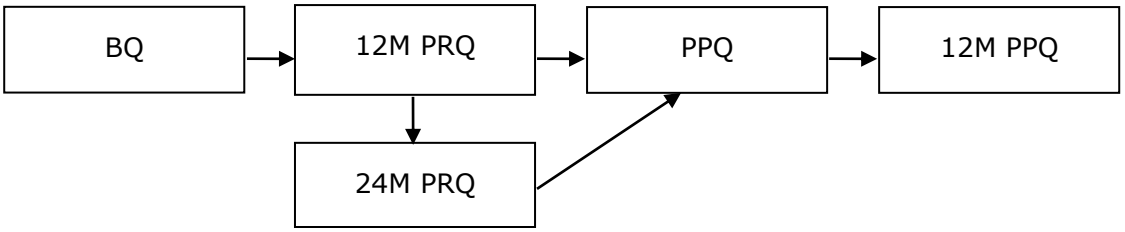


Figure 2. Allocation of all study questionnaires when the patient has their appointment more than 12 months, and possibly 24 months, after being referred.



All study packs were pre-packed by the study team and were uniquely numbered using a five-digit system whereby the first two numbers ran from 1-20 and represented the hospital identification number. The last three numbers ran from 1-500 and identified each patient and which wave of recruitment they were from.

The first study pack posted to the patient by the hospital contained the BQ, a letter to the patient on hospital headed notepaper with the signature of the local hospital consultant affiliated with the study on the bottom, a "Frequently Asked Questions" sheet containing contact numbers, a Freepost envelope and a green postcard, which patients were asked to complete with the date of their endoscopy appointment and return the day after they had attended their procedure. On the outside of the pack were two blue hospital postcards that were removed prior to posting the pack to the patient and attached to the patients' notes or referral letter by the endoscopy staff. On the day that the patient attended for their procedure, one of the postcards was returned to the study team to inform them whether the patient had attended or, if not, of the outcome (if the patient was given a second appointment or was discharged back to the GP). The second postcard was returned to the study team if they attended a subsequent appointment.

4.3.2 The pilot study

The questionnaire process was piloted in October 2003 in the endoscopy unit of Singleton Hospital, Swansea (not one of the ENIGMA study sites) with 160 packs over a period of two months. The pilot indicated a response rate of only 38%, a refusal rate of 27% and a non-responder rate of 35%.

The documentation was amended and a system of following up patients who did not return the BQ was established before a second phase was initiated with 50 packs in March 2004. The response rate increased to 59%. The refusal rate was still 27%, but the number of non-responders had reduced to 14%. The main study began with all changes implemented in the second pilot as standard.

4.3.3 Outcome measures

The primary outcome measure was GSRQ, secondary outcome measures were the SF-36, EQ-5D and GESQ.

4.3.4 Statistical methods

The primary analysis was by intention to treat, i.e. all patients who were properly recruited were included even if they did not follow their intended pathway, and all significance tests were two-sided and set at a significance level of 0.05. Correction tests were not applied to the data because they are highly conservative and were likely to mask any significant results (Perneger 1998). Instead we examined the proportion of significant tests in relation to the number of tests performed to determine if the results represented true differences or mere chance. For example in applying a significance level of 0.05 we would expect at least one in 20 tests to be significant by chance. If a greater proportion than this were significant this would represent a true difference in outcomes.

In addition, ANOVA plus post-hoc tests comparisons were carried out to determine if there were any significant differences between the consenter, responder and non-responder groups at recruitment. Prior to any statistical comparisons between the Intervention and Control groups being carried out, a sensitivity analysis was undertaken whereby the proportion of consenters, refusers and non-responders were compared for their demographic characteristics including age, gender, DOU, procedure type and waiting time, split according to the corresponding wave of patient recruitment. The generalisability of the consenting group of patients to the general population was tested by a comparison of the consenters and non-consenters using Chi-squared tests for categorical data variables and independent samples t-tests for continuous data variables. Where a 2x2 contingency table was analysed, the Yate's continuity correction was used.

Post hoc analysis was done to determine the source of any significant differences.

The refusers and non-responders were later merged into a non-consenter group and any baseline characteristics that were found to be significantly different between the consenting and non-consenting groups were subsequently weighted in the consenting group to ensure that it was representative of the whole patient population.

Missing items within individual outcome measures were treated according to the scale developer's instructions for that particular measure. Where data were missing for the 12M PPQ values, the last case carried forward policy was adopted. For example where the BQ (time point 0) and PPQ (time point 1) data were present but the 12m PPQ (time point 2) data were missing, data were carried forward from the PPQ. A further weighting of the carried forward PPQ, based on the relative relationship of the PPQ to the 12m PPQ data, was not adopted in this instance as it was anticipated that it was unlikely to have any major impact on the results. Mean substitution was used for other missing items.

Independent samples t-tests were used to determine whether there were any differences between the Intervention and Control groups in waiting time. In addition the difference between the study groups was assessed within each of the five waves of recruitment.

Baseline scores were analysed using Analysis of Variance (ANOVA) and post hoc tests with data split according to procedure type to determine whether there were any significant differences between the scores reported by patients having a UGE, FS or colonoscopy.

Data were also analysed to determine whether there were any significant differences in HRQoL scores over time using a repeated measures analysis and post hoc analysis with the data split according to procedure type to determine whether the mean HRQoL of patients having UGEs, FS or colonoscopies improved significantly from the time of referral to the time at 12 months post procedure.

Multilevel modelling was conducted to determine if there were any significant differences between the Control and Intervention sites with respect to the subscales on the GSRQ, the two SF-36 summary measures (the Physical Component Summary (PCS) and the Mental Component Summary (MCS)). The resultant models would take account of site effects, in particular of systematic differences between the models of service delivery adopted by each centre. The primary dependent variable was the 12m PPQ scores (for each of the three outcome questionnaires). Patient-level covariates included: the site type (Intervention or Control), BQ scores, adjusted age, gender, adjusted procedure type, DOU, time to 12m PPQ, and waves of recruitment. Site-level covariates included: innovation score, teaching hospital status and bed size. Multilevel modelling was also performed on the patient satisfaction (GESQ) data with each of the sub-scale scores as the dependent variable, with a similar set of covariates. As this measure was only used in the PPQ, BQ scores were not included and time to PPQ was used instead of time to 12m PPQ.

Where more comprehensive models were slow or failed to converge, the findings from a less complex model were reported. Similarly, when the final Hessian matrices were negative, the findings from a less complex, flat model were reported. The speed of convergence and the final Hessian matrix were checked to ascertain the validity of the fitted models. Goodness of fit tests based on maximum log likelihood were used to assess how well the models fitted the data.

The size and the direction of the effect of individual covariate on the dependent variable would be estimated by the size and the sign on the coefficient (positive or negative). The coefficient showed how much the dependent variable was expected to increase (if the coefficient was positive)

or decrease (if the coefficient was negative) when that covariate increased by one, holding all the other covariates constant.

One way between-groups analysis of covariance comparisons were conducted to determine if there were any significant differences between the Control and Intervention sites with respect to the EQ-5D outcomes. The independent variable was the assigned group (Intervention or Control) and the primary dependent variable was the 12m PPQ scores. BQ scores, age, gender, procedure type, DOU, time to 12m PPQ, teaching hospital status, bed size, wave of recruitment and innovation scores were used as covariates in the analysis. Preliminary checks were conducted to ensure that there was no violation of the assumptions of normality, linearity, homogeneity of variances, homogeneity of regression slopes, and reliable measurement of the covariate.

The number and types of comments made in each of the three questionnaires (BQ, PPQ, 12m PPQ) were examined to determine if there were any differences between the Intervention and Control groups in each of the five waves. Chi-squared tests were carried out to determine if any of the differences were significant and a significance level of 0.05 was regarded as statistically significant.

4.4 Results

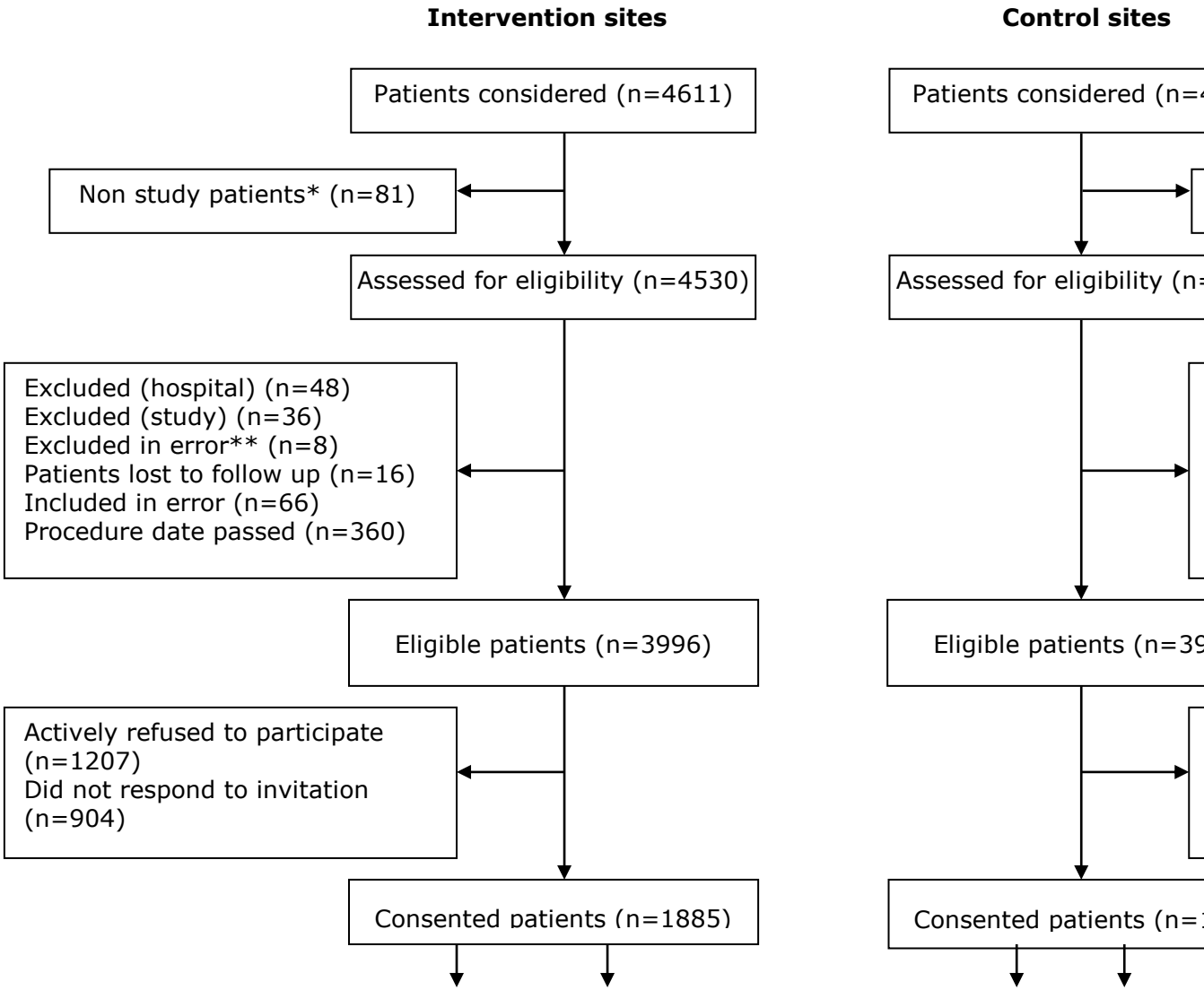
Patient outcomes data were available for 18 of the original 20 recruited hospitals. One hospital withdrew its involvement completely and a second was unable to manage the questionnaire distribution within the defined time period. Patients were recruited into the study from 19th April 2004 to 26th January 2007. Returned questionnaires were accepted until 31st December 2007.

4.4.1 Participant recruitment and flow

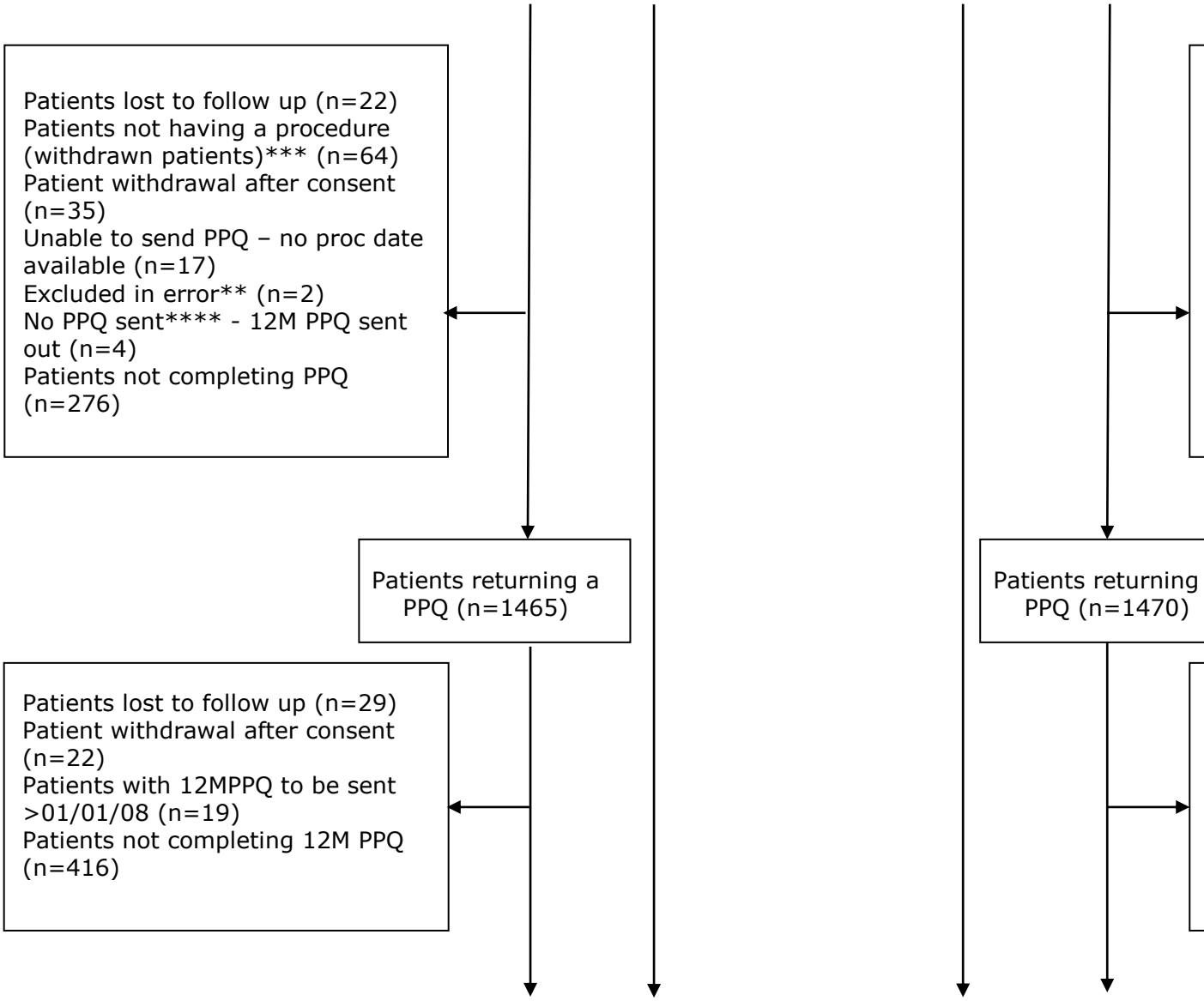
There was a significant difference between all three patient types in terms of age at recruitment, gender, DOU, waiting time and procedure type. Post hoc analysis for age and waiting time revealed that for age, all three groups were statistically different from each other, whilst for waiting time the non-responders were significantly different from both the refusers and the consenters but the waiting time for consenters and refusers was not significantly different.

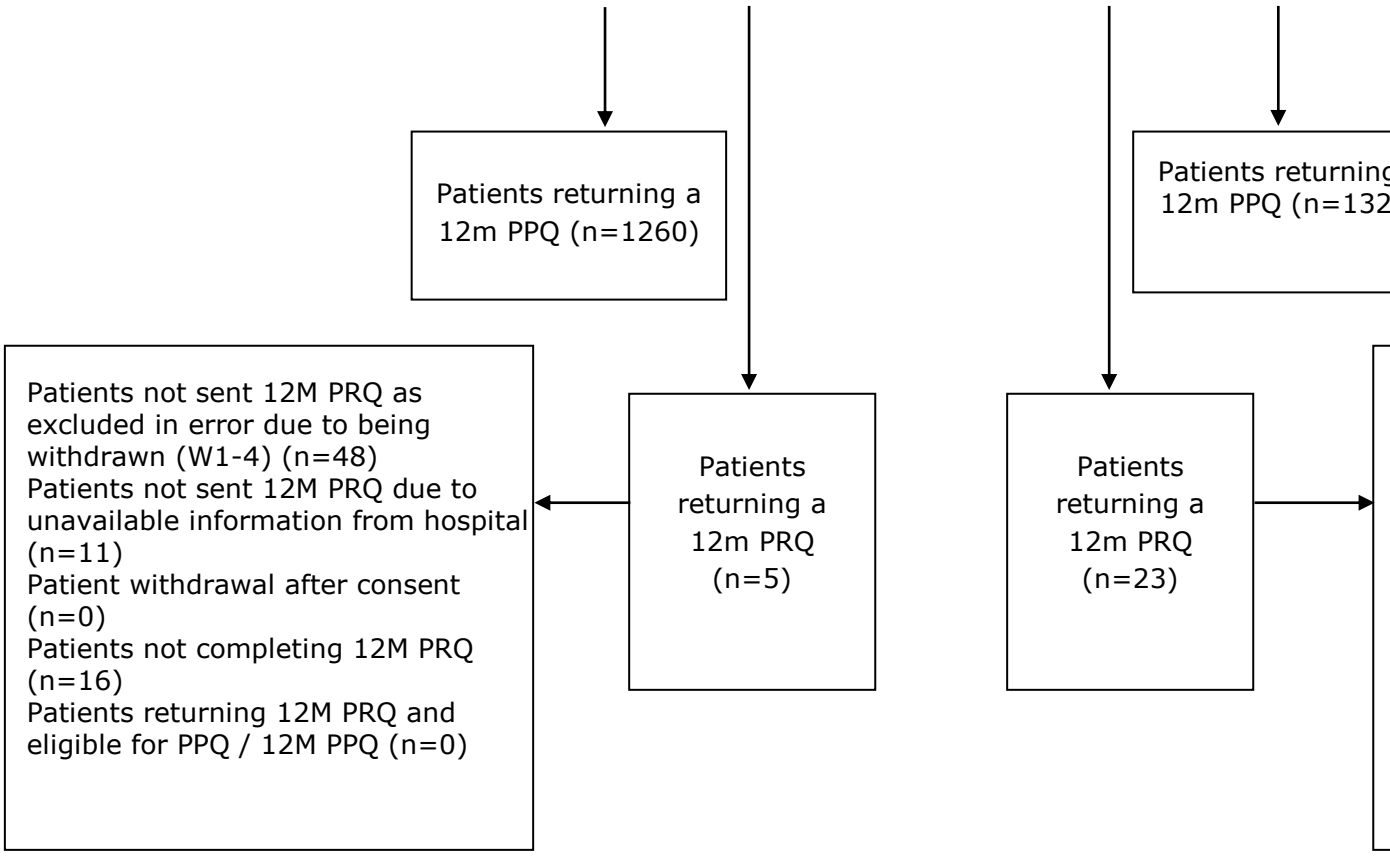
Details of the participant recruitment and flow through the study is summarised in Figure 3.

Figure 3. Consort diagram



The ENIGMA study





* Non study patients – no information available on these patients from the hospital

** Excluded in error – patients originally excluded as 'other' (e.g. patient went private, patient
Some patients from waves 4 and 5 were subsequently re-instated and followed up.

*** Patients not having procedure (withdrawn patients) – patients originally not followed up due
from procedure. Some patients from waves 4 and 5 were subsequently re-instated and follow

**** No PPQ sent out – due to the time lapse between the actual procedure being carried out and
of the procedure date, the PPQ was not sent out. However, 12M PPQ was still sent out if appl

In total 3818 patients were enrolled in the study, 1885 (49.4%) to the Intervention group and 1933 (50.6%) to the Control group.

4.4.2 Questionnaire response rates

Of the 3818 patients completing the BQ, a further 2935 (76.9%) returned the PPQ and 2587 (67.8%) returned the 12m PPQ (Table 8). There was no significant difference in response rates for each questionnaire type between Intervention and Control patients (Chi-squared = 0.806, p = 0.668).

Table 8. Questionnaire response rates

	Total	**Intervention**	**Control**
BQ (%)	3818	1885 (49.4%)	1933 (50.6%)
PPQ (%)	2935	1465 (49.9%)	1470 (50.1%)
12m PPQ (%)	2587	1260 (48.7%)	1327 (51.3%)

4.4.3 Patient demographics and sensitivity analysis

Those returning a completed BQ were classified as Consenters, whilst those actively refusing to participate, both verbally and in writing were classified as Refusers. Those patients who did not respond to any attempts to contact them by post and by telephone were classified as Non-responders. The baseline characteristics of the three patient groups invited to participate in the ENIGMA study are shown in Table 9. When the three groups were compared, there were significant differences for age, gender, DOU, waiting time and procedure type. Post hoc analysis determined that the differences for aged all three groups were statistically different from each other, whilst for waiting time the Non-responders were significantly different from both the Refusers and the Consenters but the waiting time for Consenters and Refusers was not significantly different.

Table 9. Baseline characteristics of patients invited to participate in the study. The significance level is 0.05

Characteristics	**Consenters** N=3818	**Refusers** N=2426	**Non-responders** N=1731	**P-value**
Age at recruitment (y)				
Mean (SD)	55.5 (15.24)	62.6 (14.8)	48 (15.9)	**<0.001**
Range	18.1 – 97.1	18.5 – 96.5	18.1 – 95.5	
Gender (%)				
Number of males	1708 (48)	955 (26.8)	897 (25.2)	**<0.001**
Number of females	2110 (47.9)	1463 (33.2)	834 (18.9)	
Wave (%)				
1	820 (47.3)	538 (31.1)	374 (21.6)	0.81
2	742 (48.2)	473 (30.7)	326 (21.2)	
3	781 (49.2)	468 (29.5)	337 (21.2)	
4	769 (47.7)	473 (29.3)	370 (23)	
5	706 (46.9)	474 (31.5)	324 (21.5)	

(Cont…)

(Cont…)

DOU (%)				
Two Week Rule (TWR)	139 (52.9)	92 (35)	32 (12.2)	<0.001
Urgent	1140 (48.6)	790 (33.7)	417 (17.8)	
Soon	811 (49.3)	460 (28)	373 (22.7)	
Routine	1688 (46.5)	1045 (28.8)	899 (24.8)	
Site type (%)				
Intervention	1885 (47.2)	1207 (30.2)	904 (22.6)	0.132
Control	1933 (48.6)	1219 (30.6)	827 (20.8)	
Waiting time (days)				
Mean (SD)	56.44 (60.46)	52.77 (61.89)	62.35 (66.04)	**<0.001**
Range	-14 – 654	-7 – 844	-7 – 690	
Procedure type (%)				
Upper GIs †	2030 (46.2)	1369 (31.1)	996 (22.7)	**0.019**
FS	753 (49)	444 (28.9)	341 (22.2)	
Colonoscopy	838 (50.7)	494 (29.9)	322 (19.5)	
Combination	179 (50.6)	107 (30.2)	68 (19.2)	
Procedure type (%)				
Upper GIs †	2030 (46.2)	1369 (31.1)	996 (22.7)	**0.006**
Lower GIs ‡	1591 (49.8)	938 (29.4)	663 (20.8)	

Key: † Gastroscopies and OGDs combined; ‡ FS and colonoscopy combined.

Examination of the Refuser and Non-responder groups highlighted the differences of these two groups with the Consenters. However, the differences between the Refuser and the Non-responder group were in opposite directions. Since weighting of the HRQoL data was to be based on the completed patient questionnaire, the demographics of the Refuser and Non-responder groups were aggregated into one group to become a "Non-consenters" group. Consequently, the effect of those differences were cancelled out when the two groups were aggregated. The baseline characteristics of Consenters and Non-consenters are shown in Table 10.

Table 10. Baseline characteristics of patients who consented to the study and those patients who did not (refusers and non-responders combined). The significance level is 0.05.

Characteristics	**Consenters** N=3818	**Non-consenters** N= 4157	**P-value**
Age at recruitment (y)			
Mean (SD)	55.52 (15.24)	56.49 (16.89)	**0.007**
Range	18.1 – 97.1	18.1 – 96.5	
Gender (%)			
Number of males	1708 (48)	1852 (52)	0.948
Number of females	2110 (47.9)	2297 (52.1)	
Wave (%)			
1	820 (47.3)	912 (52.7)	0.74
2	742 (48.2)	799 (51.8)	
3	781 (49.2)	805 (50.8)	
4	769 (47.7)	843 (52.3)	
5	706 (46.9)	798 (53.1)	

(Cont…)

(Cont…)

DOU (%)			
TWR	139 (52.9)	124 (47.1)	0.063
Urgent	1140 (48.6)	1207 (51.4)	
Soon	811 (49.3)	833 (50.7)	
Routine	1688 (46.5)	1944 (53.5)	
Site type (%)			
Intervention	1885 (47.2)	2111 (52.8)	0.216
Control	1933 (48.6)	2046 (51.4)	
Waiting time (days)			
Mean (SD)	56.44 (60.46)	56.76 (63.82)	0.823
Range	0 – 661	0 – 1841	
Procedure type (%)			
Upper GIs †	2030 (46.2)	2365 (53.8)	**0.008**
FS	753 (49)	785 (51)	
Colonoscopy	838 (50.7)	816 (49.3)	
Combination	179 (50.6)	175 (49.4)	
Procedure type (%)			
Upper GIs †	2030 (46.2)	2365 (53.8)	**0.002**
Lower GIs ‡	1591 (49.8)	1601 (50.2)	

Key: † Gastroscopies and OGDs combined; ‡ FS and colonoscopy combined.

There were significant differences between the Consenters and Non-consenters for age and procedure type. Consequently, the age and procedure type of the Consenters have been weighted accordingly in all subsequent analyses.

The baseline characteristics of the Consenters split according to whether they were recruited from Intervention or Control sites are shown in Table 11. There were significant differences between Consenters from the Intervention and Control sites for age, DOU, waiting time and procedure type.

Table 11. Baseline characteristics of consenting patients from Intervention and Control sites.

Characteristics	**Intervention** N=3979	**Control** N=3996	**p-value**
Age at recruitment (y)			
Mean (SD)	55.63 (16.17)	56.43 (16.08)	**0.026**
Range	18.1 – 97.1	18.1 – 94.5	
Gender (%)			
Number of males	1769 (49.7)	1791 (50.3)	0.558
Number of females	2219 (50.4)	2188 (49.6)	
Wave (%)			
1	832 (48)	900 (52)	0.271
2	767 (49.8)	774 (50.2)	
3	801 (50.5)	785 (49.5)	
4	816 (50.6)	796 (49.4)	
5	780 (51.9)	724 (48.1)	

(Cont…)

(Cont…)

DOU (%)			
TWR	25 (9.5)	238 (90.5)	**<0.001**
Urgent	958 (40.8)	1389 (59.2)	
Soon	898 (54.6)	746 (45.4)	
Routine	2076 (57.2)	1556 (42.8)	
Waiting time (days)			
Mean (SD)	54.65 (54.86)	58.58 (68.81)	**0.006**
Range	-13 – 690	-14 – 844	
Procedure type (%)			
Upper GIs †	2173 (49.4)	2222 (50.6)	**<0.001**
FS	976 (63.5)	562 (36.5)	
Colonoscopy	673 (40.7)	981 (59.3)	
Combination	147 (41.5)	207 (58.5)	
Procedure type (%) *			
Upper GIs †	2173 (49.4)	2222 (50.6)	0.06
Lower GIs ‡	1649 (51.7)	1543 (48.3)	

* combinations of procedures not included.

4.4.4 Disease specific HRQoL – GSRQ

Patients in both groups in each of the five waves reported a decrease in each of the four GSRQ subscales from BQ to PPQ, with a further decrease in scores from PPQ to 12m PPQ. This indicated fewer symptoms following a procedure which was maintained 12 months later (see Table 12).

Table 12. The mean unadjusted GSRQ scores for patients for each questionnaire split acco

Mean Score (SE)	Intervention			
	BQ Max n=385	**PPQ** Max n=302	**12m PPQ** Max n=272	**BQ** Max n=399
***GSRQ* Factor 1: Upper GI** Scored 0 (no symptoms) – 100				
Wave 1	23.46 (1.1)	19.51 (1.15)	15.96 (1.11)	22.52 (0.98)
Wave 2	25.26 (1.11)	20.82 (1.17)	15.75 (1.16)	23.68 (1.07)
Wave 3	22.54 (1.07)	17.89 (1.1)	12.38 (0.93)	22.53 (0.95)
Wave 4	23.66 (1.06)	19.98 (1.12)	14.1 (0.99)	22.9 (1.06)
Wave 5	21.79 (1.07)	16.89 (1)	13.06 (1.03)	22.95 (1.11)
GSRQ Factor 2: Lower GI Scored 0 (no symptoms) – 100				
Wave 1	30.57 (1.56)	26.47 (1.61)	22.31 (1.58)	33.22 (1.61)
Wave 2	30.05 (1.56)	25.85 (1.53)	24.38 (1.64)	32.26 (1.63)
Wave 3	27.89 (1.52)	22.95 (1.65)	22.13 (1.66)	33.19 (1.57)
Wave 4	34.91 (1.61)	27.59 (1.68)	23.77 (1.58)	30.96 (1.56)
Wave 5	32.5 (1.6)	28.86 (1.77)	22.29 (1.81)	29.04 (1.53)
***GSRQ* Factor 3: Wind** Scored 0 (no symptoms) – 100				
Wave 1	45.3 (1.38)	41.08 (1.54)	35.33 (1.57)	45.25 (1.34)
Wave 2	47.65 (1.42)	41.84 (1.56)	34.88 (1.57)	46.64 (1.38)
Wave 3	44.06 (1.44)	41.02 (1.57)	33.68 (1.68)	44.05 (1.34)
Wave 4	49.12 (1.35)	43.2 (1.46)	34.34 (1.4)	44.39 (1.43)
Wave 5	43.92 (1.38)	41.22 (1.47)	34.48 (1.65)	45.34 (1.42)
***GSRQ* Factor 4: Defaecation** Scored 0 (no symptoms) – 100				
Wave 1	25.84 (1.27)	23.56 (1.37)	19.88 (1.23)	24.09 (1.21)
Wave 2	26.44 (1.31)	23.51 (1.46)	22.87 (1.51)	24.8 (1.23)
Wave 3	24.21 (1.26)	21.87 (1.4)	19.5 (1.34)	24.58 (1.16)
Wave 4	23.8 (1.13)	22.19 (1.23)	20.64 (1.29)	24.03 (1.24)
Wave 5	22.18 (1.13)	19.93 (1.21)	18.84 (1.41)	22.9 (1.2)

4.4.5 GSRQ baseline scores

There were significant differences in the baseline scores of the four GSRQ measures (Upper GI and lower GI symptoms, wind and defaecation) according to UGE, FS or colonoscopy. Post hoc analysis was done to determine which of the three procedures were significantly different to the others using a Bonferroni adjustment. The results of this analysis are shown in Table 13.

Post hoc tests highlighted at baseline UGE patients had significantly worse symptoms than FS and colonoscopy patients in relation to the GSRQ factors of upper GI symptoms and wind but significantly better symptoms than FS and colonoscopy patients in relation to wind. UGE patients had significantly better symptoms than colonoscopy patients in relation to defaecation symptoms.

4.4.6 GSRQ – changes in BQ, PPQ and 12m PPQ scores

All three procedure types showed a statistically significant improvement in all four GSRQ scores from BQ to 12m PPQ. Most of the sub-scales also showed a statistically significant improvement from BQ to PPQ (see Table 13).

Table 13. Illustration of the differences in baseline scores according to each procedure typ tests.

	Analysis by ANOVA					
GSRQ factor	**Mean Baseline UGE score (SE) [n]**	**Mean Baseline FS score (SE) [n]**	**Mean Baseline Colonoscopy score (SE) [n]**	**P-value**	**Mean Difference UGE - FS (p-value)**	**M**
1 (Upper GI)	29.13 (20.15) [1902]	14.5 (16.32) [705]	16.59 (16.77) [788]	**<0.001**	**14.628 (<0.001)**	**1**
2 (Lower GI)	24.36 (26.52) [1947]	38.4 (31.66) [725]	41.11 (32.46) [812]	**<0.001**	**-14.04 (<0.001)**	**-**
3 (Wind)	49.31 (26.03) [1923]	39.2 (25.35) [710]	42.33 (26.01) [800]	**<0.001**	**10.11 (<0.001)**	
4 (Defaecation)	22.75 (23.17) [1952]	24.88 (22.46) [718]	26.34 (22.8) [809]	**<0.001**	-2.13 (0.099)	

Table 14. Table of the mean GSRQ scores from each questionnaire split according to proce mean difference between each procedure type

GSRQ factor	Procedure type	Mean BQ score (SE)	Mean PPQ score (SE)	Mean 12m PPQ score (SE)	P-value	Mean Difference BQ - PPQ (p-value)
1 (Upper GI)	UGE [n=1139]	27.31 (0.57)	22.66 (0.57)	16.22 (0.51)	**<0.001**	**4.64 (<0.001)**
	FS [n = 432]	12.7 (0.73)	11.75 (0.68)	10.23 (0.66)	**<0.001**	0.96 (0.1)
	Colonoscopy [n = 497]	16.16 (0.74)	15.32 (0.74)	13.76 (0.73)	**<0.001**	0.84 (0.168)
2 (Lower GI)	UGE [n = 1206]	22.49 (0.74)	20.51 (0.72)	19.39 (0.69)	**<0.001**	**1.98 (0.001)**
	FS [n = 456]	37.19 (1.47)	32.05 (1.36)	25.36 (1.24)	**<0.001**	**5.14 (<0.001)**
	Colonoscopy [n = 521]	41.57 (1.42)	35.97 (1.36)	30.93 (1.28)	**<0.001**	**5.6 (<0.001)**
3 (Wind)	UGE [n = 1151]	48.26 (0.76)	43.29 (0.78)	35.69 (0.73)	**<0.001**	**4.97 (<0.001)**
	FS [n = 442]	37.24 (1.15)	35.57 (1.11)	30.76 (1.1)	**<0.001**	1.67 (0.103)
	Colonoscopy [n = 506]	42.19 (1.14)	40.5 (1.14)	35.96 (1.13)	**<0.001**	**1.69 (0.047)**
4 (Defaecation)	UGE [n = 1199]	21.87 (0.66)	20.97 (0.66)	19.42 (0.63)	**<0.001**	0.9 (0.215)
	FS [n = 455]	23.92 (1.06)	22.22 (0.96)	20.97 (0.99)	**0.006**	1.7 (0.096)
	Colonoscopy [n = 517]	25.89 (1)	22.78 (0.97)	20.04 (0.92)	**<0.001**	**3.11 (<0.001)**

4.4.7 GSRQ at 12 months – multilevel modelling

Random intercept models (which assumed random site effects and common linear effect of the covariates) and random slope models (which assumed random site effects and differing covariate effect between sites) were fitted. The findings were similar but the random slope models were slow to converge. Therefore, only the random intercept models were reported.

There were no statistically significant differences between the study groups in the four GSRQ subscales (see Table 15). Baseline scores were found to have significant effects on all the GSRQ subscales, i.e. if patients were more ill at Baseline they had worse symptoms at 12m. Males were found to have better outcomes as measured by GSRQ3 and GSRQ4. If a patient was male their GSRQ scores were 1.61 and 2.49 point better on the GSRQ3 and GSRQ4 respectively. Those patients having a colonoscopy (scores worse by 3.25 units) and those who waited longer (scores worse by 0.013 units) were found to have worse outcome for GSRQ1 and patients recruited at later waves were found to have better outcome (0.53 units better) at 12 month follow up as measured by GSRQ1.

Table 15. Effects of covariates on primary outcome measure (12 months GSRQ scores)

Effect size (SE) [sig]	**GSRQ1 Upper GI**	**GSRQ2 Lower GI**	**GSRQ3 Wind**
Gender	-0.74 (0.53) [0.16]	-1.36 (0.86) [0.12]	**-1.61 (0.7 [0.04]**
Age	0.005 (0.019) [0.78]	-0.055 (0.03) [0.08]	-0.04 (0.02 [0.12]
Upper GI	0.67 (1.21) [0.58]	1.18 (1.96) [0.55]	0.033 (1.7 [0.99]
FS	2.11 (1.36) [0.12]	0.11 (2.21) [0.96]	2.2 (1.98 [0.27]
Colonoscopy	**3.25 (1.38) [0.02]**	2.84 (2.25) [0.21]	3.74 (2.0 [0.063]
Urgency of referral	0.0.14 (0.31) [0.66]	0.93 (0.51) [0.07]	-0.07 (0.4 [0.88]
Baseline scores	**0.58 (0.015) [<0.001]**	**0.52 (0.014) [<0.001]**	**0.61 (0.01 [<0.001**
Time to 12m PPQ	**0.013 (0.004) [0.005]**	0.008 (0.007) [0.26]	0.012 (0.0 [0.077]
Innovation score	-0.003 (0.01) [0.754]	0.009 (0.017) [0.60]	0.015 (0.0 [0.39]
No of beds	0.0004 (0.002) [0.785]	0.003 (0.002) [0.26]	0.0007 (0.0 [0.76]
Teaching hospital	-0.15 (0.799) [0.85]	0.001 (1.27) [0.99]	-0.14 (1.2 [0.91]
Wave	**-0.53 (0.19) [0.004]**	-0.47 (0.31) [0.12]	-0.2 (0.28 [0.48]
Intervention/Control	-0.20 (0.59) [0.74]	-0.61 (0.94) [0.52]	-0.71 (0.9 [0.46]
N	2395	2468	2414
-2 Log Likelihood	18932.60	22048.58	21029.50

N.B. GSRQ Score 0 (no symptom) to 100

4.4.8 GSRQ at post procedure

Multilevel models were fitted but the final Hessian matrices were not positive. Therefore, findings from flat models were reported. See Table 16.

There were no statistically significant differences between the study groups in the four GSRQ subscales (see Table 16). Baseline scores were found to have significant effects on all the GSRQ subscales, i.e. if patients were more ill at baseline they had worse symptoms at PPQ. Males were found to have better outcomes as measured by GSRQ1, GSRQ3 and GSRQ4. Older patients had fewer defaecation symptoms as measured by the GRSQ4. Those patients having a UGE or a FS had fewer symptoms on the GRSQ1. Those patients that were regarded as urgent had worse symptoms and those patients who waited less time for their procedure had fewer symptoms on the GSRQ4. Those patients treated in a hospital with a higher innovation score had more symptoms on the GSRQ3.

Table 16. Effects of Covariates on Primary outcome measure (post procedure GSRQ scores

Effect size (SE) [sig]	**GSRQ1 Upper GI**	**GSRQ2 Lower GI**	**GSRQ3 Wind**
Gender	**-2.20 (0.47) [<0.001]**	-1.26 (0.70) [0.073]	**-2.82 (0.6 [<0.001**
Age	-0.015 (0.017) [0.36]	-0.037 (0.025) [0.13]	-0.038 (0.0 [0.11]
Upper GI	**-2.25 (1.08) [0.037]**	-0.52 (1.62) [0.75]	-0.94 (1.5 [0.54]
FS	**-3.01 (1.22) [0.013]**	0.13 (1.81) [0.94]	-0.59 (1.7 [0.73]
Colonoscopy	-1.70 (1.24) [0.17]	1.26 (1.85) [0.50]	0.64 (1.76 [0.71]
Urgency of referral	-0.05 (0.27) [0.84]	0.21 (0.41) [0.62]	-0.091 (0.3 [0.82]
Baseline scores	**0.74 (0.013) [<0.001]**	**0.71 (0.012) [<0.001]**	**0.75 (0.01 [<0.001**
Time to PPQ	0.0055 (0.0037) [0.13]	-0.0064 (0.0056) [0.26]	0.0025 (0.00 [0.64]
Innovation score	0.012 (0.0090) [0.18]	-0.0085 (0.014) [0.53]	**0.026 (0.0 [0.045]**
No of beds	-0.00050 (0.0012) [0.69]	-0.0030 (0.0019) [0.11]	0.0010 (0.00 [0.18]
Teaching hospital	-0.07 (0.66) [0.97]	1.85 (1.0009) [0.064]	0.34 (0.95 [0.72]
Wave	-0.0066 (0.16) [0.97]	0.13 (0.25) [0.49]	0.24 (0.24 [0.31]
Intervention/Control	-0.016 (0.50) [0.97]	-0.38 (0.75) [0.61]	0.58 (0.72 [0.44]
N	2614	2778	2669
-2 Log Likelihood	20289.78	24029.54	22732.15

N.B. GSRQ Score 0 (no symptom) to 100

4.4.9 SF-36

Patients in both groups in each of the five waves reported improvements in each of the eight SF-36 subscales and the physical and mental component summary scores from baseline to post-procedure indicating improved overall health. Although the scores at 12 months were still greater than baseline scores, only minor changes (positive or negative) were exhibited in the PPQ to the 12m PPQ scores. This indicated only minor changes in the perceived health of the patient from PPQ to 12m PPQ. The largest differences were apparent in the subscales social functioning, pain and role limitation physical (Table 17).

There were significant differences in the baseline scores of the two SF-36 summary measures (PCS and MCS) according to UGE, FS or colonoscopy. The results of this analysis are shown in Table 18. Post hoc analysis illustrated that for the SF-36 summary measures UGE patients exhibited significantly worse health than FS patients on both the PCS and MCS scales and significantly worse health than colonoscopy patients on the PCS scale. FS patients had significantly better health than colonoscopy patients.

4.4.10 EQ-5D

Patients in both groups in each of the five waves reported improvements in the EQ-5D scores from baseline to post-procedure indicating improved health. Although the scores at 12 months were still greater than BQ scores, only minor changes (positive or negative) were exhibited in the PPQ to the 12m PPQ scores. This indicated only minor changes in the perceived health of the patient from PPQ to 12m PPQ (Table 17).

There were significant differences in the baseline scores for the EQ-5D according to procedure type (see Table 18). Post hoc analysis highlighted that UGE patients exhibited significantly worse health than FS and colonoscopy patients.

4.4.11 SF-36 & EQ-5D – changes in BQ, PPQ and 12m PPQ scores

All three procedure types showed a statistically significant improvement in both the SF-36 summary measures and the EQ-5D from baseline to 12m PPQ. The SF-36 summary scores and EQ-5D similarly showed a significant improvement from baseline to PPQ for all procedures, with the exception of colonoscopy patients on the SF-36 PCS summary score and the EQ-5D. Although not significant the colonoscopy patients did exhibit and overall improvement in this period (see Table 19).

Table 17. Secondary outcome measures (EQ-5D, SF-36) – unadjusted figures, split by wav

	Intervention			
Mean Score (SE)	**BQ** Max n=376	**PPQ** Max n=309	**12m PPQ** Max n=319	**BQ** Max n=405
EQ-5D Scored -0.594 (the worst imaginable health state) to 1				
Wave 1	0.66 (0.01)	0.7 (0.2)	0.7 (0.02)	0.65 (0.02)
Wave 2	0.64 (0.02)	0.68 (0.02)	0.67 (0.02)	0.64 (0.02)
Wave 3	0.66 (0.02)	0.75 (0.02)	0.73 (0.02)	0.68 (0.01)
Wave 4	0.67 (0.01)	0.72 (0.01)	0.7 (0.01)	0.66 (0.02)
Wave 5	0.67 (0.01)	0.74 (0.01)	0.72 (0.02)	0.65 (0.02)
SF-36 - Physical Functioning Scored 0 (worse health) – 100				
Wave 1	70.28 (1.59)	71.32 (1.67)	70.95 (1.68)	68.61 (1.57)
Wave 2	70.33 (1.52)	70.16 (1.77)	70.28 (1.76)	69.36 (1.54)
Wave 3	71.35 (1.57)	75.97 (1.67)	73.66 (1.76)	71.08 (1.46)
Wave 4	72.33 (1.39)	72.86 (1.57)	73.66 (1.58)	70.59 (1.43)
Wave 5	71.88 (1.55)	74.42 (1.68)	74.37 (1.66)	69.87 (1.57)
SF-36 - Social Functioning				
Wave 1	65.3 (1.54)	73.26 (1.69)	70.05 (1.71)	66.95 (1.49)
Wave 2	65.87 (1.62)	71.97 (1.84)	68.75 (1.87)	64.36 (1.57)
Wave 3	69.02 (1.55)	78.51 (1.61)	74.96 (1.73)	65.25 (1.48)
Wave 4	67.17 (1.41)	73.62 (1.63)	71.73 (1.7)	66.25 (1.47)
Wave 5	67.69 (1.48)	75.42 (1.63)	72.7 (1.74)	65.43 (1.57)
SF-36 - Role limitation – Physical				
Wave 1	63.81 (1.75)	69.07 (1.85)	68.31 (1.84)	62.16 (1.7)
Wave 2	62.95 (1.72)	68.19 (1.93)	67.68 (1.86)	62.31 (1.72)
Wave 3	67.27 (1.78)	75.56 (1.79)	72.07 (1.9)	63.64 (1.64)
Wave 4	65.2 (1.65)	70.45 (1.75)	69.92 (1.71)	63.55 (1.68)
Wave 5	65.06 (1.63)	71.86 (1.83)	72 (1.83)	62.3 (1.75)

SF-36 - Role limitation - Mental				
Wave 1	71.83 (1.62)	74.79 (1.68)	75.17 (1.68)	71.51 (1.66)
Wave 2	70.62 (1.7)	73.21 (1.88)	75.24 (1.77)	70.38 (1.65)
Wave 3	74.98 (1.61)	80.42 (1.55)	77.97 (1.68)	70.13 (1.55)
Wave 4	71.5 (1.49)	75.72 (1.62)	76.9 (1.64)	74.7 (1.52)
Wave 5	74 (1.52)	78.26 (1.62)	76.31 (1.7)	72.92 (1.65)
SF-36 - Mental Health				
Wave 1	63.6 (0.71)	68.26 (1.29)	68.2 (1.26)	64.74 (0.67)
Wave 2	62.97 (0.73)	67.8 (1.3)	67.69 (1.28)	63.29 (0.77)
Wave 3	67.51 (0.98)	72.7 (1.19)	72.8 (1.15)	64.27 (0.86)
Wave 4	63.62 (1.1)	69.59 (1.19)	68.29 (1.21)	66.22 (1.1)
Wave 5	65.77 (1.08)	70.26 (1.26)	68.18 (1.2)	64.15 (1.25)
SF-36 – Vitality				
Wave 1	49.35 (1.13)	47.6 (1.35)	47.24 (1.34)	48.47 (1.17)
Wave 2	46.22 (1.24)	45.1 (1.45)	44.67 (1.4)	46.15 (1.19)
Wave 3	48.31 (1.25)	50.91 (1.46)	50.76 (1.38)	45.64 (1.15)
Wave 4	41.88 (1.2)	47.59 (1.34)	46.4 (1.3)	42.65 (1.23)
Wave 5	43.88 (1.17)	48.25 (1.42)	47.61 (1.31)	42.23 (1.25)
SF-36 – Pain				
Wave 1	57.81 (1.27)	68.66 (1.36)	66.19 (1.5)	59.73 (1.41)
Wave 2	55.71 (1.37)	65.4 (1.54)	63.73 (1.59)	55.42 (1.34)
Wave 3	60.36 (1.41)	71.41 (1.49)	67.59 (1.63)	57.55 (1.26)
Wave 4	60.37 (1.28)	69.36 (1.37)	64.83 (1.48)	58.84 (1.33)
Wave 5	57.17 (1.27)	68.48 (1.39)	66.45 (1.51)	56.23 (1.4)
SF-36 - General Health				
Wave 1	58.02 (0.95)	59.51 (1.21)	58.89 (1.25)	58.31 (0.97)
Wave 2	58.04 (1)	58.42 (1.3)	57.49 (1.31)	57.21 (0.94)
Wave 3	60.36 (0.99)	62.61 (1.32)	63.07 (1.3)	58.51 (0.93)
Wave 4	58.79 (0.94)	60.1 (1.2)	58.56 (1.28)	57.1 (0.92)
Wave 5	58.52 (0.94)	60.48 (1.28)	60.13 (1.28)	57.39 (0.99)

SF-36 - Physical Component Summary (PCS)				
Wave 1	45.45 (0.56)	46.49 (0.55)	46.34 (0.61)	45.3 (0.6)
Wave 2	45.08 (0.55)	45.8 (0.59)	46.3 (0.62)	45.08 (0.56)
Wave 3	45.97 (0.54)	47.8 (0.6)	47.21 (0.67)	45.42 (0.52)
Wave 4	46.17 (0.46)	46.73 (0.54)	46.77 (0.58)	45.1 (0.5)
Wave 5	47.08 (0.5)	46.82 (0.56)	47.11 (0.6)	44.27 (0.54)
SF-36 - Mental Component Summary (MCS)				
Wave 1	44.03 (0.42)	46.12 (0.65)	46.12 (0.66)	44.19 (0.42)
Wave 2	43.65 (0.48)	45.12 (0.71)	45.63 (0.68)	43.47 (0.46)
Wave 3	46.04 (0.54)	48.12 (0.63)	48.08 (0.62)	43.75 (0.48)
Wave 4	43.61 (0.57)	46.08 (0.63)	46.15 (0.62)	44.59 (0.55)
Wave 5	44.27 (0.57)	46.44 (0.66)	45.72 (0.66)	43.35 (0.62)

Table 18. Illustration of the differences in baseline scores for the SF-36 PCS and MCS and procedure type. Significance was at 0.05.

Secondary outcome measure	Mean Baseline UGE score (SE) [n]	Mean Baseline FS score (SE) [n]	Mean Baseline Colonoscopy score (SE) [n]	P-value	Mean Difference UGE - FS (p-value)	M c
SF-36 PCS	44.53 (0.22) [1741]	47.08 (0.37) [663]	45.72 (0.37) [746]	**<0.001**	**-2.55 (<0.001)**	
SF-36 MCS	43.85 (0.22) [1741]	45 (0.37) [663]	44.16 (0.34) [746]	**0.026**	**-1.15 (0.02)**	
EQ-5D	0.64 (0.01) [1952]	0.69 (0.01) [719]	0.68 (0.01) [813]	**<0.001**	**-0.05 (0.001)**	

Table 19. Table of the mean GSRQ scores from the SF-36 PCS and MCS and the EQ-5D spli along with the mean difference between each procedure type. Significance was at 0.05

Outcome measure	Procedure type	Mean Baseline score (SE)	Mean PPQ score (SE)	Mean 12m PPQ score (SE)	P-value	Mean Difference BQ PPQ (p-value
SF-36 PCS	UGE [n = 1219]	45.23 (0.26)	46.92 (0.25)	46.64 (0.28)	**<0.001**	**-1.69 (<0.001**
	FS [n = 480]	47.32 (0.41)	48.87 (0.38)	48.44 (0.4)	**<0.001**	**-1.55 (<0.001**
	Colonoscopy [n = 524]	46.54 (0.43)	47.75 (0.4)	46.73 (0.43)	**<0.001**	**-1.21 (<0.001**
SF-36 MCS	UGE [n = 1219]	44.55 (0.26)	46.23 (0.31)	45.96 (0.3)	**<0.001**	**-1.68 (<0.001**
	FS [n = 480]	45.66 (0.43)	48.49 (0.47)	47.67 (0.46)	**<0.001**	**-2.84 (<0.001**
	Colonoscopy [n = 524]	45.01 (0.39)	47.11 (0.46)	47.05 (0.44)	**<0.001**	**-2.09 (<0.001**
EQ-5D	UGE [n = 1465]	0.66 (0.01)	0.69 (0.01)	0.69 (0.01)	**<0.001**	**-0.03 (<0.001**
	FS [n = 554]	0.7 (0.01)	0.74 (0.01)	0.74 (0.01)	**<0.001**	**-0.04 (<0.001**
	Colonoscopy [n = 614]	0.7 (0.01)	0.71 (0.01)	0.71 (0.01)	**0.042**	**-0.02 (0.036)**

4.4.12 SF-36 – multilevel modelling

Multilevel models were fitted but the final Hessian matrices were not positive. Therefore, findings from flat models were reported. See Table 20.

At 12m PPQ, there were no statistically significant differences between the study groups in the SF-36 summary scores (see Table 20). Baseline scores were found to have significant effects on the SF-36 scores with patients that had worse health at baseline having worse health at 12m. Males were found to have better health as measured by the SF-36 MCS. Younger patients had worse health as measured by the SF-36 PCS. Those patients having a UGE had worse health as measured by the SF-36 MCS. The waiting time had a significant impact on outcome with those patients waiting longer exhibiting worse health on the SF-36 PCS.

Table 20. Effects of covariates on SF-36 PCS and SF-36 MCS (12m PPQ scores)

Effect size (SE) [sig]	**SF36 PCS Scored 0 (poor health) – 100**	**SF36 MCS Scored 0 (poor health) – 100**
Gender	0.07 (0.26) [0.78]	**0.87 (0.34) [0.011]**
Age	**-0.094 (0.0094) [<0.001]**	-0.00072 (0.012) [0.95]
UGE	0.16 (0.62) [0.80]	**-2.10 (0.82) [0.010]**
FS	0.23 (0.70) [0.75]	-1.20 (0.91) [0.19]
Colonoscopy	-0.46 (0.71) [0.52]	-1.49 (0.93) [0.11]
DOU	0.25 (0.15) [0.10]	-0.26 (0.20) [0.20]
Baseline scores	**0.75 (0.014) [<0.001]**	**0.69 (0.019) [<0.001]**
Time to 12m PPQ	**-0.0050 (0.0024) [0.034]**	-0.0049 (0.0031) [0.12]
Innovation score	0.0053 (0.0050) [0.30]	-0.011 (0.0066) [0.11]
No of beds	0.00022 (0.00069) [0.75]	0.0017 (0.00091) [0.064]
Teaching hospital	-0.028 (0.37) [0.94]	-0.83 (0.48) [0.084]
Wave	0.091 (0.092) [0.32]	-0.050 (0.12) [0.68]
Intervention/Control	0.026 (0.28) [0.92]	0.29 (0.36) [0.42]
N	2317	2317
-2 Log Likelihood	15008.54	16263.50

P < 0.05

Multilevel models were fitted at PPQ but the final Hessian matrices were not positive. Therefore, findings from flat models were reported. See Table 20.

At PPQ, there were no statistically significant differences between the study groups in the SF-36 summary scores (see Table 21). BQ scores were found to have significant effects on the SF-36 scores with patients that had worse health at BQ having worse health at PPQ. Males were found to have better health as measured by the SF-36 MCS. Younger patients had worse health as measured by the SF-36 PCS. Those patients classified as urgent and those waiting longer for their procedure exhibited significantly worse health as measured by the SF-36 PCS. The number of hospital beds in a unit also had an impact on patient outcome with more hospital beds leading to worse patient health on the SF-36 MCS.

Table 21. Effects of covariates on SF-36 PCS SF-36 MCS (PPQ scores)

Effect size (SE) [sig]	**SF36 PCS Scored 0 (poor health) – 100**	**SF36 MCS Scored 0 (poor health) – 100**
Gender	0.33 (0.22) [0.13]	**0.92 (0.32) [0.004]**
Age	**-0.037 (0.0078) [<0.001]**	0.012 (0.011) [0.29]
UGE	0.29 (0.51) [0.57]	-0.26 (0.75) [0.73]
FS	0.64 (0.58) [0.27]	1.22 (0.85) [0.15]
Colonoscopy	0.39 (0.59) [0.51]	0.44 (0.86) [0.61]
DOU	**0.36 (0.13) [0.004]**	0.32 (0.19) [0.086]
Baseline scores	**0.75 (0.012) [<0.001]**	**0.81 (0.017) [<0.001]**
Time to PPQ	**-0.0050 (0.0018) [0.005]**	-0.004 (0.0026) [0.101]
Innovation score	0.0036 (0.0042) [0.40]	0.00016 (0.0062) [0.98]
No of beds	0.00024 (0.00058) [0.68]	**0.0018 (0.00085) [0.038]**
Teaching hospital	0.039 (0.31) [0.90]	-0.35 (0.45) [0.4]
Wave	0.052 (0.076) [0.50]	-0.096 (0.11) [0.39]
Intervention/Control	0.049 (0.23) [0.83]	0.041 (0.38) [0.90]
N	2415	2415
-2 Log Likelihood	14871.30	16709.15

P < 0.05

4.4.13 EQ-5D – Analysis of covariance

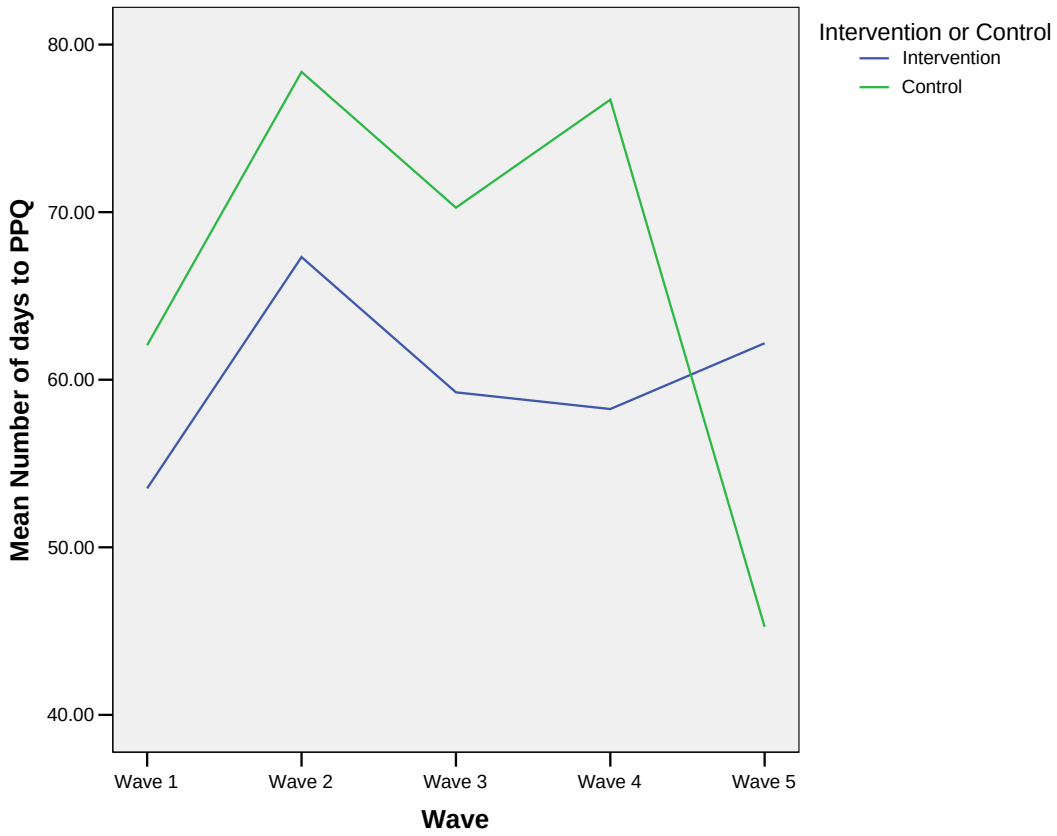
After adjusting for BQ score, type of procedure, DOU, adjusted age, gender, waiting time, time elapsed between BQ and 12m PPQ sent, hospital bed size, innovation scores, wave of recruitment and whether the hospital was a teaching hospital using analysis of covariance (ANCOVA), there were no statistically significant differences between the Intervention and Control group for the EQ-5D at 12 month post-procedure.

Similarly the ANCOVA comparison at post-procedure (adjusting for the same covariates) showed no statistical significance between the Intervention and Control group.

4.4.14 Waiting times

On average patients waited 63.52 (SD 67.08) days for their procedure. There was a significant difference between the Intervention and Control groups in waiting times (Intervention- 60.04d, Control- 66.96d, p= 0.002). When each wave was examined, the first four waves showed a difference in favour of the Intervention group (Wave 1: Intervention- 53.93d, Control- 58.95d, Wave 2: Intervention- 67.32d, Control- 78.37, Wave 3: Intervention- 59.25d, Control- 70.27d, Wave 4: Intervention- 58.25, Control- 76.21d). This was reversed in the final wave with the Control group exhibiting shorter waiting times than the Intervention sites (Intervention- 62.18, Control- 45.26d) see Figure 4. There was no overall change in waiting times from April 2004 to January 2007.

Figure 4. Mean number of days waited from referral to procedure for each wave of recruitment split by Intervention and Control group.



This overall picture does not change when the analysis is confined to referrals categorised as routine (see Figure 5) except that differences are no longer significant in Waves 1 and 5 (see Table 22).

Figure 5. Mean number of days waited from referral to procedure for patients classified as 'Routine' for each wave of recruitment split by Intervention and Control group.

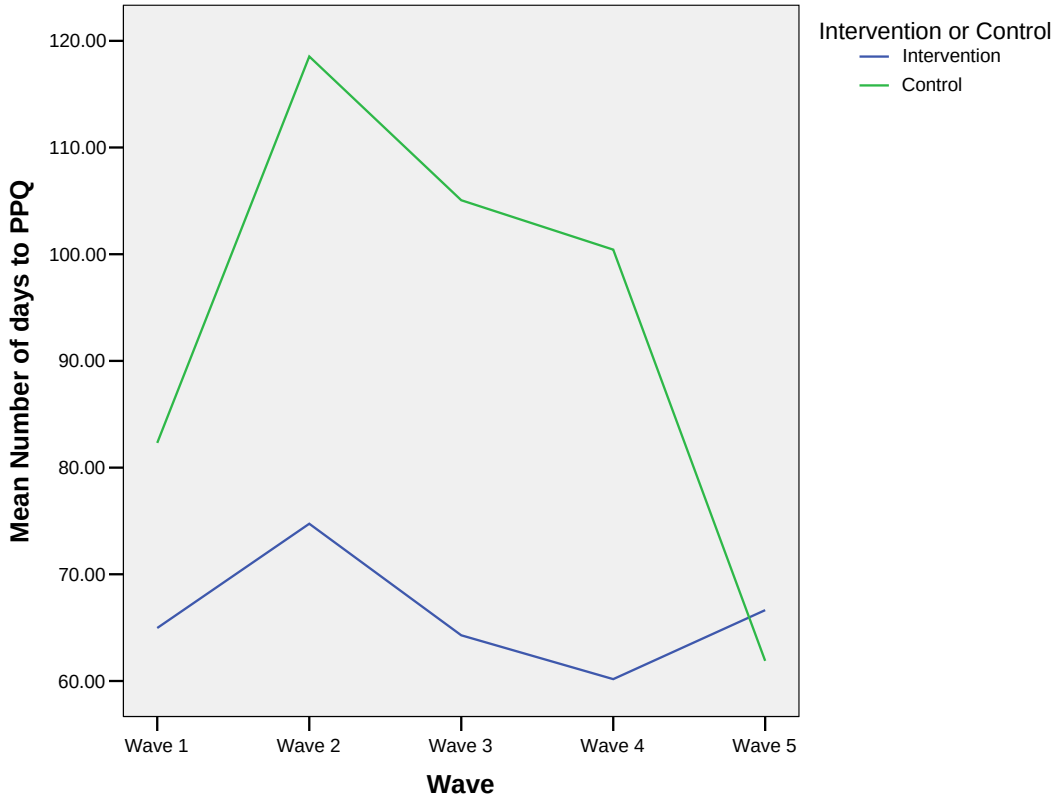


Table 22. Mean waiting times (SE) for patients classified as 'routine' split by Intervention and Control

Wave	Intervention (days)	Control (days)	p-value
1	64.97 (5.24)	82.31 (7.61)	0.062
2	74.74 (4.19)	118.53 (8.30)	**0.000**
3	64.28 (3.08)	105.05 (6.02)	**0.000**
4	60.17 (3.78)	100.43 (7.00)	**0.000**
5	66.63 (4.98)	61.88 (4.99)	0.503

4.4.15 Patient Satisfaction

Patient satisfaction: GESQ (one day post endoscopy)

With the exception of the sub-scale information quality before endoscopy (Wave 2), there were no significant differences between the Intervention and Control group in any of the four sub-scales (see Table 23). Accounting for the number of tests performed (n=20), this significant result is likely to have arisen by chance.

Multilevel models were fitted to the GESQ data but the final Hessian matrices were not positive. Therefore, findings from flat models were reported. See Table 23.

There were no statistically significant differences between the study groups in any of GESQ scores (see Table 24). Males were found to be more satisfied with the skills and the hospital and were less likely to suffer pain and discomfort following treatment. Older patients were more satisfied with the skills and hospital, had more pain and discomfort but were happier with the information before and after endoscopy. UGE patients exhibited more pain and discomfort following procedure. Those patients that had to wait less time for their procedure were more satisfied with skills and hospital.

Table 23. Mean scores (SE) for the GESQ in the Intervention and Control groups, split by wave

Mean Score (SE)	**Intervention** Max N= 304	**Control** Max N=302	**p-value**
GESQ *Scored 0 (satisfied) – 100 (unsatisfied)* **Factor 1: Skills & Hospital**			
Wave 1	10.74 (0.23)	10.70 (0.24)	0.89
Wave 2	11.04 (0.25)	10.63 (0.23)	0.23
Wave 3	10.74 (0.24)	10.77 (0.23)	0.93
Wave 4	10.81 (0.23)	10.18 (0.23)	0.06
Wave 5	10.59 (0.24)	10.59 (0.24)	0.99
Factor 2: Pain & Discomfort			
Wave 1	8.23 (0.19)	7.94 (0.20)	0.30
Wave 2	8.63 (0.21)	8.16 (0.20)	0.10
Wave 3	7.99 (0.20)	8.15 (0.19)	0.55
Wave 4	8.44 (0.20)	8.00 (0.21)	0.12
Wave 5	8.69 (0.21)	8.18 (0.20)	0.09
Factor 3: Information quality before endoscopy			
Wave 1	12.53 (0.20)	12.26 (0.20)	0.32
Wave 2	12.94 (0.22)	12.01 (0.18)	**0.001**
Wave 3	12.47 (0.20)	12.17 (0.19)	0.28
Wave 4	12.24 (0.18)	12.13 (0.21)	0.66
Wave 5	12.39 (0.19)	12.36 (0.20)	0.92
Factor 4: Information after endoscopy			
Wave 1	10.04 (0.18)	9.64 (0.17)	0.10
Wave 2	9.92 (0.19)	9.67 (0.17)	0.33
Wave 3	9.68 (0.20)	9.92 (0.18)	0.37
Wave 4	9.92 (0.17)	10.10 (0.19)	0.47
Wave 5	9.94 (0.19)	9.87 (0.20)	0.82

GESQ multilevel modelling

Random intercept models (which assumed random site effects and common linear effect of the covariates) and random slope models (which assumed random site effects and differing covariate effect between sites) were fitted. The findings were similar but the random slope models were slow to converge. Therefore, only the random intercept models were reported.

Table 24. Effects of covariates on SF-36 PCF SF-36 MCF and EQ-5D

Effect size (SE) [sig]	**Factor 1: Skills & Hospital**	**Factor 2: Pain & Discomfort**	**Info bef**
Gender	**-0.37 (0.15) [0.001]**	**-0.57 (0.12) [<0.001]**	
Age	**-0.060 (0.0051) [<0.001]**	**-0.050 (0.0042) [<0.001]**	
UGE	0.25 (0.34) [0.46]	**-0.98 (0.28) [0.001]**	
FS	0.50 (0.38) [0.19]	0.46 (0.32) [0.15]	
Colonoscopy	0.144 (0.39) [0.71]	-0.48 (0.32) [0.14]	
DOU	-0.044 (0.095) [0.65]	-0.13 (0.08) [0.11]	
Time to PPQ	**0.0031 (0.0013) [0.013]**	0.0010 (0.0011) [0.34]	
Innovation score	0.0010 (0.0061) [0.12]	0.0059 (0.0057) [0.32]	
No of beds	-0.000047 (0.00083) [0.96]	0.00031 (0.00071) [0.70]	

Teaching hospital	-0.095 (0.45) [0.84]	-0.10 (0.42) [0.81]	
Wave	-0.083 (0.052) [0.11]	0.024 (0.043) [0.57]	
Intervention/Control	0.067 (0.33) [0.84]	0.24 (0.31) [0.46]	
N	2804	2818	
-2 Log Likelihood	15536.20	14604.18	

N.B. GESQ Scored 0 (satisfied) – 100 (unsatisfied)
p < 0.05

4.4.16 Patient comments

There were no significant differences between the Intervention and Control group in each wave with respect to the number and types of comments made in each of the three questionnaires (see Table 25).

Table 25. Counts of the number of comments made by patients split by site type, wave and comment type

Questionnaire	Intervention (N)	Control (N)	p-value
BQ			
Total comments			
Wave 1 (n=820)	75	83	0.90
Wave 2 (n=742)	70	95	0.22
Wave 3 (n=781)	80	87	0.91
Wave 4 (n=769)	63	75	0.18
Wave 5 (n=706)	71	66	0.95
Describing symptoms			
Wave 1 (n=158)	44	46	0.68
Wave 2 (n=165)	32	40	0.64
Wave 3 (n=167)	32	34	0.93
Wave 4 (n=138)	27	30	0.73
Wave 5 (n=137)	29	24	0.59
Other problems impacting on questionnaire answers			
Wave 1 (n=158)	14	14	0.77
Wave 2 (n=165)	20	22	0.43
Wave 3 (n=167)	12	25	**0.033**
Wave 4 (n=138)	4	8	0.37
Wave 5 (n=137)	9	9	0.87
Long wait for appointment			
Wave 1 (n=158)	5	6	0.89
Wave 2 (n=165)	1	7	0.08
Wave 3 (n=167)	2	2	0.93
Wave 4 (n=138)	5	4	0.54
Wave 5 (n=137)	2	3	0.59
PPQ			
Any Other Comments 1			
Total comments			
Wave 1 (n=659)	136	158	0.48
Wave 2 (n=577)	123	153	**0.021**
Wave 3 (n=591)	142	157	0.85
Wave 4 (n=572)	142	113	0.39
Wave 5 (n=536)	137	140	0.51

Good treatment			
Wave 1 (n= 294)	18	131	0.36
Wave 2 (n=276)	97	135	**0.034**
Wave 3 (n=299)	124	146	0.10
Wave 4 (n=255)	129	105	0.55
Wave 5 (n=277)	120	128	0.30
Sedation issues			
Wave 1 (n= 294)	3	7	0.29
Wave 2 (n=276)	2	2	0.83
Wave 3 (n=299)	1	6	0.08
Wave 4 (n=255)	7	3	0.35
Wave 5 (n=277)	1	3	0.32
Complaints about treatment			
Wave 1 (n= 294)	2	3	0.78
Wave 2 (n=276)	3	3	0.79
Wave 3 (n=299)	1	4	0.21
Wave 4 (n=255)	2	0	0.21
Wave 5 (n=277)	3	1	0.30
PPQ Any Other Comments 2 **Total comments**			
Wave 1 (n=659)	70	84	0.51
Wave 2 (n=577)	52	85	**0.002**
Wave 3 (n=591)	81	90	0.87
Wave 4 (n=572)	83	68	0.71
Wave 5 (n=536)	78	72	0.80
Suggestions			
Wave 1 (n=154)	50	49	0.090
Wave 2 (n=137)	32	55	0.71
Wave 3 (n=171)	53	57	0.69
Wave 4 (n=151)	58	41	0.22
Wave 5 (n=150)	48	48	0.51
Better sedation			
Wave 1 (n=154)	6	11	0.37
Wave 2 (n=137)	6	7	0.52
Wave 3 (n=171)	4	5	0.87
Wave 4 (n=151)	9	2	0.06
Wave 5 (n=150)	10	5	0.23
More information before/after			
Wave 1 (n=154)	5	12	0.16
Wave 2 (n=137)	6	11	0.81
Wave 3 (n=171)	13	16	0.81
Wave 4 (n=151)	14	15	0.42
Wave 5 (n=150)	10	16	0.13

Difficulty remembering results because of sedation			
Wave 1 (n=154)	4	3	0.53
Wave 2 (n=137)	1	2	0.87
Wave 3 (n=171)	1	4	0.21
Wave 4 (n=151)	2	1	0.68
Wave 5 (n=150)	2	2	0.94
Lack of privacy			
Wave 1 (n=154)	6	4	0.34
Wave 2 (n=137)	1	2	0.88
Wave 3 (n=171)	6	4	0.53
Wave 4 (n=151)	1	1	0.89
Wave 5 (n=150)	4	4	0.91
PPQ Any Other Comments 3 **Total comments**			
Wave 1 (n=659)	104	100	0.40
Wave 2 (n=577)	89	112	0.06
Wave 3 (n=591)	91	90	0.44
Wave 4 (n=572)	99	98	0.24
Wave 5 (n=536)	87	76	0.49
Follow-up issues			
Wave 1 (n=204)	9	9	0.93
Wave 2 (n=200)	12	2	**0.001**
Wave 3 (n=181)	6	14	0.054
Wave 4 (n=187)	10	4	0.10
Wave 5 (n=163)	11	8	0.72
Endoscopy who did it/how it went			
Wave 1 (n=204)	13	14	0.75
Wave 2 (n=200)	13	21	0.44
Wave 3 (n=181)	26	21	0.42
Wave 4 (n=187)	19	19	0.97
Wave 5 (n=163)	23	25	0.37
Good treatment			
Wave 1 (n=204)	19	12	0.21
Wave 2 (n=200)	15	21	0.26
Wave 3 (n=181)	23	17	0.51
Wave 4 (n=187)	24	17	0.39
Wave 5 (n=163)	14	16	0.69
Delay in unit			
Wave 1 (n=204)	2	1	0.59
Wave 2 (n=200)	1	3	0.31
Wave 3 (n=181)	1	9	**0.009**
Wave 4 (n=187)	2	1	0.56
Wave 5 (n=163)	0	0	No data

General comments re: too long for appointments			
Wave 1 (n=204)	4	4	0.96
Wave 2 (n=200)	4	4	0.74
Wave 3 (n=181)	2	3	0.99
Wave 4 (n=187)	2	3	0.64
Wave 5 (n=163)	2	1	0.64
General comments re: getting appointments			
Wave 1 (n=204)	1	0	0.33
Wave 2 (n=200)	2	0	0.11
Wave 3 (n=181)	2	2	0.99
Wave 4 (n=187)	1	1	0.99
Wave 5 (n=163)	3	1	0.38
NHS in general - negative comments			
Wave 1 (n=204)	0	1	0.31
Wave 2 (n=200)	2	7	0.17
Wave 3 (n=181)	1	4	0.17
Wave 4 (n=187)	0	0	No data
Wave 5 (n=163)	0	0	No data
Other problems - impacting on questionnaire answers			
Wave 1 (n=204)	10	13	0.39
Wave 2 (n=200)	19	20	0.53
Wave 3 (n=181)	17	15	0.72
Wave 4 (n=187)	20	23	0.58
Wave 5 (n=163)	23	18	0.69
12m PPQ **Total comments**			
Wave 1 (n=585)	67	89	0.17
Wave 2 (n=503)	73	86	0.46
Wave 3 (n=531)	69	73	0.67
Wave 4 (n=520)	68	72	0.51
Wave 5 (n=448)	57	49	0.35
Changes made to diet/weight that helped condition			
Wave 1 (n=156)	9	15	0.56
Wave 2 (n=159)	5	4	0.55
Wave 3 (n=142)	9	4	0.12
Wave 4 (n=140)	2	4	0.45
Wave 5 (n=106)	7	3	0.28
Good treatment			
Wave 1 (n=156)	6	6	0.61

Wave 2 (n=159)	7	9	0.86
Wave 3 (n=142)	6	3	0.26
Wave 4 (n=140)	4	7	0.37
Wave 5 (n=106)	5	6	0.56
Issues relating to how endoscopy went			
Wave 1 (n=156)	3	2	0.43
Wave 2 (n=159)	2	1	0.47
Wave 3 (n=142)	0	2	0.052
Wave 4 (n=140)	2	4	0.45
Wave 5 (n=106)	1	2	0.47
Now know cause of symptoms			
Wave 1 (n=156)	9	5	0.09
Wave 2 (n=159)	1	4	0.24
Wave 3 (n=142)	2	6	0.17
Wave 4 (n=140)	5	4	0.67
Wave 5 (n=106)	5	4	0.91
Sense of 'who cares?'			
Wave 1 (n=156)	0	2	0.22
Wave 2 (n=159)	0	2	0.19
Wave 3 (n=142)	0	0	No data
Wave 4 (n=140)	0	0	No data
Wave 5 (n=106)	0	0	No data
Asking for advice			
Wave 1 (n=156)	0	2	0.22
Wave 2 (n=159)	1	1	0.91
Wave 3 (n=142)	0	0	No data
Wave 4 (n=140)	0	0	No data
Wave 5 (n=106)	1	0	0.35
Other problems impacting on answers			
Wave 1 (n=156)	10	19	0.31
Wave 2 (n=159)	16	22	0.59
Wave 3 (n=142)	10	14	0.46
Wave 4 (n=140)	16	18	0.13
Wave 5 (n=106)	12	13	0.51
Describing ongoing problems			
Wave 1 (n=156)	20	33	0.35
Wave 2 (n=159)	25	26	0.59
Wave 3 (n=142)	20	32	0.07
Wave 4 (n=140)	23	22	0.88
Wave 5 (n=106)	20	11	0.15
Follow-up issues			
Wave 1 (n=156)	2	4	0.30
Wave 2 (n=159)	2	4	0.53

Wave 3 (n=142)	5	3	0.42
Wave 4 (n=140)	9	4	0.12
Wave 5 (n=106)	4	0	0.06
NHS general negative comments			
Wave 1 (n=156)	1	2	0.73
Wave 2 (n=159)	3	0	0.06
Wave 3 (n=142)	2	3	0.70
Wave 4 (n=140)	1	1	0.97
Wave 5 (n=106)	0	0	No data
Everything just takes too long			
Wave 1 (n=156)	3	3	0.72
Wave 2 (n=159)	2	0	0.12
Wave 3 (n=142)	1	2	0.59
Wave 4 (n=140)	1	0	0.30
Wave 5 (n=106)	2	1	0.65
Talking about IBS			
Wave 1 (n=156)	3	2	0.43
Wave 2 (n=159)	0	13	**0.001**
Wave 3 (n=142)	3	6	0.34
Wave 4 (n=140)	9	3	0.055
Wave 5 (n=106)	2	2	0.88
Diet-would have liked more advice			
Wave 1 (n=156)	1	0	0.25
Wave 2 (n=159)	1	0	0.28
Wave 3 (n=142)	2	1	0.53
Wave 4 (n=140)	1	2	0.59
Wave 5 (n=106)	4	1	0.23

4.5 Discussion

4.5.1 Summary of results

- Intervention patients waited on average seven days less than the Control patients. On a wave by wave basis the difference in waiting time between the Intervention and Control groups increased from Wave 1 (5d) to Wave 4 (18d) in favour of the Intervention group. This trend was reversed at Wave 5 with the Control group exhibiting a smaller waiting time than the Intervention group (17 days).
- The differences in the second, third and fourth waves reflected an increase in waiting times in the Control group. They did not decrease in the Intervention group, and overall waiting times did not shorten from April 2004 to early 2007.

- Important covariates that had an impact on patient HRQoL were BQ scores, age, gender, procedure type and waiting time to procedure.
- There was a significant improvement in both disease specific (GSRQ) and generic (SF-36 and EQ-5D) HRQoL following all types of endoscopy procedure for both Intervention and Control groups.
- There was no difference between the Intervention and Control groups in any of the HRQoL measures.
- There was no significant difference in HRQoL across any of the five waves of recruitment with the exception of the GSRQ-upper GI symptoms (at 12m PPQ).
- There were no significant differences in the number or types of issues raised by patients in their written comments.

4.5.2 Internal validity

- Although patient recruitment rates were low (~40%), they were consistent over the five waves of recruitment.
- The study recruited 3818 patients for HRQoL score analysis. This was 818 patients more than the 3000 specified by the initial power calculation for this study.
- All covariates that could have affected the modelling were incorporated into the model, reducing the potential for confounders.
- Results from the modelling were shown to be consistent when tested using different models (random intercept and random slope model, random intercept and fixed slope model and fixed intercept and fixed slope model) and when employing different software (MLWin and SPSS).

4.5.3 External validity

- The sites participating in the ENIGMA study were randomly selected from a cohort of sites applying to participate in the MES programme. The sites were stratified according to bed number prior to sampling to ensure that there was a mixture of different hospital types included in the study.
- The patients were recruited from each site using strict criteria so that there was no over-representation of a specific patient type or procedure type per wave per site.
- The scores reported by the consenting patients were weighted accordingly to ensure that the adjusted scores were more representative of the population of patients referred for GI endoscopy.

4.5.4 Implications

- Endoscopy has been shown to be an effective procedure as patients have better health related quality of life following endoscopy procedures. This supports previous studies (Williams, Russell, Durai, Cheung, Farrin, Bloor et al. 2006) that have also illustrated this benefit.
- Modernisation through the MES programme significantly affected patient waiting times, with the Intervention group

exhibiting shorter waiting times than the Control group for the second, third and fourth waves of the study.

- Overall waiting times did not decrease in either group over time.
- Although differences were seen in patient waiting times in the Intervention group, this did not translate into any added improvement in disease specific or generic patient health related quality of life.

5 Hospital process data

5.1 Executive summary

5.1.1 Aim

To evaluate the MES programme using routinely collected, service-related endoscopy data.

5.1.2 Methods

One aspect of the ENIGMA study involved comparing service-related data collected from Intervention and Control sites for eight specific time points in order to (1) determine whether the services in both Intervention and Control sites had changed over time and (2) identify whether there were any significant differences between the Intervention and Control sites at specific points in time. All 20 study sites were asked to submit service-related data pertaining to Referral numbers, Number of patients waiting more than three months (Wait >3m), Total number of patients waiting (Snapshot), Number of lost appointment slots (Lost slots) and Activity for eight time points: Jan, Jun & Dec 03, Apr & Nov 04, Apr & Oct 05 and Apr 06. Where endoscopy units did not provide data, Trust data was obtained. Data was aggregated into years (2003, 2004, 2005/06) and by site type (Intervention and Control groups) for statistical analysis using a two-way ANOVA.

5.1.3 Results

Analysable data was obtained from only eight sites (three Intervention and five Controls). There were no significant differences in the data over time for Referral numbers, Wait >3m, Snapshot, Lost slots or Activity within either the Intervention or the Control group. There was also no significant difference between Intervention and Control group data at any point in time for Referral numbers, Wait >3m or Lost slots. However, there was a significant difference in the data from the Intervention and Control groups for (1) Snapshot for 2004 and 2005/06 due to a decrease in the Intervention group matched by an increase in the Control group, and for (2) Activity for 2003 due to significant differences in data at the start of the study for the Intervention and Control groups.

5.1.4 Conclusion

The MES programme had no significant impact on the services of participating endoscopy units as a whole, and had limited benefits when compared to the Control site endoscopy units. Only the waiting lists of the Intervention sites benefited from the project, although that improvement was sustained long after the project closed. It appears that while the MES programme may have been a focus for thinking about redesigning services for both Intervention and Control sites during the application phase in 2002, the project itself did not appear to significantly improve endoscopy services

overall in the Intervention sites over and above what could have been achieved independently.

5.2 Aims and objectives

The aim of this aspect of the study was to evaluate the impact of the MES programme by comparing routine collected data relating to demand, activity and waiting times in each study site. The data encompassed Referral numbers, Referral source, Number of patients waiting, Number of lost appointment slots and Number of procedures performed. These outcome measures were referred to collectively as "process data".

More specifically, the aims of this study were:

- To make an assessment of the impact of the MES programme based on the comparative analysis of process data from Intervention and Control sites.
- To determine the availability and the accuracy of routinely collected process data from National Health Service (NHS) endoscopy units and their corresponding Trust Information Departments.

This would be achieved by fulfilling the following objectives:

a) To retrieve routinely collected process data from all 20 study sites.
b) To determine whether there were any significant improvements in process data in both the Intervention sites and the Control sites over time.
c) To explore whether there were any significant differences in process data between Intervention and Control sites at specific points in time.
d) To measure the extent of any changes (in terms of time) in process data from both Intervention and Control sites.

5.3 Methods

5.3.1 Details of the process data requested

The selection of the 20 study sites ensured that all had access to the MES Toolkit™. The Intervention sites were bound to its compulsory data collection regime while the Control sites, which had attended NHSMA workshops and indicated their intention to redesign independently, were able to use the data collection software as they wished.

The process data variables used in this study were all based on measures collected and analysed by the MES Toolkit™ as it was considered to be a fundamental part of the redesign process as an invaluable tool for analysing processes and measuring changes following modernisation. The NHSMA advocated the need for high quality data collection and so, the ENIGMA study opted to use these datasets as outcome measures with which to evaluate the MES programme.

Referral numbers - This was the number of referrals received by the endoscopy unit for diagnostic or therapeutic UGE, FS or colonoscopy procedures made to the endoscopy unit during a specified time period. We requested the data be split where possible into referral types, including day

cases (outpatients), Two Week Rule (TWR) referrals, inpatients, follow-ups and emergencies.

Referral sources - This was the number of referrals from a specific source for diagnostic or therapeutic UGE, FS or colonoscopy procedures made to the endoscopy unit during a specified time period. It was split where possible into numbers of referrals from GPs, consultants and private sources.

Number of patients waiting (Nº patients waiting) - This was the number of patients waiting for diagnostic or therapeutic UGE, FS or colonoscopy procedures on the active waiting list for more than one month, three months, six months and 12 months during a specified time period. The number of patients waiting more than three months (designated "***Wait >3m***") was used 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. The total number of patients waiting on the active waiting list for diagnostic or therapeutic UGE, FS or 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***"). Sites were asked to provide both data types where possible.

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

Number of procedures performed (Activity) - This was the total number of diagnostic or 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.

The total number of UGEs was requested as opposed to the numbers of gastroscopies and oesophageal-gastro-duodenoscopies (OGDs) separately because the terminology differed between study sites: some differentiated between the two while others grouped them into "upper GIs".

5.3.2 Time periods of data collection

All process 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. The months falling in 2003 corresponded to the start, middle and end of the MES programme, while all other months corresponded to the five waves of patient recruitment of the ENIGMA study. Where these dates were not available, data was accepted if ± one month.

The calendar months for which data was requested were: 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 T value is the time lapsed in months since the start of the ENIGMA study. The T0 data was to be used as a baseline measurement against which all subsequent data would be compared. Where T0 data were not available, the next time point with data were used instead. Data was retrospectively

requested in two phases, the first to cover T0 to T4 and the second to cover T5 to T7.

5.3.3 The endoscopy unit data request

The data were supplied by the endoscopy units themselves. All participating endoscopy units were approached by phone or email in January 2005 to provide copies, either electronic or hard copy, of any process endoscopy data that had been routinely collected for the calendar months specified. The purpose of the data request was twofold: firstly to find out what type of data was collected by the endoscopy unit, if any, and secondly to provide datasets at their rawest (and probably their truest) levels, free from manipulation or misinterpretation by Trust Information Departments. Units sending in-house datasets were asked to provide detailed descriptions of the data and any definitions used to make sure the data 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 was specified for five reasons: (1) The ENIGMA sites had not originally agreed to collect any process data for this study as it was not part of the 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 collection of these datasets if they were not routinely available, (4) it allowed the quantification of the availability of routinely collected process data and (5) to assess the quality of the data being collected in terms of detail and relevance to the analysis of the service over time.

Mann-Whitney U Tests were used to analyse the time taken to return these datasets to determine whether there was a significant difference in the time taken by the endoscopy units of Intervention and Control sites.

5.3.4 The NHS Trust Information Services endoscopy data request

In April 2005, managers of the Trust Information Services (TIS) of all 20 study sites were contacted by letter to ask whether they would be prepared to release copies of any process 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 the NHS wide clearing service for Hospital Episode Statistics (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 asked for data for periods T0 to T4. Follow-up datasets to cover T5 to T7 were 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, a proforma was made available for completion. The proforma was

designed as an Excel-based "*TIS form*" (see Appendix 7) that consisted of five pages requesting data on *Referral numbers* (Form A), *Referral sources* (Form B), *Nº patients waiting* (Form C), *Nº Lost slots* (Form D) and *Activity* (Form E) respectively, with the sub-variables described earlier incorporated within the form. 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 the Department of Health (DoH):

- Endoscopic operations on the oesophagus (G16 to G19) using Oesophageal-Gastro-Duodenoscopy (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.

Mann-Whitney U tests were used to analyse the time taken to return these datasets to determine whether there was a significant difference in the time taken by the TIS contacts from both Intervention and Control site Trusts.

5.3.5 Data collection forms

The process described replaced the unsuccessful attempt to obtain data, in which each endoscopy unit was contacted early on in the ENIGMA study to determine whether they could provide 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. For the data corresponding to T0 to T3, all four forms were sent in one go and all subsequent forms were sent singularly on the month immediately following the month specified on the data request.

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

1. The number of patients waiting more than 13 weeks for their endoscopy.
2. The % Did Not Attend (DNA) rate.
3. The average time from GP referral to procedure.
4. The number of referrals made to the unit.

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 programme.

Unfortunately, this aspect of data collection was not particularly successful in most sites, with low response rates and even lower sustained responses over time. As a result, this aspect of the ENIGMA study was abandoned in favour of the data collection and analysis procedure described in this chapter. However, the data accumulated within these early forms was available for analysis, if necessary.

5.3.6 Formation of the final dataset

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 submitted. The *TIS forms* were 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.

During the data extraction process, the data were assessed for their compliance to strict specifications and in accordance with the instruction sheet accompanying the *TIS Form*. Where a dataset 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), it was excluded from any analyses. Data were also excluded when it was not split according to procedure type because it was likely to include additional endoscopic procedures, albeit small, that would artificially inflate the totals and make the dataset inaccurate for comparison.

The exclusion criteria 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 where possible.

Where data were extracted from routinely collected in-house data to complete the *TIS forms*, they were validated by selecting approximately 20% of the datasets by randomising site numbers and *TIS forms* using SPSS v13.0 (Chicago, USA) software and re-completing them based on the original data. Any inconsistencies were amended and a further 20% of all sites and forms were 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 another 20% of the data being validated until no errors occurred.

The datasets for this study were categorised according to whether they corresponded to "*total procedures"* data (all three procedure types – UGEs, FS and colonoscopy - combined) or "*split procedures"* data (UGEs, FS and Colonoscopies separately). The *total procedures* data was calculated from the sum of the data provided for all three procedure types.

The data from the individual time periods were aggregated according to the corresponding year (2003, 2004 and 2005/06) for further analysis to improve the accuracy of the mean values from each site by providing a larger sample number from which the mean was taken. This would provide a truer reflection of the data for that period in time if missing data became a problem. Since there was only one time period for 2006, the data for 2005 and 2006 was merged to become 2005/06. Two time scales (T0 - T7 and 2003 - 2005/06) were used to contend with any missing data at the early and late time points. By presenting analyses using both time scales, any

changes in the outcome measures over time would be captured more effectively.

5.3.7 The validation of the study datasets

Since the data compiled for this study used up to three separate data sources (the endoscopy unit, the NHS Trust of each study site or the early ENIGMA data collection request), it was necessary to validate the final study datasets to ensure that any significant findings could be reported with confidence.

HES data is the national statistical data warehouse for England of the care provided by NHS hospitals and for NHS hospital patients treated elsewhere. While tailor-made requests can be made at a cost, there are also freely available datasets online (www.hesonline.org.uk/). Since HES data is collected at the Trust-level, it contains data combined from each endoscopy unit within a Trust. Hence, it was not appropriate to include all 20 study sites in a comparative analysis, since all study sites had submitted data to us corresponding to one endoscopy unit and not for the Trust as a whole. Where there were two or more endoscopy units within a Trust, the study data could not be compared with the HES data. Only those sites with a single endoscopy unit in the Trust were eligible for comparison. Of the 20 sites in this study, eight had just one endoscopy unit in the Trust. Of these eight, there were equal proportions of Intervention (6, 16, 18 and 19) and Control (2, 3, 9 and 12) sites.

The most complete dataset collected that would be 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 Table 28, while the actual data can be found in Appendices 8-11.

A written request was sent to the Health Information Research Unit (HIRU) based at Swansea University for 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 study data and HES 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: $$\%Difference = \frac{HESdata - STUDYdata}{STUDYdata}$$

The datasets were then compared using Wilcoxon Sign Rank test (given that the data was not normally distributed) to identify whether there were any statistically significant differences between them. Both datasets were compared initially according to procedure type (UGEs, FS and colonoscopies) at each time point before being further split according to Site type. A p-value of ≤ 0.05 was considered to be statistically significant.

5.3.8 Intervention and Control site data analysis

Exploratory data analysis (EDA) was performed on the data submitted by each study site to identify any outlying data and to explore any site-level data trends. This involved plotting the data from each site over time on a line graph according to Site type (Intervention and Control) and outcome measure. The Intervention and Control group means were also plotted and any sites with data deviating from the corresponding group mean were described.

5.3.9 Description of Intervention and Control group datasets split by procedure type

The data from the Intervention sites and Control sites were merged to become Intervention group and Control group datasets for use in all subsequent analyses. Stacked bar graphs were used to describe *split procedures* data for the Intervention and Control groups to identify outlying data and to examine data trends at individual time points (T0 to T7) and for data aggregated according to year (2003, 2004 and 2005/06).

5.3.10 Correlation of outcome measures

Correlation was used to determine whether there were any significant linear relationships between any of the five outcome measures and if so, to identify their strength and direction. Spearman's correlation was chosen as the best test due to low sample numbers, since this test was based on ranks rather than the actual data. This analysis was done using *total procedures* data for data aggregated according to the corresponding year, split according to Site type.

5.3.11 Two-way analysis of variance

A two-way analysis of variance (ANOVA), also known as a mixed between-within groups ANOVA, was performed to determine the impact of Site type (Intervention and Control) and Time (2003, 2004 and 2005/06) on *Referral numbers, Wait >3m, Snapshot, Lost slots* and *Activity* using *total procedures* data. The test also identified any significant interaction effects between Site type and Time, which would indicate whether there was the same type of change in scores over time for the two different Site types. As well as a significant p-value, a significant interaction effect can be illustrated graphically whereby the two lines plotted for the means of each Site type are not parallel.

5.4 Results

5.4.1 The availability of process data from the endoscopy units

Only eight of the 19 endoscopy units were able to provide copies of any process data for any of the time periods requested, of which three were Intervention sites and five were Control 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). One of the Toolkit™ files had been submitted by a Control site that had attended an NHSMA workshop and were keen to use the data collection software. Closer examination of the dataset contained within the Toolkit™ file confirmed that they were only interested in completing specific aspects of the Toolkit™ as some tabs were left blank. One site (1) agreed to pilot the *TIS form* and searched Patient Administration System (PAS) to extract the necessary data. Since the completed form held data of superior quality, it was used for further analysis, replacing the original dataset submitted - a printout of part of the Toolkit™ for January 2003 only.

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 it was not submitted for this study due to excessive staff workloads (9 and 15). The remaining seven stated that they did not routinely collect any process data within the unit and relied on the Trust 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 study, they mentioned their intention to initiate data collection.

Of the eight sites providing routinely collected process data, not all of the outcome measures were collected. When examining the data from Intervention and Control sites, the Control sites provided more of the outcome measures requested than the Intervention sites. When looking at all six outcome measures in this study (number of patients waiting was split into *Wait >3m* and *Snapshot*), one Intervention site provided four data types (1), while the other two were only able to provide one (7 and 19). One Control site provided five data types (2), one provided four (5), two provided three (12 and 17) and only one provided just one data type (10). A breakdown of the actual data provided by each endoscopy unit is illustrated in Table 26.

Table 27 shows the time taken for the endoscopy units to return the process endoscopy 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 (4 and 6). No significant differences were found between Intervention and Control sites in their response times ($p \leq 0.05$, Mann-Whitney).

This study hypothesised that all NHS endoscopy units would routinely collect some degree of process 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 process endoscopy data. 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 the data and allow a tentative comparison, so long as any conclusions would bear in mind the different sources of the data making up the datasets being analysed.

5.4.2 The availability of process data from TIS departments

Of the 20 Trust sources contacted to provide data files, responses were received from 19, including one IT department (3), with the one non-responder (7) not responding to any attempts to make contact by email, phone or letter. Ten Trusts were able to send electronic copies of their data or reports (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) sent the exact same file as was submitted by the corresponding endoscopy unit, while another TIS contact (1) sent a report but advised the researcher to consult with the corresponding endoscopy unit, commenting that they deferred to the endoscopy staff for accurate data collection from PAS.

Table 27 shows the time taken for the TIS contacts to return the process 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. No significant differences were found between Intervention and Control sites in their response times ($p \leq 0.05$, Mann-Whitney).

5.4.3 The availability of process data from the ENIGMA study

A total of 14 of the 19 ENIGMA sites returned at least one form to correspond to a time point (T0 to T7) requested (1, 2, 3, 4, 6, 7, 8, 11, 12, 13, 14, 16, 17 and 20). A further two indicated early on that the data was 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 (4, 6, 7, 8 and 14) and a further three did not return the final form corresponding to T7 (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.

Table 26. The availability of the six outcome measures provided by the eight endoscopy u collected process data for this study.

Site ID	Site type	Referral Numbers	Referral source	Wait >3m	Snapshot	Lost slots	Activit
1	Intervention	Yes	No	No	Yes	Yes	Yes
7	Intervention	No	No	No	Yes	No	No
19	Intervention	No	No	No	No	No	Yes
2	Control	Yes	Yes	Yes	Yes	Yes	No
5	Control	Yes	Yes	No	No	Yes	Yes
10	Control	No	No	No	Yes	No	No
12	Control	Yes	No	No	Yes	No	Yes
17	Control	Yes	Yes	No	No	No	Yes

Table 27. Description of the time taken in weeks to receive data pertaining to T0 to T4 from the endoscopy units and the corresponding Trusts of all sites. Data from sites 4 and 6 were completed jointly by the endoscopy unit and Trust. Data from Hospital 18 was not requested from the endoscopy unit.

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

5.4.4 Categorisation of datasets

Based on discussions with site contacts (endoscopy unit and/or TIS contacts), definitions provided and observational comparisons, data from endoscopy units was used in preference to Trust data 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 from a few Trusts concerning a change in coding practices for endoscopies, making the data from these sites less accurate when analysing for trends over time, although there was no published evidence of this occurring. Trust data was only used in the complete absence of any endoscopy data and where possible, the TIS data submitted was the same as the data that would have been sent to the endoscopy unit on request.

In all, four types of data were available from three sources for this study. Each was ranked according to its accuracy, then by its availability. While data completed by the endoscopy unit was considered to be most accurate, the ENIGMA data collection forms completed by each endoscopy unit were not completed very rigorously and were not used unless all other data sources were exhausted. The final data rankings used for this study 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 five *TIS forms* to allow consistency and enhance comparability. Data sources were allowed to vary between *TIS forms* where absolutely necessary, but not within the *TIS forms* or else it would not be feasible to compare the data.

5.4.5 Exclusion of datasets

In most cases, data from sites was excluded because it 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), the datasets had to be excluded because there was doubt cast upon their accuracy because they included a number of zeros. When this was queried with the TIS contact, she commented on changes in coding practices over the time period requested that, in her opinion, made the dataset unsuitable for analysis over time. All Site 15 datasets were subsequently completely excluded from all analyses.

Referral numbers data was excluded from Sites 14, 15 and 19. In two of these sites, the data was not split according to referral type (14) or procedure type (19). The request for *Referral source* data (*TIS Form* B) was poorly collected in the majority of sites and so, this outcome measure was excluded from any analyses.

Number of patients waiting data was excluded from sites 5, 11, 13, 15 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 was excluded from Sites 14, 15, 16, 17 and 19 because *Lost slots* data needed to include DNAs, patient and hospital cancellations data to compute an accurate total for comparison with other sites. 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 was excluded from 7, 14 and 15, two of which did not split their data according to procedure type (7 and 14).

5.4.6 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 of varying types and subsequent ranking of data according to its source. Table 28 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 correspond to a key identifying the source of that data item based on the final rankings. Grey-shaded cells highlight those data items where the exclusion criteria meant that it had to be excluded for one of the reasons stated previously. Black cells indicate that no data was available from any source.

Table 28. Description of sources of data for the final dataset split according to site ID, site type (I = Intervention; C = Control), time point (T0 to T7) and data type based on *TIS form* completion (A = Referral numbers; B = Referral sources; C = Waiting lists; D = Lost slots and E = Activity).

Site …		Jan-03 (T0)					Jun-03 (T1)					Dec-03 (T2)					Apr-04 (T3)				
ID	Type	TIS Forms					TIS Forms					TIS Forms					TIS Forms				
		A	B	C	D	E	A	B	C	D	E	A	B	C	D	E	A	B	C	D	E
1	I	1		1	1	1	1		1	1	1	1		1	1	1	1		1	1	1
2	C					3					3	1		1	1	3	1		1	1	3
3	C	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
4	I	4		4		4	4		4		4	4		4		4	4		4		4
5	C			3					3					3			1	1	3	1	1
6	I	5		5	4	4	5		5	4	4	5		5	4	4	5		5	4	4
7	I	5		1		3	5		1		3	5		1		3	5		1		3
8	I	3		3		3	3		3		3	3		3		3	3		3		3
9	C	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3
10	C					3					3					3			1		3
11	I	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
12	C											1		1		1	1		1		1
13	I	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
14	C	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3
15	C	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
16	I				3	3				3	3	5			3	3	5			3	3
17	C											1	1	1	1	1	1	1	1	1	1
18	I	3		3	3	3	3		3	3	3	3		3	3	3	3		3	3	3
19	I	3		3	3	1	3		3	3	1	3		3	3	1	3		3	3	1
20	C					2					2					2					2

(Cont'd…)

(…Cont'd)

Site …		Nov-04 (T4)					Apr-05 (T5)					Oct-05 (T6)					Apr-06 (T7)				
ID	Type	TIS Forms					TIS Forms					TIS Forms					TIS Forms				
		A	B	C	D	E	A	B	C	D	E	A	B	C	D	E	A	B	C	D	E
1	I	1		1	1	1	1		1	1	1	1		1	1	1	1		1	1	1
2	C	1		1	1	3	1		1	1	3	1		1	1		1		1	1	
3	C	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
4	I	4		4		4	4		4		4	4		4		4	4		4	4	4
5	C	1	1	3	1	1	1	1	3	1	1	1	1	3	1	1		1	3	1	1
6	I	5		5	4	4	5		5	4	4				4	4	5			4	4
7	I	5		1		3	5		1		3			1		3			1		3
8	I	3		3		3	3		3		3	3		3		3	3		3		3
9	C	3	3	3	3	3			3	3	3			3	3	3			3	3	3
10	C			1		3			1		3					3					3
11	I	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2		2	2
12	C	1		1		1	1		1		1	1		1		1					
13	I	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
14	C	3	3	3	3	3	3	3	3	3	3										
15	C	2	2	2	2	2	2	2	2	2	2										
16	I	5			3	3	5					5									
17	C	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1		1	1
18	I	3		3	3	3	3		3	3	3	3		3	3	3	3		3	3	3
19	I	3		3	3	1	3		3	3	1	3		3	3				3		
20	C	5		5		2	5		5		2	5		5			5		5		

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 was excluded and the black cells indicate that no data was available from any source.

5.4.7 Results of the data validation process

HIRU were able to provide all HES datasets requested at a cost of £315. The results of applying formulae A and B to the datasets are shown in Table 29 for the Intervention sites and Table 30 for the Control sites. Any *% Difference* values ≥ 50% are illustrated in bold.

It was clear from the table that Sites 16 and 18 had extremely large differences between their HES data and the data collected for this study (see Table 31) whereby the HES data was 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 so the *% Difference* appears 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 actual HES data from Sites 16 and 18, shown in Table 28 below, revealed extremely low counts for UGEs and colonoscopies during the calendar months specified as T0 to T7, so low as to cause serious concerns regarding their accuracy, especially when comparing the data to that received for this study (see Appendices 8-11).

Further interrogation of the HES database in collaboration with a HIRU data analyst revealed that the error was "true" and was not the fault of any incorrect queries. It became apparent that it was the number of day cases being reported that was problematic, with Site 16 reporting three endoscopy day cases in total for 2003/04 and six for 2005/06, while Site 18 reported 21 endoscopy day cases in total for 2003/04 and 30 day cases for 2005/06.

The reason for this discrepancy was not obvious, since the study datasets from these two sites had both come from the Trust. The researcher pursued the matter further with both TIS contacts and found that they tended to record their endoscopies as outpatient procedures instead of day cases. This meant that they were not reported to HES, since the HES database did not include outpatient procedures until more recently.

Given the non-normal distribution of the Activity data, non-parametric tests were used to analyse the data. We used the Wilcoxon signed rank test to determine whether there was a significant difference between HES and Study data, split according to procedure type and time point of data capture. Data from all eight sites were used in the first instance, followed by the exclusion of the data from Sites 16 and 18 for more accurate analysis.

First-stage analysis – all datasets

When examining the two sets of eight datasets split according to procedure type and time, there was no significant difference between HES data and Study data value. The same was true when data was split according to Intervention and Control sites.

Second-stage analysis – edited datasets

Following the exclusion of the *split procedures* datasets from Sites 16 and 18 from the analysis, there were significant differences between the HES data and Study data for UGEs at T0 ($Z = -2.023$, $p = 0.043$), T1 ($Z = -2.023$), T2 ($Z = -2.023$), for Colonoscopies at T0 ($Z = -2.023$, $p = 0.043$) and for FS at T0 ($Z = -2.023$, $p = 0.043$), T1 ($Z = -2.023$, $p = 0.043$), T2, ($Z = -2.201$, $p = 0.028$), T4 ($Z = -2.201$, $p = 0.028$) and T5 ($Z = -1.997$, $p = 0.046$).

When the analysis was split according to Site type, there was no significant difference between HES data and study data.

Table 29. *Difference (Diff)* and *% Difference (% Diff)* between HES data and study data fo sites.

Site ID	Proc. type	T0		T1		T2		T3		T4		
		Diff	*% Diff*	*Diff*	*% Diff*	*Diff*	*% Diff*	*Diff*	*% Diff*	*Diff*	*% Diff*	*Diff*
6	1	9	4	71	**61**	0	0	-2	-1	-5	-3	-2
6	2	-7	-15	3	5	-3	-5	0	0	1	2	1
6	3	7	11	6	13	3	5	1	3	2	4	8
16	1	-31	**-52**	-101	**-80**	-101	**-73**	-143	**-85**	-146	**-85**	
16	2	-140	**-93**	-338	**-95**	-342	**-96**	-350	**-96**	-316	**-96**	
16	3	4	**400**	-9	**-75**	6	**200**	-1	-9	-24	**-83**	
18	1	-290	**-85**	-351	**-89**	-272	**-84**	-291	**-85**	-358	**-90**	-334
18	2	-278	**-95**	-334	**-94**	-354	**-94**	-334	**-92**	-334	**-92**	-403
18	3	-44	**-90**	-60	**-92**	-21	**-91**	-13	**-81**	3	**300**	-7
19	1	21	11	6	3	9	5	110	**169**	14	6	24
19	2	4	11	2	4	6	14	-45	**-53**	0	0	15
19	3	11	9	5	4	6	8	-122	**-58**	10	10	16

Figures in bold illustrate a *% Difference* ≥ 50%. Procedure types: 1 = UGEs; 2 = FS and 3 = Colonoscop data was available from this study.

Table 30. *Difference (Diff)* and *% Difference (% Diff)* between HES data and study data fo sites. Figures in bold illustrate a *% Difference* ≥ 50%. Procedure types: 1 = UGEs; 2 = I Shaded areas indicate that no data was available from this study.

Site ID	Proc. type	T0		T1		T2		T3		T4		T5
		Diff	*% Diff*	*Diff*	*% Diff*	*Diff*	*% Diff*	*Diff*	*% Diff*	*Diff*	*% Diff*	*Diff*
2	1	53	15	89	23	41	11	55	15	38	10	58
2	2	38	39	35	37	37	34	36	46	52	**59**	25
2	3	15	42	25	**89**	11	37	0	0	18	30	4
3	1	22	7	19	7	22	7	27	9	21	7	22
3	2	18	33	16	18	19	34	17	26	27	32	21
3	3	1	4	2	6	3	7	0	0	9	20	2
9	1	128	44	99	30	120	42	-129	**-51**	-115	-49	-119
9	2	47	42	42	39	57	**65**	-51	**-61**	-35	-41	-63
9	3	4	**80**	10	**333**	10	**91**	6	**86**	-1	-8	-6
12	1					57	**66**	64	49	53	48	36
12	2					-13	-11	0	0	7	6	17
12	3					17	39	7	13	10	11	8

Table 31. Actual data provided from HES for Sites 16 and 18 for UGEs and colonoscopy.

Hospital ID	Procedure type	T0	T1	T2	T3	T4	T5	T6
16	UGEs	29	25	37	26	25	22	34
16	Colonoscopy	10	16	16	14	14	21	25
18	UGEs	50	43	51	53	42	48	38
18	Colonoscopy	15	23	22	29	28	33	20

5.4.8 Description of Intervention and Control site datasets

In the case of *total procedures* data: *Referral numbers* were available for nine Intervention sites and seven Control sites; *Wait >3m* data was available for six Intervention sites and four Control sites; *Snapshot* data was available for four Intervention sites and five Control sites; *Lost slots* data was available for five Intervention sites and four Control sites and *Activity* data was available for nine Intervention sites and eight Control sites. Availability of the *Split procedures* data was 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 8-11, split according to *total procedures* data and *split procedures* data, namely UGE, FS and colonoscopy datasets.

5.4.9 Intervention and Control site data analysis

The following section describes the data for each outcome measure from each study site, split according to Site type. The data is represented graphically according to Site type using *total procedures* data at individual time points, with individual sites' data plotted using different coloured lines. The Intervention and Control group mean was also included for comparative purposes. The Intervention site and Control site graphs did not have matching scales because the data was better illustrated this way and also, because they were not meant for comparative purposes at this point. This will be dealt with later in the chapter.

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

Wait >3m for Intervention and Control sites are plotted in Figures 6 and 7 respectively. Data were limited, especially from Control sites, although most time points were available. The trends of both Intervention and Control sites appeared to be fairly constant over time, with the exception of Sites 4 and 18 for the Intervention sites and Site 14 for the Control sites, which dramatically deviated from the Control 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 Intervention site (18) and one Control site (14) showed increases in *Wait >3m* over time, while four Intervention sites (4, 6, 7, 8 and 19) and three Control sites (2, 3 and 20) showed decreases. One Intervention site data remained unchanged (6).

Figure 6. Total procedures Referral numbers for each Intervention site and the Intervention group mean.

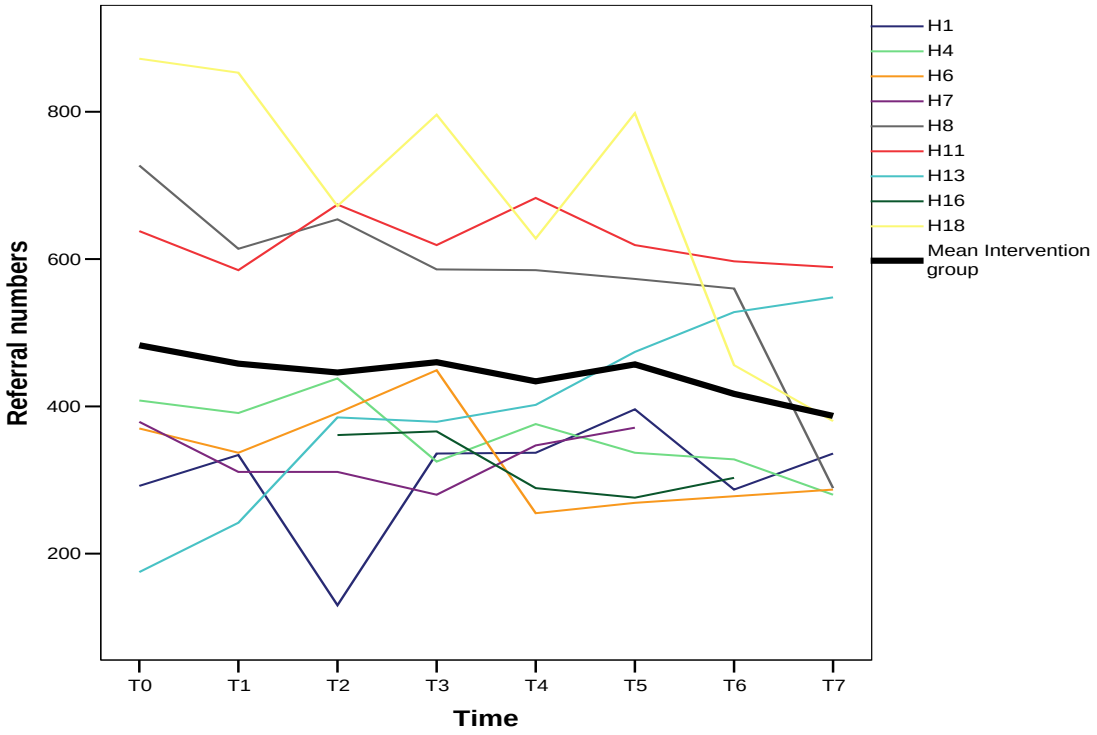


Figure 7. Total procedures Referral numbers for each Control site and the Control group mean.

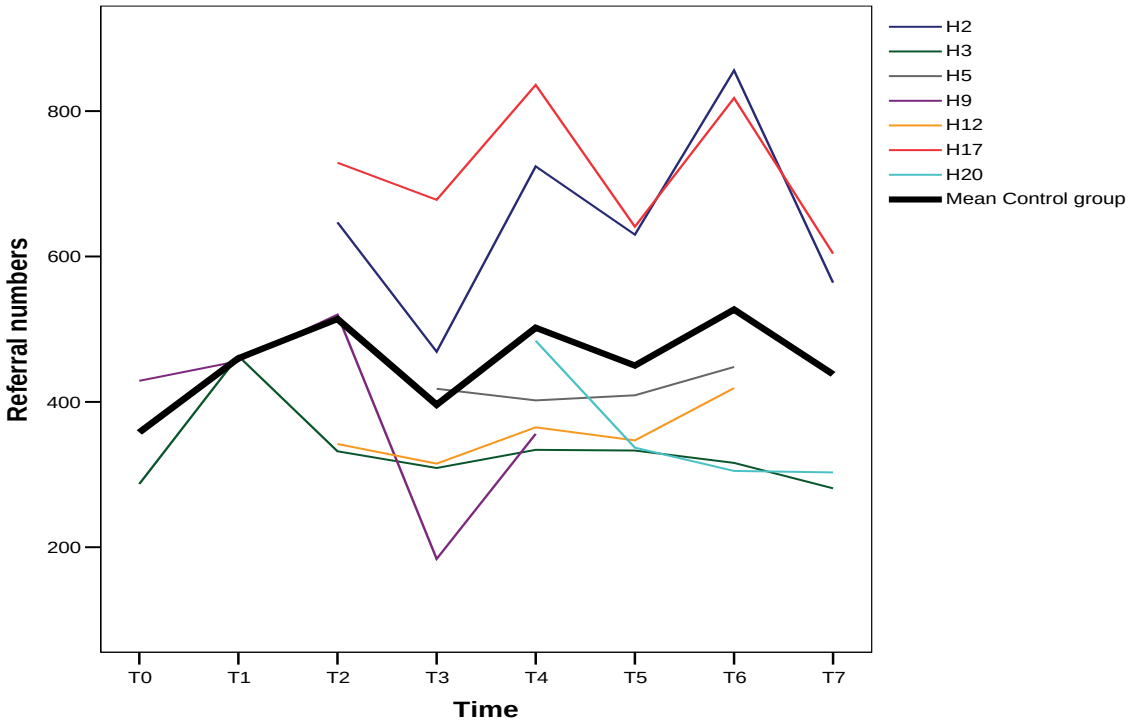


Figure 8. Total procedures Wait >3m for each Intervention site and the Intervention group mean.

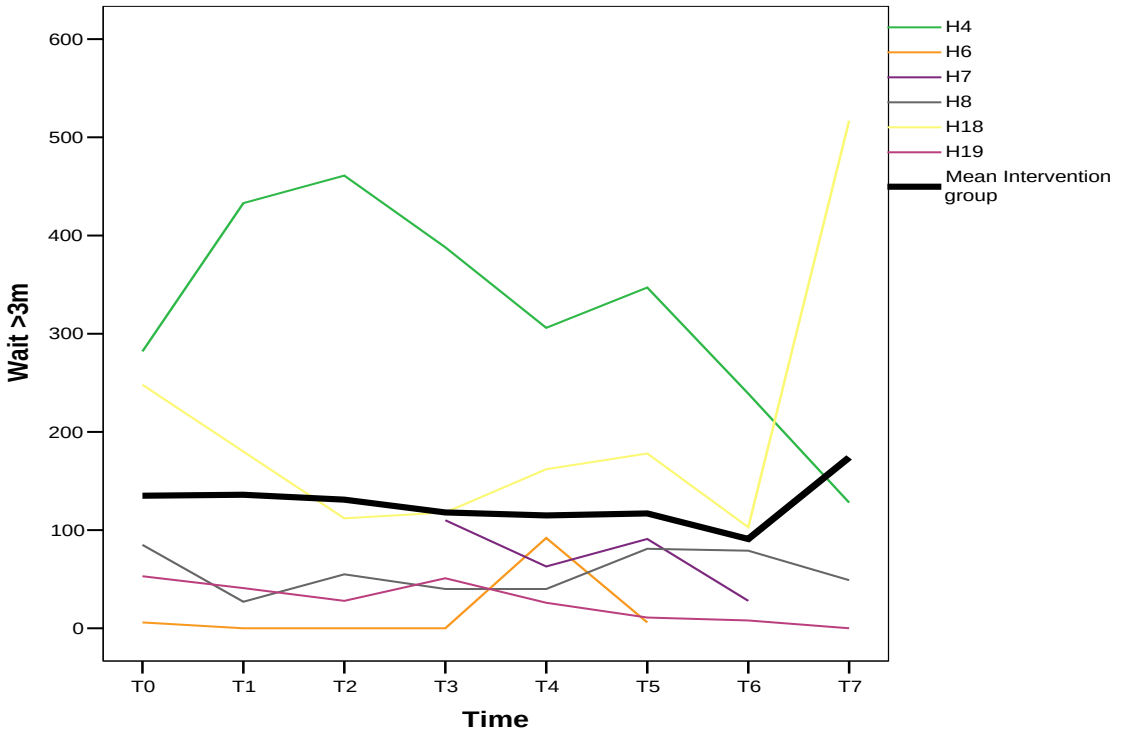
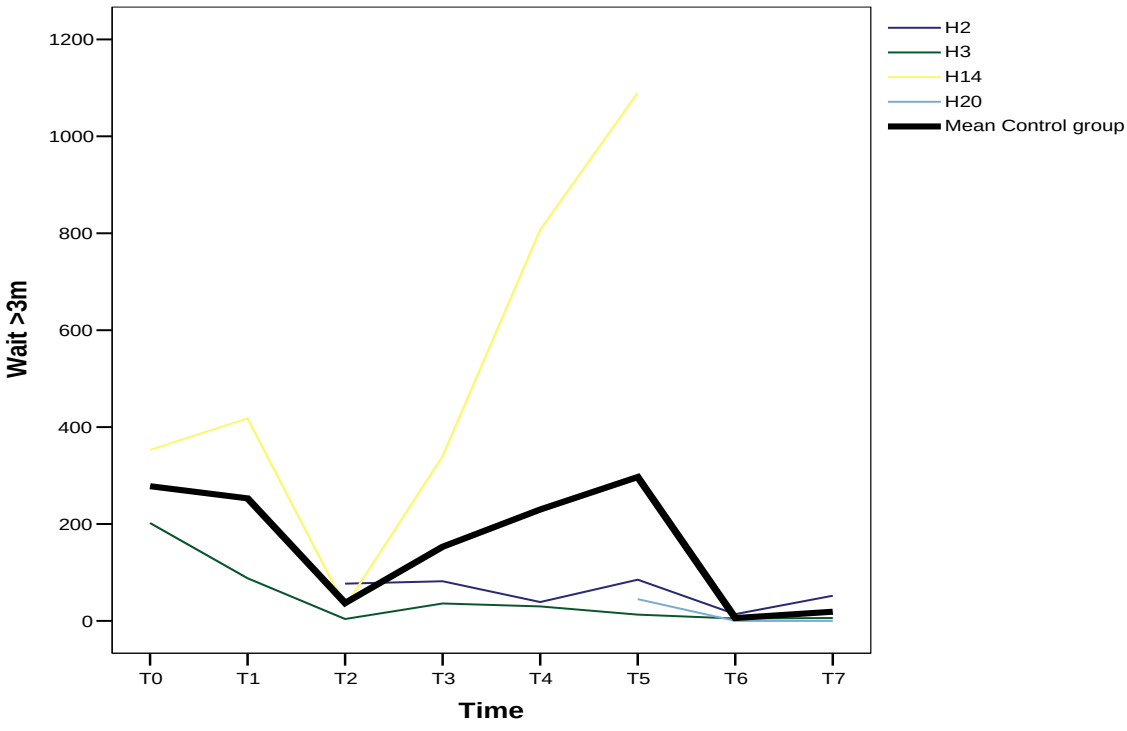


Figure 9. Total procedures Wait >3m for each Control site and the Control group mean



Snapshot for Intervention and Control sites are plotted in Figures 10 and 11 respectively. Data were extremely limited from both Site types, although most time points were available. The trends of both Intervention sites were highly variable while Control sites appeared to be fairly constant over time. The Intervention group mean was not representative of any of the individual sites, although none seemed to deviate from the mean for any extent, while the Control group mean showed a similar trend to many of the constituent sites. Site 9 showed extensive deviation from the Control 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 Intervention site (18) and four Control sites (9, 10, 11 and 12) showed increases in *Snapshot* over time, while three Intervention sites (1, 8 and 19) and one Control site (2) showed decreases.

Lost slots for Intervention and Control sites are plotted in Figures 12 and 13 respectively. Data were limited from both Site types, although most time points were available. The trends of both Intervention and Control sites appeared to be fairly constant over time, as reflected in the corresponding group means. Site 18 was generally double that of the Intervention group mean and the same trend was seen for Site 9 compared to the Control group mean from T2 onwards. When examining the data from the earliest to the latest available time points, no Intervention sites showed increases in *Lost slots* while two Control sites did (2 and 5). All five Intervention sites (1, 6, 11, 13 and 18) showed decreases in their *Lost slots* over time compared with only two Control sites (3 and 9).

Activity for Intervention and Control sites are plotted in Figures 14 and 15 respectively. Data were available from most sites and for most time points. The trends of both Intervention and Control sites appeared to be fairly constant over time, as reflected in the corresponding group means. Site 18 deviated from the Intervention group mean, while Site 17 appeared to deviate from the Control 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 Intervention sites (16 and 19) and four Control sites (2, 12, 17 and 20) showed increases in *Activity*, while seven Intervention sites (1, 4, 6, 8, 11, 13 and 18) and four Control 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 according to 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 32 with the actual difference in the data illustrated numerically, along with signs to illustrate whether the direction of the differences as increases (+) or decreases (-).

Figure 10. Total procedures Snapshot for each Intervention site and the Intervention group mean.

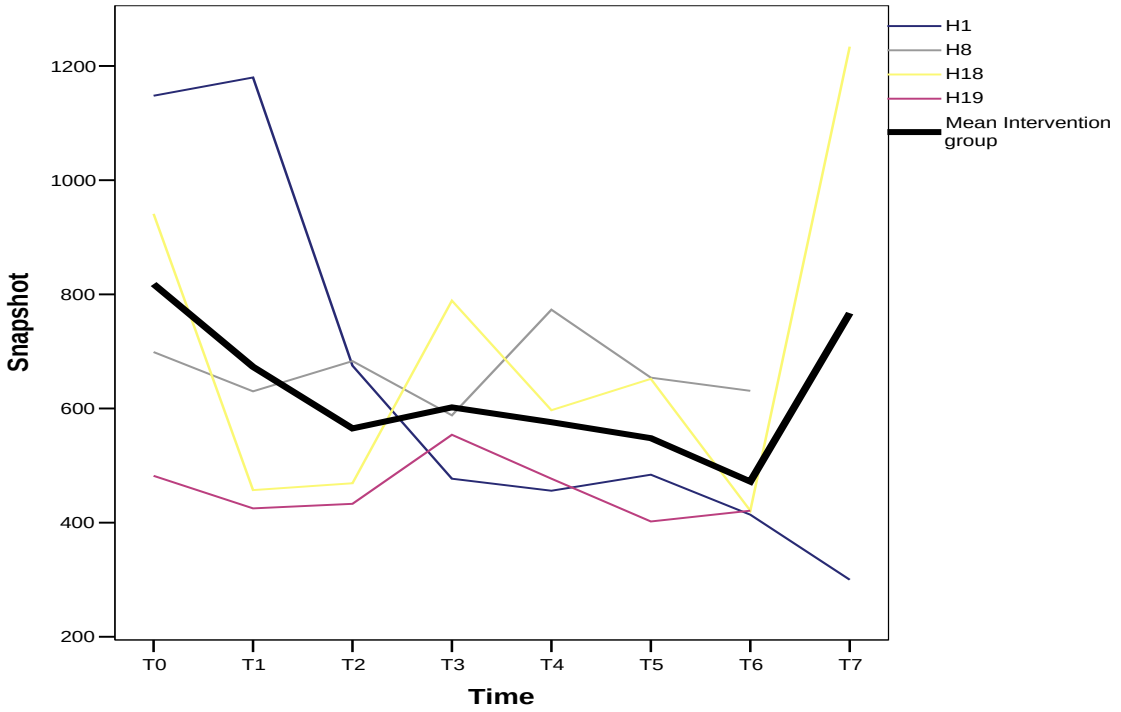


Figure 11. Total procedures Snapshot for each Control site and the Control group mean.

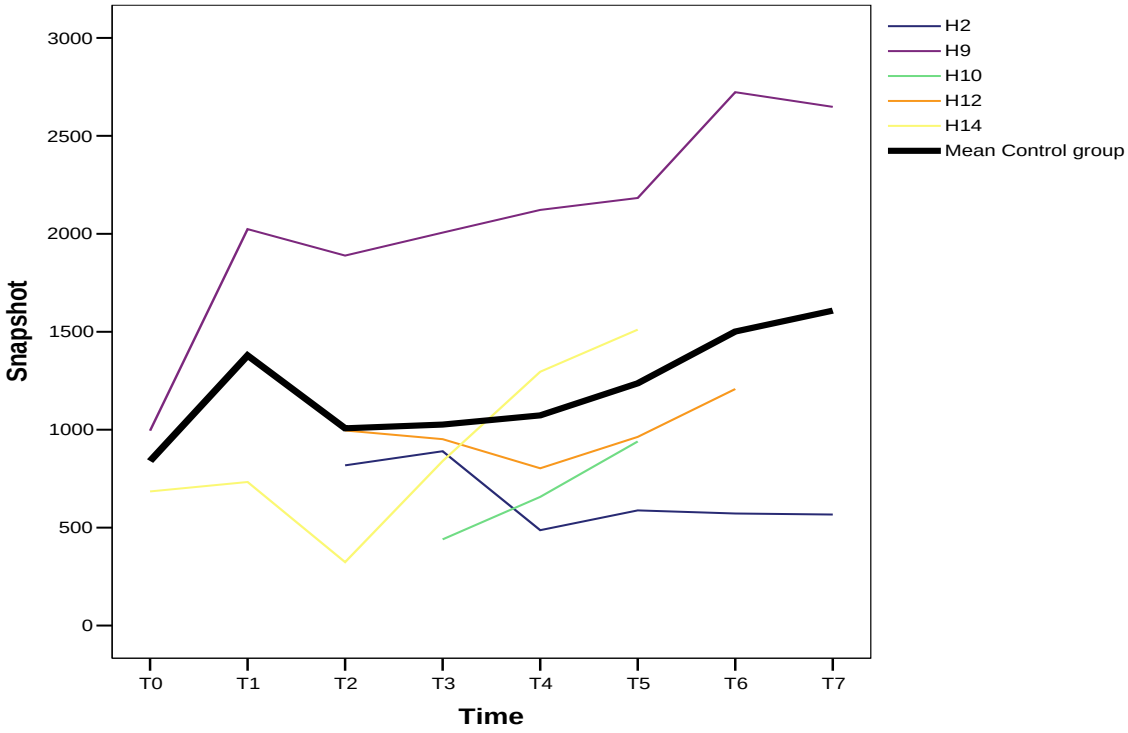


Figure 12. *Total procedures Lost slots* for each Intervention site and the Intervention group mean.

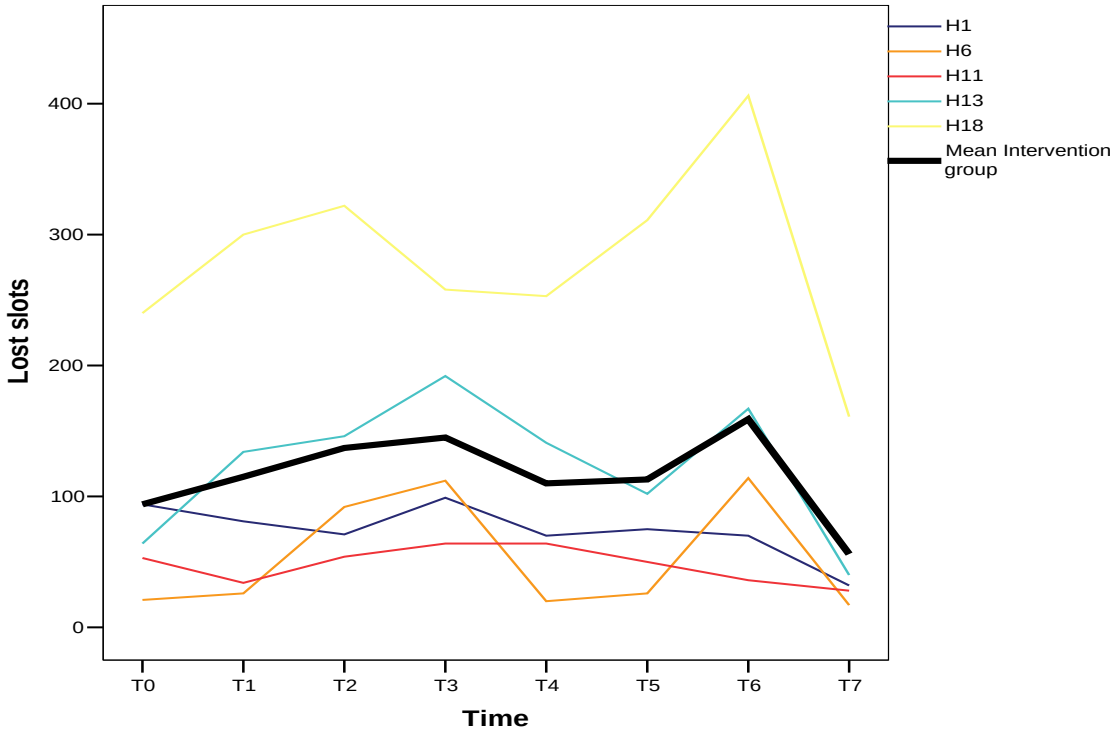


Figure 13. *Total procedures Lost slots* for each Control site and the Control group mean.

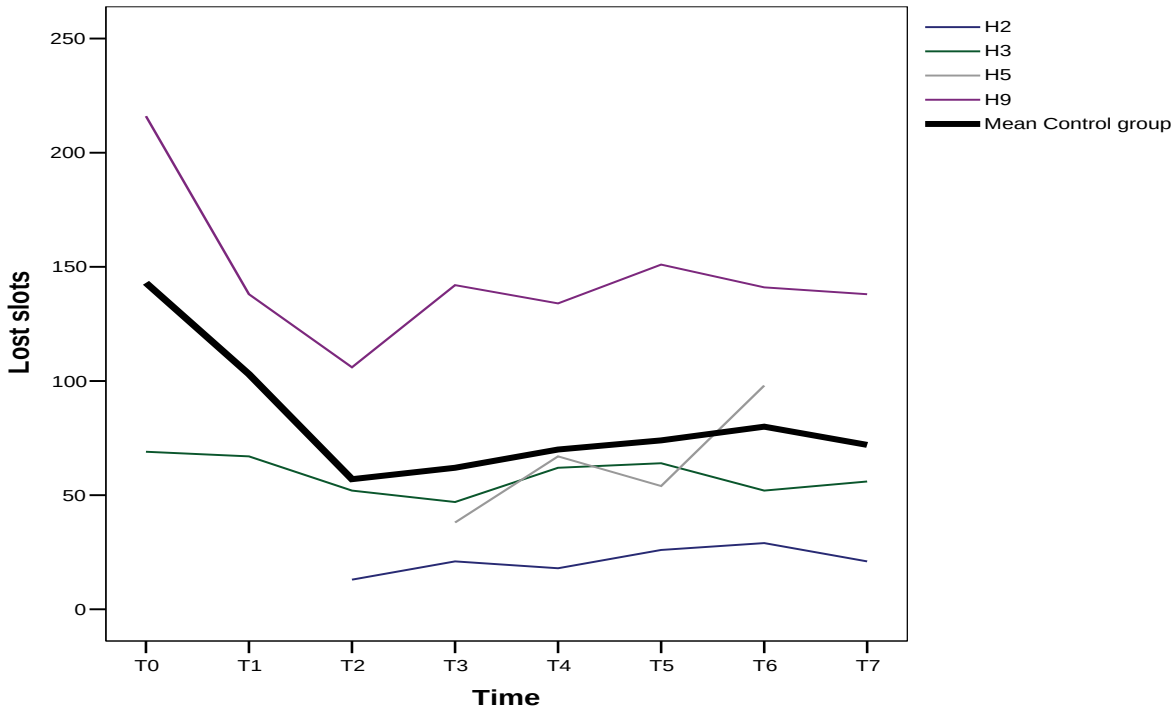


Figure 14. Total procedures Activity for each Intervention site and the Intervention group mean.

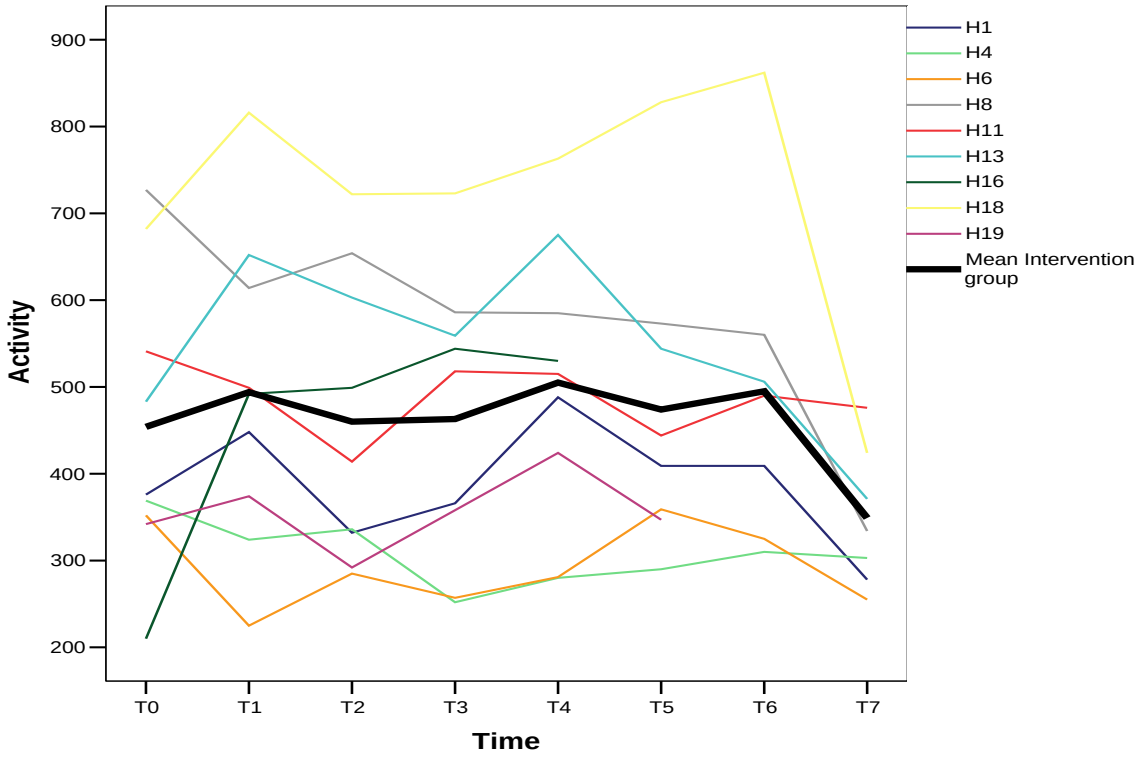


Figure 15. Total procedures Activity for each Control site and the Control group mean.

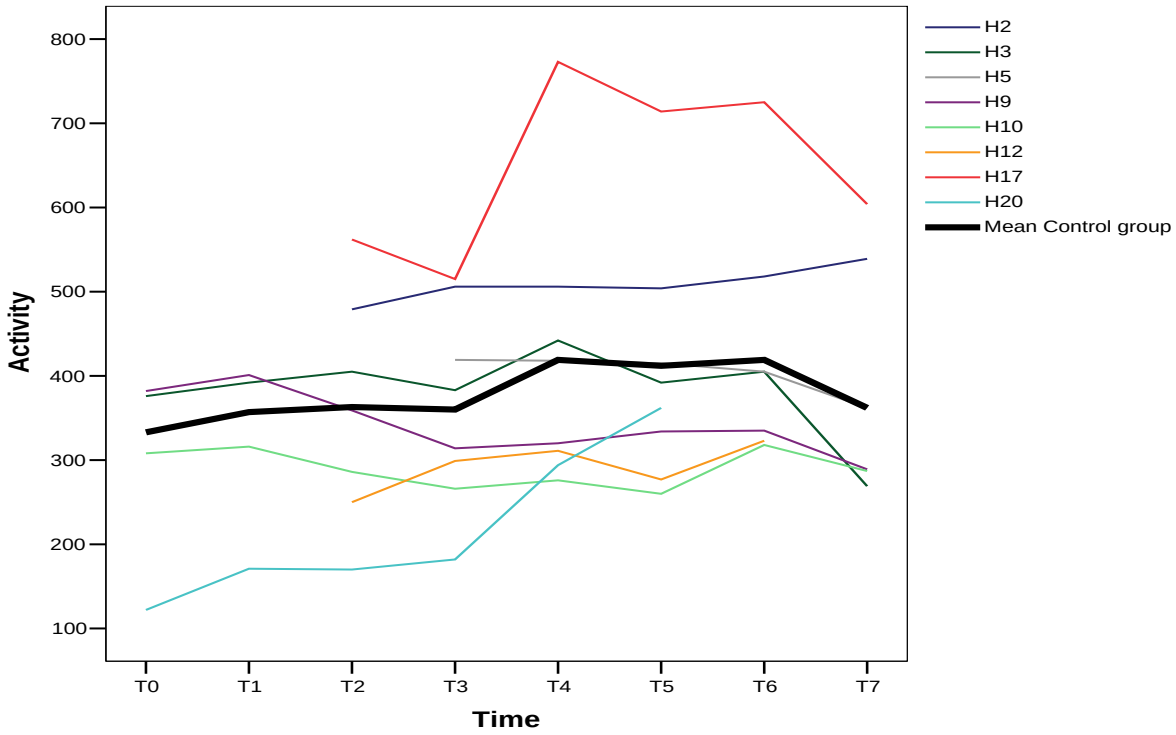


Table 32. Summary of the trend of data for *Referral numbers, Wait >3m, Snapshot, Lost s*
Data illustrates the difference in counts for each outcome measure from (i) T0 to T7 (o
data) and (ii) 2003 to 2005/06. Key: + = increase in counts; - = decrease in counts. Th
signified the actual difference in counts.

Site ID	Site type	Time Period	Referral Nºs	Wait >3m	Snapshot	
1	I	T0 - T7	+ (44)	No data	- (848)	
		2003 - 2005/06	+ (88)		- (602)	
2	C	T0 - T7	- (83)	- (25)	- (251)	
		2003 - 2005/06	+ (36)	- (27)	- (242)	
3	C	T0 - T7	- (6)	- (196)	No data	
		2003 - 2005/06	- (51)	- (90)		
4	I	T0 - T7	- (128)	- (154)	No data	
		2003 - 2005/06	- (97)	- (154)		
5	C	T0 - T7	+ (30)	No data	No data	
		2003 - 2005/06	No 2003 data			N
6	I	T0 - T7	- (83)	No change	No data	
		2003 - 2005/06	- (88)	+ (4)		
7	I	T0 - T7	- (8)	- (82)	No data	
		2003 - 2005/06	+ (37)	No 2003 data		
8	I	T0 - T7	- (438)	- (36)	- (68)	
		2003 - 2005/06	- (191)	+ (14)	- (28)	
9	C	T0 - T7	- (73)	No data	+ (1653)	
		2003 - 2005/06	No 2005/06 data		+ (882)	
10	C	T0 - T7	No data	No data	+ (500)	
		2003 - 2005/06			No 2003 data	

(Cont'd…)

(…Cont'd)

Site ID	Site type	Time Period	Referral Nºs	Wait >3m	Snapshot	Lo
11	I	T0 - T7	- (49)	No data	No data	
		2003 - 2005/06	- (31)			
12	C	T0 - T7	+ (77)	No data	+ (212)	N
		2003 - 2005/06	+ (41)		+ (90)	
13	I	T0 - T7	+ (373)	No data	No data	
		2003 - 2005/06	+ (249)			
14	c	T0 - T7	No data	+ (737)	+ (826)	N
		2003 - 2005/06		+ (823)	+ (930)	
15	C	T0 - T7	No data	No data	No data	N
		2003 - 2005/06				
16	I	T0 - T7	- (58)	No data	No data	N
		2003 - 2005/06	- (72)			
17	C	T0 - T7	- (125)	No data	No data	N
		2003 - 2005/06	- (41)			
18	I	T0 - T7	- (492)	+ (269)	+ (293)	
		2003 - 2005/06	- (254)	+ (86)	+ (147)	
19	I	T0 - T7	No data	- (53)	- (61)	N
		2003 - 2005/06		- (34)	- (35)	
20	c	T0 - T7	- (181)	- (45)	No data	N
		2003 - 2005/06	No 2003 data	No 2003 data		

5.4.10 Description of Intervention and Control group data

The data from each Intervention site and each Control site were merged to become Intervention and Control group datasets. The mean values of each outcome measure at each individual time point and for data aggregated by year were tabulated for Intervention and Control groups using *total procedures* data (see Table 33) and *split procedures* data (see Table 34 for Intervention site data and Table 35 for Control site data). 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).

In addition to this, the group mean for each outcome measure was plotted graphically according to Site type and timescale 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.

Referral numbers

The mean *total procedures Referral number* trend for the Intervention group fell from 483 to 387 between T0 and T7 while the Control group mean increased from 358 at T0 to 438 at T7. The Control group mean showed more variability over time than the Intervention group mean. When the data was aggregated according to year, the Intervention group mean showed a decrease from 462 at 2003 to 423 at 2005/06. The Control 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 was split by procedure type, the Intervention group means for each procedure appeared to be relatively constant from T0 to T7 (see Figure 16) and 2003 to 2005/06 (see Figure 17). The only variation was for UGEs (OGD in the graph), which appeared to decrease over time. Data for all three procedures for the Control group were more variable over time for T0 to T7 and 2003 to 2005/06, with increasing numbers of LGEs (FS and colonoscopy on the graph) matching decreasing numbers of UGEs.

Table 33. Mean values with standard deviations of each outcome measure for *total proced* points and according to year for the Intervention and the Control group.

Site type	Time	Time	Outcome measure			
			Referral Nºs (n)	Wait >3m (n)	Snapshot (n)	L
Intervention	Individual time points	T0	483 ± 238 (8)	135 ± 123 (5)	818 ± 289 (4)	
		T1	458 ± 207 (8)	136 ± 180 (5)	673 ± 350 (4)	1
		T2	446 ± 187 (9)	131 ± 189 (5)	565 ± 133 (4)	1
		T3	460 ± 172 (9)	118 ± 140 (6)	602 ± 133 (4)	
		T4	434 ± 157 (9)	115 ± 105 (6)	576 ± 145 (4)	
		T5	457 ± 177 (9)	119 ± 128 (6)	548 ± 126 (4)	1
		T6	417 ± 133 (8)	91 ± 91 (5)	472 ± 106 (4)	1
		T7	387 ± 129 (7)	174 ± 235 (4)	767 ± 660 (2)	
	Data by year	2003	462 ± 202 (25)	134 ± 154 (15)	685 ± 270 (12)	1
		2004	447 ± 160 (18)	116 ± 118 (12)	589 ± 130 (8)	1
		2005/06	423 ± 147 (24)	124 ± 145 (15)	561 ± 266 (10)	1
Control	Individual time points	T0	358 ± 100 (2)	278 ± 107 (2)	840 ± 219 (2)	1
		T1	460 ± 5 (2)	253 ± 233 (2)	1379 ± 913 (2)	
		T2	514 ± 178 (5)	37 ± 37 (2)	1007 ± 653 (4)	
		T3	396 ± 170 (6)	153 ± 164 (3)	1026 ± 584 (5)	
		T4	502 ± 198 (7)	230 ± 385 (4)	1073 ± 659 (5)	
		T5	450 ± 147 (6)	297 ± 530 (4)	1237 ± 623 (5)	
		T6	527 ± 247 (6)	6 ± 7 (3)	1501 ± 1105 (3)	
		T7	438 ± 170 (4)	19 ± 29 (3)	1608 ± 1472 (2)	
	Data by year	2003	467 ± 147 (9)	167 ± 163 (7)	1058 ± 594 (8)	
		2004	453 ± 186 (13)	197 ± 291 (7)	1049 ± 588 (10)	
		2005/06	476 ± 187 (16)	127 ± 340 (10)	1390 ± 844 (10)	

Table 34. Mean values with standard deviations of each outcome measure for FS, Colonos each at individual time points and according to year for the Intervention group.

Procedure type	Time	Time	Outcome me		
			Referral Nºs (n)	Wait >3m (n)	
Flexible sigmoidoscopy	Individual time points	T0	79 ± 59 (8)	22 ± 29 (5)	
		T1	72 ± 41 (8)	16 ± 25 (5)	
		T2	72 ± 57 (9)	20 ± 25 (5)	
		T3	76 ± 45 (9)	17 ± 13 (6)	
		T4	74 ± 53 (9)	14 ± 14 (6)	
		T5	79 ± 54 (9)	11 ± 11 (6)	
		T6	86 ± 57 (8)	9 ± 10 (5)	
		T7	79 ± 61 (7)	12 ± 10 (4)	
	Data by year	2003	75 ± 51 (25)	19 ± 25 (15)	
		2004	75 ± 47 (18)	15 ± 13 (12)	
		2005/06	81 ± 55 (24)	11 ± 10 (15)	
Colonoscopy	Individual time points	T0	121 ± 93 (8)	69 ± 93 (5)	
		T1	144 ± 150 (8)	74 ± 91 (5)	
		T2	121 ± 83 (9)	53 ± 66 (5)	
		T3	129 ± 102 (9)	47 ± 55 (6)	
		T4	139 ± 92 (9)	57 ± 60 (6)	
		T5	145 ± 97 (9)	61 ± 70 (6)	
		T6	119 ± 60 (8)	51 ± 53 (5)	
		T7	105 ± 36 (7)	69 ± 86 (4)	
	Data by year	2003	128 ± 107 (25)	65 ± 79 (15)	2
		2004	134 ± 94 (18)	52 ± 55 (12)	
		2005/06	125 ± 70 (24)	60 ± 65 (15)	

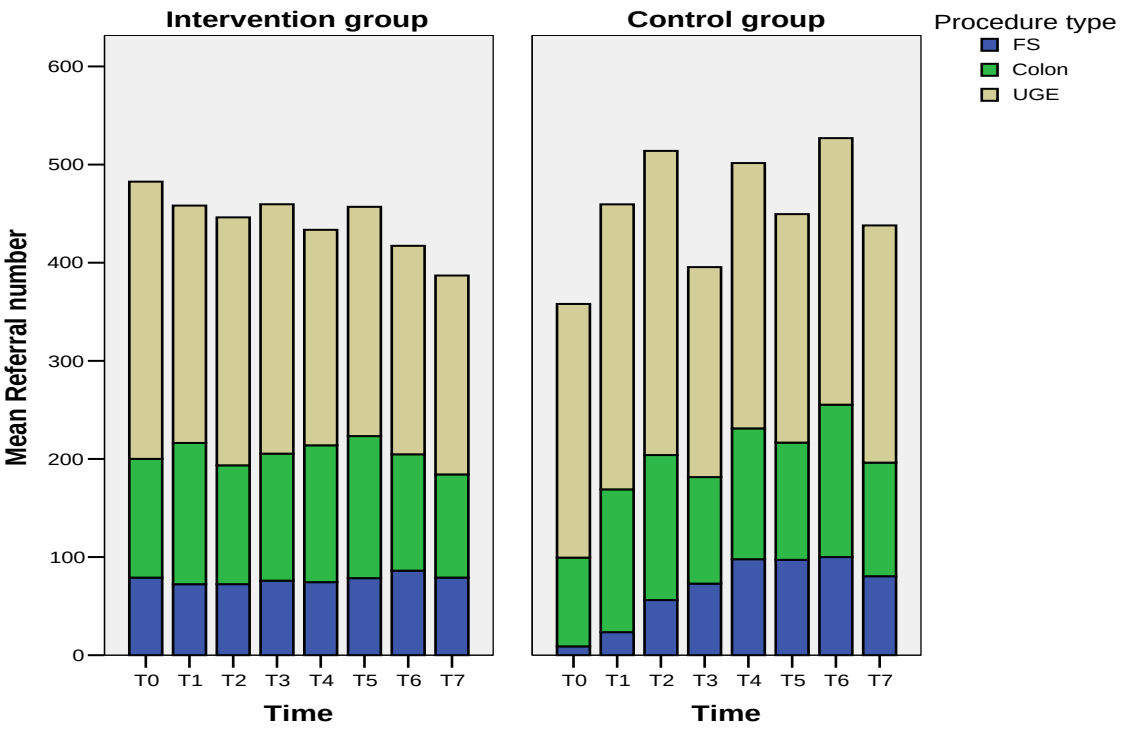
UGEs	Individual time points	T0	283 ± 130 (8)	44 ± 61 (5)	
		T1	242 ± 82 (8)	46 ± 86 (5)	
		T2	253 ± 115 (9)	59 ± 108 (5)	
		T3	254 ± 102 (9)	55 ± 84 (6)	
		T4	220 ± 94 (9)	44 ± 45 (6)	
		T5	234 ± 113 (9)	47 ± 70 (6)	
		T6	213 ± 98 (8)	31 ± 40 (5)	
		T7	203 ± 67 (7)	93 ± 153 (4)	
	Data by year	2003	259 ± 107 (25)	50 ± 81 (15)	3
		2004	237 ± 97 (18)	49 ± 65 (12)	
		2005/06	218 ± 93 (24)	54 ± 89 (15)	3

Table 35. Mean values with standard deviations of each outcome measure for FS, Colonos each at individual time points and according to year for the Control group.

Procedure type	Time	Time	Outcome me		
			Referral N°s (n)	Wait >3m (n)	
Flexible sigmoidoscopy	Individual time points	T0	9 ± 4 (2)	17 ± 2 (2)	
		T1	24 ± 28 (2)	9 ± 6 (2)	
		T2	56 ± 56 (5)	1 ± 2 (3)	
		T3	73 ± 63 (6)	5 ± 5 (3)	
		T4	98 ± 71 (7)	9 ± 14 (4)	
		T5	97 ± 65 (6)	19 ± 23 (4)	
		T6	100 ± 53 (6)	2 ± 3 (3)	
		T7	81 ± 69 (4)	5 ± 9 (3)	
	Data by year	2003	38 ± 46 (9)	8 ± 8 (7)	
		2004	86 ± 66 (13)	7 ± 11 (7)	
		2005/06	94 ± 58 (16)	10 ± 16 (10)	

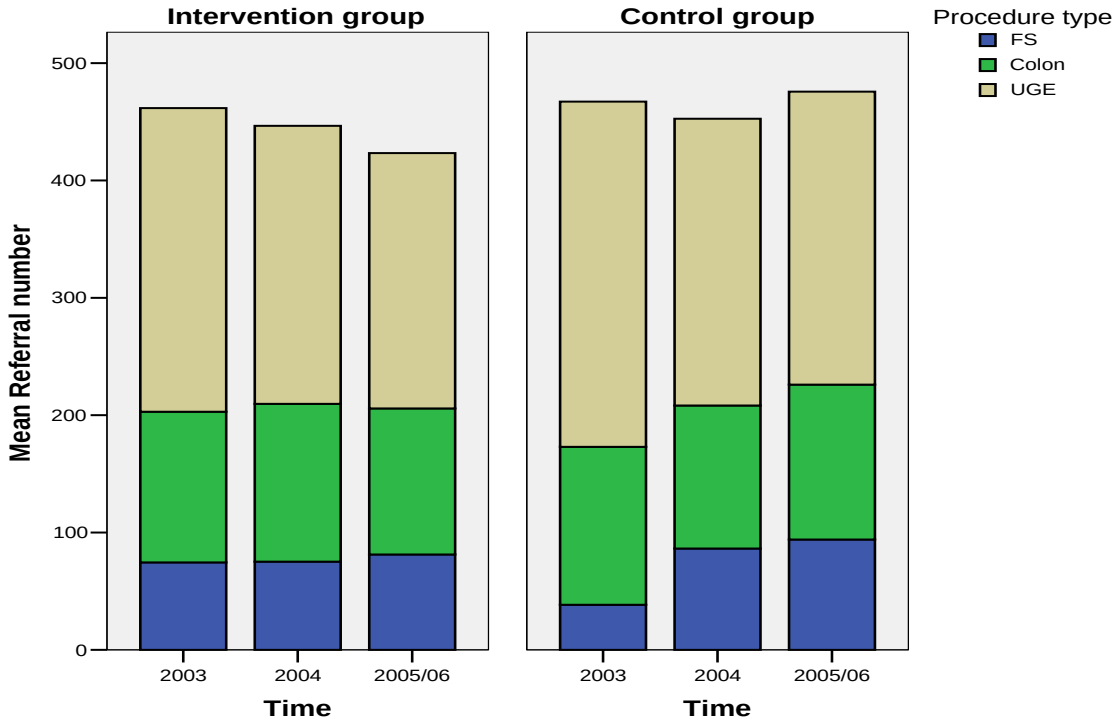
Colonoscopy	Individual time points	T0	91 ± 9 (2)	199 ± 116 (2)	
		T1	146 ± 5 (2)	211 ± 204 (2)	
		T2	148 ± 39 (5)	24 ± 20 (3)	
		T3	109 ± 39 (5)	95 ± 92 (3)	
		T4	133 ± 53 (7)	139 ± 233 (4)	
		T5	120 ± 58 (6)	179 ± 334 (4)	
		T6	155 ± 98 (6)	4 ± 5 (3)	
		T7	116 ± 54 (4)	12 ± 18 (3)	
	Data by year	2003	135 ± 37 (9)	127 ± 137 (7)	
		2004	122 ± 47 (13)	120 ± 175 (7)	
		2005/06	132 ± 73 (16)	76 ± 213 (10)	
UGEs	Individual time points	T0	259 ± 96 (2)	62 ± 7 (2)	
		T1	291 ± 18 (2)	33 ± 24 (2)	
		T2	310 ± 121 (5)	12 ± 16 (3)	
		T3	214 ± 100 (6)	53 ± 71 (3)	
		T4	270 ± 113 (7)	83 ± 139 (4)	
		T5	233 ± 86 (6)	99 ± 192 (4)	
		T6	272 ± 140 (6)	1 ± 2 (3)	
		T7	242 ± 86 (4)	2 ± 2 (3)	
	Data by year	2003	294 ± 95 (9)	32 ± 26 (7)	
		2004	244 ± 107 (3)	70 ± 107 (7)	
		2005/06	250 ± 104 (16)	41 ± 122 (10)	

Figure 16. Mean split procedures Referral numbers for the Intervention and Control group datasets for individual time points



(T0 to T7).

Figure 17. Mean split procedures Referral numbers for the Intervention and Control group datasets for data, aggregated by year (2003, 2004 and 2005/06).



Wait >3m

The mean *total procedures Wait >3m* data showed an overall increase from 135 at T0 to 174 at T7 due to a similar sharp increase in Hospital 18 data. The Control 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. When the data was aggregated according to year, the Intervention group mean showed a slight decrease from 134 at 2003 to 124 at 2005/06. The Control group mean showed a peak for 2004 but overall, there was a slight decrease from 167 at 2003 to 127 at 2005/06.

When the data were split by procedure type, the Intervention group mean for each procedure showed consistent trends until T7, when there was a large increase in UGEs (see Figure 18). This increase was not seen in the 2005/06 dataset (see Figure 19). Data for all three procedures for the Control group was highly variable over time for T0 to T7, and to a lesser extent for 2003 to 2005/06, due to inconsistent changes in the colonoscopy figures and low sample numbers for T6 and T7.

Snapshot

The mean *total procedures Snapshot* data for the Intervention group fell from 818 at T0 to 767 at T7 to 387, while the Control group mean increased from 840 at T0 to 1608 at T7. Both the Intervention and the Control group mean showed remarkably constant trends over time that were also highly comparable. The aggregated data for the Intervention group mean decreased from 685 at 2003 to 561 at 2005/06 and the Control group mean increased from 1058 at 2003 to 1390 at 2005/06.

When the data was split by procedure type, the Intervention group means for each procedure appeared to be relatively constant from T0 to T7 (see Figure 20) and 2003 to 2005/06 (see Figure 21). The only variation was for UGEs, which appeared to decrease over time, as was the case for *Wait >3m* data. Data for all three procedures for the Control group were more variable over time for T0 to T7 and 2003 to 2005/06, with varying numbers of LGEs and increasing numbers of UGEs.

Figure 18. Mean split procedures Wait >3m for the Intervention and Control group datasets for individual time points (T0 to T7).

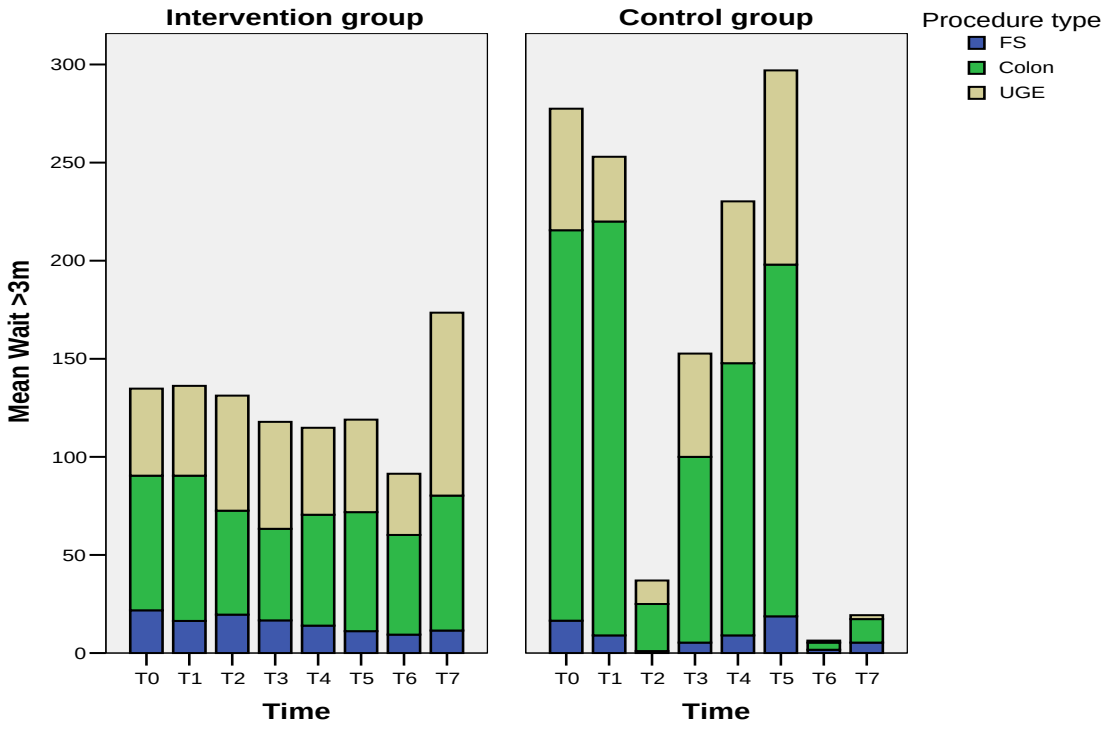


Figure 19. Mean split procedures Wait >3m for the Intervention and Control group datasets for data, aggregated by year (2003, 2004 and 2005/06).

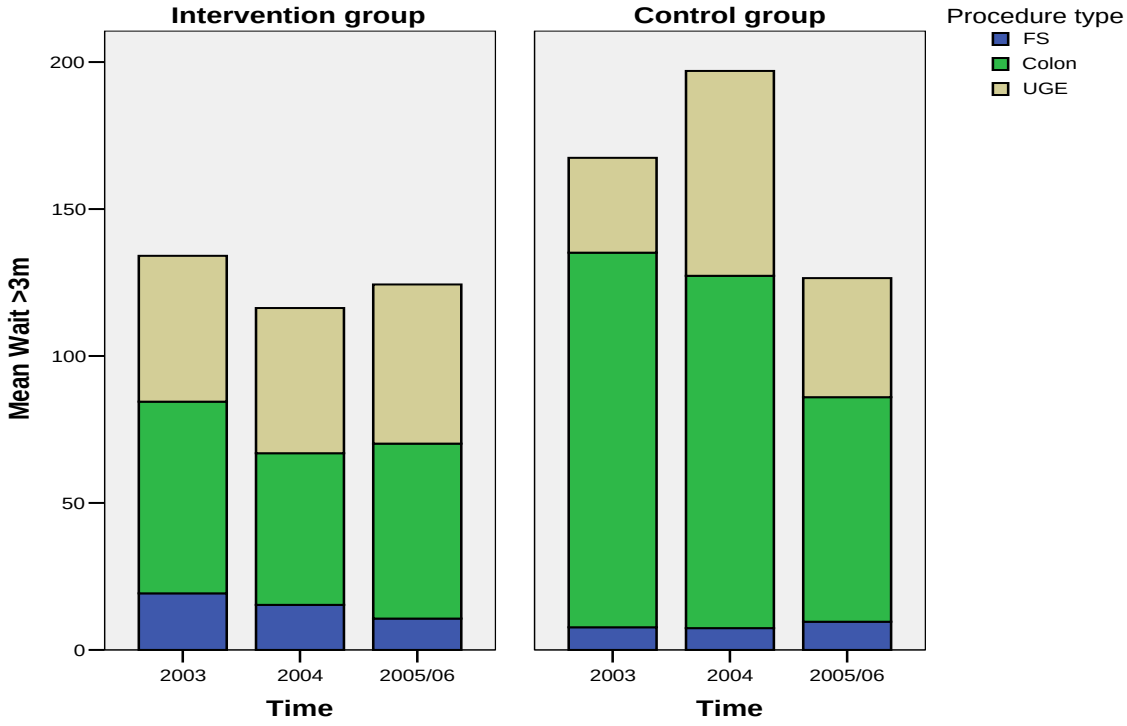


Figure 20. Mean split procedures Snapshot for the Intervention and Control group datasets for individual time points (T0 to T7).

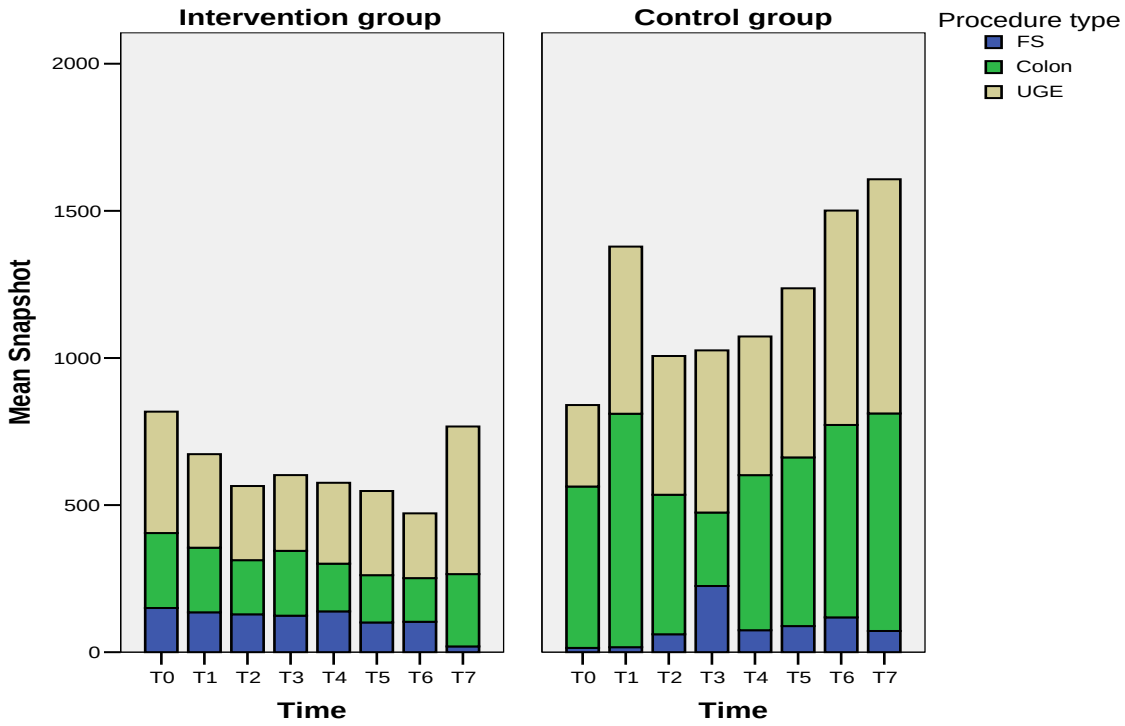
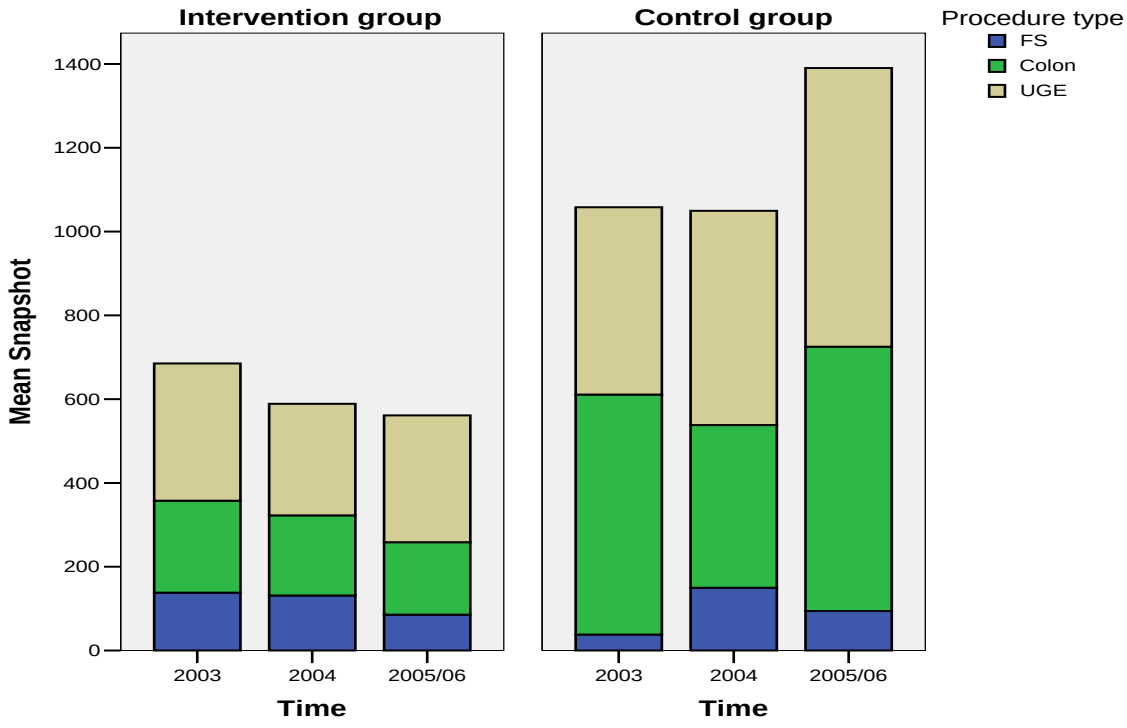


Figure 21. Mean split procedures Snapshot for the Intervention and Control group datasets for data, aggregated according to year (2003, 2004 and 2005/06).



Lost slots

The mean *total procedures Lost slots* trend for the Intervention group fell from 94 at T0 to 56 at T7, while the Control group mean showed an overall decrease from 143 at T0 to 72 at T7. Both the Intervention and the Control group mean showed remarkably constant trends over time that were also highly comparable. When aggregated according to year, the Intervention group mean showed a slight decrease from 116 at 2003 to 109 at 2005/06 and the Control group mean showed a decrease from 94 at 2003 to 75 at 2005/06. *Lost slots* data was not split by procedure type so no further analysis was possible.

Activity

The mean *total procedures Activity* trend for the Intervention group fell from 454 at T0 to 349 at T7, while the Control group mean increased from 333 at T0 to 362 at T7. Both the Intervention and the Control group mean showed small variations in data over time. When aggregated according to year, the Intervention group mean showed a decrease from 469 at 2003 to 441 at 2005/06 and the Control group mean showed an increase from 352 at 2003 to 401 at 2005/06.

When the data was split by procedure type, both the Intervention group and Control group means for each procedure appeared to be relatively constant from T0 to T7 (see Figure 22) and 2003 to 2005/06 (see Figure 23), although the Control group means did show a slight increase in colonoscopies over time for both time scales.

Figure 22. Mean split procedures Activity for the Intervention and Control group datasets for individual time points (T0 to T7).

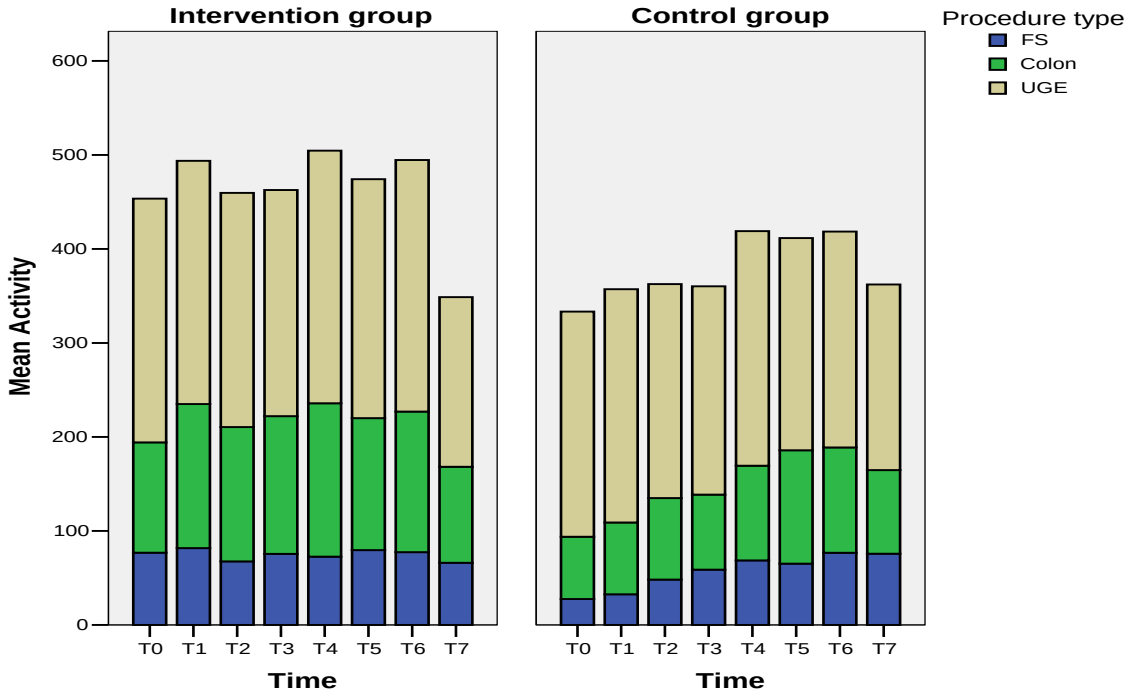
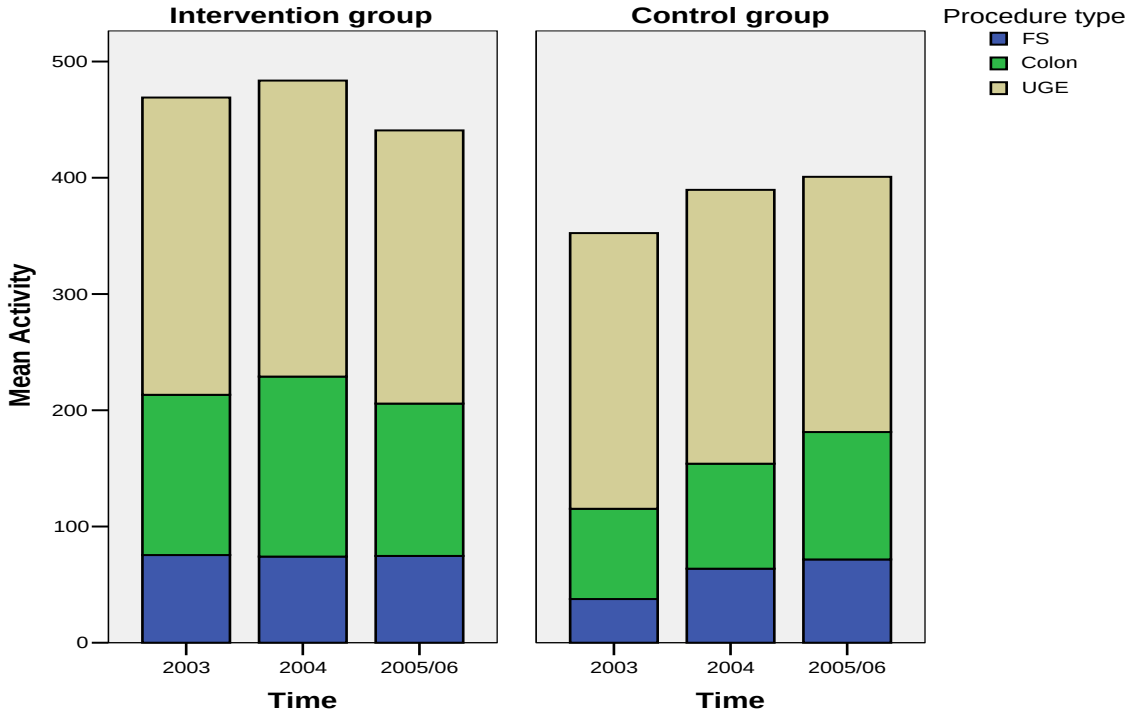


Figure 23. Mean split procedures Activity for the Intervention and Control group datasets for data, aggregated according to time (2003, 2004 and 2005/06).



5.4.11 Correlation

Significant relationships between combinations of each process 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, while those between 0.3 and 0.49 were medium and those between 0.1 and 0.29 were low. Positive correlation results indicated that an increase in one variable corresponded 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), while negative correlation indicated that as one variable increased, the other decreased.

For the Intervention 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 35). *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* proportionally. There were no other significant linear relationships identified for the other combinations of outcome measures.

For the Control 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* ($p = 0.021$). This indicated that for that point in time, these sites appeared to have successfully reduced their *Lost slots* while also coping with increasing *Referral numbers* (see Table 36). However, this result was obtained from relatively low sample numbers ($n = 8$) and may not be a true representation of the service in Control sites for this time period. Data for 2003 and 2005/06 were 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 Control 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 Control sites for this time period. There were no other significant linear relationships identified for the other combinations of outcome measures.

Table 36. Table of all significant (p ≤ 0.05) relationships between *total procedures* data aggregated according to year for *Referral numbers, Lost slots* and *Activity* from Intervention and Control group datasets using Spearman's correlation coefficient (*rho*). Sig. = Significance.

Site type	Variable 1	Variable 2	Sample Nº.	Year	Correlation Coefficient	Sig. (2-tailed)
Intervention	Referral Nºs	Activity	22	2003	0.569	0.006
	Lost slots	Activity	15	2003	0.675	0.006
	Referral Nºs	Activity	16	2004	0.574	0.02
	Lost slots	Activity	10	2004	0.681	0.03
	Referral Nºs	Activity	21	2005/06	0.725	<0.001
	Lost slots	Activity	15	2005/06	0.649	0.009
Control	Referral Nºs	Lost slots	8	2004	-0.786	0.021
	Referral Nºs	Activity	13	2004	0.61	0.027
	Lost slots	Activity	8	2004	-0.881	0.004
	Referral Nºs	Activity	12	2005/06	0.799	0.002

5.4.12 Two-way analysis of variance

When using a two-way ANOVA to analyse the *total procedures* data, there was no significant between-groups or within-groups effects for *Referral numbers, Wait >3m, Snapshot, Lost slots* or *Activity*. The only significant interaction effect reported was for the *Activity* dataset ($F(2, 26) = 3.594$, $p = 0.042$), indicating that there was a significant difference in the changes in the *Activity* data over time between the Intervention and Control groups (see Table 37). Closer examination of the *total procedures* data indicated that the significant interaction effect was attributable to a decrease in Intervention group *Activity* over time corresponding with an increase in Control group *Activity* over time (see Figure 24).

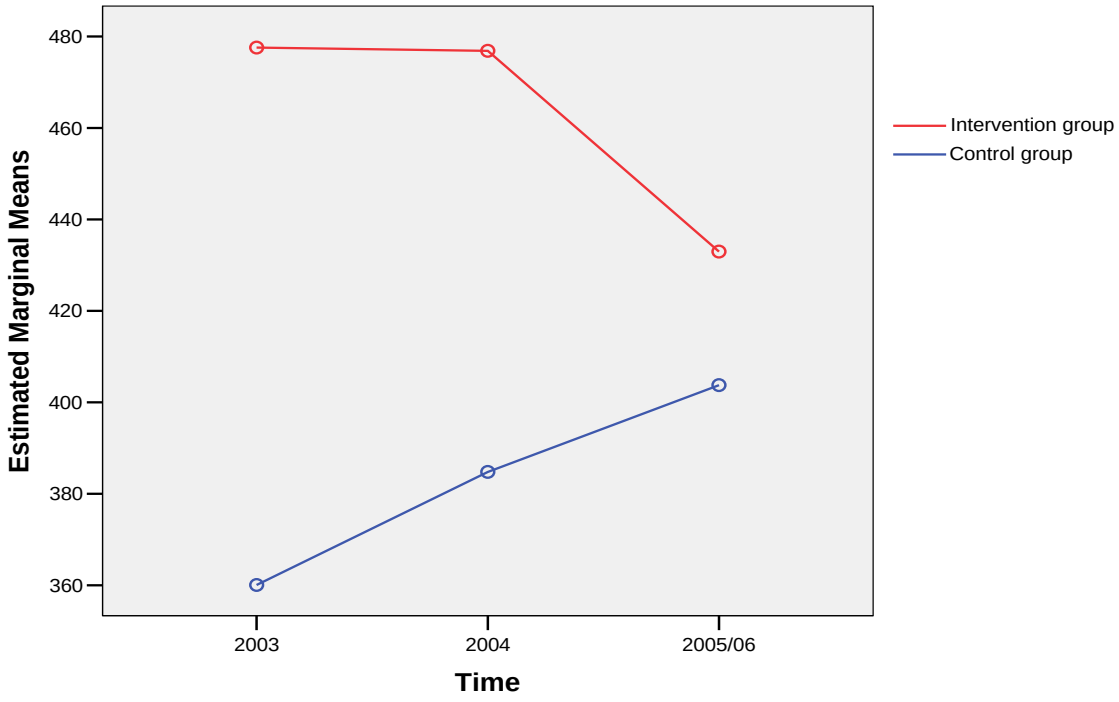
When the data was split by procedure type, there were no significant between-groups effects for any of the five outcome measures (see Table 36). The only significant within-group results were for UGEs over time for *Referral numbers* ($F(1, 11) = 5.15$, $p = 0.03$) and for *Activity* ($F(1, 13) = 5.25$, $p = 0.012$), indicating that the data changed significantly over the three time periods analysed within the Intervention and Control groups.

There were also significant differences in the UGE *Activity* data for the Intervention group ($p = 0.03$) but not for the Control group ($p = 0.368$). On closer examination of the raw data, it appeared that the mean *Referral numbers* data from the four sites constituting the Control group significantly decreased from 310.7 in 2003 to 260.1 in 2005/06 and that the mean *Activity* data from the eight sites constituting the Intervention group significantly decreased from 274.2 in 2003 to 232.4 in 2005/06.

Table 37. Results of the two-way ANOVA for each of the five outcome measures using *tota* *procedures* data. All significant values are highlighted in bold. Proc. Type: 1 = FS; 2 = C Total procedures.

Outcome measure	Proc. type	Intervention group means for 2003, 2004 and 2005/06	Control group means for 2003, 2004 and 2005/06	Within-subje effects (F ratio, sig.
Referral numbers	1	72.9, 75.2, 79.5 (n = 9)	67.8, 89.9, 92.8 (n = 4)	2.12, 0.169
	2	127.3, 134.4, 126 (n = 9)	141.2, 143.3, 163.1 (n = 4)	0.347, 0.58
	3	254.1, 236.9, 209 (n = 9)	310.7, 271.8, 260.1 (n = 4)	5.151, **0.03**
	4	454.3, 446.6, 414.5 (n = 9)	519.7, 505, 516 (n = 4)	0.28, 0.64
Wait >3m	1	19.3, 15.7, 9.7 (n = 5)	6.7, 8.7, 15.8 (n = 3)	0.016, 0.984
	2	65.2, 58.5, 55.6 (n = 5)	108.9, 138.5, 236 (n = 3)	0.965, 0.367
	3	49.6, 48.1, 51.9 (n = 5)	31.8, 75.2, 131 (n = 3)	0.992, 0.362
	4	134.1, 122.3, 117.2 (n = 5)	147.3, 222.3, 382.8 (n = 3)	0.994, 0.36
Snapshot	1	138.2, 131.4, 101 (n = 4)	61.5, 65.1, 82.3 (n = 4)	0.313, 0.737
	2	219.4, 191.3, 161.1 (n = 4)	490.4, 594.4, 692.2 (n = 4)	0.931, 0.421
	3	327.6, 266.3, 293.6 (n = 4)	455.8, 515.1, 647.4 (n = 4)	0.812, 0.467
	4	685.2, 588.9, 555.6 (n = 4)	1007.7, 1174.5, 1422.5 (n = 4)	0.733, 0.435
Lost slots	4	115.5, 127.3, 109 (n = 5)	76.3, 70.7, 75.3 (n = 3)	0.313, 0.737
Activity	1	84.3, 73.2, 74.9 (n = 8)	46.1, 58.1, 57.5 (n = 7)	0.019, 0.981
	2	119.1, 129.6, 125.6 (n = 8)	88.1, 94.8, 129.6 (n = 7)	2.928, 0.103
	3	274.2, 274.2, 232.4 (n = 8)	228.4, 232.6, 219.4 (n = 7)	5.249, **0.012**
	4	477.6, 476.9, 433 (n = 8)	360.1, 384.8, 403.8 (n = 7)	0.348, 0.71

Figure 24. Estimated Marginal Means of *Activity* using *total procedures* data.



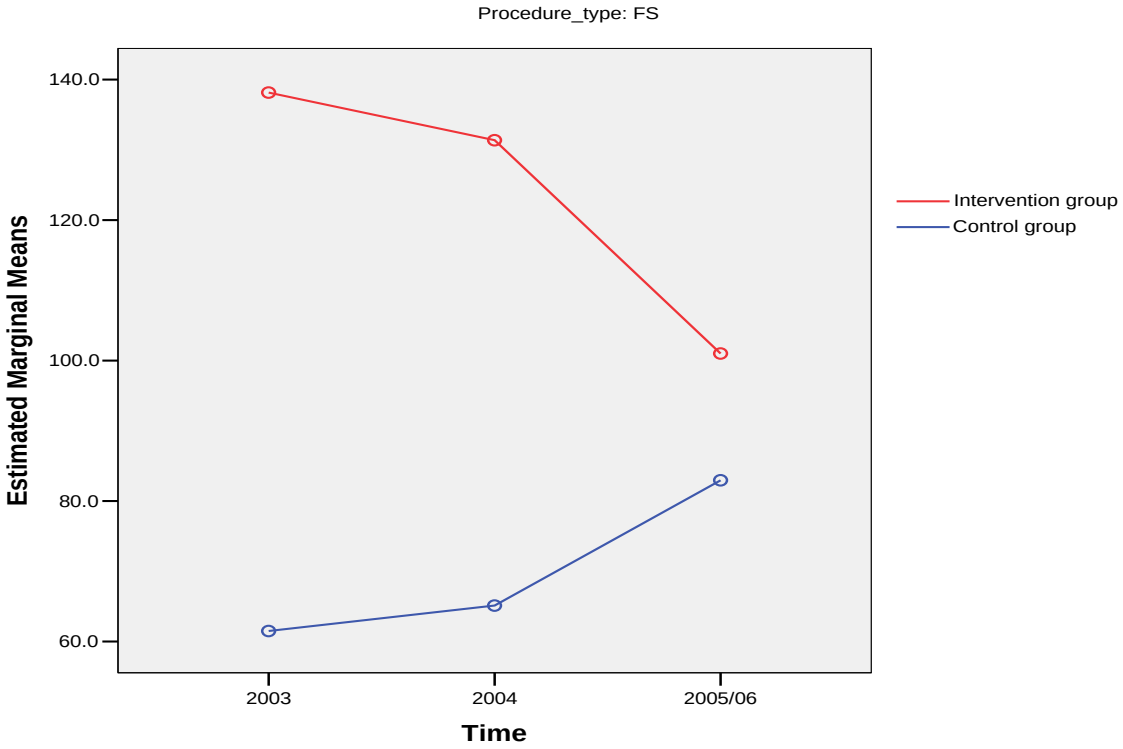
The only significant interaction effect was associated with FS *Snapshot* data ($F(1, 6) = 4.43$, $p = 0.036$), indicating that there was a significant difference in the changes in the FS *Snapshot* data over time between the Intervention and Control groups. The data corresponding to the significant interaction effect between Intervention and Control groups for FS *Snapshot* data, highlighted by mean plots whereby the lines are not significantly parallel, are illustrated in Figure 25.

5.5 Discussion

5.5.1 The availability of routinely collected process data

Only four of the nine Intervention sites approached submitted any routinely collected, process data, and one of those was only for one time period in 2003. This lack of data availability was surprising, since the MES programme based its redesign theories on the collection and analysis of accurate, measurable process data prior to the implementation of targeted innovations to improve services from a patient-centred perspective to address waiting list targets published by the *NHS Cancer Plan(Department of Health 2000(a))*. It also advocated the routine collection of this data by the endoscopy units themselves using data collection software, in preference to liaising with Trust departments.

Figure 25. Estimated marginal means of *Snapshot* for FS



The study 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 Intervention sites.

It is clear that the key issue of the need for high quality data collection and analysis advocated by the MES programme was not taken on board with many Intervention sites. This may be explained by the fact that the data were routinely uploaded to the MESPT on a monthly basis and the staff were not properly trained in how best to analyse and understand the data at the ground level and so, they may not have realised its true potential for implementing effective, targeted changes or for measuring the impact of any modernisation strategies.

Informal discussions with some Intervention site contacts during the data collection phase highlighted the difficulties they experienced in using and extracting any meaningful datasets from the Toolkit™ for their own use. Since the data collection process for the Toolkit™ was so labour-intensive, sites may have found it impossible to maintain the Toolkit™ in accordance with the strict deadlines imposed by the MESPT while also inputting the data into a second, more meaningful dataset for their own use and so, the Toolkit™ took priority. Many 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. This problem was further exacerbated with the change from the Excel-based version to the web-based version. They commented that they were less able to manipulate the data than before and viewed the Webtool as disadvantageous when compared to the Excel-based Toolkit™.

It is also possible that the rigorous nature of the data collection required by the Toolkit™ put them off continuing such a labour-intensive task, especially

since many sites commented on the fact that they had used some of the MES programme funding to pay for a data entry clerk to input data and when the funding ended, so did the data collection.

They were however quite happy to agree that some form of data collection was necessary and acknowledged the Toolkit™ as being the instigator for their own in-house data collection processes, although this study suggests that routine data collection processes never really flourished in the same way they were spoken about.

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

It is possible that the messages of accurate data collection advocated by the MES programme were disseminated to these sites and they began their own data collection processes, albeit later in the study. The raw datasets provided by the Control sites covered more of the outcome measures requested than those of the Intervention sites. It is feasible that having access to the 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. This backs up the theory that the Toolkit™, the strict timetables and the high quality data collection processes associated with the MES programme may have deterred Intervention sites from ongoing data collection while the Control sites felt no pressure to collect specific datasets in conjunction with a strict timetable and as a result, were more motivated to capture data.

During the course of the study, we were concerned to hear from some Trust 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, it is questionable whether they were being given accurate process data. 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, but it was evident that the data were used by the units in the absence of anything else, irrespective of its origins and 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 (Audit Commission 2002; Audit Commission 2004; Benneyan, Lloyd and Plsek 2003; Thorne, Hutchings and Elwyn 2008). However, there is currently no national impetus to collect routine data in NHS endoscopy services, even in light of the MES programme which reported significant improvements in the services of Intervention sites based, in part, on high quality data collection and analysis (NHS Modernisation Agency 2004). With increasing demands on NHS endoscopy services from TWR referrals and the National Bowel Cancer Screening Programme (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, Hutchings and Elwyn 2006). Even the most basic understanding of the demand and Activity within the endoscopy unit can identify seasonal effects, underused resources and potential problems for further investigation, as well as providing a baseline measurement with 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.

Perhaps the lack of experience in data analysis in some NHS managers can go some way towards explaining the ineffective working practices of many NHS services, not just endoscopy, as many NHS managers are not properly trained in redesign concepts that 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 properly accepted by the Intervention 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.

5.5.2 The validation of the process data

When the data were first plotted as part of an Exploratory Data Analysis (EDA) exercise, there were many issues that gave cause for concern. The line graphs showed a high degree of variability over time for many sites, both Intervention and Control. As a result, it was deemed necessary to test the accuracy of the datasets received by comparing them with a nationally-held dataset from HES.

HES has been used in many health services research studies in NHS Trusts in England associated with GI disorders (Al-Sarira, David, Willmott, Slavin, Deakin and Corless 2007; Kang, Hoare, Tinto, Subramanian, Ellis, Majeed et al. 2003; Pollock and Vickers 1998), with reported cases of its use in investigating NHS endoscopy services (Williams 1999; Williams and Mann 2002). Given its wide application for the measurement of NHS management patterns, HES data was considered to be a good standard against which to validate the study data submitted by each site.

There was no significant difference between the HES and the study datasets from the eight endoscopy units. 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 Trust (Sites 2, 3 and 9) and of these three, all were Control sites. The other three data sources were from the endoscopy units, with two submitting routinely collected data (12 and 19) while the other site's data came from the ENIGMA data collection forms (6).

In most analyses, the mean study data were lower than that of the mean HES data. This may be because the HES data was 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 request by HIRU. Alternatively, the HIRU request may not have been refined enough to block the procedures not included in the study data.

It is clear from these findings that the accuracy of the datasets used in this study has been validated by the use of a comparative analysis using the equivalent HES dataset. For this reason, we felt that it was reasonable to advocate the use of the study datasets presented in this study in the evaluation of the MES programme.

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 need to clarify with Trusts how they report their endoscopy Activity 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.

5.5.3 The analysis of the data

The problem with the availability, consistency and validity of the data so far discussed mean that any analysis has to be interpreted with caution. With this caveat the 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 Control sites. However, both the Intervention and Control group means were relatively more stable over time.

Referral numbers appeared to decrease over time in the Intervention group, but were more variable in the Control group. This may be explained by the Intervention sites taking a more proactive approach to managing the demand on their services, as advised by the MESPT. Examples of this management advice included validation of referrals, introducing new referral pathways and most importantly, the introduction of partial and full booking – a target stipulated by the MESPT. The implementation of partial and full booking for patients gave them the choice of appointment dates and may have affected the demand for Intervention sites more so than the Control sites. Another major contributor to changing the demand on NHS endoscopy services in both Intervention and Control sites has been the implementation of guidelines to allow health professionals to correctly refer their patients. This has reduced the number of inappropriate referrals, 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 2004).

The *Wait >3m* measure remained relatively stable over time in Intervention sites, but was slightly higher and more variable in Control sites. However, both Site types showed decreases in *Wait >3m* over time. This was probably due to the fact that it was a nationwide target set by the Government in the *NHS Plan (Department of Health 2000(b))*. There were differences in the proportion of patients waiting for a colonoscopy between the Intervention and Control group, although this decreased over time as the Control sites reduced the number of patients waiting for this procedure by more than three months.

The *Snapshot* variable differed between the MES and Control group. While the Intervention group *Snapshot* decreased slightly over time, the *Snapshot* of the Control group increased dramatically to become more than double of that seen in the Intervention group. The Intervention sites may have successfully introduced a number of initiatives advocated by the MESPT, including waiting list validation and pooling. The Control sites may not have sought this advice and implemented innovations that did not improve their waiting lists. The need to meet the three month Government target may have been another confounding factor for the Control sites as, in a bid to meet Government targets, 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 borne out when looking at the number of patients waiting for a colonoscopy over time. The *Wait >3m* data in the Control 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 Government target, as evidenced by the *Snapshot* data presented here.

Lost slots were lower in the Control group than in the Intervention group and both showed differing trends: the Intervention group data showed a peak whereas the Control group data showed a trough, indicating that the Control sites may have been better at reducing their *Lost slots* over time. This brings into doubt the validity of the findings of the MES report which stated that 71% of their 26 sites reduced their DNAs to less than 5%. The findings also show that any improvements in their DNA rates were subsequently not sustained over time. The reasons for this are unknown. What is more interesting is the fact that the Control group managed to reduce their DNAs over time without any MES programme support. Perhaps with less financial backing to implement changes, they sought to get the most out of their initiatives and if DNAs and cancellations were a huge problem for these sites, they may have focused in on them more 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, although the numbers saved would not have stood out in the *Snapshot* dataset, given the large numbers contained within.

The *Activity* in the Intervention group decreased over time while the Control group *Activity* increased, although the Intervention group *Activity* was far higher than that of the Control group to begin with. The MESPT provided endless advice and support to allow Intervention sites to increase their throughput by analysing their services and introducing targeted innovations. The introduction of Nurse Endoscopists (NE) 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 Intervention sites may have been attributable to the introduction of nurse-led clinics as outpatient consultations which will 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 Control sites too. When looking at the *split procedures Activity* data, it paints a clearer picture. The *Activity* in the Intervention sites for all three procedure types remains relatively constant, with only a minor drop in UGEs for 2005/06 while the Control sites show an increase in colonoscopies that approaches that seen in the Intervention sites.

There was a significant, strong, positive correlation between *Referral numbers* and *Activity* over time in both the Intervention and the Control

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 Intervention 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 Control 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 Control 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 Intervention and Control 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 changes in the *Activity* data over time between Site types. This was illustrated graphically with decreases in Intervention group *Activity* mirrored by increases in Control group *Activity* over time. This result highlights an interesting finding that was contrary to the original hypothesis that the Intervention 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 Control sites had obviously made a degree of improvement in their services that, when compared to the Intervention sites, resulted in the significant difference found.

When the data was 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 Intervention and Control groups for these two outcome measures. There was one significant interaction effect whereby the changes in FS *Snapshot* data were significantly different over time between the Intervention and Control groups. When the data was illustrated graphically, there was an obvious downwards trend in Intervention group data over time that was significantly different to the trend in data seen from the Control group data over time.

Whilst the Bonferroni test was used in this analysis, it is plausible that such a conservative test would affect the results of the two-way ANOVA, making results less significant. P-values of 0.5 or less indicate a 5% chance of a significant result occurring by chance. When adding together the number of tests included 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 – see Table 36). Of these, four were statistically significant, approximately 7.8% of the tests. Since this is a just a little over the 5% figure we would expect to see given the number of tests being done, we can plausibly conclude that there were in fact no significant two-way ANOVA results and that those found by the analyses were probably due to chance alone due to the p-value being set at ≤ 0.05.

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 Toolkit™, using these measures in order to assess the performance of endoscopy services within Intervention sites during the MES programme. The evaluation method used in this study was based on the Toolkit's own evaluation of Intervention sites by measuring changes within each study site and each Site type in *Referral numbers, Wait >3m, Snapshot, Lost slots* and *Activity* over time.

It should be noted that all discussions in this section are based on the data analysed and are open to criticism based on the low sample numbers for some of the outcome measures at certain time points. This may account for some of the variability seen in the data, although it was hoped that by aggregating the data, there was less likelihood of using anomalous data. 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 Intervention sites and Control sites were all geographically widespread, the data trends seen in this study were not likely to have been due to regional effects.

5.6 Implications

Unfortunately, the NHSMA disbanded in March 2005, making this evaluation of the MES programme 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 programme did not significantly improve service delivery in Intervention sites when compared to the Control sites. This would have had a major impact on the NHSMA, had they still been in operation today. They would have been forced to re-evaluate their modernisation programmes in light of the evidence presented by this study, in particular the message of high quality data collection, since this study was able to identify major shortcomings in the data collection practices of Intervention sites both during and after the MES programme.

Expanding on the issue of poor data collection, this study found that none of the Intervention sites continued to use the Toolkit™ following the close of the MES programme. 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 Intervention sites. There appears to be 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. 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.

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 other sites 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 of the service to proactively evaluate and manage services from within those departments. This is because much of the NHS is not rigorously managed by data. There are numerous audits and improvement projects that occur within NHS endoscopy units but they are sporadic and isolated. The service needs to adopt an ethos of data collection and analysis if it hopes to make and sustain any improvements in its delivery of care to patients. Endoscopy 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 service. 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 need to realise that setting NHS targets does not facilitate data collection - instead they only serve to encourage the manipulation of data to best serve 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.

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 was shown here 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 design and sound research experience. It placed the impact of the MES programme in a more realistic light by describing the services of the Intervention sites in vivo using unbiased data that was analysed using the appropriate statistical tests. This study fully illustrated different aspects of service delivery relating to all 10 Intervention 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 programme 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 programme 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 programme they still made clear improvements to their services over time, a message that may serve to sufficiently motivate endoscopy staff to improve their services.

6 Health Economics

6.1 Executive summary

6.1.1 Introduction

This study is evaluating an intervention which involved extra financial and non-financial support by the NHSMA to selected hospital sites to assist them in modernising their endoscopy services. Given the underlying climate of modernisation which prevailed during the period of the study, the economics of ENIGMA can be seen more generally as being concerned with the costs and effects of modernising endoscopy services and the extent to which the intervention acted as a catalyst toward modernisation.

6.1.2 Objectives

The objectives of the economics component of the study were to address the following 5 questions;

1. What has been the cost of modernisation in each of the ENIGMA sites?

2. Did modernisation costs differ between Intervention and Control sites?

3. Was there a difference in other NHS resource use between Intervention site patients and Control site patients?

4. Was there a difference in time off work by patients in Intervention versus Control sites?

5. Was there a difference in health outcomes (as measured by Euroqol 5D (EQ-5D) and GSRQ)) between Intervention and Control site patients?

6. If results are non-dominant, what are the extra costs (+ or -) per Quality Adjusted Life Year (QALY) and per unit of Gastrointestinal Symptom Rating Questionnaire (GSRQ) of Intervention versus Control site patients?

6.1.3 Methods

Cost of modernisation

Two semi-structured interviews held one year apart were undertaken with key personnel at each study site to identify the resources which had been deployed to facilitate modernisation of the endoscopy service. Identified incremental resources were classified as investments which produce a flow of benefits over time (e.g. staff training), one off activities (e.g. sending patients to a private provider to clear a backlog) and recurring revenue costs (e.g. new posts). These were valued using standard methods.

Other NHS costs

NHS resource use data were obtained from patients via the baseline questionnaire (BQ), post procedure questionnaire (PPQ) and 12 month post procedure questionnaire (12m PPQ). These data were multiplied by unit costs to assess primary care, secondary care, drug and total NHS costs. Costs were adjusted to account for baseline effects, group effects, and variations in length of time between baseline and subsequent questionnaires. Patients reported time off work was also examined.

Incremental cost per Quality Adjusted Life Year and per unit GSRQ

The intention was to plot differences in changes in EQ-5D scores (Intervention versus Control) across the five waves of the study and assess the QALY gain attributable to the intervention on the basis of the area under the curve. As the results showed no significant differences in EQ-5D scores (or GSRQ scores) this analysis was not undertaken.

Lost productivity

Data on patients' time off work were reported on the BQ, PPQ and 12m PPQ. Time off work was valued using average male and female earnings.

6.1.4 Results

Cost of modernisation

The extra financial support provided by the Modernisation Agency to Intervention sites was relatively small compared to the amount of funding most sites were able to secure from other sources. Total investments in modernisation were greater in Control sites although differences were not statistically significant.

The mean total cost for one year of the intervention period was £131,446 (sd = £81,890) in Intervention sites and £133,973 (sd = £100,928) in Control sites but the difference (£2,527) was not significant (p = .95, 95% CI = -£94,369 to £89,315).

The mean total cost for subsequent years in Intervention sites was £79,557 (sd = £72,282) and for Control sites was £93,209 (sd = 95,295). These differences (£13,652) were also not significant (p = .736, 95% CI = = -£98,171 to £70,867).

There were no significant differences in the marginal cost per patient between Intervention and Control sites either in the first or in subsequent years. The mean difference in first year marginal costs was £7.26 (p = .47, 95% CI = -£28.06 to £13.55) and the difference in marginal costs for subsequent years was £3.48 (p = .68, 95% CI = -£21.24 to £14.27). A sensitivity analysis, which assumed a 10 year life for training and equipment did not change the relative costs of Intervention and Control sites and differences were not statistically significant.

Other NHS Costs

The unadjusted analysis showed that in virtually all cases, primary and secondary costs were lower for patients in the Intervention group but the differences only rarely reached statistical significance. There were significant

differences in favour of the Intervention group (lower costs) in drug costs at 12 month post procedure in Waves 1 - 4 but this was not seen Wave 5. Total NHS costs were significantly lower for patients in the Intervention group at 12 month post procedure in Wave 3 but not in the other waves.

Application of multilevel modelling on a selection of resource variables did not show any important site-level effects on the resources used. As site-level variations were statistically insignificant in all cases no further multilevel analyses were attempted.

Adjusting for baseline effects, group effects and length of time between questionnaires showed broadly similar results with again almost all differences being in favour (lower costs) of the Intervention group but with few differences reaching statistical significance. Adjusted mean differences (Intervention minus Control) in primary care costs were statistically significant only on the PPQ in Wave 3 (adjusted mean difference = -£21.60, p<.01, 95% CI = -£32.50 to -£10.80)) but this was not seen at the 12M PPQ (adjusted mean difference = -£8.88, p = 0.34, 95% CI = -£27.10 to £9.31).

There were no statistically significant differences in secondary care costs across in any wave.

Adjusted mean difference in drug costs were statistically significantly lower only on the 12M PPQ in Wave 4 (adjusted mean difference = £10.80, p=.04, 95%CI = -£21.10 to -£0.50).

No statistically significant differences in total NHS costs were seen apart from on the PPQ at Wave 3 (adjusted mean difference = -£86.90, p=0.04, 95% CI = -£169.80 to -£4.10). Again this significance was not maintained on the 12M PPQ (adjusted mean difference = -£80.10, p = 0.06, 95% CI = -£162.50 to £2.30).

Adjusted mean differences in time off work – again in favour of the Intervention group - achieved statistical significance only on the PPQ in Wave 4 (adjusted mean difference (days off) = -1.78, p = 0.04, 95% CI = -£3.47 to -0.09).

Lost productivity

The adjusted mean difference in the value of lost productive output (-£27.00) was not statistically significant (p = 0.07, 95% CI = -£56.7 to £2.60).

Patient Outcomes

Results of analyses of patient outcomes are reported in Chapter 4. As with costs, differences rarely reached statistical significance. The overall conclusion is that patient outcomes were not affected by the intervention.

6.1.5 Discussion

The intervention appears to have had little effect on NHS costs either in terms of direct investments in modernisation by study sites, or in terms of indirect effects on primary care, secondary care, drugs or total NHS costs. In the few instances where statistically significant results in adjusted mean

differences were shown, these tended not to be sustained either at the subsequent questionnaire or in subsequent waves. In virtually all cases, however, results tended to favour the Intervention sites (lower total modernisation costs) and the patients treated at Intervention sites (lower NHS resource use).

From a cost effectiveness perspective, the lack of evidence for differences in either costs or outcomes makes is unnecessary to calculate an incremental cost effectiveness ratio.

6.2 Introduction

This study is evaluating an intervention which involved extra financial and non-financial support by the NHSMA to selected hospital sites to assist them in modernising their endoscopy services. It is evident, however, that in some sense 'modernisation' of health services is a natural process that is always going on and during the period of the ENIGMA study, all parts of the NHS were operating in a climate where modernisation was an explicit overarching philosophy of the Department of Health (DoH).

The additional support provided by the NHSMA to ENIGMA Intervention sites has, therefore, to be seen in the context of a general trend toward modernisation which has to varying degrees influenced all NHS facilities. Moreover, the financial support provided by the NHSMA to the Intervention sites was not the only source of finance available for purposes of modernisation and many sites, both Intervention and Control, were able to secure funding from other sources to support their modernisation plans. In many cases these sums were considerably larger than those provided by the NHSMA.

For these reasons the cost of modernisation is here regarded as all investments in modernisation regardless of how they were funded. While the intervention involved extra support by the NHSMA to selected sites, the economics of ENIGMA can also be seen more generally as being concerned with the costs and effects of modernising endoscopy services and the extent to which the intervention acted as a catalyst toward modernisation.

For present purposes the term modernisation refers only to *changes in the ways that endoscopy services are provided (delivery and/or administration*). This excludes many improvements which, from a different perspective, could also be regarded as 'modernisation'. For example, expanding a service without changing any of its processes, while clearly representing an *improvement*, essentially means doing more of the same. To be perceived here as a modernisation activity required changes in the ways that things are done, for example changing methods (e.g. new IT systems to manage waiting lists), altering staff skill mix (e.g. substituting nurse for consultant Endoscopists), introducing new types of sessions (e.g. emergency early morning slots to deal with overnight bleeds), purchasing different types of equipment (e.g. ultrasonography), setting up new processes to monitor progress (e.g. staff modernisation meetings) and so on.

Investments in new facilities were considered as modernisation only if they were explicitly part of the unit's modernisation plan. For example, altering the waiting area to improve the patient journey was considered to be modernisation but a recent move of the whole department to a new build

Treatment Centre was not. While the latter also improved the service – often dramatically – the decision to move to the new facility would have been made long before the MES programme and therefore could not be regarded as a direct response to the modernisation initiative.

New equipment which was purchased as part of the unit's rolling replacement programme was excluded for similar reasons. While old equipment will inevitably be replaced with newer models, ongoing replacement was not regarded as being a response to the modernisation initiative.

6.3 Objectives

The economics of ENIGMA set out to address the following economic questions:

1. What has been the cost of modernisation in each of the 18 ENIGMA sites? (NB: As economics concerns the relationship between costs and effects – in this case between investments in modernisation and patient outcomes – only the 18 sites for whom patient level data were available have been included here)

2. Did modernisation costs differ between Intervention and Control sites?

3. Was there a difference in NHS resource use (apart from the costs of endoscopy) between Intervention site patients and Control site patients?

4. Was there a difference in health outcomes (as measured by EQ-5D and GSRQ) between Intervention and Control site patients?

5. In the case of non-dominance, what are the extra costs (+ or -) per Quality Adjusted Life Year and per unit of GSRQ of Intervention versus Control site patients?

6.4 Methods

6.4.1 Cost of modernisation:

Economics is based on the principle that resources are scarce relative to the demands made on them. This means that every resource commitment involves an opportunity cost (benefit forgone from alternative uses of these resources). The cost of modernisation is thus equal to the value of all resources devoted to modernisation regardless of whether or not they were separately funded. Thus, for example, the time devoted by existing staff to modernisation activities is a cost of modernisation.

In order to identify the resources devoted to modernisation, two semi-structured interviews with key personnel at each study site were held one year apart; the first during December 2005 and January 2006 and the second during December 2006 and January 2007.

Prior to the first visit each site was asked to provide any relevant documentary sources describing their modernisation efforts and related resource consequences e.g. bids to the NHSMA and internal reports to Trusts

related to modernisation plans. These were reviewed prior to the first interview which began with an explanation of principles to ensure that respondents had a clear understanding of what was to be considered a cost of modernisation. Respondents were asked to identify only the incremental resources deployed to facilitate modernisation of the services.

Summaries of the resources identified were subsequently circulated to each respondent for validation. In addition, data were triangulated with another ENIGMA data collection tool (the Innovations Form – see Chapter 3) to check concurrence and ensure that that no key resource consequences of sites' modernisation efforts were omitted. The second set of interviews provided the opportunity to address queries from the first interview, discuss any discrepancies with responses on the Innovations Form and identify any developments since the first visit.

Thereafter, a basic cost analysis was undertaken using standard methods (Drummond, Sculpher, Torrance, O'Brien and Stoddart 2005). Identified resources were measured in relevant natural/physical units and valued using local data, where available, or national sources. A list of assumptions made and unit costs is provided in Appendix 12.

Modernisation costs were regarded as being of three types; investments which produce a flow of benefits over time (these included equipment and training), one off activities such as demand and capacity studies which did not continue beyond the period of study, and recurring revenue costs such as those associated with newly created staff posts which are devoted to modernisation activities.

All costs have been adjusted to 2006 prices using the Health Service Cost Index (Curtis and Netten 2006). Overall investment and the annual marginal cost of the modernised services are reported in Table 37 and 38. For the latter, capital and training costs are expressed in equivalent annual costs terms (Drummond, Sculpher, Torrance, O'Brien and Stoddart 2005) assuming in all cases a five year life for the investment and using a discount rate of 3.5% as currently recommended by HM Treasury. A sensitivity analysis was undertaken to show the effect of assuming a 10 year life on training and equipment.

Results report separately the annual costs incurred during the modernisation period (reported as "first year costs") and those incurred after the one off activities were completed (subsequent year cost). These were added to the marginal annual recurring revenue cost of the modernised service. In order to relate the costs of modernisation with patient level outcomes, the above costs for each site have been divided by the total number of procedures undertaken by each site in 2005.

Mean total costs between Intervention and Control sites and mean per patient marginal costs in year one and subsequent years were compared using t tests.

6.4.2 Other Health Service Costs

Modernising an endoscopy service can also have indirect resource consequences across other parts of the NHS. For example a modernisation activity which leads to reduced waiting times could reduce the demands on primary care made by patients between referral and the time the procedure is undertaken.

NHS resource use data were obtained from patients via the BQ, PPQ and 12M PPQ. Questions referred to visits to a GP surgery, home visits, hospital admissions and day cases, outpatient clinic visits and drugs taken in the three months prior to completing each questionnaire. Patient recall has been shown to be a valid means of obtaining data on resource use for at least three months (Brown and Adams 1992). As modernisation could potentially affect patients' time off work a question on days lost due to illness or in order to see a health professional was also included.

Unit costs of each resource are shown in Appendix 12. The period between the 2nd and 3rd questionnaires was one year and the period between the 1st and 2nd was normally relatively short i.e. weeks or months. Accordingly, resource costs were not discounted.

6.4.3 Quality of Life

Quality of life was assessed in the ENIGMA project using three measures, Short Form 36 (SF-36), GSRQ and the EuroQol instrument EQ-5D. The latter was included for the economic analysis. EQ-5D measures patients' health state across five dimensions (mobility, self-care, usual activities, pain/discomfort and anxiety/depression) with three possible responses for each (no problems / moderate problems / severe problems). This locates each patient into one of 245 mutually exclusive states. Valuations of each state are provided by the EuroQol Group (2008) (EuroQol Group). The version preferred by the National Institute for Health and Clinical Excellence (version UK 1) was used here. This is based on a survey of 3395 members of the UK public (Dolan 1997). Values are on a scale from 1 (perfect health) to zero (equivalent to dead) with negative values for states considered to be worse than dead. Details of methods and results of the EQ-5D analysis are given in chapter 4.

EQ-5D produces a single index number which can be converted to QALY for use in cost utility studies. In most evaluative studies, the object of interest is a patient level treatment with the focus on responses to treatment between Intervention and Control patients. QALYs are derived by plotting EQ-5D scores at various time points and then calculating the area Intervention and Control patients time profile curves. In the case of ENIGMA, however, the issue of concern is an organisational intervention. If effective, the QALY gain difference between patients in Intervention and Control sites should be greater at Wave 5 (post modernisation) than in Wave 1 (early stage of modernisation).

6.5 Results

6.5.1 Modernisation costs

The costs of modernisation are shown in Tables 38 and 39 below. Column 3 of Table 38 shows investments in medical and non-medical equipment. As anticipated there was wide variation in equipment costs – from between zero and £260,000.

The magnitude of investment in new equipment, however, cannot be taken as an indication of post modernisation service quality since it was inevitably related to the situation at the start of the modernisation period. For

example, Site 7 reported no investment in new equipment apart from regular rolling replacements which are not included here. The lack of investment in equipment, however, was due to the fact that this endoscopy service had recently been re-provisioned in a new-build unit at a cost of some £2.5 million. However, since its modern equipment was in place before the NHSMA modernisation initiative it was clearly not a cost of that initiative. At the other extreme, Site 15 also made no investments in modernisation equipment, but the reason here was that the unit had been experiencing serious budget problems over the previous several years which meant that the climate was not one which was conducive to making new investments. (To quote the interviewee "we were not in a modernisation mood").

Training costs (Table 38 Column 4) also varied widely, from between £450 and £32,000 and included a range of activities from a two hour session to train nurses to perform cannulations to full training courses to become Endoscopists. Again these costs were influenced by the training needs at the start of the modernisation period.

Training and equipment have a common feature in that they are both one off costs which lead to a flow of benefits over time. Accordingly, Column 4 of Table 38 expresses them in term of their equivalent annual costs (EAC). Variations here are directly related to variations in equipment and training costs.

Column 6 of Table 38 shows the value of 'one off' costs. These include a heterogeneous range of activities which were of finite duration and which were wound up when a given modernisation task was completed. Examples include running extra sessions on Saturday mornings to deal with backlogs, verifying waiting lists, undertaking demand and capacity studies, setting up project groups to oversee modernisation and so on. These are reported as "first year modernisation costs" although they did not necessarily occur within a 12 month period. Unsurprisingly, there was large variation in these costs due largely to the variation on the activities undertaken. One site, for example, produced a modernisation initiative endoscopy list and cleared it by sending patients to the local private hospital (£68,000).

Column 7 of Table 38 shows recurring costs such as new permanent posts associated with modernisation. Many sites created new consultant and nursing posts solely for the purpose of increasing capacity but with no element of change to methods or processes. For reasons explained earlier these have not been included here. Only posts which changed the ways of working have been included. Where members of staff were re-graded following training it was assumed that the newly graded post included a modernisation role and the extra cost of the higher grade has been included here. Also included are a variety of ongoing activities such as permanent modernisation committees.

Column 3 of Table 39 shows first year total modernisation costs made up of the one off costs described above, the EAC of equipment and training costs and the annual recurring costs. Marginal costs per patient based on 2004 Activity figures are shown in Column 5 of Table 39. Columns 7 and 9 of Table 39 show total and marginal costs per patient for subsequent years.

The mean total cost for first year in Intervention sites was £131,446 (sd = £81,890) and for Control sites was £133,973 (sd = £100,928). Difference in year one costs (£2,527) were clearly not significant (p = .95, 95% CI = -£94,369 to £89,315).

The mean total cost for subsequent years in Intervention sites was £79,557 (sd = £72,282) and for Control sites was £93,209 (sd = 95,295). Differences in subsequent year costs (£13,652) were also clearly not significant (p = .74, 95% CI = = -£98,171 to £70,867).

There were also no differences in marginal costs between Intervention and Control sites either in the first or in subsequent years. The mean difference in first year marginal costs (£7.26) was not significant (p = .47, 95% CI = -£28.06 to £13.55) and the difference in marginal costs for subsequent years (£3.48) was similarly not significant (p = .68, 95% CI = -£21.24 to £14.27).

The sensitivity analysis, which assumed a 10 year life for training and equipment did not change the relative costs of Intervention and Control sites. First year marginal costs for Intervention sites fell from £26.62 to £24.29 and for Control sites from £33.88 to £30.33. Subsequent year marginal costs in Intervention sites fell from £17.43 to £15.08 and Control sites from £20.91 to £19.47. Differences were not statistically significant.

Table 38. Site Investments Totals

SITE ID	I/C	Equipment	Training	EAC	One Off Costs
1	I	£ -	£ 9,804.00	£ 2,171.43	£ 23,399.00
2	C	£ 200,000.00	£ 444.00	£ 44,395.13	£ 77,081.00
3	C	£ -	£ 700.00	£ 155.04	£ 127.00
4	I	£ 2,400.00	£ 16,439.00	£ 4,172.54	£ 22,520.00
5	C	£ 142,054.00	£ 8,091.00	£ 33,254.71	£ -
6	I	£ 10,000.00	£ 8,891.00	£ 4,184.05	£ 12,574.00
7	I	£ -	£ 13,747.00	£ 3,044.74	£ 7,852.00
8	I	£ 7,500.00	£ 1,417.00	£ 1,974.97	£ 49,403.00
9	C	£ 15,000.00	£ 3,254.00	£ 4,042.97	£ 72,610.00
11	I	£ 25,120.00	£ 1,055.00	£ 5,797.34	£ 245,168.00
12	C	£ 260,000.00	£ 2,379.00	£ 58,112.74	£ 10,468.00
13	I	£ 48,915.00	£ 2,072.00	£ 11,292.80	£ 42,873.00
14	C	£ 8,062.00	£ 31,085.00	£ 8,670.43	£ 87,159.00
15	C	£ -	£ 1,393.00	£ 308.53	£ 31,229.00
16	I	£ 957.00	£ 4,193.00	£ 1,140.64	£ 51,157.00
17	C	£ 16,000.00	£ 2,670.00	£ 4,135.11	£ 78,105.00
19	I	£ 206,000.00	£ 11,927.00	£ 48,267.33	£ 12,046.00
20	C	£ 10,000.00	£ 5,297.00	£ 3,388.04	£ 10,091.00
Total Int		£ 300,892.00	£ 69,545.00	£ 82,045.85	£ 466,992.00
Total Con		£ 651,116.00	£ 55,313.00	£ 156,462.68	£ 366,870.00
Total		£ 952,008.00	£124,858.00	£ 238,508.53	£ 833,862.00

Table 39. Site investments: year 1 and subsequent year total cost and marginal cost per p

SITE ID	I/C	1st yr cost	2004 Activity	1st yr MC/PT	2nd yr cost	2005 Activity
1	I	£246,943.43	5,124	£48.19	£ 223,544.43	4908
2	C	£354,829.13	6,072	£58.44	£277,748.13	6132
3	C	£28,790.04	4,950	£5.82	£28,663.04	4788
4	I	£129,731.54	3,192	£40.64	£107,211.54	3600
5	C	£56,636.71	5,022	£11.28	£56,636.71	4920
6	I	£113,391.05	3,228	£35.13	£100,817.05	4104
7	I	£28,616.74	5,220	£5.48	£20,764.74	5280
8	I	£59,100.97	7,026	£8.41	£9,697.97	6792
9	C	£105,699.97	3,804	£27.79	£33,089.97	4008
11	I	£269,465.34	6,198	£43.48	£24,297.34	5604
12	C	£176,247.74	3,660	£48.16	£165,779.74	3600
13	I	£105,660.80	7,404	£14.27	£62,787.80	6300
14	C	£121,961.43	2,364	£51.59	£34,802.43	1884
15	C	£53,506.53	3,300	£16.21	£22,277.53	4764
16	I	£70,783.64	6,444	£10.98	£19,626.64	6444
17	C	£100,849.11	7,728	£13.05	£22,744.11	8640
19	I	£154,889.33	4,692	£33.01	£142,843.33	4164
20	C	£207,235.04	2,856	£72.56	£197,144.04	4344
Avg MC	I			£26.62		
Avg MC	C			£33.88		

6.6 An illustration of the costs of modernisation: Site 19

Site 19 was an Intervention site. The site had requested £30,000 from the MA to be spent as follows: training of colorectal Nurse Endoscopist (NE) (£3,000), video conferencing equipment to support training and supervision (£7,000), a feasibility study for the physical integration of endoscopy services (£6,000) and redesigning the facility following the feasibility study (£14,000).

The 'sign off report' form to the NHSMA does not ask for details of how the funding was actually spent. The report from Site 19 still spoke of the lack of physical integration as being a problem and referred to the feasibility study in the future tense. It was evident that by the time the interviews were undertaken, however, that both the feasibility study and the redesign of the facility had gone ahead. There was no mention of the purchase of video conferencing equipment.

As stated earlier, the cost of modernisation is equal to the value of all the resources devoted to modernisation regardless of whether they were paid from NHSMA funding, other external funding or by using existing resources. On this basis, the total cost of modernisation at Site 19 was as follows.

The one off activities included the feasibility study on unit re-design (£6,000), audits (£1,638), review of referral pathways (£580), patient evaluation (£362), revising patient information leaflets (£2,714) and pooling/validating lists (£752). Total one off costs, which were assumed to all occur in one year of modernisation, were £12,046.

The unit was re-designed at a cost of £14,000 with an additional £5,000 for easy chairs. New medical equipment included a GI scribe system (£30,000), an ultrasound system (£94,000), pH manometry (£28,000), and capsule endoscopy kit with data recorder (£35,000). Total cost of the above was £206,000.

Training costs included sending a nurse on an advanced ERCP course (£3,000), training one nurse in manometry (£1,000), consultant training on capsule endoscopy (£2,190), pH manometry training (£2,737) and sending a NE abroad specifically to learn about modernisation (£3,000). Total cost of above was £11,927.

Equipment and training are both regarded as investments which produce a flow of benefit over time. The equivalent annual costs for the above (assuming five year life and 3.5% discount rate) is £48,267.

Recurring modernisation costs include bi monthly modernisation meetings (£238), additional sessions from a nutrition nurse (£4,174), the cost of re-grading nurses after training (£3,248), unit manager post for modernisation (£26,447), part time booking clerk manager (£10,823) and full time booking clerk (£15,446), input by a performance analyst (£668), nurse consultant clinical lead (£2,087) and a ward clerk (£13,445) plus the annual running cost of the ultrasound (£6,000) and endoscopy capsule kit (£12,000). Total cost of the above is £94,577.

The first year of the modernised service includes the one off costs, the equivalent annual cost for training and equipment and the recurring costs. This amounted to £154,889 for the first year and £142,843 thereafter. Based on Activity figures for 2004 (4692) and 2005 (4146) the marginal costs per patient were £33.01 in year one and £34.30 thereafter. The lower total costs in subsequent years produced higher marginal costs due to the higher Activity figures in the first year.

6.7 NHS Resource Use

Data on patient level resource use were obtained from six questions on the BQ, PPQ and 12M PPQ.

The full dataset was subject to a general data entry accuracy check by checking one in every ten questionnaires. However, given the potential effects of outliers on costs, the recorded data on all resource use outliers was also checked against the questionnaires.

6.8 Missing data imputations

6.8.1 Imputation using last case carried forward method

A total of 3818 BQs, 2940 PPQs and 2588 12M PPQs were available for complete case analyses. Imputation of missing data using the last case carry forward method (see chapter 4) increased the number of analysable PPQs to 3055 and 12M PPQs to 3039.

To assess the effect of the imputation, separate analyses on resource use were undertaken using complete case (Table 40) and carry forward imputation (Table 41) analyses. Comparison of mean differences between patients in Intervention and Control sites showed little differences in results between methods. All differences that were statistically significant ($p<.05$) in the complete case analysis remained significant with imputation and no non-significant items became significant. Thus although the imputation increased the sample size, it had little effect on results. It was therefore decided that this imputation method would not be used for the base case comparisons. Results using the last case carry forward imputations can be regarded as a sensitivity analysis.

Table 40. Mean differences in NHS resource use: Complete case analysis

Item (Section D)	Baseline n = 3818			Post Procedure n = 2940		
	Int Mean (SD)	**Cont. Mean (SD)**	**p.value**	**Int Mean (SD)**	**Cont. Mean (SD)**	**p.value**
(**D1**) How often have you consulted at the GP's surgery with						
Doctor	2.53 (2.46)	2.7 (2.67)	**.041**	2.13 (2.24)	2.43 (2.32)	**0.001**
Nurse	0.75 (1.69)	1.00 (3.40)	**.010**	0.66 (1.26)	0.89 (2.31)	**0.003**
Other	0.10 (0.93)	0.08 (0.64)	0.54	0.11 (0.85)	0.07 (0.53)	0.22
(**D2**) How often have you consulted at home with						
Doctor	0.20 (0.98)	0.20 (0.98)	0.99	0.13 (0.66)	0.14 (0.64)	0.87
Nurse	0.11 (0.91)	0.17 (2.9)	0.36	0.10 (0.73)	0.13 (1.13)	0.38
Other	0.01 (0.14)	0.03 (0.27)	0.14	0.01 (0.10)	0.03 (0.45)	0.16
(**D3**) How often have you been admitted for any reason to a hospital as an emergency	0.13 (0.53)	0.16 (0.59)	0.21	0.12 (0.56)	0.14 (0.79)	0.33
(**D4**) How often have you been admitted for any reason to a hospital as an non-emergency	0.16 (0.63)	0.19 (0.77)	0.17	0.26 (0.75)	25 (0.75)	0.86
(**D5**) How often have you been seen at a hospital outpatient clinic with						
Doctor	0.97 (1.28)	1.07 (1.57)	**0.033**	1.11 (1.28)	1.28 (1.89)	**0.006**
Nurse	0.20 (0.77)	0.30 (1.98)	0.09	0.30 (0.79)	0.32 (1.42)	0.70

Other	0.05 (0.45)	0.06 (0.45)	0.31	0.06 (0.44)	0.08 (0.58)	0.41
(**D6**) How many time have been admitted as a day case for						
Upper endoscopy	0.09 (0.50)	0.08 (37)	0.70	0.64 (0.62)	0.63 (0.58)	0.66
Lower endoscopy	0.12 (0.50)	0.13 (56)	0.74	0.59 (0.68)	0.57 (0.58)	0.34

Table 41. Mean differences in NHS resource use: Missing data imputed using last case car

Item (Section D)	Baseline n = 3818			Post Procedure n = 3055			End
	Int Mean (SD)	**Cont. Mean (SD)**	**p.value**	**Int Mean (SD)**	**Cont. Mean (SD)**	**p.value**	**Int Mean (SD)**
(**D1**) How often have you consulted at the GP's surgery with							
Doctor	2.53 (2.46)	2.7 (2.67)	**0.041**	2.15 (2.25)	2.46 (2.39)	**0.00**	1.71 (2.05
Nurse	0.75 (1.69)	1.00 (3.40)	0.**010**	0.66 (1.24)	0.89 (0.25)	**0.00**	0.67 (1.26
Other	0.10 (0.93)	0.08 (0.64)	0.54	0.11 (0.86)	0.09 (0.64)	0.53	0.08 (0.63
(**D2**) How often have you consulted at home with							
Doctor	0.20 (0.98)	0.20 (0.98)	0.99	0.14 (0.65)	0.13 (0.59)	0.69	0.13 (0.69
Nurse	0.11 (0.91)	0.17 (2.9)	0.36	0.09 (0.70)	0.13 (1.09)	0.27	0.11 (0.70
Other	0.01 (0.14)	.03 (00.27)	0.14	0.02 (0.27)	0.03 (0.42)	0.45	0.02 (0.21
(**D3**) How often have you been admitted for any reason to a hospital as an emergency	0.13 (0.53)	0.16 (0.59)	0.21	0.13 (0.53)	0.16 (0.59)	0.20	0.10 (0.54
(**D4**) How often have you been admitted for any reason to a hospital as an non-emergency	0.16 (0.63)	0.19 (0.77)	0.17	0.25 (0.75)	0.26 (0.76)	0.84	0.16 (0.64
(**D5**) How often have you been seen at a hospital outpatient clinic with							
Doctor	0.97 (1.28)	1.07 (1.57)	**0.033**	1.12 (2.06)	1.27 (1.87)	**0.04**	0.71 (1.26

Nurse	0.20 (0.77)	0.30 (1.98)	0.09	0.27 (0.76)	0.30 (1.35)	0.57	0.21 (1.23
Other	0.05 (0.45)	0.06 (0.45)	0.31	0.05 (0.41)	0.07 (0.54)	0.49	0.06 (0.56
(**D6**) How many time have been admitted as a day case for							
Upper endoscopy	0.09 (0.50)	0.08 (37)	0.70	0.56 (0.61)	0.54 (0.58)	0.46	0.15 (0.50
Lower endoscopy	0.12 (0.50)	0.13 (56)	0.74	0.49 (0.65)	0.48 (0.59)	0.54	0.14 (0.42

6.8.2 Imputation of missing items as zero

Total resource use is assessed by valuing each resource item and summing over primary care, secondary care and drug use. A potentially major problem with attempting to use a complete case analysis of total costs is that a questionnaire would have to be rejected from the analysis if even a single item were recorded as missing across any of the three cost elements (primary care, secondary care or drugs).

In the case of drug use, respondents were provided with a list of the 29 most commonly used drugs for gastrointestinal complaints and asked to record the dose and number of tablets taken per day. A non-response against any drug item could thus be taken as a true zero. However, in the case of other NHS resources, the questionnaire asked patients to report the number of times they had consumed each listed item in the previous three months and to record a zero against any item that they did not use. This instruction was repeated for each question. Each non response was thus recorded as missing data.

Examination of the dataset, however, suggested that while patients were reporting the number of times they had used any resource they appeared to be often ignoring those they had not – rather than reporting a zero as instructed. The high levels of missing data shown in Table 42 below – particularly for each of the "other" variables – reinforces the idea that some of these missing data were likely to have been true zero's.

Table 42. Percentage of missing data by item.

Question	Baseline (n= 3818)	Post (n
(**D1**) How often have you consulted at the GP's surgery with		
Doctor	5.7	
Nurse	15.8	
Other	27.4	
(**D2**) How often have you consulted at home with		
Doctor	4.8	
Nurse	12.2	
Other	18.7	
(**D3**) How often have you been admitted for any reason to a hospital as an emergency	2.4	
(**D4**) How often have you been admitted for any reason to a hospital as an non – emergency	3.2	
(**D5**) How often have you been seen at a hospital outpatient clinic with		
Doctor	6.4	
Nurse	18.5	
Other	20.6	
(**D6**) Times admitted as day case for		
Upper endoscopy	6.5	
Lower endoscopy	7.5	

As can be seen in Table 42 the highest cost resource items, in particular hospital admissions as emergency or non-emergency, had very low rates of missing data varying from between 2.0% and 3.2% for emergency admissions and between 2.6% and 3.7% for non-emergency. Nevertheless in a complete case analysis, data on such high cost resource items would be disregarded if the patient failed to record a zero against, for example, the number of times they had seen someone other than a doctor or nurse at a GP surgery.

Rejection of all questionnaires which had at least one missing item had the effect of reducing the number of analysable BQs by 44% (from 3818 to 2123), PPQs by 55% (from 2940 to 1310) and 12M PPQs by 39% (from 2588 to 1573). Given that many of these missing items were likely to have been zeros a separate analysis which treated missing data as zero was also undertaken. This had a major impact on the number of analysable questionnaires increasing BQ to 3802, PPQ to 2907, and 12M PPQ to 2575.

Table 43 shows mean differences in resource use between patients in Intervention and Control sites when treating missing data as zeros. Comparison of Table 43 with Table 40 shows that the use of zeros for missing values had little effect on the overall results. As with the carry forward imputation, in virtually all cases, significant differences remain significant and nothing which was non-significant becomes significant.

Table 43. Mean difference in NHS resource use: missing data imputed as zeros

Item (Section D)	Baseline (n= 3818)			Post Procedure (n= 2940)		
	Int Mean (SD)	**Cont. Mean (SD)**	**p.value**	**Int Mean (SD)**	**Cont. Mean (SD)**	**p.value**
(**D1**) How often have you consulted at the GP's surgery with						
Doctor	2.39 (2.46)	2.54 (2.67)	0.07	2.02 (2.23)	2.29 (2.32)	**0.00**
Nurse	0.63 (1.57)	0.84 (3.14)	**0.01**	0.55 (1.17)	0.75 (2.15)	**0.00**
Other	0.07 (0.80)	0.06 (0.54)	0.51	0.07 (7.11)	0.05 (0.44)	0.20
(**D2**) How often have you consulted at home with						
Doctor	0.19 (0.96)	0.19 (0.95)	0.96	0.13 (0.64)	0.13 (0.63)	0.86
Nurse	0.09 (0.85)	0.15 (2.71)	0.37	0.09 (0.68)	0.12 (1.07)	0.34
Other	0.01 (0.13)	0.02 (0.24)	0.16	0.01 (0.09)	0.02 (0.40)	0.15
(**D3**) How often have you been admitted for any reason to a hospital as an emergency	0.13 (0.53)	0.15 (0.59)	0.21	0.11 (0.55)	0.14 (0.78)	0.32
(**D4**) How often have you been admitted for any reason to a hospital as a non emergency	0.15 (0.61)	0.18 (0.75)	0.18	0.25 (0.74)	0.24 (0.74)	0.89
(**D5**) How often have you been seen at a hospital outpatient clinic with						
Doctor	0.91 (1.26)	1.00 (1.54)	**0.04**	1.02 (1.26)	1.18 (1.84)	**0.00**
Nurse	0.17 (0.70)	0.24 (1.79)	0.10	0.23 (0.71)	0.24 (1.25)	0.74

Dietician	0.04 (0.41)	0.05 (0.40)	0.36	0.04 (0.38)	0.06 (0.50)	0.41
(**D6**) How many time have been admitted as a day case for…						
Upper endoscopy	0.08 (0.48)	0.08 (0.36)	0.65	0.53 (0.61)	0.53 (0.58)	0.80
Lower endoscopy	0.12 (0.48)	0.12 (0.54)	0.79	0.46 (0.64)	0.45 (0.56)	0.77

Differences between the two approaches are summarised in Table 44 below. The difference in total costs between Intervention and Control patients shown in the 12M PPQ is significant in both the complete case and the zero imputation analyses.

Table 44. Comparison of complete cases on total costs

	n	Mean (£)	SD (£)	Mean Difference (£)	P value	95% CI (£)
Complete Case						
Baseline						
Int	1069	342.31	474.79	-11.70	.59	-51.29 to 28.95
Con	1054	353.48	468.83			
PPQ						
Int	654	774.39	525.65	-6.91	.80	-60.78 to 46.96
Con	656	781.30	466.62			
12 Month PPQ						
Int	790	193.07	360.37	-62.35	**.01**	-111.23 to -13.48
Con	783	255.42	599.45			
Imputed Zero						
Baseline						
Int	1877	347.70	506.58	-35.59	.05	-70.43 to -74.45
Con	1925	383.29	585.43			
PPQ						
Int	1450	741.31	531.58	-24.42	.23	-64.47 to 15.62
Con	1457	765.73	568.92			
12 Month PPQ						
Int	1253	230.00	437.67	-53.36	**.02**	-97.08 to -9.64
Con	1322	283.37	664.29			

Given the far greater amount of usable information and the fact that the results do not show major changes, imputation of missing data with zeros was used as the base case for analyses by wave shown below. The complete case analysis (Table 40) can be regarded as a sensitivity analysis.

6.9 NHS Resource use and costs by wave

Results comparing primary care resource use by Intervention and Control patients by Wave are shown in Table 45, for secondary care resource use in Table 46. Cost of drugs and costs of primary care, secondary care and total NHS costs are shown in Tables 47-51. In all cases the zero imputation method was used. These results have not been adjusted for any covariants or for skewness. Explanation of the adjustments made and the results of the post adjustment analyses are given in the next section.

Table 45. NHS Resource Use Primary Care by wave: Intervention versus Control.

Item (Section D)	Baseline (n= 3818)			Post Procedure (n= 2940)			12 mo
	Int Mean (SD)	**Cont. Mean (SD)**	**p.value**	**Int Mean (SD)**	**Cont. Mean (SD)**	**p.value**	**Int Mean (SD)**
(**D1**) How often have you consulted at the GP's surgery with							
Doctor							
Wave 1	2.41 (2.65)	2.53 (3.17)	0.55	2.11 (2.25)	2.14 (2.26)	0.89	1.60 (2.22)
Wave 2	2.51 (2.51)	2.61 (2.70)	0.58	2.25 (2.8)	2.4 (2.23)	0.48	1.74 (2.61)
Wave 3	2.39 (2.66)	2.45 (2.23)	0.74	1.91 (2.02)	2.46 (2.67)	**0.01**	1.41 (1.73)
Wave 4	2.26 (2.12)	2.58 (2.74)	0.07	1.87 (1.89)	2.24 (2.2)	**0.03**	1.59 (1.82)
Wave 5	2.39 (2.36)	2.53 (2.34)	0.44	1.95 (2.09)	2.21 (2.16)	0.16	1.27 (1.53)
Nurse							
Wave 1	0.68 (2.00)	0.74 (1.34)	0.58	0.51 (1.27)	0.65 (1.28)	0.18	0.51 (1.22)
Wave 2	0.60 (1.18)	0.75 (1.32)	0.09	0.59 (1.28)	0.64 (1.32)	0.65	0.68 (1.41)
Wave 3	0.61 (1.88)	0.81 (1.89)	0.15	0.55 (1.14)	1.10 (3.96)	**0.02**	0.51 (1.39)
Wave 4	0.65 (1.33)	1.12 (6.28)	0.144	0.5 (0.99)	0.71 (1.21)	**0.03**	0.52 (1.12)
Wave 5	0.63 (1.27)	0.8 (1.93)	0.16	0.61 (1.18)	0.64 (1.28)	0.77	0.56 (1.17)
Other							
Wave 1	0.02 (0.22)	0.06 (0.56)	0.24	0.11 (1.0)	0.04 (0.35)	0.29	0.03 (0.18)

Wave 2	0.15 (1.44)	0.07 (0.49)	0.27	0.15 (1.12)	0.05 (0.35)	0.11	0.06 (0.66)
Wave 3	0.02 (0.19)	0.08 (0.71)	0.16	0.03 (0.21)	0.2 (0.19)	0.61	0.07 (0.60)
Wave 4	0.10 (0.81)	0.06 (0.57)	0.33	0.04 (0.29)	0.10 (0.82)	0.24	0.11 (0.76)
Wave 5	0.05 (0.65)	0.02 (0.19)	0.38	0.04 (0.32)	0.03 (0.24)	0.59	0.05 (0.36)
(**D2**) How often have you consulted at home with							
Doctor							
Wave 1	0.18 (0.67)	0.19 (0.91)	0.74	0.17 (0.67)	0.12 (0.57)	0.31	0.10 (0.57)
Wave 2	0.26 (1.41)	0.18 (0.62)	0.32	0.21 (1.04)	0.18 (0.72)	0.64	0.14 (0.74)
Wave 3	0.24 (0.99)	0.11 (0.49)	**0.01**	0.08 (0.42)	0.14 (0.69)	0.22	0.12 (0.7)
Wave 4	0.11 (0.64)	0.23 (1.16)	0.07	0.09 (0.45)	0.11 (0.70)	0.71	0.10 (0.56)
Wave 5	0.19 (0.92)	0.26 (1.38)	0.42	0.07 (0.39)	0.1 (0.43)	0.39	0.04 (0.21)
Nurse							
Wave 1	0.07 (0.66)	0.05 (0.41)	0.56	0.09 (0.57)	0.08 (0.62)	0.87	0.15 (0.99)
Wave 2	0.08 (0.62)	0.12 (1.15)	0.61	0.10 (0.67)	0.11 (1.23)	0.86	0.14 (0.72)
Wave 3	0.16 (1.45)	0.10 (1.23)	0.47	0.05 (0.43)	0.17 (1.46)	0.19	0.04 (0.37)
Wave 4	0.08 (0.67)	0.44 (5.85)	0.23	0.15 (1.12)	0.13 (1.07)	0.81	0.11 (0.57)
Wave 5	0.07 (0.54)	0.06 (0.55)	0.92	0.03 (0.24)	0.09 (0.75)	0.19	0.04 (0.43)
Other							
Wave 1	0.02	0.03	0.29	0.00	0.06	0.20	0.00

	(0.19)	(0.27)		(0.00)	(0.77)		(0.00)
Wave 2	0.01 (0.10)	0.00 (0.05)	0.17	0.01 (0.10)	0.02 (0.19)	0.61	0.02 (0.14)
Wave 3	0.01 (0.07)	0.03 (0.25)	0.08	0.00 (0.06)	0.01 (0.1)	0.36	0.00 (0)
Wave 4	0.02 (0.13)	0.03 (0.37)	0.58	0.02 (0.13)	0.02 (0.25)	0.94	0.02 (0.23)
Wave 5	0.01 (0.12)	0.01 (0.11)	0.78	0.01 (0.09)	0.01 (0.14)	0.67	0.04 (0.39)

Table 46. Resource Use Secondary Care by wave: Intervention versus Control

Item (Section D)	Baseline (n= 3818)			Post Procedure (n= 2940)			
	Int Mean (SD)	**Cont. Mean (SD)**	**p.value**	**Int Mean (SD)**	**Cont. Mean (SD)**	**p.value**	**Int (**
(**D3**) How often have you been admitted for any reason to a hospital as an emergency							
Wave 1	0.09 (0.45)	0.14 (0.47)	0.12	0.12 (0.53)	0.15 (1.24)	0.66	(
Wave 2	0.16 (0.55)	0.16 (0.65)	0.93	0.15 (0.64)	0.12 (0.48)	0.61	(
Wave 3	0.14 (0.52)	0.17 (0.63)	0.42	0.12 (0.70)	0.16 (0.68)	0.57	(
Wave 4	0.10 (0.45)	0.16 (0.70)	0.16	0.08 (0.45)	0.12 (0.57)	0.32	(
Wave 5	0.18 (0.64)	0.14 (0.42)	0.35	0.10 (0.32)	0.13 (0.53)	0.41	(
(**D4**) How often have you been admitted for any reason to a hospital as an non emergency							
Wave 1	0.10 (0.52)	0.14 (0.51)	0.25	0.23 (0.59)	0.29 (0.96)	0.30	(
Wave 2	0.19 (0.76)	0.26 (1.28)	0.41	0.21 (0.51)	0.24 (0.70)	0.56	(
Wave 3	0.16 (0.68)	0.14 (0.52)	0.63	0.26 (0.74)	0.22 (0.69)	0.50	(
Wave 4	0.16 (0.57)	0.19 (0.58)	0.41	0.27 (1.03)	0.26 (0.64)	0.88	(
Wave 5	0.15 (0.53)	0.19 (0.63)	0.37	0.26 (0.7)	0.19 (0.56)	0.17	(
(**D5**) How often have you been seen at a hospital outpatient clinic with Doctor							
Wave 1	0.82 (1.24)	0.93 (1.23)	0.22	0.92 (1.09)	1.17 (1.41)	**0.01**	(
Wave 2	1.03 (1.38)	0.98 (1.47)	0.61	1.12 (1.35)	1.12 (1.77)	0.99	(

Wave 3	0.92 (1.29)	1 (1.50)	0.45	0.94 (1.18)	1.27 (1.60)	**0.01**	(
Wave 4	0.89 (1.17)	1.21 (2.06)	**0.01**	1.12 (1.42)	1.36 (2.9)	0.2	(
Wave 5	0.89 (1.19)	0.91 (1.33)	0.82	1.03 (1.25)	0.97 (1.17)	0.62	(
Nurse							
Wave 1	0.16 (0.71)	0.18 (0.70)	0.58	0.28 (0.84)	0.16 (0.47)	**0.03**	(
Wave 2	0.16 (0.8)	0.34 (3.18)	0.3	0.19 (0.64)	0.15 (0.48)	0.42	(
Wave 3	0.13 (0.51)	0.36 (2.14)	**0.05**	0.21 (0.58)	0.39 (2.25)	0.21	(
Wave 4	0.20 (0.81)	0.16 (0.63)	0.53	0.23 (0.63)	0.29 (1.26)	0.45	(
Wave 5	0.19 (0.62)	0.14 (0.63)	0.33	0.24 (0.80)	0.24 (0.78)	0.95	(
Other							
Wave 1	0.05 (0.62)	0.06 (0.38)	0.77	0.07 (0.53)	0.07 (0.43)	0.94	(
Wave 2	0.03 (0.24)	0.05 (0.40)	0.29	0.04 (0.31)	0.02 (0.13)	0.27	(
Wave 3	0.02 (0.17)	0.03 (0.2)	0.70	0.02 (0.14)	0.08 (0.70)	0.16	(
Wave 4	0.02 (0.18)	0.07 (0.56)	0.13	0.05 (0.40)	0.06 (0.63)	0.81	(
Wave 5	0.07 (0.57)	0.04 (0.36)	0.44	0.03 (0.38)	0.05 (0.42)	0.55	(
(**D6**) How many time have been admitted as a day case for							
Upper endoscopy							
Wave 1	0.14 (0.71)	0.12 (0.49)	0.59	0.57 (0.55)	0.54 (0.59)	0.49	(

Wave 2	0.09 (0.51)	0.09 (0.41)	0.87	0.61 (0.74)	0.6 (0.59)	0.77	(
Wave 3	0.05 (0.22)	0.06 (0.29)	0.79	0.47 (0.54)	0.49 (0.62)	0.70	(
Wave 4	0.05 (0.22)	0.06 (0.26)	0.58	0.56 (0.67)	0.48 (0.54)	0.12	(
Wave 5	0.09 (0.54)	0.06 (0.25)	0.31	0.45 (0.52)	0.53 (0.52)	0.06	(
Lower endoscopy							
Wave 1	0.11 (0.36)	0.15 (0.64)	0.22	0.47 (0.76)	0.47 (0.55)	0.92	(
Wave 2	0.09 (0.32)	0.11 (0.53)	0.56	0.47 (0.77)	0.44 (0.63)	0.65	(
Wave 3	0.12 (0.62)	0.13 (0.59)	0.9	0.42 (0.54)	0.49 (0.55)	0.13	(
Wave 4	0.13 (0.48)	0.09 (0.33)	0.2	0.44 (0.54)	0.47 (0.52)	0.45	(
Wave 5	0.13 (0.56)	0.12 (0.51)	0.72	0.50 (0.56)	0.38 (0.55)	**0.02**	(

Table 47. Drug costs by wave: Intervention versus Control

Item (Section E)	Baseline (n= 3818)			Post Procedure (n= 2940)			
	Int Mean (SD)	**Cont. Mean (SD)**	**p.value**	**Int Mean (SD)**	**Cont. Mean (SD)**	**p.value**	**Int M (S**
Indigestion medication							
Wave 1	£27.24 (58.59)	£23.52 (44.56)	0.31	£26.05 (47.07)	£27.54 (47.55)	0.69	£22 (43
Wave 2	£20.13 (38.56)	£33.07 (50.31)	**0.00**	£22.44 (41.56)	£32.77 (49.64)	**0.01**	£21 (37
Wave 3	£27.42 (55.47)	£28.93 (48.25)	0.69	£28.10 (47.87)	£30.96 (53.40)	0.5	£26 (45
Wave 4	£28.40 (60.69)	£30.31 (55.01)	0.65	£28.96 (52.39)	£32.75 (63.34)	0.43	£26 (45
Wave 5	£25.88 (51.05)	£37.08 (57.98)	**0.01**	£24.64 (47.62)	£38.89 (57.55)	**0.00**	£21 (47
Irritable bowel medication							
Wave 1	£2.22 (11.40)	£1.64 (7.65)	0.38	£1.98 (8.81)	£2.12 (8.57)	0.84	£1 (8.
Wave 2	£1.52 (9.55)	£2.05 (9.90)	0.47	£1.41 (6.00)	£1.69 (7.08)	0.61	£0 (4.
Wave 3	£2.42 (10.31)	£2.46 (11.51)	0.96	£1.88 (8.14)	£2.21 (8.09)	0.62	£1 (8.
Wave 4	£2.93 (15.00)	£1.47 (6.49)	0.08	£2.23 (12.54)	£1.39 (7.41)	0.34	£2 (12
Wave 5	£2.03 (8.85)	£1.98 (10.87)	0.95	£1.63 (8.19)	£0.84 (3.97)	0.16	£1 (12
Anti-diarrhoeal medication							
Wave 1	£0.85 (4.95)	£1.22 (6.71)	0.36	£1.10 (5.76)	£1.38 (7.55)	0.61	£1 (11
Wave 2	£0.82 (6.00)	£1.28 (6.72)	0.33	£0.56 (4.54)	£0.93 (5.25)	0.36	£0 (1.

Wave 3	£0.69 (4.49)	£1.52 (17.70)	0.38	£0.37 (3.04)	£1.01 (6.08)	0.12	£0 (2.
Wave 4	£1.61 (7.59)	£1.25 (6.61)	0.48	£0.93 (6.08)	£1.02 (6.47)	0.87	£1 (8.
Wave 5	£0.55 (4.17)	£0.88 (5.48)	0.36	£0.64 (4.42)	£0.33 (2.45)	0.31	£0 (5.
Colitis medication							
Wave 1	£3.05 (19.45)	£9.43 (64.79)	0.06	£4.15 (22.40)	£13.76 (80.42)	**0.04**	£5 (30
Wave 2	£4.55 (28.67)	£7.42 (60.06)	0.41	£4.66 (29.52)	£4.60 (25.53)	0.98	£8 (36
Wave 3	£2.78 (23.98)	£7.26 (36.37)	**0.05**	£3.25 (20.05)	£8.75 (38.43)	**0.03**	£4 (32
Wave 4	£3.48 (24.53)	£5.37 (29.14)	0.33	£4.11 (27.73)	£6.89 (33.40)	0.28	£6 (35
Wave 5	£11.63 (55.27)	£2.37 (17.43)	**0.00**	£13.71 (57.31)	£1.59 (10.85)	**0.00**	£1 (61

Table 48. Total primary care costs by wave: Intervention versus Control

Total primary care cost (£)									
Wave 1	£68.59 (84.87)	£75.37 (103.99)	0.31	£61.81 (84.28)	£60.51 (70.48)	0.83	£45.51 (65.10)	£52.03 (70.71)	0.25
Wave 2	£79.71 (127.47)	£74.32 (79.68)	0.49	£70.70 (97.47)	£68.61 (75.42)	0.77	£56.18 (88.80)	£57.00 (90.75)	0.92
Wave 3	£72.48 (95.57)	£69.25 (75.36)	0.6	£50.41 (61.39)	£72.41 (90.09)	**0.00**	£43.07 (75.21)	£52.43 (129.32)	0.32
Wave 4	£65.02 (75.77)	£84.13 (170.03)	**0.04**	£52.30 (56.88)	£63.67 (85.08)	0.06	£49.87 (73.36)	£52.84 (86.91)	0.67
Wave 5	£69.95 (87.38)	£77.19 (114.13)	0.34	£53.15 (61.64)	£59.53 (61.37)	0.23	£37.15 (47.20)	£71.46 (266.60)	0.06

Table 49. Total Secondary care costs by wave: Intervention versus Control

Total secondary care cost (£)									
Wave 1	£262.78 (479.79)	£311.05 (520.23)	0.17	£691.44 (483.62)	£714.36 (583.19)	0.59	£227.74 (506.29)	£181.84 (373.85)	0.21
Wave 2	£292.48 (495.63)	£336.44 (663.29)	0.31	£718.58 (575.50)	£694.83 (575.39)	0.62	£187.67 (382.17)	£257.31 (714.12)	0.18
Wave 3	£263.71 (467.24)	£300.95 (634.14)	0.36	£626.22 (552.18)	£717.11 (536.60)	**0.04**	£151.09 (350.28)	£222.11 (522.42)	0.07
Wave 4	£257.34 (413.61)	£301.73 (474.52)	0.17	£681.62 (517.07)	£698.94 (561.33)	0.70	£174.83 (440.70)	£265.52 (905.08)	0.15
Wave 5	£302.09 (525.71)	£275.88 (441.83)	0.48	£653.91 (415.63)	£625.13 (419.56)	0.43	£162.94 (357.18)	£207.48 (454.22)	0.25

Table 50. Total drug costs by wave: Intervention versus Control

Total cost of medication (£)									
Wave 1	£33.36 (62.07)	£35.81 (79.01)	0.62	£33.29 (53.05)	£44.80 (92.41)	**0.05**	£31.12 (55.52)	£43.05 (84.44)	**0.05**
Wave 2	£27.03 (48.84)	£43.82 (77.78)	**0.00**	£29.07 (50.87)	£40.00 (56.04)	**0.02**	£30.89 (50.71)	£42.18 (57.67)	**0.02**
Wave 3	£33.32 (60.75)	£40.17 (60.85)	0.12	£33.60 (51.00)	£42.92 (66.40)	0.06	£33.02 (56.15)	£45.87 (83.86)	**0.04**
Wave 4	£36.36 (68.34)	£38.40 (60.92)	0.66	£36.23 (62.05)	£42.05 (70.49)	0.29	£36.25 (62.01)	£48.37 (75.02)	**0.05**
Wave 5	£40.09 (72.09)	£42.32 (63.42)	0.66	£40.62 (70.57)	£41.66 (59.47)	0.86	£39.29 (85.55)	£46.65 (85.02)	0.36

Table 51. Total NHS Costs by wave: Intervention versus Control

Total NHS cost									
Wave 1	£364.72 (505.62)	£422.24 (570.86)	0.13	£786.55 (516.74)	£819.66 (630.31)	0.46	£304.37 (524.90)	£276.92 (421.02)	0.48
Wave 2	£399.22 (542.58)	£454.58 (686.78)	0.22	£818.35 (605.46)	£806.05 (604.22)	0.81	£274.74 (407.41)	£356.49 (773.49)	0.14
Wave 3	£369.52 (511.96)	£410.38 (656.77)	0.34	£715.01 (581.21)	£835.02 (582.23)	**0.01**	£227.17 (381.01)	£320.42 (577.54)	**0.0**
Wave 4	£358.72 (442.99)	£424.26 (537.86)	0.07	£770.15 (535.83)	£807.54 (591.32)	0.43	£260.95 (492.58)	£366.72 (929.23)	0.10
Wave 5	£412.12 (556.98)	£395.39 (490.63)	0.67	£747.68 (441.51)	£726.31 (448.35)	0.58	£239.38 (391.91)	£325.59 (603.66)	0.07

6.10 Adjustments

These results show that there were differences between groups even at baseline. Despite the large sample size, clustering effects are expected when randomisation is by site rather than by patient. Also, and as is common with cost data, a high degree of skewness in costs was shown.

The study also had another complicating factor in that the length of time between questionnaires varied between patients. While all patients completed questionnaires on entry to the study (baseline) and just after receiving their procedure (PPQ) the time between these two events could vary considerably. This, of course, meant that the time between BQ and 12M PPQs showed the same variation. These issues are discussed in turn.

6.10.1 Clustering

The study provides a hierarchical structure of costs, resource use and patient outcomes, which may vary across sites. This variability can be assessed using appropriate analytical methods. Studies in this area commonly use ordinary least square (OLS) models which assume that observations across patients are independent and have a common variance. This assumption is unlikely to hold when using data from different sites, as patients' resource use or costs within a particular site may be more similar than that in different sites. Multilevel models (MLMs) are able to incorporate the hierarchical structure of the data (that is, of patients within sites), and provide more appropriate estimates of patient and site-level effects. Use of a MLM in health economics has been recommended by Rice and Jones (Rice and Jones 1997). In this study we applied an MLM approach to explore site-level variation in resource use (costs) either at post-procedure or 12 month post procedure. An OLS regression model takes the form

$$y_i = \beta_0 + \beta_1 x_i + e_i\,,\ e_i \sim \text{Normal}\ (0, \sigma_e^2)$$

where y_i is the outcome variable for the ith patient, x_i is an explanatory variable with associated slope β_1 and intercept β_0. The error term, e_i represents explained variability between patients and is assumed to be normally distributed with mean zero. The OLS model assumes that the variance of the error term is the same for all patients. The most basic MLM, the random intercept models, includes an additional form which represents the unexplained variation that exists between sites. Using subscripts i and j for the ith patient in the jth site, the model can be written as

$$y_{ij} = \beta_0 + \beta_1 x_{ij} + u_j + e_{ij}\,,\quad e_{ij} \sim \text{Normal}\ (0, \sigma_e^2);\ \ u_j \sim \text{Normal}\ (0, \sigma_u^2)$$

where β_0 is a fixed quantity applying to all patients, u_j is a random variable with zero mean and constant variance (σ_u^2) which applies to site j and e_{ij} is random error term which represents unexplained variation for patients within a site. U_j indicates the random effect of site on the outcome variable over and above that explained by the explanatory variables. The intercept for the jth site is now given as a fixed component β_0 plus a random component u_j. The regression coefficient, β_1 can also be allowed to vary between sites which makes the model a 'random slope' model (i.e. site type (Intervention or Control) can be considered as a random factor in the model).

The degree of dependency between observations can be measured by the Intraclass Correlation Coefficient (ICC) defined as

$$\text{ICC} = \sigma_u^2 / (\sigma_u^2 + \sigma_e^2)$$

which further reflects the strengths of 'nesting' within the data hierarchy.

As a test case, we applied the simple MLM approach to data only on a few selected resource items at the PPQ and the 12M PPQ periods. Results from the estimated models at BQ and 12M PPQ period are presented in Tables 52 and 53 below.

These tables do not show any important effects of site on the resources used. This can be verified by the fact that the estimates of σu2, which show site-level variation, are statistically insignificant in all cases except for primary care costs. The standard error of σu2 appears large in comparison with its estimated coefficients. An estimate of ICC in an MLM also reflects the degree to which data are clustered at higher level, which is in this study is site-level. For example, the ICC of 0.032 in Table 53 shows that only 3.2% of the total variations in primary care costs are attributed to site-level variation, which is small but statistically significant. Similar findings were observed from all multilevel models developed in this section in order to see whether there are any important site-level variations in resource use data. It was therefore concluded that these analyses do not show any important site level effects for the observed patient-borne resource use data. Accordingly no further MLM analyses were attempted.

Table 52. Multilevel models for five resource use dependent variables at post-procedure: D1a (consultations with GP at GP surgery), D1b (consultations with nurse at GP surgery), primary care costs, secondary

	D1a	**D1b**	**primary care costs**	**secondary care costs**
Constant	1.417 (0.07)	0.47 (0.05)	39.5 (2.4)	615.9 (17.2)
Fixed parameters				
BQ score	0.43 (0.02)	0.42 (0.02)	0.39 (0.01)	0.38 (0.02)
Site-type				
Control	Reference	Reference	Reference	Reference
Intervention	-0.23 (0.07)	-0.14 (0.06)	-5.6 (2.7)	-10.5 (19.5)
Length of waiting	-0.003(.001)	-.001 (.000)	-0.05 (0.02)	-0.49 (0.14)
Random effects				
σ_u^2(between site)	0.002 (0.02)	0.00 (0.00)	20.4 (23.7)	1086.4 (1272.9)
σ_e^2 (within site)	3.96 (0.11)	2.53 (0.07)	4490.9 (119.2)	241331.3 (6408.3)
ICC	0.001		0.004	0.004
-2 log-likelihood	12319.7	11011.2	32900.6	44550.1

Table 53. Multilevel models for five resource use dependent variables at 12M PPQ: D1a (c surgery), D1b (consultations with nurse at GP surgery), primary care costs, secondary

	D1a	**D1b**	**primary care costs**	**secondary care costs**
Constant	0.93 (0.28)	0.76 (0.23)	50.7 (15.8)	111.7 (73.2)
Fixed parameters				
BQ score	0.25 (0.02)	0.18 (0.02)	0.20 (0.03)	0.26 (0.02)
Site-type				
Control	Reference	Reference	Reference	Reference
Intervention	-0.05 (0.08)	-0.13 (0.06)	-9.1 (4.78)	-39.3 (21.2)
Length of waiting	0.00 (0.001)	0.00 (0.001)	-0.02 (0.04)	0.09 (0.17)
Random effects				
σ_u^2(between site)	0.00	0.02 (0.02)	408.9 (187.2)	2323.2 (2382.6)
σ_e^2 (within site)	3.86 (0.11)	2.80 (0.08)	12282.4 (347.5)	264922.0 (7500.1)
ICC	0.00	0.00	0.032	0.008
-2 log-likelihood	10817.3	9933.4	31623.3	39551.3

6.10.2 Differences in timing of questionnaires

As PPQs and 12M PPQs varied in length of time from baseline, a regression based adjustment was carried out on data from these two questionnaires to account for baseline effects across all resource use items as well as for costs. The following adjustment was made;

follow up effect $_i$ = constant + *a* * Baseline effect $_i$ + *b* * Group $_i$ (C/I) + *c** length of time between questionnaires

where *i* is a patient identifier (*i* = 1, 2, …., N), *a* and *b* are estimated coefficients and group is a binary variable coded '1' for Intervention and '0' for Control. The coefficient *b* is here the effect of interest – the estimated difference between the two patient-groups after adjusting for BQ differences. This method adjusts each patient's follow up effect for his/her baseline effect, but has the advantage of being unaffected by BQ differences. The results for PPQ and 12M PPQs shown in Tables 54 and 55 below include this adjustment.

6.10.3 Skewness

Table 54 shows adjusted mean differences in individual resource use items. P values and 95% confidence intervals were calculated using a t-statistic. However, as is common with costs, the data here showed a high degree of skewness. Accordingly a non-parametric bootstrap method was used for analysis of the cost items. Table 55 reports the bootstrapped mean differences, *p*-values and 95% confidence intervals based on 10,000 bootstrapped samples.

6.11 Results of adjusted analyses

Table 54. Comparison of resource use by Wave: Intervention versus Control.

Item	Baseline (n= 3818)			Post Procedure (n= 2940)			
	Mean Difference (I – C)	***p***	**95% CI**	**Adjusted mean difference (I – C)**	*p*	**95% CI**	**Ad dif**
(**D1**) How often have you consulted at the GP's surgery with							
Doctor							
W1	-0.12	0.55	-0.52 – 0.28	0.01	0.94	-0.29 – 0.32	
W2	-0.11	0.58	-0.48 – 0.27	-0.15	0.43	-0.53 – 0.23	
W3	-0.06	0.74	-0.40 – 0.29	-0.48	**0.00**	**-0.80 - -0.17**	
W4	-0.32	0.07	-0.67 – 0.02	-0.37	**0.02**	**-0.66 - -0.07**	
W5	-0.14	0.44	-0.48 – 0.21	-0.08	0.62	-0.39 – 0.23	
Nurse							
W1	-0.07	0.58	-0.30 – 0.17	-0.03	0.73	-0.20 – 0.14	
W2	-0.15	0.09	-0.33 – 0.02	-0.04	0.67	-0.24 – 0.15	
W3	-0.20	0.15	-0.46 – 0.07	-0.48	**0.03**	**-0.92 - -0.04**	
W4	-0.48	0.14	-1.11 – 0.16	-0.16	0.07	-0.33 – 0.01	
W5	-0.17	0.16	-0.41 – 0.07	0.01	0.93	-0.18 – 0.19	
Other							
W1	-0.04	0.24	-0.09 – 0.02	0.07	0.24	-0.04 – 0.18	
W2	0.09	0.27	-0.07 – 0.04	0.09	0.17	-0.04 – 0.23	
W3	-0.05	0.16	-0.13 – 0.02	0.01	0.61	-0.02 – 0.04	
W4	0.05	0.33	-0.05 – 0.15	-0.06	0.22	-0.16 – 0.04	
W5	0.03	0.38	-0.04 – 0.10	0.01	0.58	-0.03 – 0.05	
(**D2**) How often have you consulted at home with							
Doctor							
W1	-0.02	0.74	-0.13 – 0.09	0.06	0.15	-0.04 – 0.10	
W2	0.08	0.32	-0.08 – 0.24	-0.02	0.75	-0.13 – 0.10	

	W3	0.14	**0.01**	**0.03 – 0.24**	-0.07	0.12	-0.16 – 0.02
	W4	-0.12	0.07	-0.26 – 0.01	-0.01	0.90	-0.10 – 0.09
	W5	-0.07	0.42	-0.24 – 0.10	-0.02	0.54	-0.09 – 0.05
Nurse							
	W1	0.02	0.56	-0.05 – 0.09	0.01	0.79	-0.08 – 0.09
	W2	-0.04	0.61	-0.17 – 0.10	0.02	0.73	-0.07 – 0.10
	W3	0.07	0.47	-0.12 – 0.26	-0.13	0.16	-0.30 – 0.05
	W4	-0.36	0.23	-0.94 – 0.22	0.06	0.52	-0.12 – 0.23
	W5	0.00	0.92	-0.08 – 0.08	-0.06	0.22	-0.16 – 0.04
Other							
	W1	-0.02	0.29	-0.05 – 0.02	-0.05	0.22	-0.14 – 0.03
	W2	0.01	0.17	-0.00 – 0.02	-0.01	0.68	-0.03 – 0.02
	W3	-0.02	0.08	-0.05 – 0.00	-0.01	0.46	-0.02 – 0.01
	W4	-0.01	0.58	-0.05 – 0.03	0.00	0.99	-0.03 – 0.03
	W5	0.00	0.78	-0.01 – 0.02	-0.00	0.69	-0.02 – 0.02
(**D3**) How often have you been admitted for any reason to a hospital as an emergency							
	W1	-0.05	0.12	-0.11 – 0.01	0.03	0.68	-0.11 – 0.16
	W2	-0.00	0.93	-0.09 – 0.08	0.03	0.53	-0.06 – 0.11
	W3	-0.03	0.42	-0.11 – 0.04	-0.02	0.73	-0.13 – 0.08
	W4	-0.06	0.16	-0.14 – 0.02	-0.05	0.23	-0.13 – 0.03
	W5	0.04	0.35	-0.04 – 0.11	-0.03	0.35	-0.10 – 0.04
(**D4**) How often have you been admitted for any reason to a hospital as an non emergency							
	W1	-0.04	0.25	-0.11 – 0.03	-0.06	0.33	-0.19 – 0.06
	W2	-0.06	0.41	-0.22 – 0.09	-0.02	0.65	-0.12 – 0.08
	W3	0.02	0.63	-0.06 – 0.10	0.03	0.57	-0.08 – 0.14
	W4	-0.04	0.40	-0.12 – 0.05	0.02	0.73	-0.12 – 0.17
	W5	-0.04	0.37	-0.13 – 0.05	0.08	0.15	-0.03 – 0.18
(**D5**) How often have you been seen at a hospital outpatient clinic with							
Doctor							
	W1	-0.11	0.22	-0.28 – 0.06	-0.18	**0.03**	**-0.35 - -0.01**
	W2	0.05	0.61	-0.15 – 0.26	-0.08	0.45	-0.29 – 0.13
	W3	-0.08	0.45	-0.27 – 0.12	-0.31	**0.00**	**-0.52 - -0.10**
	W4	-0.32	**0.01**	**-0.56 - -0.09**	-0.03	0.83	-0.33 – 0.26

W5	-0.02	0.82	-0.21 – 0.16	0.07	0.46	-0.12 – 0.26	
Nurse							
W1	-0.03	0.58	-0.12 – 0.07	0.12	**0.02**	**0.02 – 0.22**	
W2	-0.18	0.29	-0.52 – 0.16	0.03	0.52	-0.06 – 0.12	
W3	-0.22	**0.05**	**-0.45 - -0.00**	0.04	0.64	-0.13 – 0.21	
W4	0.03	0.53	-0.07 – 0.13	-0.08	0.34	-0.24 – 0.08	
W5	0.05	0.33	-0.05 – 0.14	-0.01	0.88	-0.13 – 0.11	
Other							
W1	-0.01	0.77	-0.08 – 0.06	0.00	0.91	-0.07 – 0.07	
W2	-0.03	0.29	-0.07 – 0.02	0.03	0.10	-0.01 – 0.06	
W3	-0.01	0.70	-0.03 – 0.02	-0.04	0.31	-0.12 – 0.04	
W4	-0.05	0.12	-0.10 – 0.01	-0.01	0.76	-0.10 – 0.07	
W5	0.03	0.44	-0.04 – 0.10	-0.02	0.55	-0.09 – 0.05	
(**D6**) How many time have been admitted as a day case for							
Upper endoscopy							
W1	0.02	0.59	-0.06 – 0.11	0.03	0.46	-0.05 – 0.12	
W2	-0.01	0.87	-0.07 – 0.06	0.01	0.82	-0.09 – 0.12	
W3	-0.01	0.79	-0.04 – 0.03	-0.02	0.68	-0.11 – 0.07	
W4	-0.01	0.58	-0.04 – 0.02	0.07	0.18	-0.03 – 0.17	
W5	0.03	0.31	-0.03 – 0.09	-0.07	0.10	-0.17 – 0.01	
Lower endoscopy							
W1	-0.04	0.22	-0.12 – 0.03	0.01	0.86	-0.09 – 0.11	
W2	-0.02	0.56	-0.08 – 0.04	0.03	0.56	-0.08 – 0.15	
W3	-0.01	0.89	-0.09 – 0.08	-0.06	0.17	-0.15 – 0.03	
W4	0.04	0.20	-0.02 – 0.09	-0.04	0.35	-0.13 – 0.04	
W5	0.02	0.72	-0.06 – 0.09	0.12	**0.01**	**0.02 – 0.21**	

Table 55. Comparison of costs by Wave: Intervention v Control. Bootstrapped data.

Item	Baseline (n= 3818)			Post Procedure (n= 2940)			End
	M.D. (I – C) (bs)	***p* (bs)**	**95% CI (bootstrap)**	**Adj. M.D. (I – C)**	*p*	**95% CI**	**Adj. M.D (I – C)**
primary care cost (£)							
W1	-£6.74	0.15	-19.8 – 6.0	£5.15	0.33	-5.28 – 15.58	-£5.97
W2	£5.35	0.75	-7.19 – 24.4	-£2.47	0.69	-15.92 – 9.99	-£1.28
W3	£3.34	0.71	-7.9 – 16.11	-£21.6	**0.00**	**-32.5 - -10.8**	-£8.88
W4	-£19.3	**0.02**	**-43.8 - -4.22**	-£9.16	0.11	-20.23 – 1.92	£0.87
W5	-£7.28	0.17	-25.2 – 5.9	-£1.42	0.76	-10.65 – 7.82	-£35.6
secondary care cost (£)							
W1	-£48.3	0.08	-111.3 – 23.8	-£12.5	0.76	-91.7 – 66.6	£37.6
W2	-£43.4	0.16	-122.5 – 48.4	£23.0	0.62	-66.7 – 112.7	-£62.6
W3	-£37.6	0.17	-116.8 – 37.4	-£66.6	0.10	-146.2 – 12.9	-£62.9
W4	-£44.3	0.08	-107.1 – 17.6	-£7.98	0.85	-89.1 – 73.2	-£58.6
W5	£26.2	0.76	-45.8 – 98.7	£32.7	0.34	-34.9 – 100.4	-£48.6
drug care cost (£)							
W1	-£2.46	0.31	-12.3 – 6.9	-£9.99	0.08	-21.1 – 1.1	-£10.6
W2	-£16.9	**0.00**	**-26.5 - -8.2**	-£3.9	0.32	-11.7 – 3.8	-£5.9
W3	-£6.9	0.06	-15.4 – 1.4	-£6.1	0.13	-14.1 – 1.8	-£8.5
W4	-£2.05	0.33	-10.5 – 7.6	-£5.0	0.24	-13.4 – 3.3	-£10.8
W5	-£2.23	0.33	-11.8 – 8.1	-£2.5	0.54	-10.5 – 5.5	-£6.4
Total NHS cost (£)							
W1	-£57.5	0.06	-128.2 – 19.8	-£17.2	0.69	-101.6 – 67.3	£20.6
W2	-£54.9	0.12	-137.3 – 45.9	£15.5	0.74	-77.0 – 108.0	-£66.0
W3	-£41.1	0.16	-123.9 – 37.9	-£86.9	**0.04**	**-169.8 – - 4.1**	-£80.1
W4	-£65.6	**0.03**	**-135.8 – 3.1**	-£21.2	0.62	-105.6 – 63.3	-£64.0
W5	£16.7	0.66	-62.1 – 93.7	£27.2	0.45	-43.8 – 98.0	-£91.4

6.12 Lost Productivity

Table 56 below shows the reported mean number of days off work and value of lost productivity by Intervention and Control patients. In terms of time off alone, there was a statistically significant difference in favour of the Intervention group (adjusted mean difference = -1.78 days, p = 0.04, 95% CI = -£3.47 to -0.09) at Wave 4 but not at any other wave. When valued using the relevant average earnings (male or female), however, the adjusted mean difference (-£27.00) was not statistically significant (p = 0.07, 95% CI = -£56.7 to £2.60). This result replicates those of NHS resource use i.e. that there is a consistent tendency for patients in the Intervention sites to have less time off work but no firm conclusions can be reached due to the lack of statistical significance show.

6.13 Discussion

The Quasi-experimental approach used here is comparing sites which received additional support from the NHSMA (Intervention) with those that did not (Control). However, any effects of the intervention need to be seen in the context of a general climate of modernisation being pursued by the DoH and the fact that all participating sites had registered their intentions to modernise. The effects of the intervention as a catalyst to modernisation were thus inevitably going to be relatively small.

In the event, most sites managed to secure funding from other sources either instead of, or in addition to, the financial support provided by the NHSMA to Intervention sites. More importantly, the costs of modernisation are not restricted to financial expenditures. For example, the time devoted by existing staff to modernisation activities is a cost of modernisation regardless of the fact that it does not incur a change in the wages bill.

Analysis of the costs incurred by ENIGMA sites shows major investments in equipment, training, one off activities and in recurring costs. The extent to which these increased the per patient cost of the endoscopy services was, however, slightly lower in the Intervention sites (£26.62 v £33.88 first year and £17.43 v £20.91 subsequent years) although the differences were not statistically significant.

Table 56. Time off work and value of lost productivity by Wave: Intervention v Control

Item (Section D)	Baseline (n= 3818)			Post Procedure (n= 2940)			12 m
	M.D. (I – C)	***p***	**95% CI**	**Adj. M.D. (I - C)**	*p*	**95% CI**	**Adj. (I**
(**D7**) Time off from work							
W1	-0.03	0.97	-1.55 – 1.49	0.27	0.61	-0.75 – 1.28	-0
W2	-1.20	0.22	-3.11 – 0.71	0.49	0.56	-1.16 – 2.13	0.
W3	0.55	0.37	-0.64 – 1.74	-0.55	0.22	-1.41 – 0.32	-0
W4	1.59	0.07	-0.13 – 3.32	-0.04	0.95	-1.26 – 1.18	-1
W5	-0.82	0.28	-2.33 – 0.68	-1.04	0.31	-3.04 – 0.97	-0
Cost of Time off from work							
W1	£0.86	0.95	-27.5 -29.2	£5.47	0.59	-14.4 – 25.3	-£
W2	-£18.6	0.28	-52.6 - 15.3	£14.05	0.37	-16.9 – 45.0	£2
W3	£12.3	0.29	-10.7- 35.3	-£10.7	0.15	-25.4 – 3.9	-£1
W4	£32.0	0.05	-0.30 – 64.3	£1.60	0.88	-20.6 – 23.9	-£2
W5	-£17.3	0.22	-44.9 – 10.2	-£20.7	0.29	-59.7 – 18.3	-£

Similarly the intervention seemed to have slightly reduced the subsequent NHS costs incurred by patients in terms of primary care, secondary care and drugs although again the differences were rarely statistically significant. It should be noted that in the adjusted analyses of resource use/cost, 170 tests of significance were performed on post procedure and 12 month post procedure data. Of these only 13 showed statistically significant mean differences in resource use items or in costs; 9 at post procedure and 4 at 12 months post procedure. Thus despite the consistent tendency for costs to be lower in patients at intervention sites, no firm conclusion can be drawn regarding whether or not the intervention is cost saving.

At the same time, the results of the patient outcome analyses suggest that the intervention did not impact on patients' health. Although there was a statistically significant difference in the adjusted mean difference in EQ-5D scores in favour of the Control group at Wave 2 ($p = .04$), there was also a statistically significant difference favouring the Intervention group at Wave 5 ($p = .04$). The differences in the other 8 analyses were insignificant with 4 favouring the Intervention group and three favouring the Control (mean EQ-5D scores were identical the remaining two tests).

Taken together these results suggest that the intervention is likely to fall in the South West quadrant of the cost effectiveness plane (see for example Drummond, 2005 (Drummond, Sculpher, Torrance, O'Brien and Stoddart 2005)) as it is equally costly or possibly less costly and at least equally effective as compared with the controls – a dominant result.

A number of caveats need to be applied to these conclusions. Many of these can be related back to the 'philosophy' section (2.1) which explained and justified the decision to evaluate the MES programme as an area wide complex intervention. For example, the sampling of sites had to be within a sampling frame determined by the NHSMA and where all sites had undergone some degree of pre-intervention preparation.

Perhaps a greater caveat, though, has to be applied to the lack of a clear definition by the NHSMA regarding what was to be considered as 'modernisation' – and in particular how (if at all) modernisation was seen as being different from improvement. This ambiguity led to difficulties in teasing out the 'costs of modernisation' from those interviewed at the site visits. Although every effort was made to explain how the term was being used for present purposes – in particular to ensure that all interviewees were responding to the same question – it is possible that some interviewees regarded investments to improve the endoscopy service as being modernisation even when they did not fit the chosen definition.

7 Patient Views

7.1 Executive summary

As part of the evaluation and to understand more about Intervention and Control sites in terms of patients' perceptions, telephone interviews were undertaken with patients referred either as urgent or non-urgent, to the nine Intervention and nine Control sites, to elicit responses on their experience of the referral process. In keeping with the overall aims of the study this enabled an understanding of patients' views of the accessibility and acceptability of service provision The interviews took place after the second and fifth waves (hereafter referred to as first round and second round interviews) of patient recruitment. Patients were randomly selected from lists of Intervention/Control and urgent/non-urgent patients who had agreed to take part in the study. The interviews, conducted by two researchers, lasted five to 10 minutes, were recorded and transcribed. The interviews were analysed using content analysis.

Five key themes emerged from the data: waiting for an endoscopy, information provision, staff, differences in experience of endoscopy services over time and suggestions for improvement. As this study was evaluating the MES programme, the research team looked for differences between Intervention and Control sites. However, there were no detectable differences between the responses from patients attending Intervention or Control sites. There were also no discernable differences in the opinions of patients over time.

7.1.1 Waiting for an endoscopy

First round interviews

Patients referred as urgent were satisfied with the time they had to wait. The majority of non-urgent patients anticipated and accepted waiting some time for their test. However, suggestions for improvement were often connected with speeding up the time from referral to procedure.

Second round interviews

The majority of urgent and non-urgent patients were satisfied with the time they had to wait and many were surprised at the speed of their appointments, while fewer patients than in the first round said they would like to have had the procedure sooner.

7.1.2 Information provision

First round interviews

Most patients felt that the information given to them before the procedure was sufficient and were satisfied with being given an appointment date and time with the option to change it.

Second round interviews

The majority of patients were satisfied with the amount of information. Patients appreciated being able to book appointments themselves but there was criticism of the amount of paperwork sometimes involved in the appointment system.

7.1.3 Staff

First round interviews

The majority of patients felt the treatment and care received was good. There were very few negative comments about staff or treatment but, when expressed, concerns were about the insensitivity of staff to personal feelings and the physical surroundings.

Second round interviews

The majority of patients felt the care and treatment was good. There were no negative comments about staff and patients were empathetic towards the stresses and strains of health professionals' working lives.

7.1.4 Differences in experience of endoscopy services over a period of time

First round interviews

Of 14 patients who had had an endoscopy in the past, five (two from Intervention, three from Control sites) felt that their recent experience was better and one patient felt this might have been because the procedure was performed by a Nurse Endoscopist (NE).

Second round interviews

Of 26 patients who had had an endoscopy in the past, 11 (six Intervention/five Control) felt that their recent experience was better for a variety of reasons such as quicker appointments, more modern units and better appointment making systems.

7.1.5 Suggestions for improvement

First round interviews

One third of patients found it difficult to think of suggestions for improvement in the referral process and spoke about their satisfaction with the service and with staff attention. However, two-thirds made suggestions for change and improvement most often related to a reduction in the waiting time for their procedure and the desire for more information in advance about the procedure.

Second round interviews

Many patients found it difficult to think of suggestions for improvement to the referral process and two-thirds made no suggestions. The approximate third of interviewees who made suggestions most often related to a reduced waiting time, improvement in communication before and after the procedure and a desire to have another person present when being told results having had sedation.

7.1.6 Summary - Differences between Intervention and Control sites

The first and second round patient interviews show no detectable differences between Intervention and Control sites in terms of service delivery and organisation and demonstrate that, from a patient perspective, the MES programme appeared to have no detectable impact. However, across all sites, at the time of the second interviews (autumn 2006), patients were getting their procedures more quickly and had fewer suggestions for improving the service than at the time of the first interviews (summer 2005). This suggests that in spite of no detectable differences resulting from the MES programme, the changes that both groups are making to their services are impacting positively on patient views. However, this could be related to demographic differences rather than an improvement in services, as there was a significant difference in patients' ages between first and second round patient interviews.

7.1.7 Major issues arising

First round interviews	Second round interviews
Waiting for an endoscopy ▪ Patients referred as 'urgent' were satisfied with the waiting time for endoscopy ▪ Patients referred as 'non-urgent' accepted having to wait but would prefer a quicker investigation	**Waiting for an endoscopy** ▪ Patients referred as 'urgent' were satisfied with the waiting time for endoscopy ▪ Majority of 'non-urgent' patients thought the waiting time was better than expected ▪ More patients expressed surprise at speed of getting procedure ▪ Less patients saying they would have liked the procedure sooner
Information provision ▪ Information provided in advance of endoscopy was satisfactory ▪ Patients appreciate the ability to alter an appointment	**Information provision** ▪ Information provided in advance of endoscopy was satisfactory ▪ Patients appreciate the ability to book an appointment themselves ▪ Criticism of paperwork involved in some appointment systems
Staff ▪ Patients were satisfied with treatment and care received	**Staff** ▪ Patients were satisfied with treatment and care received ▪ Patients had empathy for working lives of staff

Differences in experience of endoscopy services over time ▪ General perception that there had been no change in experience since a previous endoscopy	**Differences in experience of endoscopy services over time** ▪ General perception that there had been no change in experience since a previous endoscopy ▪ However, where better reasons – quicker appointments, more modern units, better appointment making systems
Suggestions for improvement ▪ Two-thirds made suggestions for improvement including more information in advance of procedure and the need for shorter waiting times	**Suggestions for improvement** ▪ One third made suggestions for improvements to services including need for shorter waiting times, improved communication and another person present when being told results after sedation

7.2 Aims

The main aim of the interviews was to clarify how patients perceived the accessibility and acceptability of the innovations in service delivery and organisation in endoscopy units that were being evaluated in this study.

7.3 Objectives

a) To understand patients' experiences of innovations in terms of their satisfaction with endoscopy services, in particular their experience of the referral process;
b) To describe differences between Intervention and Control sites;
c) To capture patient experience over time, at two stages during the study, as innovations impacted on service delivery;
d) To clarify whether patients' views of current endoscopy services tell us more about the successes and failures of innovations.

7.4 Method

Telephone interviews were undertaken with patients from the second wave of patient recruitment which started in November 2004 and with patients from the fifth wave of recruitment which started in April 2006 (hereafter referred to as first and second round interviews). Patients were given the opportunity to indicate whether or not they wished to be interviewed by ticking a box in the Baseline Questionnaire (BQ) completed when consenting to take part in the study, and had the opportunity to amend this whilst completing a Post Procedure Questionnaire (PPQ) soon after their endoscopy. Issues concerning ethics, consent and selection of study sites, are detailed in chapter 2.

It was decided that for the first round interviews two patients would be interviewed per site, from the 18 sites recruiting patients. More patient views on the differences in experience of endoscopy over time were required from second round interview patients, so interviews specifically sought out these patients (see Figures 26 and 27).

The aim of this aspect of the study was to interview patients as soon as possible after their endoscopy to encourage an easier recall. To ensure the views of recruited patients could be ascertained, whose waiting time for an endoscopy varied from less than two weeks to many months, one patient referred as an 'urgent' case and one referred as a 'non-urgent' case, from each site, were interviewed (see Figures 26 and 27).

7.4.1 Telephone interviews

Telephone interviews were selected as the most appropriate method of data collection. It is recognised that telephone interviews have advantages and disadvantages. Advantages include reduced interviewer effects, better uniformity in delivery, greater standardisation of questions, researcher safety, greater cost-efficiency and fast results (Shuy 2002). Limitations to telephone interviews include difficulties in contacting people as a result of call screening, answer phones and ex-directory numbers. To some extent this can be overcome by the use of a computer randomly selecting telephone numbers (Bryman 2004) but is not appropriate when targeting a specific sample. To overcome this, a letter can be sent to potential interviewees asking them to make the initial contact. However, this was not an issue in this study as the researchers had access to the majority of patient telephone numbers. There are also the difficulties of respondents with hearing impairment, and evidence that telephone interviews may be shorter and less effective when asking about sensitive issues (Bryman 2004). However, as the sample of patients to be interviewed was geographically dispersed, telephone interviews were seen as the method of choice. They could take place at a time convenient to the patient and did not involve the patient in additional travel. They also saved researcher travel time and ensured a wide population view (Platt 2002).

7.4.2 Interview schedule

At a Project Steering Group (PSG) meeting prior to the interviews, it was agreed that as interviews were to take place over the telephone they should be brief and focused. Each interview should consist of between four and six questions and should last approximately 20 minutes and no longer than 30 minutes.

The interview schedule was semi-structured in design (Bryman 2004). It was understood that as the ENIGMA study was recruiting patients newly referred for endoscopy, many patients would be unaware of issues such as 'new models, innovations, novel systems or nurse substitution'. It was therefore agreed that the questions had to be simple and an interview schedule was produced to elicit responses from patients on their experience of the referral process (see Appendix 13 for detail).

7.4.3 Pilot study

A pilot study (Janesick 1998) was conducted using the patients recruited from the pilot study described in chapter 2. Three patients recruited into the pilot study were randomly selected and interviewed. The transcripts were circulated to the PSG. Following feedback and discussion it was agreed that the interview schedule was providing data in keeping with the project aims and objectives. It was decided that no changes to the interview schedule were necessary although it was acknowledged that patients would have a limited knowledge of changes that might be taking place.

7.4.4 Sampling strategy and recruitment

Once all 100 patient recruitment packs for wave 2 (round one interview cohort) had been sent out by a hospital and the reminder process had been completed, two lists were created for patients returning the BQ, for each hospital – one list of urgent referrals, one of non-urgent referrals, using the degree of urgency (DOU) designated on the study register. The two lists would capture the views of patients who were seen within a matter of weeks of their referral (urgent) and those who might have waited for many months to have their endoscopy (non-urgent).

Exclusion criteria were applied to the list:

- all patients not wishing to be interviewed according to the BQ or PPQ
- patients with no retrievable telephone number.

The same strategy was followed for patients from wave 5 (round two interview cohort).

The lists were exported into the SPSS V13 (Lead Technologies, USA) computerised statistics package. For wave 2, five random numbers were selected from each urgent and each non-urgent list, per hospital. For wave 5 no random selection took place but the lists were reordered randomly. The researchers contacted patients in the order in which they presented on the list.

Once the patient's procedure date had passed, the researchers attempted to contact the first patient on the list by telephone to arrange a date and time to interview. If no contact was made, the researchers made two more telephone attempts on different days, at different times. Voice messages were left where possible. If there was no response to the voice message by the next day, the researchers tried ringing again.

If no contact was made, a letter was posted to the patient asking whether they would like to take part in the interview and asking them for a convenient day and time for a phone call. At the bottom of the letter was a return slip for them to complete and return in a FREEPOST envelope. The researcher's phone number was also printed on the letter to answer any queries.

If no contact was received within a week of sending the letter, the researchers moved on to the next patient on the list.

Figure 26. First round interview patient sampling strategy

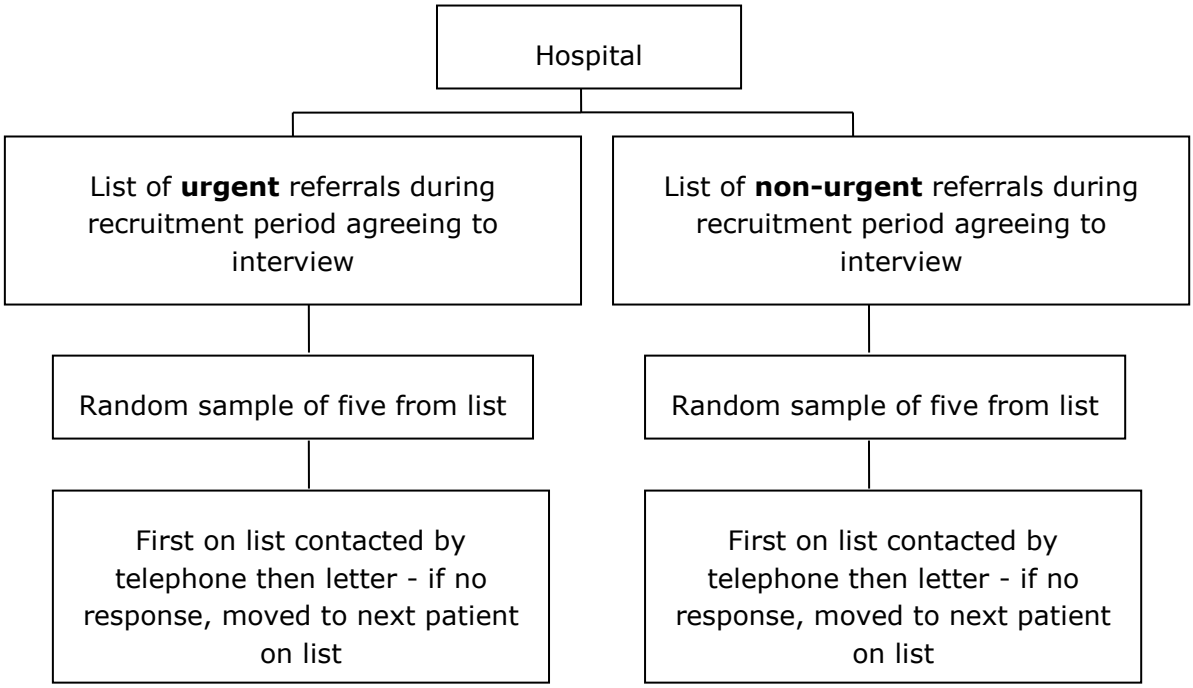
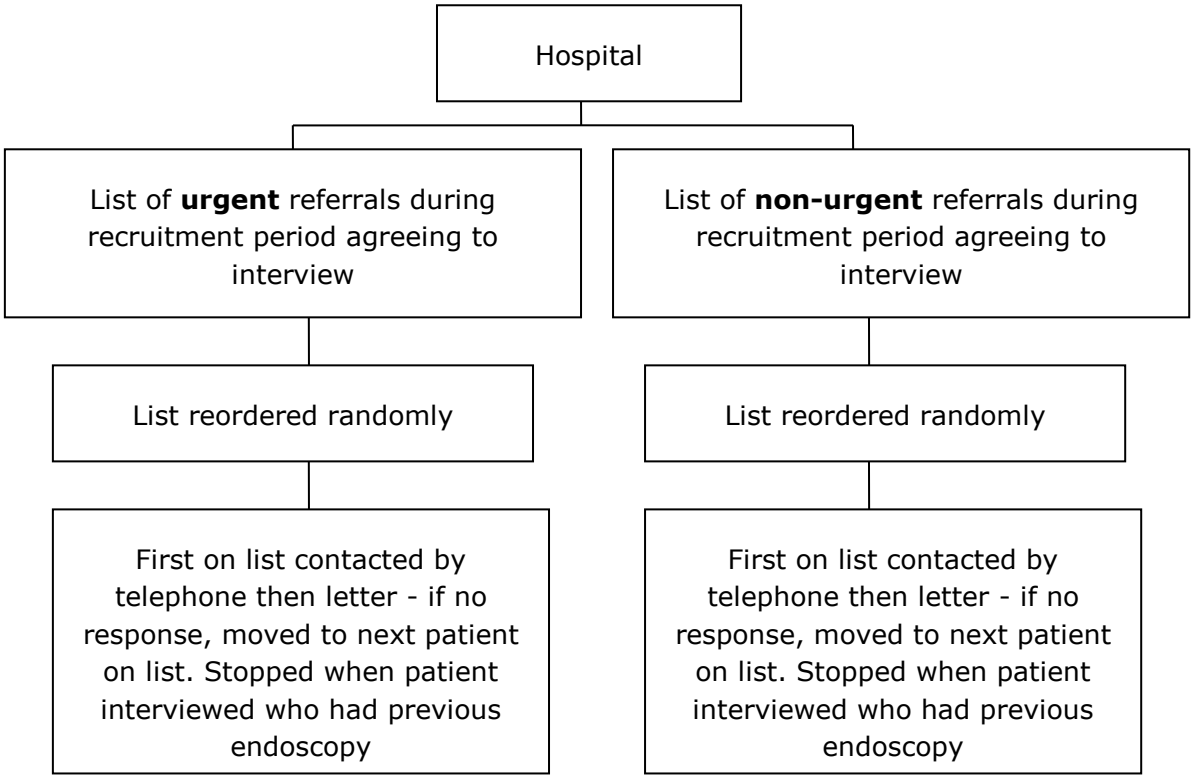


Figure 27. Second round patient sampling strategy



7.5 Data collection and analysis

First round interviews

Thirty six first round interviews were planned with patients (one urgent referral and one non-urgent referral from each site) from the 18 sites recruiting patients. At two hospitals, no patients who had been referred as 'urgent' had indicated on their BQ that they would take part in an interview. At one hospital the only patient referred as 'non-urgent' who had indicated that they would take part in an interview could not be contacted and did not respond to a letter inviting them to take part. There were no other patients referred as 'non-urgent' who had indicated they would take part in an interview. During two interviews it was discovered that the patients were having repeat surveillance colonoscopies so they were not included in the analysis. It was possible to replace only one of these as there were no other appropriate referrals. A total of 32 interviews were conducted that were suitable for analysis (see Table 57).

Table 57. Number of second wave interviews

36	Interviews planned
-2	no urgent referrals agreeing to take part
-1	discovered to be repeat surveillance so excluded
-2	discovered to be repeat surveillance so excluded
+1	Only possible to replace one surveillance-no other appropriate referrals
=32	interviews for analysis

Second round interviews

In the first round interviews 50% of patients were found to have had a previous endoscopy. As a result the second round interviews sought the views of patients who had had a previous endoscopy to clarify the differences in experience over time. In order to do this, interviews were conducted until one patient who was an urgent referral and one who was a non-urgent referral from each site were interviewed and if any of these patients had had previous endoscopies no further interviews with patients from these sites were pursued. At sites where the first patient interviewed had not had a previous endoscopy, further interviews were conducted until a patient was interviewed who fell into this category. Consequently, a total of 103 interviews were conducted. In keeping with the first round interviews, the first interview from each site, urgent and non-urgent, was included in the analysis. Where a first interview patient had not had a previous endoscopy, the first interview conducted with a patient who had had a previous endoscopy was included in the analysis. Table 58 shows that 11 of the first interviews (numbers in italics/red) included patients who had had a previous endoscopy. A blank indicated that either where no patients in that category agreed to take part in an interview or where patients could not be contacted or replaced by another patient. To make sure we conducted a thorough analysis of telephone interviews with patients, we analysed over half of the total interviews conducted (n=61), in qualitative terms a large body of data for analysis purposes, to ensure that we would be able to account for all the major themes arising. Of the 61 interviews, 26 were with patients who had had a previous endoscopy.

The interviews were conducted by the same two researchers as for the first round. All interviews were conducted by telephone and recorded by the

researchers on an interview template. Patients were asked for their permission to record the interviews before they began; no patients refused. The interviews were transcribed by the Project Secretary soon after completion and the transcripts were reviewed independently by the two researchers.

Data were analysed using content analysis. This method enables the reduction of qualitative data to manageable portions of text that can be analysed by searching for patterns and themes in the data as well as incongruities between different participants' views (Patton 2002). The researchers read the transcripts and developed a coding system. The transcripts were then read again to ensure complete coding of the data. The coding system was also used to count the number of instances that reportage adhered to each category (Silverman 2001). This process established the following emergent themes: waiting for an endoscopy, information provision, staff, differences in experience of endoscopy services over time and suggestions for improvement.

While conducting the interviews and undertaking the analysis, it was clear that very similar themes were emerging. It was therefore decided to write up the findings from the first and second rounds of interviews as one piece.

Table 58. Patients (ID numbers) included in analysis of second round interviews

	1st interview			Previous endoscopy	
Site	Urgent	Non-urgent		Urgent	Non-urgent
1	1402	1446		-	1413
2	2411	*2455*		2426	*2455*
3	3421	3474		3402	3405
4	4478	*4481*		-	*4481*
5	5414	5411		5478	-
6	6407	6421		-	6433
7	*7480*	7462		*7480*	7492
8	8457	8404		-	8429
9	-	9414		-	-
10	Withdrawn from patient recruitment				
11	11459	11470		11428	11477
12	12429	12444		12459	-
13	*13455*	*13448*		*13455*	*13448*
14	*14492*	14489		*14492*	14486
15	*15468*	*15452*		*15468*	*15452*
16	*16446*	16466		*16446*	16403
17	17465	17479		17420	17430
18	Withdrawn from study				
19	19432	*19404*		-	*19404*
20	*20410*	20435		*20410*	-

7.6 Findings first and second round interviews

Results will be presented under the following five headings in keeping with the five themes that emerged from the data:

1. Waiting for an endoscopy
2. Information provision

3. Staff
4. Differences in experience of endoscopy services over time
5. Suggestions for improvement

A detailed examination of the themes follows a description of differences between Intervention and Control sites.

7.7 Differences between Intervention and Control sites

First round interviews

To ensure that the patient sample in both groups (Intervention and Control) was not significantly different, descriptive statistics were performed which showed no significant difference in age, gender, DOU or procedure type.

In spite of the patient sample being defined according to urgent and non-urgent cases, differences between these two groups were not apparent in these data in terms of responses to the questions, except in relation to waiting times.

At the time of the interviews the researchers did not know what the sites were doing with regard to modernising their referral processes.

Patients were unaware whether they fell into an Intervention or Control site group and there were no detectable differences in the responses of patients between Intervention and Control sites.

Analysis of the data from the patient interviews shows no differences between Intervention and Control sites and this demonstrates that, from a patient perspective, the MES programme appeared to be having no detectable impact.

Second round interviews

To ensure that the patient sample in both groups (Intervention and Control) was not significantly different, descriptive statistics were performed which showed no significant difference in age, gender, DOU or procedure type.

To check for differences between the groups of patients interviewed in round one and round two, descriptive statistics were performed. There was no significant difference in gender, DOU or procedure type. However, second round interview patients were significantly older than first round interview patients (first round = 53y, second round = 64y, $p=0.03$).

As in the first round, patients were unaware whether they fell into an Intervention or Control site group and there were no detectable differences in the responses of patients between Intervention and Control sites.

In spite of the patient sample being defined according to urgent and non-urgent cases, differences between these two groups were not apparent in these data in terms of responses to the questions.

In the second round there were fewer patients expressing a desire for quicker waiting times and more expressing surprise at the speed with which

they had their endoscopy. There were also less suggestions for improvements from patients. However, whilst second round patients are less likely to have wanted their procedure done sooner, this could be related to demographic differences between the two rounds of interviews rather than an improvement in services between the two study time points.

Summary

Analysis of the data from the second round patient interviews (April 2006) shows no detectable differences between Intervention and Control sites in terms of, for example, information provision, satisfaction with treatment, service provision, and this demonstrates that, from a patient perspective, the MES programme appeared to be having no detectable impact. However, across Intervention and Control sites patients appear to be getting their procedures more quickly than when the first round of interviews were reported (summer 2005) and it could be said that, because fewer patients are making suggestions for improvement, the delivery and organisation of endoscopy services is improving. This suggests that while there are no detectable differences between the Intervention and Control sites as a result of the MES programme, the fact that sites are modernising their services does seem to be having some positive impact on patient views. However, this could be related to demographic differences rather than an improvement in services, as there was a significant difference in patients' ages between first and second round patient interviews.

7.8 Examination of findings in detail

7.8.1 Theme 1 – Waiting for an endoscopy

The patients being interviewed were drawn from two types of referral – urgent and non-urgent. Urgent referrals are seen within a matter of weeks whereas the non-urgent referrals can be on a waiting list for many months before their procedure.

First round interviews

The patients interviewed from Intervention and Control sites who fell within the urgent referral group, thought the speed at which they were seen was better than expected:

> *I was impressed, I was expecting something like 6 months, something like that, and then all of a sudden the letter came through and it was about 3-4 weeks from seeing her to the actual appointment so that was quite, I was impressed. (1166)*

The remaining patients were referred as non-urgent cases and many of them anticipated having to wait some time for their endoscopy because they were being referred to hospital and a wait was expected:

> *Obviously having to wait 3 months, something like that, when you've got an indigestion problem is a little bit frustrating but you just accept that as part of the thing , you know. (3150)*

> *Yes obviously everybody's going to say any wait is too long but you, you know, on the other hand you appreciate that there is going to be a wait and 3 months is far better than 6 months or 9 months. (3150)*

However, two-thirds of the non-urgent group (split evenly between Intervention and Control sites), actually felt that the speed of access to their endoscopy appointment was good - in one case eight months was considered a speedy referral:

> Patient -*Good points – quick, thorough.*
> Researcher – *when you say quick – you have waited a total of 8 months and you think that's OK?*
> Patient – *For around here, that's quick. (2132)*

In spite of having to wait for an endoscopy, a couple of patients were simply relieved that their symptoms were being investigated:

> *I felt better knowing that I had been referred because then you think well if things don't get better, I know…. (7111)*

Just four (two Intervention/two Control site) of the 32 interviewees felt they had waited too long (one of these had their appointment expedited by their General Practitioner (GP)). A couple of patients expressed surprise at getting an appointment sooner than expected, one being offered a cancellation while phoning to find out where he was on the waiting list. While patients accepted having to wait, a quarter of patients did express the view that a shorter wait would have been preferable:

> *Well we all want it a bit shorter don't we? It's not possible … tend to want it the next day don't you which is not possible, not unless you are paying. (5103)*

A few commented on the fact that they understood there were other patients with symptoms that should take priority:

> *"…it was a long wait but because I was OK, more or less, and I know that there are an awful lot of people who need endoscopies for serious problems". (4153)*

Four patients felt that their GPs had not referred them quickly enough in the first place, but once referred, were satisfied with the length of time they had to wait for their endoscopy.

Second round interviews

The majority of the 23 patients from Intervention and Control sites who fell within the urgent referral group, were satisfied at the speed with which they were seen:

> *I didn't have to wait very long at all. Well you know you hear of such long waits in some areas and I mean I'm 81 years old, I didn't expect such treatment quite so soon. (17465)*

Of the patients referred as non-urgent cases, two-thirds were satisfied at the length of time they had to wait and were quite understanding: *the NHS, they are having problems I know so I'm afraid there are waits for everything (7462).*

Of the nine patients (six Intervention/three Control site) who felt they had waited too long, just one fell into the urgent referral group. The main issue for these patients was that while waiting for an appointment they were experiencing pain:

> *I had been in a lot of discomfort for a long, long time and I'd waited a long time to get the appointment to see the doctor and then sort of having to wait again it just seemed to last forever really – quite annoyed, a bit upset, because as I say I was in so much discomfort that I just wanted it over and done with. (4481)*

Many patients (both urgent and non-urgent) expressed surprise at getting their appointment sooner than expected:

> *I'd been told I'd be waiting about three months but I certainly didn't have to wait three months. I was quite impressed. (20435)*

> *I was quite surprised how quick it was …well because most people seem to wait ages for their appointment. (12459)*

Summary – Waiting for an endoscopy

First round interviews

The patients were drawn from two lists – urgent and non-urgent referrals to capture the views of patients who are seen within weeks of their referral for endoscopy and those who wait for many months for their procedure. The patients referred as urgent were satisfied with the time they had to wait for their procedure. The majority of patients, referred as non-urgent, anticipated having to wait some time for their test but accepted this and some were pleasantly surprised when the wait was less than expected. While many patients accepted waiting for their procedure, the suggestions for improvement were often connected with speeding up the time from referral to procedure.

Second round interviews

The majority of patients referred as urgent and non-urgent cases thought the waiting time for the procedure was better than expected and many patients were surprised at how quickly they were seen. While talking about the length of wait, few patients said they would have liked to have been seen sooner.

7.8.2 Theme 2 – Information provision

First round interviews

Fourteen (six Intervention and eight Control site) of the 32 interviewees felt they had enough information given to them prior to their endoscopy and ten patients thought the information was of a high quality standard:

> *A really good self-explanatory leaflet. (16129)*

> *I had very good information from the hospital. Their letter part was very good. It did explain quite a bit of it actually. (7119)*

> *I was given all the information I wanted and then I was told to ask questions before they did it if I didn't understand anything. (6129)*

Just one patient said they had received no information, while two felt the information provided was not sufficient:

> *I wasn't given any information about what was going to happen to me at that particular referral. They just sort of said to me I'm going to refer you to have a camera put down and have a look and see what is going on and see if they can find anything from that. That was all I knew, I didn't know anything about how it was done or anything, that was all I sort of knew. (1166)*

> *No not really [enough information] (9103)*

> *I can't remember. I remember I received a few packages, like one must have been quite close at the time because it contained the details about an enema. … We didn't seem to have enough details about where to actually go which was a bit of a problem, so there weren't any specific directions either to the hospital or specifically what part of the hospital we had to go to apart from on the address it said … (20116)*

Seven patients said they would have liked more information. Of these, five (two Intervention and three Control site) would have liked more information before the procedure, with two specifically mentioning they would have liked more information about sedation options and one suggesting it would have been helpful to have been given links to websites about the procedure. One patient would have liked more condition-specific information having been given a diagnosis and another would have liked the opportunity to see the doctor who performed the procedure after it was done:

> *After the endoscopy I would have liked more information but the doctor doing the endoscopy doesn't have time to see patients afterwards does he. I would have liked to have known, I 'd have liked him to say to me what the staff nurse said. I'd like him to have said to me personally I've seen something there so I'm going to take a biopsy just to make sure everything's OK. I didn't see anyone else who'd had it done asking for information. (4153)*

The majority of patients had been contacted by letter with three contacted by telephone. When asked if they were offered a choice of appointment, just five said yes and 24 said no. However, half went on to say that if the appointment was not convenient they had instructions to contact the unit to arrange an alternative:

> *No, just that date and if you can't make it please telephone them and make another appointment. (7119)*

Three patients linked appointments to employment issues. One self-employed patient commented on how it was easy to attend any appointment he was given, whereas another said being given a choice of appointments was important. The third patient commented on the problems caused in her workplace when the hospital altered the appointment:

> *My only difficulty is that I work in a job where it is very difficult to take time off … so if a date was changed it made it slightly tricky for me in terms of arranging time off work. (17172)*

Second round interviews

Thirty-nine (19 Intervention/20 Control site) of the 50 interviewees felt they had enough information given to them before the endoscopy with the majority considering that the information was of a good standard:

> *I think it was acceptable. You were given as much information as you need. (7462)*

> *You couldn't ask for anything more, plus you've got phone numbers so if you've got any queries you just phone up. (2455)*

> *That was excellent, I knew exactly what to expect. (17479)*

Just two patients (one Intervention/one Control) said they had received no information, while three (two Intervention/one Control) would have preferred more information:

> *I would have liked a bit more information I think, you know a bit more detail … I could have been told more, I feel myself, you know rather than … you know all that I was told was that they would put a camera down and that was it sort of thing, you know. (1413)*

Two patients pointed out that the information did not indicate the possibility of a long wait on the day of the endoscopy although one of these understood that this was because the unit had to see inpatients:

> *Because they do inpatients from within the hospital as well as the outpatients and of course when you haven't had anything to eat or drink all that time and I mean it's not the patients fault and it's not the hospital's fault… (14489)*

Just over half of the patient interviewee group had been contacted by letter to make an appointment, 13 had been contacted by telephone and three had made appointments directly from clinic. The latter system was appreciated for its efficiency and a patient able to make an appointment by telephone praised the facility:

> *The new thing is where you have to phone up and make your own appointments so that you keep them. It fitted in for when I wanted it – with four children it's a lot easier you see. (16466)*

There was some criticism from one patient who had previous experience of endoscopy who felt *"it's a bit long winded now. It's a bit messy to what it was before" (8429)* because of the amount of letters sent from the hospital about just one appointment.

When asked if they were offered a choice of appointment 25 said yes and 10 indicated no; for the remainder it had not been an issue as they were able to keep the first appointment offered.

Summary – Information provision

First round interviews

The fact that most patients felt that the information given to them before the procedure was sufficient, is highlighted by less than a quarter of patients expressing a desire to have had more information before the procedure.

Patients were satisfied with being given an appointment date and time as long as there was the opportunity to change it if it was not convenient.

Second round interviews

Once again, the majority of patients felt the information provided before the procedure was sufficient, with only three patients stating that they would have preferred more information. However, it was suggested that the information should indicate the possibility of a long wait once in the endoscopy unit. The ability to book an appointment directly with the unit was appreciated, as was the flexibility of changing appointments. However, the booking system that results in several letters going to and fro, was criticised.

7.8.3 Theme 3 – Staff

First round interviews

Many patients from both Intervention and Control sites spoke about the care, sensitivity and efficiency with which they had been treated:

> *I can't fault the hospital, the staff the treatment, anything really. It's all, as far as I'm concerned, they've really dealt with me brilliantly. (17136)*

> *It was all done very efficiently and the staff were very kind and considerate. I was amazed really. (6190)*

Very few patients had negative comments about the staff or units, however, one patient said she felt staff were rude and she was made to feel like a hypochondriac because comments about 'getting a hernia or bad back' were made by staff about handling her very large set of notes:

> *The nurse there said 'oh what a lot of notes, I'll do my back in lifting these', just jokingly and I didn't say nothing but I do feel as if they are insensitive sometimes about a patient's notes. I can't help having that amount of notes, I can't help being born with a birth defect. (5156)*

Another (from the same Control site as the patient above) found the hospital staff unprofessional and did not know who people were or what role they played:

> *I didn't really understand the situation or who these people were because I've never seen them before. They were either dressed in black or navy blue, I'm not sure what. What role they played there, I*

> *have no idea at all. They seemed very unprofessional to me, both in their behaviour and their speech. I don't know why they were or why there were there. … very unprofessional sounding interview – I was steadily losing confidence… until by the end of it I was full of indecision as to whether I should proceed or not. (5103)*
>
> *From all my dealings with consultants, I don't think they are very good at talking to patients and that's a general thing. (16121)*

Unsatisfactory circumstances on the day of the procedure were described by one patient:

> *There was a hell of a lot of waiting and there weren't enough chairs for everybody so there were a lot of people who were quite stressed about it all and we were all sort of hanging about in the corridor. (12101)*

One patient (16129) spoke about her feelings at being seen on a Saturday. She had queried the appointment with the hospital but had been told that she had to be seen within 11 weeks and as 11 weeks had almost passed, it had to be on a Saturday. She had excellent treatment but felt dreadful, as she was the only one there with a doctor and two nurses.

Second round interviews

As in the first round interviews, patients spoke about compassion and care from staff and the efficiency with which they were treated:

> *Apart from there was a wait I was treated exceptionally well, I couldn't fault any of them at all. I couldn't have had better treatment had I been the Queen of England. (7462)*
>
> *It was nice having somebody on my left hand, someone was telling me what was going on and all the rest of it. (3421)*

Apart from a couple of comments relating to how the actual procedure had been undertaken and about there being too many administrators, there were no direct criticisms of staff. Even when there were criticisms about waiting times or the fact that a hospital appeared dirty, these were quickly followed up by how good the nurses and doctors were:

> *I was disappointed in the condition of the hospital and particularly the ward where I was situated. I thought it was antiquated. I actually thought it was quite dirty. Apart from that I thought the staff were very good and I can't complain, I mean everything went well. (3474)*

Indeed there was a degree of sympathy for the staff working in difficult times:

> *In the circumstances and the fraught existence they have and the cut down of staff, I think they are marvellous. I do care about the nurses and doctors and I think they have a very hard time. (13448)*

Summary – Staff

First round interviews

The majority of patients felt that the treatment and care they received was good with very few negative comments about staff or treatment. Where there were concerns, they were about the insensitivity of staff to personal feelings and the physical surroundings and one patient was concerned at being seen at a weekend.

Second round interviews

As in the first round, many patients spoke about the good care and treatment they received. There were no negative comments about staff, rather empathy for them working in what were considered difficult times in the National Health Service (NHS).

7.8.4 Theme 4 – Differences in experience of endoscopy services over time

First round interviews

Just under half of the patients (seven from Intervention sites, seven from Control sites) had had previous endoscopies but some were many years ago and could not be recalled. However, six patients (five of these from Intervention sites) felt there was no difference in their experience since previous endoscopies, while five (three of these from Control sites) felt the most recent procedure was better. One suggested this was because, having gone through the experience before, they were less stressed:

> *Well I think it was better this time but I really don't know if that's because I'd done it before and I sort of knew what was going to happen. (9115)*

> *The other patient (from a Control site) wondered if it was because the person performing the endoscopy, a Nurse Endoscopist, was better than the doctor who performed the previous one (9103):*

> *I don't know if things have come on or if it was that the woman that did it was better than the doctor or person who did it in … I had a Nurse Endoscopist who did it … and actually it was the nurse who was better than the doctor. (9103)*

Second round interviews

When the first round interviews were conducted it was found that half of the patients interviewed had had previous endoscopies. It was therefore decided to interview second round patients until one urgent and one non-urgent referral from each site who had had a previous endoscopy were found, where possible. This resulted in a total of 26 patients interviewed who had experience of a previous endoscopy. Some patients found it difficult to accurately recall details, which might reflect the brevity of an endoscopy procedure in terms of a patient's overall care pathway. However, half of the group (split evenly between Intervention and Control sites) felt there was no difference in their experience since previous endoscopies, while just under a half (split evenly between Intervention and Control sites) felt the most recent procedure was better for a variety of reasons. These included being seen quicker than previously, more modern units, improvements in making appointments, more information given about what was going to happen on

the day and the time spent in the unit on the day was thought to be quicker:

> *The process probably was a lot quicker this time because I was surprised to have got an appointment so quickly so I'm guessing that from past experiences I thought 'oh that's a lot quicker' so the process must have got a lot quicker. (11428)*

> *Tremendous changes because when I went the first time they were actually reconstructing the whole of the area so they now have a very nice suite. (2426)*

> *It's been a lot quicker than when I first had it done a few years ago, you know a sort of quicker procedure rather than having to wait in the waiting rooms for sort of an hour on the day. (1413)*

> *I do think that hospitals are different now, I do think they tell you more and discuss things more. I don't think that everything in hospitals is better but I think the information that you are given when you go for this sort of thing is better. They tell you more. As I say, I don't always want to know so sometimes I'd rather not, but you do have access to exactly what they are going to do and what the results will be and all that sort of thing at the time. (12459)*

However, two patients (one Intervention/one Control) felt that their most recent experience was worse than their previous one, with one commenting on having to wait longer and the other disliking the appointment system where the hospital send letters at different stages:

> *I mean it was just easy before. You went to see your doctor and they arranged an appointment to see the specialist and you went to the specialist. There was no letter flowing backwards and forwards. (8429)*

Summary – Differences in experience of endoscopy services over time

First round interviews

Of the 14 patients who had had an endoscopy in the past and could recall the experience, six felt there was no difference in their experience while five felt that their recent experience was better but, interestingly, one of these, from a Control site, commented on the possible reason for this being that the procedure was performed by a NE. The mix of patients from Intervention and Control sites responding in this way, highlights the lack of detectable difference in patient responses.

Second round interviews

Of the 26 patients who had had an endoscopy in the past and could recall their experience, half felt there was no difference in their experience while just under half felt that their recent experience was better for a variety of reasons such as quicker appointments, more modern units and better appointment making systems. As in the first round, the mix of patients from Intervention and Control sites highlights the lack of detectable difference in patient responses.

7.8.5 Theme 5 – Suggestions for improvement

First round interviews

When asked for suggestions for improving the referral process, many patients found it difficult to think of any and 11 of the 32 patients, from both Intervention and Control sites, were satisfied and had no suggestions. However, two-thirds of patients made the following suggestions (number in brackets indicates the number of patients making the suggestion):

- waiting time should be less (6)
- more information before procedure (5)
- more information after procedure (2)
- GP should refer sooner (2)
- hospital should contact patient soon after referral (1)
- there should be a choice of dates (1)
- opportunity to discuss with specialist first (2)
- cut out outpatient appointment to reduce waiting times (1)
- more hospital staff (1)
- hospital should try not to alter dates (1)
- should be referred to hospital with shortest waiting list (1)
- follow up appointment with consultant too long (1)

Second round interviews

As in the first round, many patients found it difficult to think of any suggestions for improvement and 35 of the 50 patients had no suggestions. However, just under a third of patients made the following suggestions (number in brackets indicates the number of patients making the suggestion):

- waiting time should be less (5)
- communication, before and on the day, could be improved (2)
- another person should be present when being told results after sedation (2)
- should be given realistic view of waiting time to procedure (1)
- appointment by telephone better than too many letters to and fro (1)
- honesty about what found (1)
- would like results on day (1)
- clearer instructions on who to contact about problems after the procedure and when (1)
- administration of follow up inefficient (1)

Summary – Suggestions for improvement

First round interviews

When asked for suggestions for improving the referral process, many patients found it difficult to think of any and a third of patients spoke about their satisfaction and had no suggestions. Two-thirds of patients made suggestions which most often related to a reduced waiting time and desire for more information in advance of a procedure.

Second round interviews

Many patients found it difficult to think of suggestions and interestingly only just over a third of patients made suggestions the majority of which related to a shorter waiting time, improved communication before and after the procedure and a desire to have another person present when being told results having had sedation.

8 Professional views at study sites

8.1 Executive summary

As part of the evaluation, interviews were undertaken with clinicians and key people, based in the 10 Intervention sites and 10 Control sites that had played a role in modernising units. Two rounds of interviews took place. The first between May and October 2004, concentrated on the two years since 2002, to cover the period of the MES programme. The second follow up interviews took place two years later. To enable an understanding of the impact of the MES programme the interviews aimed to capture the views of clinicians and key people on innovations in service organisation and provision, clarifying their perceptions of the accessibility and acceptability of the innovations, and exploring how each unit functioned to consider what innovations had been made or were planned.

Interviews were recorded and lasted between half an hour and one and a half hours, most being approximately one hour. A total of 39 first round interviews (one site withdrew before the Key Person could be interviewed) and 38 second round interviews were conducted and analysed using thematic content analysis (Bowling 2002; Robson 2002; van Manen 1990).

Three key themes emerged: **Drivers for change, the human dimension of endoscopy units and financial resources**.

As this study was evaluating the MES programme, the research team looked for differences between Intervention and Control sites. It was found that the majority of all sites were actively modernising their units and that while Intervention sites achieved this more quickly, Control sites had also, or were shortly to, modernise. The MES programme appears to have been a catalyst for change rather than an arbiter of change and for those actively taking part, it resulted in timelier implementation of modernisation.

8.1.1 Theme 1 – Drivers for change

First round interviews

The NHSMA was seen as a catalyst for change and units had benefited from involvement in the MES programme but there was overwhelming criticism of the Toolkit™ training and the Toolkit™ itself, reflected by the fact that no Intervention sites continued with its use after the year of obligatory data collection. However, units had benefited from data collection in assessing and understanding their service and data had supported business cases and many Intervention and Control sites were continuing with some form of data collection.

Second round interviews

The Global Rating Scale (GRS) and NHS Bowel Cancer Screening Programme (NBCSP) have taken over from the NHSMA/MES programme in terms of the way people think about modernisation in their units. These initiatives have

been welcomed because they have raised the profile of endoscopy services with Trusts and made their work more visible. Interviewees focused on quality aspects of endoscopy, however, it was difficult to say if the focus resulted from awareness of the needs of patients or from politically and managerially driven targets that had to be met and, as a consequence, that led to patient benefits almost by default.

8.1.2 Theme 2 – The human dimension of endoscopy units

First round interviews

The majority of interviewees responded positively to the plans for modernising endoscopy units but recognised that they faced particular challenges regarded the sharing of services and equipment across different specialties. Change to the autonomy of doctors was described as one of the major hurdles to overcome in influencing their views on the NHSMA. Interviewees noted the importance of leadership in the unit and a lack of clear leadership roles affected all unit staff. They also discussed the complexities of: working relationships, morale, teamwork, communication, resistance to change, training, staffing levels and skill mix, all of which were perceived as both facilitators and barriers to modernisation. Where barriers existed, such as low morale and lack of training for staff, efforts were being made to overcome them.

Second round interviews

In the first round of interviews working relationships and staff morale were clearly problematic and an important issue, discussed at great length. This was clearly different in round two, where participants moved on to other topics but spoke about the benefits of staff working in new ways. There were ongoing tensions raised between physicians and surgeons across a range of issues: scoping each other's patients, personal autonomy, the significance of endoscopy, attendance at meetings and pressures of new referral systems, however, it was acknowledged that working relationships were improving. More appropriate skill-mix had been achieved as a result of more staff training and greater flexibility in staff roles. However, the issue of low staffing levels and the need for increased training and skilling was mentioned alongside the need for an appropriate number of staff to fulfil the demands of units. The process of modernisation has brought resolution to some of the issues raised in the first round. People are less averse to the notion of change and have adopted a mindset of modernisation as a result of their involvement in the MES programme, its impact on all sites, both Intervention and Control, and are, therefore, less resistant to change.

8.1.3 Theme 3 – Financial resources

First round interviews

Some modernisation was considered to be cost-neutral whereas other changes to services were not pursued as a result of insufficient funding. Units are creative and inventive in their search for funding but Trusts (many in financial deficit) are criticised for crisis management and short term funding. As a consequence, there is an 'ad hoc' approach to modernisation among endoscopy staff and Trusts. However, many endoscopy units have been successful in obtaining funding, albeit short term, and found that data

collected in endoscopy units supported business cases, which made a significant difference to obtaining funding.

Second round interviews

As in the first round, financial resources are seen as an ongoing concern and the situation is said to have deteriorated in the previous two years. There is recognition that a certain amount can be achieved through motivated staff and innovative ideas but frustration arises over the limitations to further development because of financial constraints and there are concerns about the way endoscopy will be funded in the future. There is a recognition that some money has been spent on, for example, equipment and more appropriately skilled staff, however continuing lack of appropriate staffing levels impacts on appropriate use of these new resources. GRS and NBCSP are said to provide useful leverage in gaining additional resources.

The extensive data sets, accessibility to views and range of views from senior consultants and key people across units in both rounds of interviews suggests that the study achieved a valid cohort, providing reliable data, representative of the views of people working in the endoscopy units.

8.1.4 Major issues arising from the interviews

Table 59. Major issues arising from first and second round interviews

ROUND ONE	ROUN
Theme 1 – Drivers for Change **NHSMA/NHSMA Funding** • The NHSMA was a catalyst for change but the changes introduced could not have been predicted at the outset; • MES programme funding was a short term solution, but by its very nature, lacked continuity; • MES programme staff lacked practical endoscopy experience and therefore credibility; **Training** • The MES programme training was offered too early by ill prepared teachers; **Toolkit**™ • The MES programme Toolkit™ was strongly disliked but had led to changes as a result of the opportunities it initiated in developing understanding of unit need; • No Intervention sites continued using Toolkit™ after year of obligatory data collection; • Data collection was acknowledged as necessary to understand services and was an important aspect in support of business cases and other unit initiatives; • In-house data collection was ongoing in many Intervention and Control sites.	**Theme 1 – Drivers for Change** **Progression from NHSMA/MES** **Cancer Screening** • The Endoscopy GRS (GRS) ha programme; • Prior experience of modernisa Control sites) enabled units to • In spite of the additional work was not compulsory, all sites • With its link to Bowel Cancer S units and Trusts both aspire t successful then the MES progr endoscopy; • GRS is considered a good tool improvements and of quality was considered useful for shar • Difficulty in assessing if patie 'quality agenda' or if they be achieve high GRS scores. **The impact of Government init** • Eighteen week referral to trea on diagnostics e.g. endoscopy • Two week wait target has imp patients who are waiting long

ROUND ONE	ROU
Theme 2 – Human Dimension of Endoscopy Units **Staff** **Working relationships & staff morale** • ***Tensions*** between different specialties sharing endoscopy units, led to **poor working relationships**; • Isolated cases of ***poor working relationships*** within endoscopy units; • ***Poor morale*** due to lack of communication, lack of ownership of changes, lack of involvement in running of units and staff under pressure feeling undervalued; **Resistance to change** • ***Consultants***, in particular **surgeons**, were considered the group ***most likely to resist change*** in working practices; **Overcoming poor working relationships, poor morale and resistance** • ***Good communication with all staff and growing sense of staff ownership*** was achieved through redesign days, time out sessions and meetings, helping overcome poor working relationships, poor morale and resistance; • Ongoing ***resistance to change was further challenged*** through persuasion, patience and training; • ***Leadership*** of change was significant in overcoming problems; • Greater clarity is evident over control and leadership of units; • Key people responsible for leading change benefited from clinical lead support;	**Theme 2 – Human Dimension** **Staff** **Working relationships & staff** • ***Tensions*** between different have decreased with ***improv*** between physicians and surg • ***Staff respond positively*** to supportive and co-operative ways of working; **Resistance to change** • less ***resistance*** from **surge** • Isolated reports of ***physician*** lists resulting from concerns impact of '2 week wait target **Overcoming poor working rela** **resistance** • ***Improvements*** in units that relationships and morale • ***Strong leadership***, staff inv communication are importan

The ENIGMA study

Training • ***Training*** helped update staff and ensured appropriate skill mix to improve efficiency and flexibility of units (Nurse Endoscopists (NE) and nurse specialists); **Skill mix/staffing levels** • Training aids ***appropriate skill mix***; • ***Insufficient staffing***, particularly shortages of endoscopy nurses and clerical staff, hindered change. • Good clerical support for endoscopy units was vitally important; **Patients** • The aim of modernisation was to improve *access* to, and *experience of endoscopy services for patients*;	**Training** • ***High quality training*** is a re staff and time and sparse fin • Increase in ***training of non*** • Staff helping other units to m **Skill mix/staffing levels** • ***Achieving an appropriate s*** lack of staff and time and spa this; • ***Staffing levels are accepta*** enable further improvements **Patients** • Greater commitment to *patie* • *Access to, and acceptability o* improved with shorter waitin patient information, more res better communication betwe

ROUND ONE	ROU
Theme 3 - Financial Resources An issue of concern	**Theme 3 - Financial Resource** An issue of concern
• ***Insufficient financial resources*** for sustained change;	• Frustration of striving to impro • ***Lack of resources*** impacts o technology and facilities; • ***Financial situation has dete*** to the financial crisis of Trusts
• Trusts were criticised for adhering to ***crisis management*** tactics and ***short term funding*** instead of investing in future; • The units' search for funding highlighted the ***'ad-hoc' nature*** with which modernisation was taking place with no clear development plan.	• ***Forward planning has been*** payment by results and the in in primary care or the indepen
• Some processes were recognised as cost neutral whilst others required substantial funding;	• Some success in getting fundi leverage tools in achieving ad

Type in bold italics indicates links within the theme between the issues in the two rounds.

8.2 Aims

The main aim of the interviews was to clarify how professionals perceived the accessibility and acceptability of innovations in service delivery and organisation in endoscopy units that were being evaluated in this study.

8.3 Objectives

a) To describe differences between Intervention and Control sites
b) To clarify how the endoscopy units functioned prior to modernisation
c) To describe new models of service delivery and organisation and their impact
d) To describe professionals' experience of introducing the new models

8.4 Method

Between May 2004 and October 2004, 39 semi-structured interviews were conducted with 'clinicians' and 'key people' in endoscopy units taking part in the ENIGMA study. The ENIGMA study team were aware that the units were at different stages of modernisation and the interviews were held early in the study to clarify how each unit functioned and what innovations had been made or were planned and from this to develop an understanding of the impact of the MES programme. The interviews concentrated on events over the previous two years, i.e. since 2002, to cover the period of the MES programme. The interviews also aimed to capture the views of clinicians and key people on innovation in service organisation and provision. A second round of interviews was conducted two years later, between July and November 2006, with the same clinicians and key people (where possible) to clarify what had taken place in the intervening two years and capture changes in the perceptions of participants.

8.4.1 Interview schedule first round interviews

The interview schedule was semi-structured in design (Bryman 2004) comprising key questions that were asked of the clinicians and key people at both Intervention and Control sites (see Appendices 14-15 for detail).

The key questions were developed in line with the study aims, and were fine-tuned following preliminary visits to endoscopy units, meetings among team members and the PSG. In addition, the interview schedule was clarified through a pilot study (see below) and areas covered included the:

- endoscopy unit prior to modernisation;
- innovation/change introduced or planned;
- problems implementing innovation/change;
- source of funding for innovation/change;
- staff response to innovation/change.

8.4.2 Pilot study

A pilot study (Janesick 1998) was conducted in April 2004. One consultant and one Key Person at two hospitals not taking part in the study were interviewed as well as a Key Person from a Control site who was unavailable for the main study. The transcripts from these three interviews were

circulated among PSG members. Following feedback and discussion it was agreed that the interview schedule was providing data in keeping with the project aims and objectives. However, certain aspects of the schedule were refined and two questions were added – one an opening question to establish the role of the interviewee and another, which examined the impact of the Modernisation Agency and the Toolkit™ on Units. Consequently, the final interview schedule for the first round of interviews (found in Appendix 14) covered the following areas:

- the role of the interviewee in modernisation;
- the endoscopy unit prior to modernisation;
- innovation introduced or planned;
- problems implementing innovation;
- the funding required for innovation;
- staff response to innovation;
- the impact of the Modernisation Agency and the Toolkit™.

8.4.3 Interview schedule second round interviews

The interview schedule for the second round of interviews (found in Appendix 15) generally followed the same schedule as for round one. However, participants were not asked again about the endoscopy unit prior to modernisation and they were not asked a direct question about the NHSMA/MES programme. In round two, they were asked what changes had taken place in the intervening two years. Their views were sought on the accessibility and acceptability to patients of the endoscopy service as a result of any changes that had been made.

8.4.4 Sampling strategy

Purposive sampling which allows the selection of information-rich cases to enable the in-depth study of the topic of interest (Patton 2002; Robson 2002), was used to select the clinicians and key people to be interviewed at the ten Intervention and ten Control sites. The sampling strategy used to select the ten Intervention and ten Control sites, together with issues of ethics and consent, are detailed in chapter 2. The clinicians at the Intervention and Control sites were those who had been involved in the application for the MES programme, so were easily identifiable. 'Key people' were less easily identifiable. In Intervention sites they were those people who had been in contact with the NHSMA, but since then some had changed posts and where unavailable, the advice of the clinician was sought for the most appropriate person. In certain Control sites no single person was clearly identified and, again, the clinician's advice was sought for the most appropriate person to interview. It was decided by PSG members that, if necessary, a third person could be interviewed in order to collect as much rich, in-depth data as possible. The second round of interviews were to be conducted by the same researcher as first round interviews with the same clinicians and key people.

8.5 Data collection and analysis

The first round interviews were conducted by two researchers between May and October 2004 - eight in May, 13 in June, 13 in July, four in August and one in October. Interviews were recorded and transcribed by the Project

Secretary soon after completion and transcripts were reviewed by two researchers and the qualitative lead.

Four interviews were selected at random (two clinicians and two key people, one each from Intervention and Control site) to be read independently by four people (a Professor, a qualitative specialist and the two researchers) and, using thematic content analysis (Patton 2002), these data were considered in terms of 'first level' emergent themes (May 1998). Group discussion led to broad agreement that emergent categories concerned: people, the organisation within which innovation was taking place, the political climate, funding, NHSMA, Toolkit™ and outputs (sustainability, continuity, vision). Themes were considered during the process of data collection and analysis in terms of their ability to throw light on the issues hindering or supporting innovation. Two researchers revisited the four interviews and an additional six interviews were analysed and themes were refined to include: people, NHSMA/MES programme and financial resources. The two researchers coded a total of ten interviews each and following consensus, one coded the remaining interviews. The qualitative lead confirmed data saturation when no new themes or categories were emerging and group agreement over interview data suggested validity and reliability had been achieved in the analysis process. In addition, data regarding endoscopy unit function prior to modernisation and innovation taking place were used to triangulate health economics data (see chapter 6).

The second round interviews were conducted by one researcher between July and October 2006 (four in July, twenty-six in August, two in September, four in October, two in November). Interviews were recorded and transcribed by the Project Secretary soon after completion and transcripts were reviewed by the researcher and the qualitative lead. Analysis was conducted using thematic content analysis, as outlined above.

The findings section (below) includes verbatim quotations, anonymised and presented in terms of an identifier number and line number. Thus, it is possible to identify quotes from 'clinicians' as .1, for example, 17.1/20, and quotes from 'key people' as .2, for example, 17.2/30.

8.6 Findings: First round of interviews

Three major themes emerged from the data: 'Drivers for Change', 'The Human Dimension of Endoscopy Units' and 'Financial Resources':

- Drivers for Change
  - NHSMA Funding
  - Training
  - Toolkit™
- The Human Dimension of Endoscopy Units
  - Staff
- Working relationships and staff morale
- Resistance to change
- Overcoming poor working relationships, poor morale and resistance
- Training
- Skill mix/staffing levels
  - Patients
- Financial Resources
  - An issue of concern

A detailed examination of themes and categories from the first round of interviews follows a description of differences between Intervention and Control sites and their responses to modernisation which enables an understanding of the impact of the MES programme. A detailed examination of themes and categories from the second round of interviews starts on page 238.

8.6.1 Differences between Intervention and Control sites and their responses to modernisation

As mentioned above, the study team were aware that, at the time of the first interviews, the units were at different stages of modernisation and this became obvious in the interviews.

Six Intervention sites indicated that modernisation had commenced in their units before the MES programme, while modernisation in the remaining four seemed more in line with the timing of the MES programme (see Table 59). Of these ten sites it was perceived that all had made good progress in modernising their units but that two had some outstanding issues such as one unit experiencing ongoing problems with working relationships between consultants and their lack of involvement in the endoscopy unit, while the other had reached a point where further modernisation was restricted because of a lack of space.

The Control sites were at more varied points within the modernisation process; two sites indicated that modernisation had commenced before the MES programme, three sites had made a lot of changes over the previous two years and one had made some changes (see Table 60). This latter site was limited by space but was due to move to a new unit. The remaining four Control sites were still considered to be at the start of the modernisation process but three of these were moving to new units and of these, two described detailed plans for new ways of working. Of the ten Control sites, five were perceived as having made good progress and one Control site that was very limited by resources (financial and structural), with no new unit planned, was perceived by interviewees to be a long way behind in the modernisation process.

Table 60. Stage in the modernisation process at time of first interview

	Stage in modernisation process at time of interview				Overall progress at time of interview		
	Sites started modern-isation before MES programme	**Sites modern-ised in previous 2 years**	**Sites with some modern -isation**	**Sites at start of modern-isation**	**Good progress**	**Issues to be resolved**	**Modern -isation yet to start**
Intervention	4 7 8 11 13 18	1 6 16 19			1 4 6 7 8 13 16 19	11 18	
Control	3 9	12 17 20	5	2 10 14 15	3 9 12 17 20	5	2 10 14 15
	Number = site identification number						

The fact that all of the Intervention sites had made a lot of changes in comparison to half of the Control sites, could be interpreted as being a direct result of the MES programme. However, there should be caution with this interpretation as many of the Intervention sites had already started modernising prior to the MES programme, while just two Control sites were in this position. This raises issues about the selection of sites by the NHSMA and the impact of this on the ENIGMA sampling strategy. It is possible that the NHSMA were biased in their selection, preferring sites that had already shown the ability to modernise. The criteria to take part in the MES programme included the ability to complete three months' data collection and to submit an appropriate action plan. However, the sites that had already started modernisation may have been more likely to fulfil these criteria and more likely, as a result, to be accepted by the NHSMA programme, rather than the NHSMA itself being biased in their selection. The NHSMA stated that they 'went for those teams that we felt would benefit from the funding and improve their service'. It is difficult to judge from this whether they selected sites that, while able to meet the criteria, had poor services and therefore could improve, or sites that met the criteria and had a reasonable service, but could benefit further; this detail was not known by the ENIGMA study team. ENIGMA sampled the ten Intervention sites from the twenty-six selected by the NHSMA to take part in the MES programme and was therefore subject to the effects of the NHSMA selection and it is possible that strong sites were over-represented. As a result of these issues, it is difficult to be absolutely clear whether the fact that Intervention sites have made a lot of changes in comparison to the Control sites, is directly due to the MES programme or whether the Intervention sites were always going to be stronger.

The research team perception is that the majority of Control sites were pursuing modernisation but were lagging behind the Intervention sites for the following possible reasons:

- Control sites had no obligation to adhere to the tight deadlines of the MES programme;
- Control sites did not necessarily have the benefit of a specific person appointed to oversee the modernisation process;
- the lack of financial support, albeit a relatively small amount, from the NHSMA, meant Control sites were less likely to employ additional staff to help with data collection. (Data collection will be shown below to be important in understanding the way a unit works and identifying problems);
- Control site data collection was less efficient in the early stages of modernisation so identification of the way a unit works and its problems may have taken longer;
- financial resources acquired by Control sites were earmarked for specific use, in comparison to the MES programme funding which could be used flexibly;
- the absence of backing from an NHSMA project could result in a lower profile of modernisation efforts at more senior levels within the unit and the Trust resulting in less support in terms of resources and encouragement from senior staff;
- Control sites moving to new units had modernisation plans in place to implement after the move;
- most Control sites started modernising at a later date, so to some extent were always 'catching up'.

All the sites in this study had applied to take part in the MES programme indicating that from the outset they had an interest in modernising their units and it was found that the majority of all sites were actively modernising their units and that while Intervention sites achieved this more quickly, Control sites had also, or were shortly to, modernise. The MES programme appears to have been a catalyst for change but for those taking part, it resulted in timelier implementation of modernisation.

Apart from the differences in the stages of modernisation in the units, there were no other detectable differences between Intervention and Control sites as the same issues arose when participants spoke about the modernisation of their units.

8.7 Findings in detail – First round of interviews

8.7.1 Theme 1 – Drivers for change

Introduction

A major theme to emerge from the data concerned Drivers for Change. The issues that emerged in relation to this theme are examined below.

Ten of the endoscopy units were part of the MES programme (Intervention sites) and had to use a "Toolkit™" for data collection and analysis so the majority of comments were from clinicians and key people in those sites. The Toolkit™ was a computer-based management tool to record demand, capacity, Activity and waiting list data, produce tables and graphical reports from this information and help analyse capacity and demand information. The tool collated and manipulated information at the request of the user. The remaining ten sites (Control sites) had access to the Toolkit™ and

training and also expressed views about it. The issues that emerged about the MES programme centred on funding, training, the Toolkit™ and the project in general.

NHSMA

There were mixed views about the NHSMA in general, with some people questioning if the motivation behind the NHSMA was political. However, the majority of interviewees felt that the concept was sound and as there was an acknowledgement that changes were necessary within the NHS, suggested the NHSMA had acted as a catalyst for change providing necessary tools, techniques and organisational skills:

> *I think it was a good concept and I think it has certainly enabled the NHS to look at change in a different light and through involvement in projects. (16.2/290) (16=site ID, .2=Key Person, 290=line number)*

> *If it hadn't been for the MA and the spread of some of the tools and techniques such as capacity and demand study and process mapping, it's because of those things that we've been able to better understand our service … I think it has been a very positive influence on the way in which the NHS works. (12.2/425)*

There were, however, criticisms levelled at the scale of change – that it was just not large enough to make a significant difference – and there were criticisms about the credibility of the NHSMA and it was felt that staff lacked practical experience of endoscopy units:

> *To staff on the whole, talking across the board here, it's the suit category, if you know what I mean, people talking about change who've not actually done the job. The fact that they live in, seen as living in their ivory towers, without actually listening the other way round. (13.2/207)*

NHSMA Funding

The funding provided by the NHSMA appears to have played an important role in the modernisation in four Intervention sites who highlighted that the MES programme and funding had identified the areas for modernisation, without which, they would not have proceeded. However, six units would have pursued modernisation irrespective of the MES programme but would have had to source funding from elsewhere for changes that carried cost implications:

> *"…lot of them were natural progression anyway. … most of the things were in our plans anyway to do. We've always been quite forward thinking really". (4.2/181)*

> *No, because we wouldn't have had the information to be able to help us pinpoint the problems and help us make decisions about where the problem was or identify the problem. (16.2/244)*

The sites that were unsuccessful in their bid to be part of the MES programme were disappointed not to receive funding from the NHSMA having demonstrated a willingness to change. However, this was combined with a determination to push ahead with modernisation:

> *Oh well, we'll just get on and do it anyway (9.2/593)*
>
> *There is no point in crying about it. Part of me belligerently would take the attitude of s** you, we'll do it without you. (10.1/518)*

The NHSMA funding enabled Intervention sites to employ staff, including a project manager, Information Technology and clerical staff, to help with the additional workload, particularly the Toolkit™ data collection and maintenance. In addition, funding had been used to employ receptionists, nursing auxiliaries and staff to wash scopes. In most instances, Trusts agreed to fund these posts for a further year once the NHSMA funding ceased. However, there was frustration over the lack of continuity when the project manager post was discontinued, as there was no one to follow up on what had been started. In some units the funding was used to run additional lists to decrease waiting lists, to validate waiting lists and reduce Did Not Attend (DNA) and cancellation rates. Some equipment was purchased and the funding was also used for minor refurbishments, often to reception or office space, areas that do not attract funding easily. The funding had also been used to cover travel and subsistence for attending NHSMA events.

Some of the changes that had been introduced were considered to be cost-neutral as they had been achieved through the modernisation of processes within existing resources, for example, pooling of lists, validation of waiting lists:

> *"… a lot of it didn't need to be funded it was just a different way of working. … it is changing the way that you work really in some respects rather than more staff." (6.2/824)*

However, there were three clinicians who felt that 'change' always carried cost implications.

Training

As part of the MES programme, the NHSMA ran training events focussing on the Toolkit™ and on practical methods to improve services. This training was open to staff from Intervention and Control sites and while some key people from the latter attended, it was, in the main, key people from Intervention sites.

The training in the practical methods to improve services was considered satisfactory but highlighted the fact that sites were at different points in their modernisation. Some units found they were quite advanced in what they were doing and felt they had little to learn from the training sessions, the discovery of which gave them confidence:

> *"… we were quite far advanced from a lot of other areas so we were going along and listening to sort of projects that were going on in other Trusts that we were already carrying out here. So it wasn't really applicable to us" (8.2/565)*

However, the training in practical methods to improve services was satisfactory and, together with regional 'buddy groups', was seen as a networking opportunity to exchange ideas, leaflets and information.

> *"…nice to see what other Trusts had done both with and without funding and where they are going. You can sort of benchmark a bit,*

how you've gone and things like that and get lots of ideas from other Trusts as well. It's nice to share information" (9.2/437)

There was overwhelming criticism of the Toolkit™ training, with many interviewees feeling it was introduced too early and that the trainers were ill-prepared:

The people delivering the training obviously hadn't any chance to work the systems themselves because they were sort of showing us, there was no written guidance. (8.2/558)

It was implemented very badly, it was implemented before it was ready, before it was technically ready, there was no training provided. I went to a training day and I walked out it was so bad. It was like a scene from The Office. (19.2/707)

Toolkit™

All the Intervention sites had to use the MES programme Toolkit™ for data collection and analysis and while only two Control sites used it, several had considered it and expressed views about it. The data collection itself caused problems initially because of the additional work involved in manual data collection - *"the amount of work that went into it was horrendous (8.2/499)"* - but sites had found ways of overcoming these difficulties. Some had designed forms to make the data collection easier and some had employed or freed up staff to help with data collection.

Interviewees' comments regarding the Toolkit™ were overwhelmingly negative, and this was reflected by the fact that at the end of the year of obligatory data collection for the NHSMA, none of the Intervention sites continued to use the Toolkit™. Indeed, the Toolkit™ presented users with problems from the time it was transferred to a web-based system from the Excel computer software used in the pilot phase of the MES programme.

The Toolkit™ was fine when it was Excel-based but the web-based was a nightmare and I don't think it was actually reasonable to introduce something new part way through a project when it hasn't been properly trialled, endless problems. (11.1/664)

The Toolkit™ was not considered 'user friendly', used unhelpful technical language and management jargon and technical problems were experienced, resulting in several units requesting assistance from the NHSMA or Trust Information Technology (IT) staff to help them understand how to use it:

"… major problems with the Toolkit™. Major technical problems which I know have been a national problem. It was horrendous. But we got past that because we had this performance analyst who was brilliant and she worked with the IT people who run the Toolkit™ to get round some of the problems." (19.2/616)

There were also concerns that the Toolkit™ did not accurately reflect the true level of work and the data did not meet the organisational needs of units, as it could not be manipulated locally:

I felt it was negatively weighted such that you could never perform anywhere near your capacity which is misleading. (18.1/113)

> *Once the data was put in you could only get back a presentation in a manner that the Toolkit™ wished to give you it. You can't get back to your raw data and re-manipulate it. So all of that work, once it's gone centrally is essentially lost. (4.1/363)*

There were also issues about the reliability of the data: *"You can look at one sheet and you put in two and the graph will be showing six" (16.2/336)* and the fact that, on occasion, data were lost while being downloaded to the NHSMA:

> *They would spend two days downloading all the information and then it would all get lost. It was heart rending, sometimes the staff were in tears so it wasn't all easy going. (4.2/325)*

The pressures of the amount of work and time involved with data collection and maintenance of the Toolkit™ were compounded by the NHSMA deadlines:

> *There was always pressure on, they were always ringing them up saying 'we must have your report by this date'. (4.2/322)*

However, the deadlines proved useful for some, keeping them on schedule and acting as a reminder of what needed to be done:

> *"…I would think I haven't done anything about that, right OK, and we would do something about it. So it was quite a good prompt. It kind of put it back on the agenda. That was useful." (6.2/954)*

In contrast, being free from the strictures of the MES programme was appreciated within some of the Control sites:

> *"… to be honest it has been better because we haven't had to use the Toolkit™ and we haven't had to report like the other sites have. In some way that is probably, from my perspective, I feel we have benefited lots not being a pilot site in some ways." (17.2/395)*

The collection of data was a central tenet of the MES programme and it is clear that this was seen as a way forward by Control sites as, while only two used the Toolkit™, the majority developed their own system of data collection, selecting the most relevant data to collect. Several of the Intervention sites also developed their own data collection systems alongside the Toolkit™:

> *We had our own Toolkit™, or our own capacity and demand data which was in line with our true capacity. (18.1/450)*

In spite of the difficulties associated with the data collection there was a very positive response by those implementing modernisation to the data that resulted from the Toolkit™ and the in-house data collected. Firstly, the data had allowed units to assess their service, see exactly how it was working, understand it better and introduce changes where necessary and had demonstrated differences resulting from the changes that had been made:

> *"… had the information to be able to help us pinpoint the problems and help us make decisions about where the problem was or identify the problems." (16.2/244)*

Secondly, the data proved helpful in making business cases as it was hard evidence to back up cases for both Intervention and Control sites and in the case of Intervention sites, it also carried the weight of the NHSMA:

> *It is fair to say that without really good data it would have been much more difficult to make that case, so it has been a tool to back up the case for more staff, nursing time, Nurse Endoscopists and most important in the last year, a new consultant. (4.1/207)*

Having found the data useful, Intervention sites were likely to continue some form of data collection, but using an in-house system:

> *We have abandoned the endoscopy Toolkit™… We developed our own Excel spreadsheet so we could look at patient journey time which the endoscopy Toolkit™ was never designed to collect and that is what we are maintaining. (16.2/318)*

Interestingly, one Control site planned to continue using the Toolkit™ as "it is part of the way of life really" (2.2/415) and another Control site, that had developed an in-house detailed data collection method, was continuing with high level data collection. Other Control sites planned to continue data collection as and when they felt it was required:

> *Reactive data collection rather than continuous. (20.1/556)*

While acknowledging the issues with training and the Toolkit™, the general perception was that involvement with the MES programme had benefited units and raised their profile within their Trusts, in part, due to the fact that evidence could be provided to support business cases which in turn led Trusts to understand that if they required data from the units, it was readily available. Within the units it led to a better understanding of exactly how the unit worked and consequently had introduced more efficient ways of working. However, involvement in the project had a personal impact with people describing increased stress and pressure:

> *Personally, it added a good 5 hours to my work, my dining room became my office, my other half knows more about the project than me. (13.2/137)*

Summary – Drivers for change

While interviewees involved in the first round of qualitative interviews revealed mixed views about the success of the NHSMA's MES programme there was the overall sense that the units had benefited from involvement in the MES programme. Not only had the Project raised their profile within Trusts, it had acted as a catalyst for change to service provision and delivery. Where the MES programme was less well received, however, criticisms were directed at the scale of change, which was considered insufficient for any significant difference to be experienced in terms of service provision, and the lack of credibility afforded to MES programme staff, who did not have necessary practical experience of endoscopy.

The funding provided by the NHSMA was used to employ staff, to introduce new waiting list initiatives, to buy in new equipment and enable minor refurbishments to take place. This funding was also used for staff travel and subsistence to attend NHSMA events. Some of the staff employed collected data for the Project and while a number of these posts were funded by

Trusts for an additional year, the concern was raised that these roles would not be continued when funding ceased.

There were mixed views about the training provided by the NHSMA, in part due to the fact that different sites had different needs. The training in practical methods to improve services was satisfactory. However, there was overwhelming criticism of the Toolkit™ training, with interviewees keen to stress that ill-prepared trainers offered training far too early. Indeed, the reaction to the use of the Toolkit™ was particularly negative, reflected in the fact that none of the Intervention sites had continued with its use after the first year of obligatory data collection. The Toolkit™ was described as time consuming, not at all 'user friendly', full of technical problems and leading to too tight deadlines. In addition, it employed obtuse technical language and management jargon and did not meet organisational needs because it could not be manipulated locally. Finally, there were doubts about the reliability of the data it produced. This resulted in several Intervention sites developing their own systems of data collection alongside the Toolkit™. Interestingly, as a result of having used the Toolkit™, units had moved forward in their assessment and understanding of the service. The process had enabled units to support business cases, which had the knock-on effect of introducing appropriate change. This was emphasised by the majority of Control sites developing their own data collection systems and many Intervention and Control sites continuing with some form of data collection, be it of their own design.

8.7.2 Theme 2 – The human dimension of endoscopy units

Introduction

All staff involved in the endoscopy units – the consultants, nurses, administrators, managers and clerical staff, recognised the need to provide patients with high-quality care and support, with the expectation that modernisation would improve access to, and experience of, endoscopy services.

The interviews highlighted, however, that the units were at very different stages in the process of modernisation, some very much still at the planning stage, while others were advanced in their thinking and implementation of change. Nevertheless, all interviewees recognised there was still some way to go before implementation was fulfilled and still more to be done. This resulted in some interviewees speaking in anticipation of what would happen, while others spoke from experience. In spite of this difference in perspective, interviewees covered similar topic areas - working relationships and staff morale, resistance to change, training, skill mix and staffing levels, recognising in each case the potential for these aspects of staffing to hinder or support change.

Working relationships and staff morale

Historically, some units have been managed under more than one directorate, for example, surgery and medicine or medicine and radiology, and this has led to a lack of clarity as to exactly who has responsibility for control and leadership of units:

> *There was no ownership either, there was no leadership within the department from the clinicians … no pulling it all together." (6.2/103)*

> *There is no data stored in this trust for the way endoscopy has been practiced – I think it is just because it has never had a leader. (10.1/148)*

While, it was clear that all hospital departments face challenges when modernising their service delivery and organisation, endoscopy units faced additional challenges resulting from the facilities being used by a variety of specialties, often with different working practices and perspectives on change. Those responsible for implementing change have had to work with staff from a range of specialties and in a quarter of units, poor working relationships with these staff were highlighted:

> *It's not an endoscopy service, it is medical and surgical and so there is a big divide. (11.1/66)*

> *The big problem really was that I had to speak to 7 consultants. You can't just go through the 2 lead people because as you know with personalities, not everybody gets on with everybody… (6.2/122)*

There were also a limited number of examples of poor working relationships within disciplines in units, for example:

> *The nurses get assigned to a section, you know recovery or whichever room. If say a nurse was assigned to room 2 but they were stood by the telephone in recovery, they won't pick up the phone because they are not assigned to that area (15.2/421)*

There were also examples of tensions between nursing and clerical staff:

> *The nursing team feel that they don't cross react with the clerical team and vice versa … nurse could be sitting there doing nothing and the clerical staff have got jobs that they could do even if it is only sticking labels on a pack … needs one person directly controlling both things and saying if one hasn't got work-that isn't happening. (11.1/332)*

Poor working relationships and a lack of leadership could contribute to the development of poor morale among unit staff and in less than a quarter of units, poor morale was highlighted as being an issue of particular note at the beginning of the modernisation process, when trying to introduce change in endoscopy units. This stemmed from management problems within units, a lack of communication, ownership and involvement in how units were run, staff feeling under pressure and undervalued and a failure to recognise and reward staff at all levels. In some units it also stemmed from a lack of training and a sense that endoscopy had a low priority within Trusts:

> *We had a rather dysfunctional unit with poor performance in lots of ways and very unhappy staff … unhappiness with the management of the whole unit from the sister, lead clinician through to the manager. (16.1/12)*

> *The resource of the business that partial booking hit us … completely under resourced … hence a very high level now of time off, people*

> *feeling that they are under serious pressure in their day to day work and vast numbers of telephone calls. (4.1/269)*

Poor morale was sometimes reflected by high absenteeism:

> *It is too easy to take a day off for a headache or a cold which a lot of people won't even, even though it impacts on their colleagues who are here. I think absenteeism like that is a sign of poor morale. (11.1/419)*

At other times poor morale was reflected by a high turnover of staff:

> *For some reason a lot of units have high turnover and I guess a lot of that comes down to in a lot of places, overruns from lists, not getting away on time, family commitments, people work in endoscopy purely because of the 9-5 or whatever, they want to get away. (19.1/130)*

As mentioned above, poor working relationships and poor morale were issues raised by a quarter of the interviewees. However, half of the interviewees reported no problems of this nature. Indeed in these units, staff commented on the positive way in which change was accepted:

> *We are quite lucky because we have a lot of motivated staff who do embrace change rather than running away from it. (9.2/452)*

> *In terms of the endoscopy teams themselves you know most of them have taken it in their stride really and indeed there are levels of enthusiasm for improving the service which is a priority for all of us really. (2.1/530)*

Resistance to change

Clinicians and key people demonstrated an awareness of staff's resistance to change, even if they do not actually experience resistance themselves and they understood that poor working relationships and poor morale could contribute to resistance to change:

> *"… change per se is not a good thing and the majority of folk don't like it." (4.1/401)*

It was important to have all consultants 'on board' and this was seen as a big challenge as it was this group, and particularly surgeons, who were noted in approximately half of the interviews, to have demonstrated more resistance to change than nursing or clerical staff. They were resistant to changing their work practices, such as the way in which their patients and waiting lists were managed and resistant to changing list templates, as well as disliking work being monitored and their methods questioned:

> *I think engaging clinicians was probably the biggest challenge, to change practice. (19.2/567)*

> *Surgeons are, I'm sure they won't mind me saying, are recognised as an interesting group of people, they tend to have very strong opinions about things, like to do things the way they have always done them and changing surgical practice is difficult. (10.1/466)*

Clinicians and key people also mentioned some resistance to change from the nursing staff, but this was not perceived as a major problem and often related to specific issues, such as nurse consent and inpatient link nurses. There were very few direct comments relating to resistance to change from clerical staff with just one Key Person noting strong resistance in this direction.

Overcoming poor working relationships, poor morale and resistance

Identifying a named person to lead the change process was seen as significant in both achieving change and overcoming any problems that might arise. Clinicians leading change saw themselves as a *"front man to talk to various people" (10.1/383)*, someone to lead *"from the front showing what could be done" (16.1/50)* and as achieving change through *"perseverance and being a pain" (17.1/561)*. Where key people were responsible for leading change, they noted the importance of having a supportive clinical lead:

> *He is willing to listen and is very supportive and I get on OK with him and we have an arrangement, if I need something doing, it's all right, I have to do, it but he will support me if it goes wrong. (16.2/279)*

Ensuring good communication between all members of staff, staff involvement and staff ownership of the change process, were also seen as significant steps forward in overcoming poor working relationships, poor morale and resistance to change. Communication, both within endoscopy units and with other hospital departments, through redesign days, time out sessions and regular meetings, gave staff a sense of ownership and involvement over the changes taking place and ensured that everybody knew what was happening at all times:

> *From the start they were involved and all of the training that we had, we did mixed training sessions, so that health record staff were there with nursing staff and staff from admin, the nursing officers, the consultants, they were all mixed sessions so they weren't segregated and doing it on their own, they were mixed in with everybody else and then everybody knew what everybody else was going to be doing. (9.2/516)*

Meetings, such as Endoscopy User Groups' meeting, gave credibility to the plans for change and in six cases were said to raise the low profile of endoscopy units:

> *"I think the first obstacle was the low priority given to endoscopy … because there were no political targets attached to endoscopy … senior management level didn't really take it seriously because the senior managers were really concentrating on the national targets. But we addressed that by developing the GI Steering Group which was high level support." (19.2/559)*

When met with ongoing resistance, clinicians and key people described how they managed to gain acceptance of change or at least to reach a compromise by persevering through 'nagging', 'persuasion', and a lot of 'patience' and could illustrate problems by offering staff good quality information (such as evidence obtained through data collection):

> *One particular surgeon wanted to keep his own waiting list and that just took a lot of, I mean, it took a year to gradually wear him down. (20.1/354)*

Training was also a means of overcoming resistance to change as illustrated by the story of a booking clerk who was resistant to new methods but was eventually won over:

> *I've retrained the booking clerk. She had old ideas and didn't believe in the new changes. After lots of patience, she now realises what a major impact the changes have made. They've improved things tenfold. (7.2/79)*

The efforts made by clinicians and key people to overcome poor working relationships, poor morale and resistance to change by ensuring good communication and involvement in change was said to have had a number of positive outcomes. In just over a quarter of units' relationships among staff and team working practices had improved within both the units themselves and other departments in the hospital:

> *Whereas you previously tended to work a bit in isolation, there was a problem with retention and recruitment, now we have a very close integration with the ward, with exchanges and acquaints and that is going to increase because we have been successful in establishing a day case unit which is co-located with the ward, adjacent to the ward ... staffed both from endoscopy and the ward. (17.1/381)*

Furthermore, this had led to better working relationships for managers with both clinicians and endoscopy staff. While two clinicians expressed negative views about managers, in a number of units, clinicians spoke about the benefits of the process in terms of gaining a better understanding of the role of managers:

> *I feel it has brought me a lot closer to the management because I understand more of what goes on and I think when you begin to understand the whole funding management process you have a lot more sympathy for managers than you do if you don't understand these things. (10.1/569)*

> *"…if I have somebody go sick tomorrow who has got a list they all rally round and help me and I think they share responsibility for the unit whereas before they'd have just thought let the manager get on with it, it's her problem not ours." (6.2/664)*

Training

The majority of clinicians and key people recognised the training needs of staff in their units (doctors, nurses and clerical staff) and the importance of developing staff skills *"training is good for the employee and employer – it's investment in the future" (3.1/271)*, noting the lack of training prior to modernisation in some units which was attributed to lack of funding, lack of space and concerns over staffing levels:

> *Many of the staff had worked there for many years and had never had development opportunities. (19.2/101))*

However, there were units with clear training pathways such as training that enabled nursing staff to rotate between the various areas within endoscopy, thus allowing for greater flexibility;

> *We rotate nurses through different rooms so they become universally trained in all endoscopic procedures (18.1/385)*

Where appropriate, staff had been sent on external training courses, supplemented by in-house training. However, in-house training was mentioned as being potentially problematic when long patient waiting lists existed;

> *All our lists are totally full even when they have got somebody who is training which they should be half – you should reduce the lists. (6.2/603)*

Training was noted as essential in keeping staff up-to-date with the latest techniques, developing staff skills and ensuring an appropriate skill mix (see below). With an ever-increasing demand for more Endoscopists and growing demand for governance of units and good quality control, some units had appointed or planned to appoint a clinical lead with a specific remit on training. Where there was evidence of an ongoing lack of training, it was suggested that this was due to a lack of a dedicated budget, insufficient staffing and the pressures of full lists.

Skill mix and staffing levels

Linked with training is the skill mix of staff in endoscopy units and as part of modernisation, many units had reviewed staff roles to get the right skill mix at all levels in order to increase efficiency and flexibility. Prior to modernisation, nurses were carrying out many non-nursing duties, such as setting up equipment, washing scopes and arranging appointments, which the majority of interviewees deemed inappropriate. In these cases, interviewees felt the priority for nurses should be to be with patients. To facilitate this, units had attempted to employ staff such as endoscopy technicians and health care assistants to remove clerical duties from nurses:

> *"… nurses were doing a lot of non-nursing duties so one of the main issues was relieving nurses of these non-nursing problems. Through the project we have employed a person from HSDU to clean the scopes and we have employed a receptionist to help with the filing of notes before and after procedures, ring the wards confirming appointments, ring porters for the staff and all that sort of things, so that has been a big change." (1.2/47)*

Adapting the roles of nurses had clearly had an impact on working practices as evidenced by the fact that NEs were in post in all but two units. However, most NEs were trained to undertake upper GI procedures and, in preparation for the Government's plans for colorectal cancer (CRC) screening and the anticipated increase in demand for colonoscopy, many were also involved in on-going training to perform colonoscopy and flexible sigmoidoscopy. NEs were seen as the best way forward, always in the unit, not on-call or required to attend meetings and consequently available to cover cancelled lists and utilise otherwise wasted capacity:

> *One of the important aspects of the next stage of modernisation is to have our two Nurse Endoscopists working flexibly covering the lists*

> *that are cancelled so that you increase our outputs without increasing the number of staffed lists that you are actually performing. (20.1/505)*

The implementation of nurse specialists was also seen to have contributed to the flexibility of endoscopy units. Nurse specialists often take a particular interest in a specific aspect of the work of the unit such as screening for CRC, irritable bowel syndrome, feeding access, dyspepsia and some use protocols to determine appropriate follow up for patients who have had a biopsy:

> *Very successful in implementing specialist nurses within gastroenterology and they are a very key component to the smooth running both to the gastroenterology service overall but actually also impacting on organisation in matters endoscopic really. (2.1/252)*

Other examples of nurses taking on duties traditionally performed by doctors included: taking consent, performing cannulation, performing pH manometry and giving sedatives and antibiotics.

While nurses were clearly an essential part of endoscopy unit workings, there was recognition from both clinicians and key people of the important role played by clerical staff in the efficient running of a complex unit, and the responsibility of that role:

> *In terms of my opinion about what makes an effective endoscopy service, I think the clerical part of the service is as important as the clinical part. … one of my top ten tips would be – get your clerical service right. (12.2/175)*

However, it was felt that there was a lack of appreciation of just how much clerical support endoscopy units needed and that staff on low A&C grades were often performing jobs that were *"significantly more complex than they appear to be on paper" (4.1/324)*.

The problem of insufficient staff could hinder a unit's aims to achieve an appropriate skill mix and this was raised frequently by clinicians and key people, with a major concern being the inability to cover for cancelled lists, holidays or study leave because of a lack of Endoscopists:

> *It is also important to make sure that when people go on holiday there is not a huge void in endoscopy because there isn't anyone else to do it and that does rely both on nursing manpower, administrative manpower and medical or nurse specialist manpower as well and if we are going to improve the service it does cost money because it is salaries for experienced staff effectively. (14.1/522)*

In this respect, it was suggested that there were shortages in nursing and clerical staff rather than doctors and that while NEs were not always easy to recruit, the shortage of endoscopy nurses could impact on the work of units:

> *There are a number of slots that cannot be used, potentially they are available. But that has been hampered by lack of nursing staff, just numbers not being there to run it. (1.1/72)*

While more staff had been recruited, from consultants to nurses and clerical staff, few units were fully staffed, with some running on minimum staff. In some areas this was not solely due to lack of financial resources, but

resulted from local difficulties recruiting and retaining staff because of the high cost of living in the area and it was noted that as endoscopy units traditionally work a nine-to-five day, staff do not have the opportunity to boost their income by working 'out of hours' shifts. Where lack of staff related to lack of financial resources, there was frustration about the fact that some ideas for change could not be taken forward:

> *Funding is an issue, in particular health record staff. I think that unless you have sufficient administration staff to institute these changes to booking and the whole way that lists are administered, it is very hard to introduce change. (10.1/473)*

Patients

The patient and their well being was recognised as an important aspect of positive change in endoscopy units and modernisation of endoscopy services was aimed at improving access to, and experience of, endoscopy for patients. Clinicians and key people acknowledged that waiting times were unacceptable for patients and needed to be reduced to provide more timely access to endoscopy and that the actual experience of patients before, during and after their endoscopy could be improved:

> *Our sole focus is a better patient experience. We aim to reduce waiting times and improve quality. We need to speed up the management of the patient's clinical condition. We need to be more patient friendly. (7.1/122)*

There were efforts to improve the experience of both outpatients and inpatients. Some units had redesigned their patient information leaflets with the help of patients. They found that sending this information in advance of their procedure together with admission forms and consent forms, meant that patients were better informed and could complete the forms in their own time and in the comfort of their own home. Reducing the time a patient spent in a unit by sending information in advance and by better scheduling of appointments was considered advantageous, as patients are *"less anxious and irritable" (3.1/215)* and, as this clinician pointed out:

> *…it is important for the success of what we do, if the patients leave here feeling they have been well dealt with I think that is going to make a big difference to them and their other doctors in the future and looking after them, so I think that is very important. (3.1/235)*

Some units had wanted to improve the physical surroundings for patients and had made changes to reception areas, such as replacing carpets, which it was felt made a difference to patients when they arrived at a unit. However, there were concerns about the lack of privacy and dignity for patients *"sitting in open waiting areas wearing nothing, the breeze flying between their legs!" (2.1/351)* and the lack of a suitable place to speak to patients or take a patient history, acquire consent and explain results.

There were many examples of staff responding positively to plans for modernisation of their endoscopy unit, recognising that ultimately the patients would benefit:

> *Generally an excellent group of workers in the unit and they are well motivated and they are a very patient-centred group of nurses. They*

> *all set off to do whatever they can to improve the patient experience. (6.1/493)*
>
> *Our sole focus is a better patient experience. (7.1/122)*
>
> *We want to make the patients more comfortable and relaxed and enjoy the process as much as possible and that is very important. (3.1/232)*
>
> *If there is something that comes on board which is exciting or will make life better especially for patients then we will look at it. (11.2/131)*

Even in a unit with ongoing issues over morale and poor working relationships, the basic sense of wanting a better service for patients came through:

> *I think everyone who runs or is involved in an Endoscopy Unit want to provide a better quality of service. (15.1/27)*

Summary – The human dimension of endoscopy units

The aim of modernisation is to provide a better quality service for patients, that is to say, more timely access to endoscopy and improved experience before, during and after endoscopy while in the unit. The majority of the staff interviewed in the first round of interviews responded positively to the plans for modernising endoscopy units, in the knowledge that patients would benefit from the changes. This, in spite of the fact that little was reported on the manner in which services, would now be more patient-focused.

In the past, some units had been managed under more than one directorate, leading to a lack of clarity over the responsibility for the control and leadership of units. As a result of restructuring, units are now often managed under a single directorate and the issue of control and leadership of units has become clearer. However, issues of clear lines of accountability and leadership-through-example remain, exacerbated by the need for unit staff to share space, and rifts between surgeons and physicians.

As a result of shared facilities and spaces across specialties, a quarter of sites taking part in the study highlighted tensions between staff groups and poor working relationships. However, it should be stressed that working relationships within units are described in positive terms with only isolated cases of poor working relationships.

The negative impact of across-group tension is low staff morale, resulting in lack of communication among staff, a sense of lack of personal ownership and involvement in the running of units, and additional pressure on staff, leaving them feeling undervalued. This was noted within a quarter of units, particularly at the beginning of the modernisation process, while other units reported no experience of these signs and described staff as responding positively to modernisation with good morale. The remainder did not talk about these issues.

Poor working relationships, poor morale and resistance to change could be overcome through the development of better lines of communication between members of staff, staff involvement in the process of change and staff ownership of change. Enhancing lines of communication and group

involvement was supported by 'redesign days', time out sessions and regular meetings, which gave staff a greater sense of commitment by their units. In addition, these meetings gave credibility to the plans for change and raised the profile of endoscopy units.

Consultants, and in particular surgeons, were seen as the staffing group most likely to resist change in terms of working practices, others managing their patients and waiting lists and others attempting to monitor or question their work and methods of practice. Nevertheless clinicians and key people were working together to overcome resistance to change, employing a range of measures including compromise and negotiation tactics such as persuading staff to change, displaying patience with them and offering them additional training. Training ensured that staff were kept up-to-date with the latest techniques and helped develop their skills, however it was limited in terms of the scope it offered to ensure change, exacerbated by a lack of funding and lack of space, as well as the pressures of full lists.

Ensuring the right skill mix helped increase the efficiency and flexibility of units, achieved through the adaptation of the role of nurses with many units having NE and nurse specialists as well as ensuring that endoscopy nurses were free from any non-nursing duties. Of equal importance was the role played by clerical staff for the efficient running of what were seen to be complex units. However, achieving the right skill mix was often hindered by insufficient staff – most commonly endoscopy nurses and clerical staff rather than doctors or NEs – with few units fully staffed, which in turn led to the inability of units to cover cancelled lists, holidays or study leave.

In spite of all these difficulties, efforts were being made to improve working relations, enhance staff morale and overcome resistance to change. Indeed, it was in the very process of working towards improved working relations where the most promising outcomes were recognised – stronger collaborations among staff were being engendered, both within and outside of endoscopy units. This was particularly successful where units identified a 'Key Person' or clinician to lead the change process and in the case of the responsibility falling on a 'Key Person', that they then gained the support of the clinical lead.

8.7.3 Theme 3 – Financial resources

Introduction

The issue of financial resources was raised throughout the interviews by clinicians and key people in both Intervention and Control sites with the majority facing the challenge of insufficient resources. As one clinician put it:

> *Endoscopy is a black hole, you give us more money and we will spend it. (9.1/299)*

An issue of concern

There was acknowledgement that some modernisation initiatives do not require funding as they are based on redesigning work processes:

> *These changes have just been made with just tweaking the existing system. It is just looking at how we function and how we can improve it, cutting down duplication, cutting time down, wasting of*

> *time. We have had efficiency gains within the existing provision rather than new capacity. (1.1/254)*

However, as one clinician said: *"… one of the devils of the NHS is this nonsense that change has to be cost neutral, change is never cost neutral" (4.1/422)* and there was frustration and disappointment that further modernisation plans could not be pursued due to the lack of financial resources, a situation that was unlikely to change in the foreseeable future:

> *I think that is the thing that irritates us most of all, us clinicians, is that you join these things with good motivation, goodwill, and you start off accepting that there is no investment but we all hope that once we have shown that we have done A, B and C that there is some investment, some true investment at the end of it. (18.1/500)*

> *I think the sad thing is when you want to make a change and there is a financial implication and you just can't move it forward because of that. (14.2/384)*

Areas where more could be achieved but where funding was problematic, related to the need for additional staff, from clerical to consultant, and effective IT which was not available in all units. IT was seen as essential for the smooth running of an efficient unit and, in addition, equipment was often lacking, with many units struggling with old equipment, needing rolling replacement programmes. The funding of NEs was raised frequently in terms of the difficulty some units had in obtaining funding for the post which also had to take into account the support required to run additional lists with nursing support, equipment and space:

> *No funding of the modernisation changes seem to be straightforward … difficulty in funding has been on the clinical end where there has been an inability to understand the needs for more endoscopy staff and an inability to accept the justification for the Nurse Endoscopists that we were requesting. (20.1/374)*

The lack of financial resources led to an ongoing search for funding and an element of creativity and inventiveness was recognised:

> *"… you do sort of get some yourself don't you by being inventive and using what there is available." (9.2/571)*

> *We packaged it up, not saying we just needed more staff to do that, into a new package where we had nurse led surveillance. (17.1/184)*

In the search for funds it was an advantage to have a knowledge of the various sources of funding, such as charitable funds and cancer funds and the need to be able to cope with the frustrations of writing and submitting business cases and having to go out to tender for equipment.

However, obtaining funding was never a certainty and rather than being able to follow a clear development plan, modernisation initiatives appeared to happen on an 'ad hoc' basis:

> *We took the opportunity of having things on the shelf that you could put forward and just entire opportunism. (17.1/456)*

The fact that many Trusts are in financial deficit was seen to impact on funding for endoscopy units and Trusts were criticised for funding on a crisis

management basis, providing short term funding and not recognising the need to invest in the short term in order to gain in the long term:

> *The Trust is in a big financial deficit so it is very difficult. At the moment we are having great difficulty getting anything from them. (5.1/266)*

> *"… in a way you have to fail before money can be allocated … there are many conflicting an differing demands on cash so it's only when something becomes flagged up as an issue that could mean you loose one of your stars, that they suddenly allocate resources." (15.1/381)*

However, in spite of the ongoing problems with financial resources many Intervention and Control sites had been successful in obtaining funding, albeit short term, from various sources for additional staff including consultants, NEs, nurses, health technicians and administrative staff. There had also been some funding for equipment and to improve IT facilities although some units were still struggling with old systems. The data collected, either through the MES Toolkit™ or in-house versions in Control sites, had made a significant difference in getting funding approved as it had been used to support business cases by illustrating exactly what the issues were.

Summary – Financial resources

Trusts' financial deficits had impacted on the majority of endoscopy units who faced the challenge of insufficient resources and did not anticipate the situation changing in the foreseeable future. Trusts were criticised for crisis management, for providing short term funding and for not investing in the future.

Some modernisation was recognised as achievable at no additional cost, by redesigning work processes. Other aspects of modernisation such as extending the working day, expanding the NE service, having rolling replacement programmes for scopes, achieving effective IT systems and introducing one stop clinics, had not been pursued. This resulted from the funding implications of additional staff, effective information technology, new equipment and NEs. This led units to continue to search for funding from alternative sources such as charities and cancer funds, with an element of creativity and inventiveness necessary. As a consequence, rather than following a clearly developed plan this created an 'ad hoc' approach to modernisation.

In spite of these issues, many endoscopy units had been successful in obtaining funding, albeit short term, for additional staff, equipment and IT and data collected in endoscopy units had been used to support business cases put forward to Trusts which had made a significant difference in obtaining funding.

8.8 Findings: Second round of interviews

This section reports on the findings from the second round of interviews.

As described in the Method section on page 211 the aim was to conduct the second round of interviews with the same clinicians and key people as two years previous. One Intervention site had withdrawn form the study by the

time of the second interviews. Table 60 shows the breakdown of the roles of people interviewed and shows that all but one of the clinicians were the same. An SpR was nominated by a clinician to be interviewed because he himself was unavailable on the day of the interview. Of the key people, six were the same in each of the Intervention and Control sites. Two General Managers had moved on, one Sister was not available, one Nurse Manager had left, one administrator had left. The same procedure was followed as the first round of interviews in that, where an original interviewee was not available, the clinician was asked to nominate someone with a good knowledge of endoscopy. At one site a manager with a specific remit for endoscopy was nominated and a new manager was interviewed at the site used as a pilot. Two new key people interviewees (one Intervention, one Control) wanted to be accompanied by another member of staff from the endoscopy unit 'in case they forgot something'. There was a real possibility that the interviews would not take place unless this was agreed to so the researcher went ahead with this and found that the other members of staff corroborated what the main interviewee was saying.

Table 61. Role of interviewees and changes between interviewees in first and second interviews

	INTERVENTION		**CONTROL**	
	Clinical representatives	**Key People representatives**	**Clinical representatives**	**Key People representatives**
	7 Consultants	3 Sister	10 Consultants	3 Sister
	1 Nurse Research Manager	1 Matron		1 NE
	1 SpR	1 NE		Nurse Specialist
		3 Manager (2 General, 1 Nurse Manager)		5 Manager (3 General, 2 Nurse Managers)
		1 Administrative staff		1 Administrative staff
TOTAL	**9**	**9**	**10**	**10**
	Same except for SpR	6 same 2 Sisters & 1 General Manager different	Same	6 same 1 Nurse Manager, 1 Sister, 2 General Managers different

Although seven different key people were interviewed it was reassuring to find that the same issues arose across the group.

The interviewees in both rounds were recognised by the team as a valid cohort, providing reliable data that was representative of the views of people working in the endoscopy units. It could be considered that clinicians nominated key people they felt would give a positive account of endoscopy. However, the fact that interviewees included nurses, managers and administrative staff, who spoke about the same issues, emphasises a cross-section of views and validates the representative nature of the sample.

While conducting the interviews and undertaking the analysis, it was clear that similar themes were emerging but that clinicians and key people were responding to questions in the context of being two years further on in the change process and some of the questions would have been familiar to them. It was therefore decided to write up the findings from the second round of interviews as a follow up piece following the same themes and headings, where appropriate.

As in the first round, three themes emerged from the data. 'Drivers for Change', 'The Human Dimension of Endoscopy Units' and 'Financial Resources'. However, the content of 'Drivers for Change' had changed as there was little mention of the NHSMA or the Modernising Endoscopy Services Project, and it became clear that other drivers for change had emerged in the intervening two years, in particular the Endoscopy GRS and other Government initiatives such as Bowel Cancer Screening and the 18 week target.

- Drivers for Change
  - Progression from NHSMA/MES programme to GRS and Bowel Cancer Screening
  - The impact of Government initiatives
- The Human Dimension of Endoscopy Units
  - Staff
- Working relationships and staff morale
- Resistance to change
- Overcoming poor working relationships, poor morale and resistance
- Training
- Skill mix/staffing levels
  - Patients
- Financial Resources
  - An issue of concern

A detailed examination of themes and categories follows a description of differences between Intervention and Control sites two years after the first interviews.

8.8.1 Differences between Intervention and Control sites and their responses to modernisation

The first round of interviews suggested that the MES programme was a catalyst for change and had resulted in timelier implementation of modernisation as Control sites appeared to be lagging behind Intervention sites. However, as illustrated in Table 62 Control sites had made progress in the intervening two years with no sites perceived as 'modernisation yet to start'. Two Control sites while making progress, were considered by the researcher to be modernising their services but had specific ongoing problems that were limiting their progress, for example, expensive location causing staff difficulties. Thus Control sites appear to be 'catching up' in modernising the service delivery and organisation of their units.

However, it is interesting to note that midway between the two rounds of interviews the Endoscopy GRS was introduced and although not compulsory, all the ENIGMA sites were taking part. In spite of the differences between Intervention and Control sites in terms of the funding they received from the NHSMA, the different levels of support they received in modernising their service and the different stages they may have been at, they all embraced the use of the GRS and seemed able to adapt to its use easily.

There was no detectable difference between the responses of Intervention and Control sites to the GRS and their experience of modernising their units over the previous two years, whether with or without support from the NHSMA, facilitated their ability to use it. By the time the GRS was introduced, all of the units had adopted a mindset of modernising their units

and were used to collecting data and to many, the GRS seemed a natural progression, moving from the MES programme's emphasis on the process side of endoscopy to the quality issues of endoscopy.

As in the first round, there were no detectable differences between Intervention and Control sites and the same issues arose when participants spoke about the modernisation of their units.

8.8.2 Recommendations from second round interviews

When the data from the interviews are considered, a particular issue that stands out is the implementation of the GRS during the study period and the fact that the professionals interviewed perceived it as driving change in endoscopy units. Therefore, we recommend a sixth wave of patient recruitment, including further interviews with professionals, to enable a greater understanding of the impact of the GRS on endoscopy services.

Table 62. Progress in the stage of modernisation between the first and second interviews

	Stage in modernisation process at time of first interview				Overall progress at time of first interview			Ove sec
	Sites started modern-isation before MES programme	**Sites modern-ised in previous 2 years**	**Sites with some modern-isation**	**Sites at start of modern-isation**	**Good progress**	**Issues to be resolved**	**Modern-isation yet to start**	**Goo prog**
Intervention	4 7 8 11 13 18	1 6 16 19			1 4 6 7 8 13 16 19	11 18 (since withdrawn)		1 4 6 7 8 11 13 16 19
Control	3 9	12 17 20	5	2 10 14 15	3 9 12 17 20	5	2 10 14 15	2 3 5 9 10 12 17 20
	Number = site identification number							

This table shows where the researcher perceives the units to be in the process of modernisation in first interview. Sites 11 and 5 have moved from 'Issues to be resolved' to 'Good progress'.
Sites 2 and 10 have moved from 'Modernisation yet to start' to 'Good progress'.
Sites 14 and 15 are modernising their service but have 'Issues to be resolved'. Site 14 has only 1 funding issues and Site 15 is limited by the structure of the old hospital where it is situated and ha its expensive, city location. N.B. Site 18 withdrew from the study so there was no follow-up intervi

8.9 Findings in detail – second round of interviews

8.9.1 Theme 1 – Drivers for change

Introduction

This theme concentrates on drivers for change and specifically drivers that have emerged over the last two years - the Endoscopy GRS and Government targets for Bowel Cancer Screening, 'two week wait' referral and '18 week' referral to treatment, all of which are explained below.

The GRS is a tool that enables endoscopy units to assess how well they provide a patient-centred service across two dimensions – Clinical Quality and Quality of Patient Experience (Valori 2005). The primary purpose of the scale is to support quality improvement by helping endoscopy staff identify areas for improvement and provide ideas and information to help staff make changes. It was introduced in March 2005, almost midway between the two interviews. Completion was not compulsory but, in spite of its additional workload, it was widely accepted by endoscopy units, in part because the GRS became part of the accreditation process to become a Bowel Cancer Screening Centre, something many units aspired to. The NBCSP is being introduced as a screening procedure for CRC, and Screening Centres were presented as the local management point to provide endoscopy and nurse clinics for the follow up of individuals with positive faecal occult blood tests (a test that raises the suspicion of cancer) (Weller, Moss, Butler, Campbell and Coleman 2006).

The other drivers for change that emerged in the interviews and are explored below are the Government targets of 'two week wait' referrals and the '18 week referral to treatment' target. The 'two week wait' was introduced in the NHS Cancer Plan in 2000 with the aim that everyone with suspected cancer would be seen by a specialist within two weeks of their GP deciding they needed to be seen urgently and requesting an appointment (Department of Health 2000(a)). The '18 week' target was introduced in the NHS Improvement Plan in 2004 with the aim that by the end of 2008 no one will have to wait longer than a maximum of 18 weeks from the point of referral up to the start of any treatment (Department of Health 2004).

In the first round of interviews the NHSMA and the MES programme was a clear theme emerging from these data, but in the second round fewer people talked about these drivers for change. It was apparent that, to a great extent, the NHSMA and MES programme have been superseded in people's minds by the GRS and the NBCSP. This theme will clarify the relationship between the NHSMA's MES programme and the GRS and Bowel Cancer Screening drivers and will show how little was said about the drivers for change that came to light in the first round of interviews. The impact of the 'two week wait' and '18 week' target will also be explored.

Progression from NHSMA/MES programme to GRS and Bowel Cancer Screening

As mentioned above, in the first round of interviews the NHSMA and the MES programme emerged as the drivers for change but in the follow up interviews there was little mention of either the NHSMA or the MES

programme. However, as the overall aim of this study is to evaluate the impact of the NHSMA and the MES programme, it is relevant to report what was said and to indicate how the comments were often linked to the GRS.

When people did talk about the NHSMA and the MES programme in the second round interviews they often related these issues to the GRS, with some people seeing the GRS as a natural progression from the MES programme and suggesting that the MA had been a catalyst for all that had happened since:

> *I think it is excellent. I think it is a really good tool. … As a tool I think it is fantastic, a really, really good innovation and I think it's done more for endoscopy than anything else really. … I think the MA brought about the mindset of modernisation … started the ball running. Without the MA Programme you wouldn't have had Roland Valori, Liz Allen or Debbie Johnston who came up with the GRS so really in my view the GRS came from the MA programme and it's just been a natural progression of the scheme. (19.2/615)*

It was acknowledged that the MES programme had dealt with the process of delivering an endoscopy service and the GRS then followed on from this by addressing the quality aspects of an endoscopy service:

> *".. the MA Toolkit™ for endoscopy focused on measuring and counting and looking mainly at the process of what happened … but there is so much more to running an endoscopy service than the bit about actually processing patients on a daily basis … the GRS is a more rounded tool." (12.2/179)*

The introduction of the GRS was viewed by the majority of interviewees as a good idea. The GRS assessment tool is a web-based tool that calculates the GRS scores providing units with a summary view of their service. The GRS was considered a useful tool, focused units on the quality of clinical care and patient experience and provided evidence of quality improvements in the form of higher GRS scores:

> *"… you can improve your score very quickly by focussing on passing that particular part of the test … it's sort of when you are doing an exam, it's knowing how to answer the questions but that is no bad thing. … makes you focus on areas that otherwise, because they are not directly medical areas, a lot of them are quality areas that are to do with patient interaction and patient flow through the unit, but as a doctor, as an Endoscopist you are not directly involved with so they don't come high priority. So I think it's useful in that sense." 20.1/309*

> *"…they show the markers and competition I suppose. I think that always makes a difference doesn't it. They don't like to think that they are all Ds or something like that and it's the way it's been marketed I suppose really. It is a continuation and an improvement so I think how that was set up wouldn't have happened maybe." 4.2/170*

Intervention sites felt that their experience of the MES programme and Control sites their experience of modernising their units, had been of benefit when undertaking the GRS, as it had prepared staff for the type of activity required for the GRS and in particular they were used to collecting data:

> *The advantage of having been part of the MA stuff is that the nurses are already doing it. It wasn't a big shock to add on the extra bits for the GRS because we were all familiar with the needs of doing the data collection. It is all still happening but it's now bigger. 19.1/149*

As explained above, the GRS assessed units on clinical quality and quality of patient experience and while interviewees were not asked specifically about 'quality' it was spoken about by interviewees across Intervention and Control sites in a more patient focused manner than in the first round of interviews:

> *I think actually there was a genuine desire to improve the efficiency of the service and to improve the quality of the service for the patients. (9.1/275)*

> *"… so often in the NHS you're driven by targets and sort of quantitative issues. With the GRS it focused the mind on the quality issues." (12.2/156)*

This appears to stem from the 'quality' agenda which has come to the fore in endoscopy units as a result of the GRS with its assessment of clinical quality and quality of patient experience. Changes have been made in units as they try to achieve high GRS scores and this has given rise to interviewees talking a great deal about quality. However, as quality or high-quality patient experience is never clearly defined, and how talk is directed at target-driven assessment it is difficult to ascertain whether the patient has actually become the focus of the drive to improve quality or whether the focus is achieving high GRS scores and almost by default, the patient has become the focus and benefited as a result:

> *"… I'm a big fan of the GRS. It's bringing quality into the service - most of us in medicine want to provide a good quality service. We are not so interested in quantity, we are more interested in quality and because you have to have quality in service to achieve the appropriate GRS and I suppose we all like to come first … if you have got a good quality unit the person who gets the greatest benefit is the patients, that is important." 9.1/721)*

A specific quality issue that arose was the point that there was variation in the quality of the performance of endoscopy, in particular colonoscopy, between various practitioners, but that this was now being addressed through audits which meant that evidence was available to demonstrate performance. Those found to be poor at conducting high quality colonoscopy could either be given additional training or stopped from performing procedures:

> *"… where there may be a discrepancy in quality between various practitioners, you know colonoscopy is a prime example, but we've found with those we proved that aren't necessarily the best at the procedures, have decided not to be seen doing them any more, so the total pool has gone down but the quality as a result has gone up, which is the way it should be." (19.1/106)*

The importance to many units of improving their GRS scores was directly linked to the aspiration of becoming a Bowel Cancer Screening Centre (which generates income and equipment), as eligibility is, in part, determined by the GRS score:

> *"… because the carrot at the end of the whole thing is to get Bowel Cancer Screening going …" (4.1/436)*

For this reason it was felt that the GRS had been more useful than the MES programme in raising the profile of endoscopy and driving change as Trusts were keen to acquire the status of being a Bowel Cancer Screening Centre:

> *It's a massive driver because everyone wants to do it … competitive across the area with five Trusts competing. That has been a massive driver which has brought endoscopy to the forefront, which we didn't manage to do with the previous project. (11.1/75)*

Because of this, units were finding Trusts more supportive than in the past as there was a higher level of awareness of endoscopy and its requirements. This combined with the data from the GRS audits provided evidence to acquire funding specifically to target problem areas, for example, long waiting lists, in order to improve GRS scores:

> *"… but we have waiting lists which need to be hit and things like the Bowel Cancer Screening are very effective levers in getting additional money." (10.1/565)*

While the majority of clinicians and key people felt the GRS was of benefit to service provision, there were aspects of the GRS that were criticised and these included the additional workload and increase in paperwork – *"what I lack is manpower to do it" (11.1/274)* and lack of time to undertake audits:

> *"… always torn between providing an acceptable clinical service with waiting lists not too bad, yet doing all this other stuff like audit, which I fully endorse and think is important but probably in the past hasn't played a major part in services, and having time to do that properly." (16.2/387)*

Some of the GRS targets were considered to be unrealistic in that some elements within the GRS are beyond the control of the endoscopy unit, such as ensuring that pathology reports are received within five working days and there was some frustration at how the 'goalposts' had changed in the early days of the GRS. A few interviewees felt that certain elements within the GRS were easy to achieve giving rise to comments about it being a tick box exercise, for example, patients should be able to make their views known and this is easily achieved by putting a suggestion box on the wall. The final criticism related to the fact that the GRS can be too specific and does not allow for variation in the set up of units which can result in a score being dragged down by just one element not being achieved:

> *So like most sites we have no problem with 90% of our procedures but one procedure has a horrendous waiting list, i.e. colonoscopies, and that drops you down to a D where for colonoscopies it would be a D but for everything else we would be an A. (13.2/269)*

While the majority of interviewees spoke about the GRS there were a few Intervention and Control site interviewees who did not express an opinion about it while one clinician expressed a wholly negative view:

> *"..most of it is a complete waste of time, it's taken a lot of time from senior nursing staff who should have been looking after patients rather than filling in questionnaires and going to lots and lots of meetings." (14.1/533)*

The positive aim of the MES programme Toolkit™ to speed up productivity was acknowledged, however, it was also criticised once again with interviewees recalling how it was time consuming, not user friendly and that the web based Toolkit™ was a *"nightmare" (11.1260)*. Nevertheless, an Intervention and a Control site reported that they were still using the Toolkit™, albeit the old, version and one, who stated that *"it's not user friendly at all" (13.2/245)*, was only using parts of it simply because she has a Personal Assistant who was happy using it and it was preferable to maintaining various databases.

In contrast there was no criticism of the arrangements for data collection for the GRS (apart form the additional workload) and the accessibility of the website associated with the GRS was praised for the way it encouraged the sharing of good practice:

> *"… the GRS website and it makes you put in your information yourself so you do it yourself. You can then actually look at what other people have done and it's a useful tool as well because if there is any, if you are looking for guidelines that you want to look at, maybe somebody else has done them and they are actually on the website now so you can go and see if there is anything or if there is not then go ahead and do it. So I suppose it has really, it's been good." (3.2/66)*

In spite of a few aspects of the GRS being criticised, all of the Intervention and Control sites were undertaking the necessary data collection and audits required for the GRS and for the majority that was directly linked to Bowel Cancer Screening:

> *You know if you had spoken to me nine months ago I would have been fairly down in the dumps because I didn't think we were making much progress over all the things we had done but I think year on year we've made better and better progress. Getting Bowel Cancer Screening was a huge, huge thing. (10.1/429)*

Whatever was considered to be the driver behind the changes to services and care provision, the majority of participants considered that the changes that had been made had improved the endoscopy service:

> *It's hugely better than it was when I first came here which was six years ago. It's come on leaps and bounds really. (6.1/109)*

However, interviewees felt there was still more to be done that could improve the service such as opening additional endoscopy rooms, better reporting systems, one stop clinics (where patients have an outpatient appointment and if needed an endoscopy the same day) and providing out of hours service. There were some concerns about the ability to cope with the additional demands of Bowel Cancer Screening (increased referrals) because units face limitations mainly relating to funding and space within the units:

> *The facilities that we have got available to us are still under great pressure. We are trying to keep up with numbers. (7.1/14)*

The impact for Government initiatives

In addition to the Government initiative for Bowel Cancer Screening, other targets have been introduced that have impacted on endoscopy units. The Government's introduction of waiting time targets for the period from referral to treatment (18 weeks including the diagnostic element), was acknowledged as a further driver for change because for the first time, *"the journey time being in the spotlight that has put diagnostics in the spotlight" (9.1/721)*. This has resulted in endoscopy becoming a higher priority for senior Trust management, who have focused on endoscopy, as a diagnostic service, needing to fall within the 18 week target.

However, there was criticism from just under a third of participants about the 'two week wait' target for patients with symptoms that may suggest cancer. It was felt that some GPs and clinicians were referring patients inappropriately in order to get their patients seen quickly and this was impacting on the waiting times of patients with other serious gastrointestinal diseases and those referred as routine cases:

> *Now if anybody is referred by the 2 week wait target, has to have all their investigations within a short period in order to meet the overall Government targets. From a patient perspective that is absolutely right. However, it would only be right if the GPs were only referring the patients who were suspected of having cancer as opposed to the fact that they were worrying for other reasons. The 2 week wait is widely abused. (17.1/84)*

Summary – Drivers for change

It is clear that the GRS and NBCSP have been very strong drivers for change and that while the NHSMA and MES programme are acknowledged as having been helpful in preparing the way for the GRS, they have largely faded into the background. The 18 week referral to treatment target has been welcomed because for the first time a target includes the diagnostic element of a patient's referral and as a consequence the profile of endoscopy within Trusts has been raised. In contrast, the two-week-wait referral, while being of benefit in speeding up referral times for patients with possible cancers, has had a negative impact on waiting times for other patients.

The second round interviews focus more on the patient and the quality of their clinical care and experience. However, it is not clear from the data whether this is truly because interviewees and their units are more patient focused, or whether the real focus is the achievement of the highest possible GRS scores in the quest to become a Bowel Cancer Screening Centre. The GRS tool measures units' clinical quality and quality of patient experience so it is almost by default that the patient has become more central to discussion. Whichever way it is viewed, interviewees perceived that the GRS is driving changes that are improving the service and so benefiting patients.

While the drivers for change have altered over the two years since the first interviews and clinicians and key people felt changes had improved the service and ensured patient benefits there was no sense of complacency. Interviewees feel further improvements could and should be made, such as providing an out-of-hours service, one-stop-shop clinics and opening additional endoscopy rooms. They are also aware of the increased demands

that might be placed on their units with the advent of NBCSP and resultant increased referrals.

8.9.2 Theme 2 – The human dimension of endoscopy units

Introduction

This theme concentrates on the human dimension of endoscopy units - staff and patients. The first round of interviews identified that units were at different stages in the process of modernisation and therefore interviewees' experiences of change in their units varied but issues concerning working relationships, morale, resistance to change, staffing levels, training and skill mix and patients were raised. Two years later all the units had undergone modernisation to some extent and interviewees were able to talk about what had actually happened rather than, as some had done previously, in anticipation of what might happen. However, interviewees moved away from speaking quite so much about staffing issues and this second round of interviews will clarify how their perceptions have changed over the intervening two years and will explore whether the issues concerning staffing of the unit have changed and the way that the topic has progressed in two years. This theme will also explore the views of the interviewees about the need for staff to provide patients with quality care and support and their reflections on the experience of patients.

Working relationships and staff morale

In the first round of interviews issues of poor working relationships and poor morale were raised by a quarter of interviewees. However, in the second round there were only isolated reports of this and the overall perception was that working relationships and morale were good and that staff had responded positively to change, were supportive and co-operative and had welcomed the challenge of new ways of working:

> *There is a lot of very positive nursing input and again from the administrative staff and the reception staff, it's all very 'please can we look at doing this' … (8.1/590)*

> *I think our staff have been brilliant. … Of course, morale has been low at areas but mainly people are motivated. Nursing staff have been completely brilliant … clerical staff have been great and very obliging. (17.1/512)*

The issue of working relationships between the different specialties was highlighted again but by only four interviewees who commented on the ongoing tensions between physicians and surgeons. This takes the form of surgeons not attending meetings, inappropriately referring their patients as urgent and being unwilling to scope medical patients. As one clinician put it:

> *It's not run as an endoscopy unit, it's run as a unit that has other hospital departments using it. (8.1/582)*

There was, however, some insight into the tensions between physicians and surgeons from a clinician who suggested that they *"have very different ideas about what endoscopy is and how important it is to the grand scheme of things" (10.1/481)* and a Key Person explaining that they work in different ways following different clinical pathways:

> *"…the surgeons are probably more likely to investigate a patient using a barium enema and flexible sigmoidoscopy rather than colonoscopy, where the physicians have a gold standard" (19.2/504)*

Interestingly in this round of interviews physicians were noted by two interviewees as becoming unwilling to scope surgical patients. This was a consequence of the 'two week wait' referral system resulting in more surgical patients being referred as a 'two week wait' meaning that in sites with pooled lists, physicians found they were scoping more surgical patients while their own patients were having to wait longer. It was also acknowledged that physicians have concerns about the quality of scoping by some surgeons.

However, it was felt that working relationships between physicians and surgeons had improved and there had been a realisation among surgeons that change was necessary to utilise capacity:

> *"… there has been a real cultural shift, particularly between the physicians and surgeons and it is going in the right direction" (19.2/427)*

The comments of one Control site clinician are particularly interesting in that he speaks of his embarrassment at not getting surgeons on board with modernisation during his five years as Clinical Lead and yet within six months of the role being taken over by someone else, there had been a complete turnaround. He explained that the new Clinical Lead ensured that meetings were held when surgeons could attend and this had made a difference in the level of attendance by surgeons and their subsequent involvement in changes.

There were isolated incidences of clinicians feeling they lacked control of the endoscopy service, *"just don't control your unit" (17.1/411)*, in that they were unable to appoint or dismiss staff or open up endoscopy rooms across the Trust. It was suggested this was due to the Trust which *"looks at money these days rather than service to patients" (14.1/298)*.

A unit cited in the first round as having poor working relationships and morale within the unit reported great improvements within their reception/booking office following a change in personnel. This same site, however, was still experiencing problems with the morale of nursing staff resulting in issues with sick leave. The clinician felt this was due in part to the location of the hospital in an expensive area and the consequent inability to attract quality staff to work there.

It was highlighted in the first round of interviews that several units were due to move to new units. Four units reported that they had moved but had experienced difficult and disruptive periods when moving which had caused anxiety and stress but the interviewees involved reported that staff had pulled together and this, combined with the benefits of working in new units, had resulted in improved morale:

> *Having got a nice new unit that has certainly improved the morale of the staff. (14.1/507)*

There were two personal stories from key people (one Intervention, one Control) whose morale had suffered as a result of issues that arose when they took over the modernisation process in other units in the Trust while

continuing to manage their own unit. Initially both had found that staff at the other site felt they were being taken over:

> *That would happen at any two sites wouldn't it, it's the bigger hospital and the smaller, they view it as a takeover, we see it as a merger. (13.2/409)*

Both had found it a huge challenge and one could not understand *"why it gets so personal, but it does" (13.2/457)* and the other spoke about *"reaching rock bottom" (10.2/58)*.

While low morale was not generally viewed as a problem in the sites a clinician suggested that the media coverage of the NHS – that it is failing, jobs are on the line, hospitals are under pressure – could lead to feelings of insecurity among staff and another commented on the lack of acknowledgement at a senior level of the excellent service that the endoscopy unit delivered under great pressure.

Resistance to change

Once again clinicians and key people demonstrated an awareness of people's reaction to change:

> *I think people find change difficult. Any sort of change management programme, people like their set ways and their ways of doing things. So it's always difficult for people to take on and change new roles. (15.1/459)*

However, very little actual resistance was reported and in contrast to the first round of interviews just four interviewees spoke specifically about surgeons resisting change. It was suggested that the more recently trained clinicians were more accepting of change:

> *We are a young unit so I think some of these things were easier to bring in. …the consultants are young here, almost across the board within GI. … I just think people get in a rut, they get used to doing things they have always done. (2.1/632)*

As noted above some physicians were becoming resistant to the pooling of waiting lists. There were two reasons given for this, firstly, physicians were concerned about the quality of scoping by their surgical colleagues and secondly, more surgical patients were being referred as a 'two week wait' referral and physicians were finding they were scoping a lot of surgical patients and their own patients were being pushed further down the waiting list:

> *It is difficult to convince the medics that it should be pooled because there is such a huge disparity in the number of patients and that if we pooled lists all of us would be scoping surgical patients all the time and it's become very obvious certainly with the 2 week wait that the medical patients are just being bumped from list to list to list in order to get the urgent patients in and the medical urgents are getting on to longer and longer waiting lists. (8.1/171)*

Two Unit Nurse Managers (one Intervention, one Control) reported that they had faced huge resistance when they were tasked with running and modernising another unit in their Trusts. They felt this was due to different

working cultures in the other units and the fact that rather than being viewed as a merger of units it was viewed as being a take over:

> *That would happen at any two sites wouldn't it, it's the bigger hospital and the smaller, they view it as a takeover, we see it as a merger. (13.2/409)*

The Control site manager also experienced resistance from within its own unit as staff resented having to cover for sickness in the other unit.

Overcoming poor working relationships, poor morale and resistance

As interviewees had reported that working relationships and morale were generally good, there was little said about how to overcome problems in these areas. However, certain elements were, once again, spoken about as being important in achieving change such as leadership, involving staff, teamwork and communication:

> *"…got to have a coherent team and you've got to listen but underlying it you've got to have a belief in what you are doing." (17.1/512)*

As in the first round of interviews, the importance of someone leading the change process with vision and direction and the right approach was highlighted and in some units it was noted that a change in leadership could be effective:

> *"..with fresh eyes and a real desire to crack the problems." (20.2/212)*

One of the Intervention sites that reported surgeon resistance, *"I'm not changing, I've always done it that way, I think it's best" (11.1/736)*, explained that this was improving as this particular surgeon had become clinical lead and was becoming more involved but also because the Clinical Director has given assurances that he will be forced to change.

The importance of involving staff in any change is still seen as significant, and regular meetings to discuss key issues and the direction of the service help with this and are an effective means of involving staff which is seen as important in managing change:

> *If I put it [change] forward to them [staff] right from the beginning and say look you know we are looking at doing this, how you feel about doing so and so, I involved them right from the beginning. (7.2/389)*

Of the two Unit Managers who faced huge resistance when they were tasked with running and modernising another unit in their Trusts, one reported a huge improvement and suggested this was in part due to rotating staff between the units so they could experience different ways of working, get to know other staff and be more involved in different types of endoscopy, e.g. emergency bleeds. The other Manager is still facing resistance but is persevering and sees rotating staff as one way forward.

Training

Once again training was recognised as important to ensure that staff have the appropriate education and expertise but lack of staff and time make it difficult to release staff for training because everyone is working to capacity and the endoscopy unit has to continue its work. There is the ongoing pressure, as reported in the first interviews, of accommodating training lists which should have less patients on:

> *Training is an issue. We have 2 medical SpRs and occasional surgical SpRs that all need training in endoscopy and find fitting in the training requirements quite difficult even though we have the luxury of short waiting times and can cut down some of the lists a little bit, but it's still quite a burden especially in the last 3 years we have also had to train the Nurse Endoscopists – 3 people training in one particular type of endoscopy, that is really hard, everybody's list is a training list. (20.1/373)*

There is also the ongoing issue of training budgets highlighted by one interviewee who explained that in the absence of a training budget the unit now do fund raising events such as sponsored walks to raise money for training. Some units felt there was less money available for study leave and conference attendance and as a result most training was now done in-house.

Skill mix and staffing levels

In spite of the limitations on training, it is clear that it still takes place as training staff to achieve an appropriate skill mix is still high on the agenda for the majority of sites. There is greater flexibility as more nurses are trained to undertake various additional roles such as admitting and discharging patients, taking consent, performing cannulation, triaging referrals, visiting inpatients to assess them before endoscopy, running pre-assessment clinics and writing patient information:

> *We've looked more at skill mix and we've upped the skills of our nursing assistants so they now discharge patients and take cannulas out and do much, more than they did a year ago. (6.2/423)*

In many units nurses rotate within the unit so that they fully understand the various aspects and can provide cover as and when necessary. Nurses are able to take on these additional roles because health care assistants are carrying out non-nursing duties such as setting up equipment and washing scopes, something that was also highlighted in the first round of interviews. However, three sites reported the further development of health care assistants in that one was training to do ERCP and another two as Training Associate Practitioners (TAPs).

In the first round of interviews there were just two units that did not have NEs. Two years later all the endoscopy units have NEs and units reported that while many nurses were still training, particularly in colonoscopy, many were now fully competent and running their own lists which helps throughput, they are able to take on the routine work of consultants freeing them up for more complex procedures and are also flexible and being used to backfill adding to the efficiency of units. In one Control site a NE had

become the Clinical Lead for endoscopy, a role usually taken by someone at directorate level.

A clinician pondered on the future of the role of the NE believing that with technological advances, the demand for diagnostic endoscopy and therefore routine flexible sigmoidoscopy and colonoscopy will fall in the future and there will be little work for NEs unless they become *"super specialised as consultants" (14.1/166)*.

There is a growing interest in training non-medical, non-nursing people to undertake roles that would traditionally have required a medical background, with three sites currently involved in training endoscopy technicians and one site training a member of staff who has run a physiology service for 10 years now training to run a dyspepsia clinic:

> *"…I think it is the principle, that you can train someone who is not medically qualified to not only do the procedure but also use sedation." (15.1/229)*

It is interesting to note that staff in several units reported becoming involved with other units within their Trust to help in the modernisation process and promote standardisation of practice across the Trust. Those that spoke about it felt it was important to standardise practice for various reasons such as patients receiving the same information wherever they were referred within a Trust and in order to streamline nursing practice:

> *It is all streamlined from the nursing aspect, just the same documentation and we are all moving in the same direction, working together as one big team rather than four separate teams. (14.3/208)*

Moving to a new unit had given some units an opportunity to review their staffing and at one site the move had initiated changes in the work of some nurses because they had started undertaking day case procedures related to gastroenterology, e.g. blood transfusions, paracentesis and iron infusions which had impacted on bed stays in the hospital as patients would previously have been admitted to a ward.

In the first interviews the importance of clerical staff was highlighted and this was reiterated:

> *"… getting the booking co-ordinator really trained I think for the running of the unit you need, that is the first port of call and you need that to run efficiently." (3.2/179)*

It was also apparent that in the last two years clerical roles had expanded with almost a quarter of interviewees explaining that clerical staff had taken on more responsibility:

> *The two secretaries, one on each site, have become service co-ordinators and they are going to link in with the doctors filling the sessions – their jobs have expanded. They are in close liaison with the consultants so hopefully they will be able to look at the templates and get them to swap about. (4.2/46)*

As in the first round of interviews it was reported that more staff had been recruited such as scope cleaners, data analysts, clerical support, endoscopy managers, nurses and consultants. However, when interviewees spoke

about staffing levels it was often set in the context of current difficulties arising from Trusts being in financial crisis and many reviewing jobs, restricting the use of bank staff and maintaining a freeze on recruitment resulting in half of the interviewees commenting on the need for additional staff at all levels including clerical:

> *"… poor 7.21 is our booking clerk and her workload is humungous … could do with another admin person really." (7.2/537 & 553)*

Just two Intervention sites reported actually losing staff but had overcome this by planning with what staff were available and by changing shift patterns.

Given the current climate, interviewees were reasonably satisfied with staffing levels but acknowledged that this impacted on their work, for example, restricting waiting list initiatives, lists being cut, an inability to backfill lists, restricting training:

> *If you don't have enough staff then you can't do the job anyway, then you can run into training issues and you need so many staff to train and then you've got to encourage them to train and it's just an ongoing cycle but it's always down to numbers in the end I think. (2.2c/518)*

Patients

In the first round of interviews sites were at different stages of modernising their units and participants spoke about the way in which they hoped to modernise endoscopy services to improve access to, and experience of, endoscopy for patients. As all sites had made progress in modernising their units by the time the second round interviews took place, participants were able to reflect on the changes and their impact on patients.

As in the first round, participants recognised the need to provide patients with high quality care and support but in the second round they spoke more about 'quality' and how this issue has moved up the agenda as a result of the GRS and its assessment of 'clinical quality and quality of patient experience'. However, they did not define or elaborate on what they meant by quality or patient-centred, high quality care. As mentioned on page 240, because the conversation about quality relates closely to data about the GRS and Bowel Cancer Screening, it is difficult to assess whether the patient is really at the centre of this quality agenda or benefiting almost by default as units strive to achieve high GRS scores. Nevertheless, participants did talk about patients in ways that demonstrate that the aim of the modernisation process is to improve the service for patients and these are described below.

In the first round of interviews it was clear that many of the changes were aimed at improving the service for patients and this was similar in the follow up interviews with many of the changes introduced over the last two years aimed at improving the service for patients:

> *So there have been a lot of improvements, not directly necessarily relating to the endoscopy procedure itself but globally we are able to do a lot more with patients than we ever before have. (14.1/701)*

However, in the second round of interviews there was evidence of a greater commitment to patient satisfaction with most interviewees referring to patient satisfaction and the fact that they take action on patients' comments, for example, keeping patients informed when there is a delay caused by an emergency. Patients appear to be more involved in that they have been shadowed and in some units are invited to take part in patient forums *"that has been great because it has given us a handle on what is going on" (9.1/31)*. However, it was pointed out that getting patients engaged in a forum can be difficult and it was suggested this might be because the time in endoscopy is only a short part of their overall pathway but for this very reason it was *"really important for us to be seen as being professional" (5.2/566)*.

Some of the general changes mentioned in the first round of interviews were mentioned again such as improved information leaflets, some now accessible on the internet, patients being given patient-friendly reports and translation facilities when required. An example of a change introduced in one unit in the last two years that directly impacts on the service for patients, is evening clinics which enable patients to attend without having to take time off work.

It was noted that anxiety that can be caused to patients when guidelines are changed resulting in patients being removed from waiting lists or having less frequent surveillance procedures. It was felt that it was important to bring the patient up to a clinic to explain the reasons behind the decision:

> *"… we don't want to cause anxiety in patients' minds so usually I will book them into a clinic to have a chat with them. We do that pretty quick because these people have been waiting for a long time, it's not fair to leave them waiting again for clinic." (1.1/46)*

In addition to quality improvements, the majority of interviewees also believed that patients have better access to endoscopy because of shorter waiting times, greater throughput, more patient information, including, in some units, a copy of the endoscopy report, choice of date and booking from outpatient clinics so patients have an appointment before leaving hospital. They also felt units were more responsive to patients' views and comments, and in some units that there was better communication between reception staff and patients:

> *There is much more patient information provided, for example, a simple thing, they now get a copy of the endoscopy findings so I think patient information has improved. (7.1/371)*

> *I think patients are more aware of being able to phone in, talk about their procedures, get their appointments and talk to anybody that they need to talk to. (3.2/443)*

However, a minority of interviewees felt that accessibility had not improved because colonoscopy waiting lists remain too long, and guidelines have restricted access to endoscopy, although this was acknowledged as necessary to cope with demand:

> *In the past it's been a case of 'they've got a bit of heartburn, scope them', but now perhaps we're not becoming so accessible with all the new guidelines. I think we've got to be choosy in who we do, haven't we? (1.2/487)*

At a small number of sites accessibility was felt to be impeded because of difficulties getting through to booking centres and at one site, accessibility for patients in terms of contacting the unit had deteriorated as a result of the hospital's automated telephone system and the fact that when patients got through to the unit they often reached an answerphone.

The majority of clinicians and key people from all sites also felt that the service was more acceptable to patients with several citing the good results of patient satisfaction surveys and stating that units do respond when patients highlight problems:

> *"…picking up on a few things that the patients have said with the satisfaction survey – noting the privacy bit, we are a bit short on space here but being aware of that sort of thing is good ... so we got rid of all the seats, made our sub-wait area bigger so we only had two seats in reception, so there is only one person there at a time, confidentiality was the impact there." (3.2/466)*

Specific reasons for the service being acceptable included: shorter waiting times, nicer environment, more privacy, better patient information, choice of appointment, improved quality and patient focused staff.

> *The aesthetics of it are better. It's nicer, it's a nicer place to be. The safety side of it is much better controlled. … décor is reassuring I think … somebody meets the patient, books them in, talks them through their procedure and that is somebody who has got time because they are the person who has been designated to do that and then they chat to them as they go along the corridor and accompany them to the rooms so it's just better. I think it's much more acceptable to patients. (12.1/489)*

While many of the changes were undertaken to benefit patients and the majority of interviewees felt that the service had improved, was more accessible and acceptable, there were some reservations about particular aspects of the service. A quarter of interviewees felt that there could be more privacy and dignity for patients and that changing the structure of units would help with this but this was not really feasible because the recovery area has to be set up in the way it is for patients to be cared for:

> *"… obviously your dignity is preserved because you are in a different unit, a room to have the procedure done, but actually it's the recovery area isn't it … it's not very private, I mean there are screens and things so your dignity is preserved but if I had to chose that would be the one thing I would change." (20.2/381)*

The idea was raised that patients, particularly patients with cancer, just want to be seen and treated quickly and that resources are not available to respond to everything that patients want:

> *"… the NHS hasn't got the resources to listen to every single person and that is why they are having a problem because every single thing you do has an audit on patient satisfaction and we are killing ourselves trying to provide an efficient service, increase capacity and make everyone happy and we can't do that with the funding we have got." (16.2/287)*

Summary – The human dimension of endoscopy units

As in the first round of interviews, working relationships and morale was generally reported as high in the units under scrutiny, and staff were positive about, and supportive of change, as long as there was good communication among them and they all felt fully involved. However, some units had seen improvements in morale and this was evident in the four sites that had moved to new units. While this had proved to be a difficult and disruptive time, it was an experience that pulled staff together and combined in a positive way the benefits of working in new units.

There are still tensions, albeit reduced, between those who use the facilities of the endoscopy units. Physicians and surgeons, for example, display ongoing tensions with regard to scoping each others' patients. In addition the introduction of the two-week-wait referral has created tension as physicians' patients are pushed down the waiting list. However, it appears that working relationships are improving and there was less emphasis in this round of interviews on infighting between physicians and surgeons. Indeed, there is a reported improvement in relations and it has emerged that better understanding is in evidence between the two groups, with specific examples of such as less resistance to change from surgeons.

This reduction in the reporting of resistance is reflected in the interviews generally. In the first round of interviews some interviewees spoke about resistance, not from experience but in anticipation of what might happen. However, all the units had now gone through the process of modernisation and the fact that resistance was mentioned infrequently reflects the fact that it was less of an issue.

Better working relationships and stronger staff morale are attributes that are important in supporting the achievement of an appropriate skill mix within units, something that is still high on the agenda. There has to be understanding and flexibility when staff are undergoing training and an acceptance of the development of training non-medical, non-nursing people to undertake roles that would traditionally have required a medical background. There is greater flexibility as the nurses who were reported as undertaking training in the first round of interviews, for example in colonoscopy, have completed their training. Nurses also continue to undertake various additional roles and in many units rotate so that they are trained in all aspects of the unit. There are also reports of the expansion of some clerical roles with staff taking on more responsibility.

While achieving an appropriate skill mix is of importance to the efficient delivery and organisation of endoscopy services, it does make demands on staffing levels and while additional staff had been recruited over the last two years, it was clear that because of the pressure of work more are needed, in particular nurses and clerical staff.

Patients are perceived to benefit from units where staff have good working relationships and high morale and where the modernisation process has resulted in improvements in the delivery and organisation of the service. While it is difficult to assess whether the quality agenda is driven by targets or patients, there is evidence that the aim of the modernisation process is to improve the service for patients and there is greater commitment to their satisfaction. The service is generally thought to be more accessible and acceptable to patients although it is acknowledged that there are areas where further improvements can be achieved.

Two years after the first interviews there are some ongoing issues with regard to staffing but it appears that going through the process of modernisation, with someone to lead the change, has built stronger collaborations among staff, particularly with those outside endoscopy units. With morale improving further there is also less resistance to change. It is difficult to ascertain whether the patient is really the focus of the modernisation process or whether the focus is the achievement of targets, and neither patient-centred, quality care nor quality services were clearly defined. Nevertheless, in achieving the targets patients are benefiting from improvements in the clinical quality and quality of experience when having an endoscopy.

8.9.3 Theme 3 – Financial resources

Introduction

This theme picks up on the availability of financial resources and, as in the first round interviews, links many of the interviewees, who have similar concerns about the limitations of resource restrictions and how lack of finances impacts on: staffing, equipment, information technology and facilities. The theme also highlights those issues that arise when money is available and examines people's successes or otherwise in getting funding. This theme will identify important changes that have raised the profile of endoscopy within Trusts and elaborates upon how interviewees perceive funding policy to have changed in the last two years. It explores the impact of these changes on their units, the concerns over 'payment by results', and the implications of endoscopy being done in primary care and the independent sector.

An issue of concern

As in the first round of interviews it was acknowledged that some modernisation initiatives could be achieved within existing resources such as the more efficient use of lists, but there was frustration that for very little extra funding it was felt a lot could be achieved. However, some interviewees disagreed strongly with the idea that change is cost neutral, one blaming the Department of Health (DoH) and the other tabloids as the source of the idea:

> *There is a management ethos which I think probably stems somewhere from the DoH that change has to be cost neutral which, of course, is rubbish. (4.1/479)*

The majority of clinicians and key people from all sites felt that the financial situation had deteriorated in the last two years and that *"everything is cost orientated, much more than it used to be" (2.2/275)*. It was appreciated that the use of resources needed to be carefully controlled and almost all interviewees, while accepting their current financial situation agreed that they are facing greater financial constraints than two years ago because of tighter control of finances within the Trust often explained as a consequence of financial crisis within Trusts. Interviewees were frustrated over the demands of striving to improve the service but within tighter financial constraints and this was impacting on the ability of endoscopy units to recruit staff, run weekend lists, purchase equipment, update IT systems, train staff to achieve an appropriate skill mix, allow study leave, make

minor structural changes, open additional endoscopy rooms and develop the service. There appears to be a constant battle to win additional resources:

> *Personally I think we are restricted by the lack of NHS funds and therefore re-equipping and the rolling replacement programme, I don't think we've actually got enough endoscopes for the procedures that we are doing. We could be doing more. (12.1/282)*

> *This hospital has had a major financial crisis in the last two years and there has been a very strict review of expenditure. We can't employ people on the bank any more … I'm sure that's had an impact on the amount of work that is done here. (3.1/341)*

However, it is clear that similar to two years ago, various sources of funding are being sought and while the submission of business cases remains *"…a tortuous process" (14.2/633)* important changes in the form of the introduction of the GRS and Bowel Cancer Screening have occurred, raising the profile of endoscopy within Trusts and proving to be useful leverage tools when applying for funding. Some interviewees reported success in bids for equipment and staff but emphasised that in comparison to two years ago the GRS and Bowel Cancer Screening had made a difference when applying for funding:

> *I mean it's always been difficult to get hold of money but I think particularly in the last six months to get service improvement pushed ahead with additional monies is very difficult but we have waiting lists which need to be hit and things like the Bowel Cancer Screening are very effective levers in getting additional money. (10.1/565)*

The overall picture was that finding additional resources for equipment, additional staffing, training and modernisation initiatives was not easy and had to be fought hard for and just a few interviewees expressed some optimism for the future:

> *I predict that it will be more favourable, we will have a fairer amount of funding from now on, partly linked to payment by results … partly linked to the fact that we have got the 18 week target in 2008 and we know that we have got to get our diagnostic waits down to six weeks to be successful. So I think that as long as we continue to demonstrate that we are using current resources efficiently ... then I think it is going to be easier to argue and get extra resources…. (12.2/568)*

However, there were concerns about 'payment by results' especially expressed in terms of the tariff that will be attached to procedures and whether the money will actually reach the endoscopy unit:

> *Whether that money comes down to us is a different question. … They will spend it on other bits. If we are being efficient and we're gaining lots of money they may have to … there are some services that are crucial but aren't money spinners. I think we are sort of low hanging fruit really, easy picking to make money. (9.1/509 – 519)*

Linked to payment by results is anxiety that as the procedures have a fixed cost in secondary care, PCTs may find cheaper endoscopy in primary care or the independent sector. One clinician, while welcoming the transfer of some capacity to an independent treatment centre, felt the amount of money

being transferred was far in excess of what they are paid to do the procedures:

> *Any strategic planning thrown into complete disarray by DoH decision to remove 20% of activity and to transfer what will amount to 50% of our funding to an independent sector who will build an endoscopy service. (17.1/159)*

The concerns over payment by result and the impact of endoscopy in primary care and the independent sector makes forward financial planning difficult for those trying to manage endoscopy units.

Summary – Financial resources

It is clear that financial resources are an ongoing concern in the majority of endoscopy units and there is tighter financial control than two years ago due to the financial crisis in the majority of Trusts. While there is an understanding of the need for careful control of finances (and once again recognition that some changes that can be made at no additional cost), there is clearly frustration that the lack of funding does place limitations on further development of the endoscopy service. Lack of funding restricts the appointment of additional staff, opening more endoscopy rooms, purchasing equipment and updating IT. The situation has also impacted on the ability of staff to attend study days and conferences. Nevertheless, staff continue to seek funding and go through the process of submitting business cases, some of which are successful.

There is concern about the future of the units with regard to the impact of 'payment by results' and the financial implications of endoscopy taking place in primary care or the independent sector, making planning for the future difficult. In spite of the concerns, however, it was felt that the GRS, NBCSP and the 18 week target have pushed endoscopy up the agenda in Trusts and have raised the profile of units. As a consequence, these services have been useful levers in acquiring funding.

9 Professional views at non-study sites

9.1 Executive summary

Four focus groups were conducted, the first (FG1) in England with non-participant endoscopy specialists who had not been involved in the study. The other three (FG2, FG3 and FG4) were in Wales with gastroenterology professionals who had no connection with the ENIGMA study, but were aware of the NHSMAs work.

9.1.1 Aim

The aim of the focus groups was to capture people's views on innovations in service delivery and organisation and to examine whether any of the issues raised by the group had resonance with other study data. In addition, the Welsh focus group data were considered in terms of overlapping themes and data resonance with the English focus group data and in addition, Welsh focus group participants' responses to the NHSMA's support for English endoscopy units and the impact change in England had had on Welsh units.

9.1.2 Participant groupings

FG1 comprised five gastroenterology professionals (four consultants one nurse researcher). FG2 comprised three participants, one endoscopy consultant and two endoscopy nurse specialists. FG3 comprised six participants (physicians and surgeons) and FG4 comprised six participants (physicians and surgeons).

Participants who took part in the Welsh focus groups represented hospitals across Wales, between Carmarthen and Merthyr Tydfil. Four of these hospitals were teaching hospitals. Participants were accessed through the British Society of Gastroenterology's (BSG) list of all registered gastroenterologists in the UK and were sent details of the study and the request to take part in a focus group. On the day of the focus group participants were reimbursed in recognition of their time.

9.1.3 Method

Each focus group followed a similar procedure, lasted approximately one hour and was tape recorded and transcribed. Focus groups were facilitated by the ENIGMA qualitative research lead (FR) or one of two senior research officers working on the study (AS, GJ). In each case an observer was present to take notes, manage the tape recording equipment and discuss their overall impression of the focus group with the facilitator at the end of the session. The focus groups were facilitated according to a pre-designed interview schedule. The same schedule was used for all focus groups with the Welsh groups having one additional question regarding the NHSMA's support for English units and the impact of change in English units on Welsh units. The interview schedule was devised to respond to the other qualitative datasets in the study, such as the professional interviews, and

concentrated on issues connected with: staffing, changes in units, funding, and barriers and facilitators to change. The focus groups enabled all participants to have an equal say in discussions, whilst many questions were directed to each participant in turn.

9.1.4 Analysis

Analysis was undertaken to derive first summative paragraphs from group analysis sessions and then a final paragraph that defined the main aspects of each focus group. Using the 'wholistic' (sic) approach to data analysis and management (van Manen 1990) , all summative workings attempted to capture the essential significance of the text. This approach was supported by in-depth examination by seven data analysts working as part of the ENIGMA team. The whole process was managed by the lead qualitative researcher with support from the two researcher officers.

9.1.5 Findings

Major themes arising suggest similar issues are of concern to both English and Welsh focus group participants and there was little variation across themes. Two of the three Welsh focus groups, in particular, presented a disappointed group of individuals, with disparate opinions, seeing recent changes in gastroenterology as predominantly for the worse.

The major points to arise concerned:

1) The lack of senior management understanding and management systems in place to appropriately support the work of the units. The lack of support and support systems meant units were unable to make appropriate and long-lasting changes to service delivery and organisation, whilst decisions towards modernisation were made by ill-informed management with neither scientific, clinically experienced nor evidence-based approaches to change. This was exacerbated by a lack of funding for necessary changes, particularly in Wales, and a general sense across English and Welsh groups of extensive resource deficit.

2) Resource deficits such as under staffing meant that those changes that had taken place, such as the investment in new equipment or the implementation of new procedures could not be best utilised. However, participants were keen to stress that in spite of lack of funding some positive changes had taken place such as pooling of lists that did not have resource implications, but most changes towards innovation and modernisation could not be undertaken without funding. This deficit de-motivated participants, as they felt their needs were not being recognised or met, particularly nursing staff, where training would enable them to take more responsibility, meet tasks more appropriately and take a stronger leadership role.

3) Staff – internal discord within units: There was also an awareness of discord between factional groups, both in England and Wales, and a sense of tribalism within units. Here different groups working in the same unit spaces were unhappy to accommodate each others' needs as a result of a sense of territorialism over patients and lack of communication between groups. This was most evident amongst surgeons and physicians, but also amongst junior and senior staff and between staff and managers.

4) Erosion of professional self-identity: Lack of recognition by senior management for the work of the units, lack of steer (particularly discussed in Welsh groups) from the Government, lack of match between political, managerial and unit agendas, low profile for endoscopy in the Trust, lack of support systems in place and factional discord led to disillusionment particularly amongst senior clinicians. It also led to an erosion of individual autonomy, whereby notions of professionalism linked to the individual's ability to make informed decisions that could impact on modernisation, was being undermined. This left a dispirited workforce, with low morale, perceived as employees rather than professionals. This could be countered, to some extent, by a few motivated individuals who tried to make a difference and were described by their colleagues as leaders in the field and by the excellent support of nursing staff and the good working relationships and team working within teams. Indeed, much progress had been made in terms of team working. However, particularly in Wales it would appear that sticking together was part of a 'sinking ship' mentality, where people cling to the same life raft, because all around is chaos, creates a sense of team commitment, integration and belongingness.

5) Patient focus versus Government targets: Where facilitators to change and their outcomes were mentioned, reduction in waiting times was of particular note. Interestingly however, this was rarely discussed in terms of patient benefit or changes to patient care or increased patient satisfaction. Rather, patients were noticeably absent from the conversations, and it was the need to meet Government targets, such as a reduction in waiting times, that drove change. From participants' narratives it became apparent that reduced waiting times, almost by default, are of primary benefit to patients.

6) Political Visibility of Gastroenterology: Participants mentioned the Global Rating Scale (GRS) and NHS Bowel Cancer Screening Programmes (NBCSP) as helping to bring more visibility and credibility to the work of the units, and they saw these initiatives as predominantly positive. There was also the opportunity that these initiatives would bring further funding to units and 'put units on the map'. Finally Welsh groups described Welsh units as lagging behind their English counterparts, though they were considered on a par when it came to services. To some, lagging behind was disadvantageous, whilst others spoke of the opportunity to learn from successes or mistakes following the changes that had been engendered in England through the work of the MA.

9.2 PART 1 - Focus Group 1: Non-participant endoscopy specialists in England

Part 1 describes a focus group that took place with a group of endoscopy specialists in England who did not participate in the ENIGMA study, neither as an Intervention or Control site. **Part 2** describes a further three focus groups that took place with endoscopy specialists in Wales to put the English focus group data into perspective. Each of the four focus groups will be discussed in turn. In both English and Welsh cases, each Part begins with a background section, followed by methods and group conduct and analysis. Each focus group starts with a summary of results followed by the major themes arising. A presentation of individual research analysts' summative analytic paragraphs can be found in Appendix 16.

9.2.1 Focus group 1: Background

On March 21st 2006 a one-hour focus group was conducted with five Gastroenterology professionals (4 consultants and 1 nurse researcher) representing five units from five Trusts and who were members of five different Endoscopy Units not directly involved in the ENIGMA study. The aim of the focus group was to capture their views on innovations in service delivery and organisation and to examine whether any of the issues raised by the group had resonance with other study data.

The study team felt it was important to talk to those not sponsored in any way by the NHSMA to gain an understanding of the barriers and achievements in units completely independent of the NHSMA. To facilitate this, details of the ENIGMA study were circulated to members of the BSG asking those who were committed to genuinely independent redesign of their gastroenterology services, to contribute to the study. Thirteen gastroenterologists responded and when contacted again, five of these were available to take part in the focus group.

The focus group was held halfway through the ENIGMA study. As these sites were independent of the NHSMA, the ENIGMA study team had not contacted them in the intervening period, so the extent of redesign in the sites was unknown. It was hoped that by the time the focus group was convened, the sites would have had sufficient time to have some experience of redesigning their gastroenterology services.

9.2.2 Method

The focus group was supported by an interview schedule comprising five key questions. These were derived from the literature and developed in line with study aims and interview schedules from previous interviews with key people and consultants in Control and Intervention sites. This ensured consistency within the data collected and enabled the team to consider any emergent cross-comparator themes. Issues covered included:

- Perceived facilitators and barriers to change;
- Changes made in units;
- The necessity for funding for innovation development;
- Staff responses to the introduction of change within and across services;
- The success of those changes that had been implemented.

A qualitative methodologist with expertise in focus group work facilitated the focus group (FR). A researcher took notes, and observed and recorded the session (AS). The facilitator was responsible for questioning the group and prompting for detail, the observer, for observing the session and taking notes about group interaction, body language and agreement or disagreement across topics. Both facilitator and observer discussed what had taken place at the end of the focus group and further insights were noted.

9.2.3 Analysis

Analysis was undertaken in accordance with an adapted analysis framework developed by the Dutch pedagogue, Max van Manen (van Manen 1990). van Manen describes his 'wholistic' or 'sententious' approach as a means of

encouraging summative paragraphs of text that capture a text's essential significance, before in-depth examination of data can take place. van Manen argues for the examination of meaning crystallised from the whole, rather than from small, workable portions of text. The sententious approach can be used with large or small data sets and concentrates how understanding can be drawn out into essential and non-essential themes, which are then codified. This approach involves both individual and group work. Individual researchers write a paragraph of text that is taken forward and reviewed by a group of research analysts. Researchers read each other's paragraphs and use the group session(s) to explore comparative themes and features that might be described as outliers within the text. Group discussions encourage sharing of ideas and reflect on the main impact of data towards a concordance of views.

Six researchers analysed the data individually and five were involved in one group analysis session discussing how text might be distilled into its essential properties. Thorough, in-depth examination of the data enabled the group to work towards individual and group summative paragraphs.

9.2.4 FG1

In line with the analysis process, results are presented in terms of the group's summative paragraph followed by a detailed examination of the main, emergent themes. Individual summative paragraphs have been included in Appendix 16.

9.2.5 FG1 Summary of results

Discordance between groups

There was some discordance identified between three groups of people: those supporting change or 'change hungry' innovators (such as a number of those people involved in the focus group interview), those colleagues with whom innovators came into contact who were resistant to change (such as surgeons), and managers.

Lack of cohesion

Differences were mentioned between the different groups of professionals, particularly doctors and nurses. Doctors were seen as more resistant to change, nurses as more compliant, though not universally so. Reasons for differences between these groups were related back to doctors' medical arrogance, the sense that they were already overburdened with work and clinician autonomy.

Positive changes

Changes that had been introduced that had made a difference included the pooling of lists, guidelines for patient management and referral and the new Nurse Endoscopist (NE) role.

Barriers to change

Focus group participants discussed many more barriers than facilitators to change. In addition, barriers to change were mentioned first, and the

Government, senior management and lack of resources came in for particular criticism.

Affecting real change

Frustration was strongly felt alongside a sense of failure to affect improvement. Improvement had been achieved, but there was the notion of failure to affect real change. Frustration was also linked to lack of resources and poor working relationships with management.

Lack of managerial support

As the keepers of resources, managers were perceived as needing to work more closely with the individual units to support their needs. Good management could help facilitate change whilst bad management could clearly discourage change.

Funding

Funding was critical for achieving change, but it was recognised that there was still an identified lack of resources for the purpose of innovation. Furthermore, there was the need to re-deploy resources to affect change.

Low staff morale

Low staff morale, resulting from staff pressure and stress, was in evidence. This was described as being exacerbated by an increase in referrals, the burden of extensive workloads and the manner in which change was introduced, without clear implementation strategies in place.

9.2.6 FG1 Results in detail: main themes arising

Discordance and lack of cohesion between professional groups

There was discordance between different groups of people in terms of their views of the need for change and innovation: change hungry innovators, those colleagues with whom innovators came into contact (such as consultants) and managers. This was exacerbated by a lack of cohesion between doctors and nurses. Doctors were considered the most awkward of the professional groups, ready to resist change within what was perceived as an environment dictated to by out-of-touch management. Doctors were particularly resistant to those changes relating to management agendas and unwilling to adapt to changes of which they did not approve. Doctors were more likely to respond to changes introduced by their peers with whom they came into regular contact and those changes that were part of a more gradual, accumulative process.

> *If you can get one or two clinicians on board then others start responding, if it's the right kind of environment and not dictated to by management (FG1.1).*

Doctors were described as overburdened by change, especially changes introduced 'through the back door'.

> *We feel saturated so that any other change that is brought on is seen as another thing we need to do (FG1.5).*

They saw themselves as at the pinnacle of their career and consequently powerful, autonomous individuals, most likely to know the necessities of their job.

> *We are trained to be autonomous individuals, we think quite highly of ourselves, or we did… through research and things we are encouraged to develop our own hypotheses and take things through. And all of that's being challenged… so it can feel a little bit like a nuclear attack (FG1.1).*

> *Doctors are trained in a certain way to be independent thinkers and to make decisions and to hold a view (FG1.2).*

Nurses were also perceived as resistant to change in certain circumstances, and this resistance had led to bad relationships with management.

> *There are limits up to where nurses will come on board as well (FG1.5).*

Poor management came in for criticism, seen to be discouraging change, even preventing it.

> *The main barrier is the management team (FG1.5).*

Managers were described as resistant to changes introduced by endoscopy professionals, unable to develop close working relationships with endoscopy professionals, unsupportive of individuals and determined to push through unpopular initiatives. Nevertheless, in different ways participants recognised that good management had the potential to facilitate change.

Facilitators and barriers to affecting real change

Focus group participants, with possibly one exception, were keen to express their support for the modernisation of endoscopy units, the improvement of services through change and the innovation of service delivery. However there were a number of recognised impediments to long-lasting change. Firstly, when asked to discuss changes that had been implemented, there was an expression of general scepticism, with barriers to change highlighted over and above facilitators to change. Secondly, many more barriers than facilitators were mentioned, and the Government, senior management and resources all came in for particular criticism.

> *Backlogs are getting even worse, being driven by Government directive rather than clinical need (FG1.3).*

Thirdly, there was little belief in those changes that had been introduced affecting any real change. Finally, there was discontentment at the speed with which changes were introduced and disappointment that those changes that had been introduced were time-limited.

> *It's not change that is the problem it's the rate of change – trying to get a BMW into a mini. What have we done? (FG1.3).*

Facilitators to change included: fast tracking of patients, more NEs, sensible targets, pooled lists, new guidelines for referral and management of endoscopies, prep nurses and more specialist staff. Longer waiting lists were also, paradoxically, seen as a facilitator for change, encouraging the generation of new resources and acting as impetus to the fulfilment of waiting list targets.

> *Longer waiting lists generate pressure on managers to put resources in to get rid of them (FG1.2).*

Nevertheless, lack of resources was still in evidence, alongside: lack of involvement by managers, staff's inability to overcome traditional working patterns and little agreement as to who should be leading on strategy in relation to innovation.

Funding

It would appear that much can be achieved within existing resources through greater efficiency, driven by targets, audit and guidelines, as well as changing roles, notwithstanding the feeling that funding is the main barrier to improvements. Indeed, the notion that not all change requires funding was defined in terms of professionals' ability to cleverly re-deploy funds and manipulate the service to meet their own goals.

> *You can out-manoeuvre a manager any day you like… I bet you've got yourself into trouble like we have because we're too good (FG1.3).*

However, re-deployment and manipulation was countered by the sense that Government driven initiatives and associated funding opportunities as well as poor resource decisions were undermining the power of the professionals to move forward and influence local need.

> *They have just completely redone the car park and employed two car park attendants to facilitate the patients arriving in the hospital… that is the sort of thing that gets intelligent little chaps like me a little bit flustered and wanting to give up (FG1.3).*

Funding was, nevertheless, seen as critical to achieving real change: "You have to invest a bit and that's where funding comes in" (FG1.2), and examples of where funding was particularly necessary, included: the appointment of extra staff, the purchase of new health and information technology, the replacement of old equipment, the payment of incentives, and the refurbishment of buildings.

Staff morale

Staff morale was described as being low, especially amongst doctors, a downside to change.

> *There is an attitude of suspicion (FG1.1).*

> *Nurse morale is really low and if they don't do something, they'll all be leaving (FG1.4).*

However, there was general agreement that changes had been effective and had led to greater efficiency, with people working more quickly but perhaps achieving less.

> *Our unit is more efficient than it used to be, bit more consistent (FG1.4).*
>
> *Maybe the numbers of referrals have gone up so much that we can't seem to be making any inroads (FG1.5).*

Change may be a good thing: *"I think they have worked well" (FG1.2)*, but this was often described as being at the expense of morale, which had worsened of late: *"They were good changes but it doesn't feel that way, I can't explain why" (FG1.5)*. There was also the sense that participants, though not directly involved, perceived the NHSMA Programme as being neither run smoothly nor well received. They commented that in general, professionals had been left with: *"all the responsibility and no authority" (FG1.5)*, failing to recognise improvements in their units and feeling that they were under attack. When Trusts functioned well and changes fitted in with the professionals' ways of working, the results were more effective. The group concluded that there needed to be better retention of staff, greater nurse engagement, less staff pressure and stress and fewer challenges to doctors' autonomy from management.

> *We found that nurses that are leaving through natural wastage are not being replaced, it's a deliberate act not to replace them (FG1.3).*

The sense of frustration and failure to affect improvement was strong and 'change fatigue' was in evidence, though there was also the hint that strong leadership and the application of change management is vital to progress.

9.2.7 Additional points of note

1. Although no questions were directly addressed about patient experience, patients were on the periphery of the conversation.

2. Innovations have been a success in terms of outcomes (speed of referral, waiting list reduction, improvements to the process of patient throughput). This must be tempered by anecdotal evidence of weak management, missed opportunities, poor relationships between professional groups and perceptions of misuse of funding.

3. Staff morale is low, but it is unclear whether this is as a result of failure to change or because of the impact of change.
4. Although the outcomes, such as lower waiting lists, may have been achieved from innovations to service delivery, this may be at the expense of staff motivation and staff morale.

5. The FG, supported by findings from first round interviews with patients and professionals, suggests that further detail needs to be elicited around the following issues:

- Whether the lowering of waiting times, which is seen as successful, is a result of innovations to service delivery and organisation.

- Which aspects of innovation are having a detrimental effect on staff morale, which appears to have worsened since the introduction of innovations?
- Why are innovations to service delivery and organisation not improving patient experiences, which appear to have remained unchanged since the introduction of innovations, with a generally positive outlook on endoscopy procedures and interventions?

9.3 Part 2 - Three focus groups with endoscopy specialists in Wales

9.3.1 Focus groups 2-4: Background

In October 2007 three one-hour focus groups were conducted with a total of 15 Gastroenterology professionals (13 consultants and two nurse practitioners) who were members of Welsh Endoscopy Units. As with the focus group we conducted with English Gastroenterology professionals, those representing Welsh units were not in any way involved in the ENIGMA study, which was evaluating the impact of the MES Project.

The aim of these three focus groups was to capture health professionals' views on innovations in service delivery and organisation in Wales, to gain an understanding of barriers to change and achievements in their units, and to examine whether issues raised by these participants reflected previous study data and to put the English focus group data into perspective.

To facilitate this work, a brief study background was circulated to all Welsh members of the BSG asking those who were committed to introducing changes and innovations within their gastroenterology services, to contribute to the study. Eighteen gastroenterology consultants and nurse practitioners consented to participate; 15 of these were available to attend one of the three focus groups.

Participants represented GI units in nine different hospitals in Wales. Across the total sample of 15, one unit was represented by four participants, a further three units were represented by two participants each, and the five remaining units were represented by one person each. Three professionals participated in the first focus group, six in the second and six in the third. Each of the focus groups was recorded with a digital voice recorder and a minidisk recorder for later transcription. The first and last of the focus groups was facilitated by the lead qualitative researcher (FR), with a research officer (GJ) present to observe and take notes; the second group was facilitated by a research officer (GJ) and an observer was present to take notes (AS). On all occasions, focus group participants were very open and willing to talk about their work and their units.

9.3.2 Method

To uphold consistency across study sites, the methods of data collection were similar and reflected our previous work in England. The same interview schedule was also adopted across all three groups, covering:

- Perceived facilitators and barriers to change;
- Changes made in units;
- The necessity for funding for innovation and other developments;

- Staff responses to the introduction of change within and across services;
- The success of those changes implemented.

In a change to the focus group schedule used with the English group (see Appendix 17), in Wales we also explored:

- Responses to the NHSMA's support for English Endoscopy units;
- The impact that changes to English units made on Welsh units.

9.3.3 Analysis

Analysis followed much the same approach as the English focus group. Groupwork, involving seven members of the ENIGMA team, lead to summative paragraphs of text from each analyst to capture the essential significance of the transcript. The group then met to read and discuss each other's summative paragraphs, and to work towards a definitive understanding of the focus group content. Three one-hour discussion groups were held, one for each of the focus groups. At each session, the team's individual work was considered and discussed. The analysis group was facilitated by the lead qualitative researcher (FR), whose job it was to direct and support the group. However, the team were fully involved in defining the final output and were in general accord with each other throughout the process. Where disagreements arose, the group worked towards a final consensus position.

Prior to the analysis meetings the lead researcher conducted a basic synthesis exercise of all individual summative paragraphs. The synthesis was presented in bullet-point form at the beginning of each group analysis session. The synthesis identified major points of agreement across the group and points that only some of the seven individuals had raised. The sessions considered each point in turn and the relationship between each issue.

The results of the analytic process will be presented in the order in which the focus groups were transcribed and analysed. In view of the English focus group (FG1), the three Welsh focus groups will be defined as FG2, FG3 and FG4.

9.3.4 FG2

This focus group comprised three participants, two NEs and an Endoscopy Specialist working in Gastroenterology. All were keen to participate fully and discussed issues raised in detail and with high levels of agreement across the group.

9.3.5 FG2 Summary of results

Participants in this focus group, two nurses and an endoscopy specialist were in agreement that the major changes that had been made to their units were process-orientated, most specifically a reduction in waiting lists. Money was of major concern to all three, particularly in light of the expenditure needed for the GRS and Bowel Cancer Screening Services, but some changes had been undertaken that were not dependent on resource availability and these were considered a great success. Participants were proud of the services they could offer and noted that in spite of problems between groups within the unit (particularly the territoriality of surgeons

and physicians), the units were working as a group in a more integrated way, with pooled lists supporting that approach. The participants would have liked more recognition from the Trusts in which they worked and from external sources, and would have liked to be recognised for the hard work undertaken in their units. However, they realised that endoscopy was not perceived as a priority area. Participants looked to their English counterparts, were aware of the innovative changes and modernisation that was going on across the border and had learned from the positive aspects of those changes. They were also wary of making the mistakes their English colleagues had made and wished to guard against following in their footsteps in that respect.

9.3.6 FG2 Results in detail: Main themes arising

Resources

Participants recognised that limited resources were available for the modernisation process to be successful or sustainable. Changes had been made that were predominantly resource neutral, however the GRS, as a significant driver for change, would demand resources if it were to be sustainable: *"I don't think we can do GRS without any money" (FG2.1).* All three participants suggested that lack of money was a major barrier to change and that the small amounts of money units had already received from their Trusts and other agencies had not gone far enough in supporting them in any substantial way: *"with the bowel cancer screening and so on coming in we really need finances" (FG2.2).*

Improvements in units

Despite the limited financial support, Welsh Gastroenterology units had been able to address a range of issues towards an improved service, including: long waiting lists, lack of communication between staff particularly surgeons and physicians and poor performance. Their ability to address these issues resulted from changes to the service through better-managed and nurse-led approaches: *"the prime movers here are the nurses" (FG2.3)*. Improved workflow, changing roles and validated waiting lists had led to pooling of lists, a drop in waiting times and less territoriality over patients: *"doctors have become far less territorial over their patients" (FG2.1)*. Of all the changes mentioned, however, reduction in waiting times was seen as having the most impact. Interestingly, there was little mention of quality of care or patient benefit and the changes described were process oriented. In addition, they were predominantly of a reactive rather than a proactive nature, responding to external factors such as audits, the GRS and seeing late cancers.

Barriers to change

Improvements to service organisation and delivery were hindered by problems of poor skill mix, bad leadership and a lack of good team working as well as an opposition to change from across the different groups of professionals within the unit: *"pulling all those people together and managing change is very difficult" (FG2.2)*. Furthermore, the absence of a National Service Framework for gastroenterology, the additional workload brought about by the GRS and Bowel Cancer Screening, poor quality information from GPs regarding the prioritisation of patients for referral, and a lack of interest at an executive level, did not engender a sense of worth.

The participants commented on the fact that gastroenterology was not seen as a high priority area and did not carry a high profile in terms of its cutting edge work. As a consequence, gastroenterology was nowhere near the top of the funding list within the Trusts. This sense of low priority was exacerbated by senior managerial inertia: *"endoscopy as an area was never effectively managed" (FG2.1)*, lack of support from external sources such as the Welsh Assembly Government and discord within units.

Facilitators for change

Despite these obstacles, focus group participants were keen to emphasise the high level of camaraderie across Welsh units, the close links between units, the strongly supportive nursing teams and the positive steps some of the staff members were taking towards improved services: *"I think the community in Wales is strong and we do work well together" (FG2.1)*. Although there was little discussion of the nature of patient benefits and what was meant by 'improved quality care', they noted the need to work towards a patient focused agenda to improve the patient experience. This was at odds with the weight of discussion concentrating on service re-evaluation towards performance-related goals and targets (for example, one of the participants mentioned that they were proud of being able to keep their waiting times for patients down to below one month for two years): *"waiting lists have gone from 18 months to three weeks" (FG2.1).*

Performance

With the performance-related activities in mind, the three participants reported wide variation in performance for endoscopy across their units, reflecting not only variation in approach to modernisation, but slow movement towards change due, in part from fractured units, with enthusiasm from some professional groups and opposition from others: *"its all happening slowly, taking small steps" (FG2.2)*.

The Welsh perspective

There was a strong sense that participants considered Welsh units lacked recognition amongst the wider healthcare community for the excellent work they were doing and the changes they had already made towards an improved service. They were sceptical that funding and other resources would be made available from external sources, and emphasised that they were lagging behind their English counterparts. The changes made in English units, as a result of the work of the NHSMA, were described in predominantly positive terms, whilst the Welsh units were happy to learn from their successes and avoid repeating their failures. *"We have learnt good things and bad things especially the waiting list management, patient care, patient information, nursing care and so on and I think for us in Wales that helped us immensely" (FG2.2)*. Indeed, it was considered that being one step behind English Gastroenterology units meant that you could guard against making the same mistakes that they have made.

9.3.7 FG3

This Focus Group comprised a good mix of six specialists in gastroenterology, though all were doctors. Participants represented three units in three different Trusts in Wales.

9.3.8 FG3 Summary of results

This was a group of doctors keen to highlight their discomfort with changes that had been brought about through a management-led agenda. They discussed a range of barriers to change and some facilitators, such as motivated colleagues. The group were generally negative about changes in their units, identifying rifts between groups of physicians and surgeons, lack of training for staff, particularly nurses, and understaffing, all of which created considerable pressure for staff. Some hoped the GRS would raise the profile of endoscopy within their Trusts, but neither the GRS nor the NBCSPs featured extensively in this focus group. Lack of funding was an ongoing problem. Some changes were in evidence without finances, brought about through the efforts of a few motivated individuals prepared to lead others and instil an ethos of modernisation in their units. However, without budgetary power and with resource deficits, there was always going to be limitations to what could be achieved. This, along with little understanding from senior management about the needs of endoscopy units and their staff had led to a deflated workforce, whose sense of professionalism and status was being eroded in favour of Government-driven targets instigated within a top-down, managerial environment. Wales was lagging behind England in many respects in terms of patient care, funding and facilities, but it could still hold its own in respect to clinical outcomes, and was learning not to make the mistakes of English counterparts leading change, as a result of the NHSMA's agenda.

9.3.9 FG3 Results in detail: Main themes arising

Loss of autonomy and erosion of professionalism

The transcript presented a coherent group who saw recent changes in gastroenterology as generally for the worse. The dominant theme emerging was about the distrust and dislike felt for management, resulting from NHS Trusts in Wales being target-driven organisations, failing to base decisions on clinical knowledge or experience. The adverse consequence of managerial decisions was loss of autonomy for the senior staff: *"clinical autonomy has gone" (FG3.3)*. In addition, top-down decision-making was to the detriment of both endoscopy teams and the unit as a whole. Loss of autonomy was played out through people's evolving roles, the erosion of professionalism and loss of conventional function. Loss of autonomy led to clinicians feeling disengaged and being less flexible, and nurses spending less time caring for patients due to increasing bureaucratic demands. Participants commented on professionals being seen as mere employees rather than health professionals; a change in professional identity that caused despair and great frustration:

> *If you want my Damascus moment, when somebody came back from a meeting sitting alongside a hospital administrator who said that consultants as far as managers are concerned are really on the level of a store manager. (FG3.2)*

> *We are now, I think, seen as employees rather than professionals. (FG3.5)*

Facilitators and barriers to change

As with FG2, in this focus group participants concentrated on a reduction in waiting times as the main outcome of facilitators for change such as pooled lists and flexible staff working. *"Our waiting list has dropped a lot" (FG3.4)*. However, this was not discussed in terms of better patient care or enhanced quality of care. Indeed, patient outcomes, greater patient satisfaction with services, patient-centred care or change for the good of the patient were predominantly absent from the conversation. Rather, reduced waiting times were discussed in terms of meeting Government targets for improved service provision and as something easily measured. However, reduction in waiting times was a double-edged sword, and the participants realised that the targets driving clinicians to treat 'two week referral' patients were at the expense of other patients on the waiting list. This created: *"a depressed atmosphere" and "distressing times" (FG3.1)* and led to healthcare services that: *"lose the plot in basic patient care" (FG3.4)*. It was noted that the implementation of the new consultant contract led to a decrease in working hours and consequently the quality of patient care that could be offered.

Other facilitators to change included: committed and motivated team members who worked towards new ways of organising, managing and delivering services such as pooled lists. The group were unsure whether the NBCSP or GRS was going to have a positive impact on the unit, and Trust mergers had unknown implications. The group agreed that the decisions about some mergers were badly informed. Nevertheless, the manner in which the merger had taken place, clearly politically aligned with little involvement of endoscopy staff, was a point of great contention. The group was also unhappy about other decisions that had been made by management without their input, such as how doctors' training was going to take place. Without clinician involvement, management were less well placed to make such decisions: *"…there have been quite a few things, not so much from the science but from the dictate of managers and politicians we have now suffered immensely with training issues" (FG3.1)*. The GRS did not play a large part in this focus group, and was neither discussed in terms of a facilitator or a barrier to change, however, on the occasions it was mentioned it was clearly giving units more visibility in Trusts.

Funding

Funding was not seen as a huge catalyst for change. Furthermore, there were changes that could be implemented and were effective with little cost implication attached, such as pooled lists. Nevertheless, lack of funding was a barrier to change along with Government and Trust-driven initiatives (politicians setting Trust targets). Lack of funding had led to badly informed decisions and financial problems: *"Well I suppose funding has to be a major problem" (FG3.2)*. Badly informed decisions were twofold. Firstly there were the decisions at Trust level, such as the Trust mergers. Secondly there were decisions at the individual level, with questions raised as to whether patients had a better health status as a result of funding new services:

> *I think we are losing the plot really certainly in the hospitals I go to seeing elderly patients left on trolleys alone in various departments without a nurse or attendant we may have high powered CT scanners or MRI scans or endoscopy in our units but I think there is the danger we are loosing the plot of basic care of the patient. (FG3.4)*

The group were quick to recognise individuals who had been proactive in acquiring funding, including some of those in the focus group, who, despite limited resources and the financial ambivalence of Trust managers could bring about change. Indeed, changes that came from within were considered to have more impact and more positive.

The link to evidence-based decisions was made and it was asked why Trust management decisions affecting clinical processes are not based on evidence:

> *In practical treatment the changes we want to bring have to be evidence based. I cannot suddenly go and do something to a patient which I think is right irrespective of what the data shows. But changes are applied to us through the political and management system and there is no evidence to do it… so changes from our point of view should be evidence based and we should expect the same from the managerial point. They tell us change – show us evidenced data saying that change is good for you. (FG3.1)*

It was the individuals who were enforcing positive change based on good-science, driven by a desire to make a difference, that were the real facilitators for change. Individuals with a creative outlook could make things happen irrespective of funding, had the greatest chance of benefiting the unit:

> *People are inventing and going forward. (FG3.1)*
>
> *Colleagues with their new ideas and sort of sharing knowledge, going to conferences and courses. (FG3.6)*

Staff relationships

Difficult relationships existed within the units, not so much amongst nursing and administrative staff, but amongst different groups of staff working in the same space, such as physicians and surgeons. Difficult relationships also existed between junior staff and consultants, and between unit staff and Trust management. *"Relations with junior staff and others are difficult… junior staff come to a radiology department often having no knowledge of a particular patient" (FG3.4)*.

Trust management curtailed research, offered insufficient staff training, recruited the wrong sort of people, made uninformed decisions on behalf of the unit and dictated change. This led to factions and discord amongst groups: *"recruiting the right sort of people has been a problem at the moment" (FG3.2)*.

> *…we're looking for a specialist nurse in gastroenterology for some time and we have not been able to do that…unless it is a political priority in the Trust, they wouldn't buy that, while they will spend a lot of money on things you know is not going to bring enough benefit. (FG3.3)*

Better communication, raised morale, greater staff autonomy and better training were all opportunities for resolving some of these difficulties.

The Welsh perspective

The Welsh units were said to be lagging behind their English counterparts in terms of strategic vision, resource availability, Government and Trust support (including financial support), good management, colorectal screening and technical development. In addition, change was at a slower pace in Wales.

> *We are lagging behind – the waiting times in England are much better than in Wales. Colorectal cancer screening we are lagging probably two years behind, and some of the technological developments again we are lagging behind, but funding hasn't been as much because that wasn't the agenda of the modernising agency. (FG3.6)*

However, in spite of lagging behind England and changes taking effect at a slower pace, no major differences were mentioned regarding clinical outcomes, and Welsh units were possibly seen as better off from the medical perspective. Furthermore, Welsh units were at an advantage in being able to learn from the mistakes of the English units: *"I think Welsh gastroenterology is quite robust" (FG3.1)*.

9.3.10 FG4

This focus group was held with six doctors representing five units across three Trusts in Wales. This was a difficult group to summarise, with outspoken individuals offering very diverse and predominantly negative views. Indeed, there was more diversity of opinion in this focus group than in the other three focus groups, whilst much of the discussion highlighted the difficulties units faced rather than discussing modernisation within the units. This diversity of opinion and careful choice of issues discussed may reflect the hierarchical structure of this particular focus group, with one participating Medical Director and a number of people professionally associated with this person.

9.3.11 FG4 Summary of results

The tone of this focus group, which comprised six doctors working across endoscopy units in Wales, was predominantly negative. Doctors spoke of disempowerment of staff, lack of staff cohesion and lack of the ability within units to bring about the changes necessary to modernise. In addition, it was noted that the geography and population in Wales poses difficulties for training in general and in relation to specialisation. Whilst endoscopy teams worked well together, factions were evident between surgeons and medical specialties and clinicians and managers. In addition, team members looked after one another but as part of a 'sinking ship' mentality. They were answerable to management they disliked and distrusted and working within managerial systems that were failing them. Management was seen as making inappropriate, ill-informed decisions that did not best serve the interests of the units and units lacked the visibility to make a difference. Consequently, few positive changes were mentioned other than the GRS and NBCSP, which it was hoped would bring future change and raise the profile of endoscopy. However, it was still unclear how these would impact in the long run to ensure positive change for patients. Necessary funding was lacking and when initiatives had been funded, spending on the infrastructure required to support them, was not forthcoming. This resulted

in units that lacked staff, or sufficiently skilled and well-trained staff to make autonomous decisions and take any sort of leadership role.

9.3.12 Results in detail: Major themes arising

Management and management systems: As with the other focus groups in Wales, this group commented on a range of conflicting interests, both between groups within units, such as surgical and medical specialties, and between clinicians and managers: *"I think historically, if you look at the way endoscopy services sit in most Trusts they don't sit very easily in one service group" (FG4.4)*. Conflicting interests between units and management was a particular barrier to change and both management and management systems came up for considerable criticism throughout. Trust management were seen as not in tune with the needs of units, reactionary and distrusted: *"management have their own agenda in terms of fulfilling their local delivery plans to the LHBs [Local Health Boards]" (FG4.4).* New, target-driven, political and managerial directives had the effect of engendering bureaucracy and legislation and creating large amounts of paperwork, particularly where nursing staff were concerned. In addition, there were difficulties convincing Trust management of the importance of endoscopy, problems of pulling together different specialties using the same spaces and getting through the many layers of managerial red tape.

If management were supportive of change, then change was effected, but this was often in the context of crisis management: *"This is a reactionary, entirety management when the crisis arises" (FG4.1)*. Management systems were described as an: *"enormous and complex labyrinth" (FG4.2)*, with middle managers pressurised from senior management to reach targets and clinicians wanting to bring about change but in their own way, without targets attached. Distrust of management was exacerbated by lack of communication between clinicians and Trust managers leading to a heightened sense of frustration and futility. To pass through management structures and get changes approved and funded was complex, and often decisions were being made that were not based on clinical or medical expertise:

> *We were left to the same hierarchy that's there in terms of "go up to the unit management up to where the next management is". It would never have gone forward at all but as it happens, because of having bypassed that to come from top down, it seems to have moved forward at least to a reasonable extent. (FG4.4)*

Barriers and facilitators to change

Alongside the major barriers surrounding management and management structures, other myriad barriers to change suffused the focus group with the mention of facilitators to change, a rare occurrence. When facilitators were noted, they were mainly around the GRS and NBCSP, which it was hoped would raise the profile of the units. However it was felt that politicians had not acknowledged the extent to which change was required within gastroenterology, if Bowel Cancer Screening and the GRS were to be properly implemented.

Barriers to change covered a wide range of areas, including: training in endoscopy, the problems of gastroenterology spanning medicine and surgery, the lack of a National Service Framework in gastroenterology, staffing deficits, staff deskilling, clinical workload, lack of secretarial support

and the need for gastroenterology to be: *"politically visible" (FG4.6)*. Under-staffed units and staff deskilling were of particular concern, both for nurses and consultants. Thus, whilst expansion had been helpful, units appeared to be running without their full complement of staff with no major drives to recruit additional staff. In addition, greater staff specialism suggests some erosion to the professional 'all-rounder' role, different specialties are working according to their own individual agendas and people are unsure who should be taking on which tasks:

> *I would like to see a Welsh health strategy that decides what's being done where so it actually happens to certain things and certain places with enough people to do it sufficiently specialised and not everybody trying to do everything everywhere. (FG4.2)*

Endoscopy staff

Endoscopy staff were described as dedicated and supportive, working well as a team and, as a result of some of the more positive changes that had occurred such as the introduction of the GRS, recognising the value of team working. However there was still concern about low staff morale due to stress, indicated by high levels of staff absence and staff turnover, and although the team stuck together and supported each other – all in the same predicament – they were described as: *"People clinging to a life raft. They stick together because there is only one life raft" (FG4.2)*. This sense of being part of a sinking ship was described as follows:

> *They feel under the cosh, and I think it's because they feel under the cosh that they pull together in slightly adverse circumstances to work as a team and they don't want to let each other down because they are working in a closely-knit community (FG4.3)*

Doctors recognised the invaluable role dedicated nurses in the unit played, but at the same time talked of lack of nurse leadership, lack of authority amongst nursing staff and lack of role models for junior staff. Lack of authority bore a strong relationship to the many managerial problems mentioned above, with nursing staff neither given the power to be autonomous and make decisions for themselves nor provided with: *"an environment in which they can flourish and develop" (FG4.2)*.

Investment in endoscopy

Focus group participants described endoscopy services as disadvantaged. Not only were they a low priority for investment, Trusts failed to consult widely to use their investments wisely. Although Trusts had invested in some new equipment and facilities, for example, these were not necessarily the most essential investments that units needed. The sense of inappropriate investment was heightened by a lack of investment services and people. Indeed, the group could only think of one change to services that did not need extra funding and this was 'pooled lists'. New posts were clearly short of money and as a consequence Welsh units lagged behind their English counterparts: *"I just feel that Wales has been lagging behind far too long and it does need a kick up its pants to change things" (FG4.1)*. As with other focus group participants, English units were described as one step ahead of Welsh units and without the necessary funding, Welsh units would not be able to provide the same services or achieve the appropriate number of jobs: *"we have to acknowledge that there is just a difference in*

the resourcing in the English hospitals" (FG4.3). In spite of this, good clinical practice was still in evidence in Wales. With funding shortages, facilities that had been invested in could not be properly utilised and without the necessary staff in place, management were supporting change to the detriment of people. It was mentioned that some changes could be made without funding and that some funding was obtained through external sources. Consultant funding, for example was ensured, whilst other staff funding was not always in place:

> *We've had funding from the local health board for purchasing equipment but unfortunately we haven't got quite the staffing to open a second room full time at the moment so but it isn't all sweetness and light but we're getting there slowly. (FG4.6)*

9.4 Summary

These four focus groups with non-participants in Intervention or Control groups presented very similar data to all the other elements of qualitative data capture for ENIGMA, namely interviews with professionals and patients in Intervention and Control groups. The one area where data differed was in terms of Welsh participants' responses to the MA work in England and its impact on their English counterparts and their work procedures. It also highlighted Welsh participants' views of the changes that had taken place in England in relation to Wales. In this respect, the focus group data opened up the picture across localities and countries, highlighting that Welsh units felt on a par with England in terms of the standard of services provided but lagged behind in terms of modernising units and were disadvantaged in terms of the resource provision for new staff and greater staff training. Resource deficits were perceived as having a negative impact on Welsh units' ability to make the necessary changes to benefit staff and patients and to optimise service organisation and delivery.

van Manen's "wholistic" or "sententious" approach, which we adapted for the purpose of the analysis of focus groups, proved both timely and appropriate to group working practices across a large team of researchers and academics. It enabled the team to work both on an individual and group basis, to meet on a number of occasions through informal and formal group work, to clarify extensive, in-depth datasets and to reach consensus of opinion over the essentiality of the datasets. The approach is inclusive and with leadership and support can be used to encourage those with either a basic or advanced understanding of qualitative analytic frameworks to work together to achieve thorough codification, clarification and interpretative presentation. The approach is versatile, adaptive and easy to teach and comprehend. It can be applied as effectively to face-to-face interview data as it can to focus group data, indeed, to any textual qualitative data format. As a result, the analysis techniques we employed have far reaching possibilities for application to a range of large-scale mixed-method studies including trials.

10 GP views at study sites

10.1 Executive summary

10.1.1 Objectives

To compare General Practitioner (GP) views of changes in endoscopy services between those who referred patients to the Intervention sites with those who referred to the Control sites.

10.1.2 Methods

Questionnaires were sent to GPs who had at least one patient in ENIGMA. Responding and non-responding GPs were compared by gender, practice types and the types of unit they referred patients. GPs were asked whether they perceived a change in endoscopy services, and whether those changes improved 10 specific aspects of and the service overall.

10.1.3 Results

682 of 1979 eligible GPs completed the questionnaire (35%). There was no significant difference between responding and non-responding GPs. No significant difference was found in GP awareness of service changes between intervention and control group. More GPs thought changes made by the control sites led to better services in nine of the 10 specific aspects of endoscopy services but these did not reach statistical significance.

10.1.4 Implications

There were indications that GPs thought units without MES funding were able to achieve a similar, if not higher level of service improvement. More research is needed because of the unexpected findings.

10.2 Introduction

The MES programme facilitated modernisation of twenty-six NHS endoscopy units in England. The study assessed impact of the MES programme by comparing 10 MES-funded sites (Intervention sites) with 10 Control sites who redesigned their endoscopy services independently.

The ENIGMA brief included estimating:

- the acceptability of service delivery to professionals in primary care and their perception of the value of the models
- the outcomes as assessed by professionals in primary care.

This chapter described how the research team addressed these aspects of the ENIGMA brief and the findings about GP views of the impact of the MES programme.

10.3 Objectives

The current survey aimed to compare GP awareness and rating of changes in endoscopy services between those who referred patients to the Intervention sites with those who referred to the Control sites. The areas of enquiry included changes in: access to endoscopy services; waiting times; communication from secondary; demands on primary care and GP views of endoscopy services overall.

10.4 Method

10.4.1 Population

The study group comprised of GPs with at least one ENIGMA patient who had given consent for their GPs to be contacted. GPs referring patients to Hospital 10 and 18 were included, although these sites had been excluded from other aspects of the ENIGMA study.

10.4.2 Survey Design

GP views were collected through postal survey by a semi-structured questionnaire with closed and open-ended questions. Only one questionnaire per GP was sent, irrespective of the number of patients they had in the ENIGMA study. Questionnaires were sent out between November 2006 and February 2007. A reminder letter and questionnaire was sent if there was no response after three weeks. The deadline for completion was the end of April 2007.

10.4.3 Development of the questionnaire

The questionnaire was designed by the Project Steering Committee which consisted of gastroenterologists, experts in quantitative and qualitative methodologists, health economists and researchers. Six GPs based in the School of Medicine at Swansea University were interviewed with this questionnaire to test the layout, wording and GP understanding of the questions. Minor amendments were made to the questionnaire.

The amended questionnaire was piloted with GPs within the Neath & Port Talbot Hospital catchment area to test its use as a postal questionnaire. Out of the seventy-seven pilot questionnaires sent, 29 were returned. There were some inconsistencies in the way GPs completed the questionnaire. Further amendments were made with the advice of two GPs based in the School of Medicine at Swansea University.

The GP questionnaire asked respondents whether they had perceived any changes to 10 specific aspects of the endoscopy services delivered by the study hospitals. GPs were then asked to rate the changes as "Better", "Neither better nor worse" or "Worse". They were also invited to give free text comments to elaborate their answers (see Appendix 18).

10.5 Analysis

10.5.1 Non-respondent analysis

The proportion of GP Responders and GP Non-responders were compared to determine whether there were any significant differences in response rate for Site type (Intervention or Control), GP Gender and Size of practice (single-handed or Group). This was assessed by Pearson's Chi-squared (χ^2) tests. Possible interactive effects between Site type and GP gender or Practice size on response rate were assessed by hierarchical log linear analysis. If significant differences were found, the weighting of the answers from any under-represented group(s) would be adjusted to minimise possible bias.

10.5.2 Quantitative analysis of questionnaire response

Although information was collected from individual GPs, the purpose of the enquiry was to find out their perceptions of changes in endoscopy services delivered by the study hospitals. As the service changes were introduced by the hospital, all GPs making referrals to a study hospital were subjected to the same set of changes. There would be more than one GP making referrals to one study hospital, but the data collected from individual GPs were multiple observations of that hospital. Several techniques existed which explicitly took account of this multiplicity (Bland and Kerry 1997). A simple approach to analyse such data was to construct a summary statistic where GP observations of individual hospitals was weighted by the number of GPs making referrals to that hospital (Kerry and Bland 1998). As the hospitals were randomised to Intervention and Control groups, differences between the study groups would be assessed with a weighted two sample t test (Bland and Kerry 1998). This approach had the advantage of simplicity and the calculation of the weighted means, sums of squares and 95% Confidence Interval were published (Bland and Kerry 1998).

10.5.3 Qualitative analysis of questionnaire response

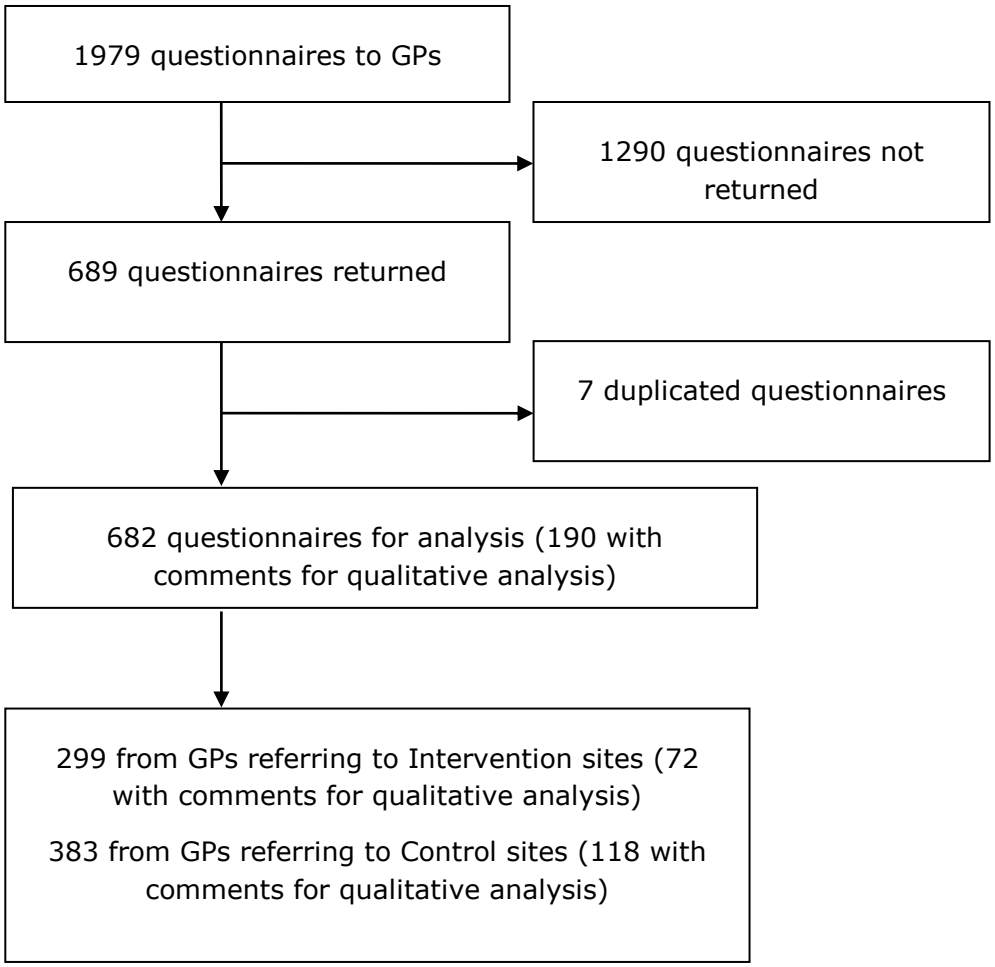
All questionnaires that included a written comment in the blank box at the end of the questionnaire were included in the qualitative analysis. Data were analysed using content analysis techniques. This method enables the reduction of qualitative data to manageable portions of text that can be analysed by searching for patterns and themes in the data. The researcher read the comments and developed a coding system. The remaining comments were then read to ensure complete coding of the full dataset. The coding system was also used to count the number of instances that reportage adhered to each category (Silverman 2001) and for differences and similarities between intervention and control sites. This process established the following emergent themes: accessing endoscopy, waiting times and communication relating to an endoscopic procedure.

10.6 Results

There were 1979 eligible GPs for inclusion in the study, 689 GPs completed and returned their questionnaires. However, there were seven GPs who returned duplicate questionnaires. After removing the duplicates, there were

682 questionnaires to be analysed (34.46%). Of these, 299 (72 with qualitative comments) were from GPs referring to Intervention sites and 383 (118 with qualitative comments) were from GPs referring to Control sites (see Figure 28).

Figure 28. Flowchart of GP recruitment for questionnaire analysis



10.6.1 Findings from non-respondent analysis

There was no significant difference between GP Responders and GP Non-responders (Table 63) for Site type ($\chi^2 = 0.836$, $p = 0.361$), Gender ($\chi^2 = 0.488$, $p = 0.485$) or Size of practice ($\chi^2 = 3.334$, $p = 0.068$).

Table 63. Profile of Responding and Non-responding GPs

	Responders % (n)	Non-responders % (n)	P value
Site type			0.361
Intervention	33.3 (299)	66.7 (598)	
Control	35.4 (383)	64.6 (699)	
Size of practice			0.068
Single-handed	25.8 (23)	74.2 (66)	
Group	35.9 (644) (	64.1 (1149)	
Gender			0.485
Male	36.8 (434)	63.2 (746)	
Female	38.7 (213)	61.3 (338)	

Hierarchical loglinear analysis showed a small interactive effect between Site type and Size of practice on GP response rate (Likelihood Chi-square change if this effect is deleted from the saturated model = 3.904, p =0.0482). Table 64 showed that the percentage of GPs from Single-handed practice making referrals to the Control sites returning the questionnaires was low (15.8%) as compared to GPs in the other categories. However, only about 3.7% of eligible GPs who used Control sites came from Single-handed practices (38 out of 1027). Data was not weighted by practice size in subsequent analysis.

Table 64. Percentage of eligible GPs returning the questionnaire, classified by Practice size and Site-type

	Intervention % (respondents / total)	Control % (respondents / total)
GPs from Single-handed practices (n=89)	33.3% (17/51)	15.8% (6/38)
GPs from Group practices (n=1793)	34.3% (276/804)	37.2% (368/989)
Total number of eligible GPs	855	1027

*There were 97 GPs with no information on Practice size

10.6.2 Findings from quantitative analysis of questionnaire response

The 682 GP respondents made referrals to 20 study sites (Intervention: 10, Control: 10). Number of GPs making referrals to the same study site ranged from four to 54.

Percentage of respondents who explicitly said in the questionnaire that they saw changes in various aspects of endoscopy services ranged from 23% (communication from secondary care concerning complications) to 55% (speed of referral). There were also some GPs who did not explicitly say they saw changes in endoscopy services but went on to give their views about whether the service had improved. These GPs were considered to be implicitly saying that they were aware of some changes. Including the

implicit responses, percentage of GPs who perceived a change in endoscopy services ranged from 47% (communication from secondary care concerning complications) to 73% (speed of referral) (Table 65). To ensure full use of the data, the implicit responses were included in subsequent analysis.

Table 65. Percentage of GPs perceiving a change in specific aspects of endoscopy services and types of response

N=682	Percentage of GPs who said they saw a change		
	Explicitly % (n)	Implicitly % (n)	Total % (n)
Way referrals made into unit	52.05 (355)	17.74 (121)	69.79 (476)
Understanding of prioritisation	37.54 (256)	20.97 (143)	58.50 (399)
Outcome of prioritisation process	36.07 (246)	20.53(140)	56.60 (386)
Speed of referral in terms of access	54.69 (373)	18.77 (128)	73.46 (501)
Information from 2º care following referral	47.51 (324)	24.05 (164)	71.55 (488)
% patients requesting further GP appointments	34.02 (232)	21.41 (146)	55.43 (378)
Communication from 2º care – outcome of endoscopy	45.60 (311)	20.82. (142)	66.42 (453)
Communication from 2º care – final diagnosis	39.88 (272)	23.75 (162)	63.63 (434)
Communication from 2º care – complications	23.17 (158)	24.05 (164)	47.21 (322)
Communication from 2º care – treatment initiated	36.07 (246)	22.29 (152)	58.36 (398)

Percentage of GPs perceiving a change in specific aspect of endoscopy service ranged from 48% to 73% for those who made referrals to intervention sites and ranged from 47% to 74% for those who made referrals to the control sites. No significant difference was found in GP awareness of service changes between intervention and control group after weighting for number of GPs who made referrals to the same hospital (Table 66).

Table 66. Differences in GP awareness of service changes between Intervention and Control groups (Weighted by number of GPs making referrals to various study sites)

Perceiving a change in:	Weighted mean percentage		Diff in means (95% CI)	P value
	Intervention Max n = 299	Control Max n = 383		
Way referrals made into unit	68.56	70.76	-2.19 (-10.99, 6.59)	0.61
Understanding of prioritisation	59.87	57.44	2.42 (-5.43, 10.28)	0.52
Outcome of prioritisation process	56.52	56.66	-0.14 (-8.73, 8.46)	0.97
Speed of referral in terms of access	72.24	74.41	-2.17 (-10.98, 6.63)	0.61
Information from 2º care following referral	72.91	70.50	2.41 (-5.55, 10.38)	0.53
% patients requesting further GP appointments	56.86	54.31	2.55 (-5.45, 10.55)	0.51
Communication from 2º care – outcome of endoscopy	65.22	67.36	-2.14 (-12.49, 8.20)	0.67
Communication from 2º care – final diagnosis	62.88	64.23	-1.35 (-10.29, 7.58)	0.75
Communication from 2º care – complications	48.16	46.48	1.69 (-5.32, 8.69)	0.62
Communication from 2º care – treatment initiated	60.20	56.92	3.28 (11.74, 4.30)	0.40

Percentage of GPs perceiving better changes in specific aspects of endoscopy service ranged from 34% to 63% for those who made referrals to intervention sites and ranged from 40% to 69% for those who made referrals to the control sites. More GPs thought changes made by the control sites led to better services in nine of the 10 specific aspects of endoscopy service but these did not reach statistical significance (Table 67).

Table 67. Differences in GP views of service changes between Intervention and Control groups (Weighted by number of GPs making referrals to various study sites)

Perceiving better changes in:	Weighted mean percentage		Diff in means (95% CI)	P value
	Intervention Max n = 218	Control Max n = 285		
Way referrals made into unit	47.32	54.98	-7.66 (-29.16, 13.83)	0.46
Understanding of prioritisation	42.46	48.18	-5.72 (-23.90, 12.46)	0.52
Outcome of prioritisation process	42.60	47.47	-4.86 (-25.24, 15.52)	0.62
Speed of referral in terms of access	55.09	60.35	-5.26 (-25.51, 14.99)	0.59
Information from 2º care following referral	55.05	59.26	-4.21 (-19.79, 11.36)	0.58
% patients requesting further GP appointments	34.12	40.38	-6.27 (-29.21, 16.68)	0.57
Communication from 2º care – outcome of endoscopy	62.56	68.60	-6.04 (-15.08, 3.00)	0.18
Communication from 2º care – final diagnosis	57.45	54.88	2.57 (-10.53, 15.66)	0.69
Communication from 2º care – complications	35.42	40.45	-5.03 (--17.13, 7.06)	0.39
Communication from 2º care – treatment initiated	46.67	52.75	-6.09 (-20.62, 8.44)	0.39

10.6.3 Findings from qualitative analysis of questionnaire response

Out of the 682 GPs returning the questionnaire, 190 GPs (28%) made free text comments on endoscopy services in the questionnaire. Seventy-two of the 299 GP respondents (24%) who made referrals to Intervention sites and 118 of the 383 GP respondents (31%) who made referrals to Control sites commented on the endoscopy services.

When the comments were considered as a whole, 62 made only positive comments and 81 only negative comments, whilst 47 GPs expressed mixed views. This is shown in Table 68, split between Intervention and Control.

Table 68. Comments made by GPs referring to Intervention and Control sites

	Intervention	Control	Total
Positive comments	26	36	62 (32.6%)
Negative comments	31	50	81 (42.6%)
Mixed comments	15	32	47 (24.7%)

Results are described below according to the main themes: Access, Waiting times, Communication and the demand on primary care.

10.6.4 Accessing endoscopy services

Seventeen GPs (five referring to Intervention sites, 12 to Control sites) felt the referral process had improved in part due to Rapid Access clinics but also because of improved referral guidelines and criteria:

> *Proforma and referral guidance has improved referral process. (203)*

However, there were many more GPs (twenty-three referring to Intervention sites, twenty-seven referring to Control sites) who were critical of changes in the referral process.

The "Choose and Book" initiative was blamed for a deterioration in the process of booking an endoscopy by four GPs, split evenly between those referring to Intervention and Control sites.

Centralised appointment systems were also criticised (six GPs referring to Intervention sites, three referring to Control sites). They were seen as being impersonal, an obstacle and slowing the referral process down:

> *Now have to refer to 'CAS' – a clearing house. I feel it is a technical rather than a wisdom-led service. (408)*

Other GPs also commented on the impersonal service highlighting the difficulty in referring a patient back to the same consultant, referring to a named consultant and finding it difficult to access consultant advice about patients who do not meet formal referral criteria.

10.6.5 Waiting times

The majority of GP comments related to the time patients were waiting to have an endoscopy. Forty-seven GPs (14 referring to endoscopy units at Intervention sites, 33 to Control sites) felt that the waiting time for procedures had improved and in particular commented on the effectiveness of the two week referral for patients with symptoms suspicious of cancer. However, 68 GPs (22 referring to Intervention sites, 46 referring to Control sites) were critical of the continuing long waits for patients who did not fulfil the two week referral criteria - the routine referrals, and in particular for referrals for colonoscopy:

> *The two week rule works well but others the WL is too long especially for bowel endoscopy. (947)*

Two GPs criticised one hospital (a Control site) which had 'rationalised' its waiting list feeling that it was *"frankly disgraceful … simply removing patients from the waiting list unless they (the patient) states that they "still want" the procedure (1480)"*.

10.6.6 Communication

Fifteen GPs referring to Intervention sites and 20 GPs referring to Control sites were satisfied with the communication from the hospital following the endoscopy. Whilst, some commented that a report had always been received promptly, many felt that this aspect of the service had improved:

> *Results are clearer and generally quicker. (747)*

> *In particular it is a great improvement that serious endoscopy findings are faxed to us the same day. (483)*

There were also a number of GPs (12 referring to Intervention sites, 26 to Control sites) who were unsatisfied with the level of communication and four GPs referring to Intervention sites and nine referring to Control sites, made specific mention that biopsy results were not always forwarded to the GP *"Often have to chase HP/biopsy results (1751)"*.

This can result in wasted GP appointments when patients have been told to return to their GP for the results:

> *Patients often come back for confirmation before it has been received especially final diagnosis/follow-up – a waste of appointment. (191)*

To avoid this situation some GPs suggested that whilst at the endoscopy unit patients should be advised to check with their surgery before making an appointment. Some also felt it would be useful to know what information a patient had been given about the endoscopy findings as some are unable to take in the information or forget:

> *Only thing I'd like is report to say what patient was told at the time as they forget!" (192)*

There were also concerns from four GPs referring to Intervention sites and four referring to Control sites, about follow-up arrangements which they felt were not always as clear as they should be with *"little comment or action on further follow-up" (1284)*.

10.6.7 GP views of endoscopy service overall

Twenty-nine GPs (16 referring to Intervention sites, 13 to Control sites) praised the overall service that was being provided *"Vastly improved service" (518)* with seven Intervention and four Control site GPs highlighting the fact that the service has always been good *"We seem to have an already good service for patients that has got even better" (1095)*.

10.7 Discussion

10.7.1 Summary of findings

This survey found no significant difference in the perception of possible changes to the endoscopy service of Intervention and Control sites indicated by GPs. The number of GPs from Intervention and Control sites who identified, either explicitly or implicitly, that a change had occurred to a particular aspect of the endoscopy service was remarkably similar in most cases.

When GPs were asked to rate the effect of the changes in the endoscopy services, more GPs thought changes made by the control sites led to better services in nine of the 10 specific aspects of endoscopy service. The difference ranged from 4% to 8% but these did not reach statistical significance.

As shown above, the views of GPs are mixed on accessing endoscopy, waiting times, and communication and it should be remembered that just under a third of GPs wrote any comment on the questionnaire. However, it is interesting to note that in relation to each theme, more GPs referring to Control sites made comments, both positive and negative, than GPs referring to Intervention sites.

Accessing endoscopy is clearly viewed by GPs as more problematic than four years ago, i.e. before changes were introduced. A similar number of GPs referring to Intervention and Control sites expressed views reflecting their perception of the negative impact of 'Choose and Book', the guidelines and referral criteria, the centralised booking systems and the impersonal nature of the process. Of note, is the fact that just over double the number of GPs referring to Control sites made positive comments relating to Rapid Access clinics and improved guidelines and referral criteria, in comparison to GPs referring to Intervention sites. However, the negative comments are distributed fairly evenly between Intervention and Control sites and outweigh the positive comments suggesting that it is difficult to determine a difference between the two types of site.

In relation to waiting times, the number of GPs referring to Control sites that felt there had been improvements was double that of GPs referring to Intervention sites. However, the number of GPs referring to Control sites who felt that waiting lists were still too long was also double that of GPs referring to Intervention sites. Overall, there were more comments about waiting times being too long (68) which reflects the frustration at the long waits for colonoscopy in comparison to the satisfaction with the two week referral (47) in both Intervention and Control sites. It is difficult to determine any difference between Intervention and Control sites because whilst Control sites appear to be doing better than Intervention sites they also have more negative comments than Intervention sites.

There was little difference in the overall number of positive (35) and negative (38) comments about the communication with and from endoscopy units. However, of GPs referring to intervention sites, over double were satisfied with the level of communication. In comparison GPs referring to control sites, were almost equal in their comments on their level of satisfaction with communication. This suggests that changes in the intervention sites had been more successful than those in control sites.

Whilst there are aspects of the endoscopy service that GPs feel have deteriorated, there are other aspects where they see improvement but they do feel that further improvements are necessary. Having considered the results of the qualitative data analysis it has not been possible to detect any particular difference in GPs perception of the changes between Intervention and Control sites.

10.7.2 Internal validity

- Our overall response rate was low though no different between Intervention and Control sites.
- GPs from single-handed practices making referrals to Control sites were less likely to return a questionnaire. However, as the number of this GP group was small we did not adjust the analysis because the impact of the adjustment would not have affected the findings.

10.7.3 External validity

- The response rate is not high but this is acceptable because it is a postal questionnaire to GPs with no incentive to complete it.

10.7.4 Implications

- There was a trend indicating that GPs using the Control sites are more positive about the changes that those sites introduced. This is an unexpected finding and further study will be needed.

There were systematic differences between GPs who gave their views about service improvements without explicitly saying they saw changes in the services were significantly less likely to perceive better changes than those who explicitly said they saw service changes (Table 69). Excluding the implicit responses from the analysis would overestimate GP acceptance of the service changes, so all the implicit responses were included in all subsequent analysis.

Table 69. Comparison of un-weighted percentage of GPs who perceived better changes between those explicitly and those implicitly said they saw changes in endoscopy services

Perceiving **better** changes in: % (n)	Type of Response to questions about seeing changes in endoscopy services		
	Explicit	Implicit	P value
Way referrals made into unit	60.1% (208/346)	31.4% (38/121)	< 0.001
Understanding of prioritisation	58.6% (146/249)	25.2% (36/143)	< 0.001
Outcome of prioritisation process	57.2% (139/243)	25.7% (36/140)	< 0.001
Speed of referral in terms of access	68.1% (250/367)	32% (41/128)	< 0.001
Information from 2º care following referral	74.2% (239/322)	25.0% (41/164)	< 0.001
% patients requesting further GP appointments	49.8% (114/229)	19.2% (28/146)	< 0.001
Communication from 2º care – outcome of endoscopy	82.4% (252/306)	33.1% (47/142)	< 0.001
Communication from 2º care – final diagnosis	73.4% (204/278)	25.8% (39/151)	< 0.001
Communication from 2º care – complications	63.0% (97/154)	15.9% (26/164)	< 0.001
Communication from 2º care – treatment initiated	69.0% (169/245)	20.3% (30/148)	< 0.001

11 Discussion

11.1 Summary of findings

In this study we have found that, although the MES programme may have reduced the number of patients on waiting lists, there is no evidence that it significantly affected waiting times, investment in modernisation, service innovation, the collection of service activity and process data, patient outcomes, their use of other NHS services or their time off work. The average time patients waited for an endoscopy was significantly shorter at those hospitals that received financial support from the MES programme than at those that did not. However there are three cogent reasons why we cannot attribute this to the MES programme: first in the absence of rigorous data on waiting times before the MES programme there is no evidence that this was not merely due to differing characteristics of Intervention and Control hospitals; secondly this effect was reversed in the final wave of data collection two years after the end of the MES programme; and thirdly the average time Intervention and Control patients waited for an endoscopy did not decrease over the duration of the study.

All participating sites made major investments in modernisation during the study period. Investments were in physical facilities, clinical and administration equipment, staff training, new posts, staff substitutions and new modernisation activities. Our assessment of the number and type of innovations introduced showed that there was no real difference between the Intervention and Control sites. Innovations included changed roles and responsibilities and many new working practices to manage demand and increase capacity. The costs of modernisation, and consequent NHS costs in both primary and secondary care, were lower in the Intervention sites. The cost of lost productivity by patients due to time off work was also slightly lower in Intervention sites. However none of these cost differences were statistically significant. So there was no strong case for calculating cost-effectiveness or cost-utility ratios.

Activity data showed no significant difference between Intervention and Control sites in the number of referrals, patients waiting more than three months, lost procedure slots or procedures performed. The total number of patients waiting decreased over time in the Intervention sites, and increased in the Control sites, a significant difference that grew over time. This finding, from data supplied by sites themselves, is concordant with the finding from patient questionnaires that average waiting times increased in the control sites until reversed in the final wave of data collection, while waiting times in the Intervention sites showed little change.

Although patient quality of life scores improved after endoscopy we found no difference in patient outcomes between Intervention and Control sites or over time. Suggestions made by patients for improvement focused on the need to decrease waiting times and communication before and after the procedure.

Staff at both Intervention and Control sites displayed a widespread wish to modernise and improve services, and there was frustration at the inability to do more. Much modernisation was possible at no cost, such as changes to service processes. Well-motivated staff and innovative ideas were recognised as facilitating such changes. However, lack of senior

management support, financial constraints or perceived inappropriate allocation of funding (such as the provision of additional funding for staff without extra equipment) were a cause for frustration. Changes to work processes and patterns were beneficial for staff, despite ongoing tensions among specific groups within endoscopy units.

The findings are summarised in tabular form in Tables 70-72 (a, b and c), using a three-layer matrix (MATRICS) to illustrate which specific target variables for each of the three perspectives were investigated (layer 1), which methods were used for each variable (layer 2), and the findings (layer 3). An alpha-numeric code links the effect sought, method used and findings, which are also displayed from three perspectives: the patient; endoscopy services; NHS and society. Thus the effect (layer 1) on patient quality of life (1), was measured (layer 2) using the SF-36 (B), EQ-5D (C) and GSRQ (D), and found (layer 3) no difference between Intervention and Control groups, but overall improvement over time (1B, 2C, 1D).

Table 70. Effects[1] that were sought (layer 1)

Effects on patients	Effects on endoscopy services	Effects on the rest of the NHS and society
1 - Patient Quality of Life **[B, D]**	**6** - Cost of modernisation **[H]**	**14** – Time off work **[I]**
2 - Total health benefit **[C]**	**7** – Service performance **[A]**	
3 - Patient experience of referral process **[E]**	**8** – Organisation, function and process of service delivery **[E, F, G, J]**	
4 – Patient satisfaction with endoscopy **[L]**	**9 –** Accessibility to services **[E, F, K]**	
5 – Waiting times **[E, M]**	**10 –** Appropriateness and acceptability of services **[F, G, K]**	
	11 – Reliability and availability of routinely collected process data **[A]**	
	12 – Patient use of drugs **[I]**	
	13 – Patient use of primary and secondary care resources **[I]**	

[1]Outcomes defined specifically for each perspective, according to Aims and Objectives.

Table 71. Methods used (layer 2)

Code	Method
A [7, 11]	Process data analysis
B [1]	Analysis of Short Form 36 (SF-36) scores
C [2]	Analysis of Euroqol 5D (EQ-5D) scores
D [1]	Analysis of Gastrointestinal Symptom Rating Questionnaires (GSRQ) scores
E [3, 5, 8, 10]	Semi-structured patient interviews
F[8, 9, 10]	Interviews with professionals and key people
G[8, 10]	Focus groups
H [6]	Health economic site visits
I [12, 13, 14]	Health economic patient reported resource use
J [8]	Innovations form
K [9, 10]	General Practitioner (GP) questionnaire
L [4]	Gastrointestinal Endoscopy Satisfaction Questionnaires (GESQ) (patient satisfaction questionnaire)
M [5]	Analysis of time difference between referral and procedure

Table 72 (a). Effects on patients (layer 3)

Code	Effects on patients
3E, 9F, 5E, 9E, 8E	Access to and acceptability of endoscopy services have improved with shorter waiting times, greater throughput, more patient information, more responsiveness to patient views and better communication between reception staff and patients.
3E	'Urgent' patients are satisfied with waiting time. Majority of non-urgent patients satisfied with waiting time. Fewer patients saying they would like procedure sooner
3E	No change in experience for patients who had had previous endoscopy
3E	Patients are satisfied with treatment and care received
9F, 10F	There is greater commitment to patient satisfaction and involvement
10F	Difficult to assess if patients are at the centre of 'quality agenda' or benefit as units strive to reach targets
10G	External/government targets implemented through Trusts and management force clinicians to concentrate predominantly on meeting targets rather than focussing on patient care.
1B	Patients had improved SF-36 MCS and PCS following endoscopy but there was no significant difference between Intervention and Control groups.
1D	Patients had fewer GI symptoms as measured by GRSQ following endoscopy but there were no significant differences between Intervention and Control groups
2C	Patients had improved EQ-5D following endoscopy but there were no significant differences between Intervention and Control groups
4L	There were no differences between Intervention and Control groups in patient satisfaction as measured by the GESQ following endoscopy
5M	There were significant differences in patient waiting times between Intervention and Control groups. These favoured the Intervention group for the first four waves of recruitment and the Control group for Wave 5.

Table 72 (b). Effects on endoscopy services (layer 3 continued)

Code	Effects on endoscopy services
10F	MES Programme training offered too early by ill prepared teachers and project staff lacked credibility.
10F	MES Toolkit™ strongly disliked but data collection recognised as important to support change
9F	Some Government targets helped put endoscopy in spotlight. Others impact negatively on some patients
10F	Working relationships of staff sharing endoscopy improving but still some resistance from clinicians
10F	Strong leadership, communication, staff ownership important in introducing change
8F	Training important to update staff and ensure appropriate skill mix but time, sparse financial resources and insufficient staff impede this
10F	Staff respond positively, are supportive and co-operative and welcome the challenge of new ways of working
9K	There was no significant difference between GPs who referred patients to Intervention and Control sites regarding perception of accessibility to services
10K	There was no significant difference between the GPs who referred to the Intervention and Control sites regarding appropriateness and acceptability of services
8F	Ongoing financial constraints that lead to crisis management, ad hoc change, and make forward planning difficult
9F	Lack of resources impacts on staffing, equipment, information technology and facilities
8F	Some change processes are cost neutral
8G	Discord between members of staff from various specialties using endoscopy units.
8G, 10G	Welsh units see themselves as lagging behind their English counterparts, but are learning from the successes and mistakes.
8G	Changes to improve processes, such as pooled lists, did not require additional resources.
8G	Lack of recognition and appreciation of professionals by management and Trusts lead to disillusionment amongst senior clinicians; an erosion of professional self-identity.
8G, 10G	Resource deficits and allocation of funds based on poorly informed decisions.
8G, 10G	Lack of management involvement and/ or interest in clinical processes and patient care
7A	There was no statistically significant improvement in the delivery of endoscopy services in Intervention sites
7A	There was no statistically significant improvement in the delivery of endoscopy services in Control sites
7A	There was no significant difference between the endoscopy services of the Intervention and Control sites at any time
11A	Process data was not routinely collected by many endoscopy units, but especially not by the Intervention sites
11A	The majority of routinely collected process data from endoscopy units and Trusts was highly comparable with the equivalent Hospital Episode Statistics (HES) datasets
12I	Overall resource investments in modernisation in terms of one-off costs, investments which produce a flow of benefits and increase in annual revenue costs.
13I	Tendency toward lower use of drugs by patients in Intervention sites
14I	Some tendency toward reduction in primary and secondary NHS resource

	use
8J	There was no significant difference in the average number of innovations introduced by Intervention and Control sites
6H	All sites made major investments in modernisation: in staff, training, equipment and modernisation activities.
6H	The Intervention did not significantly affect overall levels of investment in modernisation.

Table 72 (c). Effects on the rest of the NHS and society (layer 3 continued)

Code	Effects on the rest of the NHS and society
8F, 8G	Change due to natural realignment and evolution of services rather than as a response to specific innovations.
8F	External body can be a catalyst for change.
8F	The nature of change is ad-hoc rather than specific.
13I	Tendency toward less time off work by patients meaning less lost productivity to industry.
8F	There have been some successes in getting funding, with Global Rating Scale (GRS) and National Bowel Cancer Screening Programme (NBCSP) useful leverage tools.
10G	GRS and NBCSP help raise the political visibility and image of endoscopy units within the Trusts affecting targets and funding allocation.

There is no universally accepted definition of either innovation in, or modernisation of health services. We found a wide variety of initiatives that were undertaken to change services for the better. While we were not able to show any significant difference between Intervention and Control sites (i.e. any effect of the MES programme) apart from shorter waiting lists and a decrease in the number of patients waiting, we have shown a qualitative improvement in patient perceptions of their care and time spent waiting, communication with patients, physical surroundings and staff skill mix. Patients are satisfied with the service they receive and the majority are content with waiting times, including for routine procedures.

The approaches to modernisation in the participating sites were many and diverse, but tended to be ad hoc and opportunist, rather than strategic and co-ordinated. They were initiated and led by staff in the units themselves where strong leadership, communication and staff ownership were important in achieving effective change. Centrally initiated targets were felt to be helpful in drawing attention to endoscopy services at a local level but paradoxically were often felt to affect patients negatively by distorting priorities. This view is supported by a review of the literature on the impact of the Two-Week-Rule (TWR), which was implemented to speed referral of suspected colorectal cancer patients (CRC), but lacks the sensitivity to be effective: only 9.4% of patients referred via the TWR were subsequently diagnosed with CRC, and only 32% of all CRC patients were referred via TWR (Thorne, Hutchings and Elwyn 2006).

The primary purpose of such initiatives is to reduce delay between referral and action, but there is a complex interaction between the numbers waiting for a procedure and the time individuals spend on a waiting list. The data we received from sites were not sufficiently robust enough to enable us to explore this in depth but it is likely that the decrease in numbers waiting is the result of more effective attempts by Intervention sites to influence and manage demand (e.g. by new referral procedures, validation of referrals, guidelines and triage), while stable average waiting times reflect less

successful innovations designed to improve departmental capacity or efficiency.

We identified several barriers to innovation and change. Our qualitative research revealed staff issues such as low morale and discordance between professional groups that impacted on the effectiveness of innovations or modernisation. We also identified deficiencies relating to data management and the use of data to provide evidence on which to improve services. An analysis of the availability of such process and activity data indicated that it was routinely collected in only eight of 19 sites, and of these, only two (both Control sites) were able to provide all five service process measures that are pertinent to ongoing monitoring of service performance. Furthermore, we found HES to be unreliable with regard to endoscopic activity, confirming concerns that have been expressed previously (Williams 1999; Williams and Mann 2002). The problem appears to be mainly due to lack of consistent application of data dictionary definitions by Trust Information Departments, leading at times to gross underreporting of activity.

Focus groups with professionals elicited frustration at the lack of Trust or hospital management systems in place, at the more senior levels of management, to encourage units to implement identified change or seek finances necessary to promote change. Professionals also emphasised the lack of understanding to support the work and ambition of the units and suggested management at the more senior levels were not acting effectively to make a difference to unit working. This was exacerbated by the professionals' sense that units lacked visibility within Trusts. This meant that units were unable to make appropriate long-lasting changes to service delivery and organisation and that decisions about modernisation were made by ill-informed management without scientific or clinical experience, and without an evidence-based approach to change.

Focus group participants also suggested the culture of management was problematic, with a cultural gulf between consultants and managers. The higher managerial echelons within the Trust were seen to be working in an ad-hoc manner, making decisions without consultation or knowledge of the work on the ground. Furthermore, managerial decisions were enforced without clarity of structure or process so that the rules of engagement between unit staff and management were a moving feast. Consequently, it was difficult for consultants and clinicians to know how and when to engage with management or to recognise the processes necessary to engage effectively. This was exacerbated by a general sense of resource deficit. Focus groups with health professionals who had modernised their units independently of the MES programme suggested that to achieve long-lasting positive effects management should actively support innovations, particularly by considering staff morale and appropriate funding.

The MES programme thus does not appear to have been a major factor in bringing about change. Indeed the 'Toolkit™' introduced by the programme was disliked and not sustained. This study found that very few study sites of either Site type were actively collecting any service-related data, a finding that has been expanded upon elsewhere (Thorne, Hutchings and Elwyn 2008). From this we concluded that the Toolkit™ failed to introduce a data collection culture in the Control sites, and more surprisingly in the Intervention sites. There could be a number of reasons for this, each of which will be discussed below:

- Many site contacts commented during interviews that they saw the Toolkit™ as too rigorous. They understood the aims of the Toolkit™

in promoting data collection and analysis to better understand and monitor services, but they thought that the level of detail for the data was too fine. For example, counting activity by measuring the length of time taken for each appointment in minutes was impractical, and extremely time and resource-intensive. Whilst the data was exceptional at highlighting service processes and problems, it was not practical to collect this data on a daily basis.

- The strict data collection regime may have been too exhaustive. Data had to be collected daily and uploaded to the MES programme on a monthly basis – yet another deadline to be met in an already busy unit.
- As already mentioned, sites appeared to understand the necessity for data collection practices to be implemented and many predicted their intention to develop their own, less comprehensive but less resource-intensive version of a data collection toolkit. We have shown that most did not follow up their intention with implementation of data collection practices, most probably due to time constraints but also possibly due to a lack of experience in understanding what variables needed to be collected and analysed for effective service monitoring.
- Many sites had a change of personnel following the close of the MES programme, especially fin the Intervention sites who tended to "lose" their change agent as they moved on to other modernisation programmes within the Trust. In many cases, these were the people to dealt with the Toolkit in the Intervention sites and with their move came a loss of data capture motivation. The same may be true for the Control sites to a lesser extent, since NHS personnel often have a short-term contract within departments.
- Data collection was often driven by local targets and the need to develop bids for funding from the Trust. This led to ad hoc data collection that was usually short-lived and not applied to service delivery.

The MES programme may have initiated a more innovative culture which was receptive to the introduction of the GRS. This was introduced in spring 2005, towards the end of our study, to improve the quality of endoscopy services and was quickly identified as a stronger driver for change and innovation than the MES programme. It requires sites to monitor the quality of their clinical care and of their patients' experience themselves. Professionals have welcomed the GRS because it has raised the profile of endoscopy services with Trust management and it makes their work more visible. Notwithstanding the apparent failure of the MES programme, interviews with professionals indicated that it had encouraged change and facilitated the subsequent implementation of the GRS.

Thus the factors driving modernisation are complex, and modest investment plays little role. There is a perception that the GRS now improves both quality and activity. Hence there is a need to evaluate its effect on patient outcomes and departmental performance, especially as it may be adopted more widely, including overseas.

11.2 Internal validity

At the start to chapter 2 we discussed the methodological challenges in setting up this study. We used mixed methods, including patient and professional views, documentation of activity, health economics and patient outcomes measured in five waves from 2004 to 2006. We have thus

assessed the impact of the NHSMA MES programme from a wide variety of perspectives leading to concordant results. However the absence of a widely accepted definition of innovation or modernisation made our task more difficult. We therefore sought examples of local innovation through interviews with staff and then shared these widely with all study sites, thus helping them to complete the list of changes they had made. However, it was often difficult for them to identify the exact timing of the innovation, not least because there was little reliable data.

We used a quasi-experimental approach to assess patient outcomes. A randomised controlled trial (RCT) was not possible because the intervention we were assessing (support from the NHSMA MES) started before our evaluation. We used validated instruments to collect outcome data from patients in five waves over two years. Our original intention was to use an interrupted time series approach, but the timing of innovations by the sites were too imprecise to draw inferences. We therefore monitored progress over time, and compared Intervention and Control sites. Such an approach is weaker than an RCT, but the findings from our mix of methods are largely concordant.

One hundred patients were invited to participate by each site in each wave, identified from the referrals received in the month of recruitment, with recruitment limited to 20 patients each day to distribute allocation throughout the week. Of 9154 considered for the study, 3818 (41%) consented to take part and completed a Baseline Questionnaire (BQ). The Post Procedure Questionnaires (PPQ) was returned by 76.9% of those, and 67.8% returned the 12 month Post Procedure Questionnaire (12M PPQ). Though the response rate from patients was disappointing, it was consistent across waves and sites, thus facilitating inference, and yielded 2587 evaluable responses. There was imbalance in patient characteristics at baselines, with more urgent requests in the Control group, and more routine requests in the Intervention group. As we were able to control for such potential biases, however, we doubt that this has distorted our findings.

The intervention we studied was the active support and funding given to study sites by the NHSMA MES programme. The investment was small (£30k) and made in early 2003. By March 2005 the programme had ceased and the NHSMA itself was disbanded. We sought effects over a 33 month period from April 2004 to January 2007, and were thus looking at the impact of a programme more than a year after it started, and for two years after the host organisation was disbanded. This timescale is appropriate to assess the impact of innovations introduced, but means that our baseline data were collected after the intervention had been applied. This may explain why Intervention sites already had shorter waiting times than Control sites at the beginning of our evaluation.

The relative lack of analysable activity data from study sites is regrettable, and limits the depth of conclusions that can be drawn, but the findings we do have are concordant with the conclusions we have drawn from the data from patients.

We took a rigorous approach to the qualitative aspects of the study, obtaining views from patients by telephone interview, and using both face to face interviews and focus groups to seek the views of professionals. The response to our questionnaire to GPs was poor (35%), and reduces confidence in our finding that more GPs working in the locality of Control sites thought the changes introduced produced better results than those working near Intervention sites.

11.3 External validity

This study has looked in depth at 18 sites. These included small and large, rural and urban, district general and teaching hospitals (Table 2). We believe they are generally representative of endoscopy units in England. Our quantitative findings are in tune with the slow pace of modernisation of endoscopy services across the country at the time of the study, and are supported by the qualitative observations of both patients and professionals. The improvement in patient outcome after a procedure reflects our previous experience in the MINuET study (Williams, Russell, Durai, Cheung, Farrin, Bloor et al. 2006). The problems we encountered with routinely collected data from study sites also reflects our previous experience (Williams 1999; Williams and Mann 2002).

We are not aware of any previous systematic evaluation of endoscopy service modernisation using a mixed methods approach, but we have shown that this is feasible though difficult, both methodologically and practically. Robust service data is crucial, but not yet available in spite of the attempts of the NHSMA to promote this in the MES programme.

11.4 Wider implications

Modernisation of endoscopy services does not appear to affect patient's use of other NHS resources. It is not therefore a mechanism for reducing demand on other NHS services. Relatively small financial incentives (such as those made by the NHSMA) are unlikely to have a measurable effect. Other funding sources can compensate those denied funding from a specific programme, and potential sources should be exploited. Even so, funding itself and promotion of data collection, is unlikely to produce major improvements in services. We judge that future initiatives should concentrate on quality improvement and it will be important to engender a strong sense of local ownership, raise the profile of services, and engage the support of Trust management.

Better systems are needed to capture data, not only about activity, but also about demand, and patient outcomes, both administrative and clinical. Patient-focused clinical systems that support both individual patient management and departmental processes in one integrated approach, is the logical way to achieve this. It is hoped that the wider capture of electronic patient focused data will also enable the routine measurement of patient outcomes, either directly (Ali, Gaze, Russell, Russell and Williams 2008) or by proxy (Hutchings, Cheung, Williams, Cohen, Longo and Russell 2005).

11.5 Learning Points

11.5.1 Policy makers

- Policy should focus on improving quality, not attaining activity targets.
- Data collection to monitor both quality and activity should be embedded in the process of care and, wherever possible, not collected as a parallel activity.

- If a major initiative is to be evaluated, this should be built in *ab initio.*
- New initiatives should clearly define the issues they are addressing. For example, there should be clear distinctions defined between modernisation, innovation, improvement and change.

11.5.2 NHS Trusts

- Senior management should listen more closely to the views of the clinicians who work in their Trusts and aim to facilitate the changes that are proposed.
- Professionals are frusteated by their inability to change, which they perceive as due to a lack of support, as well as a lack of funding.
- Much change can be achieved with a facilitated, bottom-up approach.
- There is a need for senior management to work more closely with professional leaders at a Trust level, and to respect their views and aspirations.
- A more structured approach to liaison is needed.

11.5.3 Professionals

- Tribalism amongst professional groups remains a serious problem and an inhibition to positive change.
- Strong leadership is an essential requirement for effective change.
- More investment and effort should be made to fulfil the training requirements of units, particularly with routine tasks such as data capture and reporting.
- Improvements should be directed primarily at quality.
- Rigorous data collection is an essential activity if units are to be managed effectively, and needs to be recognised as the responsibility of staff at all levels.

11.5.4 Research funders

- There should be strong links between policy makers and research funders to ensure that evaluation is built in *ab initio*.
- A mixed-methods approach involving quasi-experimental methods is an effective but expensive way to evaluate complex interventions.
- A mechanism should be found to facilitate the continuation of studies that identify new issues so that the opportunities for further learning are not lost.

11.6 Need for further research

1. The MES programme was a catalyst to modernisation during a period of wider policy pressures to modernise services. The evaluation of future initiatives should be planned from the beginning so as to identify the intrinsic effects and isolate them from other trends.

2. Many of our sites identified the GRS as a strong driver for improving services, and this now needs to be rigorously evaluated.

3. Further research is needed regarding the role of management in relation to endoscopy unit staff requests for financial or unit support

and the relationship between management and the change culture of endoscopy units. This would include a clearer understanding of how management are perceived by endoscopy unit staff and how management themselves view their roles in relation to gastroenterology service developments. Additional research would explore current structures and processes in place for managerial decision making within the Trusts in relation to endoscopy units and changes to managerial functioning in respect of service delivery and organisation.

12 Conclusion

We have drawn several conclusions from this large and complex study.

12.1 There were substantial changes in the services delivered by endoscopy units during the timescale of this study

This included changed roles and responsibilities and many new working practices to manage demand and increase capacity.

12.2 Small financial incentives do not themselves trigger innovation in services

Modernisation has occurred both with and without the direct influence and funding of the NHSMA MES programme.

12.3 Modernisation to reduce endoscopy waiting lists does not improve patient outcomes

The number of patients waiting for an endoscopy fell at Intervention sites, but average waiting times did not. In sites that did not receive funding from the MES average waiting times lengthened until the end of the study when a fall was noted. The known improvement in patient quality of life after endoscopy was confirmed, but patient outcomes were unaffected by modernisation or investment.

12.4 Endoscopy activity and process data needs substantial improvement

The availability of process and activity data from sites is poor. HES data are unreliable for monitoring endoscopic activity.

12.5 Patients are largely content with services

Patients saw little change in services, and are satisfied with their treatment and care, and with waiting times, which they perceived as falling.

12.6 Endoscopy staff must be at the heart of improvement

Professional morale is low, but the ambition to improve services is strong. Staff saw the MES programme as a driver for change, but were frustrated by

lack of senior management support for clinically led change, and a perceived lack of investment. The importance of strong leadership, staff commitment, teamwork and good communication is confirmed.

12.7 Modernisation should be more patient-focused

Modernisation of endoscopy services may reduce numbers on waiting lists but, if it is to improve patient outcomes, it should focus on quality-based goals rather than activity targets. The recent introduction of the GRS has focussed attention on quality and its effectiveness should be evaluated.

12.8 A mixed method approach which includes a quasi-experimental component is feasible and valuable in the evaluation of the delivery of services

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Appendix 1 – Full Proposal

SECTION 1. SUMMARY OF THE PROPOSAL

Scientific summary of the research proposal: no more than 500 words covering the following topics: aims of the research, type and location, methods of working, measure of outcome if appropriate.

Aims of the research

- To evaluate innovations in service delivery and organisation initiated by the Modernising Endoscopy Service (MES) of the NHS Modernisation Agency (NHSMA).
- To compare the accessibility and acceptability of the resulting models of service delivery with other new models.
- Also to compare effectiveness and cost-effectiveness in improving outcomes assessed by patients and professionals.

Type and location of innovations

We shall use 25 sites across the UK. The NHSMA has selected 29 'pilot sites' in England to receive funding, training and support to analyse and redesign their current GE services. From these we shall select a stratified sample of ten 'experimental sites'. A further 70 'independent sites' applied to take part but were unsuccessful. From these we shall select a stratified sample of ten 'MES Control sites' keen to redesign their services with training and support but no extra funding. Thirteen British sites committed to genuinely independent redesign of their GE services responded to our circular to the British Society of Gastroenterology (BSG). From these we shall select a stratified sample of five 'BSG Control sites'.

Methods of evaluation

The 29 pilot sites aim to analyse their services during 2003 and redesign them during 2004. In collaboration with the NHSMA we shall invite our 10 MES Control sites to analyse their services by July 2003. We shall ask all 15 Control sites to redesign their services by July 2004. Even so we expect both types of site to vary in their speed of innovation. This differential timetable reflects the Control sites' lack of earmarked funding, which is likely to inhibit progress as they seek alternative resources for innovation (though not evaluation), and will enable us to infer from Control sites what would have happened in experimental sites in the absence of MES recognition and funding. Thus our basic research design is that of an interrupted time series design, simplified where appropriate to a controlled before-and-after study.

Measurement of outcome

To measure time between significant events in the patient journey, we shall collect data from our 25 sites over three years. To gather patients' assessments of their own outcomes (both generic through EQ-5D, and specific to the digestive tract), the quality of communication, and the extent of their own contributions and costs, we shall draw stratified samples of 40 patients per site in the spring and autumn of 2003, the spring and autumn of 2004, and the spring of 2005. We shall ask these 5000 patients to complete questionnaires at their first hospital appointment and by post 12 months later. To explore patients' views and preferences in more detail, we shall interview a 5% stratified random sample of respondents over two years from the spring of 2003. We shall interview stratified

random samples of ten health care professionals per site over the same period. To estimate the incremental cost per quality-adjusted life year of the MES, we shall estimate the NHS and societal costs of innovative models and compare them with changes in patients' EQ-5D scores.

SECTION 1. SUMMARY OF THE PROPOSAL (CONTINUED)

Plain language summary of the research proposal: in no more than 500 words please summarise your proposal in non-scientific language, using words and terms that can be easily understood by non-research communities. Do not use acronyms or abbreviations. Your summary must include a clear statement of the purpose of your research, how it will build on existing evidence where available, and its intended benefits to patients and the public. It must also describe how the research will be conducted and how patients and the public will be involved.

Introduction
The NHS Modernisation Agency has set up a national project to modernise gastroenterology services. These services investigate patients with digestive and bowel symptoms. An important role is to identify or eliminate cancer. In Phase 2 of that project 29 'pilot sites' in England are receiving funding, training and support to analyse their current services and redesign them.

Purpose of the research
Working with the NHS we shall evaluate whether the changes initiated by the national project are acceptable to patients and professionals, improve access to, and outcomes of, gastroenterology services, and provide good value for money. Existing evidence on redesigning services in this field, to which applicants have contributed, relates to specific or local projects, rather than generic and national. Nevertheless our previous work provides a rigorous basis for the proposed evaluation.

Research design
To compare the national project with other approaches to redesigning services, we shall sample representative sites – ten national project sites and 15 'Control sites'. Ten of the Control sites will be unsuccessful applicants to the national project who nevertheless chose to adopt the methods of the project without extra funding. Another five controls will have existing commitments to redesign their services independently of the national project. National project sites (both those who were successful and received funding, and those who were unsuccessful) should analyse their services during 2003 and redesign them during 2004. We shall ask Control sites to analyse their services by July 2003 and redesign them by July 2004. This differential timetable allows Control sites to seek alternative resources for redesign. More important it enables us to infer from Control sites what would have happened in pilot sites in the absence of their national project

Research methods
To compare services between pilot and Control sites over three years from the beginning of 2003, we shall extend data bases designed for the national project to cover all 25 evaluation sites. We shall also sample 200 patients per site over two years from April 2003. We shall ask these 5000 patients to complete questionnaires about their experiences, outcomes, costs (e.g. travel, time off work) and recent use of NHS resources at their first hospital appointment and by post 12 months later. To explore patients' views and preferences in more detail, we shall interview a sample of 250 respondents over two years from April 2003. We shall also interview samples of ten health care professionals per site over the same period. To assess the value for money of redesigning services we shall compare extra benefits to patients with extra costs to NHS, patients and society.

Public involvement in research
Thus we shall collect a wide range of data from representative samples of patients. We shall also build on our previous experience of public involvement by including representatives of patient organisations in the management of our research.

SECTION 2. DETAILS OF THE RESEARCH PROPOSAL

(This section must have a MAXIMUM of 10 sides of A4 paper and a minimum font of 10 points, you may LENGTHEN or SHORTEN any part from A – J ONLY)

A. Aims & Objectives
Aims

- To evaluate, both quantitatively and qualitatively, innovative models of delivery and organisation of gastroenterology (GE) services in general, and endoscopy services in particular, initiated and co-ordinated by the Modernising Endoscopy Service (MES) of the NHS Modernisation Agency (NHSMA).
- To compare the accessibility and acceptability to patents and professionals of the resulting models of service delivery and organisation with those of other new models.
- 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.

Objectives

- To describe new models of service delivery designed to improve the assessment and management, mainly but not exclusively in secondary care, of patients with new and continuing gastro-intestinal (GI) disorders. While many of these models will arise in experimental sites directly from the MES, 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 GE services in general.
- To estimate for both experimental and Control models of service delivery:
- accessibility and other measures of the quality of the process of care;
- acceptability to patients and professionals in primary and secondary care, and their perception of the value of these models;
- outcome as assessed by patients and professionals in primary and secondary care;
- resources consumed by NHS, patients and society in general; and
- effects on other aspects of the NHS.
- To develop methods to evaluate complex heterogeneous interventions designed with a common purpose.

B. Relevance to SDO Call for Proposals

Our proposal is relevant to the call for proposals from the NHS SDO R&D Programme in three main ways. First it evaluates new models of service delivery and organisation before their national adoption. Specifically it compares models of delivering GE services directly initiated and co-ordinated by the MES of the NHSMA with models generated in other ways, some indirectly by the MES and others independently of the MES. More generally it will yield important insights into effective ways of developing models of service delivery and organisation in other fields.

Secondly our proposal addresses three of the five exemplary issues specified in the commissioning brief:

- Service redesign to improve booking for outpatient or day case appointments;
- Innovations at the interface between primary and secondary care; and
- Substitution of professions. Our proposal can address this issue only if one or more of the emerging models substitute one profession for another. Nevertheless our preliminary survey of members of the British Society of Gastroenterology (BSG) has established that the use of clinical nurse specialists to enhance GE services by prioritising referrals, undertaking endoscopies and contributing to follow-up is fast increasing and thus certain to feature in emerging models of service delivery at many of the 25 evaluation sites.

These three issues are central to current NHS priorities and thus the implementation of the NHS Plan.

Thirdly the brief mentions the desirability of methodological development to complement research into substantive issues. Our third objective is to develop methods to evaluate complex heterogeneous interventions designed with a common purpose (Section A). To this end we have developed a common portfolio of process and outcome measures to cover all 25 sites under the umbrella of a multiple interrupted time series.

Finally our proposal also addresses the issue of access. Since our focus is on the organisation and management of services, however, it complements rather than replicates the SDO access programme.

C. Background, including NHS context and relevant literature

Background

The NHS is changing, in response to political, social and economic pressures, and to advances in diagnosis and treatment. Improving access to care is a high priority, highlighted in the NHS Plan in general and the NHS Cancer Plan in particular, and reinforced by National Service Frameworks. Roles are also changing. Nurses are undertaking many tasks traditionally undertaken by doctors. This is especially true of gastroenterology – a busy inter-professional specialty that cares for disorders of the gut, liver and pancreas. As in many other specialties, workload is rising and hospitals are experiencing increasing difficulty in offering patients timely and appropriate care. There is a heavy demand for rapid access to diagnostic facilities for patients with symptoms that raise the possibility of cancer. Cancers of the GI tract (oesophagus, stomach, pancreas, colon and rectum) are commoner than in any other organ system and most need endoscopy or the upper or lower gut for diagnosis. Endoscopy also has a major role in the diagnosis and treatment of benign disease. As a result, referrals are increasing and gastroenterology units have increasing difficulty maintaining appropriate, timely assessment of all patients.

National data on waiting lists for endoscopy are not available. However the NHS Modernisation Agency estimate that about one million patients are currently waiting, some for more than a year. Furthermore many benign GI disorders (e.g. oesophagitis, coeliac disease, liver disorders, Crohn's Disease and ulcerative colitis) require continuing follow-up because of the need for powerful therapy to control the disease, the likelihood of relapse, and the risk of developing cancer or other dangerous sequelae. Hence it is proving difficult to maintain rapid, appropriate and fair access to consultations and investigations, both for newly

referred patients and for those under follow-up. There is increasing recognition of the need to inform patients better and involve them more in decision making. However these trends increase consultation times, and reduce the number of patients seen at each clinic.

In response to these pressures many GE units have devised new methods for assessing patients referred from primary care, and for following up those who remain under surveillance. For referrals these methods include: novel booking systems, also the focus of the NHSMA National Bookings Programme[0]; assessment and triage by nurses; and 'one-stop' clinics that combine clinical assessment and diagnostic procedures in one visit. For follow-up there is a trend towards telephone appointments with nurses rather than booked appointments with specialist doctors. Unfortunately the evaluation of these innovations has been piecemeal, with few rigorous studies. Randomised trials have shown that both patient-initiated follow-up[1] and open access follow-up[2] are effective, maintain patients' Quality of Life, and enjoy the support of patients and general practitioners[3]. However most reports have been in abstract[4-12] and focus on benefits rather than problems. Few assess effects on secondary and primary care or the preferences of patients and professionals. Hence there is an urgent need for rigorous evaluation of the effect of these innovations on patients, professionals, workload in primary and secondary care, and NHS resource consumption.

Organisational change in the NHS reflects a growing recognition of the benefits of a systems approach to health care delivery and reorganisation[13]. Publications on the systems approach in clinical journals show increasing professional interest[13-15] in the application of business process re-engineering (BPR) to health care[16]. The Department of Health funded two projects to test the application of BPR to health care in the early 1990s and since then, the number and scale of different types of 'redesign' initiatives have grown rapidly. These initiatives all seek to improve quality of care through redesign of the patient process or pathway[17.] The NHS Plan has emphasised that redesign will play a key role in the modernisation of the NHS but there are relatively few well-conducted empirical studies on the effectiveness of the different models for redesign in health care[18] and even fewer have assessed the impact of these models on patients' Quality of Life with validated outcome measures.

The Modernising Endoscopy Service (MES)

Eight NHS Trusts in England are already taking part in the first, developmental phase of the MES. Of the remaining 161 current NHS Trusts 99 applied for the second, pilot phase of the MES. Using simple explicit criteria the NHSMA selected 29 of these 99 as 'pilot sites' in Phase 2, launched on 4 September 2002. These 29 will receive earmarked funding of £10 000 for using the MES Management Toolkit™ to analyse their current endoscopy services over the last three months of 2002, together with training and support from the MES itself. The Toolkit™ uses the principles of service improvement and redesign to enable pilot sites to assess current services in response to seven 'challenges'. Those pilot sites who use it successfully will receive further earmarked funding of £30 000 for redesigning their services over the calendar year 2003 in response to the eighth and final 'challenge' – that of promoting new ways of working. Together these 29 pilot sites epitomise the complex intervention[19] to create new models of service delivery and organisation in GE that this project seeks to evaluate.

Though the 70 unsuccessful sites will receive no funding, they are eligible to use the Toolkit™ outside the remit of the MES. In particular they can apply to attend a one-day training course in the autumn of 2002 and thereafter receive support from the NHSMA. Thus these 70 'independent sites' represent one form of control

for the 29 pilot sites – similar in many ways, but lacking earmarked resources to develop their services.

In addition our outline application aimed to evaluate genuinely independent "innovations in GE at the interface between primary and secondary care". In preparing that outline we wrote to all members of the British Society of Gastroenterology. Seventeen replied to say that they had developed, or were developing, new ways of managing patients newly referred to GE. Most of these, and two others, had also developed, or were developing, new ways of following up patients seen in GE clinics. However all 19 respondents were willing in principle to contribute to a project funded by the NHS SDO R&D Programme to evaluate innovations in managing GE referrals. We still regard the effective but efficient follow-up of patients with chronic, relapsing disease as an important issue in modernising GE services. However follow-up is not prominent in the MES Toolkit™. Given the opportunity to collaborate with the NHSMA to evaluate the MES initiatives focusing on the referral process, therefore, we have deferred our plans for a randomised trial of flexible nurse-led follow-up versus conventional doctor-led follow-up, as outlined in our outline application.

Of the 19 sites identified through the BSG, two are taking part in Phase 1 of the MES and another four in Phase 2. These six are thus ineligible to act as controls for the MES. Of the remaining 13 sites, four are in Scotland or Wales, 7 are among the 70 quasi-independent suites and the remaining 2 are among the 62 sites who did not apply to join the MES. Thus these 13 sites represent another form of control for the 29 pilot sites in that they have developed initiatives in GE independently of the MES.

In principle the proposed evaluation will compare a representative random sample of ten of the 29 MES 'pilot sites' with a comparable random sample comprising ten of the 70 MES 'independent sites' and five of the 'genuinely independent sites' identified through the BSG. Our preliminary survey of BSG members strongly suggests that, despite the link between the 10 independent sites and the MES, these 25 evaluative sites will generate a wide range of innovations covering the spectrum of outpatient and day case services, including but not limited to endoscopy services. Thus we expect new models of service delivery and organisation to address both the assessment of new patients and the surveillance of existing patients. In particular evaluative sites are likely to use a variety of approaches to improve the speed and appropriateness of referral and assessment, potentially including decision support systems, joint clinics between primary and secondary care, nurse-led consultations, nurse-led triage, one-stop assessments, on-line booking and rapid access clinics. In contrast those sites that seek to improve the efficiency of follow-up, if only to release resources for primary assessment, are likely to adopt the model of nurse-led telephone surveillance.

The contrast between the predicted heterogeneity of new models to deliver assessment services for newly referred patients and the predicted homogeneity of new models to deliver follow-up services for continuing patients has two implications for research design. First our methods of evaluation need to be sufficiently generic to provide a comprehensive comparison of the ten pilot sites and the 15 Control sites, covering both primary assessment and follow-up for 12 months after referral. Secondly there is real scope for a conventional randomised trial of flexible nurse-led follow-up versus conventional doctor-led follow-up, as outlined in our outline application. To focus on the challenging task of developing and implementing a generic evaluation package, however, we have deferred our plans for a randomised trial to evaluate the nurse-led model of GE follow-up.

D Plan of investigation

Research questions

The aims and objectives defined in Section 2A imply ten distinct research questions:

1. What new models of service delivery and organisation have stemmed from the Modernising Endoscopy Service (MES) and other current initiatives to improve the process of referral and follow-up for patients with serious or chronic gastrointestinal disorders?
2. What issues do these models create, and how do patients and professionals address these issues?
3. What is the effect of these models on speed of access from primary to secondary care, and other measures of the quality of the process of care?
4. How acceptable are these models to patients and professionals in primary and secondary care?
5. To what extent do patients and professionals in primary and secondary care value these models?
6. What is the effect of these models on outcome, as assessed by patients & professionals in primary and secondary care?
7. What resources do these models use from the NHS, patients and society in general?
8. What is the effect of these models on other health services?
9. Taking all these criteria into account, are these new models better on balance for patients? Are they better on balance for the NHS?
10. Again taking all these criteria into account, are the models initiated and co-ordinated by the MES better on balance than other new models for gastroenterology services?

Type and location of innovations

We shall use 25 sites in England, Scotland and Wales, representing three distinct approaches to innovation in GE services. The NHSMA has selected 29 'pilot sites' in England to receive funding, training and support from Phase 2 of the MES. They will use a Toolkit™ developed by the MES to analyse and redesign their current GE services, notably endoscopy. From these 29, we shall select a stratified random sample of ten 'experimental sites' keen to contribute to evaluation. A further 70 'independent sites' (NHSMA terminology) in England applied to take part in Phase 2 but were unsuccessful. From these we shall select a stratified random sample of ten 'MES Control sites' keen to use the Toolkit™ with training and support but no extra funding, and to contribute to evaluation. A further 13 sites committed to genuinely independent redesign of their GE services, including four in Scotland and Wales, responded to our circular to members of the British Society of Gastroenterology (BSG). From these we shall select a further stratified random sample of five 'BSG Control sites' keen to contribute to evaluation.

Design of evaluation

The NHSMA has specified that the 29 pilot sites, including our ten experimental sites, should complete their use of the MES Toolkit™ during 2003 and redesign their services during 2004. In collaboration with the NHSMA we plan to invite our 10 MES Control sites to complete their use of the Toolkit™ by July 2003 and to ask all 15 (MES and BSG) Control sites to redesign their services by July 2004. This differential timetable reflects the Control sites' lack of earmarked funding, which is likely to inhibit progress as they seek alternative resources for innovation, though not evaluation. Thus it allows them to seek alternative resources for redesign. More important it enables us to infer from Control sites

what would have happened in experimental sites in the absence of the national project, which gives them both official recognition and funding.

Thus our basic research design is that of a multiple interrupted time series design, in which the MES initiative 'interrupts' secular trends in the ten experimental sites, in principle from the start of 2003. In the 15 Control sites, in contrast, less formal innovations will interrupt secular trends, in principle from the second half of 2003. In practice, however, both types of site are sure to vary in their speed of innovation. This has implications for research design. First we shall use the various measures of referral performance being collected from the 29 pilot sites by the NHSMA – to identify the period of innovation in each of the ten experimental sites. Secondly we shall work with the NHSMA to extend the collection of these measures to the 15 Control sites. Similarly we shall use them to identify the period of innovation in each of the Control sites. In this way we shall plot the degree of overlap between the typical period of innovations in each type of site. This plot will assess the feasibility and power of using time series analysis to compare the effects of the MES initiative with those of the more heterogeneous control innovations. If time series analysis proves difficult to conduct or to report (more likely), we shall fall back on the simpler, though less powerful, design of a controlled before-and-after study. The main challenge of the simpler design would be to use the plots just mentioned to identify a time, perhaps towards the end of 2003, when the majority of experimental sites were well advanced in implementing their service redesigns while the majority of Control sites were not.

Measurement of outcome

To measure time between significant events in the referral process, we shall use data collected in collaboration with NHSMA from our 25 sites over three years from 2003 through 2005. To gather patients' assessments of their own outcomes (both generic through EQ-5D[20] and SF36[21], and specific to the GI tract), the quality of communication, and the extent of their own contributions and costs, we shall draw stratified samples of 40 patients per site in the spring and autumn of 2003, the spring and autumn of 2004, and the spring of 2005. We shall ask these 5000 patients to complete questionnaires at their first hospital appointment and by post 12 months later. To explore patients' views and preferences in more detail, we shall interview a 5% stratified random sample of respondents over two years from the spring of 2003. We shall interview stratified random samples of ten health care professionals per site over the same period. To estimate the incremental cost per quality-adjusted life year of the MES, we shall estimate the NHS and societal costs of innovative models and compare them with changes in patients' EQ-5D scores.

E. Methods (including the plan of analysis)

QUANTITATIVE METHODS

Study population and sample

All newly referred patients will be eligible for recruitment. We shall draw samples of 40 patients per site, stratified by age, sex and presenting complaint on five separate occasions – the spring and autumn of 2003, the spring and autumn of 2004, and the spring of 2005. We shall ask these 5000 patients to complete questionnaires at their first hospital appointment and by post 12 months later. Previously this research team has consistently followed up 75% of patients recruited to trials after one year[2,22,23]. If, as we expect, 25 centres participate in this phase, this could yield 3750 analysable patients. Given the Quasi-

experimental nature of the trial design, however, it is prudent to base power calculations on a responding sample of only 3000 patients.

Outcome measures

We shall measure time to consultation and diagnosis, and patient outcome as assessed by two widely used generic measures – EQ-5D[20] and SF36[21] – and the condition-specific UK Gastrointestinal Symptom Rating Questionnaire (GSRQ). The GSRQ, currently being validated in the MINuET study (HTA 97/37/09), covers the full range of GI symptoms and their effect on patients' Quality of Life. We shall assess the effect of changes to models of service delivery on GE services in general through median waiting times, for example for outpatient consultation and open access endoscopy, and other indicators like percentage of referrals 'fast tracked' and the outcomes of these referrals. Given the limitations of assessing patient 'satisfaction'[24], we shall assess the experience of both patients and general practitioners (GPs) through an instrument we are currently developing to map patients' pathways from the point of referral to communicated action plan. This will assess how administrative systems communicate with patients and GPs about appointments and procedures. Key items will include acknowledgement of referral and the timely provision of information about the proposed management plan to both patient and referrer. This instrument goes beyond 'satisfaction' of patient or GP to examine the critical aspects of a referral primarily intended for investigation. It should provide a valuable secondary research outcome of this study.

Statistical power

To calculate the power of this complex design at all accurately needs good information, notably about auto-correlation within time series and correlation between patients within sites. To simplify the calculation one can eschew possible gains in power from the time series analysis and possible losses from the heterogeneity of new service models, since both are likely to have much smaller effects than probable losses from intra-site correlations. There is little information in the literature, gastroenterological or more general, about the likely size of such correlations. We therefore rely on the accumulated experience of the many triallists within the MRC Health Services Research Collaboration, notably in Aberdeen, Bristol, York and Wales. This suggests that intra-cluster correlation rarely exceeds 0.01 for outcome measures. Since the total target size for each site is 200, the effective sample size is therefore unlikely to fall below 1000, viz 3000 / (1 + 200 x 0.01). Using a 5% significance level this would yield 80% power of detecting a standardised difference of 0.2 between the 10 experimental sites and the 15 Control sites in EQ5D, SF36 or GSRQ. In our judgement such a difference is the least that would be clinically important.

What will be the method of analysis?

Primary analysis will be by 'intention to treat'. We shall include all patients properly recruited even if they did not receive their intended pathway. We shall use multilevel modelling to take account of site effects, in particular of systematic differences between the models of service delivery adopted by each centre. As the basic design is Quasi-experimental, there is a danger that multi-collinearity (i.e. unintended correlation between service models and other patient characteristics) will prevent unequivocal quantitative conclusions. That is one reason why we have included a substantial qualitative component.

Economic Evaluation

Direct Service Costs

We shall estimate the NHS cost of each model of service delivery by identifying the resources consumed at each participating site using specially designed data collection forms. These will include all staff time, whether professional or administrative, devoted to managing and delivery the service. The health economic researcher will visit each site to identify a link person for each site and brief him or her on the data we are seeking and our preferred format. We shall value resources in monetary terms using standard methods[25] and derive a cost per patient referred. We shall compare the costs of the various models to the NHS and patients using methods tested in recent[2] and current trials[22,23] conducted by this research team.

Cost Utility Analysis (CUA)

In collaboration with the NHS Modernisation Agency we shall ask 200 patients per site, 5000 in total, to complete the EQ5D at their first hospital appointment and again 12 months later. The EQ5D is a global utility-based measure of health-related Quality of Life commonly used in cost utility analyses[20]. It comprises five dimensions – mobility, self care, usual activities, pain, and anxiety & depression. As different models of service delivery can affect resource use in other parts of the NHS, patients will simultaneously record NHS resource use in primary and secondary care and medication, over the previous three months. Patient recording is reliable means of collecting resource use data over this time period[26]. We shall also validate the most expensive contacts through clinical and administrative information systems in secondary care. Unless any model is dominant (i.e. achieves significantly better outcomes while costing significantly less), we shall estimate the incremental cost per quality adjusted life year (QALY) by comparing changes in EQ5D scores with NHS costs.

Cost Effectiveness Analysis

Thus CUA will compare general models of service delivery, rather than its commoner use in assessing specific interventions for well-defined patient groups. Accordingly while CUA should capture major differences in EQ5D scores, patient heterogeneity suggests that non-significant differences in this relatively insensitive measure may be more likely than in randomised trials. Accordingly we shall also conduct a cost effectiveness analysis. So patients will also complete the condition-specific GSRQ. As different models of service delivery may also affect travel and other costs borne by patients and their families, we shall also ask them to record these costs. We shall estimate cost effectiveness by comparing total societal costs (i.e. to NHS and patients) with changes in the principal symptom score on the GSRQ, that is the symptom that has the greatest effect on Quality of Life as measured by the EQ5D.

QUALITATIVE METHODS

We shall use qualitative methods to observe the processes of care and to assess the acceptability to patients and professionals in primary and secondary care of innovative models of referral, diagnosis and follow-up, and their perceptions of the value of these models. We shall use qualitative methods for four main reasons:

Models to improve the speed and appropriateness of referral are varied. They include decision support systems, joint primary-secondary care clinics, nurse-led consultations, nurse-led triage, on-line booking, one-stop assessments, and rapid access clinics. The views and experiences of those who have a stake in the models are potentially diverse. Factors affecting the success of these models are complex.

The breadth of issues to be addressed in evaluating innovations remains to be identified. Where centres use specialist nurses with telephones to reduce demand on resources, for example, they do so in different ways, including telephone clinics, telephone help-lines and telephone support. Information relating not only to outcome but also to structure and process will be important to determine.

The methodological framework – case studies and stakeholder analysis

A case study design will permit exploration in-depth and the identification of local differences while being sensitive to common issues and concerns. Those who have a stake in service delivery models include patients, consultants, GPs, specialist nurses and other professionals. The potential diversity of their experiences and views indicate the desirability of a stakeholder analysis[27,28]. This has the capacity to:

- accommodate the diversity of experiences and views;
- allow the researchers to remain relatively impartial by recognising that different stakeholders may have different success criteria;
- identify similarities and differences between and within stakeholder groups; and
- explore the attributed reasons for outcomes, which are experienced and perceived as success or failure, strength or weakness.

Sampling strategy

We shall draw random samples of patients from the same sampling frames as the quantitative patient survey. To ensure that we sample the full range of issues for patients, their questions will include:

- What are their views on the novel systems?
- How do they experience speed of access? If there are benefits, what form do they take? If there are costs, what form do they take?
- How do past experiences influence patients' present experiences of seeking advice on symptoms that raise the possibility of cancer?
- How do they compare and contrast their relationships with doctors and nurses?
- How confident are patients about consulting a nurse?
- What are the benefits and costs of nurse-led advice and consultation?

We shall identify the other stakeholder groups and cover the full range of issues relevant to them. We shall seek to establish the frequency and depth of concerns and to extrapolate directly from these samples to the populations from which they come. We shall sample professionals strategically to include those who can provide answers to questions such as:

- What are their views of all the models of service delivery they experience?
- What issues have they encountered in setting up new models? How have they and others overcome difficulties?
- What are their views of substitution as a means of improving access and speed of referral?
- How have lines of accountability changed?
- How have clinical, professional, legal and administrative responsibilities changed?
- Are there areas of overlap and ambiguity? How have they and others addressed these?

Data collection and analysis

Semi-structured tape-recorded interviews will be the main instruments of data collection. A few focus group interviews will enable patients to explore issues of importance to them as a group, using their own vocabulary, generating their own questions and pursuing their own priorities[29]. They can also generate aspects of a topic not contemplated by the researchers. In exploring the views of professionals through focus groups, experience suggests that profession-specific groups provide most useful data. In contrast individual interviews allow for the exploration at length and in depth of private concerns and issues. However this potential strength can be a weakness if interviewees feel they have revealed information that makes them vulnerable. The applicants are aware of these potential problems, and experienced in the ethical conduct of research and handling sensitive issues. In particular we shall seek written informed consent from all interviewees.

We shall transcribe tape-recorded interviews and subject them to rigorous textual analysis, both manually and where appropriate through a text analysis software package like NUDIST. Analysis will describe patients' and professionals' assessments of innovation. We shall also use SPSS to expedite the analysis of demographic data collected. We shall identify, link and categorise themes running through the data. Glaser and Strauss[30] argue that coding is essential in minimising subjectivity in the analysis of qualitative data. May[31] provides a useful practical guide to the coding of qualitative coding based on the principles of rigour and explicitness. We shall discuss the resulting themes in relation to published studies on innovations in health care delivery to see how far they confirm or challenge other published findings.

To provide contextual data, we shall observe processes of care at each site. While interviews and questionnaires yield accounts of what respondents do in principle and why, observation offers researchers an opportunity to see what people do in practice. The tradition of participant observation stems from the discipline of social anthropology and contributes widely to sociological research[32-35]. Collectively these qualitative methods of data collection are known as ethnography. This style of research seeks to understand the social meanings and activities of people in given settings. To this end it uses close association with, and often participation in, those settings[35].

CONCLUSION

This study will build on our current experience of working with gastroenterology services in a 25-centre trial of nurses undertaking upper and lower endoscopy (MINuET). Our experience in that and other multi-centre trials [e.g. 2,22,23] strongly suggests that the proposed study is feasible and potentially very valuable.

Please state the benefits of this research to the NHS

This study will yield greater understanding of the benefits and costs, to patients, professionals and the NHS, of new approaches to delivering secondary care to patients, using a specialty in which many different professionals work together, including physicians, surgeons, radiologists, pathologists, nurses, and dieticians. It will identify new models of service delivery and organisation that achieve improvements in clinical and cost effectiveness. It will disseminate these for uptake in other hospitals and disciplines, with advice on designing, preparing and implementing new models of service delivery and organisation. It will give valuable insights into the management of change within the NHS, notably change initiated by the NHS Modernisation Agency and analogous bodies. It will advance the evaluation of complex heterogeneous interventions designed with a common purpose and contribute to methodological development in this difficult field.

Please outline your proposals for the involvement of stakeholders throughout the project. This should include service users and those who plan, manage & deliver services

We plan to involve patients throughout the project. In this and many other ways we shall work closely with the NHS Modernisation Agency, who have particular responsibility for involving both patients and health professionals. One of the applicants (GE) has considerable research and clinical experience of communicating with patients and sharing decisions with them. So we are especially keen that patients contribute to the project team. We shall also seek the views and preferences of large representative samples of patients, through both interviews in depth and questionnaires validated for self-completion.

We shall also interview in depth representative samples of those responsible for planning and managing new services, and of health care professionals responsible for service delivery.

H. Plans for the dissemination of results

We shall disseminate the findings of this study energetically and extensively. We shall communicate them to the NHS through the NHS Modernisation Agency and associated bodies. We shall also make them accessible to the scientific community through peer-reviewed publication. In the first instance we shall submit them to a general medical journal like the BMJ. We shall also present them to the annual meeting of the British Society of Gastroenterology (BSG), which is attended by physicians, surgeons, radiologists, pathologists, clinical scientists, nurses and dieticians working in gastroenterology. We shall summarise the findings on the Society's website and in its newsletter. We shall also disseminate them to patients through the National Association for Colitis and Crohn's Disease, the Coeliac Society, and analogous bodies. We shall circulate an appropriate press release to the national press. We shall also encourage all collaborating centres to publicise the findings locally.

I. Justification of costs, including the time spent on the project by each researcher (even if they are being funded from an alternative source).

This complex multi-centre study will require two research assistants (Grade 2 pt 11) to coordinate the data collection from the study sites and to undertake the primary analysis required. One will have a quantitative background, be familiar with routine data, electronic handling of study data and its analysis; the other will be primarily responsible for organising, collecting and analysing the data collected through qualitative approaches (patient interviews, focus groups etc). A 0.25 FTE health economist will be retained to initiate and oversee the economic appraisal of the new models of service delivery resulting from the study sites.

The study will be supported by two clerical posts – a 0.5 FTE Grade 3 clerical assistant, who will be responsible for the quantitative data and its validation; and a full-time Grade 3 will be the main point of contact for the study sites and provide the link to the research team and steering group and will also assist with the transcription of the qualitative data collected. Both posts will be involved in the distribution of study materials to the sites and mailings to participants.

A substantial allowance for travel will be needed, as the study sites will require visits from the researchers at the beginning of the study, and patient interviews and focus groups will require travel costs to be reimbursed to researchers and participants. Regular steering group and project team meetings will also mean that the trial costs of participants are met.

5,000 questionnaires, with follow-ups and return envelopes will be required (printing and postage). A budget of £5,000 per study site has been set to offset the costs of data collection. Laptop computers will be required for the research assistants (who will have to be fully mobile) and desktop PCs for the clerical officers. Allowances for general stationery costs, audio recorder and tapes, and venue and catering costs for focus groups have also been included.

The Modernisation Agency has agreed to be fully involved in the organisation of the trial and to support this work through the involvement of its co-applicants and other members of its teams.

Appendix 2 – 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"	"2004-005"
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

Appendix 3 – Baseline Questionnaire

Study Number | | | | | |

Evaluating Innovations in Gastroenterology
for the NHS Modernisation Agency
(ENIGMA) study

Baseline Questionnaire

A questionnaire for people with digestive and bowel disorders

Please complete this questionnaire at home as soon as you have time and return to us using the prepaid envelope enclosed.

PLEASE DO NOT WAIT UNTIL YOU RECEIVE YOUR APPOINTMENT TO COMPLETE THIS.

CONFIDENTIAL

Please read all the instructions before completing this questionnaire.

Thank you for agreeing to take part in this study. The answers you give in this questionnaire will help us to find out if the treatments you receive are helpful for your condition.

The information you provide will be completely confidential and will not affect your treatment in any way.

Please answer all the questions. Although it may seem that some questions are asked more than once, it is still important that you answer every one. If you find it difficult to answer a question, please do the best you can.

Please follow the instructions for each section of the questionnaire carefully.

For each section, if you are asked to put a cross in the box, please use a cross, as if you were filling out a ballot paper, rather than a tick.

For example in the following question, if your answer is yes, you should place a cross firmly in the corresponding box.

	Yes	No
Do you drive a car?	☒	☐

Please use a black or blue pen. Do not use a pencil or any other coloured pen.

Please complete the questionnaire fully and return it in the FREEPOST envelope provided as soon as possible. Please do not wait until your appointment to complete it.

Evaluating Innovations in Gastroenterology
for the NHS Modernisation Agency (ENIGMA)

Consent

	Please cross each box to show that you agree with the statement
I have received the patient information sheet, understand the study and agree to participate.	☐
I understand that I will be asked to complete questions about my health, feelings and quality of life and views about the service.	☐
I understand that my participation is voluntary and that I can withdraw from the study at any time, and this will not affect my medical care.	☐
I understand that my General Practitioner will be notified of my participation in this study, unless I request that this does not happen.	☐
I understand that the study team may look at my medical notes. I give permission for the study team to access my medical notes for the purposes of this research.	☐

Signature _____ Date _____

Name in capitals _____

Please complete your name and address so that we can send you the second questionnaire and the name and address of your GP so that we can notify him/her of your inclusion in the study.

Name & address	GP Name & address
.....	.....
.....	.....
.....	.....
.....	.....
Postcode	Postcode .....

Please sign below if you **do not** want your General Practitioner to be notified.

I do not wish my General Practitioner to be notified that I am taking part in this study.

Signature _____ Date _____

Please enter the date you are completing this questionnaire below

D D / M M / Y Y Y Y

SECTION A

This section asks about your symptoms. When answering the questions about the effect on your life, consider how these symptoms prevented you from doing your usual activities over the **last 2 weeks**.

Answer each question by **putting a cross in the corresponding box**. Do not cross more than one box in each group. If you are unsure about how to answer a question, please give the best answer you can.

A1. In the **last 2 weeks**, how often have you experienced heartburn (a burning sensation behind your breast bone)?

- Not at all ☐
- Once a week ☐
- Two or three times a week ☐
- Most days ☐
- Everyday ☐

A2. In the **last 2 weeks**, how often have you had any discomfort in your upper abdomen (above your belly button and below your ribs)?

- Not at all ☐
- Once a week ☐
- Two or three times a week ☐
- Most days ☐
- Everyday ☐

If you have **not** had any of the symptoms or problems described in questions A1 and A2, skip question A3 and go straight to question A4 over the page

A3. In the **last 2 weeks**, how much have the symptoms described in questions A1 and A2 prevented you from doing your usual activities?

- Not at all ☐
- A little ☐
- Moderately ☐
- A lot ☐
- Extremely ☐

A4. In the **last 2 weeks**, how often have you experienced bitter bile or acid reflux (from the stomach into the throat)?

Not at all ☐
Once a week ☐
Two or three times a week ☐
Most days ☐
Everyday ☐

A5. In the **last 2 weeks**, how often have you experienced a feeling of nausea or sickness without actually vomiting?

Not at all ☐
Once a week ☐
Two or three times a week ☐
Most days ☐
Everyday ☐

A6. In the **last 2 weeks**, how often have you retched or heaved without actually vomiting?

Not at all ☐
Once a week ☐
Two or three times a week ☐
Most days ☐
Everyday ☐

A7. In the **last 2 weeks**, how often have you actually vomited?

Not at all ☐
Once a week ☐
Two or three times a week ☐
Most days ☐
Everyday ☐

A8. If you have vomited in the **last 2 weeks**, have you seen any blood in the vomit?

Yes ☐

No ☐

Not applicable ☐

If you have **not** had any of the symptoms or problems described in questions A4 to A8, skip question A9 and go directly to question A10

A9. In the **last 2 weeks**, how much have the symptoms described in question A4 to question A8 prevented you from doing your usual activities?

Not at all ☐

A little ☐

Moderately ☐

A lot ☐

Extremely ☐

A10. In the **last 2 weeks**, how often have you been bothered by a lot of belching or burping (release of wind from the stomach by the mouth)?

Not at all ☐

Once a week ☐

Two or three times a week ☐

Most days ☐

Everyday ☐

A11. In the **last 2 weeks**, how often have you been bothered by passing a lot of wind from the back passage?

Not at all ☐

Once a week ☐

Two or three times a week ☐

Most days ☐

Everyday ☐

A12. In the **last 2 weeks**, how often have you experienced bloatedness, and or a feeling of trapped wind in your stomach?

Not at all ☐
Once a week ☐
Two or three times a week ☐
Most days ☐
Everyday ☐

A13. In the **last 2 weeks**, how often have you experienced loud gurgling noises from your stomach?

Not at all ☐
Once a week ☐
Two or three times a week ☐
Most days ☐
Everyday ☐

If you have **not** had any of the symptoms or problems described in questions A10 to A13, skip question A14 and go straight to question A15 over the page

A14. In the **last 2 weeks**, how much have the symptoms described in question A10 to question A13 prevented you from doing your usual activities?

Not at all ☐
A little ☐
Moderately ☐
A lot ☐
Extremely ☐

A15. In the **last 2 weeks**, how often have you felt that your food sticks on the way down your gullet (through the chest into your stomach)?

- Not at all ☐
- Once a week ☐
- Two or three times a week ☐
- Most days ☐
- Everyday ☐

A16. In the **last 2 weeks**, how often have your eating habits been restricted because of your condition (examples might be having to eat more slowly, having to take smaller portions or having to eat different foods)?

- Not at all ☐
- Once a week ☐
- Two or three times a week ☐
- Most days ☐
- Everyday ☐

A17. In the **last 2 weeks** have you had a lack of appetite?

- Not at all ☐
- Once a week ☐
- Two or three times a week ☐
- Most days ☐
- Everyday ☐

If you have **not** had any of the symptoms or problems described in questions A15 to A17, skip question A18 and go to question A19 over the page

A18. In the **last 2 weeks**, how much have the symptoms described in question A15 to question A17 prevented you from doing your usual activities?

- Not at all ☐
- A little ☐
- Moderately ☐
- A lot ☐
- Extremely ☐

A19. Have you noticed any change in weight (not due to a change in your diet) over the **last 3 months**?

- No, my weight has been stable ☐
- Yes, I have been gaining weight ☐
- Yes, I have been loosing weight ☐

A20. In the **last 2 weeks**, how often have you been bothered by too frequent emptying of your bowels?

- Not at all ☐
- Once a week ☐
- Two or three times a week ☐
- Most days ☐
- Everyday ☐

A21. In the **last 2 weeks**, how often have you been bothered by loose stools?

- Not at all ☐
- Once a week ☐
- Two or three times a week ☐
- Most days ☐
- Everyday ☐

A22. In the **last 2 weeks**, how often have you been bothered by hard stools?

- Not at all ☐
- Once a week ☐
- Two or three times a week ☐
- Most days ☐
- Everyday ☐

A23. In the **last 2 weeks**, how often have you been bothered by constipation (constipation means difficulty in emptying your bowels)?

- Not at all ☐
- Once a week ☐
- Two or three times a week ☐
- Most days ☐
- Everyday ☐

A24. In the **last 2 weeks**, how often have you had an urgent need to empty your bowels (this urgent need is often associated with a feeling that you are not in full control)?

- Not at all ☐
- Once a week ☐
- Two or three times a week ☐
- Most days ☐
- Everyday ☐

A25. In the **last 2 weeks,** how often have you had a feeling of not completely emptying your bowels?

- Not at all ☐
- Once a week ☐
- Two or three times a week ☐
- Most days ☐
- Everyday ☐

A26. In the **last 2 weeks**, have you had bleeding through your back passage (signs of bleeding include fresh blood, staining of toilet tissue, blood mixed with stools)?

- Not at all ☐
- A little ☐
- Moderately ☐
- A lot ☐
- Extremely ☐

If you have **not** had any of the symptoms or problems described in questions A20 to A26, skip question A27 and go straight to question A28

A27. In the **last 2 weeks**, how much have the symptoms described in question A20 to question A26 prevented you from doing your usual activities?

Not at all ☐
A little ☐
Moderately ☐
A lot ☐
Extremely ☐

A28. Compared with **2 weeks ago**, how would you now rate your symptoms in general?

Much better now than 2 weeks ago ☐
Somewhat better now than 2 weeks ago ☐
About the same as 2 weeks ago ☐
Somewhat worse now than 2 weeks ago ☐
Much worse now than 2 weeks ago ☐

A29. In the **last 2 weeks**, how often have your symptoms caused you difficulties in getting to sleep?

Not at all ☐
Once a week ☐
Two or three times a week ☐
Most nights ☐
Every night ☐

A30. In the **last 2 weeks**, how often have your symptoms caused you to wake up?

Not at all ☐
Once a week ☐
Two or three times a week ☐
Most nights ☐
Every night ☐

SECTION B

This section asks for your views about your health, how you feel and how well you are able to do your usual activities.

Answer every question by **putting a cross in the corresponding box**. Do not cross more than one box in each group. If you are unsure about how to answer a question, please give the best answer you can.

B1. In general, would you say your health is:

Excellent	Very good	Good	Fair	Poor
☐	☐	☐	☐	☐

B2. Compared to **1 year ago**, how would you rate your health in general now?

Much better now than one year ago	Somewhat better now than one year ago	About the same as one year ago	Somewhat worse now than one year ago	Much worse now than one year ago
☐	☐	☐	☐	☐

B3. The following questions are about activities you might do during **a typical day**. Does your health now limit you in these activities? If so, how much? (**cross a box on each line**)

	Yes, limited a lot	Yes, limited a little	No, not limited at all
Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports	☐	☐	☐
Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling or playing golf	☐	☐	☐
Lifting or carrying groceries	☐	☐	☐
Climbing several flights of stairs	☐	☐	☐
Climbing one flight of stairs	☐	☐	☐
Bending, kneeling or stooping	☐	☐	☐
Walking more than a mile	☐	☐	☐
Walking several hundred yards	☐	☐	☐
Walking one hundred yards	☐	☐	☐
Bathing or dressing yourself	☐	☐	☐

B4. During the **past 4 weeks**, how much of the time have you had any of the following problems with your work or other regular daily activities as a result of your physical health?

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
Cut down on the amount of time you spent on work or other activities	☐	☐	☐	☐	☐
Accomplished less than you would like	☐	☐	☐	☐	☐
Were limited in the kind of work or other activities	☐	☐	☐	☐	☐
Had difficulty performing the work or other activities (for example, it took extra effort)	☐	☐	☐	☐	☐

B5. During the **past 4 weeks**, how much of the time have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)?

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
Cut down on the amount of time you spent on work or other activities	☐	☐	☐	☐	☐
Accomplished less than you would like	☐	☐	☐	☐	☐
Did work or activities less carefully than usual	☐	☐	☐	☐	☐

B6. During the **past 4 weeks**, to what extent has your physical health or emotional problems interfered with your normal activities with family, friends, neighbours, or groups?

Not at all	Slightly	Moderately	Quite a bit	Extremely
☐	☐	☐	☐	☐

B7. How much bodily pain have you had during the **past 4 weeks**?

None	Very mild	Mild	Moderate	Severe	Very severe
☐	☐	☐	☐	☐	☐

B8. During the **past 4 weeks**, how much did pain interfere with your normal work (including both work outside the home and housework)?

Not at all	Slightly	Moderately	Quite a bit	Extremely
☐	☐	☐	☐	☐

B9. These questions are about how you feel and how things have been with you during the **past 4 weeks**. For each question, please give ONE answer that comes closest to the way you have been feeling.

How much of the time during the **past 4 weeks** .....

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
Did you feel full of life?	☐	☐	☐	☐	☐
Have you been very nervous?	☐	☐	☐	☐	☐
Have you felt so down in the dumps that nothing could cheer you up?	☐	☐	☐	☐	☐
Have you felt calm and peaceful?	☐	☐	☐	☐	☐
Did you have a lot of energy?	☐	☐	☐	☐	☐
Have you felt downhearted and depressed?	☐	☐	☐	☐	☐
Did you feel worn out?	☐	☐	☐	☐	☐
Have you been happy?	☐	☐	☐	☐	☐
Did you feel tired?	☐	☐	☐	☐	☐

B10. During the **past 4 weeks**, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting friends, relatives, etc)?

All of the time	Most of the time	Some of the time	A little of the time	None of the time
☐	☐	☐	☐	☐

B11. How TRUE or FALSE is each of the following statements for you?

	Definitely true	Mostly true	Don't know	Mostly false	Definitely false
I seem to get sick a little easier than other people	☐	☐	☐	☐	☐
I am as healthy as anybody I know	☐	☐	☐	☐	☐
I expect my health to get worse	☐	☐	☐	☐	☐
My health is excellent	☐	☐	☐	☐	☐

SECTION C

This section asks about your health in general. Please indicate which statement best describes **your own health state today**.

Answer each question by **putting a cross in the corresponding box.** Do not cross more than one box in each group. If you are unsure about how to answer a question, please give the best answer you can.

C1. Mobility

I have no problems in walking about ☐

I have some problems in walking about ☐

I am confined to bed ☐

C2. Self care

I have no problems with self-care ☐

I have some problems with self-care ☐

I am unable to wash or dress myself ☐

C3. Usual Activities

I have no problems with performing my usual activities ☐

I have some problems with performing my usual activities ☐

I am unable to perform my usual activities ☐

C4. Pain / Discomfort

I have no pain or discomfort ☐

I have moderate pain or discomfort ☐

I have extreme pain or discomfort ☐

C5. Anxiety/Depression

I am not anxious or depressed ☐

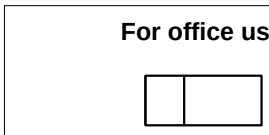
I am moderately anxious or depressed ☐

I am extremely anxious or depressed ☐

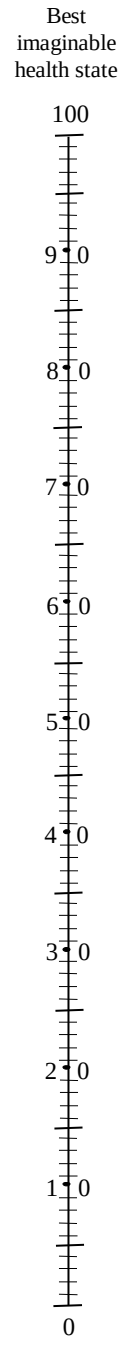
To help people say how good or bad their health state is, we have drawn a scale (rather like a thermometer) on which the best state you can imagine is marked 100 and the worst state you can imagine is marked 0.

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

For office use



Your own health state today



SECTION D

This section is about the health care you have had in the **last 3 months**. Please read each question carefully. For each question, if you have had no treatment or visits enter '0' as indicated.

We would like to know about visits to health professionals **for any reason**, not just your digestive or bowel symptoms.

D1. How often have you consulted, for any reason, any of the following at your GP's surgery in the **last 3 months**?

Your own or another GP ☐☐ If none enter '0'

Nurse ☐☐ If none enter '0'

Other (please specify) _____ ☐☐ If none enter '0'

D2. How often have you consulted, for any reason, any of the following at home in the **last 3 months**?

Your own or another GP ☐☐ If none enter '0'

Nurse ☐☐ If none enter '0'

Other (please specify) ☐☐ If none enter '0'

D3. How often have you been admitted, for any reason, to a hospital (NHS or private) as an emergency in the **last 3 months**?

☐☐ If none enter '0'

D4. How often have you been admitted, for any reason, to a hospital (NHS or private) NOT as an emergency in the **last 3 months**?

☐☐ If none enter '0'

D5. How many times have you been seen, for any reason at a hospital outpatient clinic in the **last 3 months**?

By a Doctor ☐☐ If none enter '0'

By a Nurse Practitioner ☐☐ If none enter '0'

By a Dietician ☐☐ If none enter '0'

By anyone else (please specify) ☐☐ If none enter '0'

D6. How many times have you been admitted as a day case for upper or lower endoscopy in the **last 3 months**?

Upper endoscopy ☐☐ If none enter '0'

Lower endoscopy ☐☐ If none enter '0'

D7. If you are in work, how many days work have you lost due to illness or in order to see any health professional in the **last 3 months**?

☐☐ If none enter '0'

SECTION E

Look at the list of medications below. If you take any of the medications listed below, please enter the dose of each tablet (this will be written on the tablet box or bottle) and the number of tablets you take each day. Answer 'yes' or 'no' to whether you are taking the drug regularly and if you answer 'no' please enter the average number of tablets you take each month.

	Each tablet dose in mg	Number of tablets per day	Regular?		If not regularly, average number of tablets taken per month
Indigestion medication					
Nexium (Esomeprazole)	☐☐☐	☐☐	Yes ☐	No ☐	☐☐☐
Losec (Omeprazole)	☐☐☐	☐☐	Yes ☐	No ☐	☐☐☐
Zoton (Lansoprazole)	☐☐☐	☐☐	Yes ☐	No ☐	☐☐☐
Protium (Pantoprazole)	☐☐☐	☐☐	Yes ☐	No ☐	☐☐☐
Pariet (Rabeprazole)	☐☐☐	☐☐	Yes ☐	No ☐	☐☐☐
Zantac (Ranitidine)	☐☐☐	☐☐	Yes ☐	No ☐	☐☐☐
Pepcid (Famotidine)	☐☐☐	☐☐	Yes ☐	No ☐	☐☐☐
Axid (Nizatidine)	☐☐☐	☐☐	Yes ☐	No ☐	☐☐☐
Tagamet (Cimetidine)	☐☐☐	☐☐	Yes ☐	No ☐	☐☐☐
Maxolon (Metoclopramide)	☐☐☐	☐☐	Yes ☐	No ☐	☐☐☐
Motilium (Domperidone)	☐☐☐	☐☐	Yes ☐	No ☐	☐☐☐
Medication for irritable bowel					
Spasmonal (Alverine)	☐☐☐	☐☐	Yes ☐	No ☐	☐☐☐
Merbentyl (Dicycloverine)	☐☐☐	☐☐	Yes ☐	No ☐	☐☐☐
Buscopan (Hyoscine)	☐☐☐	☐☐	Yes ☐	No ☐	☐☐☐
Colpermin	☐☐☐	☐☐	Yes ☐	No ☐	☐☐☐
Colofac (Mebeverine)	☐☐☐	☐☐	Yes ☐	No ☐	☐☐☐
Fybogel	☐☐☐	☐☐	Yes ☐	No ☐	☐☐☐
Anti-diarrhoeal medication					
Imodium (Loperamide)	☐☐☐	☐☐	Yes ☐	No ☐	☐☐☐
Codeine Phosphate	☐☐☐	☐☐	Yes ☐	No ☐	☐☐☐
Questran (Colestyramine)	☐☐☐	☐☐	Yes ☐	No ☐	☐☐☐
Lomotil (Co-phenetrope)	☐☐☐	☐☐	Yes ☐	No ☐	☐☐☐

Medication for Colitis	Each tablet dose in mg	Number of tablets per day	Regular?	If not regularly, average number of tablets taken per month
Asacol or Pentasa or Salofalk (Mesalazine)	☐☐☐	☐☐	Yes ☐ No ☐	☐☐☐
Colazide (Balsalazide)	☐☐☐	☐☐	Yes ☐ No ☐	☐☐☐
Dipentum (Olsalazine)	☐☐☐	☐☐	Yes ☐ No ☐	☐☐☐
Salazopyrin (Sulfasalazine)	☐☐☐	☐☐	Yes ☐ No ☐	☐☐☐
Entocort or Budenofalk(Budesonide)	☐☐☐	☐☐	Yes ☐ No ☐	☐☐☐
Prednisolone (by mouth)	☐☐☐	☐☐	Yes ☐ No ☐	☐☐☐

	Number per day	Regular?	If not regularly, average number per month
Predsol or Predfoam or Predenema (enemas)	☐☐	Yes ☐ No ☐	☐☐☐

If you take any other tablets/liquids for your **digestive or bowel symptoms**, that are not listed, please write the details in the list below. Please include any prescriptions and medicines you buy over the counter from the chemist or supermarket (examples include antacids and laxatives)

Name of medicine	On prescription	Dose in mg or ml	How many times taken per week
☐☐☐☐☐☐☐☐☐☐☐☐	Yes ☐ No ☐	☐☐☐	☐☐☐
☐☐☐☐☐☐☐☐☐☐☐☐	Yes ☐ No ☐	☐☐☐	☐☐☐
☐☐☐☐☐☐☐☐☐☐☐☐	Yes ☐ No ☐	☐☐☐	☐☐☐
☐☐☐☐☐☐☐☐☐☐☐☐	Yes ☐ No ☐	☐☐☐	☐☐☐
☐☐☐☐☐☐☐☐☐☐☐☐	Yes ☐ No ☐	☐☐☐	☐☐☐
☐☐☐☐☐☐☐☐☐☐☐☐	Yes ☐ No ☐	☐☐☐	☐☐☐

If you wish to add any comments regarding your medication, please enter them in the box below.

22

What test are you having? (please write in the box below)

If you are not sure what test you are having, please cross this box. ☐

Are you happy to take part in a telephone interview with one of our researchers?

Yes ☐ No ☐

Please enter your date of birth below

☐☐ / ☐☐ / ☐☐☐☐

D D M M Y Y Y Y

Please enter your sex below

Male ☐ Female ☐

Please enter your initials in the box below

☐☐☐

Thank you for completing this questionnaire.

If you have any general comments about your digestive or bowel treatment, or this questionnaire, please write them below.

Once you have completed the questionnaire please return it in the FREEPOST envelope provided, or send it to

ENIGMA Study Team
Swansea Clinical School
University of Wales Swansea
Singleton Park
Swansea
SA2 8PP

If you have any concerns about your symptoms please consult your GP or hospital doctor.

YOUR COMMENTS

Appendix 4 – Post Procedure Questionnaire

Study Number | | | | | |

Evaluating Innovations in Gastroenterology
for the NHS Modernisation Agency
(ENIGMA) study

Post Procedure Questionnaire

A questionnaire for people with digestive and bowel disorders

Please complete this questionnaire at home and return to us using the prepaid envelope enclosed

CONFIDENTIAL

Please read all the instructions before completing this questionnaire.

When you agreed to take part in this study, you kindly completed a questionnaire about your health and treatment. We would now like to repeat this following your recent procedure or test.

The answers you give in this questionnaire will help us to find out if the treatments you receive are helpful for your condition.

The information you provide will be completely confidential and will not affect your treatment in any way.

Please answer all the questions. Although it may seem that some questions are asked more than once, it is still important that you answer every one. If you find it difficult to answer a question, please do the best you can.

Please follow the instructions for each section of the questionnaire carefully.

For each section, if you are asked to put a cross in the box, please use a cross, as if you were filling out a ballot paper, rather than a tick.

For example in the following question, if your answer is yes, you should place a cross firmly in the corresponding box.

	Yes	No
Do you drive a car?	☒	☐

Please use a black or blue pen. Do not use a pencil or any other coloured pen.

Please complete the questionnaire fully and return it in the FREEPOST envelope provided as soon as possible.

Please enter the date you are completing this questionnaire below

		/			/				
D	D		M	M		Y	Y	Y	Y

SECTION A

This section asks about your symptoms. When answering the questions about the effect on your life, consider how these symptoms prevented you from doing your usual activities over the **last 2 weeks**.

Answer every question by **putting a cross in the corresponding box.** Do not cross more than one box in each group. If you are unsure about how to answer a question, please give the best answer you can.

A1. In the **last 2 weeks**, how often have you experienced heartburn (a burning sensation behind your breast bone)?

- Not at all ☐
- Once a week ☐
- Two or three times a week ☐
- Most days ☐
- Everyday ☐

A2. In the **last 2 weeks**, how often have you had any discomfort in your upper abdomen (above your belly button and below your ribs)?

- Not at all ☐
- Once a week ☐
- Two or three times a week ☐
- Most days ☐
- Everyday ☐

If you have **not** had any of the symptoms or problems described in questions A1 and A2, skip question A3 and go straight to question A4 over the page.

A3. In the **last 2 weeks**, how much have the symptoms described in questions A1 and A2 prevented you from doing your usual activities?

- Not at all ☐
- A little ☐
- Moderately ☐
- A lot ☐
- Extremely ☐

A4. In the **last 2 weeks**, how often have you experienced bitter bile or acid reflux (from the stomach into the throat)?

Not at all ☐
Once a week ☐
Two or three times a week ☐
Most days ☐
Everyday ☐

A5. In the **last 2 weeks**, how often have you experienced a feeling of nausea or sickness without actually vomiting?

Not at all ☐
Once a week ☐
Two or three times a week ☐
Most days ☐
Everyday ☐

A6. In the **last 2 weeks**, how often have you retched or heaved without actually vomiting?

Not at all ☐
Once a week ☐
Two or three times a week ☐
Most days ☐
Everyday ☐

A7. In the **last 2 weeks,** how often have you actually vomited?

Not at all ☐
Once a week ☐
Two or three times a week ☐
Most days ☐
Everyday ☐

A8. If you have vomited in the **last 2 weeks**, have you seen any blood in the vomit?

Yes ☐

No ☐

Not applicable ☐

If you have **not** had any of the symptoms or problems described in questions A4 to A8, skip question A9 and go directly to question A10.

A9. In the **last 2 weeks**, how much have the symptoms described in question A4 to question A8 prevented you from doing your usual activities?

Not at all ☐

A little ☐

Moderately ☐

A lot ☐

Extremely ☐

A10. In the **last 2 weeks**, how often have you been bothered by a lot of belching or burping (release of wind from the stomach by the mouth)?

Not at all ☐

Once a week ☐

Two or three times a week ☐

Most days ☐

Everyday ☐

A11. In the **last 2 weeks**, how often have you been bothered by passing a lot of wind from the back passage?

Not at all ☐

Once a week ☐

Two or three times a week ☐

Most days ☐

Everyday ☐

A12. In the **last 2 weeks**, how often have you experienced bloatedness, and or a feeling of trapped wind in your stomach?

- Not at all ☐
- Once a week ☐
- Two or three times a week ☐
- Most days ☐
- Everyday ☐

A13. In the **last 2 weeks**, how often have you experienced loud gurgling noises from your stomach?

- Not at all ☐
- Once a week ☐
- Two or three times a week ☐
- Most days ☐
- Everyday ☐

If you have **not** had any of the symptoms or problems described in questions A10 to A13, skip question A14 and go straight to question A15 over the page.

A14. In the **last 2 weeks**, how much have the symptoms described in question A10 to question A13 prevented you from doing your usual activities?

- Not at all ☐
- A little ☐
- Moderately ☐
- A lot ☐
- Extremely ☐

A15. In the **last 2 weeks**, how often have you felt that your food sticks on the way down your gullet (through the chest into your stomach)?

- Not at all ☐
- Once a week ☐
- Two or three times a week ☐
- Most days ☐
- Everyday ☐

A16. In the **last 2 weeks**, how often have your eating habits been restricted because of your condition (examples might be having to eat more slowly, having to take smaller portions or having to eat different foods)?

- Not at all ☐
- Once a week ☐
- Two or three times a week ☐
- Most days ☐
- Everyday ☐

A17. In the **last 2 weeks** have you had a lack of appetite?

- Not at all ☐
- Once a week ☐
- Two or three times a week ☐
- Most days ☐
- Everyday ☐

If you have **not** had any of the symptoms or problems described in questions A15 to A17, skip question A18 and go to question A19 over the page.

A18. In the **last 2 weeks**, how much have the symptoms described in question A15 to question A17 prevented you from doing your usual activities?

- Not at all ☐
- A little ☐
- Moderately ☐
- A lot ☐
- Extremely ☐

A19. Have you noticed any change in weight (not due to a change in your diet) over the **last 3 months**?

- No, my weight has been stable ☐
- Yes, I have been gaining weight ☐
- Yes, I have been losing weight ☐

A20. In the **last 2 weeks**, how often have you been bothered by too frequent emptying of your bowels?

- Not at all ☐
- Once a week ☐
- Two or three times a week ☐
- Most days ☐
- Everyday ☐

A21. In the **last 2 weeks**, how often have you been bothered by loose stools?

- Not at all ☐
- Once a week ☐
- Two or three times a week ☐
- Most days ☐
- Everyday ☐

A22. In the **last 2 weeks**, how often have you been bothered by hard stools?

- Not at all ☐
- Once a week ☐
- Two or three times a week ☐
- Most days ☐
- Everyday ☐

A23. In the **last 2 weeks**, how often have you been bothered by constipation (constipation means difficulty in emptying your bowels)?

- Not at all ☐
- Once a week ☐
- Two or three times a week ☐
- Most days ☐
- Everyday ☐

A24. In the **last 2 weeks**, how often have you had an urgent need to empty your bowels (this urgent need is often associated with a feeling that you are not in full control)?

- Not at all ☐
- Once a week ☐
- Two or three times a week ☐
- Most days ☐
- Everyday ☐

A25. In the **last 2 weeks**, how often have you had a feeling of not completely emptying your bowels?

- Not at all ☐
- Once a week ☐
- Two or three times a week ☐
- Most days ☐
- Everyday ☐

A26. In the **last 2 weeks**, have you had bleeding through your back passage (signs of bleeding include fresh blood, staining of toilet tissue, blood mixed with stools)?

- Not at all ☐
- A little ☐
- Moderately ☐
- A lot ☐
- Extremely ☐

If you have n**ot** had any of the symptoms or problems described in questions A20 to A26, skip question A27 and go straight to question A28.

A27. In the **last 2 weeks**, how much have the symptoms described in question A20 to question A26 prevented you from doing your usual activities?

- Not at all ☐
- A little ☐
- Moderately ☐
- A lot ☐
- Extremely ☐

A28. Compared with **2 weeks ago**, how would you now rate your symptoms in general?

- Much better now than 2 weeks ago ☐
- Somewhat better now than 2 weeks ago ☐
- About the same as 2 weeks ago ☐
- Somewhat worse now than 2 weeks ago ☐
- Much worse now than 2 weeks ago ☐

A29. In the **last 2 weeks**, how often have your symptoms caused you difficulties in getting to sleep?

- Not at all ☐
- Once a week ☐
- Two or three times a week ☐
- Most nights ☐
- Every night ☐

A30. In the **last 2 weeks**, how often have your symptoms caused you to wake up?

- Not at all ☐
- Once a week ☐
- Two or three times a week ☐
- Most nights ☐
- Every night ☐

SECTION B

This section asks for your views about your health, how you feel and how well you have been able to do your usual activities **since your test**.

Answer every question by **putting a cross in the corresponding box**. Do not cross more than one box in each group. If you are unsure about how to answer a question, please give the best answer you can.

B1. In general, would you say your health is:

Excellent	Very good	Good	Fair	Poor
☐	☐	☐	☐	☐

B2. Compared with **before your test**, how would you rate your health in general now?

Much better now than one year ago	Somewhat better now than one year ago	About the same as one year ago	Somewhat worse now than one year ago	Much worse now than one year ago
☐	☐	☐	☐	☐

B3. The following questions are about activities you might do during **a typical day**. Does your health now limit you in these activities? If so, how much? (**cross a box on each line**)

	Yes, limited a lot	Yes, limited a little	No, not limited at all
Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports	☐	☐	☐
Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling or playing golf	☐	☐	☐
Lifting or carrying groceries	☐	☐	☐
Climbing several flights of stairs	☐	☐	☐
Climbing one flight of stairs	☐	☐	☐
Bending, kneeling or stooping	☐	☐	☐
Walking more than a mile	☐	☐	☐
Walking several hundred yards	☐	☐	☐
Walking one hundred yards	☐	☐	☐
Bathing or dressing yourself	☐	☐	☐

B4. **Since your test**, how much of the time have you had any of the following problems with your work or other regular daily activities as a result of your physical health?

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
Cut down on the amount of time you spent on work or other activities	☐	☐	☐	☐	☐
Accomplished less than you would like	☐	☐	☐	☐	☐
Were limited in the kind of work or other activities	☐	☐	☐	☐	☐
Had difficulty performing the work or other activities (for example, it took extra effort)	☐	☐	☐	☐	☐

B5. **Since your test**, how much of the time have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)?

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
Cut down on the amount of time you spent on work or other activities	☐	☐	☐	☐	☐
Accomplished less than you would like	☐	☐	☐	☐	☐
Did work or activities less carefully than usual	☐	☐	☐	☐	☐

B6. **Since your test**, to what extent has your physical health or emotional problems interfered with your normal activities with family, friends, neighbours or groups?

Not at all	Slightly	Moderately	Quite a bit	Extremely
☐	☐	☐	☐	☐

B7. How much bodily pain have you had **since your test**?

None	Very mild	Mild	Moderate	Severe	Very severe
☐	☐	☐	☐	☐	☐

B8. **Since your test**, how much did pain interfere with your normal work (including both work outside the home and housework)?

Not at all	Slightly	Moderately	Quite a bit	Extremely
☐	☐	☐	☐	☐

B9. These questions are about how you feel and how things have been with you **since your test**. For each question, please give ONE answer that comes closest to the way you have been feeling.

How much of the time **since your test** .....

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
Did you feel full of life?	☐	☐	☐	☐	☐
Have you been very nervous?	☐	☐	☐	☐	☐
Have you felt so down in the dumps that nothing could cheer you up?	☐	☐	☐	☐	☐
Have you felt calm and peaceful?	☐	☐	☐	☐	☐
Did you have a lot of energy?	☐	☐	☐	☐	☐
Have you felt downhearted and depressed?	☐	☐	☐	☐	☐
Did you feel worn out?	☐	☐	☐	☐	☐
Have you been happy?	☐	☐	☐	☐	☐
Did you feel tired?	☐	☐	☐	☐	☐

B10. **Since your test**, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting friends, relatives, etc)?

All of the time	Most of the time	Some of the time	A little of the time	None of the time
☐	☐	☐	☐	☐

B11. How TRUE or FALSE is each of the following statements for you?

	Definitely true	Mostly true	Don't know	Mostly false	Definitely false
I seem to get sick a little easier than other people	☐	☐	☐	☐	☐
I am as healthy as anybody I know	☐	☐	☐	☐	☐
I expect my health to get worse	☐	☐	☐	☐	☐
My health is excellent	☐	☐	☐	☐	☐

SECTION C

This section asks about your health in general. Please indicate which statement best describes your **own health state today**.

Answer every question by **putting a cross in the corresponding box.** Do not cross more than one box in each group. If you are unsure about how to answer a question, please give the best answer you can.

C1. Mobility

I have no problems in walking about ☐

I have some problems in walking about ☐

I am confined to bed ☐

C2. Self care

I have no problems with self-care ☐

I have some problems with self-care ☐

I am unable to wash or dress myself ☐

C3. Usual Activities

I have no problems with performing my usual activities ☐

I have some problems with performing my usual activities ☐

I am unable to perform my usual activities ☐

C4. Pain / Discomfort

I have no pain or discomfort ☐

I have moderate pain or discomfort ☐

I have extreme pain or discomfort ☐

C5. Anxiety/Depression

I am not anxious or depressed ☐

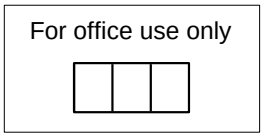
I am moderately anxious or depressed ☐

I am extremely anxious or depressed ☐

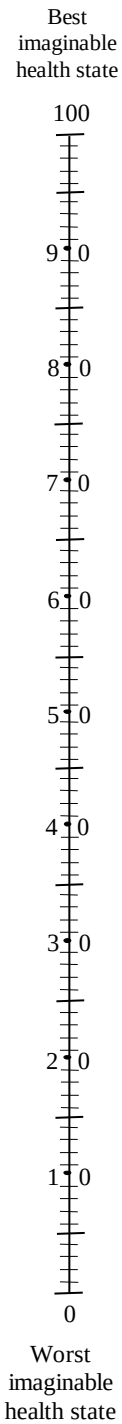
To help people say how good or bad their health state is, we have drawn a scale (rather like a thermometer) on which the best state you can imagine is marked 100 and the worst state you can imagine is marked 0.

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

For office use only



Your own health state today



SECTION D

This section is about the health care you have had in the **last 3 months**. Please read each question carefully. For each question, if you have had no treatment or visits enter '0' as indicated.

We would like to know about visits to health professionals **for any reason**, not just your digestive or bowel symptoms.

D1. How often have you consulted, for any reason, any of the following at your GP's surgery in the **last 3 months**?

Your own or another GP ☐☐ If none enter '0'

Nurse ☐☐ If none enter '0'

Other (please specify) _____ ☐☐ If none enter '0'

D2. How often have you consulted, for any reason, any of the following at home in the **last 3 months**?

Your own or another GP ☐☐ If none enter '0'

Nurse ☐☐ If none enter '0'

Other (please specify) ☐☐ If none enter '0'

D3. How often have you been admitted, for any reason, to a hospital (NHS or private) as an emergency in the **last 3 months**?

☐☐ If none enter '0'

D4. How often have you been admitted, for any reason, to a hospital (NHS or private) NOT as an emergency in the **last 3 months**?

☐☐ If none enter '0'

D5. How many times have you been seen, for any reason at a hospital outpatient clinic in the **last 3 months**?

By a Doctor ☐☐ If none enter '0'

By a Nurse Practitioner ☐☐ If none enter '0'

By a Dietician ☐☐ If none enter '0'

By anyone else (please specify) _____ ☐☐ If none enter '0'

D6. How many times have you been admitted as a day case for upper or lower endoscopy in the **last 3 months**?

Upper endoscopy ☐☐ If none enter '0'

Lower endoscopy ☐☐ If none enter '0'

D7. If you are in work, how many days work have you lost due to illness or in order to see any health professional in the **last 3 months**?

☐☐ If none enter '0'

SECTION E

Look at the list of medications below. If you take any of the medications listed below, please enter the dose of each tablet (this will be written on the tablet box or bottle) and the number of tablets you take each day. Answer 'yes' or 'no' to whether you are taking the drug regularly and if you answer 'no' please enter the average number of tablets you take each month.

	Each tablet dose in mg	Number of tablets per day	Regular?		If not regularly, average number of tablets taken per month
Indigestion medication					
Nexium (Esomeprazole)	☐☐☐	☐☐	Yes ☐	No ☐	☐☐☐
Losec (Omeprazole)	☐☐☐	☐☐	Yes ☐	No ☐	☐☐☐
Zoton (Lansoprazole)	☐☐☐	☐☐	Yes ☐	No ☐	☐☐☐
Protium (Pantoprazole)	☐☐☐	☐☐	Yes ☐	No ☐	☐☐☐
Pariet (Rabeprazole)	☐☐☐	☐☐	Yes ☐	No ☐	☐☐☐
Zantac (Ranitidine)	☐☐☐	☐☐	Yes ☐	No ☐	☐☐☐
Pepcid (Famotidine)	☐☐☐	☐☐	Yes ☐	No ☐	☐☐☐
Axid (Nizatidine)	☐☐☐	☐☐	Yes ☐	No ☐	☐☐☐
Tagamet (Cimetidine)	☐☐☐	☐☐	Yes ☐	No ☐	☐☐☐
Maxolon (Metoclopramide)	☐☐☐	☐☐	Yes ☐	No ☐	☐☐☐
Motilium (Domperidone)	☐☐☐	☐☐	Yes ☐	No ☐	☐☐☐
Medication for irritable bowel					
Spasmonal (Alverine)	☐☐☐	☐☐	Yes ☐	No ☐	☐☐☐
Merbentyl (Dicycloverine)	☐☐☐	☐☐	Yes ☐	No ☐	☐☐☐
Buscopan (Hyoscine)	☐☐☐	☐☐	Yes ☐	No ☐	☐☐☐
Colpermin	☐☐☐	☐☐	Yes ☐	No ☐	☐☐☐
Colofac (Mebeverine)	☐☐☐	☐☐	Yes ☐	No ☐	☐☐☐
Fybogel	☐☐☐	☐☐	Yes ☐	No ☐	☐☐☐
Anti-diarrhoeal medication					
Imodium (Loperamide)	☐☐☐	☐☐	Yes ☐	No ☐	☐☐☐
Codeine Phosphate	☐☐☐	☐☐	Yes ☐	No ☐	☐☐☐
Questran (Colestyramine)	☐☐☐	☐☐	Yes ☐	No ☐	☐☐☐
Lomotil (Co-phenetrope)	☐☐☐	☐☐	Yes ☐	No ☐	☐☐☐

Medication for Colitis	Each tablet dose in mg	Number of tablets per day	Regular?		If not regularly, average number of tablets taken per month
Asacol or Pentasa or Salofalk (Mesalazine)	☐☐☐	☐☐	Yes ☐	No ☐	☐☐☐
Colazide (Balsalazide)	☐☐☐	☐☐	Yes ☐	No ☐	☐☐☐
Dipentum (Olsalazine)	☐☐☐	☐☐	Yes ☐	No ☐	☐☐☐
Salazopyrin (Sulfasalazine)	☐☐☐	☐☐	Yes ☐	No ☐	☐☐☐
Entocort or Budenofalk (Budesonide)	☐☐☐	☐☐	Yes ☐	No ☐	☐☐☐
Prednisolone (by mouth)	☐☐☐	☐☐	Yes ☐	No ☐	☐☐☐

	Number per day	Regular?		If not regularly, average number per month
Predsol or Predfoam or Predenema (enemas)	☐☐	Yes ☐	No ☐	☐☐

If you take any other tablets/liquids for your **digestive or bowel symptoms**, that are not listed, please write the details in the list below. Please include any prescriptions and medicines you buy over the counter from the chemist or supermarket (examples include antacids and laxatives).

Name of medicine	On prescription		Dose in mg or ml	How many times taken per week
☐☐☐☐☐☐☐☐☐☐☐☐	Yes ☐	No ☐	☐☐☐	☐☐☐
☐☐☐☐☐☐☐☐☐☐☐☐	Yes ☐	No ☐	☐☐☐	☐☐☐
☐☐☐☐☐☐☐☐☐☐☐☐	Yes ☐	No ☐	☐☐☐	☐☐☐
☐☐☐☐☐☐☐☐☐☐☐☐	Yes ☐	No ☐	☐☐☐	☐☐☐
☐☐☐☐☐☐☐☐☐☐☐☐	Yes ☐	No ☐	☐☐☐	☐☐☐
☐☐☐☐☐☐☐☐☐☐☐☐	Yes ☐	No ☐	☐☐☐	☐☐☐

If you wish to add any comments regarding your medication, please enter them in the box below.

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SECTION F

This section aims to obtain YOUR personal views based on YOUR experience of having a test. Your answers will be treated in a confidential manner, and they will not affect your treatment in any way. The information provided will be used to find out how satisfied people are with their test, and to improve the hospital service.

Answer every question by **putting a cross in the corresponding box.** Do not cross more than one box in each group. If you are unsure about how to answer a question, please give the best answer you can.

F1. What test did you have? ☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐

F2. Date of the test ☐☐ / ☐☐ / ☐☐☐☐

F3. How much information was sent to you **before** your test?

☐ Far too much ☐ A bit too much ☐ Enough ☐ A little ☐ None

If no information was sent to you, then please go directly to question F6.

F4. How easy to understand was the information that was sent to you **before** your test?

☐ Very easy ☐ Easy ☐ Fair ☐ Difficult ☐ Very difficult

F5. Was the information sent to you **before** your test useful in answering your questions?

☐ Very useful ☐ Useful ☐ Fair ☐ Not very useful ☐ Not at all useful

F6. **Before** you had your test, how much opportunity did you have to ask questions about the test?

☐ Very good ☐ Good ☐ Reasonable ☐ Limited ☐ None

F7. **Before** you had your test, how much explanation did you receive about what would happen during your test?

☐ Far too much ☐ A bit too much ☐ Enough ☐ A little ☐ None

If you did not receive an explanation, then please go directly to question F10.

F8 . How easy to understand was the explanation given to you **before** the test?

☐ Very easy ☐ Easy ☐ Fair ☐ Difficult ☐ Very difficult

F9. Was the explanation given to you **before** your test useful in answering your questions?

☐ Very useful ☐ Useful ☐ Fair ☐ Not very useful ☐ Not at all useful

F10. How would you rate the communication skills (eg. courtesy, respect, sensitivity, friendliness) of the person who performed your test?

☐ Very good ☐ Good ☐ Fair ☐ Poor ☐ Very poor

F11. How would you rate the technical skills (eg. thoroughness, carefulness, competence) of the person who performed your test?

☐ Very good ☐ Good ☐ Fair ☐ Poor ☐ Very poor

F12. How would you rate the communication skills (eg. courtesy, respect, sensitivity, friendliness) of the other staff involved?

☐ Very good ☐ Good ☐ Fair ☐ Poor ☐ Very poor

F13. How much discomfort did you experience **during** your test?

☐ None ☐ Mild ☐ Moderate ☐ Severe ☐ Very severe

F14. How much pain did you experience **during** your test?

☐ None ☐ Mild ☐ Moderate ☐ Severe ☐ Very severe

F15. How much discomfort did you experience in the rest of the day, **after** your test?

☐ None ☐ Mild ☐ Moderate ☐ Severe ☐ Very severe

F16. How much pain did you experience in the rest of the day, **after** your test?

☐ None ☐ Mild ☐ Moderate ☐ Severe ☐ Very severe

F17. **After** you had your test, how much opportunity did you have to ask questions about the findings?

☐ Very good ☐ Good ☐ Reasonable ☐ Limited ☐ None

F18. **After** you had your test, how much explanation of the findings did you receive?

☐ Far too much ☐ A bit too much ☐ Enough ☐ A little ☐ None

If you did not receive an explanation, then please go directly to question F21.

F19. How easy to understand was the explanation given to you **after** your test?

☐ Very easy ☐ Easy ☐ Fair ☐ Difficult ☐ Very difficult

F20. Was the explanation given to you **after** your test useful in answering your questions?

☐ Very useful ☐ Useful ☐ Fair ☐ Not very useful ☐ Not at all useful

F21. How would you rate the comfort of the recovery area, if applicable?

☐ Very good ☐ Good ☐ Fair ☐ Poor ☐ Very poor

F22. Overall, how satisfied are you with your test?

☐ Very satisfied ☐ Satisfied ☐ Neither satisfied nor dissatisfied ☐ Dissatisfied ☐ Very dissatisfied

F23. If, in the future, you have another test of this sort, how satisfied would you be to have it done by the same person?

☐ Very satisfied ☐ Satisfied ☐ Neither satisfied nor dissatisfied ☐ Dissatisfied ☐ Very dissatisfied

F24. Overall, how would you rate the care you received at the hospital for the test?

☐ Very good ☐ Good ☐ Fair ☐ Poor ☐ Very poor

SECTION G

This section relates to your experience regarding the appointment for the test you told us about on **page 21**.

Answer every question by **putting a cross in the corresponding box**. Do not cross more than one box in each group. If you are unsure about how to answer a question, please give the best answer you can.

Before the appointment

G1. Overall, from the time you were first told you needed the test to the time you went to the hospital, how long did you wait for the test?

- Up to 1 month ☐
- More than 1 month but no more than 3 months ☐
- More than 3 months but no more than 5 months ☐
- More than 5 months but no more than 12 months ☐
- More than 12 months but no more than 18 months ☐
- More than 18 months ☐
- I went to the hospital without an appointment ☐
- Don't know / Can't remember ☐

G2. **Before** your appointment for the test, did you know the reason for the test?

- Yes, definitely ☐
- Yes, to some extent ☐
- No ☐

G3. **Before** your test, did you know who to contact if your symptoms or condition got worse?

- Yes ☐
- No ☐

G4. Was the date for your test changed by the hospital?

- No ☐
- Yes, once ☐
- Yes, 2 or 3 times ☐
- Yes, 4 times or more ☐

Waiting

G5. How long **after** the stated appointment time did the procedure start?

Seen on time, or early ☐

Waited up to 5 minutes ☐

Waited 6-15 minutes ☐

Waited 16-30 minutes ☐

Waited 31-60 minutes ☐

Waited more than 1 hour but no more than 2 hours ☐

Waited more than 2 hours ☐

Don't know / Can't remember ☐

Not given a stated test time ☐

G6. Were you told how long you would have to wait?

Yes, but the wait was shorter ☐

Yes, and I had to wait about as long as was told ☐

Yes, but the wait was longer ☐

No, I was not told ☐

Don't know / Can't remember ☐

If you were seen on time, then please go directly to question G8 over the page.

G7. Were you told why you had to wait?

Yes ☐

No, but I would have liked an explanation ☐

No, but I didn't mind ☐

Don't know / Can't remember ☐

Information

G8. Did a member of staff tell you about what danger signals regarding your illness or test to watch for **after** you went home?

- Yes, completely ☐
- Yes, to some extent ☐
- No ☐
- I did not need this type of information ☐

G9 Did hospital staff tell you who to contact **after** you got home if you were worried about your condition or test?

- Yes, they told me to contact my GP ☐
- Yes, they told me to contact the practice nurse at my local health centre ☐
- Yes, they told me to contact NHS Direct ☐
- Yes, I was told to dial 999 ☐
- Yes, they told me to contact a hospital doctor or nurse ☐
- Yes, I was told to contact someone else ☐
- No, I was not told who to contact ☐
- I did not need this type of information ☐
- Don't know / Can't remember ☐

G10. If you had a biopsy (ie sample taken away for testing) how long did you wait for your results?

- Up to 1 month ☐
- More than 1 month but no more than 3 months ☐
- More than 3 months but no more than 5 months ☐
- More than 5 months but no more than 12 months ☐
- More than 12 months but no more than 18 months ☐
- More than 18 months ☐
- Don't know / Can't remember ☐

Any other comments

If there is anything else you would like to tell us about your experiences in the hospital for the test, please do so here.

Was there anything particularly good about your visit to the hospital?

Was there anything that could have been improved?

Any other comments?

Are you happy to take part in a telephone interview with one of our researchers?
(Please cross appropriate box)

☐ Yes ☐ No

Thank you very much for your help.
Please check that you answered all the questions that apply to you.
Please post this questionnaire back in the FREEPOST envelope provided.
No stamp is needed.

Appendix 5 – 12 month Post Procedure Questionnaire

Study Number | | | | | |

**Evaluating Innovations in Gastroenterology
for the NHS Modernisation Agency
(ENIGMA) study**

12 month post procedure questionnaire

A questionnaire for people with digestive and bowel disorders

Please complete this questionnaire at home as soon as you have time and return to us using the prepaid envelope enclosed.

CONFIDENTIAL

Please read all the instructions before completing this questionnaire.

Thank you for agreeing to take part in this study. The answers you give in this questionnaire will help us to find out if the treatments you receive are helpful for your condition.

The information you provide will be completely confidential and will not affect your treatment in any way.

Please answer all the questions. Although it may seem that some questions are asked more than once, it is still important that you answer every one. If you find it difficult to answer a question, please do the best you can.

Please follow the instructions for each section of the questionnaire carefully.

For each section, if you are asked to put a cross in the box, please use a cross, as if you were filling out a ballot paper, rather than a tick.

For example in the following question, if your answer is yes, you should place a cross firmly in the corresponding box.

	Yes	No
Do you drive a car?	☒	☐

Please use a black or blue pen. Do not use a pencil or any other coloured pen.

Please complete the questionnaire fully and return it in the FREEPOST envelope provided as soon as possible.

Please enter the date you are completing this questionnaire below

		/			/				
D	D		M	M		Y	Y	Y	Y

SECTION A

This section asks about your symptoms. When answering the questions about the effect on your life, consider how these symptoms prevented you from doing your usual activities over the **last 2 weeks**.

Answer each question by **putting a cross in the corresponding box**. Do not cross more than one box in each group. If you are unsure about how to answer a question, please give the best answer you can.

A1. In the **last 2 weeks**, how often have you experienced heartburn (a burning sensation behind your breast bone)?

- Not at all ☐
- Once a week ☐
- Two or three times a week ☐
- Most days ☐
- Everyday ☐

A2. In the **last 2 weeks**, how often have you had any discomfort in your upper abdomen (above your belly button and below your ribs)?

- Not at all ☐
- Once a week ☐
- Two or three times a week ☐
- Most days ☐
- Everyday ☐

If you have **not** had any of the symptoms or problems described in questions A1 and A2, skip question A3 and go straight to question A4 over the page

A3. In the **last 2 weeks**, how much have the symptoms described in questions A1 and A2 prevented you from doing your usual activities?

- Not at all ☐
- A little ☐
- Moderately ☐
- A lot ☐
- Extremely ☐

A4. In the **last 2 weeks**, how often have you experienced bitter bile or acid reflux (from the stomach into the throat)?

Not at all ☐
Once a week ☐
Two or three times a week ☐
Most days ☐
Everyday ☐

A5. In the **last 2 weeks**, how often have you experienced a feeling of nausea or sickness without actually vomiting?

Not at all ☐
Once a week ☐
Two or three times a week ☐
Most days ☐
Everyday ☐

A6. In the **last 2 weeks**, how often have you retched or heaved without actually vomiting?

Not at all ☐
Once a week ☐
Two or three times a week ☐
Most days ☐
Everyday ☐

A7. In the **last 2 weeks**, how often have you actually vomited?

Not at all ☐
Once a week ☐
Two or three times a week ☐
Most days ☐
Everyday ☐

A8. If you have vomited in the **last 2 weeks**, have you seen any blood in the vomit?

- Yes ☐
- No ☐
- Not applicable ☐

If you have **not** had any of the symptoms or problems described in questions A4 to A8, skip question A9 and go directly to question A10

A9. In the **last 2 weeks**, how much have the symptoms described in question A4 to question A8 prevented you from doing your usual activities?

- Not at all ☐
- A little ☐
- Moderately ☐
- A lot ☐
- Extremely ☐

A10. In the **last 2 weeks**, how often have you been bothered by a lot of belching or burping (release of wind from the stomach by the mouth)?

- Not at all ☐
- Once a week ☐
- Two or three times a week ☐
- Most days ☐
- Everyday ☐

A11. In the **last 2 weeks**, how often have you been bothered by passing a lot of wind from the back passage?

- Not at all ☐
- Once a week ☐
- Two or three times a week ☐
- Most days ☐
- Everyday ☐

A12. In the **last 2 weeks**, how often have you experienced bloatedness, and or a feeling of trapped wind in your stomach?

Not at all ☐
Once a week ☐
Two or three times a week ☐
Most days ☐
Everyday ☐

A13. In the **last 2 weeks**, how often have you experienced loud gurgling noises from your stomach?

Not at all ☐
Once a week ☐
Two or three times a week ☐
Most days ☐
Everyday ☐

If you have **not** had any of the symptoms or problems described in questions A10 to A13, skip question A14 and go straight to question A15 over the page

A14. In the **last 2 weeks**, how much have the symptoms described in question A10 to question A13 prevented you from doing your usual activities?

Not at all ☐
A little ☐
Moderately ☐
A lot ☐
Extremely ☐

A15. In the **last 2 weeks**, how often have you felt that your food sticks on the way down your gullet (through the chest into your stomach)?

- Not at all ☐
- Once a week ☐
- Two or three times a week ☐
- Most days ☐
- Everyday ☐

A16. In the **last 2 weeks**, how often have your eating habits been restricted because of your condition (examples might be having to eat more slowly, having to take smaller portions or having to eat different foods)?

- Not at all ☐
- Once a week ☐
- Two or three times a week ☐
- Most days ☐
- Everyday ☐

A17. In the **last 2 weeks** have you had a lack of appetite?

- Not at all ☐
- Once a week ☐
- Two or three times a week ☐
- Most days ☐
- Everyday ☐

If you have **not** had any of the symptoms or problems described in questions A15 to A17, skip question A18 and go to question A19 over the page

A18. In the **last 2 weeks**, how much have the symptoms described in question A15 to question A17 prevented you from doing your usual activities?

- Not at all ☐
- A little ☐
- Moderately ☐
- A lot ☐
- Extremely ☐

A19. Have you noticed any change in weight (not due to a change in your diet) over the **last 3 months**?

- No, my weight has been stable ☐
- Yes, I have been gaining weight ☐
- Yes, I have been losing weight ☐

A20. In the **last 2 weeks**, how often have you been bothered by too frequent emptying of your bowels?

- Not at all ☐
- Once a week ☐
- Two or three times a week ☐
- Most days ☐
- Everyday ☐

A21. In the **last 2 weeks**, how often have you been bothered by loose stools?

- Not at all ☐
- Once a week ☐
- Two or three times a week ☐
- Most days ☐
- Everyday ☐

A22. In the **last 2 weeks**, how often have you been bothered by hard stools?

- Not at all ☐
- Once a week ☐
- Two or three times a week ☐
- Most days ☐
- Everyday ☐

A23. In the **last 2 weeks**, how often have you been bothered by constipation (constipation means difficulty in emptying your bowels)?

- Not at all ☐
- Once a week ☐
- Two or three times a week ☐
- Most days ☐
- Everyday ☐

A24. In the **last 2 weeks**, how often have you had an urgent need to empty your bowels (this urgent need is often associated with a feeling that you are not in full control)?

- Not at all ☐
- Once a week ☐
- Two or three times a week ☐
- Most days ☐
- Everyday ☐

A25. In the **last 2 weeks,** how often have you had a feeling of not completely emptying your bowels?

- Not at all ☐
- Once a week ☐
- Two or three times a week ☐
- Most days ☐
- Everyday ☐

A26. In the **last 2 weeks**, have you had bleeding through your back passage (signs of bleeding include fresh blood, staining of toilet tissue, blood mixed with stools)?

- Not at all ☐
- A little ☐
- Moderately ☐
- A lot ☐
- Extremely ☐

If you have **not** had any of the symptoms or problems described in questions A20 to A26, skip question A27 and go straight to question A28

A27. In the **last 2 weeks**, how much have the symptoms described in question A20 to question A26 prevented you from doing your usual activities?

- Not at all ☐
- A little ☐
- Moderately ☐
- A lot ☐
- Extremely ☐

A28. Compared with **2 weeks ago**, how would you now rate your symptoms in general?

- Much better now than 2 weeks ago ☐
- Somewhat better now than 2 weeks ago ☐
- About the same as 2 weeks ago ☐
- Somewhat worse now than 2 weeks ago ☐
- Much worse now than 2 weeks ago ☐

A29. In the **last 2 weeks**, how often have your symptoms caused you difficulties in getting to sleep?

- Not at all ☐
- Once a week ☐
- Two or three times a week ☐
- Most nights ☐
- Every night ☐

A30. In the **last 2 weeks**, how often have your symptoms caused you to wake up?

- Not at all ☐
- Once a week ☐
- Two or three times a week ☐
- Most nights ☐
- Every night ☐

SECTION B

This section asks for your views about your health, how you feel and how well you are able to do your usual activities.

Answer every question by **putting a cross in the corresponding box**. Do not cross more than one box in each group. If you are unsure about how to answer a question, please give the best answer you can.

B1. In general, would you say your health is:

Excellent	Very good	Good	Fair	Poor
☐	☐	☐	☐	☐

B2. Compared to **1 year ago**, how would you rate your health in general now?

Much better now than one year ago	Somewhat better now than one year ago	About the same as one year ago	Somewhat worse now than one year ago	Much worse now than one year ago
☐	☐	☐	☐	☐

B3. The following questions are about activities you might do during **a typical day**. Does your health now limit you in these activities? If so, how much? (**cross a box on each line**)

	Yes, limited a lot	Yes, limited a little	No, not limited at all
Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports	☐	☐	☐
Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling or playing golf	☐	☐	☐
Lifting or carrying groceries	☐	☐	☐
Climbing several flights of stairs	☐	☐	☐
Climbing one flight of stairs	☐	☐	☐
Bending, kneeling or stooping	☐	☐	☐
Walking more than a mile	☐	☐	☐
Walking several hundred yards	☐	☐	☐
Walking one hundred yards	☐	☐	☐
Bathing or dressing yourself	☐	☐	☐

B4. During the **past 4 weeks**, how much of the time have you had any of the following problems with your work or other regular daily activities as a result of your physical health?

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
Cut down on the amount of time you spent on work or other activities	☐	☐	☐	☐	☐
Accomplished less than you would like	☐	☐	☐	☐	☐
Were limited in the kind of work or other activities	☐	☐	☐	☐	☐
Had difficulty performing the work or other activities (for example, it took extra effort)	☐	☐	☐	☐	☐

B5. During the **past 4 weeks**, how much of the time have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)?

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
Cut down on the amount of time you spent on work or other activities	☐	☐	☐	☐	☐
Accomplished less than you would like	☐	☐	☐	☐	☐
Did work or activities less carefully than usual	☐	☐	☐	☐	☐

B6. During the **past 4 weeks**, to what extent has your physical health or emotional problems interfered with your normal activities with family, friends, neighbours, or groups?

Not at all	Slightly	Moderately	Quite a bit	Extremely
☐	☐	☐	☐	☐

B7. How much bodily pain have you had during the **past 4 weeks**?

None	Very mild	Mild	Moderate	Severe	Very severe
☐	☐	☐	☐	☐	☐

B8. During the **past 4 weeks**, how much did pain interfere with your normal work (including both work outside the home and housework)?

Not at all	Slightly	Moderately	Quite a bit	Extremely
☐	☐	☐	☐	☐

B9. These questions are about how you feel and how things have been with you during the **past 4 weeks**. For each question, please give ONE answer that comes closest to the way you have been feeling.

How much of the time during the **past 4 weeks** .....

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
Did you feel full of life?	☐	☐	☐	☐	☐
Have you been very nervous?	☐	☐	☐	☐	☐
Have you felt so down in the dumps that nothing could cheer you up?	☐	☐	☐	☐	☐
Have you felt calm and peaceful?	☐	☐	☐	☐	☐
Did you have a lot of energy?	☐	☐	☐	☐	☐
Have you felt downhearted and depressed?	☐	☐	☐	☐	☐
Did you feel worn out?	☐	☐	☐	☐	☐
Have you been happy?	☐	☐	☐	☐	☐
Did you feel tired?	☐	☐	☐	☐	☐

B10. During the **past 4 weeks**, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting friends, relatives, etc)?

All of the time	Most of the time	Some of the time	A little of the time	None of the time
☐	☐	☐	☐	☐

B11. How TRUE or FALSE is each of the following statements for you?

	Definitely true	Mostly true	Don't know	Mostly false	Definitely false
I seem to get sick a little easier than other people	☐	☐	☐	☐	☐
I am as healthy as anybody I know	☐	☐	☐	☐	☐
I expect my health to get worse	☐	☐	☐	☐	☐
My health is excellent	☐	☐	☐	☐	☐

SECTION C

This section asks about your health in general. Please indicate which statement best describes **your own health state today**.

Answer each question by **putting a cross in the corresponding box.** Do not cross more than one box in each group. If you are unsure about how to answer a question, please give the best answer you can.

C1. Mobility

I have no problems in walking about ☐

I have some problems in walking about ☐

I am confined to bed ☐

C2. Self care

I have no problems with self-care ☐

I have some problems with self-care ☐

I am unable to wash or dress myself ☐

C3. Usual Activities

I have no problems with performing my usual activities ☐

I have some problems with performing my usual activities ☐

I am unable to perform my usual activities ☐

C4. Pain / Discomfort

I have no pain or discomfort ☐

I have moderate pain or discomfort ☐

I have extreme pain or discomfort ☐

C5. Anxiety/Depression

I am not anxious or depressed ☐

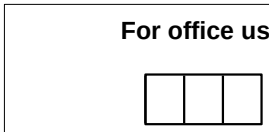
I am moderately anxious or depressed ☐

I am extremely anxious or depressed ☐

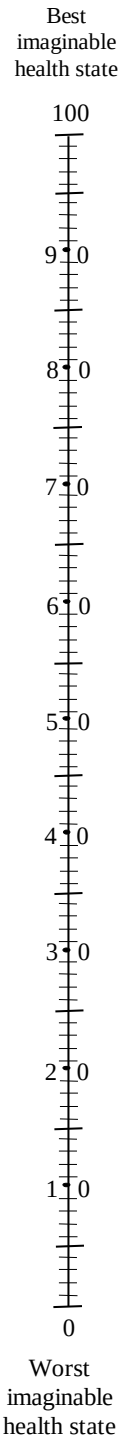
To help people say how good or bad their health state is, we have drawn a scale (rather like a thermometer) on which the best state you can imagine is marked 100 and the worst state you can imagine is marked 0.

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

For office use



Your own health state today



SECTION D

This section is about the health care you have had in the **last 3 months**. Please read each question carefully. For each question, if you have had no treatment or visits enter '0' as indicated.

We would like to know about visits to health professionals **for any reason**, not just your digestive or bowel symptoms.

D1. How often have you consulted, for any reason, any of the following at your GP's surgery in the **last 3 months**?

Your own or another GP ☐☐ If none enter '0'

Nurse ☐☐ If none enter '0'

Other (please specify) _____ ☐☐ If none enter '0'

D2. How often have you consulted, for any reason, any of the following at home in the **last 3 months**?

Your own or another GP ☐☐ If none enter '0'

Nurse ☐☐ If none enter '0'

Other (please specify) _____ ☐☐ If none enter '0'

D3. How often have you been admitted, for any reason, to a hospital (NHS or private) as an emergency in the **last 3 months**?

☐☐ If none enter '0'

D4. How often have you been admitted, for any reason, to a hospital (NHS or private) NOT as an emergency in the **last 3 months**?

☐☐ If none enter '0'

D5. How many times have you been seen, for any reason at a hospital outpatient clinic in the **last 3 months**?

By a Doctor ☐☐ If none enter '0'

By a Nurse Practitioner ☐☐ If none enter '0'

By a Dietician ☐☐ If none enter '0'

By anyone else (please specify) _____ ☐☐ If none enter '0'

D6. How many times have you been admitted as a day case for upper or lower endoscopy in the **last 3 months**?

Upper endoscopy ☐☐ If none enter '0'

Lower endoscopy ☐☐ If none enter '0'

D7. If you are in work, how many days work have you lost due to illness or in order to see any health professional in the **last 3 months**?

☐☐ If none enter '0'

SECTION E

Look at the list of medications below. If you take any of the medications listed below, please enter the dose of each tablet (this will be written on the tablet box or bottle) and the number of tablets you take each day. Answer 'yes' or 'no' to whether you are taking the drug regularly and if you answer 'no' please enter the average number of tablets you take each month.

	Each tablet dose in mg	Number of tablets per day	Regular?		If not regularly, average number of tablets taken per month
Indigestion medication					
Nexium (Esomeprazole)	☐☐☐	☐☐	Yes ☐	No ☐	☐☐☐
Losec (Omeprazole)	☐☐☐	☐☐	Yes ☐	No ☐	☐☐☐
Zoton (Lansoprazole)	☐☐☐	☐☐	Yes ☐	No ☐	☐☐☐
Protium (Pantoprazole)	☐☐☐	☐☐	Yes ☐	No ☐	☐☐☐
Pariet (Rabeprazole)	☐☐☐	☐☐	Yes ☐	No ☐	☐☐☐
Zantac (Ranitidine)	☐☐☐	☐☐	Yes ☐	No ☐	☐☐☐
Pepcid (Famotidine)	☐☐☐	☐☐	Yes ☐	No ☐	☐☐☐
Axid (Nizatidine)	☐☐☐	☐☐	Yes ☐	No ☐	☐☐☐
Tagamet (Cimetidine)	☐☐☐	☐☐	Yes ☐	No ☐	☐☐☐
Maxolon (Metoclopramide)	☐☐☐	☐☐	Yes ☐	No ☐	☐☐☐
Motilium (Domperidone)	☐☐☐	☐☐	Yes ☐	No ☐	☐☐☐
Medication for irritable bowel					
Spasmonal (Alverine)	☐☐☐	☐☐	Yes ☐	No ☐	☐☐☐
Merbentyl (Dicycloverine)	☐☐☐	☐☐	Yes ☐	No ☐	☐☐☐
Buscopan (Hyoscine)	☐☐☐	☐☐	Yes ☐	No ☐	☐☐☐
Colpermin	☐☐☐	☐☐	Yes ☐	No ☐	☐☐☐
Colofac (Mebeverine)	☐☐☐	☐☐	Yes ☐	No ☐	☐☐☐
Fybogel sachets	☐☐☐	☐☐	Yes ☐	No ☐	☐☐☐
Anti-diarrhoeal medication					
Imodium (Loperamide)	☐☐☐	☐☐	Yes ☐	No ☐	☐☐☐
Codeine Phosphate	☐☐☐	☐☐	Yes ☐	No ☐	☐☐☐
Questran (Colestyramine)	☐☐☐	☐☐	Yes ☐	No ☐	☐☐☐
Lomotil (Co-phenetrope)	☐☐☐	☐☐	Yes ☐	No ☐	☐☐☐

Medication for Colitis	Each tablet dose in mg	Number of tablets per day	Regular?		If not regularly, average number of tablets taken per month
Asacol or Pentasa or Salofalk (Mesalazine)	☐☐☐	☐☐	Yes ☐	No ☐	☐☐☐
Colazide (Balsalazide)	☐☐☐	☐☐	Yes ☐	No ☐	☐☐☐
Dipentum (Olsalazine)	☐☐☐	☐☐	Yes ☐	No ☐	☐☐☐
Salazopyrin (Sulfasalazine)	☐☐☐	☐☐	Yes ☐	No ☐	☐☐☐
Entocort or Budenofalk(Budesonide)	☐☐☐	☐☐	Yes ☐	No ☐	☐☐☐
Prednisolone (by mouth)	☐☐☐	☐☐	Yes ☐	No ☐	☐☐☐

	Number per day	Regular?		If not regularly, average number per month
Predsol or Predfoam or Predenema (enemas)	☐☐	Yes ☐	No ☐	☐☐☐

If you take any other tablets/liquids for your **digestive or bowel symptoms**, that are not listed, please write the details in the list below. Please include any prescriptions and medicines you buy over the counter from the chemist or supermarket (examples include antacids and laxatives)

Name of medicine	On prescription		Dose in mg or ml	How many times taken per week
☐☐☐☐☐☐☐☐☐☐☐☐	Yes ☐	No ☐	☐☐☐	☐☐☐
☐☐☐☐☐☐☐☐☐☐☐☐	Yes ☐	No ☐	☐☐☐	☐☐☐
☐☐☐☐☐☐☐☐☐☐☐☐	Yes ☐	No ☐	☐☐☐	☐☐☐
☐☐☐☐☐☐☐☐☐☐☐☐	Yes ☐	No ☐	☐☐☐	☐☐☐
☐☐☐☐☐☐☐☐☐☐☐☐	Yes ☐	No ☐	☐☐☐	☐☐☐
☐☐☐☐☐☐☐☐☐☐☐☐	Yes ☐	No ☐	☐☐☐	☐☐☐

If you wish to add any comments regarding your medication, please enter them in the box below.

20

SECTION F

F1. Thinking back to your **test/endoscopy** a year ago did you require any treatment after it?

Yes ☐ No ☐

If YES, please complete questions F2 and F3.

F2. How long did you wait for the treatment?

Up to 1 month ☐

More than 1 month but no more than 3 months ☐

More than 3 months but no more than 5 months ☐

More than 5 months but no more than 12 months ☐

More than 12 months but no more than 18 months ☐

More than 18 months ☐

Don't know / Can't remember ☐

F3. Did you know the reason for the treatment?

Yes ☐ No ☐

If YES, please describe briefly.

Please enter your date of birth below

☐☐ / ☐☐ / ☐☐☐☐

D D M M Y Y Y Y

Please enter your sex below

Male ☐ Female ☐

Please enter your initials in the box below

☐☐☐

If you would like to see a summary of the overall results of the study when it is complete, please place a cross in this box. ☐

Thank you for completing this questionnaire.

If you have any general comments about your digestive or bowel treatment, or this questionnaire, please write them below.

Once you have completed the questionnaire please return it in the FREEPOST envelope provided, or send it to

ENIGMA Study Team
Swansea Clinical School
University of Wales Swansea
Singleton Park
Swansea
SA2 8PP

If you have any concerns about your symptoms please consult your GP or hospital doctor.

YOUR COMMENTS

Appendix 6 – 12 month Post Referral Questionnaire

Study Number

Evaluating Innovations in Gastroenterology for the NHS Modernisation Agency (ENIGMA) study

12 month post referral questionnaire

A questionnaire for people with digestive and bowel disorders

Please complete this questionnaire at home as soon as you have time and return to us using the prepaid envelope enclosed.

CONFIDENTIAL

Please read all the instructions before completing this questionnaire.

Thank you for agreeing to take part in this study. The answers you give in this questionnaire will help us to find out if the treatments you receive are helpful for your condition.

The information you provide will be completely confidential and will not affect your treatment in any way.

Please answer all the questions. Although it may seem that some questions are asked more than once, it is still important that you answer every one. If you find it difficult to answer a question, please do the best you can.

Please follow the instructions for each section of the questionnaire carefully.

For each section, if you are asked to put a cross in the box, please use a cross, as if you were filling out a ballot paper, rather than a tick.

For example in the following question, if your answer is yes, you should place a cross firmly in the corresponding box.

	Yes	No
Do you drive a car?	☒	☐

Please use a black or blue pen. Do not use a pencil or any other coloured pen.

Please complete the questionnaire fully and return it in the FREEPOST envelope provided as soon as possible.

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Please enter the date you are completing this questionnaire below

D D / M M / Y Y Y Y

SECTION A

This section asks about your symptoms. When answering the questions about the effect on your life, consider how these symptoms prevented you from doing your usual activities over the **last 2 weeks**.

Answer each question by **putting a cross in the corresponding box**. Do not cross more than one box in each group. If you are unsure about how to answer a question, please give the best answer you can.

A1. In the **last 2 weeks**, how often have you experienced heartburn (a burning sensation behind your breast bone)?

- Not at all
- Once a week
- Two or three times a week
- Most days
- Everyday

A2. In the **last 2 weeks**, how often have you had any discomfort in your upper abdomen (above your belly button and below your ribs)?

- Not at all
- Once a week
- Two or three times a week
- Most days
- Everyday

If you have **not** had any of the symptoms or problems described in questions A1 and A2, skip question A3 and go straight to question A4 over the page

A3. In the **last 2 weeks**, how much have the symptoms described in questions A1 and A2 prevented you from doing your usual activities?

- Not at all
- A little
- Moderately
- A lot
- Extremely

A4. In the **last 2 weeks**, how often have you experienced bitter bile or acid reflux (from the stomach into the throat)?

- Not at all ☐
- Once a week ☐
- Two or three times a week ☐
- Most days ☐
- Everyday ☐

A5. In the **last 2 weeks**, how often have you experienced a feeling of nausea or sickness without actually vomiting?

- Not at all ☐
- Once a week ☐
- Two or three times a week ☐
- Most days ☐
- Everyday ☐

A6. In the **last 2 weeks**, how often have you retched or heaved without actually vomiting?

- Not at all ☐
- Once a week ☐
- Two or three times a week ☐
- Most days ☐
- Everyday ☐

A7. In the **last 2 weeks**, how often have you actually vomited?

- Not at all ☐
- Once a week ☐
- Two or three times a week ☐
- Most days ☐
- Everyday ☐

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A8. If you have vomited in the **last 2 weeks**, have you seen any blood in the vomit?

Yes ☐
No ☐
Not applicable ☐

If you have **not** had any of the symptoms or problems described in questions A4 to A8, skip question A9 and go directly to question A10

A9. In the **last 2 weeks**, how much have the symptoms described in question A4 to question A8 prevented you from doing your usual activities?

Not at all ☐
A little ☐
Moderately ☐
A lot ☐
Extremely ☐

A10. In the **last 2 weeks**, how often have you been bothered by a lot of belching or burping (release of wind from the stomach by the mouth)?

Not at all ☐
Once a week ☐
Two or three times a week ☐
Most days ☐
Everyday ☐

A11. In the **last 2 weeks**, how often have you been bothered by passing a lot of wind from the back passage?

Not at all ☐
Once a week ☐
Two or three times a week ☐
Most days ☐
Everyday ☐

A12. In the **last 2 weeks**, how often have you experienced bloatedness, and or a feeling of trapped wind in your stomach?

- Not at all ☐
- Once a week ☐
- Two or three times a week ☐
- Most days ☐
- Everyday ☐

A13. In the **last 2 weeks**, how often have you experienced loud gurgling noises from your stomach?

- Not at all ☐
- Once a week ☐
- Two or three times a week ☐
- Most days ☐
- Everyday ☐

If you have **not** had any of the symptoms or problems described in questions A10 to A13, skip question A14 and go straight to question A15 over the page

A14. In the **last 2 weeks**, how much have the symptoms described in question A10 to question A13 prevented you from doing your usual activities?

- Not at all ☐
- A little ☐
- Moderately ☐
- A lot ☐
- Extremely ☐

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A15. In the **last 2 weeks**, how often have you felt that your food sticks on the way down your gullet (through the chest into your stomach)?

- Not at all ☐
- Once a week ☐
- Two or three times a week ☐
- Most days ☐
- Everyday ☐

A16. In the **last 2 weeks**, how often have your eating habits been restricted because of your condition (examples might be having to eat more slowly, having to take smaller portions or having to eat different foods)?

- Not at all ☐
- Once a week ☐
- Two or three times a week ☐
- Most days ☐
- Everyday ☐

A17. In the **last 2 weeks** have you had a lack of appetite?

- Not at all ☐
- Once a week ☐
- Two or three times a week ☐
- Most days ☐
- Everyday ☐

If you have **not** had any of the symptoms or problems described in questions A15 to A17, skip question A18 and go to question A19 over the page

A18. In the **last 2 weeks**, how much have the symptoms described in question A15 to question A17 prevented you from doing your usual activities?

- Not at all ☐
- A little ☐
- Moderately ☐
- A lot ☐
- Extremely ☐

A19. Have you noticed any change in weight (not due to a change in your diet) over the **last 3 months**?

- No, my weight has been stable ☐
- Yes, I have been gaining weight ☐
- Yes, I have been losing weight ☐

A20. In the **last 2 weeks**, how often have you been bothered by too frequent emptying of your bowels?

- Not at all ☐
- Once a week ☐
- Two or three times a week ☐
- Most days ☐
- Everyday ☐

A21. In the **last 2 weeks**, how often have you been bothered by loose stools?

- Not at all ☐
- Once a week ☐
- Two or three times a week ☐
- Most days ☐
- Everyday ☐

A22. In the **last 2 weeks**, how often have you been bothered by hard stools?

- Not at all ☐
- Once a week ☐
- Two or three times a week ☐
- Most days ☐
- Everyday ☐

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A23. In the **last 2 weeks**, how often have you been bothered by constipation (constipation means difficulty in emptying your bowels)?

- Not at all ☐
- Once a week ☐
- Two or three times a week ☐
- Most days ☐
- Everyday ☐

A24. In the **last 2 weeks**, how often have you had an urgent need to empty your bowels (this urgent need is often associated with a feeling that you are not in full control)?

- Not at all ☐
- Once a week ☐
- Two or three times a week ☐
- Most days ☐
- Everyday ☐

A25. In the **last 2 weeks**, how often have you had a feeling of not completely emptying your bowels?

- Not at all ☐
- Once a week ☐
- Two or three times a week ☐
- Most days ☐
- Everyday ☐

A26. In the **last 2 weeks**, have you had bleeding through your back passage (signs of bleeding include fresh blood, staining of toilet tissue, blood mixed with stools)?

- Not at all ☐
- A little ☐
- Moderately ☐
- A lot ☐
- Extremely ☐

If you have **not** had any of the symptoms or problems described in questions A20 to A26, skip question A27 and go straight to question A28

A27. In the **last 2 weeks**, how much have the symptoms described in question A20 to question A26 prevented you from doing your usual activities?

- Not at all ☐
- A little ☐
- Moderately ☐
- A lot ☐
- Extremely ☐

A28. Compared with **2 weeks ago**, how would you now rate your symptoms in general?

- Much better now than 2 weeks ago ☐
- Somewhat better now than 2 weeks ago ☐
- About the same as 2 weeks ago ☐
- Somewhat worse now than 2 weeks ago ☐
- Much worse now than 2 weeks ago ☐

A29. In the **last 2 weeks**, how often have your symptoms caused you difficulties in getting to sleep?

- Not at all ☐
- Once a week ☐
- Two or three times a week ☐
- Most nights ☐
- Every night ☐

A30. In the **last 2 weeks**, how often have your symptoms caused you to wake up?

- Not at all ☐
- Once a week ☐
- Two or three times a week ☐
- Most nights ☐
- Every night ☐

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SECTION B

This section asks for your views about your health, how you feel and how well you are able to do your usual activities.

Answer every question by **putting a cross in the corresponding box.** Do not cross more than one box in each group. If you are unsure about how to answer a question, please give the best answer you can.

B1. In general, would you say your health is:

Excellent	Very good	Good	Fair	Poor
☐	☐	☐	☐	☐

B2. Compared to **1 year ago**, how would you rate your health in general now?

Much better now than one year ago	Somewhat better now than one year ago	About the same as one year ago	Somewhat worse now than one year ago	Much worse now than one year ago
☐	☐	☐	☐	☐

B3. The following questions are about activities you might do during **a typical day**. Does your health now limit you in these activities? If so, how much? (**cross a box on each line**)

	Yes, limited a lot	Yes, limited a little	No, not limited at all
Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports	☐	☐	☐
Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling or playing golf	☐	☐	☐
Lifting or carrying groceries	☐	☐	☐
Climbing several flights of stairs	☐	☐	☐
Climbing one flight of stairs	☐	☐	☐
Bending, kneeling or stooping	☐	☐	☐
Walking more than a mile	☐	☐	☐
Walking several hundred yards	☐	☐	☐
Walking one hundred yards	☐	☐	☐
Bathing or dressing yourself	☐	☐	☐

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B4. During the **past 4 weeks**, how much of the time have you had any of the following problems with your work or other regular daily activities as a result of your physical health?

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
Cut down on the amount of time you spent on work or other activities	☐	☐	☐	☐	☐
Accomplished less than you would like	☐	☐	☐	☐	☐
Were limited in the kind of work or other activities	☐	☐	☐	☐	☐
Had difficulty performing the work or other activities (for example, it took extra effort)	☐	☐	☐	☐	☐

B5. During the **past 4 weeks**, how much of the time have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)?

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
Cut down on the amount of time you spent on work or other activities	☐	☐	☐	☐	☐
Accomplished less than you would like	☐	☐	☐	☐	☐
Did work or activities less carefully than usual	☐	☐	☐	☐	☐

B6. During the **past 4 weeks**, to what extent has your physical health or emotional problems interfered with your normal activities with family, friends, neighbours, or groups?

Not at all	Slightly	Moderately	Quite a bit	Extremely
☐	☐	☐	☐	☐

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B7. How much bodily pain have you had during the **past 4 weeks**?

None	Very mild	Mild	Moderate	Severe	Very severe
☐	☐	☐	☐	☐	☐

B8. During the **past 4 weeks**, how much did pain interfere with your normal work (including both work outside the home and housework)?

Not at all	Slightly	Moderately	Quite a bit	Extremely
☐	☐	☐	☐	☐

B9. These questions are about how you feel and how things have been with you during the **past 4 weeks**. For each question, please give ONE answer that comes closest to the way you have been feeling.

How much of the time during the **past 4 weeks** .....

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
Did you feel full of life?	☐	☐	☐	☐	☐
Have you been very nervous?	☐	☐	☐	☐	☐
Have you felt so down in the dumps that nothing could cheer you up?	☐	☐	☐	☐	☐
Have you felt calm and peaceful?	☐	☐	☐	☐	☐
Did you have a lot of energy?	☐	☐	☐	☐	☐
Have you felt downhearted and depressed?	☐	☐	☐	☐	☐
Did you feel worn out?	☐	☐	☐	☐	☐
Have you been happy?	☐	☐	☐	☐	☐
Did you feel tired?	☐	☐	☐	☐	☐

B10. During the **past 4 weeks**, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting friends, relatives, etc)?

All of the time	Most of the time	Some of the time	A little of the time	None of the time
☐	☐	☐	☐	☐

B11. How TRUE or FALSE is each of the following statements for you?

	Definitely true	Mostly true	Don't know	Mostly false	Definitely false
I seem to get sick a little easier than other people	☐	☐	☐	☐	☐
I am as healthy as anybody I know	☐	☐	☐	☐	☐
I expect my health to get worse	☐	☐	☐	☐	☐
My health is excellent	☐	☐	☐	☐	☐

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SECTION C

This section asks about your health in general. Please indicate which statement best describes **your own health state today**.

Answer each question by **putting a cross in the corresponding box.** Do not cross more than one box in each group. If you are unsure about how to answer a question, please give the best answer you can.

C1. Mobility

I have no problems in walking about ☐

I have some problems in walking about ☐

I am confined to bed ☐

C2. Self care

I have no problems with self-care ☐

I have some problems with self-care ☐

I am unable to wash or dress myself ☐

C3. Usual Activities

I have no problems with performing my usual activities ☐

I have some problems with performing my usual activities ☐

I am unable to perform my usual activities ☐

C4. Pain / Discomfort

I have no pain or discomfort ☐

I have moderate pain or discomfort ☐

I have extreme pain or discomfort ☐

C5. Anxiety/Depression

I am not anxious or depressed ☐

I am moderately anxious or depressed ☐

I am extremely anxious or depressed ☐

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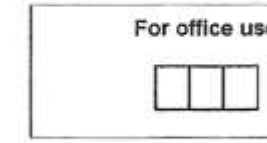
To help people say how good or bad their health state is, we have drawn a scale (rather like a thermometer) on which the best state you can imagine is marked 100 and the worst state you can imagine is marked 0.

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

For office use



Your own health state today

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SECTION D

This section is about the health care you have had in the **last 3 months**. Please read each question carefully. For each question, if you have had no treatment or visits enter '0' as indicated.

We would like to know about visits to health professionals **for any reason**, not just your digestive or bowel symptoms.

D1. How often have you consulted, for any reason, any of the following at your GP's surgery in the **last 3 months**?

Your own or another GP ☐☐ If none enter '0'

Nurse ☐☐ If none enter '0'

Other (please specify) _____ ☐☐ If none enter '0'

D2. How often have you consulted, for any reason, any of the following at home in the **last 3 months**?

Your own or another GP ☐☐ If none enter '0'

Nurse ☐☐ If none enter '0'

Other (please specify) _____ ☐☐ If none enter '0'

D3. How often have you been admitted, for any reason, to a hospital (NHS or private) as an emergency in the **last 3 months**?

☐☐ If none enter '0'

D4. How often have you been admitted, for any reason, to a hospital (NHS or private) NOT as an emergency in the **last 3 months**?

☐☐ If none enter '0'

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D5. How many times have you been seen, for any reason at a hospital outpatient clinic in the **last 3 months?**

By a Doctor ☐☐ If none enter '0'

By a Nurse Practitioner ☐☐ If none enter '0'

By a Dietician ☐☐ If none enter '0'

By anyone else (please specify) _____ ☐☐ If none enter '0'

D6. How many times have you been admitted as a day case for upper or lower endoscopy in the **last 3 months?**

Upper endoscopy ☐☐ If none enter '0'

Lower endoscopy ☐☐ If none enter '0'

D7. If you are in work, how many days work have you lost due to illness or in order to see any health professional in the **last 3 months?**

☐☐ If none enter '0'

SECTION E

Look at the list of medications below. If you take any of the medications listed below, please enter the dose of each tablet (this will be written on the tablet box or bottle) and the number of tablets you take each day. Answer 'yes' or 'no' to whether you are taking the drug regularly and if you answer 'no' please enter the average number of tablets you take each month.

	Each tablet dose in mg	Number of tablets per day	Regular?		If not regularly, average number of tablets taken per month
Indigestion medication					
Nexium (Esomeprazole)			Yes ☐	No ☐	
Losec (Omeprazole)			Yes ☐	No ☐	
Zoton (Lansoprazole)			Yes ☐	No ☐	
Protium (Pantoprazole)			Yes ☐	No ☐	
Pariet (Rabeprazole)			Yes ☐	No ☐	
Zantac (Ranitidine)			Yes ☐	No ☐	
Pepcid (Famotidine)			Yes ☐	No ☐	
Axid (Nizatidine)			Yes ☐	No ☐	
Tagamet (Cimetidine)			Yes ☐	No ☐	
Maxolon (Metoclopramide)			Yes ☐	No ☐	
Motilium (Domperidone)			Yes ☐	No ☐	
Medication for irritable bowel					
Spasmonal (Alverine)			Yes ☐	No ☐	
Merbentyl (Dicycloverine)			Yes ☐	No ☐	
Buscopan (Hyoscine)			Yes ☐	No ☐	
Colpermin			Yes ☐	No ☐	
Colofac (Mebeverine)			Yes ☐	No ☐	
Fybogel sachets			Yes ☐	No ☐	
Anti-diarrhoeal medication					
Imodium (Loperamide)			Yes ☐	No ☐	
Codeine Phosphate			Yes ☐	No ☐	
Questran (Colestyramine)			Yes ☐	No ☐	
Lomotil (Co-phenetrope)			Yes ☐	No ☐	

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Medication for Colitis	Each tablet dose in mg	Number of tablets per day	Regular?	If not regularly, average number of tablets taken per month
Asacol or Pentasa or Salofalk (Mesalazine)			Yes ☐ No ☐	
Colazide (Balsalazide)			Yes ☐ No ☐	
Dipentum (Olsalazine)			Yes ☐ No ☐	
Salazopyrin (Sulfasalazine)			Yes ☐ No ☐	
Entocort or Budenofalk(Budesonide)			Yes ☐ No ☐	
Prednisolone (by mouth)			Yes ☐ No ☐	

	Number per day	Regular?	If not regularly, average number per month
Predsol or Predfoam or Predenema (enemas)		Yes ☐ No ☐	

If you take any other tablets/liquids for your **digestive or bowel symptoms**, that are not listed, please write the details in the list below. Please include any prescriptions and medicines you buy over the counter from the chemist or supermarket (examples include antacids and laxatives)

Name of medicine	On prescription	Dose in mg or ml	How many times taken per week
	Yes ☐ No ☐		
	Yes ☐ No ☐		
	Yes ☐ No ☐		
	Yes ☐ No ☐		
	Yes ☐ No ☐		
	Yes ☐ No ☐		

If you wish to add any comments regarding your medication, please enter them in the box below.

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SECTION F ☐☐☐☐☐

The following questions are about your referral approximately **12 months ago** for the test for your gut or bowel symptoms and not about any other hospital referrals you may have.

F1. Are you still waiting for your test?

Yes ☐ No ☐

F2. If you have an appointment for your test, when is it?

☐☐ / ☐☐ / ☐☐☐☐
D D M M Y Y Y Y

F3. If you have had your test, when did you have it?

☐☐ / ☐☐ / ☐☐☐☐
D D M M Y Y Y Y

If you answered either YES or NO to question F1, please answer the following questions.

F4. Since you were referred for your test approximately 12 months ago:

a. Have you had an appointment which has been cancelled

- by the hospital? Yes ☐ No ☐
- by yourself? Yes ☐ No ☐

b. If cancelled by the **hospital**, what reason was given for the cancellation?

c. If **you** cancelled the appointment, what was the reason?

We are interested to know what communication there has been from the hospital since you were referred for the test for your gut or bowel symptoms approximately 12 months ago.

F5. Has the hospital contacted you?

Yes ☐ No ☐

If NO, please go to question F12.

If YES, please answer the following questions:

F6. Did you receive an acknowledgment that you had been referred for the test?

Yes ☐ No ☐

F7. Have you received a letter asking you to confirm that you still wanted the test?

Yes ☐ No ☐

F8. Have you had a phone call from the hospital?

Yes ☐ No ☐

F9. If YES, what was this about?

F10. Have you had any other communication from the hospital?

Yes ☐ No ☐

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F11. If YES, please describe this.

F12. Any other comments:

F13. Are your symptoms still troublesome?

Yes ☐ No ☐

F14. Do you still want to have the test done?

Yes ☐ No ☐

IF YOU HAVE ANSWERED NO TO QUESTION F14, WE WOULD ADVISE YOU TO CONTACT EITHER YOUR GP OR THE HOSPITAL TO DISCUSS THIS.

Please enter your date of birth below

☐☐ / ☐☐ / ☐☐☐☐
D D M M Y Y Y Y

Please enter your sex below

Male ☐ Female ☐

Please enter your initials in the box below

☐☐☐

Thank you for completing this questionnaire.

If you have any general comments about your digestive or bowel treatment, or this questionnaire, please write them below.

Once you have completed the questionnaire please return it in the FREEPOST envelope provided, or send it to

ENIGMA Study Team
Swansea Clinical School
University of Wales Swansea
Singleton Park
Swansea
SA2 8PP

If you have any concerns about your symptoms please consult your GP or hospital doctor.

YOUR COMMENTS

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Appendix 7 – The TIS Form proforma

FORM 1: Number of referrals received for endoscopy

Month requested	Referral type	FLEXIBLE SIGMOIDOSCOPY	COLONOSCOPY	GASTROS / OG
MM/YY	Day case / outpatient			
	2 week (cancer)			
	Inpatient			
	Follow-up (surveillance)			
	Emergency			
	Total			

FORM 2: Origin of referrals received

Month requested	Referral source	Number of procedures requested per r		
		FLEXIBLE SIGMOIDOSCOPY	COLONOSCOPY	GASTROSC / OGD
MM/YY	GP			
	Consultant			
	Private			
	Total			

FORM 3: Waiting list information

Month requested	No. patients waiting for…	FLEXIBLE SIGMOIDOSCOPY	COLONOSCOPY	GASTRO / O
MM/YY	> 1 month			
	> 3 months			
	> 6 months			
	> 12 months			
	Total			

FORM 4: Cancellations / DNAs

Month requested	Reason for lost slot	Number lost
MM/YY	Patient cancellation	
	Patient DNA'd	
	Hospital Cancellation	
	Total	

FORM 5: Number of endoscopies performed

Month requested	FLEXIBLE SIGMOIDOSCOPY	COLONOSCOPY	GASTROSCOPY / OGD
MM/YY			

MM/YY = Month/Year

Appendix 8 – Total procedures data submitted by highest each site

Data variable	Time	Hospital ID													
		1	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**	**13**	**14**
Referrals	T0	292		287	408		370	379	727	429		638		175	268
	T1	334		463	391		337	311	614	456		585		242	251
	T2	130	647	332	438		391	311	654	520		674	342	385	198
	T3	336	469	309	325	418	449	280	586	184		619	315	379	260
	T4	337	724	344	376	402	255	347	585	356		683	365	402	273
	T5	396	630	333	337	409	269	371	573			619	347	474	218
	T6	287	856	316	328	448	*278*		560			597	419	528	
	T7	336	564	281	280		287		289			589		548	
Wait >3m	T0			202	282	39	6		85			1043		1586	353
	T1			88	433	172	0		27			808		1117	418
	T2		77	4	461	60	0		55			889		1010	30
	T3		82	36	388	56	0	110	40			1020		1113	340
	T4		39	30	306	65	92	63	40			1063		1143	807
	T5		85	13	347	15	6	91	81			1265		1070	1090
	T6		14	5	239	26		28	79			2109		1080	
	T7		52	6	128				49					1787	
Snapshot	T0	1148				93			699	995					685
	T1	1180				289			630	2024					733
	T2	675	818			97			683	1889			996		324
	T3	477	890			97			588	2006	440		952		840
	T4	456	487			165			773	2122	657		803		1296

(…Cont'd)

Data variable	Time	Hospital ID													
		1	2	3	4	5	6	7	8	9	10	11	12	13	14
Snapshot	T5	484	588			25			654	2183	940		963		1511
	T6	414	572			43			631	2723			1208		
	T7	300	567							2648					
Lost slots	T0	94		69			21			216		53		64	64
	T1	81		67			26			138		34		134	63
	T2	71	13	52			92			106		54		146	29
	T3	99	21	47		38	112			142		64		192	33
	T4	70	18	62		67	20			134		64		141	46
	T5	75	26	64		54	26			151		50		102	40
	T6	70	29	52		98	114			141		36		167	
	T7	32	21	56			17			138		28		40	
Activity	T0	376	479	376	369		352	473	727	382	308	541		483	203
	T1	448	506	392	324		225	298	614	401	316	499		652	267
	T2	332	506	405	336		285	408	654	359	286	414	250	603	130
	T3	366	504	383	252	419	257	412	586	314	266	518	299	559	186
	T4	488	518	442	280	418	281	458	585	320	276	515	311	675	208
	T5	409	539	392	290	415	359	449	573	334	260	444	277	544	157
	T6	409		405	310	405	325	430	560	335	318	490	323	506	
	T7	278		269	303	362	255	331	334	289	287	476		371	

Cells shaded in grey indicate datasets subsequently excluded due to irregularities.

Appendix 9 – Data submitted from highest ranking source only

Variable	Time	Hospital ID														
		1	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**	**13**	**14**	**1**
Referrals	T0	7		12	53		72	121	188	6		97		14		
	T1	28		43	66		76	91	147	4		94		17		
	T2	6	44	33	49		69	97	193	6		97	45	82		
	T3	18	45	32	34	115	99	87	144	3		113	66	94		
	T4	18	76	30	41	119	53	114	153	16		120	73	116		
	T5	10	58	40	53	128	80	96	169			113	68	130		
	T6	17	76	46	67	137	74		170			110	86	135		
	T7	20	49	28	48		68		113			167		136		
Wait >3m	T0			18	40		0		65			29		252	15	
	T1			5	60		0		9			18		87	13	
	T2		3	0	62		0		20			45		97	0	
	T3		10	0	36		0	24	13			49		120	6	
	T4		3	3	38		16	3	19			76		110	30	
	T5		50	2	14		2	16	29			105		119	23	
	T6		5	0	20			3	20			426		124		
	T7		16	0	17				22					152		
Snapshot	T0	57							297	3					26	
	T1	65							260	14					20	
	T2	84	72						272	19			144		8	
	T3	51	80						243	27	49		128		34	
	T4	47	64						352	34	122		95		59	
	T5	57	60						221	96	155		94		39	
	T6	42	89						238	101			165			
	T7	29	70							74						

(…Cont'd)

Activity	T0	35	36	25	55		66		188	4	60	61		117		9
	T1	43	28	31	45		48		147	3	71	58		203		1
	T2	36	30	44	42		56		193	11	60	35	44	150		5
	T3	54	55	32	32	106	32		144	7	54	72	56	111		1
	T4	65	60	45	31	100	48		153	11	48	68	88	161		9
	T5	51	55	37	36	131	106		169	15	48	56	65	131		1
	T6	61		45	50	106	64		170	13	61	58	54	128		
	T7	29		30	46	110	64	97	129	16	41	87		106		

Cells shaded in grey indicate datasets subsequently excluded due to irregularities.

Appendix 10 – Data submitted from highest ranking sourc procedures only

Variable	Time	Hospital ID													
		1	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**	**13**	**14**
Referrals	T0	62		84	104		76	65	110	97		137		72	
	T1	73		142	108		89	88	113	149		140		35	
	T2	21	149	94	148		79	83	100	187		120	127	103	
	T3	71	125	75	92	57	115	68	86	102		108	127	97	
	T4	86	194	104	145	71	50	107	119	93		154	143	118	
	T5	97	196	88	94	43	94	143	114			108	154	149	
	T6	64	262	84	90	71	84		94			100	176	146	
	T7	88	155	73	86		73		63			137		147	
Wait >3m	T0			117	90		0		13			944		708	281
	T1			67	174		0		11			714		432	355
	T2		44	4	148		0		20			764		465	24
	T3		53	31	133		0	18	17			884		478	200
	T4		36	23	135		40	16	6			884		578	488
	T5		33	4	145		4	42	17			1082		628	680
	T6		9	2	123			25	15			1259		719	
	T7		33	3	74				13					1299	
Snapshot	T0	478							123	644					453
	T1	458							120	1049					538
	T2	354	302						131	1070			350		175
	T3	242	296						123	1146	107		368		451
	T4	186	205						110	1221	140		337		731

(…Cont'd)

Variable	Time	Hospital ID													
		1	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**	**13**	**14**
Snapshot	T5	179	260						105	1160	189		383		875
	T6	191	239						97	1232			491		
	T7	133	229							1250					
Activity	T0	81	97	55	99		48		110	88	51	153		85	
	T1	88	95	91	96		60		113	76	47	126		139	
	T2	63	109	56	83		61		100	74	40	91	120	111	
	T3	96	79	65	67	56	35		86	59	48	120	113	102	
	T4	131	88	84	86	61	61		119	74	40	141	112	152	
	T5	110	117	85	97	58	75		114	88	34	104	98	122	
	T6	126		99	80	75	67		94	79	48	120	136	66	
	T7	62		60	82	85	52	103	67	80	50	142		80	

Cells shaded in grey indicate datasets subsequently excluded due to irregularities.

Appendix 11 – Data submitted from highest ranking sourc procedures only

Variable	Time	Hospital ID														
		1	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**	**13**	**14**	
Referrals	T0	223		191	251		222	193	429	326		404		89		
	T1	233		278	217		172	132	354	303		351		190		
	T2	103	454	205	241		243	131	361	327		457	170	200		
	T3	247	299	202	199	246	235	125	356	79		398	122	188		
	T4	233	454	210	190	212	152	126	313	247		409	149	168		
	T5	289	376	205	190	238	95	132	290			398	125	195		1
	T6	206	518	186	171	240	*121*		296			387	157	247		
	T7	228	360	180	146		146		113			285		265		
Wait >3m	T0			67	152		6		7			70		626	57	
	T1			16	199		0		7			76		598	50	
	T2		30	0	251		0		15			80		448	6	
	T3		19	5	219		0	68	10			87		515	134	
	T4		0	4	133		36	44	15			103		455	289	
	T5		2	7	188		0	33	35			78		323	387	
	T6		0	3	96			0	44			424		237		
	T7		3	3	37				14					336		
Snapshot	T0	613							279	348					206	
	T1	657							250	961					175	
	T2	237	444						280	800			502		141	
	T3	184	514						222	*834*	284		456		355	
	T4	223	218						311	867	395		371		506	
	T5	248	268						328	927	596		486		597	

(…Cont'd)

Variable	Time	Hospital ID														
		1	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**	**13**	**14**	
Snapshot	T6	181	244						296	1390			552			
	T7	138	268							1324						
Activity	T0	260	346	296	215		238		429	290	197	327		281		
	T1	317	383	270	183		117		354	322	198	315		310		
	T2	233	367	305	211		168		361	274	186	288	86	342		
	T3	216	370	286	153	257	190		356	248	164	326	130	346		1
	T4	292	370	313	163	257	172		313	235	188	306	111	362		1
	T5	248	367	270	157	226	178		290	231	178	284	114	291		1
	T6	222		261	180	224	194		296	243	209	312	133	312		
	T7	187		179	175	167	139	131	138	193	196	247		185		

Cells shaded in grey indicate datasets subsequently excluded due to irregularities.

Appendix 12 – Costing assumptions and unit costs

Resources devoted to modernisation were gleaned from the two interviews held at each site. The level of detail that could be provided varied. The methods below were used to value each resource.

Staff

Grade/Band Reported
Interviews were held shortly after the implementation of 'Agenda for Change' in the NHS whereby staff posts were changed from Grades to Bands. Where the relevant grade or band was reported, average costs were taken from

http://www.geniushealth.com/info/nhs-pay/nursing-pay-rates.html (grades)

http://www.nhscareers.nhs.uk/details/Default.aspx?Id=767 (bands)

Titles Reported:
Where the job title was reported the following assumptions were made

Junior Nurse = Grade F
Nurse Endoscopist = Grade G
Senior Nurse= grade H
Sister = Grade H
Nurse Specialist = grade H
Nurse Consultant = grade H
Manager = 8b
Unit manager = 8b
Project manager/ modernisation manager = 8b
General manager = 8b
Service manager/ Clinical service manager = 8b
Senior manager = 8d
Directorate manager = 8d
Junior manager = 8a
A&C = 5

Job Description Reported
During some interviews, the interviewee was unable to specify the grade of staff involved in a particular activity. It was often the case, however, that the job description could be specified. In these cases staff cost were estimated by finding jobs advertised on www.jobs.NHS.uk which most closely related to the job of the staff member and using the middle point of the advertised scale.

Equipment

Equipment costs were those incurred by the sites. Where cost was unknown, the most frequently incurred cost for similar equipment by other sites was used.

Training

For training courses, actual costs incurred were used where reported. Where not known, the cost for the relevant course were as follows from http://www.bsg.org.uk/bsgdisp1.php?id=d82d268e18ad5db9500c&h=1&m=00022#training

- Basic Skills in Colonoscopy - 3 Days -£1000
- Basic Skills in GI Endoscopy - 3 Days - £900
- Basic Skills in Therapeutic GI Endoscopy - 3 Days - £1000
- Basic Skills in Flexible Sigmoidoscopy - 3 Days - £900
- Training the Trainers - 2 Days -£700
- Basic Skills in ERCP Training - 3 Days £1200
- Basic Skills in Radial Endoscopic Ultrasound - 3 Days -£1000

The opportunity cost of the time of the person being trained (see above) was added to these costs of the courses.

Unit Costs and sources

Data item	£ Unit cost	Source
GP (surgery visit)	£21	1
Nurse (surgery visit)	£8	1
GP (home visit)	£60	1
Nurse (home visit)	£11	1
Social services/ Social worker	£60	1
Support worker	£11	1
Consultant	£73	1
Dietician/ Nutritional nurse/ Nutritional therapy session	£35	2
Physiotherapist session	£36	2
Paramedics/ Ambulance	£161	2
Chiropodist/ Podiatrist	£31	2
Occupational therapist	£36	2
Chiropodist /Podiatrist	£31	2
Day case endoscopy	£457	4
Colonoscopy	£352	2
Flexible sigmoidoscopy	£279	2
Gastroscopy	£275	2
Inpatient per day: medical	£269	3
Endoscopy slot	£2727	6
Outpatient episode	£96	3
Avg. weekly earnings male	£105	5
Avg. weekly earnings female	£81.20	5
Drugs	*	7

* = individual drug costs from (7)
1 = Curtis L, Netten A. Costs of health and social care 2006. PSSRU
2 = Dept. of Health. NHS Reference costs 2005/6
3 = Netten & Curtis 2002* inflated to 2005/2006 using DH Pay and Prices Index
4 = http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/Publications

PolicyAndGuidance/DH_062884 2005-2006. Day cases. Appendix NSRC1 (TDC)
5 = http://www.statistics.gov.uk/downloads/theme_labour/LFSHQS/Table36.xls (2006)
6 = Slot is made up of 12 points. Slot cost based on assumed ½ session for colonoscopy (2 points per procedure) and ½ session for sigmoidoscopy/gastroscopy (1 point each per procedure).
British National Formulary 2007.

Endoscopy Sessions:
Costs based on NHS Reference costs 2005
Colonoscopy=2 points £352
flexible sigmoidoscopy=1 £279
gastroscopy=1 £275

Points taken from Melaine Marchette, Singleton Hospital
Session/slot= 12 points

flexible sigmoidoscopy= £279*12 = 3384
gastroscopy= £275*12 (points)= £3300
Total average= (£3384+£3300)/2=£3342

Assumption 1/2 session is for colonoscopy 3(points)*352 (average cost of colonoscopy, NHS reference cost 2005)=£1056
1/2 session for flexible sigmoidoscopy and gastroscopy= £3342/2=£1671

Cost of per slot/session= £1056+£1671=£2727

Appendix 13 – Patient Interview Schedule

	Question	Probe
1.	I'd like to talk to you about the way you were referred for your endoscopy, the xxx you had on xxx at xxx Hospital	
2.	Can you tell me how long after seeing your GP that you had the endoscopy?	
3.	Were there any good points about the way you were referred?	Speed of access Amount of information given about process - length of wait - acknowledgement Referral route – OPs, direct from GP Choice of date
4.	Do you have any suggestions for improvement about the way you were referred?	Speed of access Information about process Referral route Choice of date Bad experiences
5.	Can I ask whether you have been referred for an endoscopy before the xxx (type of procedure) in xxx (date)?	What did you have then and how long ago? Check if same hospital Flexi / Colon / Gastro
6.	Have you noticed any changes since your last referral?	
7.	Do you have any other comments?	

Appendix 14 – Clinician / Key person first round interview schedule

Question	**Prompt**
1. How did you become involved in innovation / changes in endoscopy	Prompt - background - previous skills
2. Can you describe the way the endoscopy services ran (run) before any innovations / changes were made? (last 2 years)	Prompt - what problems were you / are you trying to address - opinions WHY/HOW
Either: 3a. Can you clarify what I innovations / changes have contributed to the way the unit currently runs? Or: 3b. What innovations / changes do you hope to make?	Prompt - innovations - booking system - reduction in waiting times WHY/HOW - improvement in DNA - Nurse Endoscopist - increased staffing - alteration of staff responsibilities - change of leadership - staff training - changes in staff responsibilities - equipment - relocation / restructuring of building - process differences - why chose one innovation over another - which one successful in your view - opinions
4. Can you identify any problems / issues in implementing the innovations / changes? Or: Do you envisage any problems / issues in implementing the innovations / changes?	Prompt - funding - staff resistance WHY/HOW - staff numbers
Either: 5a. Where did you get funding for innovation/changes? Or: 5b. Where will you get funding for innovations / changes?	- (Intervention) Which innovations / changes resulted directly from MA funding? Would you have made changes without MA funding? WHY/HOW Prompt - (Control) Reaction to not receiving funding?

(…Cont'd)

6. How have staff responded to innovations/changes?	Prompt - working as team - to your leadership WHY/HOW
7. What impact has the arrival of the MA had?	Prompt - Toolkit™ - still - Training / support from MA WHY/HOW

Appendix 15 – Clinician / Key person second round interview schedule

Question	**Prompt**
1. Can you clarify what innovations / changes in the last two years have contributed to the way the unit currently runs? Are they moving the service forward? Ask if they have completed the GRS and for their scores	Prompt – innovations – booking system - reduction in waiting times WHY/HOW - improvement in DNA - Nurse Endoscopist increased staffing alteration of staff responsibilities change of leadership staff training changes in staff responsibility equipment relation / restructuring of building process differences - why choose one innovation over another - which one successful in your view - opinions Data collection Are they moving the service forward? What problems still facing?
2. Why was change introduced?	Improve services for patient Efficiency of provision
3. Can you identify any problems / issues in implementing the new innovations / changes?	Prompt - funding - staff resistance WHY/HOW - staff numbers
4. Where did you get funding for the new innovation / changes? Has funding situation changed since we last met?	Mention aware that seen by DC/SM but interested in their views on how funding is impacting on change
5. How have staff responded to innovations / changes?	Prompt Why/how
6. Do you think the service is now more accessible to patients as a result of the innovations you described? Example	Example
7. Do you think the service is now more acceptable to patients as a result of the innovations you described? Example	Example
8. If you were to have an endoscopy in this unit, what would you want to change?	WHY

Appendix 16 – Individual analysts' summative paragraphs for all four focus groups

FG1

(AW)
The speech meanders through a number of important issues. These include issues around power and threats to autonomy (e.g. between medical colleagues, nursing and medical colleagues, clinicians and managers and between teaching hospitals and DGHs). These in turn are linked to everyday, practical difficulties and opportunities around who should be scoping, making referrals, and managing the scoping environment – including new roles/ ways of working. The extract reflects tussles around who should be leading on strategy in relation to innovations. Clearly the feeling is that Government driven initiatives and associated funding opportunities may undermine moving forward on local needs. Conversely – at least to a degree – there appears to be some agreement that targets, for example waiting list targets, may act as facilitators for innovation. Communication is a key issue throughout, particularly between managers and clinicians – and this links with perceived eroded autonomy – although this is experienced differently by nurses and doctors. The latter point links up with the issue of how power is experienced. Better networking between units is mentioned as a potentially useful facilitator and of benefit to patients. Interestingly, patients are very much on the periphery of this focus group discussion – one notable exception is the point that in order to pull in resources patients are potentially inconvenienced. You will know where in the transcript reference is made to this. The issue of whether or not funding on the one hand or better management on the other would expedite better patient service is ever present between the lines and the text suggests both are key concerns.

Key issues include: power, autonomy, practicalities, strategy, funding, management, targets, new and changing roles/ways of working and communication.

(WYC)
The discussion has highlighted several barriers to changes, including conflict between clinical needs, Government directives and management agenda; resistance to changes in working practice, lack of capacity and insufficient IT support. However, it was also suggested that management agenda and Government targets could be used to facilitate changes.

Changes mentioned in the discussion included introducing pooled list, management and referral guidelines, vetting lists, getting additional staff, additional sessions and even building new units. Uncertainties about the sustainability of the changes were mentioned. Inpatient referrals and the liaison with surgeons were repeatedly mentioned as sticky points. There were also some concerns expressed about the way to handle patients with more complex needs such as those who needed PEG and sedation.

Some changes were perceived to require funding. These included staffing, IT and equipment. A difference between the participants in the understanding of the cost of providing a service could be seen, as exemplified by the discussion about

capsule endoscopy. The need to give people incentive to put the effort to introduce changes was also mentioned.

Differences between doctors and nurses in their response to changes were highlighted. Doctors were perceived to be more resistant to changes, especially to those introduced by management. Several reasons were suggested by the participants with clinician autonomy being perceived as the underlying factor of this medical resistance.

Participants admitted that changes introduced in their units seemed to be working, but some seemed to admit this with reluctance. Low staff morale, especially among doctors was mentioned as a downside of the changes introduced.

Participants were open about bad relationship with management or trying to out-manoeuvre managers. They also suggested the impact of the big environment which included the new contract, Trust deficits, differences between teaching hospitals and district general hospital and merger of Trusts.

(AS)
Resource issues are a common problem when introducing changes with a lack of funding, lack of staff and inadequate IT systems being highlighted. However, not all change requires funding, such as changing work practices and finding ways to redeploy funds and all participants described changes in their units, indicating an understanding of the need and desire to improve endoscopy services. The changes aim to reduce waiting times by managing demand and increasing list utilisation to increase capacity, but there is a sense of frustration that improvements are limited by inadequate funding to sustain and increase staffing and improve IT systems. This is compounded in areas where Trusts have financial deficits and funding is generally not forthcoming unless attached to a Government target. There has been some staff resistance but it was felt that while nurses could be persuaded of the benefits of introducing new ways of working, consultants were not so easily swayed particularly if they felt they were being dictated to by management. However, the cause of consultant resistance relates to a change in the expectations of the role of a consultant - their traditional role as an autonomous, independent decision-maker, is being challenged and they feel that while retaining the responsibility of the role, they no longer have any authority. This perceived change in role combined with the continuous demands for change in the NHS is seen as causing resistance among consultants and contributes to tension in the relationship between consultants and managers. In spite of some resistance, the group felt the changes that had been introduced in their units had worked well but there was disappointment that the effects had been limited and had not resulted in significant improvements in staff morale with nurses continuing to be under pressure. However, while recruitment continues to be difficult, retention of staff has improved.

(FR)
Focus group participants' emphasised barriers to change over and above facilitators to change, highlighting in particular a lack of resources, underpinned by a lack of understanding by managers of what is needed to progress service delivery. This is exacerbated by a slow rate of change. Some changes, however have been well received, including: centralised waiting list management, trained Nurse Endoscopists and new guidelines for referral and management of patients. Although acquiring funds is crucial for progress, as important is the clever re-deployment of funds which appears lacking, resulting in de-motivated staff. Moreover, the Trusts are seen to be managing resources unwisely and it is essential that if change is to be successful, management must come on board and work closely with Units according to their requirements. Until that happens, Units

will continue to try to manipulate the system to serve their individual needs. As for engagement of staff in modernisation interventions, doctors were considered the most difficult group, resisting change in keeping with the notion that they are overburdened, all powerful and autonomous. For improvements to progress, there needs to be better retention of staff, greater nurse engagement, less staff pressure and stress and fewer challenges to doctors' authority from out-of-touch management. Implementation programmes for innovations have neither run smoothly nor been well received. This has led to low staff morale which has worsened since the introduction of MES innovations. Ironically, this is tempered by greater efficiency. However, although people might be working more quickly, they are seen to be achieving less, perceiving themselves to have all the responsibility but no authority and Trusts to be dysfunctional.

(JGW)
There is a strong sense that, with possibly one exception, the participants are keen to improve their services through change. They are, however, frustrated by the system, particularly lack of resources and a poor relationship with management, who they see as resistant to the changes they wish to make. There is, however, an acknowledgement among the doctors of their own medical arrogance and resistance to change initiated by others. The sense of frustration and failure to affect improvement is strong, although it is clear that some changes have been initiated with good effect. It appears that much can be achieved within existing resources through greater efficiency (driven by targets, audit and guidelines) and changing roles, notwithstanding a feeling that funding is the main barrier. There is clearly a problem with staff morale and with change fatigue, though a hint that strong leadership and the application of change management is key to progress.

(ITR)
I begin with a caveat. The conclusions I draw from the transcript depend on what I know about the 5 participants: are they typical, at the good end of the performance spectrum, or al the poor end of that spectrum? To make progress I assume that they are typical.

1. That said the first question about facilitators and barriers elicited many more barriers, with the Government, management and resources all coming in for criticism. More refreshing was the member who focused on traditional working patterns. and the one who remembered to say at the end that the "national endoscopy project had facilitated the process", In aggregate, however, this group perceived the state of the endoscopy service as 'half empty' rather than 'half full'.

2. Responses to the second question, about changes since 2002, were more encouraging. Reported changes included increases in the number of Nurse Endoscopists refusing inpatient referrals for endoscopy, and pooling waiting lists (which operational researchers have been demanding ever since they failed to reduce deaths from horse-kicks In the Prussian cavalry).

3. There was general agreement in response to the third question that funding was critical in achieving change. Examples included the appointment of extra staff, the purchase of new health technology and Information technology, the replacement of old equipment, the payment of incentives, and the perception of perverse incentives to refurbish car parks before Increasing support staff.

4. There was also general consensus about staff response to change. Members saw doctors as resistant to change, while nurses were more compliant, though not universally so. In different ways members recognised the potential for good management to facilitate change and poor management to discourage it, even to prevent it.

5. The final question led to general agreement that the changes had been effective, but generated a range of qualifications: two members asserted that the changes had been at the expense of morale, manifest in failure to recognise Improvements or the feeling of being under attack.

6 Subject to my initial caveat I conclude that this focus group was convinced that modernising endoscopy had been generally successful. At the same time they cited a lot of anecdotal evidence about weak management and missed opportunities.

FG2

(AS)
Participants acknowledged that change was needed, in particular to reduce waiting lists to avoid the late detection of cancers. While further changes are needed, they (nurses in particular) reported some improvements and that staff are motivated by seeing the positive outcomes. Nursing staff instigate a lot of the changes; they are patient focused and, being in the unit all the time, see what changes are needed. However, it was acknowledged that endoscopy is a unit used by other specialties and there are differences between physicians and surgeons and their reasons for doing endoscopy. This can result in concern by physicians over the quality of scoping by surgeons and reluctance by surgeons to scope medical patients. Improving communication between groups was highlighted by one participant as an important step in introducing change. Resources for modernising endoscopy services have been limited, due in part to the lack of an NSF and targets. Nevertheless, cost neutral changes, while needing time and commitment, have been made and it is anticipated that the GRS and Colorectal Cancer (CRC) Screening, could bring additional resources but there is concern about how units will cope with the additional work. There is a sense of community within gastroenterology in South Wales and while WAG has been supportive in funding training, more financial support is needed to continue improving services. The fact that modernisation in Wales lags behind England was viewed positively in that participants felt they had learnt from the experiences, good and bad, of their colleagues elsewhere.

(HH)
There were two Nurse Endoscopists and one doctor involved in the focus group session. All were keen to participate and fully discuss issues relating to modernisation of endoscopy services both in terms of what they had done locally and what could be done long-term. There appears to be a great deal of camaraderie within endoscopy services generally with most personnel happy to instigate or accept change. The main driver for change appeared to be improving the patient experience. The nurses appear to be driving many of the changes and were very highly regarded. Difficulties were encountered where 'outside' personnel were involved. All the participants commented on successful changes that had been achieved predominantly by re-evaluating the service rather than providing financial support. Long-term however it was recognised that money would be the main driver to maintenance and improvement of the service. There was a general consensus that Wales could learn from English sites and that good relationships existed across borders. The main issues that arose relating to improvement of services were reduction of waiting times, backfilling, improving relationships and management issues.

(IC)
The informants were positive about the effects of the changes in endoscopy services made through the management of throughput. The changes highlighted included: validation of waiting lists, backfilling and pooling the lists. The impact of

delayed endoscopy on patient prognosis was highlighted as the main driver for change and nurses played an important part in the introduction of those changes. The impact of the changes on the work pattern of the endoscopy team especially the booking clerk was highlighted. Some challenges were mentioned, including the lack of investment, the need to bring senior executives on board and persuade some surgeons to work with the physicians. The need to ensure adequate information from GP referral to prioritise patients was also mentioned. These changes had been resource-neutral so far but informants had referred to the need of putting more resources into the services to maintain the momentum and took the service forward and to meet the standards set in GRS (Global Rating Scale?).

(FR)
Welsh Gastroenterology Units have been keen to make changes to address a range of issues including: long waiting lists, lack of communication between staff particularly surgeons and physicians, and poor performance. This has engendered pooled lists, a drop in waiting times and less territoriality over patients. Instigators for change are patient focused, spurred on by seeing late cancers and a recognition of ineffective management. Change has been predominantly nurse-led however with motivation most staff groups are willing to embraced change, seeing the potential for improved patient care. In spite of barriers such as funding and lack of resources, innovations have been a success and have led to re-organised nurses' work, mapped pathways and pooled lists. Funds are now needed to deal with the influx of extra cases and the GRS. Welsh units are proud of the changes they have made, looking to English Units for guidance and direction. However they see little financial support or understanding from the Trusts or from external sources such as the Welsh Assembly Government.

(JGW)
The transcript indicates general agreement between the three who participated (two nurses and a doctor). The changes instigated in the modernisation process appear to be modest and conventional (improving work flow, changing roles, validating waiting lists, collaborating better, and pooling endoscopy lists). These changes have been facilitated by better management and nurse-led change. The Global Rating Scale has clearly been a very significant driver and it would appear that there has been little money made available. In spite of this there was a feeling that this lack of money was a barrier to change, as was senior managerial inertia. Surprisingly, it was felt that the biggest achievement in these changes was a reduction in waiting lists and there was little mention of quality of care or patient benefit.

(GJ)
Changes within the participants' units were process- and staff related, such as validating, pooling and backfilling of lists, identifying problems, promoting intra-organisational collaboration and re-organising staff; with nurses being the main initiators of change. Changes appeared to be reactive rather than proactive, in response to external factors such as audits, the Global Rating Scale (GRS) and seeing late cancers. Organisational factors posed barriers to changes, as well as the 'lack of belongingness' of GI units within the wider health care context. Very little or no funding was required so far, however financial support will be needed to make improvements sustainable. The consideration of the support, which the English units have received through the NHSMA initiative, is characterised by positive reframing; emphasis is placed on support from within the Welsh community and the opportunity to observe mistakes as a learning experience.

(ITR)
The three participants reported ***wide variations in performance*** in reducing waiting for endoscopy: Hospital N (FG2.1) is very proud of keeping their waiting

time below one month for 2 years; Hospital S (FG1.3) has reduced waiting time through 'backfilling' but not to the same extent; but Hospital C (FG2.2) has apparently had little success.

These variations seem to reflect ***variations in approach*** **to** ***modernisation****:* in Hospital N senior managers persuaded surgeons and physicians to work together, notably by sharing lists (FG2.1); in Hospital S the main driver was a rigorous internal assessment leading to changes in the management of waiting lists (FG2.3); but, though Hospital C has 'done lots of audits', there is real opposition to change (FG2.2) with the result that 'conscious sedation' and a revised referral form (FG2.2) are the main changes.

Facilitators and barriers*:* it was the transition to become a screening unit that facilitated the greatly improved performance of Hospital N, despite the lack of a gastroenterology NSF and uninterested gastroenterologists (FG2.1); in Hospital S the main incentive seemed to be the desire to become a CRC screening unit (FG2.3.) with nurses facilitating progress and surgeons reluctant to lose their patients providing the main barrier (FG2.3); in Hospital C financial incentives seemed to facilitate and the absence of such incentives left inertial barriers in place (FG2.2).

FG3

(FR)
Many more barriers than facilitators to change were mentioned in FG3 – a focus group comprising 6 gastroenterology physicians and surgeons. Barriers included lack of training especially among nursing staff, organisational barriers and differences between professional group functioning. Innovation is also impeded by lack of a National Service Framework, labyrinthine management systems and lack of positive steer from the Welsh Assembly Government resulting from a political agenda that restricts the flow of funding to endoscopy. The implementation of the GRS was instrumental in ensuring changes did take place to services, raising morale and strengthening team spirit somewhat, however while pressure continues from management to move forward, the process of modernisation lacks leadership, co-ordination and the necessary finances. In addition there is the need for additional staff training, closer collaboration between staff and support for nurses. Change is at a slower pace in Wales than in English units, with Welsh units lagging behind in terms of strategic vision, resource availability, Governmental and Trust support and good management.

(HH)
The FG produced a lot of discussion about the current status of GI services in Wales. Although changes were highlighted, a number of clinicians were keen to point out that the changes were not always positive. Some of the changes made included increased staffing, reducing waiting times, changes in the way services were delivered, increasing the numbers and types of services, the introduction of specialisation and pooling of lists. It was though that the bowel cancer screening programme (NBCSP) and Trust mergers would have further unknown implications on services. Specialisation and MDT were thought to have made improvements particularly in managing cancer patients but that specialisation in itself led to its own problems particularly with respect to finding the right people out of hours and the time impact of attending MDT meetings. There was general agreement that the complexity of work had increased along with the volume as well as a requirement for more accurate reporting. There seemed to be a general consensus among the group that the relationship between Trust management and clinicians was a barrier to change with managers and politicians dictating the changes. The changes were thought of as 'target led' and did not necessarily result in improved patient outcome. It was recognised that new equipment was a

major requirement but acquiring funding for it was difficult. It was perceived that relationships between junior staff and consultants were also difficult. The major facilitator for change was thought to be forward thinking, pro-active staff who were willing to share knowledge and ideas. Better communication, IT, literature and medical education were also mentioned as facilitators. Fragmentation of departments was mentioned as a barrier, as was training and research curtailment and lack of funding to increase staffing. It was recognised that changes in the NHS were slow and this led to low staff morale. Lack of funding was highlighted on several occasions and some participants mentioned that they had received external funds from pharmaceutical companies or charities in order to buy equipment or fund staff. There were several comments regarding low staff morale due to changing roles. It was also perceived that there were too many frequent targets to achieve and that this was likely to affect patient outcomes. It was perceived that there were no major differences with England and that English units were not significantly better than Wales in terms of GI outcomes. It was thought that waiting times and cancer screening programmes may have suffered in Wales. It was also thought that Wales had lacked resources compared with England. Despite this it was felt that there were no major differences with England in terms of clinical outcomes.

(AS)
Interviewees reported changes initiated from within units (some at little cost) that had been effective particularly in reducing waiting lists, such as more consultants and Endoscopists, pooling of lists and ensuring appropriateness of referrals. In contrast, change forced by Government, considered to be too much, too often and not evidence based, was not as effective and was leading to changes in the way clinicians and nurses work that are not good for patients; clinicians were said to be losing autonomy, becoming less flexible and feeling disengaged and nurses were spending less time caring for patients. While two clinicians felt that funding was not a major issue, the remainder voiced concerns about resources for gastroenterology equipment, research, personnel and training. It was felt that something had to be a political priority to gain support from Trusts. The clinicians did not feel that the MA work in England had created a big difference between the two countries. However, some felt that Wales lacks resources and lags behind England in terms of waiting times, colorectal screening and technical development.

(GJ)
Six gastroenterology consultants and surgeons, representing Welsh units, participated in this group. Changes in participants' units included the expansion of units and staff, and increased specialisation including a focus on multi-disciplinary team work (MDT). Politicians setting targets and Trusts making badly informed financial decisions are considered as root causes of the problems that are being experienced. Two paradoxes emerged: 1) the new consultant contract essentially increases pay for reduced working hours, reducing the perceived quality of patient care considerably; 2) targets drive clinicians to treat patients on the waiting list on the expense of urgent cases. This creates, as one participant phrased it, a 'depressing atmosphere' and leads health care services to 'lose the plot in basic patient care'. Nurses and doctors are merely seen as employees and this change in professional self-identity causes frustration; management decisions are being made without consultation with the affected parties. Changes are considered to be more effective if they come from within. Participants noted that changes imposed by management should be evidence-based as it is expected within clinical practice.

(JGW)
This Focus Group had a good mix of specialists but all were doctors. The most dominant theme to emerge was the distrust and dislike of management, and the

perceived adverse influence on change. This seemed to be manifest mainly as inertia but in some instances as negative. There was felt to be a loss of clinical freedom, autonomy, influence and morale among clinicians. There was also an evolving change in roles and perception of roles with loss of conventional functions which had could have an adverse effect.

The changes described were diverse and there was no particular theme. Quite a lot was said about specialisation and the impact that this has had, both positive and negative. The discussants seemed fairly ambivalent about funding. In some instances there had been considerable investment in new units and more people but others described difficulty getting equipment. Overall the impression was that funding was not perceived as a huge catalyst for change and reorganisation was also important. Virtually nothing was said about the patient experience and there was very little about real change for the better. However, when asked for differences between England and Wales there was a general consensus that Wales was not worse off and possibly better off from the medical perspective than England, although some initiatives such as colorectal cancer screening were delayed and it was acknowledged that waiting lists were probably longer. There was an implication that less research was being done. The lack of evidence for change and the lack of consultation by management to seek professional views were highlighted

(ITR)
The transcript suggests that this was a coherent group who saw recent changes in gastroenterology as generally for the worse. To test this negative impression, I undertook a crude form of content analysis. The six members made a total of 22 comments identifying changes since 2002 – increased specialisation (FG3.3, FG3.5, FG3.2, FG3.1), more human resources (FG3.4, FG3.3, FG3.1), reduced waiting times (FG3.4, FG3.6, FG3.3), new or expanded endoscopy unit (FG3.4, FG3.1), introduction of referral criteria (FG3.4, FG3.3), more multi-disciplinary teams [MDTs] (FG3.5, FG3.2), more colonoscopies (FG3.4), merger of NHS Trusts (FG3.4), changes due to Innovations in Care (FG3.6), pooled lists (FG3.3), better investigation (FG3.2) and centralised training (FG3.1).

The group made ***nine*** comments identifying facilitators of change – clinical colleagues (FG3.5, FG3.6), scientific advance (FG3.1), the internet (FG3.2), video technology (FG3.2), access to literature (FG3.2), better communication (FG3.2), investment (FG3.3), political support (FG3.6), commercial funding (FG3.2) and 'bottom up' innovation (FG3.1). In contrast they made ***14*** comments identifying barriers to change – funding (FG3.2, FG3.5, FG3.6), target-driven NHS (FG3.5, FG3.3), European Time Directive (FG3.1), bureaucracy (FG3.2), loss of clinical autonomy (FG3.3), loss of morale (FG3.3), slowness of NHS to change (FG3.6), political interference (FG3.6), loss of continuity of care (FG3.4), difficulty of providing out-of-hours care (FG3.4), increased specialisation (FG3.4), difficulty in recruitment (FG3.2) and 'top down' innovation (FG3.1).

The group identified ***three*** changes not needing extra resources – rationalising open access (FG3.4), pooled lists (FG3.3) and specialised wards (FG3.1). In contrast they made ***six*** comments identifying changes needing resources – technological equipment (FG3.4, FG3.6, FG3.3), more MDTs (FG3.5, FG3.2) and more human resources (FG3.5).

The group identified ***one*** positive staff response to change, namely some staff welcome specialisation (FG3.2). In contrast they identified ***seven*** negative staff responses: nurses rarely nurse (FG3.1); junior doctors are unhappy with training and appraisal (FG3.1); some staff do not like specialisation (FG3.2); loss of professionalism and commitment (FG3.5); change has been overwhelming

(FG3.3); frustration at pace of change (FG3.6); and diversification is reducing quality of patient care (FG3.4).

Three comments classified the changes as successful – 'tremendous improvement' (FG3.3), 'they have worked' (FG3.5), 'good overall' (FG3.1). In contrast ***seven*** comments classified them as adverse: centralisation questions future role of DGH (FG3.4); NHS targets have taken control (FG3.6); more risk-taking (FG3.5); inappropriate merger (FG3.2); consultants' loss of autonomy (FG3.2) few changes are evidence-based e.g. MDTs & pooled lists (FG3.1); and imposed changes have been distressing (FG3.1).

The group identified ***three*** advantages that gastroenterology in Wales enjoys over England – better pay (FG3.2), fewer changes (FG3.1) and no independent treatment centres (FG3.6). However they also identified ***three*** disadvantages – fewer jobs (FG3.1), longer waiting times (FG3.6) and fewer resources (FG3.3).

In conclusion I judge that this content analysis confirms the impression of a coherent (or well chaired?) group who saw recent changes in gastroenterology as generally for the worse.

FG4

(FR)
FG4 comprised six gastroenterology surgeons and physicians who described a number of positive aspects to change that had taken place in their units, including: a greater number of consultant appointments, reduced waiting times, pooled lists and new inpatient referral systems. However, this has led to more complex working arrangements and a greater volume of work. Barriers and facilitators to change were mentioned in equal measure. Barriers included: new political and managerial directives, target driven workloads, lack of training and decrease in research. Facilitators included: greater sub-specialism in surgeons and better science. Bureaucracy has grown, affected by change to managerial and political functioning which has challenged working practices and led to large amounts of legislation and paperwork. As a consequence of a "depressing atmosphere" and "distressing times", stress levels among staff are high. Many changes have been undertaken without funding, such as pooled lists, however Welsh endoscopy lacks necessary funding and lags behind its English counterparts in this respect as well as in the number of jobs that have been created, but not in terms of good clinical practice.

(AS)
The major barrier related to the management of endoscopy. Problems included convincing Trust management of the importance of endoscopy, an inability to pull together the different specialties using endoscopy, difficulty getting through the layers of management - "enormous and complex labyrinth management systems" (106) and crisis management. Other barriers included the low profile of endoscopy, lack of NSF, insufficient staff and funding and the problems of geography, population and capacity that create issues with training programmes. Few facilitators were mentioned but included by-passing management, specialty based services facilitating additional staff and the need for motivated people. Some changes were described (pooling, specialist clinics, additional staff) but there was a greater sense of what they were working towards and the problems experienced. While endoscopy staff were dedicated and supportive and work as a team, there was concern about low morale and described as like "people clinging to a life raft" (465). It was seen as important to raise the profile of endoscopy and anticipated that Bowel Cancer Screening and GRS would help with this. There was frustration that Wales was lagging behind England but it was felt that progress was being made.

(HH)
The original innovations introduced in Wales in 2004 were mentioned as major facilitators for change although it was felt that things had faltered in more recent years. Barriers to change in Welsh units included changes to the GI training programmes which appear to have faltered at the expense of devolution. The Trust management also were perceived as a barrier and passing through the management structure to get changes approved and funded was complex. There also appeared to be a lack of communication between the surgical and medical specialties which made consolidation of services difficult. It was also felt that there was poor management of different specialties within endoscopy and that each one had its own agenda so there was a lack of cohesion. It was thought that GI services had lost out to other specialties because they were not high profile enough. It was also mentioned that gastroenterology may have suffered for a number of years because it did not have a National Service Framework. It was however recognised that the introduction of bowel cancer screening would have an impact. Running GI units effectively was difficult due to staffing deficits and the increased workload. Units appeared to be running without their full complement of staff with no major drives to recruit additional staff. Lack of time to communicate with colleagues also slowed progress. Changes appear to be Assembly led. Some of the changes were the appointment of specialist nurses, endoscopy user groups, engaging with GPs regarding referrals, previous Trust mergers, changes to endoscopy services, pooled lists and dedicated clinics. The implementation of the global rating score was also felt to have made an impact and has provided a template for change. It was felt that politicians had not acknowledged the extent of the changes required within gastroenterology in order to implement cancer screening and the GRS. Also it was felt that although changes had been made they did not always lead to improvement. For example increased facilities could not be utilised fully due to staff shortages. It was felt that changes that were deemed necessary by management were funded but that clinical changes were not. It also appeared that some of the participants were unsure if funding was given or not. Some funding was obtained from external sources initially but was eventually Trust funded. It was recognised that consultant funding had been funded but that other staff funding was not always in place. It was felt that staffing levels in general were quite low in gastroenterology and that although training existed for doctors this was not the case for nurses. Costs for this type of training appeared to rely on external funding. Despite working in difficult conditions it was felt that there was a strong sense of teamwork. However it was recognised that the staff did not feel appreciated by the management and that general morale was low. It was commented that there was a lack of leadership at some levels. It was generally felt that Wales lagged behind England in terms of changes. Issues that were mentioned were lack of funding for training, development of the English cancer network, lack of resources, geographical issues. It was felt however that progress was now being made in Wales. Increasing the profile of gastroenterology was thought to be the major factor in improving it long term.

(GJ)
Six gastroenterology consultants and surgeons, representing Welsh units, participated in this group. Changes included the expansion of units, the implementation of endoscopy unit user groups, and changes to the referral and booking system. Prioritization in Trust management conflicts with priorities set by the service group management, leading to decisions that are not based on clinical or medical expertise. Unstructured investment (such as the employment of additional consultants without the additional provision of equipment) leads to a deterioration in waiting times, and management decisions were noted to be reactive rather than proactive. Staff morale was considered to be an indicator of perceived support by Trust management. High levels of staff absence and

turnover as well as intra-organisational discord indicate a low morale. The development of team cliques and considerable diversity in levels of commitment were also noted. Slow and traditional change was considered preferable and rather than 'window-dressing' to appear to comply with targets, honesty about performance will be of more benefit. Welsh units lagging behind innovations in English units appeared to be cause for frustration.

(JGW)
This was a difficult group to summarise as a lot of the discussion was not very articulate. It would appear that all the group were doctors and there was more diversity of view than in other groups. Much of the discussion was negative, highlighting difficulties and problems rather than summarising modernisation. Management again was felt to be a barrier to change – not in tune with needs, reactionary and distrusted. If supportive, then change was effected but this was often in the context of crisis management. It was felt that endoscopy was disadvantaged by being a low priority, both in terms of gastroenterology and specifically endoscopy. The specialty suffers from not having a National Service Framework. Under-staffing is an issue, both in terms of nurses and consultants, and expansion has been helpful. The main changes have been the Global Rating Scale, better team work and more nurse specialists. Training was highlighted as important but inadequate for nurses. The Agenda for Change has been very negative.

Wales is clearly seen as lagging behind across a range of issues including training, modernisation, Global Rating Scale, and suffers by being a small country. There was a feeling that Wales is catching up and is perhaps less unencumbered by other aspects of change.

(ITR)
The transcript suggests that this was a disappointed group who saw recent changes in gastroenterology as predominantly for the worse. To test this negative impression, I undertook a crude form of content analysis. Between them the six members identified ***two*** facilitators of change – senior Trust management (FG4.4) and the innovations in 2004 (FG4.1). In contrast they made ***16*** comments identifying barriers to change – management of endoscopy service (FG4.4, FG4.3, FG4.5), training in endoscopy (FG4.6), size of Wales (FG4.6), 'gastroenterology spans medicine and surgery' (FG4.4), lack of NSF in gastroenterology (FG4.3), staffing deficits (FG4.4), generic management system (FG4.2), 'all Trusts trying to do everything' (FG4.2), '2004 innovations petered out' (FG4.1), clinical workload (FG4.5), secretarial support (FG4.5), 'gastroenterology is politically invisible' (FG4.6) and epidemiological trends e.g. in alcoholic liver disease (FG4.6).

The six members made a total of 15 comments identifying real changes since 2002 –introduction of the Global Rating Scale [GRS] (FG4.3, FG4.6), increasing nurse endoscopy (FG4.4, FG4.6), endoscopy users group (FG4.1), dyspepsia guidelines & workshops (FG4.1), teamwork leading to the introduction of special clinics (FG4.3), substitution of clinical nurse specialists for Specialist Registrars (FG4.3), merger of NHS Trusts (FG4.4), pooled lists (FG4.4), centralised booking (FG4.4), more consultants (FG4.6), second endoscopy room (FG4.6), reduced waiting times (FG4.6) and flexible training (FG4.6). Sadly two members hardly contributed to this topic, offering wishful thoughts about appointing clinical nurse specialists (FG4.5) or creating a nutrition team (FG4.5), or else waffle about 'the sort of work coming in' (FG4.2) and 'the sort of things we can do' (FG4.2).

The group identified ***only one*** change not needing extra resources – pooled lists – and ***three*** needing such resources, all relating to new posts (FG4.5, FG4.1, FG4.2). Similarly the group identified ***only one*** positive staff response to change,

namely dedication during staff shortage (FG4.3). In contrast they identified ***four*** negative staff responses – unhappiness caused by Agenda for Change (FG4.4), loss of support caused by unhelpful environment (FG4.2), unreliability of junior staff (FG4.2) and low morale due to stress (FG4.1). The fact that members who identified many changes were slow to elaborate on them in response to these two follow-up questions also suggests low morale.

The group identified ***three*** advantages that gastroenterology in Wales enjoys over England – no payment by results (FG4.4) or private sector commissioning (FG4.4), thus maintaining a traditional integrated health service (FG4.6). However they also identified ***six*** disadvantages – fewer resources (FG4.5, FG4.3), Wales 'slower off the mark' especially with training (M), fewer innovations (FG4.1), weaker management of cancer (FG4.1), later implementation of GRS and thus later improvement in standards (FG4.3), geography difficult for local services (FG4.6) and difficulty in maintaining strong research (FG4.6).

In conclusion I judge that this content analysis confirms the impression of a disappointed, even depressed, group who saw recent changes in gastroenterology as predominantly for the worse.

Appendix 17 - Focus group schedule

Scripted introduction …

i. What do you see as facilitators and barriers to change in endoscopy services?

ii. What changes have you made in your unit since 2002?

iii. Was funding necessary?

iv. How have staff responded to change / lack of change?

v. How well do you think changes have worked?

In addition Welsh Focus Groups explored:

- Responses to the MA's support for English Endoscopy units
- The impact that changes to English units made on Welsh units

Appendix 18 – GP Questionnaire

GP Questionnaire

When referring patients to the endoscopy unit at xxx Hospital, have you noticed any of the following changes in the last 4 years?

Please answer each question by putting a cross in the corresponding box.

HAS CHANGE OCCURRED IN THE FOLLOWING AREAS (QUESTIONS 1-5 BELOW AND 6-9 OVERLEAF):

	NO	DON'T KNOW	YES
1. The way referrals are made to the endoscopy unit	☐	☐	☐

If YES, has the change led to a better or worse service compared to 4 years ago?

Better ☐ Neither better nor worse ☐ Worse ☐

2. a. Your understanding of the way referrals are prioritised when received by the hospital ☐ ☐ ☐

If YES, has the change led to a better or worse service compared to 4 years ago?

Better ☐ Neither better nor worse ☐ Worse ☐

b. Outcome of the prioritisation process for your individual patient ☐ ☐ ☐

If YES, has the change led to a better or worse service compared to 4 years ago?

Better ☐ Neither better nor worse ☐ Worse ☐

3. Speed of referral in terms of access to services ☐ ☐ ☐

If YES, has the change led to a better or worse service compared to 4 years ago?

Better ☐ Neither better nor worse ☐ Worse ☐

4. Information back from secondary care following your referral request ☐ ☐ ☐

If YES, has the change led to a better or worse service compared to 4 years ago?

Better ☐ Neither better nor worse ☐ Worse ☐

5. The % of patients requesting further GP appointments whilst waiting for their endoscopy ☐ ☐ ☐

If YES, has the change led to a better or worse service compared to 4 years ago?

Better ☐ Neither better nor worse ☐ Worse ☐

(Cont…)

(Cont…)

For office use only ☐

HAS CHANGE OCCURRED IN THE FOLLOWING AREAS (QUESTIONS 6-9):	NO	DON'T KNOW	YES
6. Communication from secondary care about the outcome of the endoscopy	☐	☐	☐

If YES, has the change led to a better or worse service compared to 4 years ago?

Better ☐ Neither better nor worse ☐ Worse ☐

7. Communication from secondary care about the final diagnosis	☐	☐	☐

If YES, has the change led to a better or worse service compared to 4 years ago?

Better ☐ Neither better nor worse ☐ Worse ☐

8. Communication from secondary care about any complications	☐	☐	☐

If YES, has the change led to a better or worse service compared to 4 years ago?

Better ☐ Neither better nor worse ☐ Worse ☐

9. Communication from secondary care about any treatment initiated	☐	☐	☐

If YES, has the change led to a better or worse service compared to 4 years ago?

Better ☐ Neither better nor worse ☐ Worse ☐

IN SUMMARY:

10. Do you think the service is better or worse than 4 years ago?

Better ☐ Neither better nor worse ☐ Worse ☐

11. Overall, are your patients getting a good deal from the service?

Better ☐ Neither better nor worse ☐ Worse ☐

Thank you for completing the questions. If you would like to elaborate on how the current service is better or worse compared to four years ago please use the space below.

If you would like a summary of the overall results, please place a cross in this box ☐

If you have any queries please contact Anne Seagrove (01792 513411) or Kym Thorne (01792 602062), Research Assistants.

Please return in the FREEPOST envelope provided to: ENIGMA, School of Medicine, University of Wales Swansea, FREEPOST SWC4951, Swansea, SA2 8ZZ.

