

UNIVERSITY OF SOUTHAMPTON

**FACULTY OF MEDICINE, HEALTH, & BIOLOGICAL SCIENCES
GRADUATE SCHOOL**

School of Medicine

**Randomised controlled trial to evaluate a direct referral service for
investigation of patients with low risk symptom clusters suggestive of
colorectal cancer, as against usual care.**

by

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ABSTRACT

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RANDOMISED CONTROLLED TRIAL TO EVALUATE A DIRECT
REFERRAL SERVICE FOR INVESTIGATION OF PATIENTS WITH LOW
RISK SYMPTOM CLUSTERS SUGGESTIVE OF COLORECTAL CANCER,
AS AGAINST USUAL CARE.

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The body of this work was conducted between October 2001 and March 2003;
analysis and write up was completed by November 2004.

A randomised controlled trial was executed to compare three recognised outpatient investigation strategies for patients with gastrointestinal symptoms considered "low risk" for colorectal cancer. Over a one year period consenting patients referred to Lymington Hospital were randomised to one of three study arms: 'Colonoscopy', 'Flexible Sigmoidoscopy & Barium Enema', and 'Usual Care'.

A novel endpoint was defined as the day on which the patient was informed of diagnosis, discharged with reassurance, or the need to further investigate. Measurements were taken in terms of time, number and nature of all appointments and visits; and patient satisfaction assessed by a purpose developed patient satisfaction questionnaire validated during the execution of the study.

111 patients were recruited of which 95 (85.6%) reached end point; 91 of these patients (95.8%) returned a completed questionnaire. There was no significant difference between the three study arms in terms of days to endpoint, nor in expressed patient satisfaction. The number of attendances required to reach endpoint was statistically fewer for the 'Colonoscopy' arm; the cost of investigation to the NHS was also lower for the this group. Patients in the 'Colonoscopy' arm did, however, have to wait longer for a first hospital appointment; a colonoscopy appointment was also the most likely to be cancelled. Survival analysis demonstrated a weighting towards the 'Usual Care' arm at the upper limit of patient experience (in terms of time to endpoint). Patients experiencing an unusually long wait were responsible for cancelling one or more appointments.

The study supports the use of colonoscopy as a method of direct investigation: it is cheaper, requires less hospital visits, and attains a high level of satisfaction despite its shortcomings. However, the criteria for which patients are suitable require refinement and colonoscopy facilities must be expanded considerably for the strategy to be a viable option of care.

CONTENTS

Title	I
Abstract	ii
Contents	iii
List of Tables, Figures, & Diagrams	x
Declaration	xiii
Acknowledgements	xlv
1 INTRODUCTION	1
1.1 CANCER IN GENERAL	4
1.1.1 Cancer – the size of the problem	4
1.1.2 Incidence and mortality	4
1.1.3 How has the problem changed?	6
1.1.4 The cost of cancer	8
1.2 COLORECTAL CANCER	9
1.2.1 The disease in England & Wales	9
1.2.2 Incidence and mortality	9
1.2.3 Epidemiology	10
1.2.4 Aetiology	11
1.2.4.1 Diet.....	11
1.2.4.2 Increased risk populations and Genetics.....	12
1.2.4.3 Polyps.....	15
1.2.5 Modes of Presentation	15
1.2.5.1 Rectal Bleeding.....	17
1.2.5.2 Change of Bowel Habit.....	18
1.2.5.3 Palpable Mass.....	18
1.2.5.4 Pain.....	19
1.2.5.5 Nausea, Vomiting & Weight loss.....	19
1.2.5.6 Acute Presentation.....	20
1.2.5.7 Anaemia.....	21
1.2.5.8 Metastatic Disease.....	22
1.2.6 Methods of Investigation	22
1.2.6.1 Faecal Occult Blood Testing.....	22
1.2.6.2 Rigid Sigmoidoscopy/Proctoscopy.....	23
1.2.6.3 Colonoscopy.....	23
1.2.6.4 Flexible Sigmoidoscopy.....	25
1.2.6.5 Double Contrast Enema Examination.....	25
1.2.6.6 Plain Radiographs.....	28
1.2.6.7 Ultrasound.....	28
1.2.6.8 Computerised Tomography.....	29
1.2.6.9 Magnetic Resonance Imaging.....	29
1.2.6.10 Radionucleotide Scan.....	29

1.3	COLORECTAL CANCER IN COMPARISON TO OTHER MAJOR CAUSES OF CANCER DEATHS.....	30
1.4	RECENT CHANGES, AND INFLUENCES ON THE WAY IN WHICH COLORECTAL CANCER IS PERCEIVED AND MANAGED.....	33
1.4.1	The General Public and Colorectal Cancer.....	33
1.4.2	The Calman-Hine Report.....	34
1.4.2.1	A new structure for cancer services.....	35
1.4.3	The EUROCARE Study.....	38
1.4.4	Royal College of Surgeons Guidelines.....	41
1.4.5	Improving Outcomes in Colorectal Cancer.....	42
1.4.6	The NHS Cancer Plan.....	42
1.4.7	Manual of Cancer Services Standards.....	44
1.5	DIAGNOSTIC DILEMMAS IN COLORECTAL CANCER.....	47
1.5.1	An absence of classical symptoms.....	47
1.5.2	The incidence of gastrointestinal symptoms in an apparently healthy population.....	48
1.5.3	The effect of patient age.....	49
1.5.4	The demand on diagnostic facilities.....	50
1.5.5	Diagnostic delays.....	52
1.5.5.1	The Causes of Diagnostic Delay.....	52
1.5.5.2	The Effects of Diagnostic Delay.....	54
1.5.6	Summary of Dilemmas.....	55
1.6	CURRENT INITIATIVES TO IMPROVE COLORECTAL CANCER CARE STANDARDS AND OUTCOMES.....	57
1.6.1	The “fast-track” / 2-week-wait clinic and referral guidelines.....	57
1.6.2	Nurse Specialist Endoscopists.....	59
1.6.3	Cancer Services Collaborative projects.....	60
1.6.4	Screening for Colorectal Cancer.....	61
2	STUDY DESIGN.....	66
2.1	RATIONALE BEHIND STUDY SELECTION.....	66
2.1.1	Demand on services.....	66
2.1.2	Current practices.....	67
2.1.2.1	Usual care (outpatient appointment first).....	67
2.1.2.2	Direct investigation.....	68
2.1.2.3	What is best?.....	68
2.2	STUDY DESIGN.....	70
2.2.1	The process and evolution of this study’s design.....	70
2.2.2	Prospective.....	70
2.2.3	Randomisation and concealed allocation.....	71
2.2.4	Patient Suitability.....	71
2.2.4.1	Inclusion Criteria.....	71
2.2.4.2	Exclusion Criteria.....	72
2.2.5	A three-armed study.....	74
2.2.5.1	Usual care.....	75
2.2.5.2	Direct Investigation.....	75

2.2.5.3	Relative costs.....	75
2.2.6	Setting an endpoint.....	76
2.2.7	Measurements.....	77
2.2.8	The Concept of patient satisfaction.....	77
2.2.8.1	What is patient satisfaction?.....	78
2.2.8.2	Why is patient satisfaction important?.....	78
2.2.8.3	How is a patient's satisfaction determined?.....	80
2.2.8.4	How is patient satisfaction measured?.....	82
2.2.9	Sample size.....	83
2.2.10	Study site.....	84
2.3	ETHICAL APPROVAL AND DISSEMINATION OF INFORMATION....	85
2.3.1	Referring General Practitioners.....	85
2.3.2	Endoscopy Staff.....	86
2.3.3	Radiology Staff.....	86
3	THE HYPOTHESIS.....	87
3.1	STUDY AIMS.....	87
3.2	NULL HYPOTHESIS.....	88
4	PATIENTS AND METHODS.....	89
4.1	INTRODUCTION.....	89
4.2	PHASE 1 - PATIENT RECRUITMENT AND RANDOMISATION.....	91
4.2.1	Recruitment Window.....	91
4.2.2	Patient Identification.....	92
4.2.3	Patient Eligibility.....	92
4.2.4	Patient Information.....	93
4.2.5	General Practitioner Information.....	93
4.2.6	Telephone Contact with Patient.....	94
4.2.7	Inability to Contact the Patient.....	95
4.2.8	Patient Meeting.....	96
4.2.9	Consent.....	96
4.2.10	Randomisation.....	97
4.3	PHASE 2 – PATIENT PROGRESSION ALONG THE PATIENT PATHWAY.....	98
4.3.1	Requesting appointments/investigations.....	98
4.3.2	Intention.....	99
4.3.3	Tracking patient progress.....	99
4.3.4	Outcomes and Informing the patient.....	100
4.3.5	Reaching the study endpoint.....	101
		102
4.4	PHASE 3 – MEASURING PATIENT SATISFACTION.....	102
4.4.1	Patient Satisfaction Questionnaire.....	102
4.4.2	First Mailing.....	102
4.4.3	Second Mailing.....	103

4.4.4	Re-test	103
4.5	DATA ENTRY	105
5	QUESTIONNAIRE DEVELOPMENT	106
5.1	WHY A PATIENT SATISFACTION QUESTIONNAIRE?	106
5.1.1	The difficulties of measuring patient satisfaction	106
5.1.1.1	Methods of gathering information on satisfaction.....	107
5.1.1.2	The multi-dimensionality of satisfaction.....	109
5.1.1.3	Detecting dissatisfaction.....	110
5.1.1.4	The patient as a judge.....	111
5.1.1.5	The importance of a representative sample.....	112
5.1.1.6	Methods of administration.....	113
5.1.1.7	An instrument to meet the needs of this study.....	114
5.2	QUESTIONNAIRE DESIGN	115
5.2.1	Item Generation	116
5.2.1.1	Semi-structured small-group interviews.....	117
5.2.1.2	Analysis of small-group interviews.....	118
5.2.1.3	Choosing a mode of response.....	120
5.2.1.4	Composing the items.....	121
5.2.2	Questionnaire Design	122
5.2.3	Pre-testing	124
5.2.4	Pilot testing	124
5.3	PILOT QUESTIONNAIRE EVALUATION	126
5.3.1	Questionnaire response rate	126
5.3.2	Patient feedback and omitted questions	127
5.3.2.1	Omitted questions.....	127
5.3.2.2	Highlighted questions.....	128
5.3.2.3	Time taken to complete the Questionnaire.....	129
5.3.2.4	Free text feedback.....	129
5.3.3	Variation in response	131
5.3.4	Internal Consistency	132
5.3.4.1	Alpha value of the full questionnaire.....	133
5.3.4.2	Individual item's effect on internal consistency.....	134
5.3.5	Questionnaire Sub-Scales	134
5.3.5.1	Factor analysis.....	134
5.3.5.2	Re-evaluation of sub-scales.....	135
5.3.6	Test-Retest Reliability	136
5.3.6.1	Choosing the re-test interval.....	137
5.3.6.2	Kappa Coefficient.....	137
5.3.7	Conclusions of Pilot Questionnaire Analysis	138
5.4	FULL STUDY QUESTIONNAIRE EVALUATION	140
5.4.1	Response rate	140
5.4.2	Omitted questions	140
5.4.3	Highlighted questions	140

5.4.4	Variation in response	140
5.4.5	Internal consistency	141
5.4.5.1	Internal consistency of full scale.....	141
5.4.5.2	Internal consistency of sub-scales.....	141
5.5	SUMMARY OF QUESTIONNAIRE ASSESSMENT	143
6	RESULTS	144
6.1	PATIENT RECRUITMENT	144
6.1.1	Patients affected by recruitment hiatus	144
6.1.2	Eligible patients	145
6.1.3	Demographic features of recruited patients	145
6.1.4	Demographic features of non-participants	146
6.1.5	Randomisation into study groups	146
6.2	PROGRESSION THROUGH STUDY	147
6.2.1	Study completion rate	147
6.2.2	Patient pathways	147
6.2.2.1	“Colonoscopy” group.....	150
6.2.2.2	“Barium Enema and Flexible Sigmoidoscopy” group.....	151
6.2.2.3	“Usual Care” group.....	151
6.2.3	Withdrawal from study	152
6.2.3.1	Withdrawals from the “Colonoscopy” group.....	153
6.2.3.2	Withdrawals from the “Flexible Sigmoidoscopy & Barium Enema” group.....	153
6.2.3.3	Withdrawals from the “Usual Care” group.....	154
6.2.3.4	Withdrawal from study before investigation commenced.....	154
6.2.3.5	Withdrawal from study once investigations had commenced.....	157
6.2.3.6	Withdrawal from study once investigations had been completed but before study endpoint was reached.....	159
6.3	PRIMARY STUDY MEASUREMENTS	161
6.3.1	Time taken for patient to reach study endpoint	161
6.3.1.1	Time taken for all patients to reach study endpoint.....	161
6.3.1.2	Time taken for study groups to reach study endpoint.....	162
6.3.2	Measurement of expressed patient satisfaction	167
6.3.2.1	Overall satisfaction (total score).....	168
6.3.2.2	Understanding of Events (subscale 1 score).....	171
6.3.2.3	Anxiety (subscale 2 score).....	174
6.3.2.4	Professionalism (subscale 3 score).....	177
6.3.2.5	Confidence / Trust in Staff (subscale 4 score).....	180
6.3.2.6	Substance of Consultation (subscale 5 score).....	183
6.3.2.7	Mechanics (subscale 6 score).....	186
6.3.2.8	Results (subscale 7 score).....	189
6.3.2.9	Disclosure (subscale 8 score).....	191
6.3.2.10	Preparation (subscale 9 score).....	195
6.3.2.11	Involvement/Control (subscale 10 score).....	198
6.3.2.12	Taken Seriously (subscale 11 score).....	201

6.4	SECONDARY STUDY MEASUREMENTS	203
6.4.1	Number of hospital attendances	203
6.4.2	Assessment of costs to the NHS	206
6.5	TERTIARY STUDY MEASUREMENTS	210
6.5.1	Time to first hospital appointment	210
6.5.2	Booked appointments & patient hospital attendances	213
6.6	RETROSPECTIVE POWER CALCULATION	216
6.6.1	Power to identify a significant difference in - “Time taken for patient to reach study endpoint”	216
6.6.2	Power to identify significant differences in expressed patient satisfaction	218
6.6.3	Power to identify a statistically significant difference in number of hospital attendances between study groups	219
6.6.4	Power to identify a statistically significant difference in cost to the NHS between study groups	219
6.6.5	Power to identify a statistically significant difference in time to first hospital attendance between study groups	220
6.6.6	Power to identify a statistically significant difference in the number of cancelled hospital attendances per patient by study group	220
6.7	PATIENTS’ FREE TEXT QUESTIONNAIRE RESPONSES	221
6.8	CLINICAL OUTCOMES AND DIAGNOSES	226
7	DISCUSSION	228
7.1	KEY STUDY FINDINGS - A RETURN TO THE NULL HYPOTHESIS	228
7.1.1	Time	228
7.1.2	Costs	228
7.1.2.1	Cost incurred by the NHS	228
7.1.2.2	Number of hospital visits made by the patient	229
7.1.3	Outcomes	229
7.1.3.1	Patient satisfaction	229
7.1.3.2	The nature of study endpoint	229
7.2	PROBLEMS ENCOUNTERED	230
7.2.1	Execution of the study	230
7.2.1.1	Labour intensive	230
7.2.1.2	Long recruitment process	231
7.2.1.3	Patient information	231
7.2.1.4	Clerical error	232
7.2.2	Recruitment & sample size	232
7.2.2.1	Retrospective power calculations	233
7.2.2.2	Recruitment shortfall	234
7.2.2.2.1	Over-estimation of potential recruits	235
7.2.2.2.2	Failure to identify potential recruits	236
7.2.2.2.3	Inclusion / exclusion criteria	236
7.2.2.2.4	Failure to recruit eligible patients	237

7.3	INTERPRETATION OF FINDINGS	243
7.3.1	Continued relevance of study	243
7.3.2	Population sample	244
7.3.3	Randomisation	245
7.3.4	Patient withdrawal from study	246
7.3.4.1	Implications of patient withdrawal	247
7.3.4.1.1	<i>Expenditure and waste</i>	247
7.3.4.1.2	<i>Failure to fully investigate</i>	247
7.3.4.1.3	<i>Did the wait for investigation have an effect on withdrawal?</i>	248
7.3.5	Primary study outcomes	249
7.3.5.1	Time taken to reach study end point	250
7.3.5.2	Measurement of expressed patient satisfaction	251
7.3.5.3	Free text patient Feedback	253
7.3.6	Secondary study outcomes	253
7.3.6.1	Number of hospital attendances as an indication of patient costs	254
7.3.6.2	Cost to the NHS	255
7.3.7	Tertiary study outcomes	257
7.3.7.1	Time to first hospital appointment	257
7.3.7.2	Appointment cancellations	268
7.3.8	Diagnostic outcomes	260
7.4	CONCLUSIONS	263
7.4.1	Which patients are suitable for direct investigation?	263
7.4.2	The strain on endoscopic services	264
7.4.2.1	Time to first appointment	264
7.4.2.2	Fewer visits fails to deliver benefit	264
7.4.2.3	Colonoscopy appointments most likely to be cancelled	264
7.4.3	The assessment of patient satisfaction	265
7.4.3.1	Measurement of satisfaction	265
7.4.3.2	Free text feedback	265
7.4.3.2.1	<i>General satisfaction</i>	265
7.4.3.2.2	<i>Empathy with staff</i>	266
7.4.3.2.3	<i>Treatment / advice about ongoing symptoms</i>	266
7.4.4	Cancelled appointments	266
7.5	IMPLICATIONS FOR CLINICAL PRACTICE	268
7.5.1	Direct investigation by colonoscopy in comparison to usual care	268
7.5.2	Direct investigation by barium enema and flexible sigmoidoscopy in comparison to usual care	268
7.5.3	Implications and recommendations	269
7.6	IMPLICATIONS FOR FUTURE RESEARCH	271
7.6.1	Criteria for direct investigation	271
7.6.2	Patient satisfaction	271
7.6.3	Computer modelling of services	272
	APPENDICES	273
	REFERENCES	304

LIST OF TABLES, FIGURES, & DIAGRAMS

Section 1 INTRODUCTION

Figure 1.1.2a	Age specific incidence of cancer.....	5
Figure 1.1.2.b	Incidence of all cancers: frequency distribution by age.....	5
Figure 1.1.3	Age standardised mortality by cause of death.....	7
Figure 1.2.3	Age specific incidence of colorectal cancer.	11
Table 1.2.5	Department of Health criteria for high and low risk of bowel cancer	16
Table 1.3	Summary and comparison of the 4 major forms of cancer.....	30
Diagram 1.4.2.1	Cancer Network Structure.....	36
Table 1.4.7	Performance Indicators for colorectal cancer as set out by the Manual of Cancer Services Standards 2000.....	45
Table 1.5.1	Incidence of colorectal cancer by grouping of gastrointestinal symptoms.....	48
Table 1.6.1	2-week standard implementation timetables.....	57
Figure 1.6.1	Colorectal cancer: guidelines for urgent referral.....	58
Table 1.6.3	Aims of the Cancer Services Collaborative.....	60
Figure 1.6.4	American Gastroenterological Association guidelines on screening for colorectal cancer.....	62

Section 2 STUDY DESIGN

Table 2.1.2	Advantages and disadvantages of different patient management strategies.....	68
Figure 2.2.5	The three study arms.....	74
Figure 2.2.7	Primary & secondary study measurements.....	77
Table 2.2.8.2	Reasons for measuring patient satisfaction.....	79
Table 2.2.8.3	Examples of patient satisfaction factors.....	81

Section 4 PATIENTS AND METHODS

Figure 4.1	Trial protocol.....	90
Figure 4.2	Phase 1 - Patient recruitment & randomisation.....	91
Figure 4.2.3	Study inclusion / exclusion criteria.....	92
Figure 4.2.10	The three study arms.....	97
Figure 4.3	Phase 2 – Patient Progression Along the Patient Pathway.....	98
Figure 4.4	Phase 3 – Patient Satisfaction Questionnaire.....	102

Section 5 QUESTIONNAIRE DEVELOPMENT

Table 5.1.1.2	Dimensions of patient satisfaction.....	109
Figure 5.2	Key questionnaire features	116
Figure 5.2.1.2	An explanation of units of general meaning.....	119
Figure 5.2.1.3	A Likert Type question.....	121
Figure 5.3.1	Days taken for the pilot group to return questionnaire.....	126
Table 5.3.2.1	Questions omitted by 2 respondents.....	127
Table 5.3.2.2	Questions identified by three patients as problematic.....	128
Figure 5.3.2.3	Time taken for respondents to complete questionnaire.....	129

Figure 5.3.3	Questions receiving responses on only 2 scale points.....	131
Table 5.3.5.2	Subscales & alpha values as identified following the 50-questionnaire pilot.....	136
Figure 5.3.6.2	Guidance on degree of agreement.....	138
Table 5.4.5.2	Sub-scale alpha values.....	142

Section 6 RESULTS

Table 6.1.2	Reasons given by non-participants for not taking part in trial....	145
Table 6.1.5	Demographic details of study groups.....	146
Table 6.2.1	Rate of study completion.....	147
Diagram 6.2.2a	Patient pathway for those randomised to “Usual Care” group...	148
Diagram 6.2.2b	Patient pathway for those randomised to “Barium Enema & Flexible Sigmoidoscopy” group.....	149
Diagram 6.2.2c	Patient pathway for those randomised to “Colonoscopy” group	150
Figure 6.3.1.1	Time taken to reach study endpoint (all groups).....	161
Figure 6.3.1.2a	Time taken to reach study endpoint (by study group).....	162
Table 6.3.1.2	Descriptive statistics of “days to study endpoint” for all patient groups.....	163
Figure 6.3.1.2b	Box plot of time taken to reach study endpoint (by study group).....	163
Figure 6.3.1.2c	Kaplan-Meier Survival plot of time taken for study participants to reach endpoint.....	164
Figure 6.3.1.2d	Kaplan-Meier survival plot of time taken for study participants to reach endpoint demonstrating extreme values.....	165
Figure 6.3.2.1a	Expressed satisfaction of all study participants.....	168
Figure 6.3.2.1b	Expressed satisfaction of study participants by study group....	168
Figure 6.3.2.1c	Box plot of expressed satisfaction (total scale score) by group.	169
Figure 6.3.2.2a	“Understanding of Events” – Subscale 1 score of all study participants.....	170
Figure 6.3.2.2b	“Understanding of Events” - Subscale 1 score by study group..	170
Figure 6.3.2.2c	Box plot of “Understanding of Events” (Subscale 1 score) by group.....	171
Figure 6.3.2.3a	“Anxiety” - Subscale 2 score of all study participants.....	174
Figure 6.3.2.3b	“Anxiety” - Subscale 2 score by study group.....	174
Figure 6.3.2.3c	Box plot of “Anxiety” (Subscale 2 score) by group.....	175
Figure 6.3.2.4a	“Professionalism” - Subscale 3 score of all Study Participants..	177
Figure 6.3.2.4b	“Professionalism” - Subscale 3 score by study group.....	177
Figure 6.3.2.4c	Box plot of “Professionalism” (Subscale 3 score) by group.....	178
Figure 6.3.2.5a	“Confidence / Trust in Staff” - Subscale 4 score of all study participants.....	180
Figure 6.3.2.5b	“Confidence / Trust in Staff” - Subscale 4 score by study group	180
Figure 6.3.2.5c	Box plot of “Confidence / Trust in Staff” (Subscale 4 score) by group.....	181
Figure 6.3.2.6a	“Substance of Consultation” - Subscale 5 score of all study participants.....	183
Figure 6.3.2.6b	“Substance of Consultation” - Subscale 5 score by study group.....	183
Figure 6.3.2.6c	Box plot of “Substance of Consultation” (Subscale 5 score) by group.....	184
Figure 6.3.2.7a	“Mechanics” – Subscale 6 score of all study participants.....	186
Figure 6.3.2.7b	“Mechanics” – Subscale 6 score by study group.....	186
Figure 6.3.2.7c	Box plot of “Mechanics” (Subscale 6 score) by group.....	187

Figure 6.3.2.8a	“Results” - Subscale 7 score of all study participants.....	189
Figure 6.3.2.8b	“Results” - Subscale 7 score by study group.....	189
Figure 6.3.2.8c	Box plot of “Results” (Subscale 7 score) by group.....	190
Figure 6.3.2.9a	“Disclosure” - Subscale 8 score of all study participants.....	192
Figure 6.3.2.9b	“Disclosure” - Subscale 8 score by study group.....	192
Figure 6.3.2.9c	Box plot of “Disclosure” (Subscale 8 score) by group.....	193
Figure 6.3.2.10a	“Preparation” – Subscale 9 score of all study participants.....	195
Figure 6.3.2.10b	“Preparation” – Subscale 9 score by study group.....	195
Figure 6.3.2.10c	Box plot of “Preparation” (Subscale 9 score) by group.....	196
Figure 6.3.2.11a	“Involvement / Control” - Subscale 10 score of all study participants.....	198
Figure 6.3.2.11b	“Involvement / Control” - Subscale 10 score by study group.....	198
Figure 6.3.2.11c	Box plot of “Involvement / Control” (Subscale 10 score) by group.....	199
Figure 6.3.2.12a	“Taken Seriously” - Subscale 11 score of all study participants.....	201
Figure 6.3.2.12b	“Taken Seriously” - Subscale 11 score by study group.....	201
Figure 6.3.2.12c	Box plot of “Taken Seriously” (Subscale 11 score) by group....	202
Figure 6.4.1a	Histogram showing number of visits made to hospital by all study participants.....	203
Figure 6.4.1b	Box plot of patient visits to hospital by study group.....	204
Figure 6.4.1c	Bar chart of patient visits to hospital by study group.....	204
Table 6.4.2	Abridged table of NHS 2001 reference costs.....	206
Figure 6.4.2a	Cost of investigation for all study participants.....	207
Figure 6.4.2b	Cost of investigation by study group.....	208
Figure 6.4.2c	Box plot of cost of investigation by study group.....	208
Figure 6.5.1a	Time (days) to first appointment for all study participants.....	210
Figure 6.5.1b	Time to first appointment by study group.....	211
Table 6.5.1	Descriptive statistics of “time to first appointment” for all patient groups.....	211
Figure 6.5.1c	Box plot of time to first appointment (days) by study group.....	212
Figure 6.5.1d	Kaplan-Meier Survival plot of time taken for study participants to attend their first appointment.....	213
Figure 6.5.2a	Number of cancelled hospital appointments per patient across all study recruits.....	214
Figure 6.5.2b	Number of cancelled hospital appointments by study group.....	214
Table 6.5.2	Cancelled appointments by type.....	215
Table 6.6.1	Summary of study’s power to identify a statistically significant difference in “time taken for patient to reach study end point” between the three study groups.....	217
Table 6.6.2	Summary of study’s power to identify a statistically significant differences in expressed patient satisfaction.....	218
Table 6.7	Questionnaire free text patient feedback by dimension and polarity.....	222
Table 6.8	Clinical outcomes for study recruits.....	226

Section 7 DISCUSSION

Table 7.3.8	Comparison of diagnostic yields from endoscopic examinations for patients in the “Direct Investigation” study group, and those undergoing investigation for iron deficiency anaemia.....	261

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1 - INTRODUCTION

Patients with colorectal cancer present in a variety of ways; with approximately 20% presenting as emergencies. Using guidelines prepared by a Department of Health steering group in association with the Royal College of Surgeons it is estimated that up to 30% of colorectal cancer patients can be detected after having been channelled into “fast track” clinics for people with symptoms considered to indicate a “high risk” of colorectal cancer. Of patients directed into these clinics, however, it has been shown that only one in ten actually have malignant disease. [Flashman et al 2004, Pountney et al 2004]

Around 50% of colorectal cancer cases will continue to come through normal diagnostic pathways, and will have symptom complexes indistinguishable from those exhibited by patients with a variety of other conditions affecting the colon and rectum (e.g. haemorrhoids, polyps, colitis), and who will be coming through the same diagnostic pathways. There are often considerable delays before outpatient appointments and subsequent investigations take place.

Whilst there is some debate about the precise relationship between treatment delay and survival, the most important indicator of prognosis is the ability to fully resect the malignancy at the time of initial operation. This becomes less likely the larger and more invasive a lesion becomes. Also, local progression of disease, and invasion of peri-colic structures, including blood vessels, increases the chances of distant spread.

Currently “fast track” patients (a group which was estimated would contain up to 30% of colorectal cancer cases, and has been shown to contain 26% in some centres) are provided with an appointment at a dedicated clinic within two weeks of receipt of a referral pro-forma from the patient's GP. Both the “fast track” criteria, and GPs appropriate application of them are the subject of ongoing interest. Even in this selected population the incidence of colorectal cancer varies from 1.7% to 14% between centres. [Flashman et al 2004, Pountney et al 2004, Lewis et al 2004]

It would clearly be impossible to offer this type of service to all patients. Rising referral rates, probably resulting from increased awareness of the significance of colorectal symptoms, make it difficult to estimate the proportion of patients in the routine colorectal outpatient group who will have colorectal cancer. It is accepted in the west that between 25 & 30 patients will require investigation in order to detect one with significant pathology. Even though the proportion is likely to be small, these patients do make up around 50% of all colorectal cancer cases. This suggests that streamlining the process by which patients with “low risk” symptoms reach a definitive investigation is necessary in order to reduce the delay before patients are treated or reassured as appropriate. It may also be possible to change the cut-off point that separates “fast-track” from “low-risk” patients in order to optimise the process.

This thesis compares and contrasts three established methods of assessing new colorectal outpatient referrals in the NHS setting. Comparisons were made in terms of time taken, costs, and patient satisfaction.

To this end a prospective randomised controlled trial was designed and conducted at a single self-contained unit. A patient questionnaire was also developed, piloted, and validated during the execution of the study in order to provide a measure of satisfaction.

The thesis contains an over view of cancer in general, a detailed discussion of colorectal cancer, and an account of the current practices and changing landscape of colorectal cancer care.

The rationale behind study selection, design, and methodology is discussed.

The field of satisfaction and its measurement is discussed, and a detailed account of questionnaire design and development included.

All results and statistical analyses are included along with graphical representations. The results, their relevance and implications are discussed before highlighting logical avenues of progression if the subject of the study is to be assessed further.

1.1 CANCER IN GENERAL

1.1.1 Cancer – the size of the problem

The impact of cancer in the United Kingdom is far reaching; with physical, emotional and financial repercussions. Approximately 1 in 3 individuals will be diagnosed with some form of malignancy (excluding non-melanoma skin lesions*) during their lifetime, though it will not necessarily be the cause of death. 2% of people alive today (1.5% of men & 2.3% of women) have been diagnosed as having cancer at some point in their life; this is likely to be an under estimate as the earliest cancer registration records available start in 1971. [Quinn et al 2001]

Not only is the incidence of cancer high, it is now recognised that cancer is the single most common cause of death for both men and women in England & Wales. For 27% of men and 23% of women cancer, in some form, is registered as the cause of death. [Quinn et al 2001]

1.1.2 Incidence and mortality

In England & Wales during 1997 there were 108,000 cancer registrations among males, and 112,900 cancer registrations among females. In 1999 there were 69,000 cancer deaths among men and 64,000 among women. For both sexes three sites account for approximately 50% of cancer incidence and mortality; in males these are lung, prostate, and colorectal cancer; in females breast, colorectal, and lung cancer. [Quinn & Babb 2000, Coleman et al 2000]

**Throughout this thesis the discussion of cancer/malignancy will exclude non-melanoma skin lesions*

The incidence of cancer is not evenly distributed between the sexes and age groups. Rates begin to increase during the 4th decade of life (30s) though the initial rate of increase is greater in women: in the 40-44yrs group the rate for women is double that for men. From then on the rate increases more sharply among men: by 60-64yrs the rates are roughly equal, by 65-68yrs the rate for men is approx 45% greater than that for women, and by 80-84yrs the rate is almost double that of women. The peak cancer incidence for both sexes is during the 8th decade of life (70-79) [Quinn et al 2001].

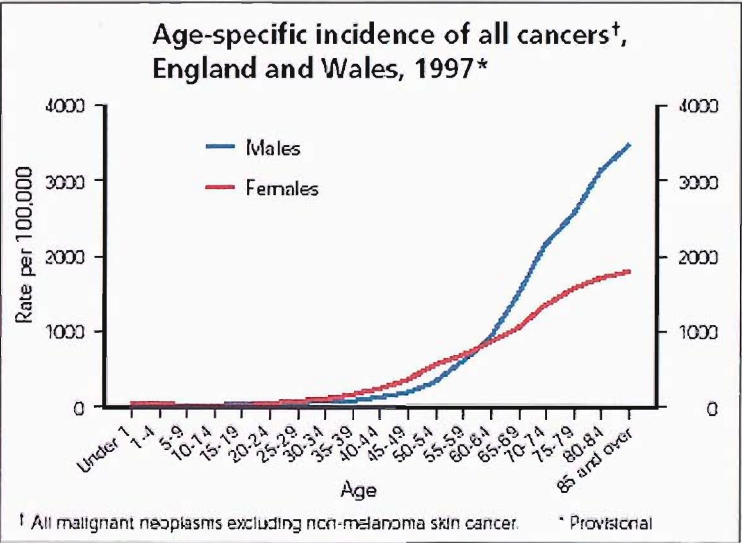


Figure 1.1.2a – Age specific incidence of cancer. (reproduced from Quinn et al 2001)

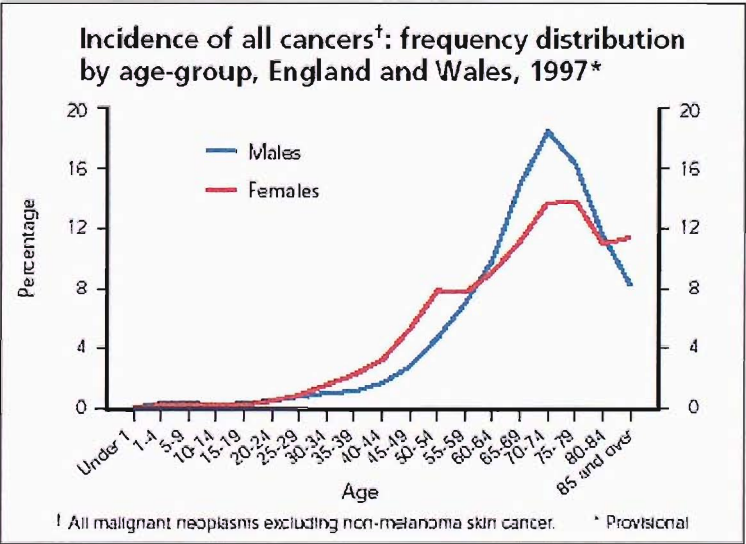


Figure 1.1.2.b – Incidence of all cancers: frequency distribution by age. (reproduced from Quinn et al 2001).

1.1.3 How has the problem changed?

Cancer has not always been the leading cause of death. Among women cancer became the leading cause of death in 1969, but this trend did not follow in men until as recently as 1995. Over the period 1950 to 1999 the proportion of deaths due to cancer has increased from 15 to 27% in males, and 16 to 23% in females [Quinn et al 2001].

Age standardised mortality for cancer as a whole has varied very little over the last 50 years; though there have been fluctuations. For men there was an increase in mortality throughout the 1950s and 1960s that levelled out during the 1970s and later decreased through the 1980s; among women there was also a rise in the rate to a plateau in the late 1980s followed by a slight decrease. These patterns closely follow the changing incidence of cigarette smoking in the 20th century.

Despite these variations the mortality rate for males has remained in the 250-280 per 100,000 range, and the rate for females in the 170-180 per 100,000 range. [Quinn & Babb 2000, Quinn et al 2001]

If there has been little change in the death rate from cancer over the last 50 years why then has it become the leading cause of death? The mantle has been earned by default as a result of a reduction in other causes of mortality such as heart disease, stroke, and infection. Age standardised mortality for all causes of death fell by 45% over the period 1950-1999 for both men and women, while the sub-group of cancer deaths remained static hence accounting for a greater percentage. [Quinn et al 2001].

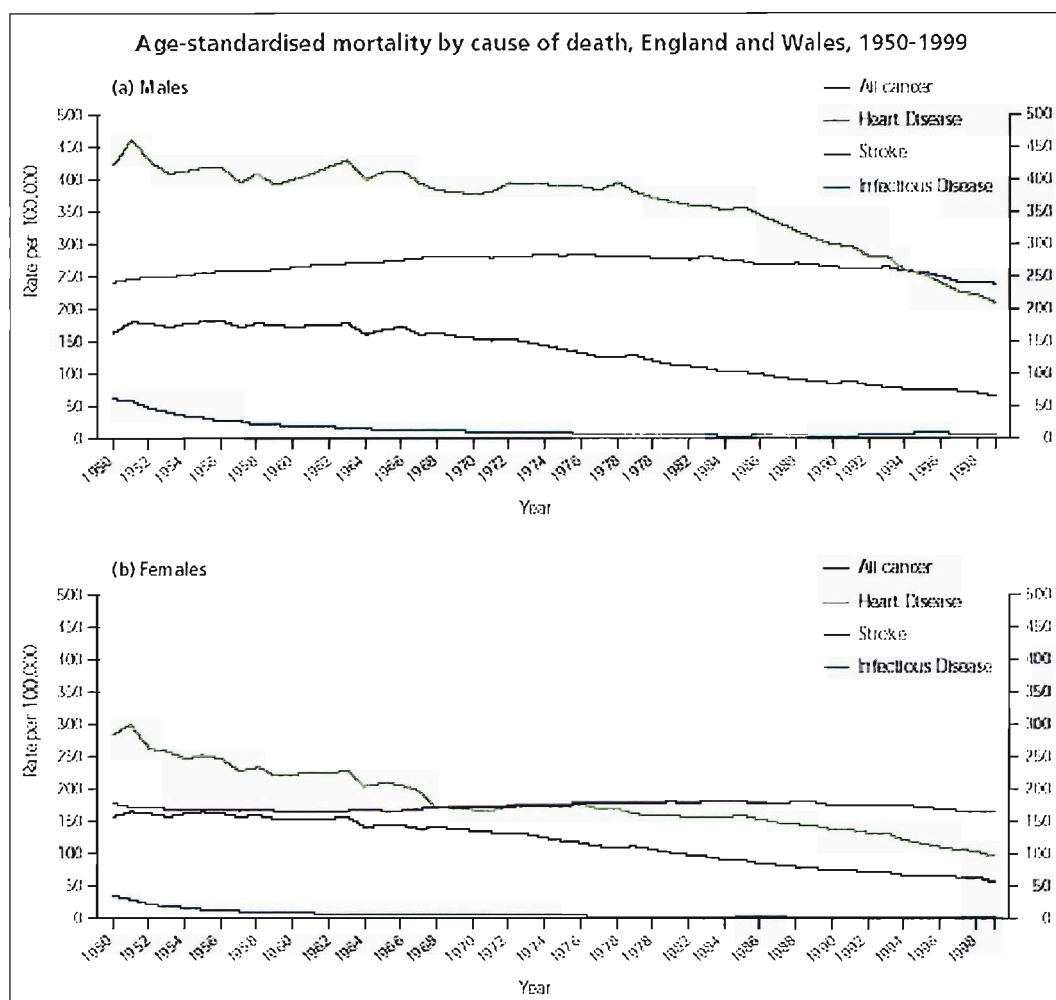


Figure 1.1.3 – Age standardised mortality by cause of death. (reproduced from Quinn et al 2001).

Newly diagnosed cases of cancer have increased by 45% in men and 55% in women over the period 1971 to the early 1990s; some of this increase particularly during the 1970s will have resulted from improved case detection as a result of the then new cancer registries. [Quinn & Babb 2000, Quinn et al 2001]. Among men the incidence in the under 65 group has changed little in contrast to an increase among older men; the rise being most marked in the over 85s. The incidence has also remained fairly constant among women under 55; where as women in the 65-74 and 75-84 age groups saw a rise of 45% [Quinn & Babb 2000].

Changes in age specific mortality are in contrast to the changes in incidence, though these trends are largely due to the shift in smoking habits among the population and thus deaths from lung cancer and other smoking related cancers (which equate to approximately 40% of cancer deaths).

Over the period 1950-1999 deaths in men under 55 from cancer fell by 40%.

The 55-64 group saw a rise to a plateau through the 1960s and 1970s followed by a fall, men in the 65-74 and 75-84 groups saw similar patterns with a plateau in the 1970s and 1980s respectively. Among elderly men mortality doubled up to 1994 but has since seen a decline.

For women aged 55-84 there was a drop in mortality during the 1950s but a rise through the 1960s 1970s and 1980s. Mortality began to fall again in the mid-1970s for those aged 45-54, mid-1980s for those aged 55-64, and the mid-1990s for those aged 65-74. Mortality among elderly women has increased though not to the degree seen in men [Quinn & Babb 2000].

1.1.4 The cost of cancer

The measurable financial cost of cancer (NHS hospital expenditure) is in excess of £1 billion [Calman-Hine 1995]. A commitment of this size has an effect on the national economy and as a result the entire population. The demands made on primary and palliative care services also have to be considered; as do financial costs of lost individual incomes for patients and carers.

A measure cannot be put on the emotional costs to individual patients, their families and carers.

1.2 COLORECTAL CANCER

1.2.1 The disease in England & Wales

As detailed in section 1.1 cancer is now the leading cause of death in England and Wales. Colorectal cancer is one of three cancer types that are responsible for 50% of cancer deaths in both men and women (the three differing between the two sexes) [Quinn et al 2001, Quinn & Babb 2000, Coleman et al 2000]. When examining the cause of death for the entire population (regardless of gender) colorectal cancer is second only to lung cancer among malignancies.

1.2.2 Incidence and Mortality

The incidence of colorectal cancer in England and Wales was 28,500 during 1997 ($\frac{2}{3}$ in the colon and $\frac{1}{3}$ in the rectum); there were 14,500 deaths due to the disease in 1999, and when the figures for Scotland and Northern Ireland are included this rises by several thousand.

The lifetime risk for developing colorectal cancer is 1:18 for men and 1:20 for women; average patient survival from diagnosis is three years [Quinn et al 2001, Guidance on Commissioning Cancer Services 1997]. Relative 1-year and 5-year survivals for those patients diagnosed with colorectal cancer during 1991-93 were 65% and 41% respectively (there is greater variation when analysed in terms of sub-site, age, sex, and tumour stage) [Coleman et al 2000].

1.2.3 Epidemiology

Colorectal cancer has been discussed thus far with reference to the United Kingdom but it is a global disease, posing both a public health and political problem. Colorectal cancer is seen throughout the world regardless of a country's development. There were 783, 000 new cases diagnosed in 1990 making it the 4th commonest form of cancer world wide, accounting for 9.4% of all cancers in men and 10.1% in women [Kerr et al 2001].

The incidence of colorectal cancer is not the same throughout the world, however: it is predominantly a disease of developed countries. The incidence in "high risk" developed western countries such as North America, Australia, New Zealand, North & Western Europe, is ten times higher than that of the "low risk" developing countries for colon cancer, and seven times higher for rectal cancer (an incidence of 3.4 cases per 100, 000 in Nigeria compared to an incidence of 35.8 cases per 100, 000 in certain areas of the United States Of America) [Shearman & Finlayson 1989, DeVita et al 2001].

This relationship is not static however with both "high risk" and "low risk" countries reporting changes in incidence for better and worse, [DeVita et al 2001].

The incidence of colorectal cancer varies markedly with age from 2/100,000 in the under 45s to in excess of 350/100,000 in women and 450/100,000 in men over 85 [Quinn et al 2001, Guidance on Commissioning Cancer Services 1997].

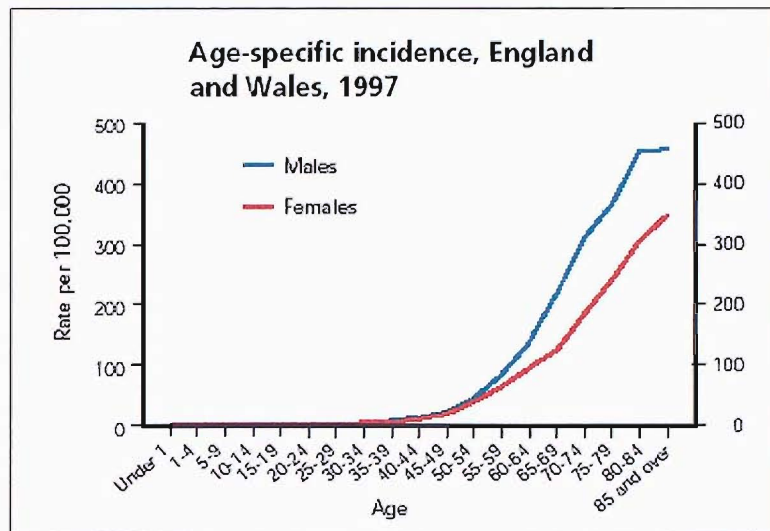


Figure 1.2.3 – Age specific incidence of colorectal cancer. (reproduced from Quinn et al 2001).

Although the overall number of colorectal cancer registrations is roughly equal in men and women, the incidence for males has remained approximately 1/3 higher than that seen in females over the last fifty years (250-280/100,000 compared to 170-180/100,000) [Quinn et al 2001, Coleman et al 1999]. There is also a difference in the distribution of the cancer throughout the bowel, rectal cancer being seen more commonly in males, while colon cancer is seen more commonly amongst females [Keddie & Hargreaves 1968, Mulcahy & O'Donoghue 1997].

1.2.4 Aetiology

1.2.4.1 Diet

One strongly supported theory is that colorectal cancer is caused by or promoted by environmental factors, chiefly diet. National and international trials (both ecological and individual level cohort and case control) have repeatedly identified an association between diet and the incidence of colorectal cancer. Diets high in animal fat and low in fibre have been

implicated, although the reported details of the relationships are conflicting. The effects of diet are believed to account for the differences in incidence seen between countries, races, and socio-economic groups. This theory is reinforced by migrant studies where immigrants from a “low risk” population encounter an incidence of colorectal cancer similar to that of their new community. There is also an association between colorectal cancer (particularly rectal cancer) and high alcohol consumption [Shearman & Finlayson 1989, DeVita et al 2001, le Marchand et al 1997, Pietinen et al 1999].

The mechanism is thought to involve substrates present in a high fat diet being acted on by gut flora to produce mutagens. These then act on the bowel mucosa to cause or promote dysplasia and eventually malignancy. A low fibre diet results in slower bowel transit times, thus increasing exposure of the mucosa to the luminal mutagens [Shearman & Finlayson 1989, DeVita et al 2001].

1.2.4.2 Increased risk populations and Genetics

Around 15-20% of colorectal cancers occur in people with one or more first-degree relative(s) affected by the disease. The degree of risk (up to 5 times greater than the norm) increases with the number of relatives affected, and the age of the patient [Anwar et al 1998, Guidance on Commissioning Cancer Services 1997].

In the absence of a detectable genetic defect it is believed increased risk in this group is due to interplay of common genetic, environmental, and dietary factors [DeVita et al 2001].

1-5% of colorectal cancer is thought to be attributable to HNPCC (Hereditary Non-polyposis Colorectal Cancer) [Neal & Hoskin 1997, Guidance on Commissioning Cancer Services 1997]. HNPCC has been linked to defects in a number of genes which results in a defect in the DNA mismatch repair system; this in turn leads to micro satellite instability which was the first noticed common genetic factor in almost all cases of HNPCC. [De Ponz et al 1999; Järvinen et al 2000]

Familial Adenomatous Polyposis (FAP) accounts for less than 1% of all colorectal cancer cases. FAP displays an autosomal dominant inheritance pattern with near complete penetrance. Without surgical intervention (in the form of a pancolectomy/panproctocolectomy with either ileostomy or restorative pouch/ileorectal anastomosis) almost 100% of patients with FAP will develop colorectal cancer. New mutations, rather than inherited, are responsible for 20-30% of index cases.

The development of colorectal cancer from normal mucosa is not a single event, it is the result of a number of changes at the genetic level that are exhibited as increasing dysplasia (the majority of cancers arise in adenomas, which are by definition dysplastic). The only histological feature discriminating between severe dysplasia and malignancy is the detection of invasion.

Genetic changes tend to occur in a stepwise progression, their order and nature are not identical for each cancer.

The list of oncogenes and prospective oncogenes is ever growing, though there are a small number of key genes.

The p53 gene is a transcriptional activator for a DNA binding protein and is capable of arresting the cell cycle in the presence of DNA damage; the p53 gene locus is the site most frequently exhibiting loss of heterogeneity in colorectal cancer. The action of p53 is antagonised by mutant forms of p53 and by the action of Bcl-2 (an antiapoptotic gene).

The APC gene (that associated with FAP) is a tumour suppressor gene, which is inactivated in over 80% of colorectal cancers. Its normal role is to prevent the intracellular accumulation of a number of compounds associated with cancer, such as catenins. Catenin accumulation can result in the transcription of the oncogenes c-myc (which promotes cell proliferation), and the inactivation of E cadherin by binding to it (acts as a tumour suppresser gene). Mutation of the APC tends to occur early in the adenoma carcinoma sequence along with hypermethylation, followed by k-ras mutation (seen in 40% of colorectal cancers). Mutation of p53 and DCC (deleted in colon cancer) tend to occur late, though the order is not consistent [dePonz et al 1999, Hamilton 1992].

Less than 1% of colorectal cancer cases are associated with inflammatory bowel disease [Guidance on Commissioning Cancer Services 1997]. The risk is mainly linked to ulcerative colitis but a small increase in risk is also seen in those with Crohn's disease. With ulcerative colitis the risk is related to both extent and duration of the disease (pancolitis for 30 years or more confers a risk of developing colorectal cancer in excess of 35%) [Neal & Hoskin 1997; Shearman & Finlayson 1989; DeVita et al 2001].

1.2.4.3 Polyps.

The majority of colorectal cancer cases are believed to arise in benign adenomatous polyps (adenomas are subdivided into three subtypes, tubular, tubulovillous, and villous). The association between malignancy and polyps has three dimensions: size, type and number.

Polyp size shows a stronger correlation with malignancy than histological type; up to 60% of polyps 2 cm in diameter are associated with malignancy. For this reason hyperplastic polyps 0.5-1cm in diameter and adenomas of any size are normally treated by polypectomy [DeVita et al 2001; Neal & Hoskin 1997; Rees et al 1993].

Hyperplastic polyps are rarely associated with malignancy, while adenomas are (giving rise to the theory of the “adenoma-carcinoma sequence”). Villous adenomas show the strongest link to malignancy being 8-10 times more likely than tubular adenomas to harbour malignancy [DeVita et al 2001].

Patients with one adenoma have an increased incidence of synchronous and metachronous polyps; this is most common if the index polyp is greater than 1cm in length, of the villous histological subtype, or exhibiting severe dysplasia [Zarchy & Ershoff]. The more adenomas the greater the chance of developing malignancy, the most extreme and graphic example being FAP.

1.2.5 Modes of Presentation

Colorectal cancer can present in many different ways, and although many symptoms are associated with it, few if any are unique. Symptoms can occur in isolation or more commonly in clusters. Much effort has gone into

identifying which symptom clusters are most commonly associated with malignancy. While this may identify subgroups of patients in whom a diagnosis of colorectal cancer is more likely, it does not rule out the possibility among those with less common symptoms. Colorectal cancer can remain asymptomatic even when locally advanced or metastatic, its eventual identification being incidental.

Higher risk	Age Group
Rectal bleeding with a change in bowel habit to looser stools or increased frequency of defaecation persistent for 6 weeks	All ages
Change in bowel habit as above without rectal bleeding and persistent for 6 weeks	>60
Rectal bleeding persistently without anal symptoms*	>60
Palpable right sided abdominal mass	All ages
Palpable rectal mass (not pelvic)	All ages
Unexplained iron deficiency anaemia:	
Men: haemoglobin <110g/l	All ages
Women: haemoglobin <100g/l	Postmenopausal
Low risk	
<i>Patients with no iron deficiency anaemia, no palpable rectal or abdominal mass, and:</i>	
Rectal bleeding with anal symptoms and no persistent change in bowel habit	All ages
Rectal bleeding with an obvious external cause (such as anal fissure, thrombosed or prolapsed pile, rectal prolapse)	All ages
Change in bowel habit without rectal bleeding	<60
Transient changes in bowel habit, particularly to harder or decreased frequency of defaecation	All ages
Abdominal pain as a single symptom without signs and symptoms of intestinal obstruction	All ages

Table 1.2.5 – Department of Health criteria for high and low risk of bowel cancer (Soreness, discomfort, itching, lumps, prolapse, or pain). [Thompson et al 2003]

Colorectal cancer can present at any stage of the disease from carcinoma in situ as a malignant focus within an adenomatous polyp to metastatic disease; the presenting symptoms and signs will not always echo the stage of the

disease. The following discussion of modes of presentation is by no means exhaustive.

1.2.5.1 Rectal Bleeding

One of the two cardinal symptoms of colorectal cancer, blood loss per rectum can present in many different ways, influenced by the site of the tumour its vascularity and the degree of mucosal ulceration. 60-90% of patients with a rectal tumour report bleeding as a symptom compared with approx 50% of patients with a left sided tumour and less than 5% of those with a right sided malignancy. [Shearman & Finlayson 1989]

The blood loss may be occult with no visible evidence of bleeding. Such cases may present as a result of positive faecal occult blood sampling, or as iron deficiency anaemia; this is more often the case in caecal or right-sided tumours.

Rectal blood loss may also be macroscopic. Blood can appear as though dark/old or bright red/fresh. Bleeding is usually reported as being in small amounts but can be so heavy that motions are almost entirely clotted blood. The blood can be mixed in, streaking the surface, or separate from the stool. Dark mixed-in blood is suggestive of a more proximal tumour while bright red blood streaking the stool is more commonly associated with a distal tumour; this assumes that a longer bowel transit time facilitates mixing and alteration of the blood. These are only associations however, and a heavily bleeding caecal tumour can present as a bright red rectal bleed.

1.2.5.2 Change of Bowel Habit

The second of the two cardinal symptoms of colorectal cancer, like rectal bleeding “change of bowel habit” is a cluster of symptoms rather than a single entity. A change of bowel habit may be used to describe a change in frequency (increase vs. decrease), consistency (looser vs. firmer), a combination of the two, or fluctuation between extremes. A change in bowel habit is believed in large part to be due to the obstructive effect a tumour has on the bowel lumen, it is also reported less frequently in right-sided tumours where the bowel content is more liquid and less susceptible to obstruction.

[Staniland, Ditchburn & De Dombal 1976]

As a single symptom in a large population a change of bowel habit is the most important indicator as to the likelihood of a patient having colorectal cancer; in combination with rectal bleeding a positive predictive value of approximately 11% for patients with both symptoms has been described in some series [Dodds et al 1999].

1.2.5.3 Palpable Mass

The two most common palpable masses encountered in colorectal cancer are a rectal mass on digital rectal examination, and a right iliac fossa mass palpable per abdomen.

Low rectal tumours may be evident on rectal examination if within digits length of the anal verge, but even then only the lower margin may be palpable. The rectal tumour is characteristically firmer than the surrounding mucosa, with a rolled margin surrounding a central ulcer.

A mass palpable per abdomen is most commonly a caecal tumour in the right iliac fossa though it is possible to palpate tumours elsewhere in the large bowel in a lean patient. Local chronic perforation and abscess formation can also give rise to a mass that is palpable on abdominal examination.

1.2.5.4 Pain

Not all patients experience pain, the incidence varying from over 80% in caecal/ascending colon lesions to less than 1/3 with recto sigmoid lesions.

Pain in colorectal cancer varies in site and nature. Pain tends to localize poorly and can be experienced anywhere within the abdomen. Site of pain does not necessarily correspond to site of the tumour although rectal pain is more common in recto-sigmoid lesions.

Divided broadly pain tends to be either constant or intermittent (colicky), and may reflect the mechanism of the pain i.e. obstruction, invasion, infection.

Right sided lesions have a tendency towards constant pain while left sided lesion tend to intermittent pain; this may be due to the differing likelihood of obstruction occurring at the two sites. [Staniland, Ditchburn & De Dombal 1976; Majumdar et al 1999]]

1.2.5.5 Nausea, Vomiting & Weight loss

The presence of nausea, vomiting and weight loss is dependant on disease stage at presentation. [Keswami et al 2002; Cummins et al 2004] With the exception of advanced metastatic disease nausea and vomiting are relatively uncommon in colorectal cancer even in the presence of obstruction. The incidence of reported symptoms varies from series to series but approximately

10% of patients have experienced nausea or vomiting to some extent by the time of presentation; these symptoms are also reported more commonly in right-sided malignancy. In stark contrast weight loss is reported by almost all sufferers presenting with symptomatic disease to a greater or lesser extent. [Ed-Shearman & Finlayson 1989; Keswami et al 2002; Cummins et al 2004]

1.2.5.6 Acute Presentation

The proportion of patients presenting as an emergency varies widely from centre to centre but figures of 20-30% are not uncommon. [Ploednak 2000, McArdle & Hole 2004] Of the patients presenting acutely many will have had other symptoms preceding the emergency presentation which are attributable to colorectal cancer.

Acute obstruction is one of the causes of “acute surgical abdomen” associated with colorectal cancer. Obstruction does not always present acutely, in most cases it is a chronic, insidious process resulting in a disruption of the normal bowel habit and pain (as discussed above).

Obstruction is more often encountered in left sided malignancy, the combination of a more formed stool and an annular stenosing tumour resulting in a mechanical impasse.

There are a small number of patients who present with appendicitis secondary to a caecal tumour obstructing the appendiceal lumen, or simply have the symptoms of appendicitis and at operation are discovered to have a caecal tumour but a normal appendix. Intussusception of the large bowel is an unusual cause of acute obstruction though in 60% of cases this is secondary to a colonic tumour.

Acute perforation is a second major cause of “acute surgical abdomen” in colorectal cancer. Acute perforation can occur either at the site of the tumour as a result of local invasion, or proximal to the tumour as a consequence of obstruction.

Perforation can be a chronic process. A locally contained perforation can lead to local abscess formation that may be palpable as a mass. Perforation into adjacent hollow organs such as bladder, vagina, or other loops of bowel results in the formation of a fistula; malignant fistulae, unlike benign fistulae, will not heal.

1.2.5.7 Anaemia

Iron deficiency anaemia identified either as a result of targeted investigation for a symptomatic patient (e.g. shortness of breath, lethargy, fatigue etc.), or incidentally on “routine” bloods, is a common mode of presentation for colorectal cancer. Even when anaemia is not the presenting symptom it is a common finding, with an incidence as high as 50% in some series. [Cummins et al 2004]

Other gastrointestinal cancers (oesophageal and gastric) can result in iron deficiency anaemia but colorectal cancer is the most common. An incidence of colorectal cancer of 15% is reported in patients undergoing colonoscopy and oesophagogastroduodenoscopy on the grounds of iron deficiency anaemia alone. [Davis, Bowman & Shepherd 2004, Devane – personal correspondence]

1.2.5.8 Metastatic Disease

Patients with metastatic disease commonly present with non-specific symptoms such as anorexia, weight loss, general malaise, though in some cases the symptoms of metastatic disease are specific to the site involved. Although it is unusual patients with colorectal cancer do sometimes present with the symptoms of metastatic disease.

Patients with liver metastasis (the most common site) can suffer with hepatic pain and are found on examination to have hepatomegally. Patients with numerous peritoneal deposits experience abdominal distension and discomfort secondary to malignant ascites. Patients with pulmonary metastases can progress to dyspnoea, either as a result of malignant effusion or mechanical obstruction/replacement of parenchyma by infiltration. Cerebral metastases become apparent through neurological signs. Bone metastases can result in pain and pathological fractures.

1.2.6 Methods of Investigation

Investigations have key roles in both the diagnosis and treatment of colorectal cancer (assessment of operability, monitoring treatment, and follow up).

Investigations can be arbitrarily divided into those that have a primarily diagnostic function, and those principally used for assessing the disease, though the employment of any investigation is not isolated to a single role.

1.2.6.1 Faecal Occult Blood Testing

Although frequently used, faecal occult blood (FOB) testing has poor sensitivity and specificity, resulting in large numbers of both false positive and

false negative results. This carries the risk of over investigating the false positive population (with the accompanying morbidity and expense) while the false negative population are inappropriately reassured; which in turn runs the risk of delaying diagnosis.

Even when performing as desired FOB testing only detects the presence of blood in the stool, it does not suggest the mechanism; this inevitably leads to patients undergoing investigation for both malignant and benign conditions. FOB has a (debated) role as a screening test rather than a method of investigation. [Scholefield et al 2002]

1.2.6.2 Rigid Sigmoidoscopy/Proctoscopy

Rigid sigmoidoscopy and proctoscopy have the benefits of being both cheap and accessible. The title of sigmoidoscopy is somewhat misleading as most examinations only permit assessment of the last 20cm of the bowel (from the anal verge) and as such the majority of the sigmoid colon remains out of reach. Rigid sigmoidoscopy does allow biopsies to be taken of the colonic mucosa or any lesions.

1.2.6.3 Colonoscopy

Colonoscopy (the endoscopic examination of the colon and rectum) is recognised as the gold standard for colonic investigation. The procedure not only allows direct visual assessment of the mucosa and the taking of tissue biopsies but it also has a therapeutic role in the form of polypectomy.

While false positive results have an almost negligible occurrence because of the high diagnostic accuracy offered by visual assessment and biopsy,

colonoscopy is susceptible to a high incidence of incomplete examination and false negative results. [Walker et al 1991] A colonoscopy is only considered complete if the caecum has been visualised; definitions for this vary locally but have included confirmation by X-ray screening, visualisation of the appendiceal lumen, or visualisation of the ileo-caecal valve (and are subject to local audit). The reasons for an incomplete examination or a false negative result include bowel constriction, poor bowel preparation, and inexperience.

The learning curve for colonoscopy is gradual: estimates vary but it has been proposed that an endoscopist will need to perform over 100 (and possibly as many as 200) supervised colonoscopies before they are competent to deal with the demands of normal practice (rather than selected “easy” cases).

[Cass et al 1993] When an examination is recognised as incomplete (often for technical reasons or those of patient safety) full colonic assessment is achieved by referral for barium enema. Colonoscopy's true weaknesses are then unrecognised incomplete examination and the false negative report.

Colonoscopy has recognised complications, and minor complications are poorly reported and so published literature focuses on major complications. Reported complication rates vary in the range of 0.15% to 1.0%. [MacRae, Tan & Williams 1983; Cass et al 1993] The most common complications are haemorrhage (which almost exclusively follows polypectomy) and perforation, which one UK study reported as having incidences of 1% and 0.1% respectively. Polypectomy not surprisingly encounters a higher complication rate than a purely diagnostic procedure; the same study reporting a

haemorrhage rate of 2.7%, perforation 1%, and death 0.1% (compared to a mortality rate of 0.06% for all colonoscopies at the same centre). [MacRae, Tan & Williams 1983] It is vital to recognise that while the complication rate of colonoscopic polypectomy appears high it replaces the surgical option of laparotomy and polypectomy by colotomy, which historically carried a high morbidity and mortality (it would be unfair to use current surgical polypectomy cases as a comparison as these are a self selecting technically difficult group).

1.2.6.4 Flexible Sigmoidoscopy

Flexible Sigmoidoscopy allows assessment of up to the last 60cm of the large bowel (typically to the splenic flexure) after preparing the bowel with a phosphate enema. Within this 60cm maximum reach it is able to provide those services outlined for colonoscopy (above).

1.2.6.5 Double Contrast Enema Examination

The use of barium as a contrast media for the radiographic assessment of the colon and rectum predates colonoscopy by several decades. The initial single contrast technique where the bowel lumen was filled with a core of barium has been superseded by the double contrast barium enema (DCBE). The DCBE is different in that after coating the mucosa barium is replaced by gas (usually carbon dioxide or air) to produce superior definition films and greater diagnostic potential. The standard double contrast barium enema requires that the bowel be prepared to remove faecal residue that can both obscure and simulate colorectal lesions. A technically adequate examination is able to

identify polyps, polypoid or stenosing lesions (classically described as apple core in the case of colorectal cancer) and permit comment on the mucosa.

DCBE suffers from two potential (well recognised) errors in relation to colorectal cancer; a failure to demonstrate the presence of a lesion, and a failure by the reporting radiologist to identify a lesion that is later identified on review. The Wessex regional audit of 1995 disclosed that while 97% of colorectal lesions had been identified (with the benefit of retrospect) only 85% of lesions had been successfully diagnosed on the initial reporting. [Thomas, Fairhurst & Frost 1995] The rectum and sigmoid colon are the anatomical sites in which the DCBE has a lower diagnostic accuracy. 7 of 18 (approx 40%) cancers not demonstrated at DCBE were in the recto-sigmoid, a situation only further complicated by the presence of diverticular disease. The ascending colon and caecum were also reported as sites particularly susceptible to technical examination failure (the lesion was not demonstrated rather than missed on reporting). [Thomas, Fairhurst & Frost 1995]

Diagnostic accuracy of DCBE has been reported to be poorest for Dukes A & B lesions within 15cm of the anal margin, it is also poor at detecting polyps especially those less than 0.5cm in diameter as they are often mistaken for faecal residue. [Thorpe et al 1981; Wolff et al 1975]

Supplementary visualisation of the recto sigmoid is mandatory because of the DCBE's lack of reliability in this region and to this end rigid and flexible sigmoidoscopy are utilised.

The role of the double contrast barium enema is in the diagnosis of both colorectal cancer and premalignant/malignant polyps.

In the assessment of a patient with acute obstruction a water soluble contrast enema may rule out the differential diagnosis of pseudo-obstruction, it will not however provide a detailed assessment of the colonic mucosa.

In addition to being a purely diagnostic procedure requiring that any abnormalities require further measures (usually colonoscopy in the first instance) DCBE does suffer from the occurrence of false positive investigations. The reporting of an lesion or abnormality when none exists is most frequently due to the presence of faecal residue or severe colonic contraction, never the less it does lead to a further (unnecessary) procedure.

Complications are inescapable when conducting invasive examinations.

Published literature focuses on major complications not only because they are of the greatest significance but also because minor complications such as nausea, mild discomfort etc. are poorly reported by patients and poorly recorded by those conducting the investigation (and so invariably suffer from marked under reporting). A survey assessing barium enemas conducted between 1992 and 1994 by UK consultant radiologists reported a complication rate of 1/9003 (0.01%) and a mortality rate of 1/56,786 (0.002%).

[Blakeborough et al 1997]

Colonic perforation had historically been the leading cause of death following barium enema examination and while in this survey it remained the commonest major complication at 1/25,000 (0.004%) the mortality rate fell to only 10% of this number (an overall mortality from perforation of 1/250,000 or

0.0004%). This reduction is believed to be the result of improved management. [Blakeborough et al 1997] Cardiac complications have now become the leading cause of death following DCBE, with an incidence of 1/46,000 (0.002%) and 56% of these dying (an overall mortality from cardiac events of 1/81,000 or 0.001%). The use of Buscopan as an anti-spasmodic has been implicated in several of these deaths leading to the advice that glucagon is used in its place for patients with a history of cardiovascular disease. [Blakeborough et al 1997]

1.2.6.6 Plain Radiographs

Plain radiographs have a limited role in the investigation of colorectal cancer, although plain abdominal films form a major part of the assessment of patients presenting acutely. Signs on plain films which may be present in cases of colorectal cancer include obstruction (with a discrete cut off point in some cases), soft tissue mass with distorted luminal shadow, calcification of the primary tumour or hepatic metastases, intussusception, and air in the bladder from fistulating disease.

1.2.6.7 Ultrasound

The main role for ultrasound is in assessing the liver for evidence of metastatic spread. Less commonly an abdominal ultrasound scan may be the primary mode of diagnosis of colorectal carcinoma when it detects a soft tissue mass. For some patient groups (particularly a thin elderly patient) with a right iliac fossa mass ultrasound is the first line single investigation of choice and may reveal diagnostic features.

1.2.6.8 Computerised Tomography

Computerised Tomography (CT) has many roles in both diagnosis and assessment of colorectal cancer. As well as an ability to give an indication as to the extent of the primary tumour, CT can sometimes detect the presence of a lymph node mass resulting from loco-regional spread, and the presence of metastases (hepatic, peritoneal, bone, lung, and brain). CT with intravenous contrast enhancement is the most sensitive imaging modality for the detection of occult hepatic metastases.

CT has a vital role in the detection of recurrent disease; early detection of extraluminal loco-regional recurrence may permit a second laparotomy with a view to excising residual disease. Percutaneous CT guided biopsy can be used to obtain histological confirmation in the above instances.

1.2.6.9 Magnetic Resonance Imaging

Magnetic Resonance Imaging (MRI) offers many of the same applications as CT, often with greater definition and detail. It is particularly useful in assessing rectal disease where the pelvic bones can make CT technically inadequate; though at present lack of availability limits many of its uses.

1.2.6.10 Radionucleotide Scan

Radionucleotide scanning had its major role in the detection of liver metastases before the widespread availability of CT and MRI; while sensitive, specific, and comparatively cheap it does not offer the anatomical detail of CT or MRI. With little to offer over other modalities radionucleotide scanning is seldom used these days.

1.3 COLORECTAL CANCER IN COMPARISON TO OTHER MAJOR CAUSES OF CANCER DEATHS.

As detailed in section 1.1.2, three types of cancer are responsible for approximately 50% of cancer incidence and mortality for both men and women. These are lung cancer, prostate cancer, and colorectal cancer in men; breast cancer, colorectal cancer, and lung cancer among women. There is enormous variation between these 4 major malignancies in terms of characteristics and behaviour. Because of this the demands any one type of malignancy places on health services and the medical profession is unique.

		1997 incidence No. (% of total)	1999 deaths No. (% of total)	Lifetime Risk	Survival	
					1yr	5yr
Lung Cancer	♂	21,000 (19%)	18,300 (27%)	1/13 (↑ in smokers)	20%	5%
	♀	12,300 (11%)	11,100 (17%)	1/23 (↑ in smokers)		
Colorectal Cancer	♂	14,900 (14%)	7,500 (11%)	1/18	70%	40%
	♀	14,000 (12%)	7,100 (11%)	1/20		
Breast Cancer		33,100 (29%)	11,100 (18%)	1/9	90%	75%
Prostate Cancer		18,300 (17%)	8,500 (12%)	1/14	80%	50%

Table 1.3 - Summary and comparison of the 4 major forms of cancer. Data from Quinn & Babb 2000, Coleman et al 2000.

An individual does not live in a vacuum and cannot be purposefully analysed in isolation, the same is true of any form of cancer. The investigation and treatment of any condition will have to compete with the investigation and treatment of other conditions for facilities and resources.

The main obstacle to improving survival in colorectal cancer is early detection. Media coverage and reporting have raised the general public's awareness of the condition but the cardinal symptoms of colorectal cancer are also common among a healthy normal population and as a result are often not taken seriously by the patient. The prospect of a screening programme is being pursued and appears to be a logical progression (see section 1.6.4). The investment made in time, facilities, and expertise in order to identify patients with colorectal cancer is high as only a fraction of those investigated prove to have the condition. Treatment demands a high level of provision with patients requiring surgery, chemotherapy, radiotherapy, stoma & postoperative care; as well as symptomatic relief and palliation for up to 50% of patients.

Lung cancer in England and Wales is effectively a social disease resulting from smoking. To encourage cessation and dissuade new smokers would have a dramatic effect on a disease that, at present, has an appalling prognosis. The majority of patients present too late for curative treatment, and die within a year of diagnosis. Healthcare's main contribution to these patients is symptomatic and palliative care. The possibility of screening does hold some hope for improved survival but pales into insignificance when we are reminded that the great majority of lung cancers could be prevented if only people stopped smoking.

The management of breast cancer has undergone major change over the last two decades and is a flagship for the expectations of all cancer care. Patient awareness (and thus seeking medical advice early) has increased as a result

of media exposure, and the introduction of the NHS Breast Cancer Screening Programme in 1988 has lead to earlier disease presentation. The re-structuring of breast care into dedicated units with surgeons specialising in the diagnosis and treatment of breast disease; and improvements in treatment (hormone manipulation and breast conserving surgery) together have produced an improvement in breast cancer survival and are expected to continue to produce improving results.

Prostate cancer has been an underestimated cause of death especially among the general public. Recent media coverage has increased public awareness of the condition that in turn is likely to have increased the amount of ad-hoc PSA screening conducted by GPs. Prostate cancer management requires that three key questions be answered, firstly in which groups should the disease be treated, secondly how then should they be treated, and thirdly will screening reduce (rather than increase) morbidity and mortality. A small percentage of patients undergo radical prostatectomy (the only treatment with a curative aim). The majority under go some form of hormonal manipulation managed on an outpatient basis and TURP if they have symptoms of bladder outflow obstruction; but difficulty comes in deciding whether to start hormonal therapy immediately or on the development of symptoms of metastatic disease. Practices differ both internationally and nationally.

1.4 RECENT CHANGES, AND INFLUENCES ON THE WAY IN WHICH COLORECTAL CANCER IS PERCEIVED AND MANAGED.

Although many of the features of colorectal cancer (such as incidence, survival, and to a lesser extent treatment) have changed little over the last 50 years, awareness of the disease as well as its role as a threat to health have. Many of these changes have occurred over the later decades and this section attempts to highlight some of the influences on the way in which colorectal cancer is looked upon both by the medical profession and the general public.

1.4.1 The General Public and Colorectal Cancer.

Cancer as a whole has always been a taboo subject. Historically cancers have been associated with unpleasant (often mutilating) treatments, poor prognosis, and an unpleasant death. Colorectal cancer has been no exception. Such association among the general public leads to a fear of diagnosis and patients refusing to seek medical attention for worrying symptoms; the outcome of which is late presentation of advanced disease and a strengthening of the associations which discourage patients to seek medical attention in the first place.

Breast cancer was arguably the first form of cancer to overcome many of its stereotypes (“mutilating” treatment with little hope of cure). Increased public awareness, media coverage, and the introduction of the widely advertised NHS Breast Cancer Screening Programme have thankfully changed the way in which the majority of women deal with breast lumps and symptoms. The

patient presenting with an infected fungating tumour is an increasingly rare occurrence.

Colorectal cancer has undergone similar changes in public awareness and understanding. Media exposure of the disease both in terms of treatment changes and high profile cases have gradually chipped away at the general public's often fixed opinions. The association of colorectal cancer with stoma formation or "a bag" is understandably a mental obstacle for too many patients. Although the frequency of stoma formation as part of disease treatment has decreased dramatically it remains one of patients' major concerns and dreads.

The general public's awareness of colorectal cancer has changed, as has its willingness to discuss bowel habit. The medical profession has also undergone similar changes, specifically enquiring after symptoms and making prompt referrals. The two changes together can only result in earlier presentation and a hope of improved survival.

1.4.2 The Calman-Hine Report

The document "A Policy Framework for Commissioning Cancer Services – A Report by The Expert Advisory Group On Cancer to the Chief Medical Officers of England & Wales", or the Calman-Hine report as it has come to be better known (after the chief medical officers) was published in the April of 1995.

The expert advisory group on cancer was formed in response to the government White Papers "The Health of the Nation" and "Working for Patients" which identified cancer as an area of health care which should be

targeted for improvement if the nation's overall health was to see improvements.

The report examined cancer as a whole and made a number of recommendations that continue to direct cancer services today. Key to many of the report's recommendations was the observed variation in treatment and outcomes across the United Kingdom. The report recommended the delivery of a uniformly high standard of care with cancer site sub-specialisation; a patient centred multidisciplinary approach to care with patient participation in decision making whenever possible; and improved links between primary and secondary care (among many others). It also emphasised that an expansion in the role of palliative care was needed to assist in symptom relief at an earlier stage, and that strong formalised links to both primary and secondary care should be formed.

In order to deliver these recommendations the report proposed a new structure for cancer services throughout the UK; this has been by far the most enduring and influential of the proposals made by the expert advisory group.

1.4.2.1 A new structure for cancer services.

By necessity the move towards the structure proposed by the Calman-Hine report is an ongoing evolutionary process (health care can not be closed down, re-branded, and then launched as something new). The authors of the report were careful to avoid a dogmatic approach stating that needs would

differ dependant upon the demographics of the population served and local geography.

Cancer services in the United Kingdom are now delivered by a jig-saw of interlocking cancer networks which aim to deliver an equal standard of care but are capable of functioning independently of each other. Each network comprises an integrated 3-tier system of primary care, the cancer unit, and the cancer centre organised in hub and spoke manner (Diagram 1.4.2.1).

Referral guidelines, referral pathways, and avenues for the timely sharing of information should be established between the components of each cancer network.

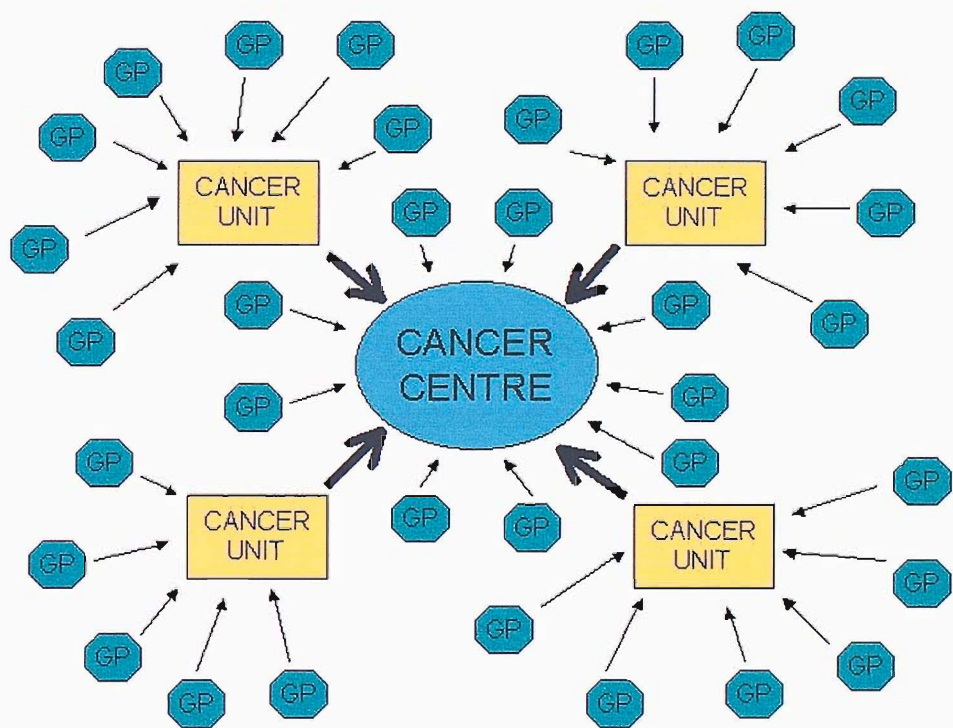


Diagram 1.4.2.1 - Cancer Network Structure

At the primary care level cancer services are co-ordinated through the patient's General Practitioner. General practice is the gateway of presentation for the majority of cancers, an important provider of after care, and when necessary palliative care. Recognised and established avenues of communication between general practice and the cancer unit should be available for the two-way passage of information.

The cancer unit (typically a district general hospital) serves the local population. Facilities and local expertise should be adequate to deal with common cancers (e.g. lung, breast etc.) and the number of cases managed should be adequate to maintain skill levels. Less common cancers, and common cancers requiring more specialised treatments, should be referred to the cancer centre according to prearranged protocols and referral pathways. In many cases a patient's care would be shared between centre and unit necessitating formalised pathways for the passage of information.

The cancer centre (e.g. a large general hospital or teaching hospital) acts as both a referral centre for its regional cancer units and fills the role of cancer unit for the surrounding population. A cancer centre should be adequately equipped and experienced to deal with all aspects of care thus providing a specialist and comprehensive service.

The exception to the above network structure is the management of very rare tumours. In such cases a small number of national centres should be identified in order to concentrate the limited number of cases and thus

experience. This strategy does not meet the aim of providing a locally available uniform high level of care for the entire population but is necessary in order to provide a multidisciplinary team with adequate experience. In this way a balance is struck between equity of access in terms of distance having to be travelled for treatment, and efficiency of treatment provision.

1.4.3 The EUROCARE Study.

The initial EUROCARE study was also published in 1995 (followed by Eurocare II in 1999). Produced by the International Agency for Research on Cancers (IARC) European Commission the EUROCARE studies are a statistical comparison of cancer incidence and survival across Europe in terms of site, age, and country.

The overall trend demonstrated that cancer survival was roughly equal in countries with similar socio-economic status. England & Wales and Scotland did not adhere to this overall trend, performing badly when compared to both countries with a similar socio-economic base and the European average.

When compared to similar data from the USA (which was not part of the Eurocare study) the United Kingdom's record on cancer survival appeared even worse. [Berrino et al 1999, Quinn & Babb 2000]

This reported poor performance in the United Kingdom has fuelled medical and political initiatives to improve the standard of cancer services.

The EUROCARE studies have been the subjects of criticism centering on whether there is an actual difference in survival or simply differences in data collection between registries; put another way, are the international

differences reported in the EURO CARE studies a product of more effective care in some countries or simply less effective cancer registration?

Firstly definitions and diagnostic accuracy have been shown to differ between countries. Carcinoma in situ has been graded as invasive disease on some cancer registers, thereby up staging the disease and improving survival statistics. [Prior, Woodman & Collins 1998] The thoroughness of disease staging by imaging and histological examination has also been shown to vary from centre to centre. In the case of colorectal cancer pre-operative ultra sound scanning of the liver to assess metastatic spread varied from 50-80%, and histological examination of 12 or more lymph nodes only occurred in 31% of registered cases (both down staging the disease). No stage at all was recorded for 45% of patients. [Gatta et al 2000]

It has been suggested that the main cause of survival variation in colorectal cancer has been the stage of the disease at presentation; there was less variation in survival for patients who underwent resection of their disease and the majority of differences in survival are confined to the first 6 months following diagnosis. [Quinn & Babb 2000] Further correction of the figures for disease stage produced a reduction in survival variation though the rank order of best to worst survival across Europe was not changed. [Gatta et al 2000]

Secondly the registration processes also vary, both nationally and internationally. Many subtle differences in cancer registration practices have been identified; some worthy of singling out as they have great potential for distorting reported survival rates. How are cases identified? Is it an active or

passive process as failure to report new cases promptly can result in advanced cases being missed? A lack of active death notification can falsely increase reported survival.

Some cancer registries only accept a histological diagnosis and again advanced cases where the diagnosis may be solely clinical may be excluded. From what point is survival measured? Some registries take the date of histological confirmation, others use the date the patient was first seen by a doctor in relation to what later transpires to be a cancer.

Thirdly cancer registry coverage varies from country to country. In some cases registries covering only small sections of a country's population were used to project figures for the entire country; these were then compared with data collected from nationally co-ordinated programmes with near 100% population coverage. This phenomenon is also believed to account for the figures from the USA where a large proportion of the population (approximately 20%) are not covered by health care of any sort and thus not included in statistics; with no healthcare this subgroup would be expected to contain those patients with the worst outcomes.

The EURO CARE studies' main failings, then, are that they fail to compare like with like, or employ a common methodology for data collection. These would be considered serious flaws in any study and throw results and conclusions into doubt.

1.4.4 Royal College of Surgeons Guidelines.

“Guidelines for the Management of Colorectal Cancer” was published in June 1996 in response to a Department of Health request to the Royal College of Surgeons of England. The expert advisory group comprised members of numerous professional bodies representing the many aspects of a colorectal cancer patient's treatment and care. The published treatment guidelines are aimed at clinicians, the aim being to provide a uniform level of care to the highest possible standard.

The guidelines are structured into a series of recommendations; both the evidence supporting a recommendation and the recommendations are graded to aid critical appraisal. Recommendations are grouped into categories that loosely follow the patient pathway-

- Initial Investigation
- Access to treatment
- Preparation for surgery
- Elective surgical treatment
- Record Keeping
- Emergency Treatment
- Adjuvant Therapy
- Treatment of advanced disease
- Outcomes
- Follow up
- Pathology

1.4.5 Improving Outcomes in Colorectal Cancer

“Guidance on Commissioning Cancer Services, Improving Outcomes in Colorectal Cancer” is NHS executive document published in 2 companion volumes in November 1997. The Colorectal cancer COG as it is often referred to (after clinical outcomes group) lays out a series of recommendations and their expected benefits in the first volume “the manual”, and provides the rationale behind the recommendations in the second volume “the research evidence”.

Aimed at Chief Executives and other purchasers of health care services its intention is to guide the commissioning, planning, and development of colorectal cancer services in a direction that not only enables clinicians to treat colorectal cancer patients in accordance with Royal College of Surgeons, but also conforms to the Calman-Hine report.

1.4.6 The NHS Cancer Plan

The NHS Cancer Plan was published by the Department of Health in September 2000, and is the product of a consultation process led by the National Cancer Director. It is a political rather than medical document aimed at the United Kingdom populus in general. It sets out the government’s intention to bring about a co-ordinated approach to management of cancer (in terms of prevention, diagnosis, treatment, care & research) and as such is a driving force behind current cancer services and their future development. Although not its only purpose the NHS cancer plan is in part the government’s response to the apparent shortcomings of UK cancer care identified in the

EUROCARE studies (see section 1.4.3), indeed it takes measures to report the differences in survival across Europe clearly.

The document declares 4 main aims-

- To save more lives.
- To ensure that people with cancer get the right support & care as well as the best treatment.
- To tackle inequalities in health (geographic and economic).
- To invest in order not to fall behind again (meaning Europe & USA).

The stated aim of the new NHS cancer plan is to achieve 5-year survival rates comparable to the best in Europe by 2010. In order to achieve this the government has set a series of milestones and targets to be achieved. Many of the targets and milestones appear to be politically driven rather than being based on medical evidence (which is juxtaposed to the evidence-based approach to health care sanctioned by the National Institute for Clinical Excellence). Those targets having the greatest effect on cancer services and colorectal cancer in particular are concerned with reducing waiting times-

- Maximum of 2-week wait to first appointment for urgent suspected cancer referrals by December 2000.
- Treatment to commence within 1 month of diagnosis by 2005.
- Treatment to commence within 2 months of urgent referral by 2005.
- Maximum of 1 month from referral to first treatment by 2008.

These targets cite “Best care available in Europe and USA” as their justification; there is no current evidence to suggest such arbitrary timing of care effects survival.

1.4.7 Manual of Cancer Services Standards

The Manual of Cancer Services Standards was released by the NHS Executive in December 2000 and contained a number of national standards and performance indicator measures for cancer services across the United Kingdom. Taking a lead from, and continuing the work of, both the Calman-Hine report and the site-specific “Improving Outcomes” documents the intention was to provide a document to facilitate self assessment and provide a frame work for peer review site visits. The importance of peer review visits is considered central to the continued evolution of cancer services and a standardisation of the level of care.

The manual is organised in checklist form and structured into ten topics.

- Patient Centred Care
- Specialist Multi-disciplinary Teams
- Diagnostic Services
- Provision of Non-surgical Oncology to cancer Units
- Radiotherapy
- Chemotherapy
- Specialist Palliative Services
- Education, Training & Continuous Professional Development
- Communication Between Primary, Secondary and Tertiary Sectors
- Cancer Services Organisation & Management

Each topic has a number of specific objectives followed by a list of standards; the fulfilment of which is considered necessary if the objectives are to be met. The standards are graded to either Level 1 or Level 2 in order to indicate relative priority to the user; Level 1 standards considered of top priority are marked with an asterisk (i.e. Level 1*) to indicate that they should be achieved first.

In addition to setting down standards the manual also lists a number of performance indicators by which cancer units and centres can be assessed and compared. Initially indicators have only been provided for breast, colorectal, and lung cancer but the intention is to expand the performance indicators to other cancer sites.

Indicator	Title & Description
NCI 1	Colorectal cancer incidence <i>Age/sex standardised rates of registration by stage of primary cancer of the colon and rectum at diagnosis</i>
NCI 2	Colorectal cancer survival <i>Age/sex standardised survival by stage at diagnosis</i>
NCI 3	Colorectal cancer mortality <i>Population based mortality rates for cancer of the colon and rectum in adults</i>
NCI 4	Access to specialist (MDT) treatment <i>% of patients surgery for suspected cancer of the colorectum is performed by specialist surgical team</i>
NCI 5	Quality of colonoscopy <i>Completion rates</i>
NCI 6	Quality of surgery <i>Permanent end colostomy rates</i>

Table 1.4.7 – Performance Indicators for colorectal cancer as set out by the Manual of Cancer Services Standards 2000.

These performance indicators are not comprehensive or fully representative of all aspects of cancer care but they do provide a straw poll snapshot of a site's

performance and this is a necessary starting point from which more accurate indicators can be developed.

1.5 DIAGNOSTIC DILEMMAS IN COLORECTAL CANCER

There are a number of issues clouding the timely diagnosis and treatment of colorectal cancer that, while receiving much attention and debate, remain unresolved. These issues are rarely if ever isolated and the problems and potential solutions will undoubtedly overlap. This section attempts to highlight some of the dilemmas encountered in colorectal cancer diagnosis.

1.5.1 An absence of classical symptoms

Colorectal cancer lacks a classical symptom or sign (such as breast lump in breast cancer) and shares many of its symptoms with far more common benign conditions. [Keddie & Hargreaves 1968] There is a plethora of symptoms associated with the presentation of colorectal cancer including rectal bleeding, change of bowel habit, abdominal pain, tenesmus, weight loss, abdominal or rectal mass, anaemia, and weakness among others.

In isolation many of the symptoms associated with colorectal cancer are poor indicators of the disease. The single symptom most strongly associated with colorectal cancer when comparing groups of cancer patients with community controls is a change in bowel habit; unfortunately patient abilities to recall aspects of their bowel habit accurately is notoriously poor. [Curless et al 1994] Rectal bleeding which is more accurately reported by patients has a positive predictive value for colorectal cancer of 7%; this increases with age to the 70-79 age group (colorectal carcinoma peak) before declining in the over 80s.

Rectal bleeding's sensitivity for colorectal cancer is only around 30%.

[Wauters, Van Casteren & Buntinx 2000; Chapuis et al 1985]]

Much work has been done (and is ongoing) on identifying symptom clusters that better indicate the probability of colorectal cancer in an individual. Such work has been used in the development of referral guidelines for suspected colorectal cancer. [Referral guidelines for suspected Cancer 2000] It is hoped that with increased experience and thorough record keeping these symptom clusters will be further refined to provide a more useful instrument.

Symptoms	Incidence of Colorectal Cancer in Symptomatic patient group.
Rectal Bleeding & Change of Bowel Habit	1:8
Change of Bowel Habit alone	1:17
Rectal Bleeding alone	1:18
Rectal Bleeding & Perianal Symptoms	1:148

Table 1.5.1- Incidence of colorectal cancer by grouping of gastrointestinal symptoms (adapted from Dodds et al 1999)

At present even the best symptom indicators will require 8 normal patients to be investigated in order to diagnose one case of colorectal carcinoma; clearly in practice the actual numbers of healthy patients investigated are far greater. (As discussed in section 1.2.5.2)

1.5.2 The incidence of gastrointestinal symptoms in an apparently healthy population.

Compounding the fact that colorectal cancer is present in only a minority of individuals experiencing gastrointestinal symptoms is the high incidence of

such symptoms in the general population. The estimated incidence of rectal bleeding in the general population is reported to be in the order of 15-20% (10% in the 40-60 age group). [Dent et al 1986; Mant et al 1989; Jones & Lydeard 1992] A fluctuating bowel habit is reported by 32% of the population in the 6 months prior to questioning (48% in those over 65) with constipation or diarrhoea specifically complained of in 12% and 13% of the population respectively. [Dent et al 1986; Mant et al 1989; Jones & Lydeard 1992] Abdominal pain is also common among the apparently healthy with 8% reporting abdominal pain lasting for more than 2 weeks in the preceding 6 months [Dent et al 1986] and as much as 25% reporting 6 or more episodes of pain over the same time period [Jones & Lydeard 1992].

In spite of the high prevalence of symptoms that could be attributable to colorectal cancer in the general population only a minority of $\frac{1}{3}$ to $\frac{1}{2}$ seek medical advice (the over 60s are more likely to consult). [Crosland & Jones 1995] The perceived seriousness of the symptoms is the key to whether an individual presents to their GP or not.

1.5.3 The effect of patient age.

Colorectal cancer has a strong association with increasing age, 99% of cases occurring in the over 40s and 85% of cases in the over 60s. (see Figures 1.1.2a & 1.1.2b)

Age also affects several factors associated with colorectal cancer. When questioned the healthy elderly are more likely to report gastrointestinal symptoms than the wider population, though the accuracy of reported bowel

habit is poor with increased self reporting of features such as constipation. [Curless et al 1994] Fluctuating bowel habit is reported in 48% of those over 65 questioned about symptoms. [Dent et al 1986] In addition to having the highest incidence of GI symptoms the over 60s are more likely to consult their GP about them when compared to the population as a whole. [Crosland & Jones 1995]

As a group there are differences in the ways in which elderly patients with colorectal cancer present. Symptomatic anaemia and non-specific symptoms such as malaise or asthenia are more common presenting symptoms in the over 70s. Older patients with rectal carcinoma are less likely to complain of localising symptoms such as tenesmus than rectal cancer patients as a whole. [Curless et al 1994]

Diagnostic delay is no greater among the elderly than in all colorectal cancer patients. While the elderly are no more likely to present as emergencies than the greater group; elderly patients with colorectal cancer are more frequently referred to medical or geriatric services. [Curless et al 1994]

1.5.4 The demand on diagnostic facilities.

The demand on diagnostic facilities is high and only set to grow further. As detailed above symptoms that may be due to colorectal cancer are common in the healthy community. At present there are no reliable symptom combinations that differentiate between malignant and benign disease. Based purely on symptoms such as rectal bleeding a GP or hospital specialist's ability to predict whether or not a patient's symptoms are due to

colorectal cancer (even after rigid sigmoidoscopy in clinic) is poor, and cannot be relied upon. [Goulston, Cook & Dent 1986] Until and unless this situation changes large numbers of patients will have to be investigated in order to identify the few with colorectal cancer.

Full colonic investigation relies on endoscopy and radiology services in order to provide colonoscopy, flexible sigmoidoscopy, and barium enema examinations. These two diagnostic modalities demand a heavy investment in the form of dedicated facilities and staff (both trained and support). As practice continues to change towards the investigation of a higher proportion of referrals (part clinical judgement and part defensive) the demand on services has escalated. Demand on services has also been driven by improved patient awareness (and thus presentation to GPs), an increased referral rate from GPs (as a result of increased awareness and defensiveness), and government initiatives placing arbitrary upper limits on the time taken to make a diagnosis. The result is that diagnostic services are heavily over subscribed and waiting lists spiral.

While there is some scope for maximising the yield of diagnostic facilities by streamlining the services the true answer lies in increasing facilities. Even when funding is available this process is slow as facilities must be procured and staff trained to an adequate standard. Colonoscopy was until recent years almost exclusively carried out by doctor though now the role of nurse endoscopists appears to be ever on the increase. While expert opinion on the amount of training required varies in international reports, evidence suggests

that 100 or more supervised procedures should be completed before an individual is considered competent. Closer to home The Joint Advisory Group On Gastrointestinal Endoscopy (JAG) has set down more specific guidelines (See Appendix U).

The average colonoscopy takes 55 minutes even after performing 100 supervised procedures; illustrating that training a colonoscopist is a time-consuming labour-intensive process. [Cass et al 1993]

1.5.5 Diagnostic delays

Reducing diagnostic delay and expediting treatment is one of the government's main targets (see section 1.4.6), but what are the causes and effects of diagnostic delay, and is specifically targeting hospital services likely to have a major effect?

1.5.5.1 The Causes of Diagnostic Delay

By convention diagnostic delay is divided into three phases. Phase 1 is the time from the patient first noticing symptoms to requesting a GP appointment. Phase 2 is the time from the patient requesting a GP appointment to the GP making the referral to a specialist. Phase 3 is the time from the GP making a specialist referral to a diagnosis being made.

Studies have shown that on average patients and their doctors make equal contributions to the time it takes to reach a diagnosis of colorectal cancer, and that phase 3 (hospital stage) is the shortest of the three. [MacArthur & Smith 1984]

There are many influences on why an individual may not present promptly to their GP upon noticing gastrointestinal symptoms. As highlighted in section 1.5.2 such symptoms are very common among the general population and many people consider them to be nothing to worry about (and in the majority of cases are correct to do so). The perceived severity of symptoms, the discomfort a patient experiences, and advice received from family and friends greatly influence how promptly medical attention is sought. Patients with abdominal pain, or nausea & vomiting as an initial symptom, present to their GP more quickly than average; those with both quickest of all. [M^{ac}Arthur & Smith 1984]

Colorectal cancer has had a lower level of public awareness than other malignancies such as breast cancer. One study reported that in the 1980s 90% of colorectal cancer patients had not considered cancer as a cause for their symptoms (compared with 50% of breast cancer patients). [M^{ac}Arthur & Smith 1984] Akin to many aspects of health care, men are less likely to present promptly than women. [Young, Sweeney & Hunter 2000] As publicity improves and public awareness of colorectal cancer along with concern about GI symptoms increases this phase 1 delay can only decrease; however the number of patients presenting are also set to increase.

Phase 2 or GP delay is not as clearly explained but in the large part is influenced by the sheer volume of patients presenting with GI symptoms, the majority of which will transpire to be innocent and/or short lived. The GP's dilemma comes in trying to identify which patients have serious disease and which do not; in this respect watchful waiting has always been a great

determinant. Government initiatives and increasing public expectations appear to have culminated in a heightened rate of referral for expert opinion via both the 2 week wait “fast track” system and more conventional routes.

Phase 3 or Hospital delays have been principally the result of waiting lists, both for an initial appointment and for required investigations. However, Government targets, increased GP referrals, and a transition toward investigation over clinical decision making have produced a rapid increase in the demand on hospital services while the services have failed to expand at a similar rate: the very factors that decrease phase 1 & 2 delays only serve to increase phase 3 delays. Only time will show if overall diagnostic delay is affected, or if there is simply a redistribution of time delays between the three phases.

1.5.5.2 The Effects of Diagnostic Delay

Common sense dictates that a disease such as colorectal cancer which is not self-limiting can only progress with time, and that as the disease progresses survival will decrease. It is also to be expected that patients who have been symptomatic for longer will have more advanced disease and worse survival. While this is the opinion still held in the medical profession it is yet to be supported by compelling research evidence, in fact the reverse appears to be true.

Several studies have shown that there is no direct relationship between symptom duration and site, stage, differentiation and survival in colorectal

cancer. [McDermott et al 1981; Barillari et al 1989; Mulcahy & O'Donoghue 1997] The strongest indicators of prognosis are stage and emergency presentation; prior to correction for these factors a short symptom history (less than 3 months) is associated with a worse prognosis and survival actually appears to improve with increasing symptom duration. [McDermott et al 1981; Mulcahy & O'Donoghue 1997]

The only group of patients for whom duration of symptoms has yet been proved to effect survival are those diagnosed while asymptomatic for GI symptoms (i.e. screened or anaemic) and this is only true if they are treated promptly (within 2 months of diagnosis) after which survival is comparable with symptomatic patients. Asymptomatic patients have a significantly higher proportion of T1N0M0 disease, and node free disease (Dukes' A & B) accounts for 65% compared with 50% among the symptomatic. [Barillain et al 1989] This can only strengthen the argument for introducing a population screening programme.

It is impossible to argue that diagnostic delay does not result in anxiety among those awaiting or undergoing investigation for possible colorectal cancer; and that a reduction in the time taken to achieve a diagnosis would reduce such anxiety (which current initiatives making every day appear significant can only heighten).

1.5.6 Summary of Dilemmas

The symptoms of colorectal cancer are not unique to it and are commonplace in a normal healthy population, which prevents actual cases being readily

identified. In addition the elderly, the very group with the highest incidence of colorectal cancer, are more likely to experience GI symptoms unrelated to it, and are most likely to report the symptoms (inaccurately) to their GP.

GPs presented with increasing numbers of patients complaining of symptoms which could be due to colorectal cancer are increasingly pushed, through clinical guidelines and a fear of being later accused of missing a diagnosis of cancer, to refer these patients on for a specialist opinion in high numbers.

The hospital specialist who sees their referrals for possible colorectal cancer and GI symptoms escalate is also expected to see the patient, make a diagnosis, and commence treatment within arbitrary government set limits.

Diagnostic services become over subscribed and pushed to breaking point, with the effect that rather than waiting lists getting shorter they get longer.

The main challenge facing colorectal cancer services is to maximise what can be achieved with present facilities, and to identify those areas into which scarce new resources should be placed in order to make maximum effect.

1.6 CURRENT INITIATIVES TO IMPROVE COLORECTAL CANCER CARE STANDARDS AND OUTCOMES.

While not an exhaustive list the following sections detail some of the initiatives that have been introduced in an attempt to improve colorectal cancer care. With these and other projects it is hoped that current targets will be first met and then surpassed.

1.6.1 The “fast-track” / 2-week-wait clinic and referral guidelines.

Initially promised in the Government white paper “The new NHS – Modern, Dependable” and re-iterated in the NHS Cancer Plan the guaranteed maximum wait of 2 weeks from urgent GP referral to specialist appointment for those suspected of having cancer applies to all forms of malignancy. The date by which the 2-week standard was to be put into practice varied according to cancer site (Table 1.6.1). For colorectal cancer the 2-week standard was to be implemented by July 2000. Each unit and centre’s ability to achieve this standard is the subject of ongoing audit.

Date by which 2 week standard is to be achieved	Type of Malignancy
April 1999	Breast cancer
April 2000	Lung cancer Children's cancers Leukaemia
July 2000	Upper Gastrointestinal cancers Lower Gastrointestinal cancers
October 2000	Gynaecological cancers Skin cancers Brain/Central Nervous System cancers
December 2000	All other cancers including – Urological cancers Head and Neck cancers Sarcomas Haematological malignancies (other than leukaemia)

Table 1.6.1 – 2-week standard implementation timetables [Referral Guidelines for suspected Cancer]

To assist GPs in identifying patients requiring urgent referral for suspected cancer (and also those not requiring an urgent referral), and aid cancer units in setting referral criteria and procedures, the Department of Health published “Referral Guidelines for Suspected Cancer” in April 2000. An easy view wall chart of referral guidelines accompanied the publication, and sample referral proformas were posted on the Internet.

It is recommended that these symptoms and sign combinations WHEN OCCURRING FOR THE FIRST TIME should be used to identify patients for urgent referral under the two week standard.	
Symptoms	Age Threshold
○ Rectal Bleeding WITH a change in bowel habit to looser stools and/or increased frequency of defecation persistent for 6 weeks	<i>All ages</i>
○ A definite palpable right sided abdominal mass	<i>All ages</i>
○ A definite palpable rectal (not pelvic) mass	<i>All ages</i>
○ Rectal bleeding persistently WITHOUT anal symptoms*	<i>Over 60 years†</i>
○ Change in bowel habit to looser stools and/or increased frequency of defecation, WITHOUT rectal bleeding and persistent for six weeks	<i>Over 60 years†</i>
○ Iron deficiency anaemia WITHOUT an obvious cause (Hb<11g/dl in men or <10g/dl in postmenopausal women)	
NB. Patients with the following symptoms and no abdominal or rectal mass, are at very low risk of cancer:	
○ Rectal bleeding with anal symptoms* ○ Change in bowel habit to decreased frequency of defecation and harder stools. ○ Abdominal pain without clear evidence of intestinal obstruction	
*Anal symptoms include soreness, discomfort, itching, lumps, and prolapse as well as pain.	
†Aged 60 years is considered to be the maximum age threshold. Local Cancer Networks may elect to set a lower age threshold (e.g. 55 years or 50 years)	

Figure 1.6.1 – Colorectal Cancer: guidelines for urgent referral [Referral Guidelines for suspected Cancer]

The document applied to all forms of malignancy and gave specific guidance on referral guidelines for colorectal cancer (Figure 1.6.1). It also suggested that following the guidelines would lead to the identification of 90% of colorectal cancer cases. Individual units have used the guidelines and sample proformas to create their own referral forms (see Appendix A)

1.6.2 Nurse Specialist Endoscopists.

Although not universal the position of nurse endoscopists is becoming increasingly common in the UK; a postal survey in October 2000 identified 102 nurse endoscopists employed in the NHS with 85 performing flexible sigmoidoscopy, and 10 full colonoscopy. [Pathmakanthan et al 2001] The survey reported that lead clinicians seemed keen to restrict nurse endoscopy to oesophagogastroduodenoscopy and flexible sigmoidoscopy, possibly due to the increased risks associated with colonoscopy. While there is little research comparing nurse and medically qualified clinician colonoscopy there is clear evidence from within the UK and the USA (where physician assistants are also employed) that with adequate training nurse endoscopists are as safe and effective as trained medically qualified clinicians; they are also more cost effective. [Duthie et al 1998; Horton et al 2001; Schoenfeld et al 1999; Basnyat et al 2002]

Endoscopy services are one of the bottlenecks contributing to diagnostic delay within the NHS and the increasing numbers of referrals seen as a result of current initiatives are making matters worse. An increase in the number of nurse practitioner endoscopists would appear to be part of the solution and

may become essential if a colorectal cancer-screening programme were to be introduced.

1.6.3 Cancer Services Collaborative projects.

The Cancer Services Collaborative (CSC) is a centrally funded NHS programme aimed at cancer services delivery. It is intended that the CSC should be one of the approaches by which the improvements laid out in the NHS cancer plan will be brought into being. The overall programme is divided into tumour specific (breast, bowel, lung, gynaecological, urological, and upper GI malignancies), cross tumour (endoscopy, radiology, chemotherapy, and radiotherapy services), and primary care projects.

The goal of the cancer services collaborative is to –

“improve the experience and outcomes for patients with suspected or diagnosed cancer by optimising care delivery systems across the whole pathway of care”

which it seeks to achieve by fulfilling several stated aims (see Table 1.6.3).

The CSC aims to: ○ provide certainty and choice for patients; ○ pre-plan and pre-schedule care at times to suit patients; ○ reduce unnecessary delays and restrictions on access; ○ improve patient and carer satisfaction by providing personalised, consistent care; ○ ensure that the patient receives the best care, in the best place, by the best person/team.

Table 1.6.3 – Aims of the Cancer Services Collaborative [Cancer Services Collaborative – A Quick Guide 2002]

The CSC requires that the multidisciplinary team (MDT) and managers examine and assess the system of care and identify areas for improvement; then through locally implemented schemes effect a change in the system, principally through streamlining the processes already in place and matching capacity (actual not theoretical) with demand. The local initiatives are then shared at a national level through meetings and publications, such as the Colorectal Cancer conference held in March 2002 and the "Bowel Cancer - Service Improvement Guide" available on the internet. The scope and potential impact of the shared information varies widely from volunteers handing out leaflets on colorectal cancer symptoms in a local shopping centre, to an integrated care pathway encompassing diagnosis to discharge [Bowel Cancer – Service improvement Guide].

1.6.4 Screening for Colorectal Cancer.

If detected while asymptomatic colorectal cancer carries an improved prognosis. [Barillain et al 1989] Colonic screening would also allow some prevention by the detection and treatment of pre malignant adenomas. There are risks involved with any screening programme that may result in harm to the patient and any potential benefits must be weighed against them. Such risks include complications of any investigations resulting directly from the screen, the psychological effects of worrying about potential disease, and a negative test (either as a false negative or a true negative) being seen as a clean bill of health and potentially inhibiting future advice seeking behaviour for new symptoms. [Stewart-Brown & Farmer 1997] The potential benefits

that would result from reduced mortality in the nation's second most common cancer must out weigh potential drawbacks.

In the USA screening for colorectal cancer is commonplace and the American Gastroenterological Association (AGA) published guidelines in 1997 (Figure 1.6.4). [Winawer et al 1997] As yet a screening program has not been introduced in the United Kingdom. Much debate has surrounded which method of screening to use; and to a lesser extent which groups to screen, how often to screen them, and what constitutes a positive screening test. High-risk groups (see section 1.2.4.2) have seen a degree of ad hoc screening but there is no national standard and guidelines and criteria are set locally (see Appendix B).

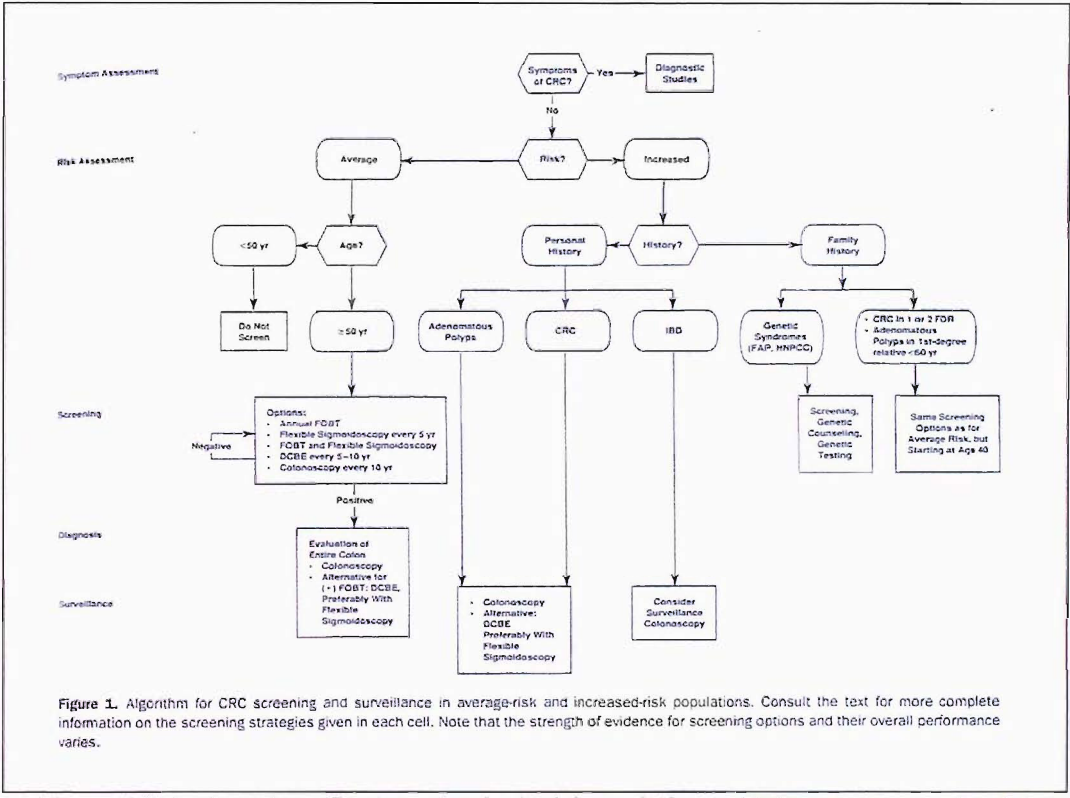


Figure 1.6.4 - American Gastroenterological Association guidelines on screening for colorectal cancer. [reproduced from Winawer et al 1997]

The United Kingdom Government made a commitment to a bowel cancer-screening programme when the health secretary addressed the Britain Against Cancer conference in October 2004. A pilot study was announced which would then be 'rolled out' to the rest of the country (England & Wales) from April 2006. Men and women aged 60-69 will be invited to take part in screening every two years. The screening test will be home FOB testing to be submitted centrally for analysis, those testing positive will then be invited for further investigation by colonoscopy. [NHS Bowel Cancer Screening Programme]

Faecal occult blood testing has the advantages that it is relatively cheap, convenient, and acceptable to the target population. Unfortunately it is known to miss many polyps and some cancers, though the low cost and high acceptance indicate that it would be tolerated at a higher frequency (annually or biennially) than the alternatives. [Winawer et al 1997] Reported sensitivity varies (according to report, test employed, and whether the sample is rehydrated) from 48% to 92% and approaches that increase sensitivity are associated with lower compliance and specificity (and thus an increased false positive rate and over investigation). [Anwar, Hall & Elder 1998]

The most encouraging findings with faecal occult blood screening are a reduction of over 15% in colorectal cancer mortality in the screened group, and an apparent "down staging" of the tumours detected (stage at diagnosis being the strongest known indicator or prognosis). Dukes A tumours have been reported in 22% of cases in screened groups in comparison to 11% in controls; Dukes C tumours are also seen significantly less frequently.

[Hardcastle et al 1997; Anwar, Hall & Elder 1998] A positive result at faecal occult blood screening is followed by referral for full colonic assessment by either colonoscopy or barium enema & flexible sigmoidoscopy.

The experiences of the Minnesota Study however suggest that a massive (possibly unattainable) increase in workload would result from a screening programme. They reported a screened population of 30,000 required 12,246 colonoscopies over a 5 year period, and this did not take into account those patients investigated outside the main study programme (almost 20% of those undergoing investigation). [Mandel et al 1993]

Flexible sigmoidoscopy is an alternative screening modality and a reasonably well-tolerated, short procedure. The procedure has high sensitivity and specificity for the length of bowel examined, in skilled hands examination to 50cm from the anal verge will miss as few as 0.168% of cancers. [Dodds & Thompson 1997] The drawback of flexible sigmoidoscopy is that it cannot detect proximal cancers and adenomas; with over 70% of proximal tumours having no associated distal lesions these cases will not be referred on for full colonic assessment and they will be missed. [Anwar, Hall & Elder 1998]

Another point of contention is which findings should be considered positive and provoke full colonic investigation. On the whole features such as polyp size >1cm, 3 or more small adenomas, villous histology or severe dysplasia are considered positive but subtle differences in protocol do occur. [Atkin et al 2002; Winawer et al 1997]

Encouragingly up to two-thirds of carcinomas and adenomas are within reach of a 60cm flexible sigmoidoscope and studies show a 30% reduction in

colorectal cancer deaths for cancers within this length of distal colon and rectum. [Anwar, Hall & Elder 1998; Atkin et al 2002]

The population group targeted by screening must be carefully selected and is dictated by age bands. The peak incidence of colorectal cancer is in the 7th decade of life and as such the consensus is that screening should be offered to the 55-64 age group (though this band does vary in size from study to study); this takes into account the 10+ years the adenoma-carcinoma sequence is believed to take to progress. [Anwar, Hall & Elder 1998; Atkin et al 2002; Hardcastle et al 1996; Winawer et al 1997] Doubtless the age bands will become better defined as experience and data grow.

2 - STUDY DESIGN

2.1 RATIONALE BEHIND STUDY SELECTION

2.1.1 Demand on services

The number of patients with colorectal symptoms referred to surgical out patient clinics is high; and numbers appear set only to increase as public awareness and initiatives within the NHS take effect. The introduction of the 2-week standard for suspected colorectal cancer effectively introduced a two-tier system in colorectal services. Patients with high-risk symptom clusters suggestive of colorectal cancer are “cherry picked” to be seen sooner because as a group they are more likely to have colorectal cancer and benefit from an expedited diagnosis. The introduction of the 2-week standard was not accompanied by extra clinics and diagnostic facilities specifically for the purpose, but instead relied on a re-organisation of existing services.

This has left a large group of patients with low risk symptom clusters for colorectal cancer who will in the majority of cases still require full colonic imaging in order to rule out malignancy and offer reassurance. On symptoms alone it is impossible to accurately discriminate between malignancy, other GI conditions (e.g. diverticulosis, colitis), and variations on the norm. The incidence of colorectal cancer in this group is low, but in such a large group this equates to considerable numbers of patients with colorectal cancer. With emergency presentations accounting for around 20% of colorectal cancer presentation and if the 2 week wait system identifies 30% this still leaves 50%

of colorectal cancer patients in the low risk group. How can we best serve this group made up of cancer patients, patients with non-malignant conditions, and those with no underlying disease?

2.1.2 Current practices

There are at present no guidelines for the management of patients with low risk symptom clusters though the overall aim must be to investigate, diagnose, and treat those with disease as swiftly as possible while also investigating and offering reassurance to those who do not, with the same timeliness. There are 2 main divisions in treatment strategy: to see patients in the outpatient setting first and then decide on investigation, or to send patients directly for investigation and then follow-up as appropriate. There is no published scientific evidence to suggest which of these strategies may be preferable. The evidence supporting the use of one strategy over the other is anecdotal at best and usually based on the personal preferences of the clinician involved and the availability of resources.

2.1.2.1 Usual care (outpatient appointment first)

Seeing all patients in clinic prior to deciding on investigations could in some instances be seen as a waste of resources. When a referral letter lists symptoms that effectively make full colonic investigation mandatory, why waste the patient's time and an outpatient slot if investigation is inevitable?

The outpatient clinic does allow a more detailed history taking and examination than a referral letter can possibly offer, however, and the clinician may then embark on quite a different set of investigations or indeed none at

all. Interaction with the “specialist” builds a patient’s confidence in the process and allows them the opportunity to ask questions and allay fears.

2.1.2.2 Direct investigation

Sending patients directly for investigation promises to reduce the time a patient has to wait before they are given meaningful information, reduce the number of visits a patient has to make to hospital, and free up outpatient slots (with the knock-on effect that the care of patients for whom an outpatient appointment is required first will be expedited). The risks are that patients may be sent for investigation when they may not have been if seen in clinic first (thus using up precious resources and exposing patients to un-necessary risk), and that patients who are too frail or ill may be referred for unsuitable investigations. The patients are also not afforded the opportunity to ask questions and may be confused as to what is happening (and so jeopardising compliance).

	ADVANTAGES	DISADVANTAGES
OUTPATIENTS FIRST	○ Greater detail to history ○ Patient has opportunity to ask questions.	○ Wasted resource if investigation is inevitable.
DIRECT INVESTIGATION	○ Decreases waiting time ○ Frees outpatient slots	○ Unnecessary investigations ○ Patient unable to ask questions

Table 2.1.2- Advantages and disadvantages of different patient management strategies.

2.1.2.3 What is best?

When comparing treatment strategies it is necessary to identify quantifiable variables on which to base the comparisons. Measurements can include time to reach end point, number of patient visits (as an indirect measure of patient

inconvenience/cost), cost, and patient satisfaction (which requires a psychometric tool in the form of a questionnaire). Comparisons made between these variables are necessarily subjective: which can be said to be better, a swift expensive strategy that elicits poor patient satisfaction, or a slower cheaper strategy with high reported patient satisfaction?

2.2 STUDY DESIGN

2.2.1 The process and evolution of this study's design

This study's design has principally been collaboration between The Southampton General Hospital Department of Surgery and The University of Southampton Health Care Research Unit. Prior to a study design time was taken by the researcher to visit several NHS trusts to meet local surgeons with a colorectal responsibility in order to discuss their management strategies (for "low risk" colorectal referrals) and the intentions for a study; comments received during this process helped to shape and direct the overall study design.

2.2.2 Prospective

In order to accurately compare a management strategy of direct investigation with a more traditional approach of an outpatient visit prior to any investigations being requested (usual care) a prospective randomised trial is required.

As already discussed above the number of colorectal referrals is steadily increasing, with the knock on effect of increased demands on diagnostic services; a situation which progresses from week to week and month to month. The use of historical controls or changing management strategies in series (i.e. 6 months of usual care followed by 6 months of direct investigation) followed by retrospective comparisons exposes all data to distortion by changing demands which a parallel study design will remove.

2.2.3 Randomisation and concealed allocation

Randomisation is essential in order to control for confounding, and concealed allocation to control for the effect of clinician choice. Were a clinician responsible for determining which study group a patient should be allocated to the study would cease to compare the effectiveness of the groups but would instead be assessing a clinician's ability to choose an appropriate management strategy for a patient. (See section 4.2.10)

2.2.4 Patient Suitability

A strategy of direct investigation would not be suitable or justifiable for all patients referred to colorectal outpatients; a set of inclusion and exclusion criteria had to be developed (see Appendix C). While setting down the study inclusion and exclusion criteria it was vital to consider the referral guidelines for the "fast track"/2-week wait clinics. As these guidelines do vary between trusts (see Appendix A) the decision was made to set down inclusion/exclusion criteria that can be applied to all colorectal referrals with the awareness that there will be some overlap with "fast track"/2-week wait guidelines at the local level. The decision of where to refer new patients remained with the General Practitioner; local referring GPs were kept ignorant as to the inclusion/exclusion criteria of the study.

2.2.4.1 Inclusion Criteria

The inclusion criteria were chosen in order to select patients for whom full colonic investigation would appear to be mandatory if the symptoms alluded to in the GP referral letter were accurate. When introducing a direct

investigation management strategy the hospital clinician must be able to rely on the information provided by the GP; to introduce a system for double-checking symptoms where the patient is contacted by the hospital before they are deemed suitable for direct investigation would negate some of the expected benefits of such a scheme (i.e. reduced waits and hospital events).

The “cardinal” colorectal cancer symptoms of change in bowel habit and/or rectal bleeding were the chief inclusion criteria. In addition patients referred with “haemorrhoids” and any mention of blood mixed with the stool or a change in bowel habit were also included. Colorectal conditions are not mutually exclusive and the presence of more than one is not unusual; taking the first possible source of bleeding to be the actual cause carries the risk of missing the true cause of bleeding in the more proximal bowel. Haemorrhoids are common and co-existence with other conditions is also common; one study has reported haemorrhoids in as many as 63% of patients with confirmed colonic lesions. [Goulston, Cook & Dent 1986]

2.2.4.2 Exclusion Criteria

The exclusion criteria were selected for a variety of reasons. Firstly to exclude those patients for whom reassurance in the presence of normal test results would not appear the main aim. Secondly to exclude patients likely to have normal investigations. Thirdly to avoid recruiting patients for whom any of the study’s investigations would not be appropriate.

The exclusion of patients under 45, and 90 or over, was for different reasons. The age of 45 is employed as a demographic age range limit in many of the United Kingdom's official publications on health statistics. [Coleman et al 2000; Quinn & Babb 2000] Although colorectal cancer does occur in the under 45s the numbers are low with age specific incidence being the lowest by far of all the demographic groups (see Figures 1.1.2a & 1.1.2b); the 15-49 age range accounts for only 5.3% of all colorectal cancers detected in England & Wales. [Coleman et al 2000] Routine investigation of the under 45s is unlikely to reveal significant colorectal disease; as such the risk to the patient and use of a limited resource has not been justified for the purposes of this study.

Patients aged 90 and over were excluded because of an expected increase in the incidence of co-morbidity or frailty, which would make some of the study methods undesirable or unmanageable for that group.

For similar reasons patients with known multiple co-morbidities were also excluded from the study if it was felt that any of the study's methods would be undesirable for that particular patient (as selection occurred prior to randomisation to study group).

For patients with abdominal pain the principal objective of referral is a resolution of the pain. A management strategy focusing on prompt investigation and reassurance if the tests prove normal is not likely to achieve this and so patients referred with pain were excluded. For certain conditions commonly presenting with pain the risks associated with the study

investigations would be increased (e.g. perforation in active diverticulitis) and as such clinical assessment is desirable prior to any invasive investigations.

Patients with a palpable abdominal or rectal mass were excluded from the study. This group of patients require urgent assessment and investigation and should have been referred along the 2-week wait/"fast track" route in all cases.

Patients with "exit bleeding" (scant bright red blood often on the paper only, thought to be of anal canal origin) or perianal symptoms (pain/pruritis/soiling) were also excluded. Although unpleasant for the patient these symptoms are rarely associated with significant colorectal disease; one study reports that the positive predictive of rectal bleeding for colorectal cancer falls from 1:18 in isolation to 1:148 when combined with perianal symptoms. [Dodds et al 1999] Perianal symptoms are also likely to make investigations such as endoscopy or barium enema an even more unpleasant experience than the norm.

2.2.5 A three-armed study

A three-armed structure was decided upon in order to compare usual care (outpatients first) with two methods of direct investigation; namely colonoscopy alone, and barium enema supplemented by flexible sigmoidoscopy. This reflects the options widely available across the UK.

Usual Care
Colonoscopy
Barium Enema & Flexible Sigmoidoscopy

Figure 2.2.5- The three study arms

2.2.5.1 Usual care

As detailed in section 2.1.2.1 clinician evaluation in the outpatient department determines both if investigation is necessary and what avenue it should take.

2.2.5.2 Direct Investigation

The merits of sending selected patients directly for full colonic investigation have been discussed above (section 2.1.2.2). Colonoscopy, and Barium enema with flexible sigmoidoscopy are recognised as the two widely available and comparable methods of full colonic investigation (Guidelines for the Management of Colorectal Cancer 1996) and are discussed in detail in section 1.2.6. While these two approaches use different techniques (and as a result have different strengths/weaknesses/complications) they are by and large seen as complementary rather than competitive, it being necessary to use more than one investigative modality in a small number of patients. [Wolfe et al 1975]

2.2.5.3 Relative costs

The relative advantages and shortcomings of the various investigative techniques are of vital importance when determining which to utilise, but so is relative cost in a health service with finite funding.

As an aside to the Nottingham faecal occult blood colorectal cancer screening program the study group published a paper comparing the costs of the different investigative modalities. [Walker et al 1991] While reporting the average local cost of performing colonoscopy, DCBE, and flexible sigmoidoscopy as £92, £39, & £26 respectively (making the DCBE with

flexible sigmoidoscopy the cheaper option) it was stressed that cost effectiveness was highly susceptible to local factors. The cost implications of delayed treatment when a malignancy is missed in a false negative report, the expense incurred by false positive DCBE necessitating colonoscopy, or the additional expense of an incomplete colonoscopy requiring completion by DCBE all having the potential to greatly effect the investigation's relative costs. The most cost effective strategy is dependant on local sensitivity & crossover referral rates rather than the basic costs of the tests.

2.2.6 Setting an endpoint

All studies require an end point, a specific event against which measurements can be made. Many medical trials assessing the effects of treatment employ patient death as a valid and easily defined endpoint. In a study where patient survival is not expected to be affected an acceptable alternative is required. An end point should be clearly and simply defined, should be relevant to the intervention being measured, and should be identifiable for all patients (unless they withdraw from the study).

In order to be relevant to all patients regardless of study arm the end point was set as –

The date on which the patient was informed of:

- i) diagnosis or***
- ii) discharge with reassurance or***
- iii) the need for further investigation.***

2.2.7 Measurements

A number of measurements were made to facilitate comparisons between the three study arms. The primary measurements of the study are time taken to reach end point (from receipt of referral letter) and patient satisfaction.

Records were also kept of the number and nature of hospital appointments including those cancelled/rescheduled in order to assess financial implications for the NHS and the patient.

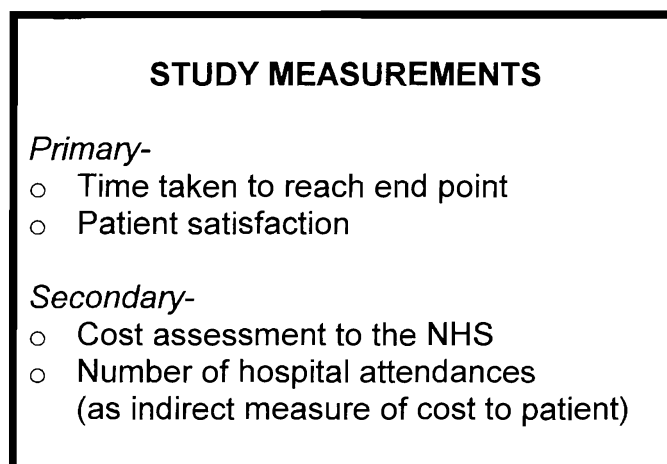


Figure 2.2.7- Primary & secondary study measurements.

2.2.8 The Concept of patient satisfaction

Patient satisfaction has its origins in consumer satisfaction. Over the last 20 years health care services have taken the lead from industry in measuring consumer's (patient's) satisfaction with the services being sought. Healthcare has often been described as a service industry and as such is subject to the same forces. [Baker 1991]

Healthcare in the United Kingdom is not as subject to market forces as in the United States. In the United States the majority of healthcare is purchased specifically by the patient, and as a result is subject to the phenomenon of

“shopping around” seen in any service industry. Even where health care is not purchased directly recent decades have seen a definite increase in consumerism within health services. [Linder-Pelz 1982] This has resulted in an increasing interest in the concept of patient satisfaction over the last 20 years. [Carr-Hill 1992]

2.2.8.1 What is patient satisfaction?

When patient satisfaction is discussed most people understand what is meant but how deep does this understanding go? It is often said that you only truly understand something if you can explain it to another; how do we define patient satisfaction?

Many definitions of patient satisfaction have been forwarded but one of the briefest (and simply comprehended) defines patient satisfaction as –

“A health care recipient’s reaction to their care; a reaction that is composed of both a cognitive evaluation and an emotional response” [Fung & Cohen 1998]

2.2.8.2 Why is patient satisfaction important?

Although initial patient satisfaction work was borrowed from industry for a similar purpose (i.e. for financial concerns) it has developed beyond that and has implications far beyond the strictly financial.

A satisfied patient is an objective of healthcare, as most providers in the majority of situations would like to fulfil the wishes of the patient; this makes

satisfaction an outcome that should be measured. [Fitzpatrick 1991; Williams & Calnan 1991; Baker 1991]

WHY IS PATIENT SATISFACTION IMPORTANT

- It is a goal of health care
- Influences behaviour
- Influences health outcomes
- Political
- Measure of quality

Table 2.2.8.2- Reasons for measuring patient satisfaction

Satisfaction can dramatically affect a patient's behaviour in terms of compliance with medication and instructions (e.g. lifestyle changes). It can also affect other behaviours such as re-attendance with the same problem or the seeking of a second opinion (which can be an unnecessary drain on resources). [Linder-Pelz 1982; Carr-Hill 1992] Satisfaction can also influence health outcomes either indirectly through its effect on patient behaviour, or directly through psychological effects (which has increasing importance with the high level of chronic disease seen in the population and the long-term care demands it entails).

Over recent decades there has been both a social and political drive towards a more patient centred healthcare system away from the paternalistic practices seen during the NHS's infancy. The NHS and its performance are a political hot potato, and set to remain high on the political agenda. Even in the absence of all other factors patient satisfaction will remain important for this reason alone. [Carr-Hill 1992]

Patient satisfaction can also be used as a yardstick, a general benchmark based on patients' values by which the performance of health care services can be measured. [Collins 1996; Carr-Hill 1992; Fung and Cohen 1998]

Patient satisfaction can offer feedback on every step of the health care process with a single measurement. [Collins 1996] It can also reflect the performance of facets of health care that are not easily examined in any other way, such as compassion, bedside manner, attendance to patient needs, patient participation, communication, or the provision of information. [Fung & Cohen 1998]

Most importantly in the context of this study patient satisfaction may be used to discriminate between different methods of organising or providing health care services. [Fitzpatrick 1991]

2.2.8.3 How is a patient's satisfaction determined?

To a large degree a patient determines their level of satisfaction subconsciously and instinctively: very rarely in every day life does an individual think about whether or not they are satisfied with a situation or events, they simply know. Asking someone to think about and explain the satisfaction they have derived from an event may alter how they have perceived that event and thus the degree of satisfaction they have experienced.

It is widely accepted that satisfaction is determined by the congruence between what is expected and what is experienced, the patient beginning with a "comparison standard" against which care is judged. [Fung & Cohen 1998]

It is important to realise that satisfaction is both relative and changeable,

altering between individuals, situations, and over time. [Goldstein, Elliott & Guccione 2000]

The “comparison standard” will vary according to the individual patient and the care setting. In broadest terms what the patient considers to be the ideal standard of care, the minimum acceptable standard of care, and the level of care they deserve will determine their “comparison standard”. [Fung & Cohen 1998] These in turn rely on the patient’s previous experiences, life style, individual values, and the values of the society in which the patient lives. [Carr-Hill 1992]

TEN CONSTRUCTS OF SATISFACTION
○ Access / convenience ○ Availability ○ Continuity of care ○ Efficacy / outcome ○ Finances ○ Humaneness ○ Information gathering ○ Information giving ○ Pleasantness of surroundings ○ Quality / competence

Table 2.2.8.3- Examples of patient satisfaction factors.
(From Linder-Pelz 1982)

A patient’s satisfaction can also be divided into different factors (also confusingly referred to as facets, dimensions, constructs, components, or domains), aspects of a patient’s care that can be considered separately (either consciously or subconsciously) but which in combination amount to a patients overall satisfaction with their care. [Goldstein, Elliott & Gucciane

2000] The number, nature, and individual importance of satisfaction factors is again dependent on the health care situation.

2.2.8.4 How is patient satisfaction measured?

The meaningful measurement of patient satisfaction is notoriously difficult.

[Baker 1991] Not only does the measurement of patient satisfaction seek to place an objective value on a subjective phenomenon, satisfaction also differs between individuals and over time. [Carr-Hill 1992; Goldstein, Elliott, & Guccione 2000] Many approaches have been used to try and meter patient satisfaction; from verbal or written feedback, patient participation in the planning of future services, one-on-one interviews, and focus groups.

When it comes to the actual measurement of satisfaction a standardised survey instrument (i.e. a questionnaire) is most frequently employed.

[Goldstein, Elliott & Guccione 2000]

The main problem with assessing patient satisfaction is that patients uniformly express high levels; the so called “halo” effect where the patient’s response is believed to be an attempt to praise, reward or avoid upsetting those responsible for their medical care. [Fung & Cohen 1998] It is only with increasingly detailed questioning that greater levels of dissatisfaction start to be revealed. [Williams & Calnan 1991]

How a questionnaire is posed is also of vital importance if responses are to be of any use. A patient is far more likely to express dissatisfaction with care if they are completing an anonymous postal questionnaire in the comfort of their own home at a distance from events (both in time and place) than if they are

asked face-to-face questions, in the hospital, by the person responsible for their well being! One extreme example of poor execution rendering all measurements near to useless was a 1978 anaesthetic satisfaction survey in which patients participated in a post operative face-to-face interview-

“100% of patients were satisfied including one lady who remembered her surgery and would prefer to be asleep the next time!” [Fung & Cohen 1998]

2.2.9 Sample size

It is normal practice to perform a power calculation to determine the number of recruits a study will require in order to detect a statistically significant differences between study groups. To perform a power calculation data on the norm (prior to any study intervention) is required.

In the case of this study a dataset on previous colorectal referrals detailing time from receipt of referral to the patient reaching the equivalent of the study end point was required, but turned out to be not available. These data are not routinely kept, with retained data concentrating on waiting lists for outpatient appointments & treatment. A retrospective search for data on these patients was unsuccessful. There is no current database available which will allow the identification of all patients referred with colorectal symptoms (all patients must be detected if bias is to be avoided). For the few patients who were identified the record keeping was not detailed enough to identify the time at which the patient was informed of diagnosis/discharge/further investigation (the study endpoint); this was not unexpected as interest in when the patient

is informed of the outcome of their tests has not historically been a healthcare priority.

In the absence of a power calculation it was decided that all available patients should be recruited if possible. It was estimated that 450-600 suitable patients would be available at the primary site during the planned recruitment window of 1 year, more if the study was extended to a further site. In the event, however, manpower limitations restricted the study to a single site.

2.2.10 Study site

The study was conducted at Lymington Hospital, Southampton Road, Lymington, Hampshire. Part of the New Forest Primary Health Care Trust, Lymington Hospital does not conform to a stereotypical NHS hospital type being neither a district nor cottage hospital. At the time of the study the hospital had 3 wards; two twenty bed wards and a 10 bed admission ward. The hospital accepted emergency medical admissions and elective surgical admissions; there was also an Accident & Emergency department (not 24hrs) which accepted blue-light ambulance cases.

Specific to this study Lymington Hospital provided a consultant led surgical outpatient service, an endoscopy unit (staffed by consultants, associate specialist, staff grade, and clinical assistants), and radiology services including barium enema examinations. The hospital serves the population of the southern New Forest; this tends to be a static elderly population.

2.3 ETHICAL APPROVAL AND DISSEMINATION OF INFORMATION

Full ethical approval for the study was obtained from the Southampton & South West Hants Local Research Ethics Committee (LREC) in June 2001 (see Appendix D).

As part of the LREC's requirements the New Forest Primary Healthcare Trust's data protection officer and Caldicote Guardian were informed of the study's aims, purpose, and design.

It was essential that NHS staff who may encounter the study or participating patients be aware that a study was being conducted. This was necessary not only as part of professional etiquette but to also allow the raising of questions in order to encourage co-operation and avoid confusion.

2.3.1 Referring General Practitioners

Prior to commencing the study Mr James Smallwood (Consultant General Surgeon responsible for endoscopy services at Lymington Hospital) contacted the lead partners of referring practices by telephone, explaining the intention to conduct the study and its reasons and potential benefits. Practices were offered the opportunity to arrange a lunchtime practice meeting where the researcher would make a small presentation and answer any questions. GPs were purposefully kept ignorant as to the study's inclusion and exclusion criteria so as not to influence referral practices; they were simply encouraged to provide as much pertinent information as possible.

Once the study had commenced, referring GPs were sent an information letter as detailed in section 4.2.5.

2.3.2 Endoscopy Staff

A meeting with involved medical and senior nursing staff was organised prior to the study beginning. The researcher was known to the endoscopy unit staff though not involved with the unit's running. As such the researcher was available to answer any questions.

2.3.3 Radiology Staff

The consultant radiologists, radiographers, and department clerical staff were fully informed participants in the study. Again the researcher was known to the staff but not involved in the department's running.

3 - THE HYPOTHESIS

3.1 STUDY AIMS

The underlying aim of this study was to investigate whether, for selected groups of patients, a management strategy of “direct investigation” and informing the patients of results as a priority could-

- i. speed an individual's progression along the patient pathway, and
- ii. reduce the number of hospital visits necessary to do this (there by saving resources and reducing costs to patients)
- iii. while maintaining or improving the level of patient satisfaction.

Neither the methods of investigation employed by “direct investigation” or the health outcomes it achieved were expected to differ from the more conventional management approach, the differences are a matter of process and health services delivery.

3.2 NULL HYPOTHESIS

In order to meet the study aims it was necessary to test the following hypotheses –

Time

- Outpatient management strategy does not affect the number of days it takes a patient to reach the study end point (from the receipt of their GP's referral letter).

Costs

- Outpatient management strategy does not affect the costs incurred by the NHS in order that the patient reach the study end point.
- Outpatient management strategy does not affect the number of hospital visits a patient must make in order to reach the study end point.

Outcomes

- Outpatient management strategy does not affect the expressed level of patient satisfaction.
- Outpatient management strategy does not affect the nature of the study end point.

4 - PATIENTS AND METHODS

4.1 INTRODUCTION

The study was conducted at Lymington Hospital in close association with the Health Care Research Unit and Department of Surgery at Southampton General Hospital. The rationale behind the study's inception and design is detailed in section 2.0; it was also hoped that study findings would help to guide a reorganisation of colorectal investigative services at Lymington Hospital as the existing model was considered not to be optimal.

A single medically qualified researcher conducted all research. While the researcher had NHS service commitments at Lymington hospital none involved the care of patients within the study.

Patient recruitment commenced 1/10/2001 and terminated 31/12/2002.

Recruited patients were randomised to three study arms. The study arms consisted of three accepted outpatient management strategies for colorectal outpatient referrals –

1. Colonoscopy
2. Barium Enema & Flexible Sigmoidoscopy.
3. Usual Care (outpatient appointment).

Patient progress along the patient pathway was followed and documented until the study end point was reached. The Study end point was taken as the time at which the patient was informed of a diagnosis, their discharge (with

reassurance and an account of test results), or a need for further investigation/treatment.

Once study endpoint had been reached all patients were sent a purpose developed patient satisfaction questionnaire (see section 5.0).

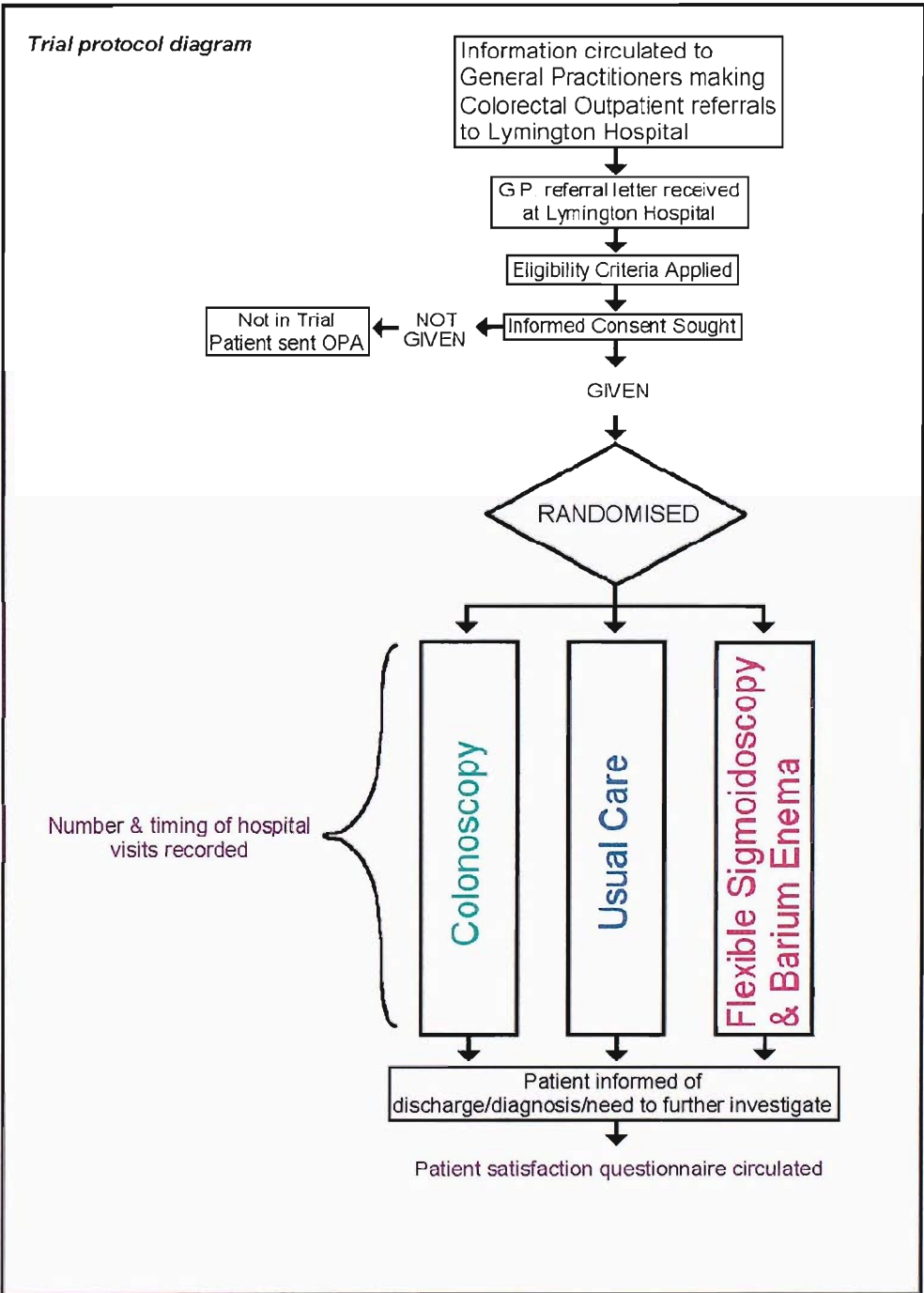


Figure 4.1 – Trial protocol

4.2 PHASE 1 - PATIENT RECRUITMENT AND RANDOMISATION

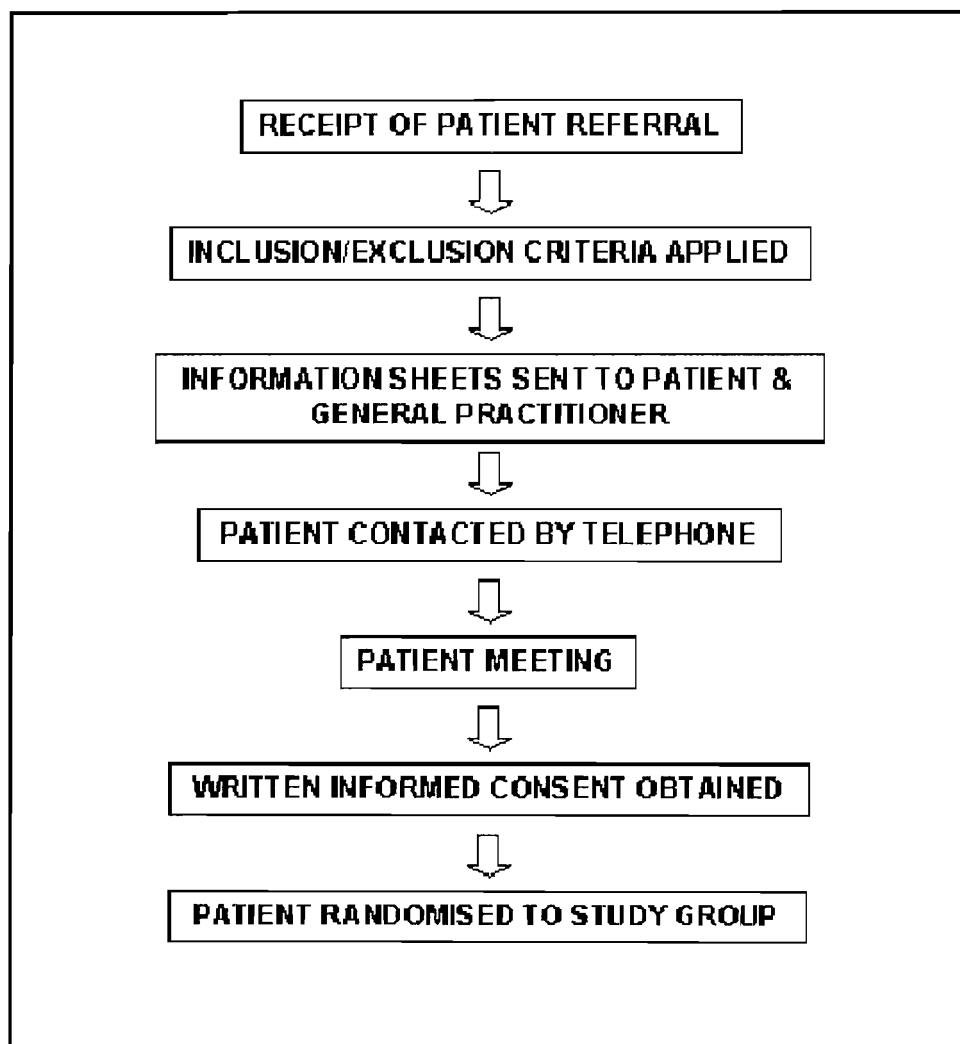


Figure 4.2 - Phase 1 - Patient recruitment & randomisation

4.2.1 Recruitment Window

The study recruitment window was 1/10/2001 to 31/12/2002. In the absence of a power calculation to indicate the number of recruits required the initial plans were that study recruitment would last for one year.

For a two month period (June – July 2002) illness on the part of the single researcher resulted in a suspension of recruitment, on return to fitness the recruitment window was extended by three months to compensate. At the

time of injury a number of patients were in the first phase of the trial, the management of this situation is detailed in results section 6.1.1.

4.2.2 Patient Identification

Possible study recruits were identified from two sources at Lymington Hospital; surgical outpatient referrals and referrals made to the day case/endoscopy unit as part of the open access endoscopy service. A check was made on new referrals 3 times weekly (Monday/Wednesday/Friday).

4.2.3 Patient Eligibility

Once identified all patients were screened according to the study inclusion/exclusion criteria, the results recorded on a purpose designed form. Only information provided in the referral by the GP was used to determine study eligibility (See Appendix C).

Inclusion	Exclusion
○ Change of Bowel habit <i>(change in frequency/consistency)</i> ○ Rectal Bleeding <i>(blood on/mixed with stool).</i> ○ Haemorrhoids <i>(in combination with blood mixed with stool &/or change of bowel habit)</i> ○ Change BH & Rectal Bleeding	○ Age 45< or >90 ○ Multiple co-morbidities ○ Abdominal pain ○ Abdominal/Rectal mass ○ Exit Bleeding ○ Perianal Symptoms

Figure 4.2.3 - Study inclusion / exclusion criteria

Once identified as eligible the patient's referral was "sidelined" while informed consent was sought to prevent the referral being acted upon more than once. "Sidelined" referrals were placed within a clearly marked folder identifying them as possible study participants and that they should not be acted on or removed; the folder remained with the other referrals so that referrals could be located by other staff if required (e.g. patient or GP enquiry).

A patient detail sheet was completed for all eligible patients (See Appendix F). A patient study record form was also started documenting the date of the referral, the date the referral was received, and the date the inclusion/exclusion criteria were applied (See Appendix G).

4.2.4 Patient Information

Once identified as eligible for study participation patients were sent a Patient Information Sheet by post (See Appendix H). The information sheet detailed why the patient was being approached, what it was hoped the study would achieve, and what study participation would entail (and how it differed from the norm). Patients were informed in the information sheet that a researcher would contact them by telephone approximately 1 week after receiving the mailing.

4.2.5 General Practitioner Information

The referring General Practitioner of patients approached to participate in the study was also sent an information pack. This pack contained a copy of the GP Information Sheet, a copy of the Local Research Ethics Committee letter giving the study approval, and the Patient Information Sheet (See Appendices

E D & H). A register of GPs to whom information had been sent was kept to avoid repetition; referring GPs were sent the information pack only once.

4.2.6 Telephone Contact with Patient

Telephone contact with the patient was first attempted 7-10 days following the posting of the patient information sheet and continued for a maximum of 10 days following the first attempt. Patients were contacted on their home number (unless the patient left instructions otherwise). No attempt was made to contact patients after 7:30pm or at weekends (unless the patient left instructions otherwise). If patients made contact with the researcher before the follow up call (a contact telephone number was provided in the Patient Information Sheet) the study progressed as though the researcher had made contact. If the patient requested that the researcher made contact again at a later date arrangements were made to do so.

No strict formula was set for the telephone conversation, as this would be unnatural and unacceptable. During the telephone conversation attempts were made to cover a number of points but only if deemed appropriate by the researcher-

- Has the patient received the information sheet and had an opportunity to read it through to their satisfaction?
- Did the patient understand why they had been contacted and invited to participate in a research study?
- Were there any questions the patient would like to ask?
- Would the patient be interested in participating in the study?

- Would the patient be willing to arrange a short meeting with the researcher where further questions could be asked, the study discussed, and if still willing to participate a consent form signed?

The telephone conversation with the patient produced one of three outcomes-

1. The patient's symptoms had resolved and/or the patient did not desire any hospital appointments. In this instance patients were told to discuss their wishes with their (referring) GP, and the referral letter was returned to the referral pool to be acted upon as normal and not as part of the study.
2. The patient did not wish to participate in the study. In this case patients were politely asked if there were any specific reasons that had led them to not accept the offer to participate, any offered reasons were documented. The referral letter was returned to the referral pool to be acted upon as normal and not as part of the study.
3. The patient expressed an interest in participating in the study and agreed to a meeting with the researcher. A meeting was then arranged for a time and place convenient to the patient, usually in the patient's home.

4.2.7 Inability to Contact the Patient

When attempts to contact the patient had failed for 10 days following the first attempt further efforts were abandoned. The patient was sent a personalised letter explaining that the study team had been unable to contact them and that their referral would be dealt with in the normal way; the referral letter was

returned to the referral pool to be acted upon as normal and not as part of the study (see Appendix I).

4.2.8 Patient Meeting

In general the patient meeting was conducted in the patient's home. The length of the meeting was governed by the patient, and influenced by the number of questions they had to ask and the depth of answer the question demanded. The patient meeting had several specific goals-

- To enable the patient to ask questions and clarify any aspects of which they were unsure.
- To give the researcher the opportunity to outline the study, what it may involve, and what the patient could expect.
- To satisfy the researcher that the patient understood what study participation would entail and that they were capable of giving informed consent.

The duration of the patient meeting varied from 5 to 50 minutes; this necessitated careful organisation of appointments to give the patient as much time as they required and avoid rushing discussions.

4.2.9 Consent

Once the needs of the patient and the researcher had been met written consent was obtained. This involved patient and researcher signing 3 copies of the study consent form (see Appendix J) one copy of which was retained by the patient. In the event that the patient did not give written informed consent

the referral letter was returned to the referral pool to be acted upon as normal and not as part of the study.

4.2.10 Randomisation

Prior to study commencement sequentially numbered sealed envelopes were prepared containing randomised allocations to one of the three study arms.

The randomisation method employed was a single 6-sided die, with opposite sides (1&6, 2&5, 3&4) representing the three study groups. This method was selected in preference to computer generated random numbers as many computer/calculator random number generators are pseudorandom, recording and taking into account previously generated numbers. Mechanical means of random number generation are not subject to this flaw.

Patients were allocated a patient identification number according to the sequence in which they had given written informed consent. The patient’s study record was marked with their identification number and the corresponding pre-prepared randomisation envelope was then opened and study group determined. This process ensured both randomisation and concealed allocation (the lack of study funding having ruled out remote telephone allocation).

Usual Care
Colonoscopy
Barium Enema & Flexible Sigmoidoscopy

Figure 4.2.10- The three study arms

**4.3 PHASE 2 – PATIENT PROGRESSION ALONG THE PATIENT
PATHWAY**

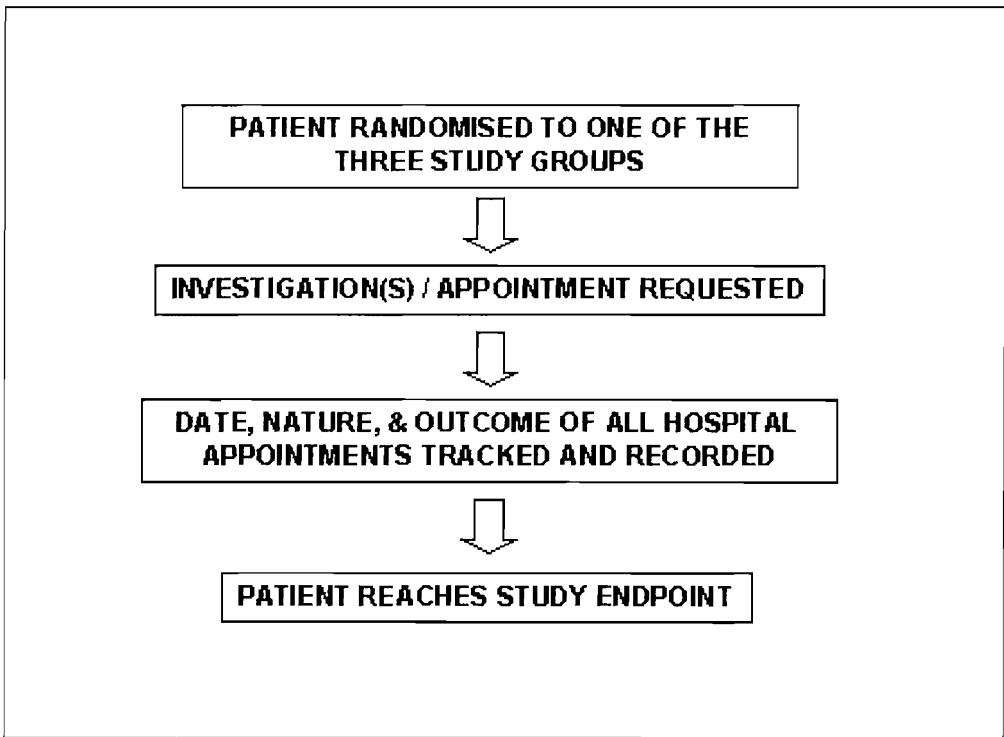


Figure 4.3 - Phase 2 – Patient Progression Along the Patient Pathway

4.3.1 Requesting appointments/investigations

Once the participating patient’s study group had been determined the relevant appointment or investigations were requested. All requests were made through the normal hospital channels and given a “soon” priority. Patients were not singled out as study participants and were not given any preferential treatment.

For “Usual Care” patients an outpatient appointment request was handed to the outpatient department booking clerk marked as “soon” priority.

For “Colonoscopy” patients a colonoscopy request card was handed to the day case bookings clerk marked as “soon” priority.

“Barium Enema & Flexible Sigmoidoscopy” patients had a barium enema request card handed to the radiology booking clerk, and a flexible sigmoidoscopy request card handed to the day case bookings clerk marked as “soon” priority. Both radiology and endoscopy request cards were marked indicating that the other had been requested to avoid booking conflicts (a flexible sigmoidoscopy following a barium enema examination too closely could be compromised by residual barium; while a barium enema following a flexible sigmoidoscopy too closely could increase the risk of perforation had biopsies been taken).

4.3.2 Intention

For the purpose of data analysis patients were assessed on an “intention to investigate” basis. Situations did arise during the course of the study where patients received treatment or appointments other than those the initial group randomisations would suggest (i.e. due to technical difficulties, incomplete examination, change in clinical picture), regardless of this all patients remained in their initial study groups.

4.3.3 Tracking patient progress

The date and nature of all appointments made for study participants were identified through the main hospital, and separate radiology, computer appointment records. This information was then recorded on the patient study record form (See Appendix G). Checks were made on a weekly basis to identify any changes. When appointments were cancelled/rescheduled the

time and reason was documented (when this data was available) to assist later economic evaluation.

4.3.4 Outcomes and Informing the patient

For the “Usual Care” group the results of any investigations were allowed to return to the outpatient clinic through the normal channels where they were acted upon by the requesting clinician.

For patients in the “Colonoscopy” group results were available either on the day of the examination or following the histological reporting of biopsies.

Dependant on the clinical situation patients were either seen in outpatients or written to. Patients requiring follow-up were sent an outpatient appointment (based either on the findings of the colonoscopy or following histological reporting). Those not requiring follow-up received a letter giving an account of the colonoscopy findings, an explanation of any diagnosis, and any relevant advice.

For patients in the “Barium Enema & Flexible Sigmoidoscopy” group two results were required. The barium enema required formal reporting but this was often completed on the day of the examination; following flexible sigmoidoscopy results were available either on the day of the examination or following the histological reporting of biopsies. Those patients requiring follow-up (determined by the findings at flexible sigmoidoscopy or following a barium enema or histology report) were sent an outpatient appointment. Those not requiring follow-up received a letter giving an account of the

investigation findings, an explanation of any diagnosis, and any relevant advice.

All letters to patients were dictated and then typed by NHS medical secretarial staff; they were not prioritised for immediate attention & were processed in turn.

4.3.5 Reaching the study endpoint

The end point of the study was the date on which the patient was informed of a diagnosis, or discharge with reassurance, or the need for further investigation. For the purposes of this study the patient was only considered to have been informed by one of two modes, either by a doctor in the outpatient clinic or by post. A patient was not considered to have been informed following a conversation on the endoscopy unit when sedation may well have been still in effect, or if a copy of test results was sent to the patient's general practitioner.

For patients reaching the study end point by being informed of results in the outpatient clinic the date of the appointment was recorded. For patients informed of test results by post the date on which the letter was signed and posted was recorded as the study end point.

4.4 PHASE 3 – MEASURING PATIENT SATISFACTION

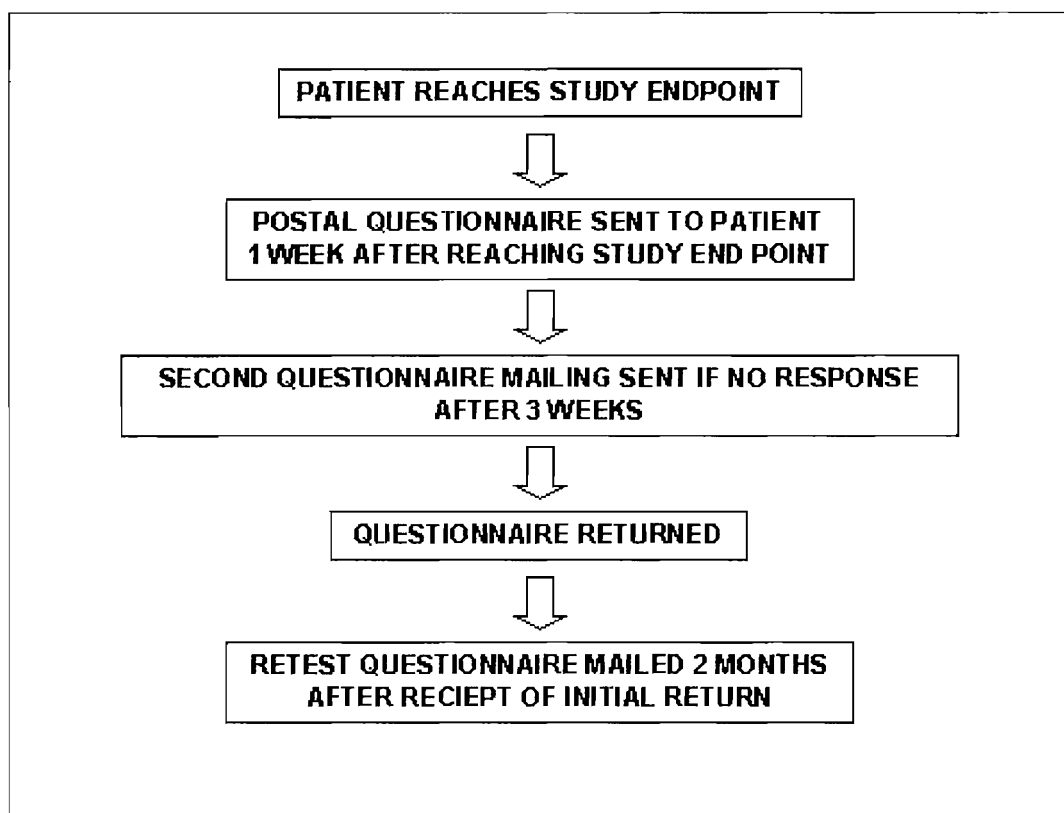


Figure 4.4 - Phase 3 – Patient Satisfaction Questionnaire

4.4.1 Patient Satisfaction Questionnaire

The patient satisfaction questionnaire (see Appendix K) employed in this study was developed during the study's planning and preliminary stages. A detailed account of questionnaire design and development is provided in section 5.

4.4.2 First Mailing

Patients were sent the patient satisfaction questionnaire by post, 1 week after reaching the study endpoint. Questionnaires were posted in a printed envelope, post franked and marked as originating from Lymington hospital. They were accompanied by a printed, signed, personalised letter (See

Appendix L) and a stamped addressed envelope for the return of the questionnaire. The letter explained that the questionnaire was part of the research study in which they had agreed to participate, that the responses were anonymous, and that their opinions now were what the researchers wanted to know (acknowledging that not all patients would have concluded investigation or treatment). The questionnaire was marked with the patient's identification number.

The date on which the questionnaire was posted was entered on the patient study record. The date on which the questionnaire was returned was taken as the date of the postmark and entered on the study record (when the post mark was absent or illegible the date on which the return was received by the researcher was entered in lieu).

4.4.3 Second Mailing

If a return had not been received by 3 weeks following the first questionnaire mailing a second was sent and the fact recorded on the patient study record. The second mailing was identical to the first save for a highlighted note at the start of the personalised letter (see Appendix M).

4.4.4 Re-test

As part of the questionnaire validation process re-testing was required. Patients who had returned the patient satisfaction questionnaire were sent a further mailing 2 months after its receipt. The questionnaire was again marked with the patient identification number and accompanied by a personalised, signed letter and a stamped addressed envelope. The letter

explained that this was part of the questionnaire's development and that it was the patient's current opinions we wished to know, not those held previously if they had changed (see Appendix N). This process was continued only until 20 re-test questionnaires had been returned.

4.5 DATA ENTRY

As data were collected they were entered into a purpose designed SPSS for Windows data base. All data were fully anonymised on a patient by patient basis as data collection for each patient was completed.

5 - QUESTIONNAIRE DEVELOPMENT

5.1 WHY A PATIENT SATISFACTION QUESTIONNAIRE?

The concept of patient satisfaction and reasons for its measurement are covered in section 2.2.8, and are not repeated here.

For the purposes of this study a method of measuring patient satisfaction was required - a psychometric tool. This would facilitate a comparison of patient satisfaction between the three study arms by assigning a numerical value to the satisfaction expressed by each patient; which would then be examined by standard statistical tests. But what form should this psychometric tool take?

5.1.1 The difficulties of measuring patient satisfaction.

The field of patient satisfaction is complex, a situation not aided by a lack of standardised terminology. [Flocke 1997] There are myriad theories as to what determines satisfaction and as yet no theoretical model. Instead of seeking to define the determinants of satisfaction research has tended to focus on its measurement. [Linder-Pelz 1982]

The main issue with measuring satisfaction is the aim to make an objective measurement of a subjective phenomenon. [Goldstein et al 2000] The absolute level of satisfaction measured in isolation is meaningless; these measurements only take on worth when used to make comparisons. [Carr-Hill 1992] In the absence of a model for satisfaction there are no meaningful units, a score determined by the use of a psychometric tool can only ever be

an indication of a patient's satisfaction. [Linder-Pelz 1982] If comparisons of satisfaction are to be fair and accurate the data collected must be comparable, this can be achieved with the use of a standardised survey instrument. [Goldstein et al 2000]

5.1.1.1 Methods of gathering information on satisfaction.

There are many methods of gathering information pertaining to a patient's satisfaction though few will allow its measurement and a score to be allocated. The simplest approach is to assess what data are already available. Letters of complaint (or thanks) can highlight both what is important to a patient and how well their expectations were met. This has the benefit of being spontaneous and unsolicited by the researcher; because as a subjective, relative and dynamic phenomenon, asking a patient to assess their degree of satisfaction is in danger of changing it. Patients offering information spontaneously by letter are in the minority, and not likely to be a representative sample (being composed of those experiencing the extremes of satisfaction). As such this source of data does not satisfy the need for a fair comparison between study arms but can be useful in identifying issues important to patients which the final tool should include if it is comprehensive.

Another method of data collection is direct patient interview. This has several benefits including the detection of non-verbal communication and tone that can significantly change the meaning of the spoken word (e.g. sarcasm). One to one interviews are more likely to gain a response to any given question posed and allow rewording in order to improve clarity. There is also the ability

to probe responses for greater detail and approach sensitive issues. [Barriball & While 1994] While a representative sample may be reached in this way standardisation is almost impossible short of enforcing a rigid interview structure that would negate many of the benefits highlighted above.

Focus groups are a useful way of raising issues with the stimulation of ideas and evolution of viewpoints seen with discussion. It is also an inexpensive way of interviewing several people at once and the interviewer (referred to as a facilitator) can adopt a more passive approach than a one-to-one interview requires, allowing ideas to develop purely from the participant's perspective rather than from starting points suggested to them. [What users and carers have to say 1997] Standardisation of a focus group is impossible as theme and direction are allowed to move in an uncontrolled manner by design. Like the other sources of information above focus groups can identify those issues that should be covered by a psychometric tool, but can not facilitate the measurement of patient satisfaction.

A questionnaire offers the essential standardised component necessary in a psychometric tool but it is limited by only being able to elicit responses to the questions it poses, if the questions fail to tap the determinants of a patient's satisfaction it will fail to be a true measure. A questionnaire must be capable of eliciting respondents' views. [Stone 1993] The development phase of a questionnaire is critical if it is to prove a valid instrument. In order to achieve this questionnaire development follows the structures and guidelines accepted

for the measurement of other psychological phenomenon, such as intelligence. [Fung & Cohen 1998]

5.1.1.2 The multi-dimensionality of satisfaction

While debate rages over the determinants of patient satisfaction one aspect that permeates the literature gaining wide spread acceptance is its multi-dimensional nature. A patient's "global satisfaction" is determined by an interaction of the dimensions. Researchers constantly seek to split satisfaction into a number of technical and interpersonal dimensions but it is unclear as to whether or not patients can or do distinguish between them. [Fung & Cohen 1998]

THE DIMENSIONS OF PATIENT SATISFACTION AS IDENTIFIED BY HALL & DORNAN (1988)

- Overall Quality
- Humaneness
- Competence
- Outcome
- Facilities
- Continuity
- Access
- Informativeness
- Cost
- Bureaucracy
- Attention to Psychological Problems

Table 5.1.1.2- Dimensions of patient satisfaction

Hall & Dornan performed a meta-analysis of 221 published patient satisfaction questionnaires, 107 of which assessed at least two dimensions of satisfaction. From the analysis they published a list of 11 dimensions (Table 5.1.1.2). The

frequency with which these dimensions were included in the questionnaires and their relative importance when they were included varied depending on the clinical situation [Hall & Donan 1988].

A psychometric questionnaire uses multiple items (questions) to examine the different dimensions of patient satisfaction which together generate a measure of “global satisfaction”. [Fung & Cohen 1998]

Difficulty can arise when trying to combine the measures of multiple dimensions into a “global satisfaction” score. While all identified dimensions contribute to global satisfaction they do not do so in equal measures. Key influences on a patient’s “global satisfaction” are the communication of information, professional competence, and the patient-professional relationship. [Carr-Hill 1992; Williams & Calnan 1991] This leads to a question of weighting the component dimensions in a manner that represents their relative importance to the patient and the influence they have on “global satisfaction”. The process of calculating weights is time consuming, expensive, fraught with methodological difficulties and susceptible to challenges of the technique’s validity. A more direct approach is to calculate and compare scores for “global satisfaction” (by simple addition of dimension scores) and scores for individual dimensions.

5.1.1.3 Detecting dissatisfaction.

Eliciting satisfaction among patients is not difficult; it is the detection of dissatisfaction that presents the main challenge. Respondents to UK questionnaires typically report 85-90% satisfaction (though this may be as

high as 100%) with very little variation. [Carr-Hill 1992; Lowe et al 1991] Even on a question-by-question basis patients report satisfaction 80% of the time. [Fitzpatrick 1991] This skewing of responses and lack of variation makes identifying statistically significant differences (between groups & individuals) a difficult proposition. [Fung & Cohen 1998]

Direct, generalised questions such as “were you satisfied with the quality of care you received?” are useless as they evoke a generalised response (which is almost always “yes”). [Improving the Quality of Cancer Services 1997] The more specific and detailed a question is the greater the degree of dissatisfaction expressed. If a satisfaction questionnaire is to be sufficiently sensitive to detect differing levels of (dis)satisfaction then it must be context-specific, examining the various dimensions of satisfaction for the given clinical event in detail by addressing a specific aspect of care with each question. [Carr-Hill 1992; Williams & Calnan 1991; Fitzpatrick 1991]

5.1.1.4 The patient as a judge.

There are questions asked concerning the validity of attempts to measure patient satisfaction and more specifically using the patient as a judge.

- Patients’ assessment of their care will always include a subjective element and, inter-observer variation is therefore uncontrollable.
- Patients can not recall all aspects of their care accurately and are more likely to recall positive events than negative events.
- Patients lack the knowledge and experience to accurately assess the technical competence of their health care providers.

- Patients may be reluctant to express negative views or attitudes towards those on whom they are dependent for medical care.
- There is an inherent desire for questionnaire respondent to want to please the enquirer.
- Patients may use the questionnaire as a means of expressing gratitude rather than giving an accurate account of their thoughts and attitudes.
- Patients are susceptible to the “halo effect” where satisfaction with one dimension leads to a false recollection of other dimensions (e.g. a good bedside manner obscuring recollection of other aspects of care).

[Goldstein et al 2000; Meredith & Wood 1995; Fung & Cohen 1998]

Despite the subjective and relative nature of patient satisfaction, and although a patient’s derivation of satisfaction and the methods available for measuring it may be imperfect its effects are no less relevant. Medicine is rife with poorly defined subjective phenomena (“pain is what the patient says it is”).

“While individual patients’ feelings and evaluations may sometimes be erroneous and even contradictory vis-à-vis objective clinical facts, this does not bear on their cumulative value” [Meredith & Wood 1995]

5.1.1.5 The importance of a representative sample.

If the conclusions drawn from a patient satisfaction questionnaire are to be meaningful the entire target population must be sampled. To this end the questionnaire must be designed and delivered in a manner that ensures a

high response rate from a cross-section of the targeted population. [Carr-Hill 1992] If a questionnaire fails to obtain responses from a sub-group of the population (be it in terms of demographic or clinical factors) all findings are at risk of being invalid; for example if those most dissatisfied with their care simply refuse to make the effort involved in responding.

The questionnaire should not be seen as a burden and should offer the patient a sense of satisfaction in completing it if a high response rate is to be achieved.

5.1.1.6 Methods of administration.

The method of questionnaire administration can influence both the response rate and the nature of the responses. Methods of administration can be broadly divided into self-completed and interviewer-completed.

Interviewer-completed questionnaires can be conducted face-to-face or over the telephone. This approach to questionnaire completion does have the advantage of a high response rate and the opportunity to re-word or clarify any questions. The draw back is that the process can be confrontational and threatening for the patient, resulting in a uniformly high level of expressed satisfaction (whether this is the case or not). Face-to-face interviewing being especially poor. [Fung & Cohen 1998]

Self-completed questionnaires can be administered in a variety of different ways; completion immediately following an event, being sent home with a questionnaire to be returned later, or a purely postal system. This system is prone to “can’t be bothered”, literature suggesting that an 80% response rate is the best that can be expected for a postal questionnaire. [Meredith & Wood

1995] The patient also lacks guidance and so the design of the questionnaire is critical, there is no point asking the most pertinent & revealing questions if the patient does not understand them or how to respond. The advantages of a self-completed questionnaire are its ease of administration and candour of the patient's responses.

5.1.1.7 An instrument to meet the needs of this study.

In order to best meet the needs of this study a self-completion, postal questionnaire was required with sufficient sensitivity to identifying the differences in satisfaction between patients in the three study arms.

A literature search (Medline & Google) failed to identify any published questionnaires dealing with outpatient colorectal investigation; as context and specificity are key determinants of a questionnaire ability to fulfil the set task the decision was made to develop a purpose designed questionnaire in parallel with the main study.

5.2 QUESTIONNAIRE DESIGN

Designing a questionnaire is a time consuming process consisting of many steps. Throughout the process certain features of a well-designed questionnaire must be kept in mind.

A questionnaire first and foremost should be appropriate to what is being measured; in the case of this study it should address a patient's satisfaction with surgical outpatient care and investigation.

The questionnaire must be intelligible, the language used appropriate to the target group. Jargon should be avoided (unless dealing with a professional group with standardised terms) and complexity of the questions kept to a minimum. In some settings both the reading age and language must be considered if the target group is to be correctly and adequately sampled.

The individual questions should be unambiguous, meaning the same to all respondents. Questions should also be unbiased, avoiding wording which may guide or influence a response; and capable of dealing with all conceivable responses.

The questionnaire should be coded in an appropriate manner with values assigned to possible responses in advance.

A questionnaire should be piloted not only if it is newly designed but if it is used on a new population or in a new setting.

Finally a questionnaire should be ethical.

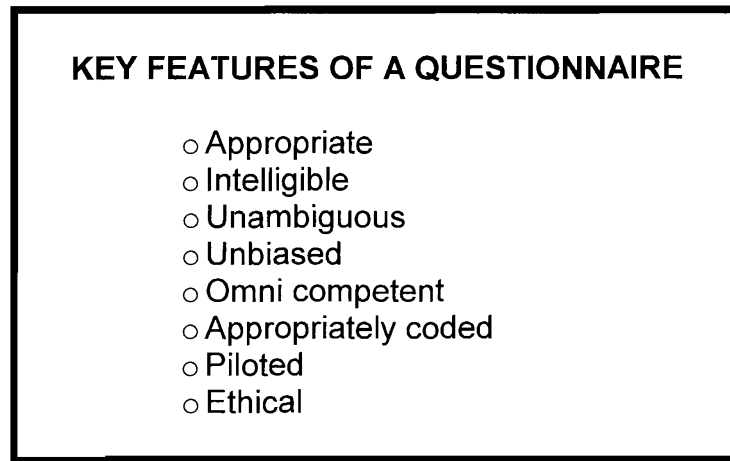


Figure 5.2 – Key questionnaire features (from Stone 1993)

5.2.1 Item Generation

The essential step in any questionnaire's design is the generation of the individual items (which will eventually become the questions). There are various sources from which items can be drawn – patients, colleagues, expert opinion, literature review, and similar questionnaires. [Risser 1975] As already stated a questionnaire will elicit a greater degree of dissatisfaction (and so be of greater use and sensitivity) the more context-specific and detailed the questions. If we rely on any source for items other than the patients we risk imposing the pre-conceived ideas of what colleagues/experts consider to be the determinants of satisfaction at the risk of missing true determinants; in many settings items can be “borrowed” from other scales as they are supported by many years of analysis but this is not the case in this clinical setting. [Streiner & Norman 1995] It was decided that items would be generated by small group patient interviews.

5.2.1.1 Semi-structured small-group interviews

During the August of 2001 three small group interviews were conducted employing a sample of convenience. The sample used was that of patients attending the Lymington Hospital Wednesday morning general surgery outpatient clinic as new referrals on three consecutive weeks. While a sample of convenience this group was appropriate to the purpose of the questionnaire as they were patients about to embark on a similar process to the target group for the final questionnaire. [Concato & Feinstein 1997; Olufade et al 1999]

Two weeks prior to the clinic dates a list of new referrals was obtained and patients contacted by telephone. The patients were asked if they would be willing to give up to an hour of their time on the morning of the appointment to take part in a recorded discussion with other patients about what they expected or considered important about outpatient care, the aim of which was to guide the design of a questionnaire. It was emphasised that this would be strictly voluntary, would have no impact on their care, and that no discussion of symptoms/diagnoses would be made.

All patients approached agreed to participate and (though no selection had been made) appeared well balanced between genders, socio-economic groups, and previous health service experience.

On the day of the interview / outpatient appointment the patients were met by the researcher at the outpatients' reception and shown to the seminar room on the floor above the outpatients' department. There the patients were introduced and written consent obtained. The researcher acted as facilitator for the discussions ensuring, but not attempting to guide, the flow of

conversation. A topic list prepared following a review of the literature (See Appendix O) for use should conversation run dry was not required for any of the three groups; all topics were covered during the natural course of conversation. All interviews ran a natural course between 45 and 60 minutes, at the close of the third interview no new issues were emerging, and as such no further small group interviews were arranged. All interviews were recorded using a main and back up device.

5.2.1.2 Analysis of small-group interviews.

The Interview recordings were subjected to a process initially proposed for the qualitative analysis interview data, the end result being a pool of potential items. [Hycner 1985] The three interview recordings were analysed one at a time.

1. Transcription – The recording was fully transcribed leaving a large right hand margin for annotation.
2. Bracketing – It is important to minimise the influence pre-conceived ideas can have on what would ideally be a totally open and impartial process. One method available to the researcher to minimise the effect of preconceptions (and that used in this instance) is to write them down. It is impossible to make the bias preconceptions disappear, but by highlighting them the researcher should have a greater awareness of when they may influence analysis and attempt to avoid it.
3. Listen & Read – The interview was listened to and the transcripts read through several times to give an impression of the interview as a whole and so give individual comments context.

4. Delineate Units of General meaning – The transcript was worked through line-by-line and broken down into the smallest possible units of meaning or fact (see Figure 5.2.1.2).

Units of General Meaning

For example, the sentence –
“I was going to go for a walk but it was raining and I didn’t have my umbrella with me.”

Can be broken down into 3 Units of General Meaning –

- *“I was going for a walk”*
- *“It was raining”*
- *“I didn’t have my umbrella”*

Figure 5.2.1.2 – An explanation of units of general meaning

5. Delineate Units relevant to research question – Units of General Meaning not concerning outpatient care / investigation were discarded.
6. Eliminate Redundancies – Units that were repetitions of those already identified were discarded.
7. Clustering Units – The set of relevant Units of Relevant Meaning were examined again to see if any naturally clustered together by virtue of sharing a common theme; some units may cluster into more than one group or none at all.
8. Determine Themes from clustered Units of Meaning – Once the units had been clustered the groups were re-examined and a definition applied. In this clinical setting the clustered units will hopefully prove to be dimensions of patient satisfaction.

Methods of phenomenological analysis are not an exact science; they are subjective in nature and prone to the effects of assessor bias. The methods employed must also be adapted to different situations. As such the conclusions of phenomenological analysis are open to debate and dispute.

[Hycner 1985]

This process when completed for all three interviews yielded a total of 93 relevant units of meaning that appeared on face value to cluster into 10 groups or dimensions. (See Appendix P)

5.2.1.3 Choosing a mode of response

Before the units of meaning can be worded into items (questions) the way in which responses are to be obtained must be selected. The decision had already been made that a self-completion postal questionnaire would be the basic model and the questionnaire's design would have to reflect this.

A 5-point Likert type scale was selected for participating patients to indicate their response. On a Likert scale the responder is asked to indicate their level of agreement with a statement. This method of response is continuous in nature and has the advantage of greater discrimination over a categorical response of simple agreement or disagreement. Theoretically the scale can have an infinite number of points but 5-7 is considered the minimum before final reliability of the scale is excessively reduced. [Streiner & Norman 1995]

Statistical analysis of Likert type scales must employ non-parametric analysis as it is impossible to gauge the distances between points (the interval

between agree and no opinion may be different from the interval between disagree and strongly disagree).

	STRONGLY AGREE	AGREE	NO OPINION	DISAGREE	STRONGLY DISAGREE
☐ I prefer dogs to cats.	1	2	3	4	5

Figure 5.2.1.3 – A Likert Type question

The choice of Likert scale was made for a variety of reasons –

- Familiarity – Likert scales are commonly used in questionnaires; any familiarity with the response method on the part of the respondent will simplify the process for them. This in turn may firstly increase the response rate (no one wants to complete a complicated form) and secondly allow a true reflection of the respondent’s opinion.
- Omni competence – The inclusion of a “no opinion” point should allow respondents to answer questions they either truly have no opinion on or which they may consider irrelevant to them.
- Coding – The distribution of responses to one of 5 points on the Likert type scale greatly simplifies the process of coding whereby responses are allocated a numerical value to facilitate analysis. [Risser 1975]

5.2.1.4 Composing the items.

The Items in the scale were phrased as comments with which the respondent would be required to indicate the degree to which they agreed. While composing the items it was important to aim for simple short statements, though not at the cost of losing the meaning of the “unit of General Meaning”

from which it was derived. Though not intended to be insulting questions were worded in a manner that the researcher would expect a child to be capable of reading and understanding to avoid misunderstanding or misinterpretation on the part of the respondent; avoiding the use of jargon was an important step in the process.

Ambiguity was looked for in all questions and where apparent the question was rewritten (as ambiguous questions would effectively leave patients completing different versions of the questionnaire with the researcher ignorant as to which they had answered). In the same manner double-barrelled questions (those asking two questions at the same time) were rewritten, split into two questions, or removed.

When composing direct questions the practice is to avoid value-laden words as these may lead the respondent's answers; with the Likert type questions the statement must be value laden in order to elicit agreement/disagreement. In this instance an effort was made to word equal numbers of questions in positive and negative manners. A total of 87 items were written and intended for inclusion in the questionnaire.

5.2.2 Questionnaire Design.

Having generated the items and selected the mode of response (Likert type scale) the questionnaire had to be designed. The aim of the design is to encourage unbiased completion from the targeted respondent, and to simplify the process of coding on the part of the researcher.

The front page of the questionnaire was on headed paper from the hospital at which the study was conducted and was clearly marked with the title "Direct

Investigation Study Patient Questionnaire” (see Appendix K). There followed a brief instruction on how to complete the form and an example question (see Figure 5.2.1.3)

The questions were presented in a simple numbered sequence down the left hand side of each page, and to the right of each question the rating scale was clearly provided.

The order of the questions on the questionnaire was deliberately random, in an attempt to ensure the respondent answered each question separately.

There is a risk if questions are arranged in face value dimensions that patients will identify the link and answer questions as groups rather than individually.

The question sequence was re-examined after random ordering to ensure grouping did not occur and to move questions which could be seen as more probing or requiring judgements towards the end of the scale.

The final page of the questionnaire was a free response section. Patients were asked to indicate how long the questionnaire had taken to complete; and if any questions were poorly worded, irrelevant, ambiguous, or uncomfortable to answer. Finally patients were asked to make any comments on their care or the questionnaire (particularly to indicate any aspects overlooked).

This final free response section is important both to researcher and respondent. For the researcher it offers invaluable feed back on the questionnaire & opinions on care not covered by the items. For the

respondent it provides the opportunity to “have their say” which the items on the questionnaire may not have provided.

In an attempt to personalise the process and enhance response rates several measures were taken. [Streiner & Norman 1995] Patients were aware on recruitment that a satisfaction questionnaire would be sent to them by mail. All questionnaires were accompanied by a personally addressed cover letter signed by the researcher indicating that the questionnaire was part of the research programme they had consented to take part in, and that responses would be anonymous. Also all questionnaires and letters were printed; this was in preference to photocopies addressed as “dear patient” (see Appendix L).

5.2.3 Pre-testing.

Once designed the questionnaire was re-evaluated for face validity (appearing on face value to measure what it is intended to be assessing) by circulating copies to NHS staff dealing with the target patient groups and to two researchers with previous experience of questionnaire development. The questionnaire was also assessed by small numbers of staff, patients, and lay people for “readability”. Only minor grammatical changes were made to the questionnaire following this process.

5.2.4 Pilot testing

The questionnaire was piloted as part of the main Direct Investigation study. The first 50 returned questionnaires were used for the initial evaluation

(section 5.3). Only 1 of the first 51 patients to reach the study end point failed to return a completed questionnaire, this response rate of 98% was in excess of the highest expectations of 90% for a targeted group. [Streiner & Norman 1995]

In order to assess re-test reliability a group of 20 patients completing a second questionnaire was required. [Oermann, Swank & Sockrider 2000]

Those patients who had completed the questionnaire were mailed a second time, two months after they had returned the first questionnaire. Again a covering letter was included explaining that the second questionnaire was needed for comparison as part of the evaluation process, and asked patients to indicate their current feelings, not to try and recall how they had answered before (see Appendix N). This process was continued until 20 re-test responses had been returned. All of the re-test questionnaires were returned completed (100%) providing 21 cases for test re-test analysis.

5.3 PILOT QUESTIONNAIRE EVALUATION

The target population of the questionnaire was consenting patient participants reaching study end point. A pilot group of 50 was required for interim evaluation of the questionnaire.

5.3.1 Questionnaire response rate

The first 50 patients to reach study end point were used as the pilot sample (see section 4.4). A final response rate of 98% was achieved in this group (76% responding after the first questionnaire mailing and a further 22% responding after the second mailing sent out at three weeks).

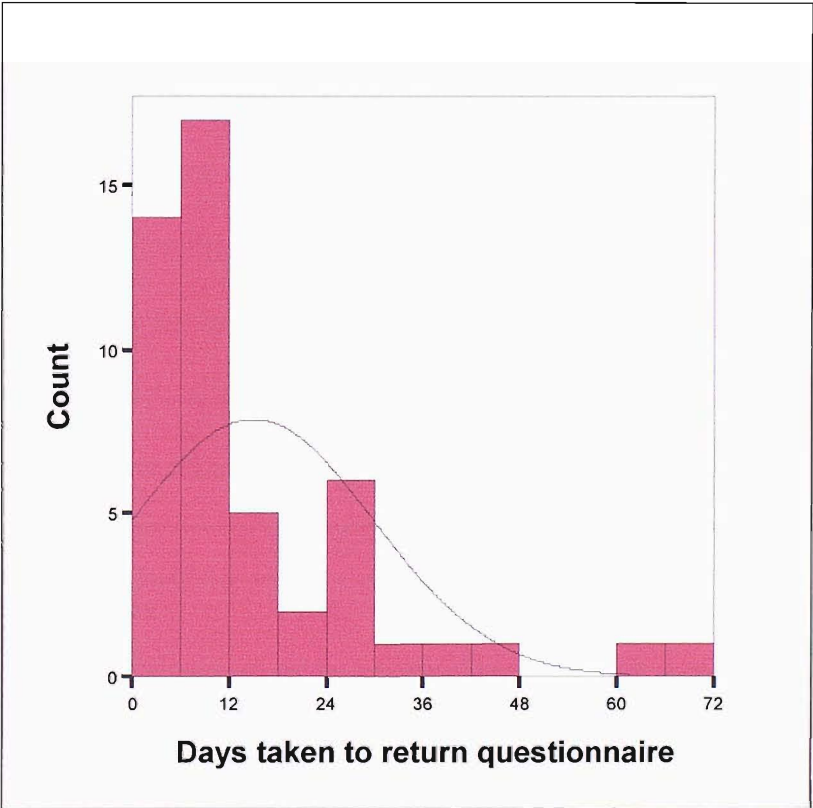


Figure 5.3.1 – Days taken for the pilot group to return questionnaire

5.3.2 Patient feedback and omitted questions

In addition to the response scales a patient feedback section was included at the end of the questionnaire. Patients were asked to indicate how long the questionnaire had taken to complete, if any of the questions seemed irrelevant/poorly worded/ambiguous, or if they felt uncomfortable answering any of the questions. A free response section was also included to make any comments about the questionnaire or the care received.

Of the 49 respondents in the pilot of 50 patients 44 (89.8%) completed at least part of the feed back form.

5.3.2.1 Omitted questions

36 of the 49 returned questionnaires had all questions answered (73.4%).

One of the thirteen patients who did not answer all questions omitted all of the questions on the last two pages of the questionnaire, but had answered all questions up to that point. It was assumed that this widespread omission was in error and so not included while assessing omitted answers.

The remaining 12 patients omitted a total of 34 between them (range of 1-12).

5 questions (see Table 5.3.2.1) were omitted by two patients, the remainder by only one. This low rate of omission did not justify removal from the scale

5	I was involved with any choices which needed to be made about my care.
43	I was left to dwell on my problem while waiting for appointments.
44	Explanations were clear and honest, making it easy to understand what was happening.
64	Enough time was available for me when I attended appointments.
85	There was a lot of waiting around at the time of appointments.

Table 5.3.2.1 – Questions omitted by 2 respondents.

5.3.2.2 Highlighted questions

Questions highlighted by responding patients were considered as a group regardless of reason (poor wording, irrelevance, ambiguity, or discomfort answering).

Seventeen of the 44 patients completing the feedback section of the questionnaire identified 1 or more questions as problematic (a range of 1-16). While a number of questions were highlighted by one or two patients, 4 questions were highlighted by three patients (see Table 5.3.2.2), no questions were highlighted by more than 3 patients.

5	I was involved with any choices which needed to be made about my care.
49	The doctors were able to choose the best course of action.
78	Parking at the hospital was a problem
83	All my attendances at hospital were necessary and worthwhile

Table 5.3.2.2 – Questions identified by three patients as problematic

It is interesting to note that question 5 features among both omissions and problematic questions. During the initial group interviews (and indeed as part of the current health care ethos) patient participation in decision-making was seen as having great importance. The nature of this study (with patients randomised into groups) does remove many of the opportunities for a patient to participate in decision-making. However as one study arm is “Usual Care” and patient satisfaction may polarise over this issue the question was left in the scale.

5.3.2.3 Time taken to complete the Questionnaire

The time a respondent takes to complete a questionnaire (or expects they will have to take) influences over the final response rate. If a questionnaire takes what the patient sees as an unacceptably long time to complete it may be hurried (and not truly representative), incomplete, or ignored altogether. Forty-four of the 49 respondents indicated how long it had taken them to complete the questionnaire, with approx 75% taking between 5 and 20 minutes (Figure 5.3.2.3). Based on this there was no need to “thin out” questions purely to reduce questionnaire length.

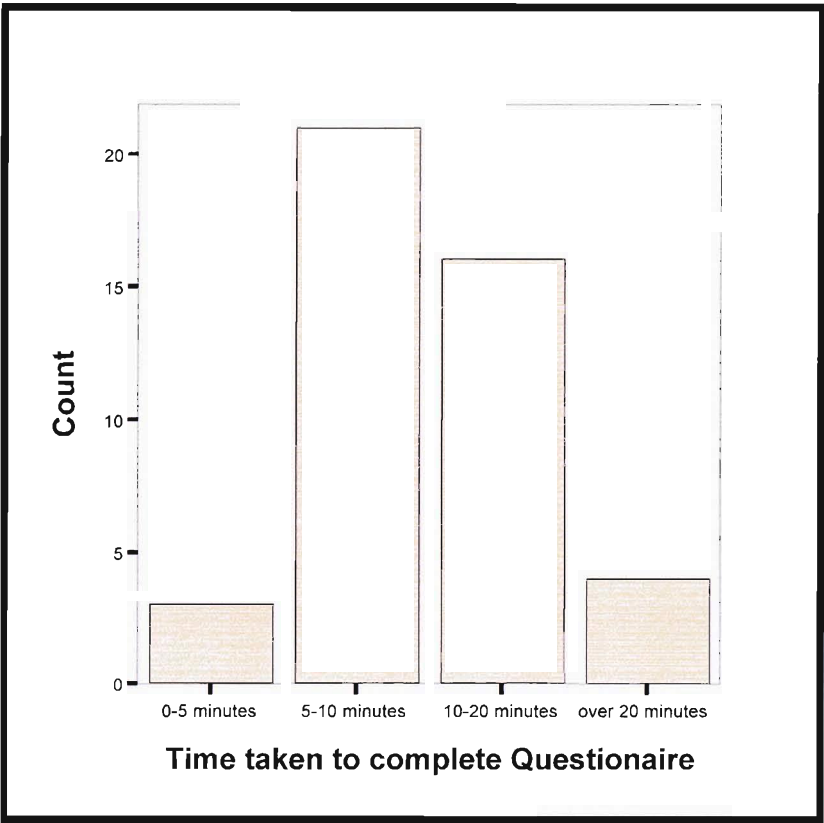


Figure 5.3.2.3 – Time taken for respondents to complete questionnaire.

5.3.2.4 Free text feedback

The free text section of the feed back form allowed the patient to make any additional comments about either the questionnaire or the care they received.

Thirty-one of the 49 responding patients made a free text comment, though only 12 of these passed comment on the questionnaire itself.

The most frequent comment was that not all questions were relevant to the respondent's experiences, focusing mainly on the lack of a dedicated consultation for those referred directly for investigation. When dealing with three related but differing treatment groups (as in this study) there will be a degree of perceived redundancy, especially if the ways in which the three study arms differ are to be assessed. All patients encountered a doctor at some point during their management even if this was not a sit down consultation; that stated the patient does have the option to respond with "no opinion". Removing all questions relating to doctor patient interactions would result in a very short questionnaire!

Comment was also received that some questions were ambiguous when the patient had attended multiple appointments illustrating that patients tend to evaluate and judge care as a sequence of individual events, rather than by general impression. This problem cannot be resolved while assessing satisfaction through a single questionnaire at the end of investigation. As only one patient made this comment no action was taken to modify questions. Patients also commented that some questions appeared repetitive and that the order seemed jumbled rather than organised. Both of these are deliberate design features of the questionnaire; it was simply unfortunate that a minority of patients had made the observation.

Only one patient commented that the questionnaire was too long-

"Just felt there were a few too many questions to answer"

5.3.3 Variation in response

When attempting to measure and compare satisfaction it is essential that variation in response be observed. If a single item on a scale receives the same response from all subjects it offers no discrimination itself and diminishes the overall ability of the scale to identify differences.

In order to assess the variation in response the answers to individual questions were subjected to simple descriptive statistics and plotted as a histogram.

The question responses were made on a 5-point scale (see Figure 5.2.1.3) numerically coded from 1 to 5. None of the questions received the same response from all patients though responses to 2 questions (4 & 55) were onto only 2 of the scale points (though a standard deviation of 0.5 was observed for both).

4	Hospital staff were friendly and polite
55	Staff were too busy/distracted to give me the attention I expected

Figure 5.3.3 – Questions receiving responses on only 2 scale points

Twenty-three of the questions had responses on 3 of the scale points; 17 answers were distributed over a single polarity (i.e. “no opinion” and either agreement or disagreement), while 6 were distributed between agreement and disagreement. The standard deviation of responses in this group varied from 0.5 to 0.8.

Forty-three of the questions had responses distributed over 4 groups (involving both agreement and disagreement) with standard deviations varying from 0.6 to 1.0.

The remaining 19 questions had responses over all five of the scale points, with standard variations of 0.9 to 1.2.

Based on these data none of the scale questions were removed on the basis of lack of variation.

5.3.4 Internal Consistency

Internal consistency is the degree to which the individual scale items (questions on the questionnaire) measure the same dimension, which in the case of this questionnaire is satisfaction in general. Measures of internal consistency assess the degree of correlation between the questions' responses. Cronbach's alpha is one of several statistical tests that can be employed to assess the internal consistency of a scale (questionnaire).

Cronbach's alpha is an advancement of Kuder-Richardson 20, which itself is an advancement on split-half reliability. Split half reliability randomly divides all items on a scale into two sub-scales and then measures the correlation between the two halves. Internal consistency in the scale will yield a high correlation (express as an integer between minus one and one). One issue with split half reliability is the number of ways a scale can be randomly split (a 12-item test can yield 462 combinations) each potentially producing a different correlation value. Kudar-Richardson 20 and Cronbach's alpha calculate the average correlation from all possible split-half tests. While Kunder-

Richardson 20 is appropriate for a dichotomous scale (only 2 possible responses) Cronbach's alpha builds on this to be suitable for scales with multiple possible responses.

Kudar-Richardson 20 and Cronbach's alpha also offer the opportunity to identify which items may be lowering the internal consistency of the overall scale; this is done by simply repeating the test with one question at a time omitted. If the removal of a question results in a marked improvement in internal consistency it should be removed from the scale. As the reliability of a scale to measure what it is attempting to measure is directly proportional to the number of questions in it, removing questions that only make a minor difference to internal consistency can damage the overall value of the scale and should be avoided.

The desired degree of internal consistency is open to debate. A low consistency suggests that the items are not measuring the scale target; while too high a correlation suggests that items are asking the same questions, indicating that some questions are redundant and that the scope of the scale may be too narrow. Streiner & Norman (1995) suggest that the alpha value of a scale should be above 0.7, *"but probably not higher than 0.9"*.

5.3.4.1 Alpha value of the full questionnaire

While calculating alpha values missing responses were coded as 3 ("no opinion"). Using SPSS for Windows 10.0.1 the alpha value of the scale based on data from the first 50 responses was calculated as 0.8196; thus placing the alpha value of the scale within target range.

5.3.4.2 Individual item's effect on internal consistency

SPSS for Windows was used to systematically assess the effect of omitting individual items on the alpha value of the scale. With all items included $\alpha=0.8196$, individual item omissions generated a range of alpha values 0.8094-0.8314 (i.e. -0.0102 to +0.0118 when compared to total scale alpha). No items were omitted on the basis of improved alpha value.

5.3.5 Questionnaire Sub-Scales

As discussed in section 5.1.1.2 overall satisfaction is the result of different dimensions, which manifest in a questionnaire as sub-scales. As detailed in section 5.2.1.2 the data generated from the original small group interviews identified 10 possible dimensions on face value alone. Using SPSS for Windows and the responses from the first 50 questionnaires the alpha values for the proposed sub-scales were calculated; the results were disappointing with a range of alpha values -0.0133 to 0.6652. Possible questionnaire sub-scales required re-evaluation from scratch.

5.3.5.1 Factor analysis

A full explanation of factor analysis is beyond the scope of this report. It is a statistical method available to the researcher when attempting to identify components contributing to the overall variation of a scale (i.e. sub-scales or dimensions) –

“Factor analysis attempts to identify underlying variables, or factors, that explain the pattern of correlations within a set of observed variables. Factor analysis is often used in data reduction to identify a small number of factors that explain most of the variance

observed in a much larger number of manifest variables. Factor analysis can also be used to generate hypotheses regarding causal mechanisms or to screen variables for subsequent analysis (for example, to identify collinearity prior to performing a linear regression analysis).” [SPSS for Windows]

Factor analysis is subject to criticism as a “fishing expedition” as it manipulates numerical data in order to achieve a “best fit” that may have no basis in fact. This analysis is further complicated as a single item may weigh onto one or more factors (sub-scales) to various degrees. Factor analysis was used only as a guide to possible relationships between questions and sub-scales; any suggested relationships that did not hold true on face value were ignored.

SPSS for Windows was used to generate an un-rotated factor matrix set to extract Eigen values over 1. This generated 22 possible factors the first of which all questions weighed to and is assumed to represent overall satisfaction.

5.3.5.2 Re-evaluation of sub-scales

The 22 factors identified by factor analysis along with the original 10 face value dimensions were used to structure new sub-scales; the new sub-scales then had alpha values calculated using data from the first 50 responses. Again by systematically excluding each item in turn those reducing the alpha value of the sub-scale were identified and removed. Excluded items were then assessed for face value with a view to placing them in an alternate sub-

scale (their acceptance being dependent on the effect inclusion had on the new scale's alpha value).

This process led to the identification of 11 sub-scales though two items (questions) did not group with any of the 11. Alpha values varied from 0.6661 to 0.8459. Once the groupings had been identified the sub-scales were given a suitable title (see Appendix Q).

Sub-scale	No. Items	Alpha Value
Understanding of events	5	$\alpha=0.7778$
Anxiety	6	$\alpha=0.6661$
Professionalism	11	$\alpha=0.8459$
Confidence / Trust in staff	10	$\alpha=0.8446$
Substance of consultation	9	$\alpha=0.8363$
Mechanics	8	$\alpha=0.7773$
Results	5	$\alpha=0.8182$
Disclosure	4	$\alpha=0.7827$
Preparation	8	$\alpha=0.7659$
Involvement / control	8	$\alpha=0.8108$
Taken Seriously	11	$\alpha=0.7838$
Scale free items	2	n/a

Table 5.3.5.2 – Subscales & alpha values as identified following the 50-questionnaire pilot.

5.3.6 Test-Retest Reliability

The reproducibility of results is part of assessing a questionnaire's reliability; referred to as test-retest reliability. In this study patients who had returned the initial questionnaire were sent a second identical questionnaire 2 months after the return of the first. The second questionnaire was accompanied by a covering letter in order that the patient did not believe it had been sent in error (see Appendix N). This process was continued until 20 re-test questionnaires

had been returned; in practice this resulted in 21 pairs of questionnaires completed a minimum of 2 months apart.

5.3.6.1 Choosing the re-test interval

Convention suggests that re-testing should be conducted 2-14 days after the initial test. [Streiner & Norman 1995] A longer re-test interval was chosen in this instance for a variety of reasons-

1. With a postal questionnaire it is not possible to know exactly when the patient completed the questionnaire (a range of 2-68 days for the first 50 respondents) and then send the re-test questionnaire at a fixed narrow interval.
2. The interval between mailings must be sufficiently large to minimise the chance of the re-test questionnaire being received before the first is completed; or so closely that the respondent can remember their initial responses.
3. A patient's satisfaction with events may well change over time (such as the drift towards the mean seen with many repeated measurements) though it is their enduring satisfaction with treatment that is more important in terms of influencing future behaviour.

5.3.6.2 Kappa Coefficient

The kappa coefficient is a statistical test used to calculate agreement between two or more raters making nominally categorised judgements; in this instance it is used to assess agreement between two judgements, made by the same observer, at different times.

Stats Direct version 2.7.7 was used to calculate unweighted kappa values for each question; Landis & Koch’s (1977) guidelines were then used to assess the strength of agreement.

Kappa	Strength of Agreement
≤ 0.2	Poor
$> 0.2 \leq 0.4$	Fair
$> 0.4 \leq 0.6$	Moderate
$> 0.6 \leq 0.8$	Good
$> 0.8 \leq 1.0$	Very good

Figure 5.3.6.2 – Guidance on degree of agreement [Landis & Koch 1977]

“Poor” agreement was seen in 20% of the questions, “fair” in 33%, “moderate” in 35%, and “good” in 12%; none of the questions demonstrated “very good” agreement between the first and second testing. The kappa values were calculated for the full 5 point scale on which each point is seen as independent from the others; no account is taken for the relationship between agree & strongly agree or disagree & strongly disagree.

5.3.7 Conclusions of Pilot Questionnaire Analysis

Having evaluated the questionnaire on the basis of-

- Completion rate
- Omitted questions
- Patient comments
- Variation in response
- Internal consistency (by Cronbach’s alpha)
- Test-retest reliability (by Kappa)

The decision was made not to alter the questionnaire and to continue with it in its current state until the end of the study. At the end of the study with all data collected response rate, omitted questions, patient comments, variation in response, and the internal consistency of the full questionnaire and sub-scales require re-evaluation.

5.4 FULL STUDY QUESTIONNAIRE EVALUATION

As no changes were made to the questionnaire following evaluation of the 50 patient integral pilot all returned questionnaires were used in re-evaluation.

5.4.1 Response rate

A total of 95 patients reached study end point and were thus targets of the questionnaire. 91 (96%) patients returned a completed questionnaire; 71 (75%) after the first mailing and a further 20 (21%) after the second mailing at 3-weeks.

5.4.2 Omitted questions

The most a single question was omitted by the respondents in the 91 returned questionnaires was 3, and this occurred on only four occasions.

5.4.3 Highlighted questions

Responding patients were asked to indicate any questions they felt were irrelevant, ambiguous, poorly worded, or which they felt uncomfortable answering. The most any single question was highlighted (regardless of reason) was 4 times from the 91 respondents.

5.4.4 Variation in response

Analysing the degree of variation in question responses from the 91 returned questionnaires revealed greater variance than after the 50-patient pilot (see section 5.3.3). None of the questions received responses on only one of the 5

scale points, and only one question received responses limited to two scale points. Four questions received responses on 3 scale points (standard deviation 0.55-0.65), though only one of these had responses encompassing both agreement and disagreement.

Twenty-nine of the questions had responses on 4 of the scale points (standard deviation 0.58-0.88); the remaining fifty-three questions had responses ranging over all 5 of the scale points (standard deviation 0.72-1.18).

Although item 4 (*“Hospital staff were friendly and polite”*) had poor variation in response it was included for the purposes of analysis.

5.4.5 Internal consistency

Cronbach’s alpha values were recalculated for both the overall scale and the subscales identified as a result of factor analysis and face value groupings (see sections 5.3.4 & 5.3.5). For the purpose of analysis missing values were coded as “no opinion”.

5.4.5.1 Internal consistency of full scale

SPSS for Windows was again employed to calculate Cronbach’s alpha for the entire scale. The alpha value for the 87-item questionnaire as calculated from 91 returns was 0.8808, reflecting a desirable level of internal consistency.

5.4.5.2 Internal consistency of sub-scales

The item sub-scales identified in section 5.3.5.2 were re-examined for internal consistency using the data collected from the 91 responses. Cronbach’s

alpha was calculated using SPSS for Windows and is illustrated in table 5.4.5.2.

Sub-scale	No. Items	Alpha Value after 50 patient pilot	Alpha value at study end (91 responses)
Understanding of events	5	$\alpha=0.7778$	$\alpha=0.7516$
Anxiety	6	$\alpha=0.6661$	$\alpha=0.7503$
Professionalism	11	$\alpha=0.8459$	$\alpha=0.8712$
Confidence / Trust in staff	10	$\alpha=0.8446$	$\alpha=0.8784$
Substance of consultation	9	$\alpha=0.8363$	$\alpha=0.8838$
Mechanics	8	$\alpha=0.7773$	$\alpha=0.7694$
Results	5	$\alpha=0.8182$	$\alpha=0.7835$
Disclosure	4	$\alpha=0.7827$	$\alpha=0.7901$
Preparation	8	$\alpha=0.7659$	$\alpha=0.8296$
Involvement / control	8	$\alpha=0.8108$	$\alpha=0.8625$
Taken Seriously	11	$\alpha=0.7838$	$\alpha=0.8627$
Scale free items	2	<i>n/a</i>	<i>n/a</i>

Table 5.4.5.2 – Sub-scale alpha values

5.5 SUMMARY OF QUESTIONNAIRE ASSESSMENT

The questionnaire developed for use in this study (and piloted within it) has been validated by several techniques.

- Face validity
- Patient feedback
- Internal consistency
- Test retest

As such it is reasonable to use it as a research tool in attempting to identify differing levels of satisfaction between patients randomised to the three study arms.

While the questionnaire has been validated as a psychometric tool it is not yet known whether or not it is sufficiently sensitive to discriminate between differing degrees of satisfaction.

If the questionnaire fails to identify a difference in satisfaction between study groups it may be for one of two reasons-

1. A difference does not exist.
2. The tool is not capable of identifying a difference.

6 – RESULTS

6.1 PATIENT RECRUITMENT

Patient recruitment was for a year long window, starting 1st October 2001 and intended to run until 30th September 2002. Due to researcher injury there was a forced hiatus in recruitment during June & July 2002. The recruitment window was then extended to 31st December 2002 in order to compensate for the loss in opportunity to recruit, and a loss to the study of those patients who were in the process of recruitment at the time of injury (letters sent / meeting arranged).

The final recruitment window amounted to 13 months (1/10/2001 - 31/5/2002; and 1/8/2002 – 31/12/2002).

6.1.1 Patients affected by recruitment hiatus

Eight possible participants were lost as a result of the recruitment hiatus forced by researcher illness. Six patients were at the mailed information stage, while meetings had already been arranged for the remaining two. Due to the practices outlined in section 4.2.3 it was possible to return all eight patients back into the normal referral pathways with a minimum of disruption. The patients with whom a meeting had been arranged were contacted by telephone to cancel the appointments and offer an apology/explanation. Patients sent information only were written to again and informed their referral would be managed in the normal manner.

6.1.2 Eligible patients

During the recruitment window a total of 180 patients suitable for study inclusion were identified using the inclusion/exclusion criteria (see Appendix C). Of these 111 gave informed consent to participate after going through the recruitment process (as detailed in section 4.2). Those not consenting to participate gave a variety of reasons (see Table 6.1.2).

Reason for not participating	No.
Did not want to be involved in “research”	9
Recently investigated / Duplicate referral	8
Lost during recruitment hiatus	8
Health problems	7
Did not want any investigations	7
Symptoms fully resolved	6
Sought private care	5
Unable to make contact	5
Moving out of area	4
Other	5
No reason offered	5

Table 6.1.2 – Reasons given by non-participants for not taking part in trial.

6.1.3 Demographic features of recruited patients.

Of the 111 recruited patients 43 (38.7%) were male, and 68 (61.3%) were female. Mean recruit age was 66.9 years (range 45-87) though recruit ages did not follow a normal distribution. Median age was 67, with an inter-quartile range of 58-78.

6.1.4 Demographic features of non-participants.

Of the 69 patients declining to participate in the study 26 (37.7%) were male, and 43 (62.3%) were female. Mean age in this group was 67.4 years (range 45-88); median age was 66, with an inter-quartile range of 59-75.

6.1.5 Randomisation into study groups.

The 111 consenting patients were randomised into study groups using the methods set out in section 4.2.10.

This resulted in 44 patients entering the colonoscopy group, 35 entering the barium enema & flexible sigmoidoscopy group, and 32 entering the usual care group. Greater demographic detail is shown in Table 6.1.5.

	All groups	Colonoscopy	Barium Enema & Flexible Sigmoidoscopy	Usual Care
No. Patients	111	44	35	32
Age Range	45-87	48-87	50-86	45-86
Mean Age	66.9	67.5	66.5	66.5
Median Age	67	71	65	68.5
I.Q.R.	58-78	54.5-78.5	58-73	59.5-78.5
No. Male (%)	42 (38%)	16 (36%)	15 (43%)	11 (34%)
No. Female (%)	69 (62%)	28 (64%)	20 (57%)	21 (66%)

Table 6.1.5 – Demographic details of study groups.

Gender comparison yielded a value of 0.583 using Chi-square analysis. A comparison of age across the three groups using a one-way ANOVA test yielded a p value of 0.682.

6.2 PROGRESSION THROUGH STUDY

6.2.1 Study completion rate

Of the 111 recruits 16 withdrew from the study leaving 95 who continued within study protocol until reaching the end point (they were informed of diagnosis, discharged with reassurance, or a need to further investigate).

Group	Number of patients	Withdrew (%)	Reached endpoint (%)
All groups	111	16 (14.4)	95 (85.6)
Colonoscopy	44	5 (11.4)	39 (88.6)
Barium Enema & Flexible Sigmoidoscopy	35	6 (17.1)	29 (82.9)
Usual Care	32	5 (15.6)	27 (84.4)

Table 6.2.1 – Rate of study completion.

Using a Kruskal-Wallis Test (SPSS 10.1.0 for Windows) for non-parametrically distributed data there was no significant difference in withdrawal rate between the three study groups, $p=0.538$.

6.2.2 Patient pathways

Study progression trees are provided in Diagrams 6.6.2a 6.6.2b & 6.6.2c. As was expected patient experiences varied even when it was intended that they be the same (in the “Colonoscopy” and “Barium Enema & Flexible Sigmoidoscopy” study groups).

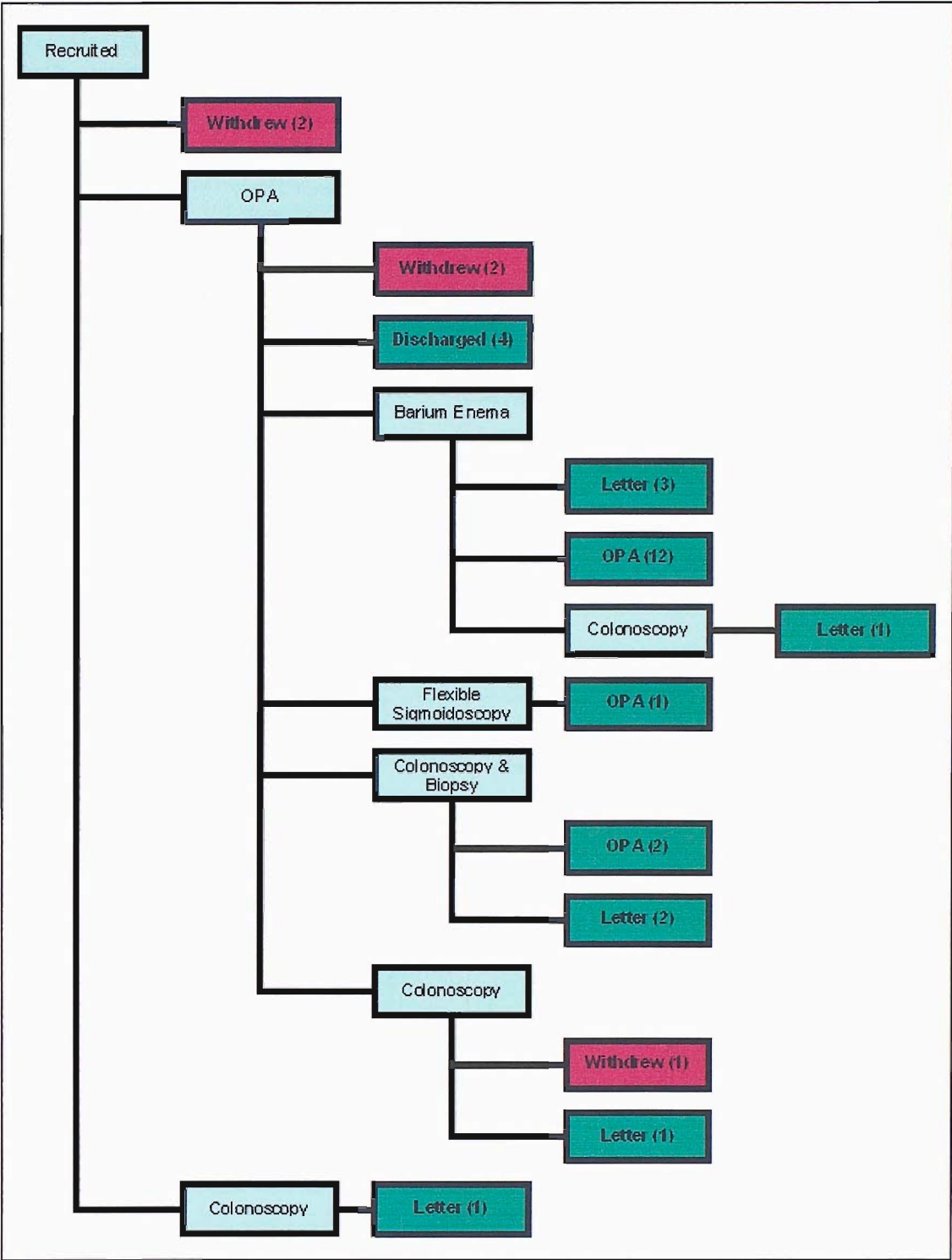


Diagram 6.2.2a – Patient pathway for those randomised to "Usual Care" group.

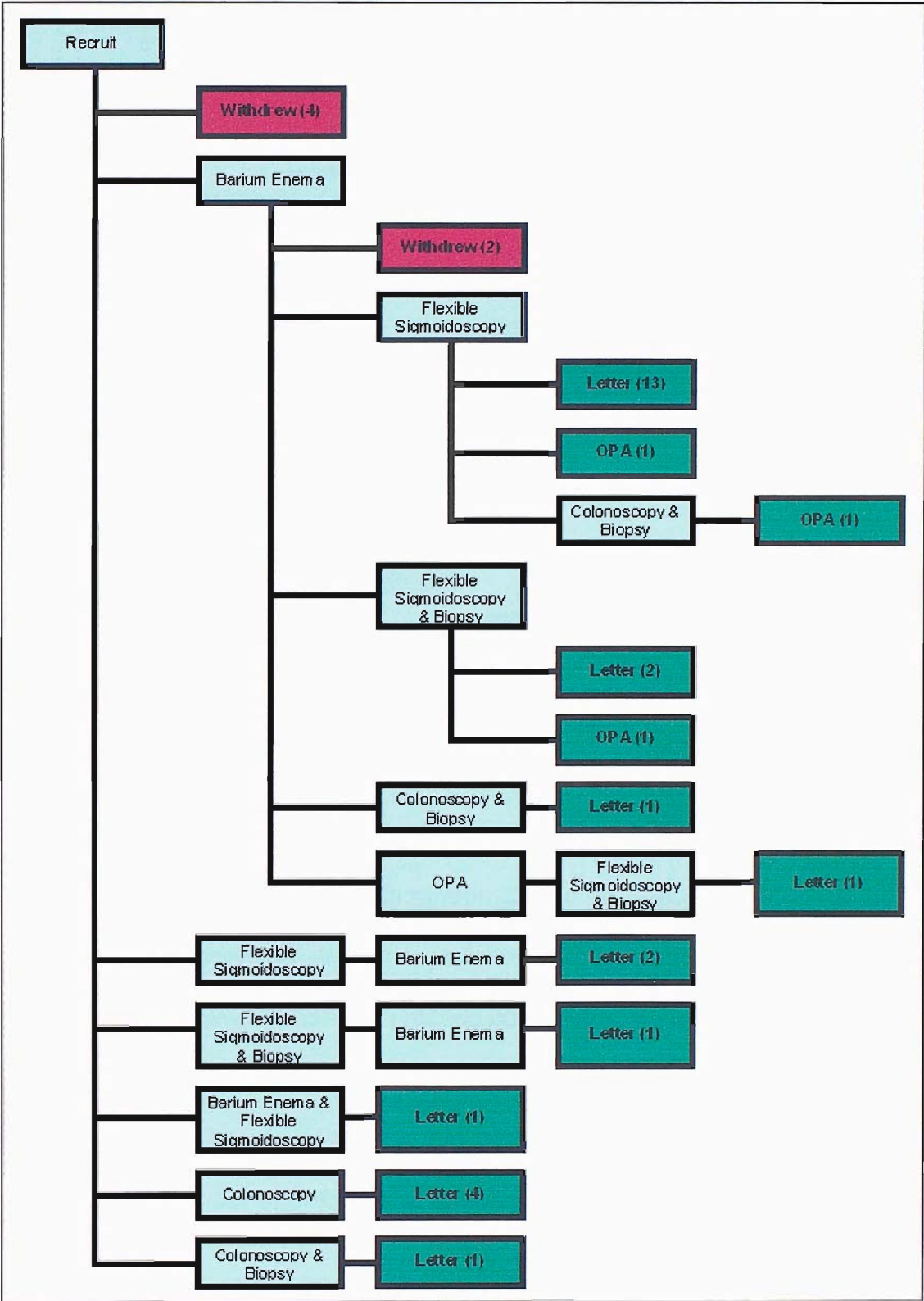


Diagram 6.2.2b – Patient pathway for those randomised to "Barium Enema & Flexible Sigmoidoscopy" group.

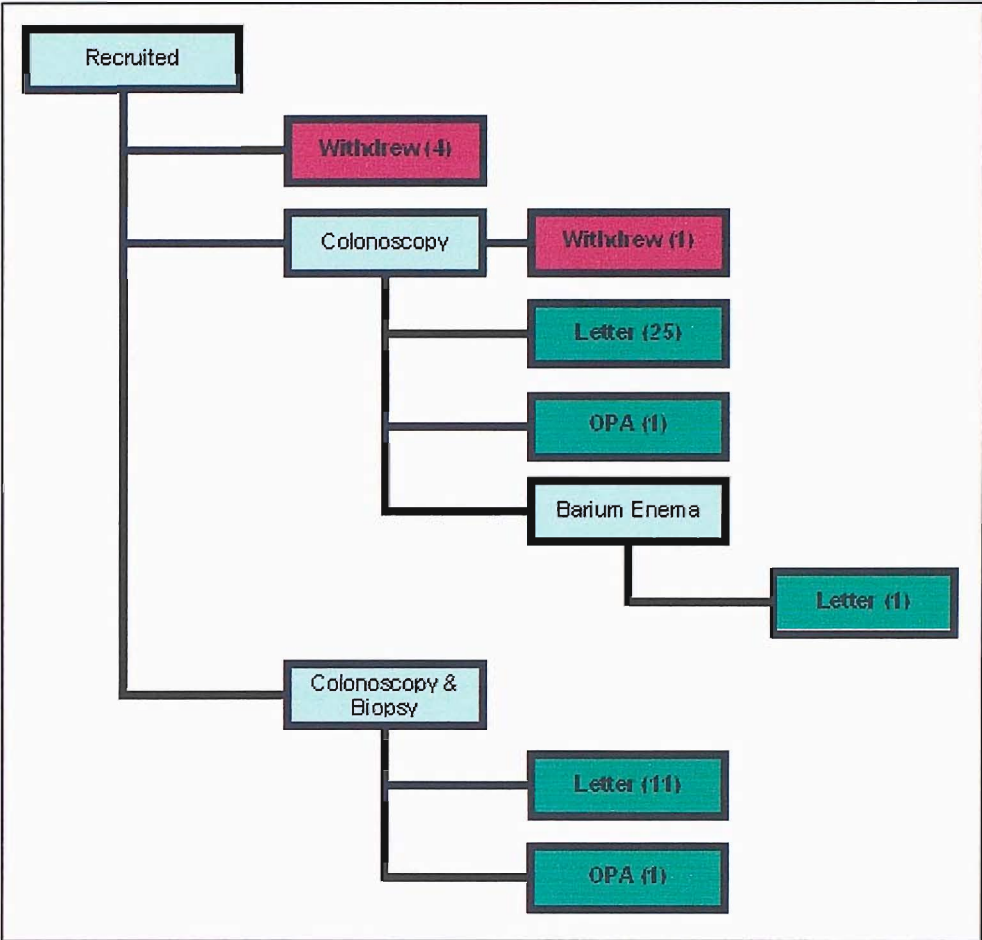


Diagram 6.2.2c – Patient pathway for those randomised to “Colonoscopy” group.

The experiences of those patients randomised to the “Usual Care” group also required close inspection. If their experiences proved to be similar to those sent directly for investigation the process can at least be said to be sound; if however they were referred for different investigations (or not investigated at all) it would draw into doubt the removal of the surgical outpatients step of patient care in favour of deferring to information provided in a referral letter.

6.2.2.1 “Colonoscopy” group

39 of the 44 patients in the “Colonoscopy” group reached study end point and they did so by only five different pathways. 36 patients went down the expected route of colonoscopy (with or without a biopsy) followed by a letter.

Only three patients veered from the expected path. One had a barium enema after an incomplete colonoscopy. Two were seen in outpatients to discuss the colonoscopy findings.

6.2.2.2 “Barium Enema and Flexible Sigmoidoscopy” group

29 of the 35 recruits in this group reached study end point. They did so by a greater variety of pathways than those in the other two study groups (12 in total). Nineteen patients reached end point after the anticipated barium enema and flexible sigmoidoscopy followed by a letter.

Three of the remaining nine patients were seen in outpatients; two in order to discuss their results but one had an outpatient appointment requested erroneously following their barium enema, but while still awaiting a flexible sigmoidoscopy.

Six of the patients in this group underwent an unexpected colonoscopy. One patient had already had a barium enema identifying a possible lesion in the right colon and so colonoscopy was performed in preference to flexible sigmoidoscopy. The other 5 patients had a colonoscopic examination when equipment failure in the radiology suite had left them in the hospital having taken full bowel preparation and the endoscopy unit was able to provide an examination instead.

6.2.2.3 “Usual Care” group

27 of the 32 patients recruited to the “Usual care” group reached study end point and despite the more open nature of their potential clinical pathways did so by only nine different routes.

The largest number of patients in this group (16) were seen in outpatients and then referred for a barium enema. The majority of these (12) were then seen again in outpatients with the results. A total of seven were referred for colonoscopy (though in one case this was due to researcher clerical error), and one for flexible sigmoidoscopy.

With the exception of the four patients who were discharge after being seen in clinic only, the investigative modalities were those used in the other two study arms and so their needs would have been met adequately in one of the other two groups.

6.2.3 Withdrawal from study.

The 16 patients who withdrew from the study did so at different stages and for different reasons. Recording patient withdrawal was beset by two main problems. Firstly patients were not pursued in order to explain their withdrawal from the study, this was not always appropriate or possible, and so reasons offered/reported were recorded.

Secondly it was not always possible to identify exactly when a patient had withdrawn from the study. Was it when a patient decided to withdraw or when they did something about it; was it the first or last appointment the patient failed to attend; when in the sequence of rescheduling did the appointment become unwanted rather than inconvenient?

For these reasons the timing of patient withdrawal is not analysed, but their progression through the study is.

6.2.3.1 Withdrawals from the “Colonoscopy” group.

- Having had one colonoscopy cancelled and rearranged by the hospital the patient phoned to cancel the new appointment as their symptoms had resolved.
- The hospital cancelled the arranged colonoscopy and the patient was removed from the list after contact from the patient's GP.
- The patient cancelled the arranged colonoscopy as they had decided to pursue private care.
- The patient cancelled the colonoscopy before it could be arranged as they had decided to pursue private care.
- The hospital cancelled the first colonoscopy. The patient underwent the rearranged colonoscopy but suffered a cerebrovascular accident during the procedure and died as a result.

6.2.3.2 Withdrawals from the “Flexible Sigmoidoscopy & Barium Enema” group.

- Having had both a barium enema and flexible sigmoidoscopy cancelled at the time of the appointment due to ill health the patient underwent a rescheduled barium enema. They then cancelled the planned follow up.
- The patient underwent a barium enema and then cancelled the arranged flexible sigmoidoscopy with their General Practitioner's approval.
- The patient failed to attend two flexible sigmoidoscopy and one barium enema appointment and no further appointments were sent as a result.

- The patient failed to attend for the barium enema and flexible sigmoidoscopy. When contacted by the radiology department it transpired they had pursued private care.
- The patient cancelled the arranged flexible sigmoidoscopy and barium enema and wanted no investigations.
- The arranged barium enema was cancelled by the hospital due to the patient's poor health.

6.2.3.3 Withdrawals from the "Usual Care" group.

- The patient had two outpatient appointments cancelled by the hospital before attending on the third occasion. The patient then cancelled the arranged barium enema and pursued private care.
- The patient attended an outpatient appointment. The hospital then cancelled the planned colonoscopy and all future investigations due to patient ill health.
- After attending an outpatient appointment and subsequent colonoscopy the patient cancelled two arranged follow up outpatient appointments.
- The patient failed to attend two outpatient appointments and no others were arranged.
- The patient cancelled the arranged outpatient appointment.

6.2.3.4 Withdrawal from study before investigation commenced

10 patients withdrew before any patient events (appointment or investigations) had occurred. These patients were distributed among the study groups with no statistically significant difference between the three.

Two “Colonoscopy” patients elected to pursue private care before any appointments had been arranged and contacted the endoscopy unit staff to inform them of the decision thus resulting in minimal wastage.

A further “Colonoscopy” patient cancelled their appointment once it had been arranged and requested that no other appointments be made (the appointment was scheduled for 93 days after the receipt of the referral); a reason was not offered for the cancellation but sufficient notice was given for the appointment to be offered to another patient. The wait of 93 days fell between the 75th & 90th centiles for all study participants (50th & 75th for study group), and may have influenced the patient’s decision to withdraw.

The fourth “Colonoscopy” patient to withdraw at this stage had one endoscopy appointment cancelled (98 days post receipt of referral) due to unit re-fitting; the replacement appointment offered (119 days post receipt of referral) was cancelled by the patient as their symptoms had fully resolved and they did not wish to be investigated. Though the patient’s reason for withdrawal was resolution of symptoms and not related to wait the day of first appointment lay between the 75th & 90th centiles (50th & 75th for study group), and the day of the second beyond the 95th centile for all participants and study group.

None of the 4 patients in the “Barium Enema & Flexible Sigmoidoscopy” who withdrew before any patient events had occurred did so before appointments had been arranged.

One patient was withdrawn from the study due to unrelated ill health (respiratory arrest) and no plans were made to investigate them at a later date due to frailty. While the GP’s referral letter does indicate some medical

problems there was no indication of respiratory disease and nothing to trigger patient exclusion. The patient was due to have a barium enema on day 48 and flexible sigmoidoscopy on day 168, both of which were reallocated. Day 48 fell between the 25th and 50th centiles for all participants and study group. A second patient telephoned to cancel their flexible sigmoidoscopy and barium enema (arranged for 120 and 136 days post receipt of referral respectively) simply stating that they no longer wanted the appointments, a reason was not offered. Adequate time was given to reallocate the appointments. At 120 days the first appointment lay beyond the 95th centile for all study participants and study group.

Only one patient in the “Barium Enema & Flexible Sigmoidoscopy” group (that is known of) elected to pursue private care; a fact discovered only once the patient had failed to attend their joint flexible sigmoidoscopy & barium enema appointment (75 days post receipt of referral) and had been contacted by the unit. These appointment slots were both wasted incurring the costs of staffing the list (the main financial outlay) and losing the opportunity to investigate another patient instead. An appointment on day 75 fell between the 50th and 75th centiles (75th & 90th for study group).

The last of the 4 “Barium Enema & Flexible Sigmoidoscopy” group patients to withdraw before a single event failed to attend first a joint flexible sigmoidoscopy & barium enema appointment (day 85 post receipt of referral) and then a further flexible sigmoidoscopy appointment (day 141) before no further appointments were offered. Again this resulted in wasted NHS resources. The appointment on day 85 fell between the 75th and 90th centiles

for all study participants (90th & 95th for study group) and the long wait may have influenced the patient's decision to not attend.

Only two patients in the "Usual Care" group withdrew before investigation was commenced. The first patient cancelled their outpatient appointment (on day 75 post referral receipt) and did not want it re-booked; the slot was reallocated. Day 75 places the appointment between the 50th and 75th centiles for all participants but between the 75th and 90th for study group. The second patient failed to attend 2 outpatient appointments (days 85 and 134) before their GP was written to and no further appointments offered. These slots were wasted and the opportunity to see another patient lost. Day 85 fell between the 75th and 90th centiles (90th and 95th for study group).

6.2.3.5 Withdrawal from study once investigations had commenced

Four patients withdrew from the study during the investigation phase.

None of the patients in the "Colonoscopy" withdrew from the study once investigation of their symptoms had begun and before it was completed. This was not surprising as the colonoscopy route was expected to be a single investigation, but the possibility did exist that alternative investigations become necessary (see Diagram 6.2.2c).

A single patient in the "Barium Enema & Flexible Sigmoidoscopy" group withdrew after their barium enema identified diverticular disease (day 47), they telephoned to cancel the flexible sigmoidoscopy appointment (day 97) after

discussion with their GP. It would appear that patient and GP were content that diverticular disease explained the symptoms triggering the referral. With inadequate or incomplete visualisation of rectum/sigmoid the risk of an additional (missed) diagnosis exists (see Figure 6.8)

Three patients in the “Usual care” group withdrew from the study and the process of investigation before it was completed.

The first patient had attended an outpatient appointment on day 33 (from receipt of referral) and was due to have a colonoscopic examination on day 61. Before this was carried out the patient was admitted as an emergency because of an unrelated condition and due to prolonged hospital admission withdrawn from the study.

The second patient to withdraw attended an outpatient appointment on day 29, followed by a colonoscopy on day 43. Colonoscopy was normal and an ultrasound scan was requested followed by an outpatient appointment. The ultrasound was performed and reported as normal, the patient then cancelled their appointments made for days 85 and then 113 before requesting that no others be made. The patient's GP was sent a letter explaining that investigation was incomplete. While the patient's investigations were normal the doctors involved clearly felt that further investigation was warranted.

While the patient did not offer a reason for cancelling the appointments there is a risk that “normal” investigations had reassured them (rightly or wrongly) that nothing was wrong before the doctor was satisfied that was the case. A patient is fully entitled not to be investigated but the decision should be an informed one in much the same way as accepting investigation/treatment.

The third patient in the “Usual Care” group was due to attend two outpatient appointments (days 55 & 75) that were cancelled by the hospital before finally attending on day 96. The patient was referred for a barium enema examination that was scheduled for day 116. At this point the patient cancelled the booked barium enema having elected to continue their care in the private sector. At day 96 the first appointment fell between the 75th and 90th centiles for all participants (90th & 95th) for study group. This is an unusually long wait and after an initial two cancelled appointments the patient was due to wait a further 3 weeks before any investigation was performed. It is understandable that they chose to pursue a different avenue of care though they did not give any reason for making their choice.

6.2.3.6 Withdrawal from study once investigations had been completed but before study endpoint was reached

Two patients withdrew from the study between completing their investigations and reaching the study endpoint.

The first patient to withdraw from the study at this point was a member of the “Colonoscopy” group. This patient had their first appointment for colonoscopy on day 109 cancelled by the hospital that was rescheduled for day 113. The patient unfortunately suffered a devastating CVA while under sedation as a result of which they died; thus failing to reach study endpoint.

The second patient from the “Barium Enema & Flexible Sigmoidoscopy Group” had a barium enema on day 46 cancelled as they were admitted as an

emergency with chest pain (the slot was “lost” due to short notice). A flexible sigmoidoscopy on day 84 was not performed as the patient had undergone angioplasty in the previous week (the decision not to proceed was made on the day and so could not be reallocated). The barium enema was performed on day 91 and an outpatient appointment scheduled for day 147. The patient called and cancelled this appointment, no reason was offered.

6.3 PRIMARY STUDY MEASUREMENTS

6.3.1 Time taken for patient to reach study endpoint

6.3.1.1 Time taken for all patients to reach study endpoint

For the 95 patients (85.6%) reaching study end point results followed a skewed normal distribution. The mean number of days taken to reach study endpoint was 107.84, with a range of 30-232 days, and a standard deviation of 38.311.

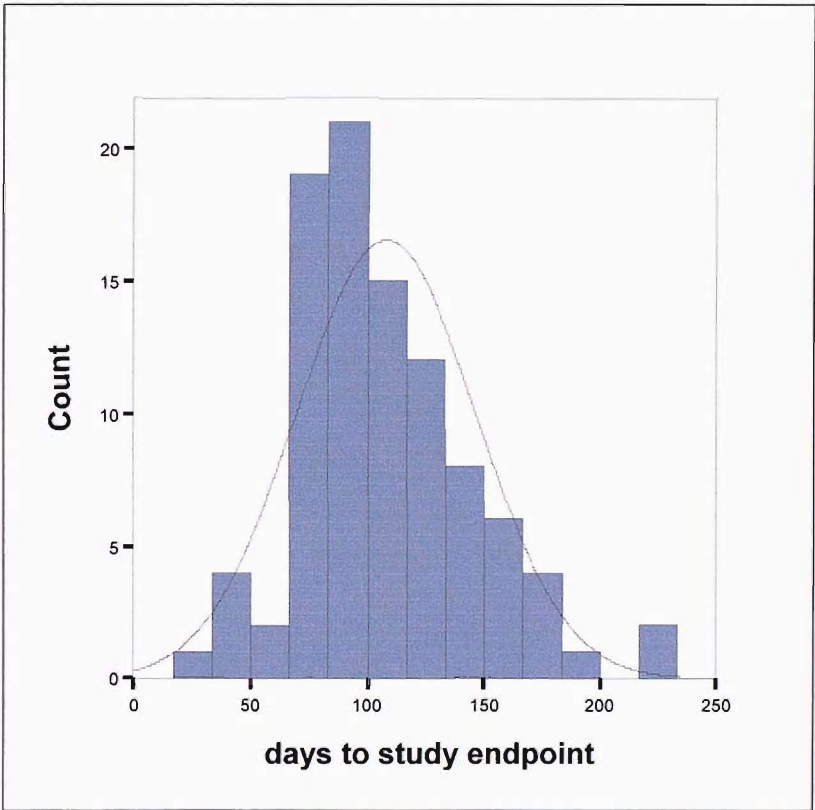


Figure 6.3.1.1 – Time taken to reach study endpoint (all groups)

6.3.1.2 Time taken for study groups to reach study endpoint

When assessed by study group the time taken to reach study end point does not conform as closely to a normal distribution (Figure 6.3.1.2a) and for that reason is treated as non-parametric data for the purpose of statistical analysis. Being time data, however, they are ideally suited to survival analysis.

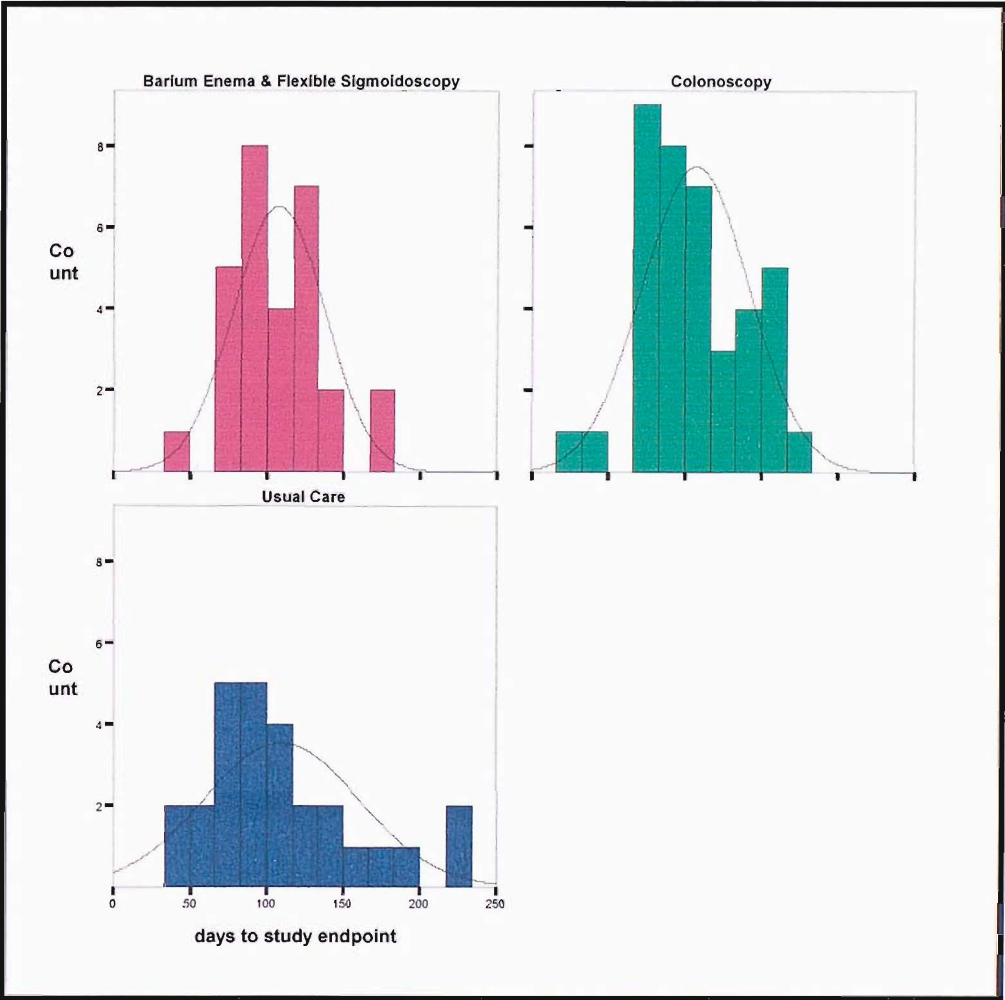


Figure 6.3.1.2a – Time taken to reach study endpoint (by study group)

Study Group	Range	Mean	Standard Deviation	95%confidence interval	Median	Inter-quartile range
All	30-232	107.84	38.311	100.04-115.65	101	48
Colonoscopy	30-180	106.97	34.729	95.72-118.23	101	56
Barium Enema & Flexible sigmoidoscopy	35-179	107.45	29.668	96.16-118.73	101	38
Usual Care	34-232	109.52	50.908	89.38-129.66	92	60

Table 6.3.1.2 – Descriptive statistics of “days to study endpoint” for all patient groups.

When analysed as non-parametric data using Kruskal-Wallis test (SPSS for Windows 10.1.0) there is no significant difference in days to end point between the three study groups ($p=0.821$). The study was inadequately powered to identify a significant difference with a power of only 0.02 (compared to a standard of 0.8); section 6.6 provides greater detail. It is remarkable how closely the figures matched when assessing time to endpoint across the three study groups (see Table. 6.3.1.2).

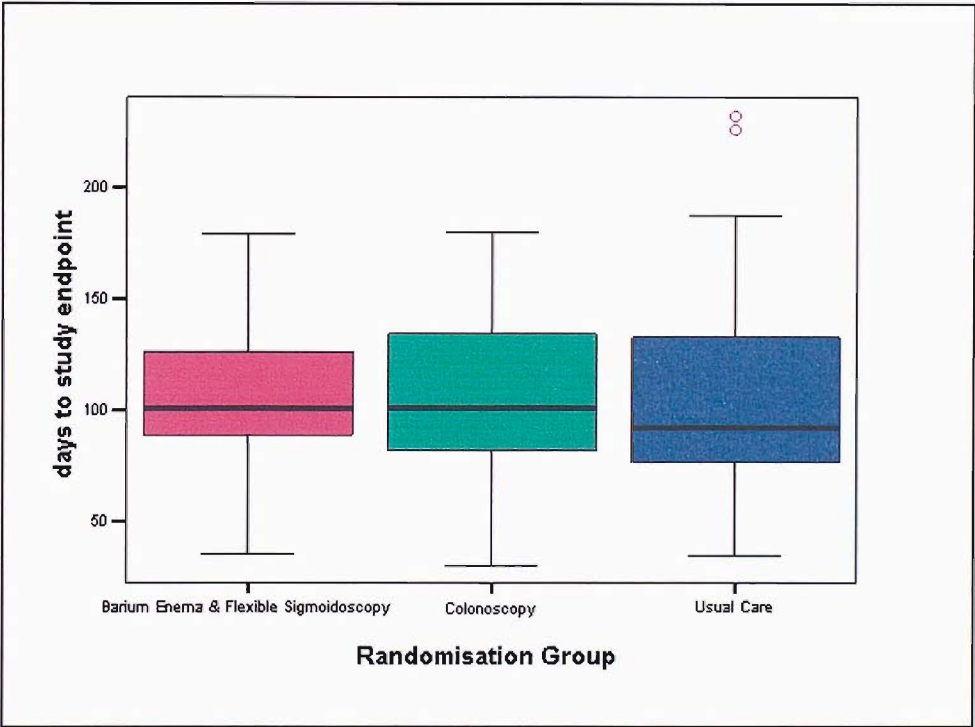


Figure 6.3.1.2b – Box plot of time taken to reach study endpoint (by study group)

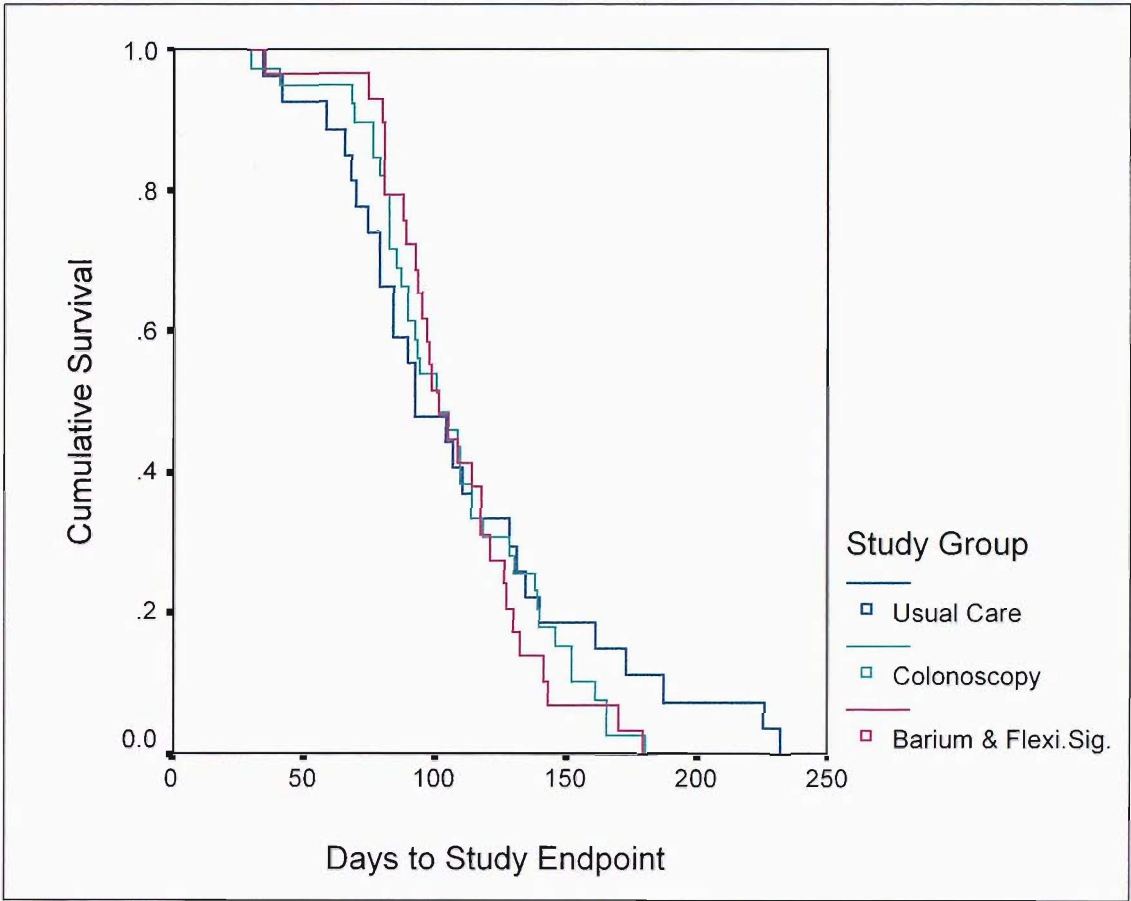


Figure 6.3.1.2c – Kaplan-Meier Survival plot of time taken for study participants to reach endpoint

The survival plot shows that patient experiences are largely similar across the three study groups and that median experiences are almost identical (see also Table 6.3.1.2). There do appear to be subtle differences with patients in the “Usual Care” group taking noticeably longer to reach end point at the extreme end of the study (see Figure 6.3.1.2d).

The first extreme value was seen in the case of a 55-year-old female. The patient attended an OPA (day 43) and was referred for a barium enema. This was performed (day 91) revealing a possible rectal polyp not seen at OPA. A further OPA was arranged (day 155) which the patient failed to attend. She cancelled the next OPA (day 204) before attending the rearranged OPA (day

232). Symptoms were reviewed and the patient told of the need to perform a flexible sigmoidoscopy and referred accordingly. This patient responded in the free text feedback section of the questionnaire –

“Results should have been posted to me A.S.A.P. There was no mention that I had a polyp on my appointment card for my second appointment. So I was surprised and worried. I have now been informed there is a six weeks waiting list. Would rather get it over and done with.”

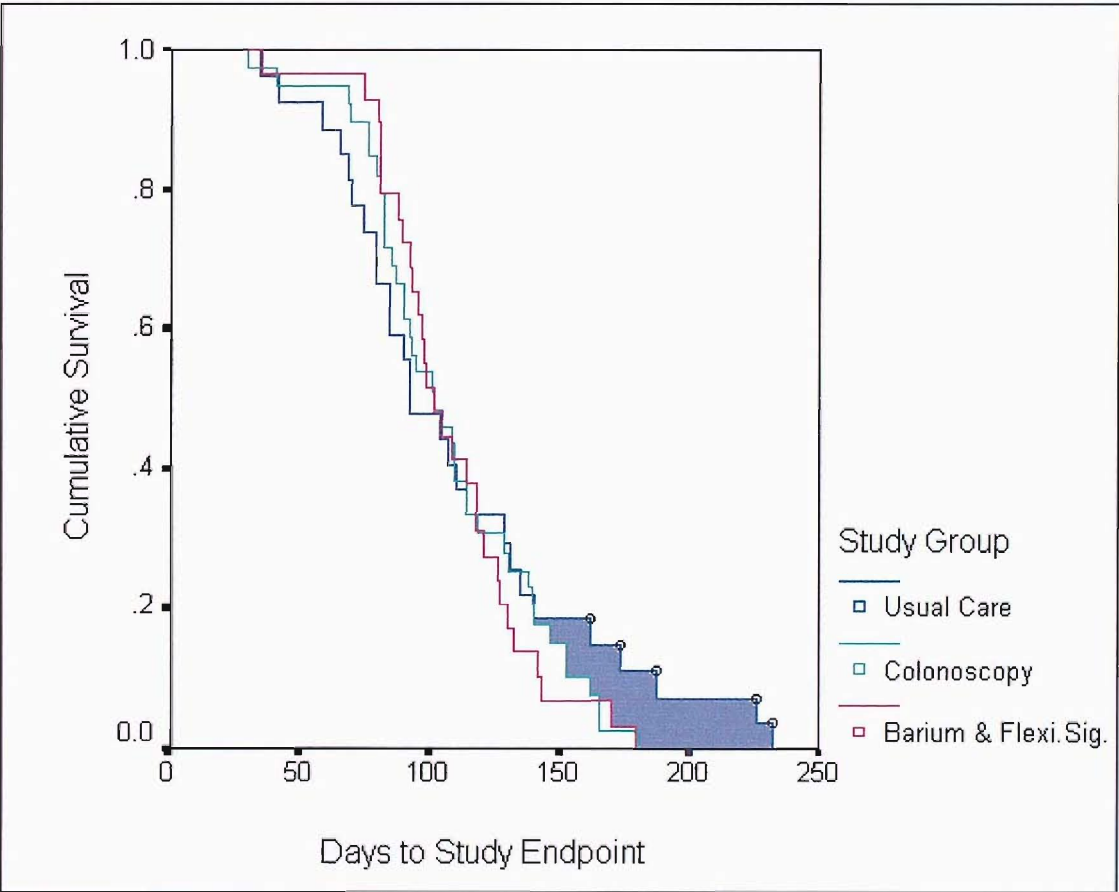


Figure 6.3.1.2d – Kaplan-Meier survival plot of time taken for study participants to reach endpoint demonstrating extreme values. (Shaded area = group divergence, O = highlighted extreme values)

The second extreme value was that of a 63-year-old male. A total of 7 appointments were made for this patient of which they attended only two. The

first OPA (day 37) was cancelled by the patient, he attended the second OPA (day 58) and was referred for a barium enema, the patient then cancelled three barium enema appointments (days 74, 86, & 102) before undergoing a normal barium enema examination (day 177). The patient then failed to attend an OPA (day 226) to discuss results. He was then written to from clinic informing him of his results and no further appointment was offered. The patient wrote the following in the free text feedback section of the questionnaire-

"I was greatly impressed by all the professionals I met. The standard of service was excellent in all aspects. Tremendous empathy was shown by all those dealing with me. Thank you to everyone."

The third extreme value was seen in the case of a 50-year-old female. Following the first OPA (day 47) a colonoscopy appointment was requested which was firstly rescheduled at the patients request (day 103), and then again by the unit (day 131), before finally occurring on the third attempt (day 159). The patient was written to with her results (day 187).

The fourth patient was an 81-year-old female. Her first OPA was cancelled by the hospital (day 75) and was rearranged (day 110). A colonoscopy and biopsy followed (day 131) and the patient was written to when histology results were available (173).

The fifth extreme case was that of a 75-year-old female. Her OPA (day 70) was followed by a flexible sigmoidoscopy (day 125), and a repeat OPA (day 161) for discussion of results.

6.3.2 Measurement of expressed patient satisfaction.

The development and validation of the questionnaire used for this study is detailed in section 5.0. For the purpose of comparing the three study groups satisfaction is analysed by overall expressed satisfaction and dimension.

When analysing the patient satisfaction data obtained from the postal questionnaires it was necessary to code the question responses. During study design the “polarity” of questions (whether agreement signified satisfaction or the dissatisfaction) was intentionally varied. In order to produce a score each questions response was assigned a value from 1 to 5; a scored response of 1 signifying minimum satisfaction and a score of 5 signifying the greatest. When calculating total scale or subscale scores the scores of the individual questions were simply added together (no attempt at weighting the questions for relative importance was made)

As the numerical values assigned to the questionnaire responses were not weighted they cannot be considered as continuous data. As such the collected data are analysed as non-parametric.

6.3.2.1 Overall satisfaction (total score)

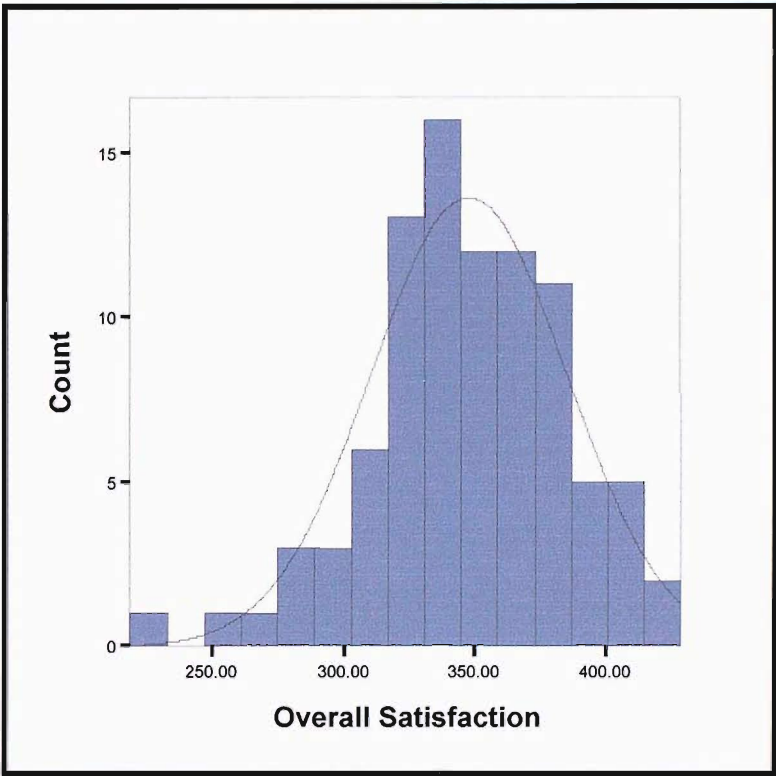


Figure 6.3.2.1a – Expressed satisfaction of all study participants.

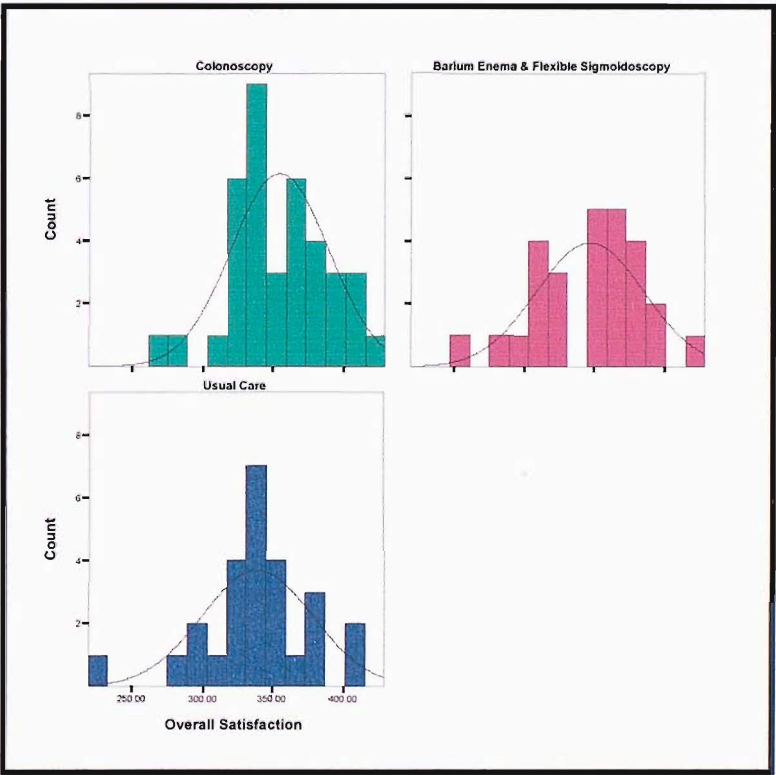


Figure 6.3.2.1b – Expressed satisfaction of study participants by study group.

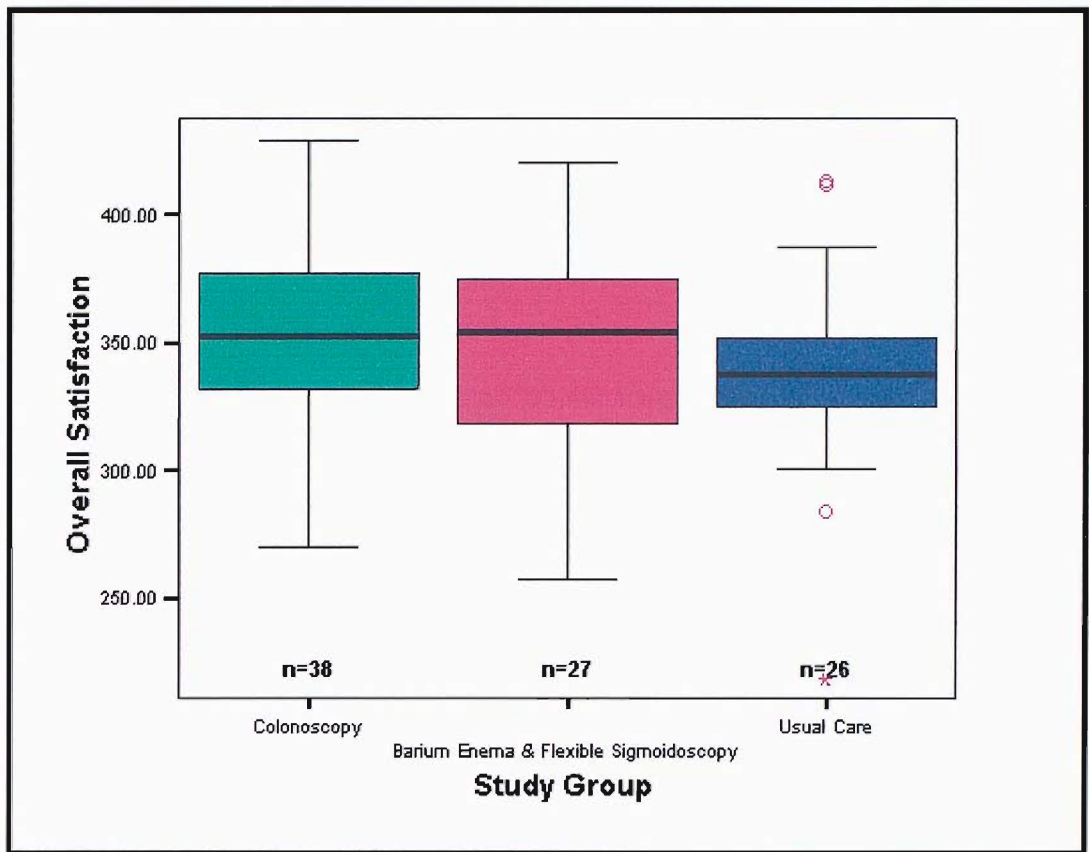


Figure 6.3.2.1c – Box plot of expressed satisfaction (total scale score) by group.

The possible total scores from the questionnaire ranged from a minimum of 86 to a maximum of 430. It was expected that the level of expressed satisfaction would form a normal distribution at the higher end of this range and the results (Figure 6.3.2.1a) have supported this preconception (minimum score 219, maximum score 429!). The detection of dissatisfaction is the true challenge.

When questionnaire scores were charted in accordance with study group the distribution remained normal.

Using a Kruskal-Wallis Test (SPSS 10.1.0 for Windows) a non-parametric test for comparing three or more independent groups no significant difference in overall satisfaction was identified ($p=0.303$), however the study was underpowered (Table 6.6.2).

A box plot of results (Figure 6.3.2.1c) showed what appear to be a lower level of overall satisfaction and a narrower range of expressed satisfaction for patients in the “Usual Care” group, while those in the “Colonoscopy” group express the highest.

There was one extreme value in the “Usual care” group (point charted more than 3 box lengths beyond the upper or lower box limit – the box length being the inter quartile range). This questionnaire was returned by a 76-year-old female. This patient wrote “first visit only” in the margin of the questionnaire and intimated that they had sought alternative arrangements by writing “had it” by the questionnaire item “I would prefer a further opinion about my symptoms”. The patient did not wait an abnormally long time, and the singling out of the first OPA suggests that the patient found the experience far from satisfactory.

6.3.2.2 Understanding of Events (subscale 1 score)

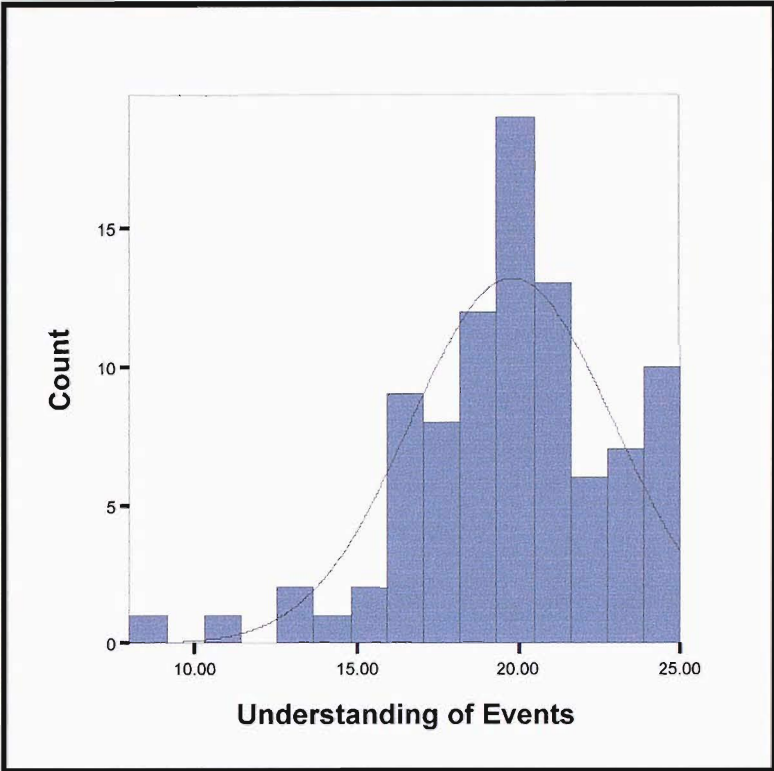


Figure 6.3.2.2a – “Understanding of Events” – Subscale 1 score of all study participants.

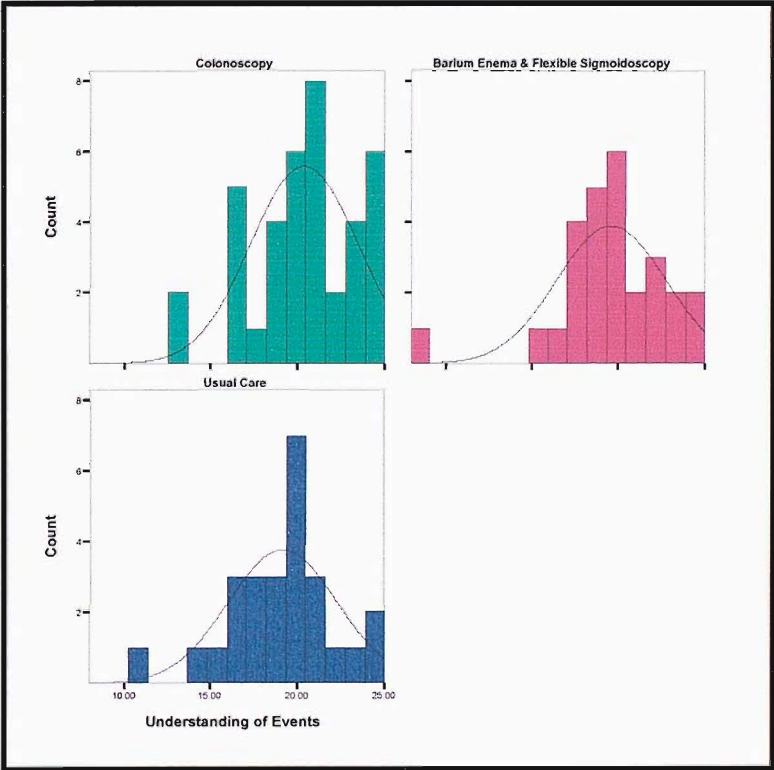


Figure 6.3.2.2b – “Understanding of Events” - Subscale 1 score by study group.

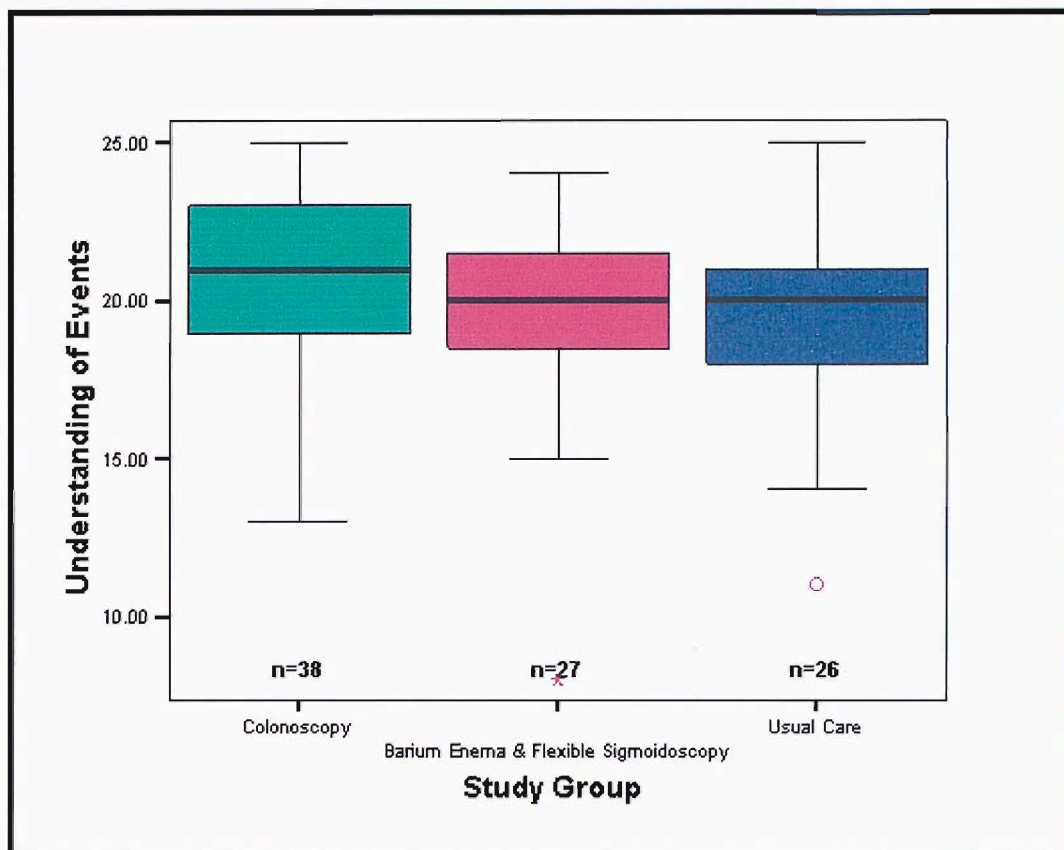


Figure 6.3.2.2c – Box plot of “Understanding of Events” (Subscale 1 score) by group.

Again the expressed level of satisfaction was at the higher end of the scale following a normal distribution for all participants, and when assessed by study arm (though not as closely as for overall satisfaction).

Using a Kruskal-Wallis Test (SPSS 10.1.0 for Windows) a non-parametric test for comparing three or more independent groups no significant difference in “Understanding of Events” was identified ($p=0.198$). There is no significant difference between the three groups, but again statistical analysis is underpowered (Table 6.6.2).

From the box plot it does appear that the “Colonoscopy” group expressed a higher level of satisfaction. This could be due to the fact that as a group they experienced fewer visits to hospital and that the literature surrounding colonoscopy is designed to be as informative as possible.

There was one extremely low score as identified on the box plot, in the “Barium Enema & Flexible Sigmoidoscopy” group. This patient was a 65 year old female who had two flexible Sigmoidoscopy appointments cancelled on the day as she was deemed unfit due to a chest infection on both occasions. This would no doubt have resulted in some confusion and frustration on the patient’s part and contributed to a poor “Understanding of events” dimension score.

6.3.2.3 Anxiety (subscale 2 score)

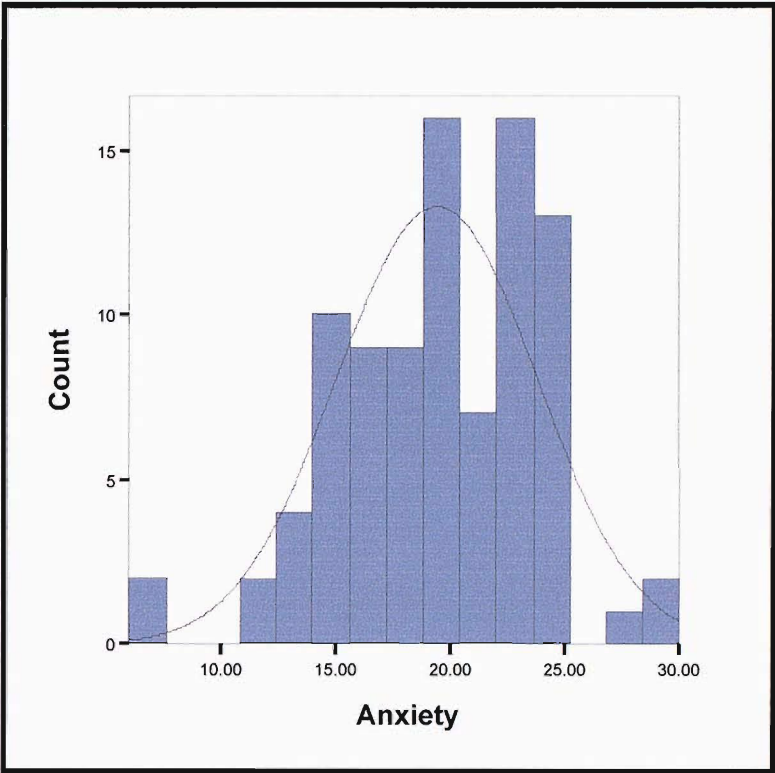


Figure 6.3.2.3a – “Anxiety” – Subscale 2 score of all study participants.

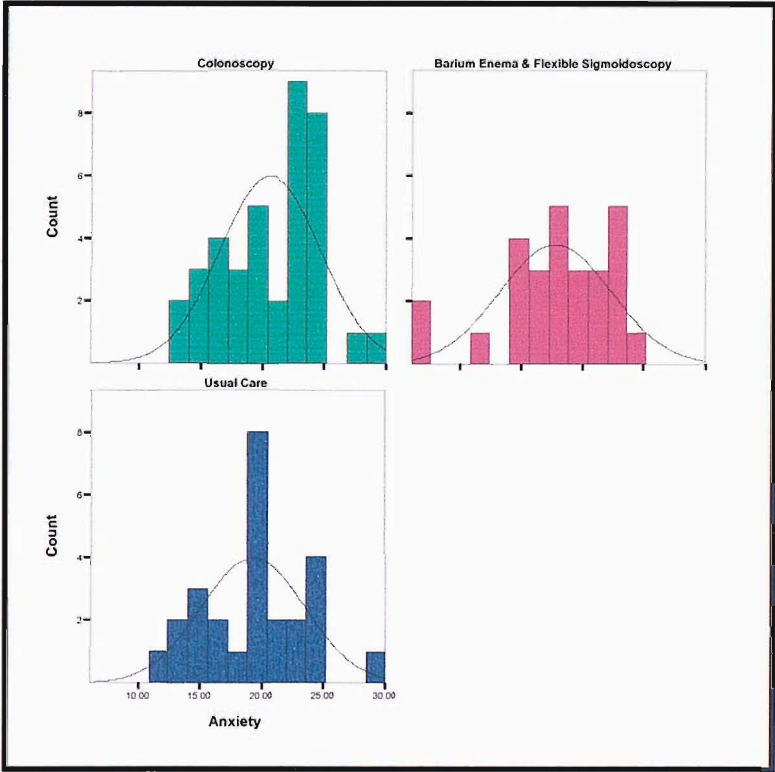


Figure 6.3.2.3b – “Anxiety” - Subscale 2 score by study group.

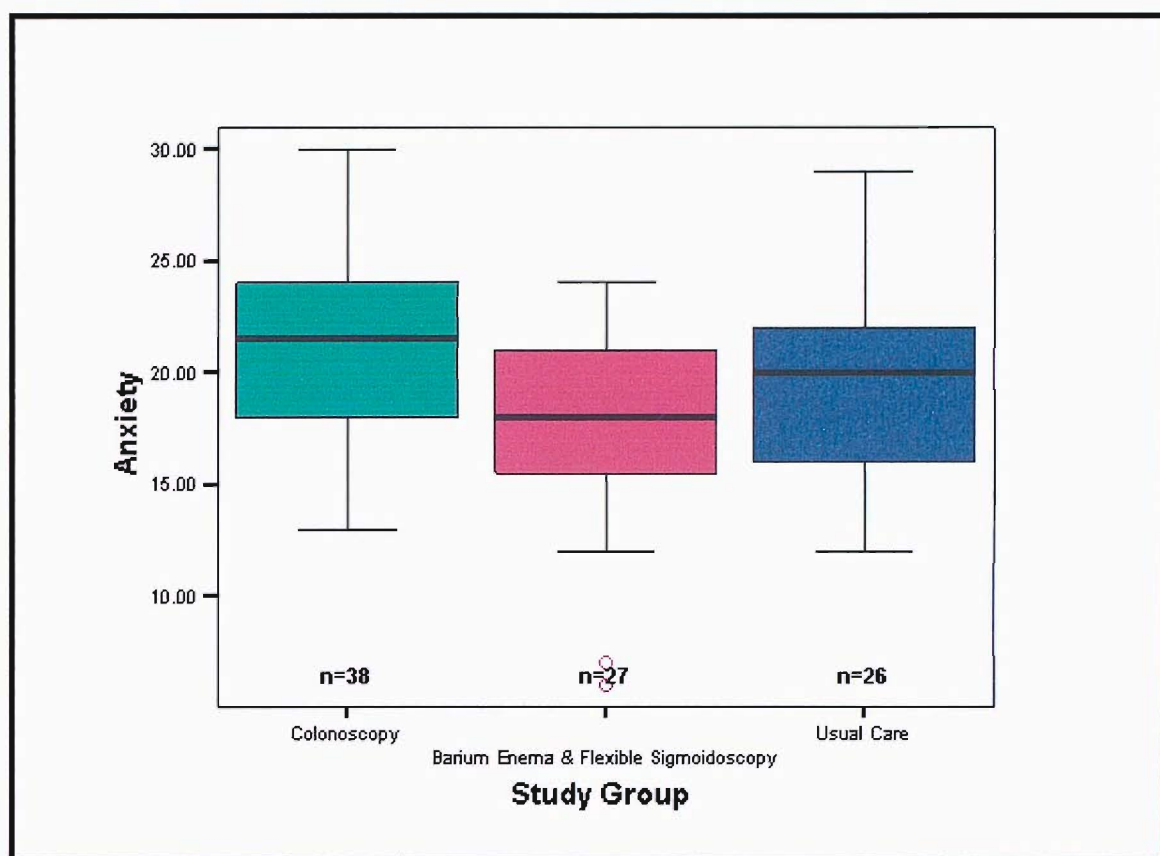


Figure 6.3.2.3c – Box plot of “Anxiety” (Subscale 2 score) by group.

The distribution of expressed satisfaction was across the full scale rather than concentrated at the upper end, the pattern only loosely adherent to a normal distribution. This pattern continued when results for the separate study groups were charted (Figure 6.3.2.3a & b). The box plot (Figure 6.3.2.3c) suggests a definite trend with the “Colonoscopy” having the highest score, followed by the “Usual Care” group, then with the lowest score the “Barium Enema & Flexible Sigmoidoscopy” group.

Using a Kruskal-Wallis Test (SPSS 10.1.0 for Windows) a non-parametric test for comparing three or more independent groups a significant difference in “Anxiety” was identified ($p=0.050$).

Further analysis between the study groups employing Mann-Whitney U test (SPSS 10.1.0 for Windows) a non-parametric test for comparing two independent groups revealed a significant difference between the “Colonoscopy” and “Barium Enema & Flexible Sigmoidoscopy” groups ($p=0.015$). There was no significant difference between “Colonoscopy” and “Usual Care” ($p=0.191$), or “Barium Enema & Flexible Sigmoidoscopy” and “Usual Care” ($p=0.329$).

The significant difference between the “Colonoscopy” and “Barium Enema & Flexible Sigmoidoscopy” study arms suggests that patients in the “Colonoscopy” group report less anxiety. The study was underpowered for all comparisons.

The comparison of “Colonoscopy” and “Barium Enema & Flexible Sigmoidoscopy” study arms for this sub-scale had the highest power of any comparison in the study (identified as 0.66 by retrospective power calculation). The sample size required to gain an acceptable power for comparison across all groups should be achievable with improved recruitment (Table 6.6.2).

6.3.2.4 Professionalism (subscale 3 score)

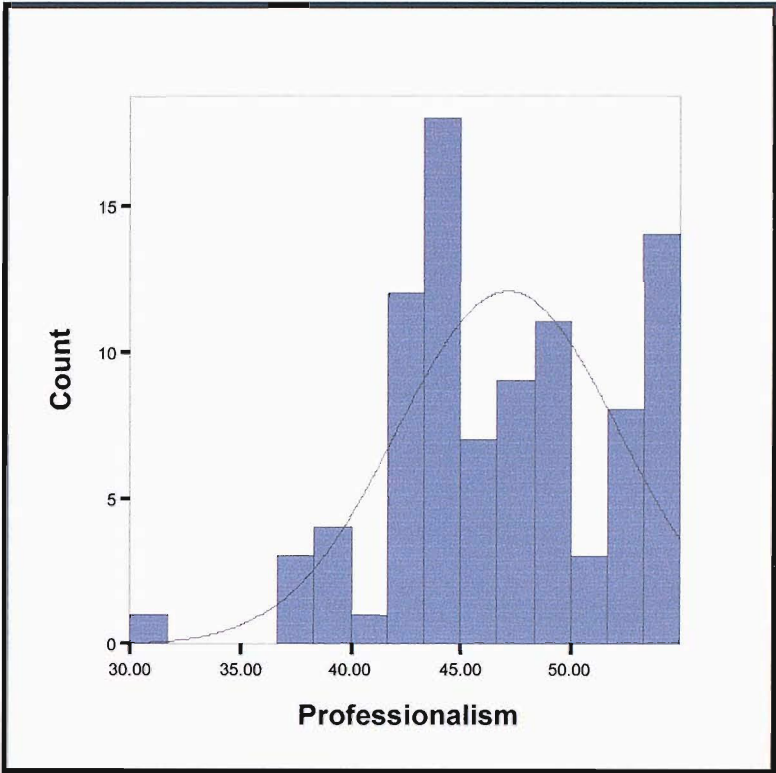


Figure 6.3.2.4a – “Professionalism” – Subscale 3 score of all study participants.

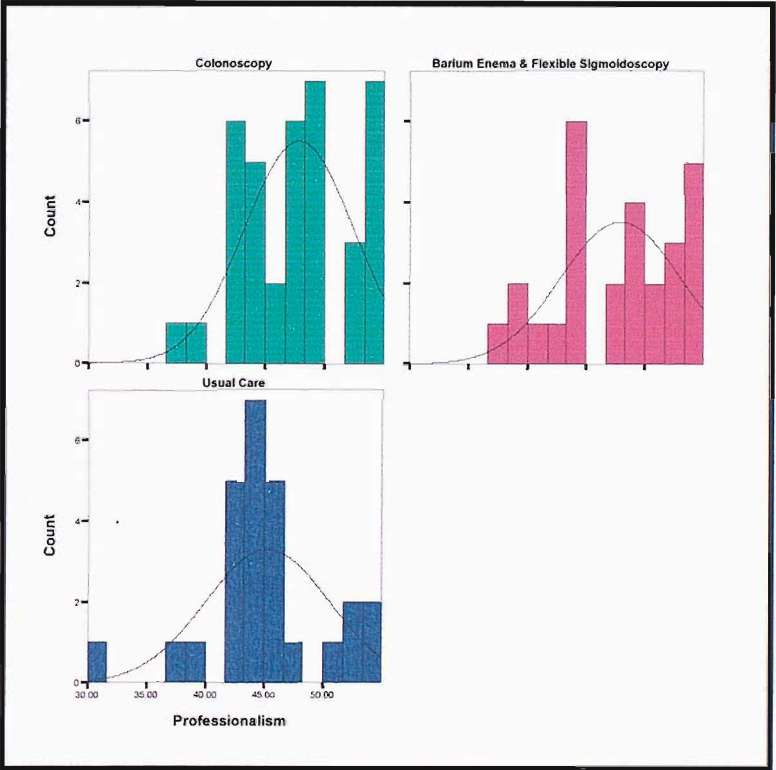


Figure 6.3.2.4b – “Professionalism” - Subscale 3 score by study group.

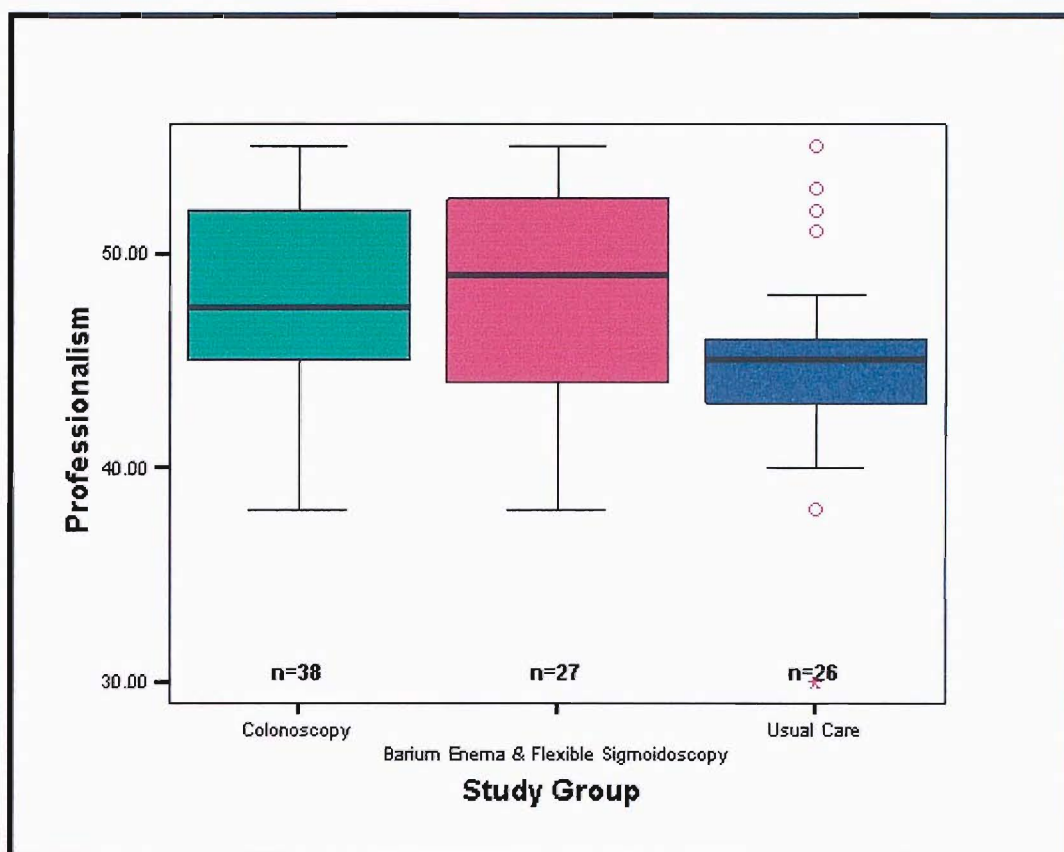


Figure 6.3.2.4c – Box plot of “Professionalism” (Subscale 3 score) by group.

The charted results are again at the upper end of the score range but the distribution only poorly confirms to a normal distribution. The box plot (Figure. 6.3.2.4c) suggests no difference between the “Colonoscopy” and “Barium Enema & Flexible Sigmoidoscopy” groups, with the scores from the “Usual care” group being lower and over a narrower distribution.

Using a Kruskal-Wallis Test (SPSS 10.1.0 for Windows) a non-parametric test for comparing three or more independent groups no significant difference in “Professionalism” across the three groups was identified ($p=0.098$).

Direct comparison supports a statistically significant difference between the “Colonoscopy” and “Usual Care” groups ($p=0.039$) though analysis was underpowered for all. The comparisons across this group come closest of all

groups to achieving the desired aim. Powers are between 0.44 & 0.46, the sample sizes to achieve a power of 0.8 are just greater than twice that achieved and should be attainable if the study were repeated with improved recruitment.

There was one extreme (low) result for the professionalism group, scored by a patient in the “Usual Care” group. This was the same 76-year-old female that returned the extremely low score for “Overall Satisfaction” (7.8.2.1). The low score in this “Professionalism” sub-scale supports the inference that the patient had a particularly poor experience at her first OPA.

6.3.2.5 Confidence / Trust in Staff (subscale 4 score)

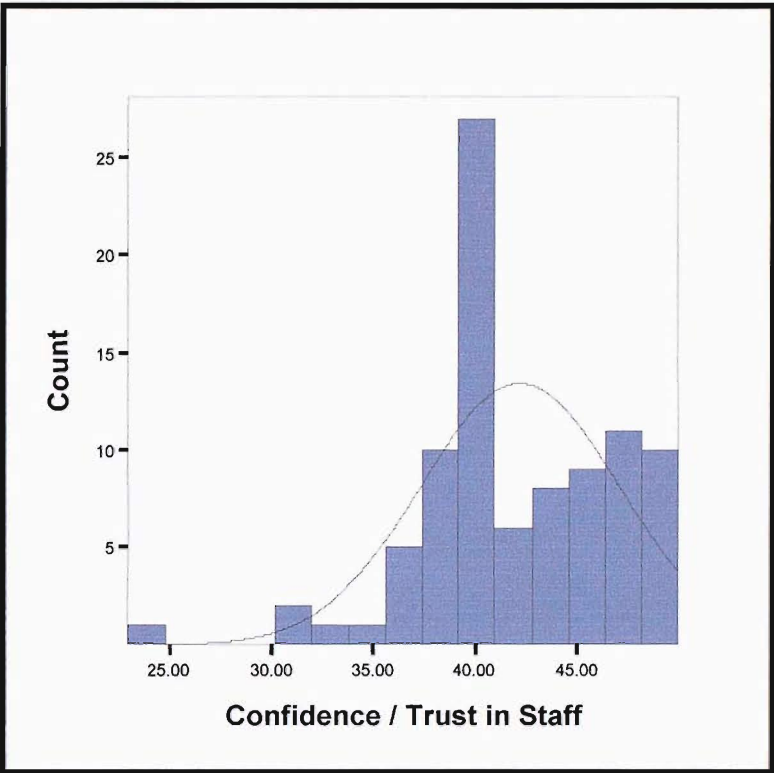


Figure 6.3.2.5a – “Confidence / Trust in Staff” – Subscale 4 score of all study participants.

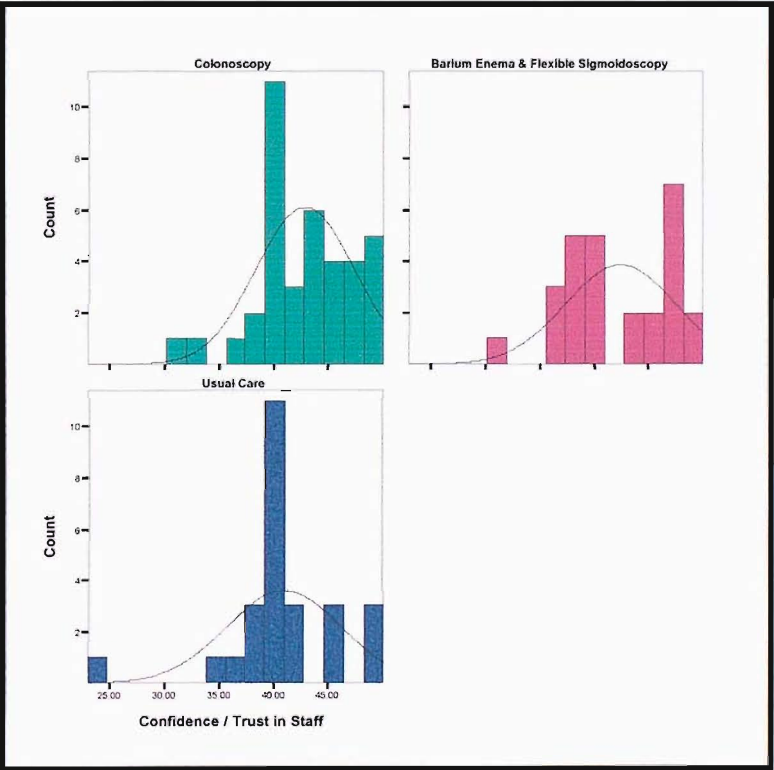


Figure 6.3.2.5b – “Confidence / Trust in Staff” - Subscale 4 score by study group.

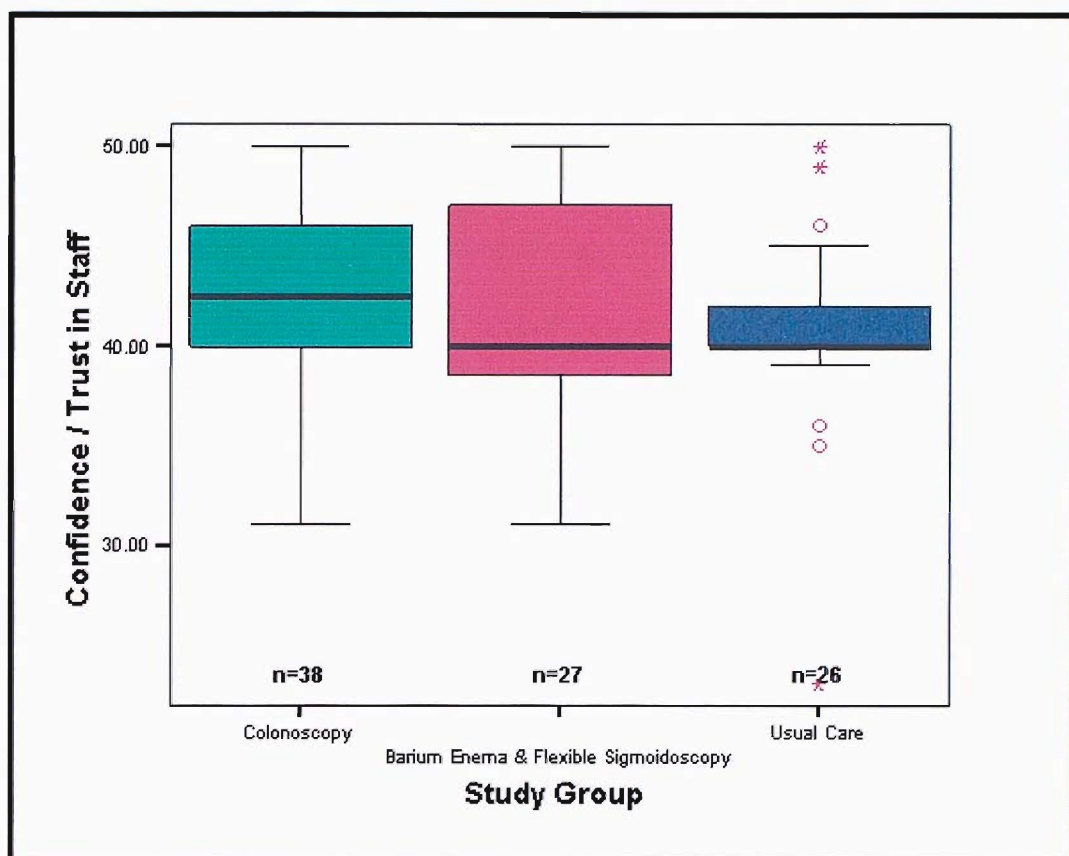


Figure 6.3.2.5c – Box plot of “Confidence / Trust in Staff” (Subscale 4 score) by group.

This subscale shows the most dramatic weighting to the top end of the score scale. This is not unexpected as items in this scale deal directly with the patients’ opinion of staff (see Appendix Q) and as a result are particularly susceptible to the “halo” effect (see section 2.2.8.4)

The box plot (Figure 6.3.2.5c) does not suggest a definite difference between the three study arms, though the “Usual Care” group do express a narrow range of responses.

Using a Kruskal-Wallis Test (SPSS 10.1.0 for Windows) a non-parametric test for comparing three or more independent groups no significant difference in “Confidence/Trust in Staff” was identified ($p=0.273$).

There are a number of extreme results, all in the “Usual Care” group due to the narrow range of differing opinion reported by the majority.

There are several abnormally high results (including five maximum scores) supporting the statement that measurement of this particular facet of satisfaction is limited by the “halo” effect.

The single extreme low result was from the same 76-year-old female giving a low “Professionalism” and “Overall Satisfaction” score; believed to be due to a poor experience at her first OPA.

6.3.2.6 Substance of Consultation (subscale 5 score)

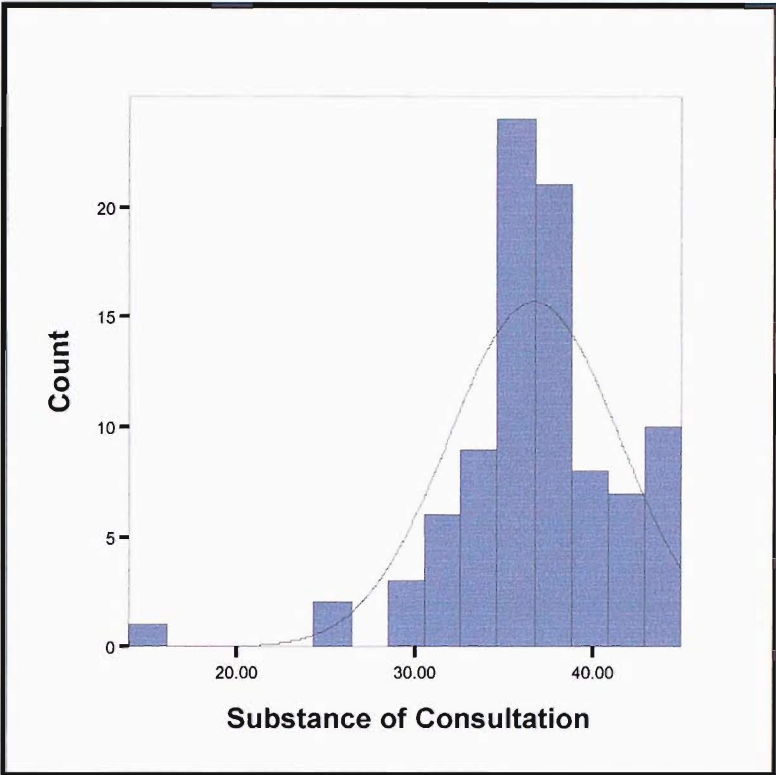


Figure 6.3.2.6a – “Substance of Consultation” – Subscale 5 score of all study participants.

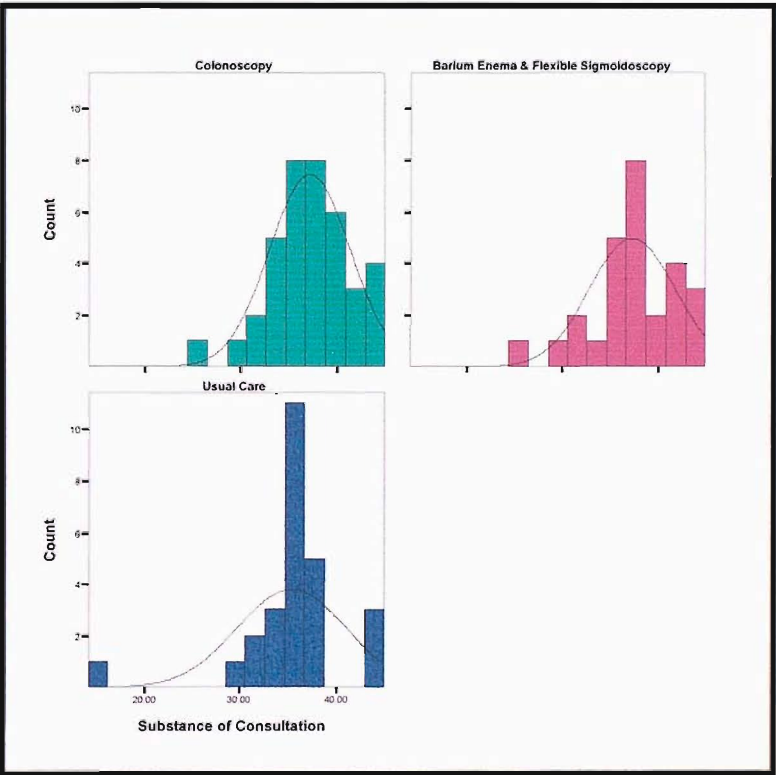


Figure 6.3.2.6b – “Substance of Consultation” - Subscale 5 score by study group.

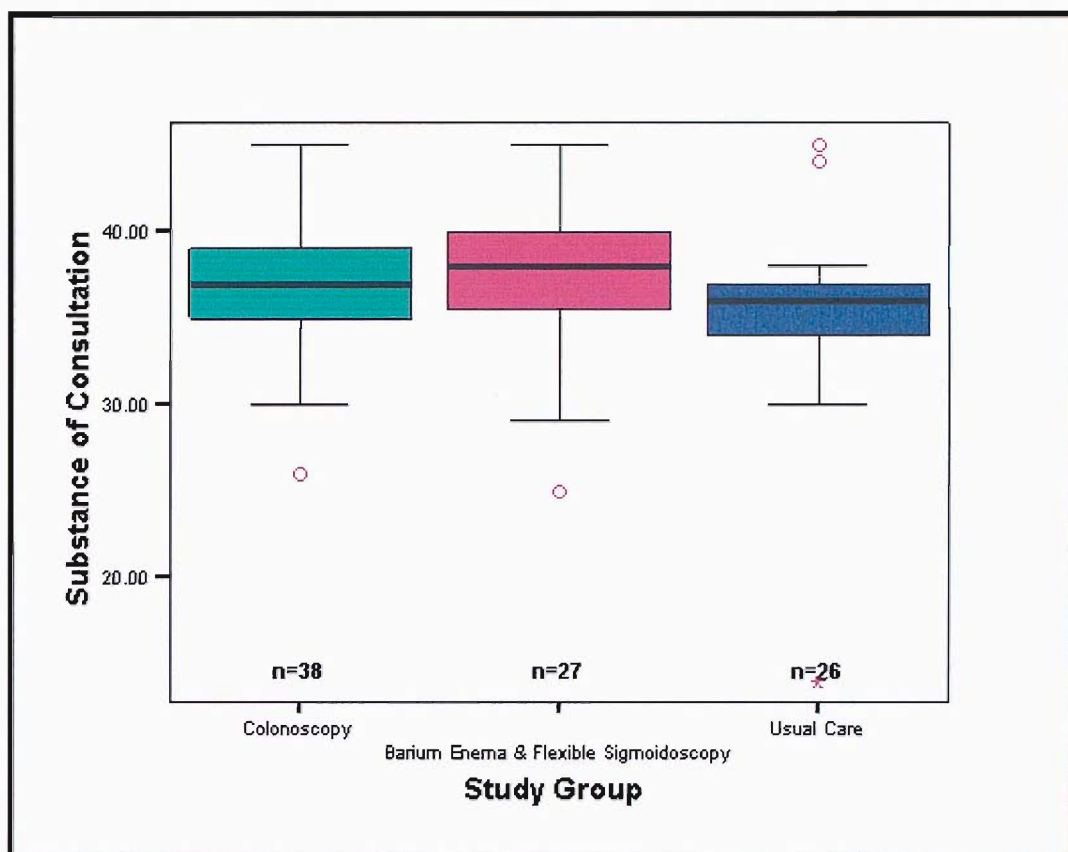


Figure 6.3.2.6c – Box plot of “Substance of Consultation” (Subscale 5 score) by group.

The results again follow a normal distribution at the upper end of the scoring scale. The box plot (Figure 6.3.2.6c) does not identify any apparent trend.

Using a Kruskal-Wallis Test (SPSS 10.1.0 for Windows) a non-parametric test for comparing three or more independent groups no significant difference in “Substance of Consultation” was identified ($p=0.130$). Statistical analysis was again limited by inadequate study power. Retrospective power calculation shows that an unusually large sample of 10,000 to each arm would be needed to make a sound analysis of differences between the “Colonoscopy” and “Barium Enema & Flexible Sigmoidoscopy” group scores.

There was one extreme (low) result in the “Usual Care” group, this was again offered by the 76-year-old dissatisfied female patient.

6.3.2.7 Mechanics (subscale 6 score)

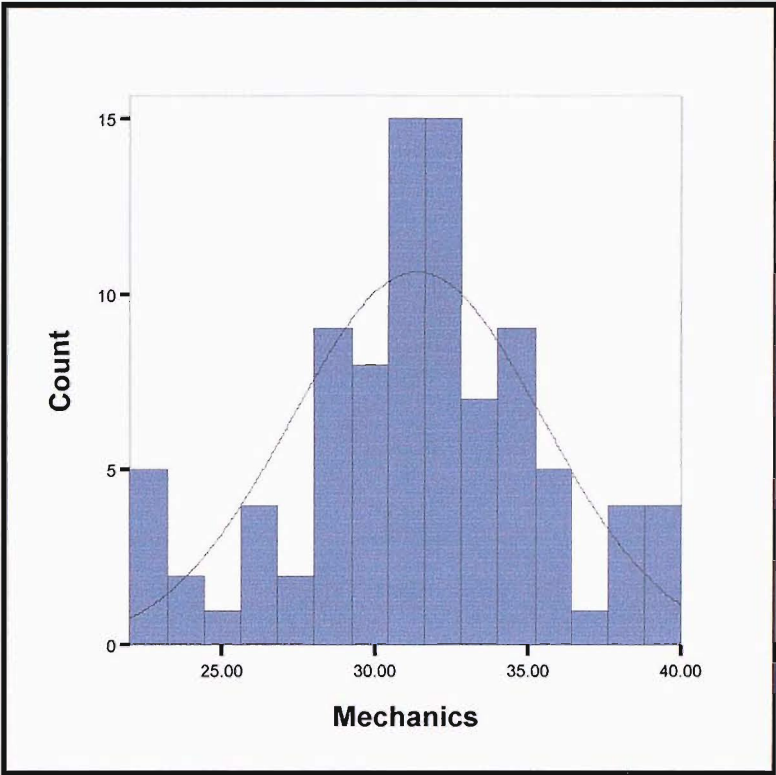


Figure 6.3.2.7a – “Mechanics” – Subscale 6 score of all study participants.

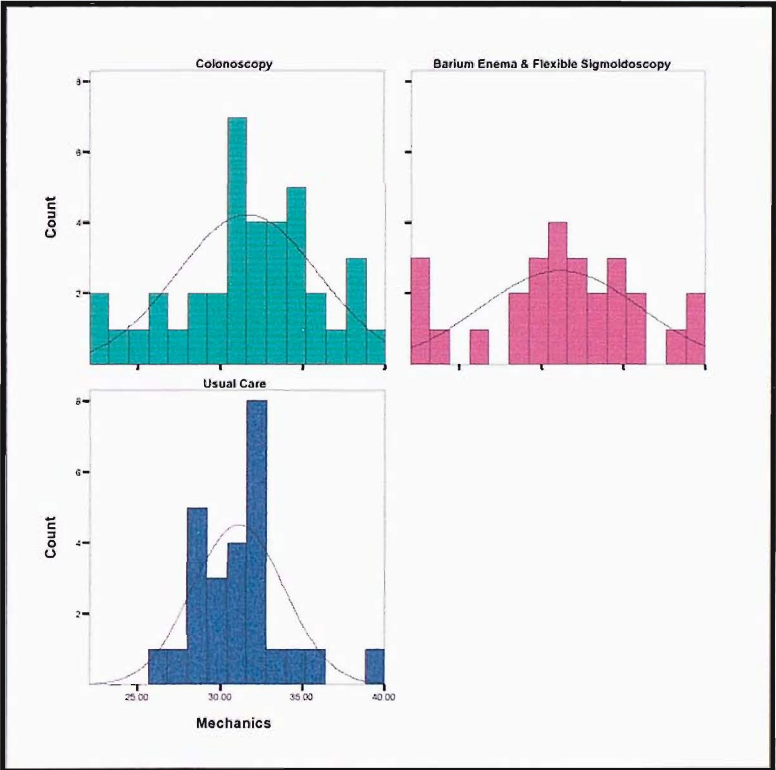


Figure 6.3.2.7b – “Mechanics” - Subscale 6 score by study group.

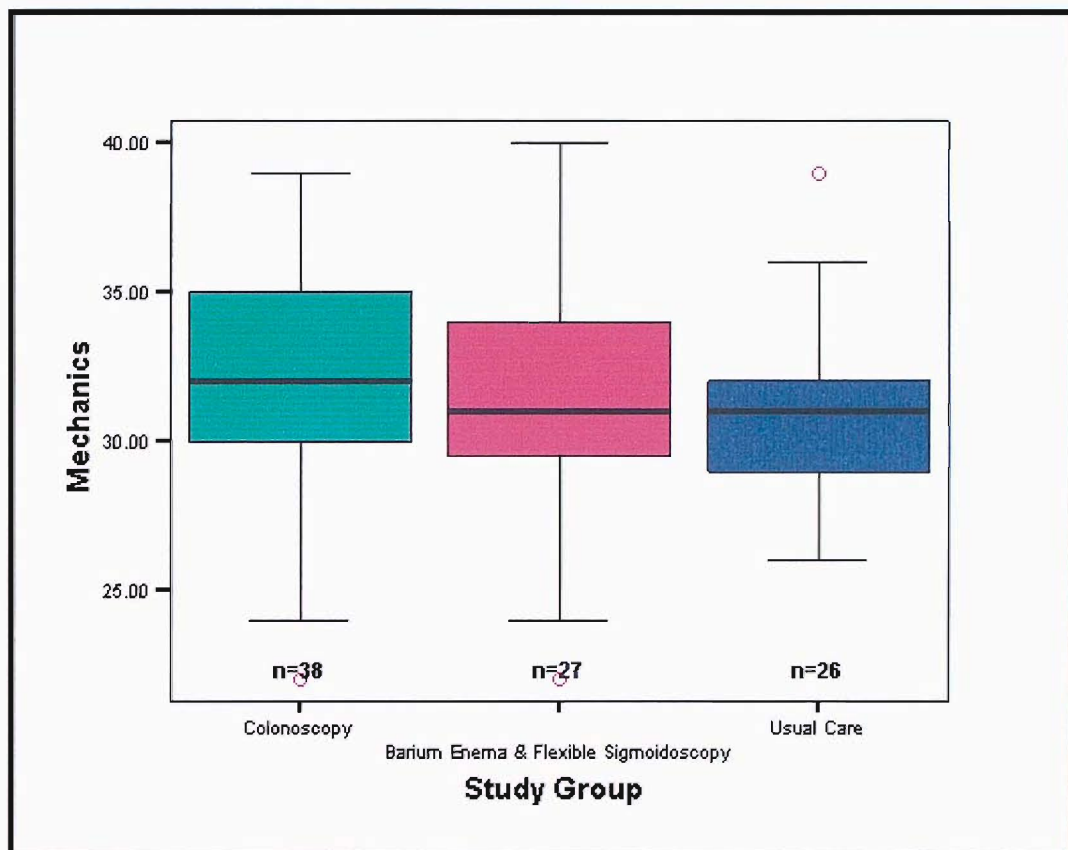


Figure 6.3.2.7c – Box plot of "Mechanics" (Subscale 6 score) by group.

The results for this scale are distributed over the full range of potential scores and conform to a normal distribution pattern. These features are still evident when the three arm's results are charted separately (Figure 6.3.2.7a & b). The box plot (Figure 6.3.2.7c) shows little difference between the three groups.

Using a Kruskal-Wallis Test (SPSS 10.1.0 for Windows) a non-parametric test for comparing three or more independent groups no significant difference in "Mechanics" was identified ($p=0.612$).

Statistical analysis was underpowered. The retrospective power calculations indicate that study sample of 200,000 patients to each arm would be required

to achieve a power of 0.8 for a “Colonoscopy” and “Barium Enema & Flexible Sigmoidoscopy” group comparison.

6.3.2.8 Results (subscale 7 score)

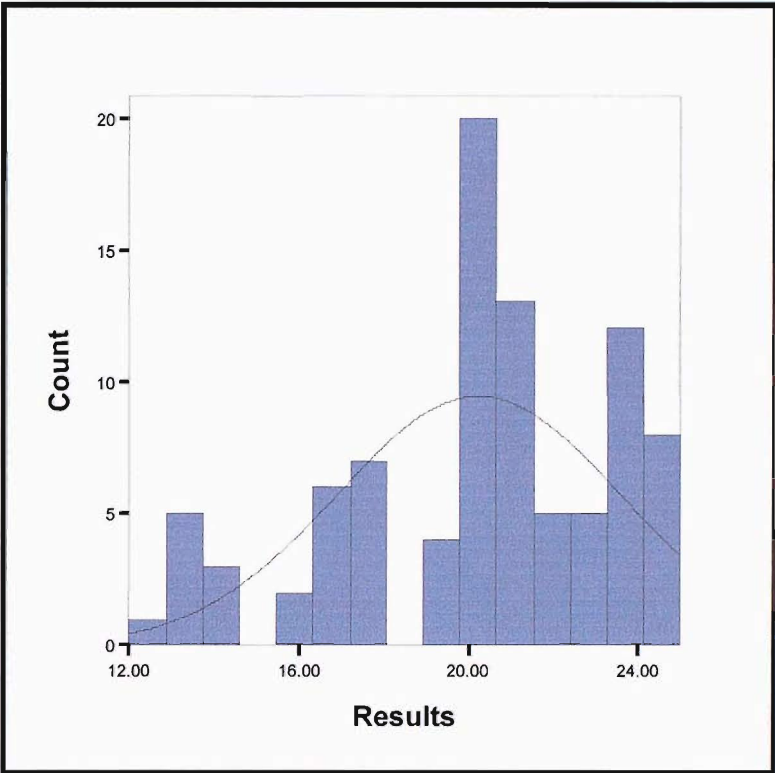


Figure 6.3.2.8a – “Results” – Subscale 7 score of all study participants.

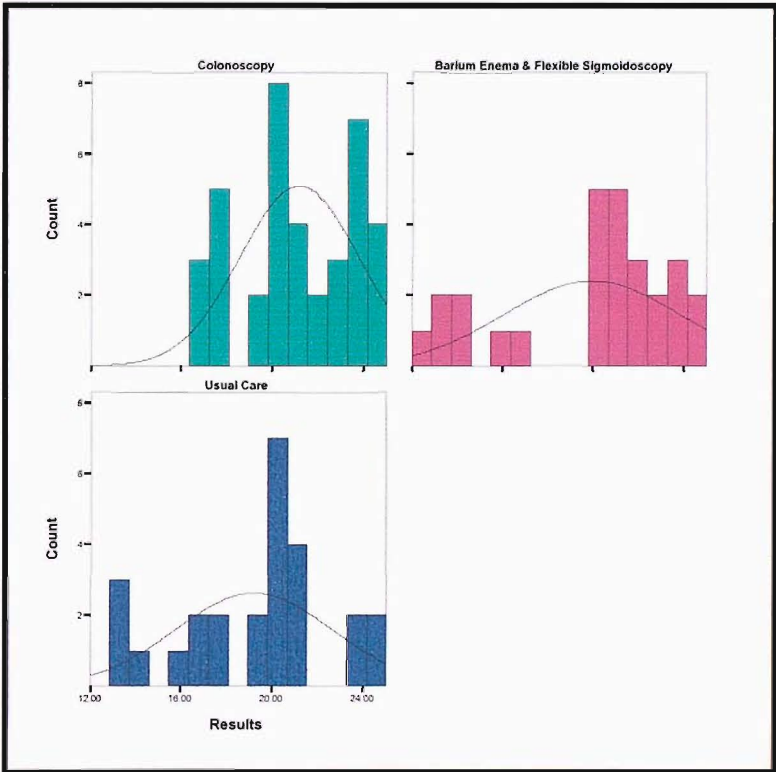


Figure 6.3.2.8b – “Results” - Subscale 7 score by study group.

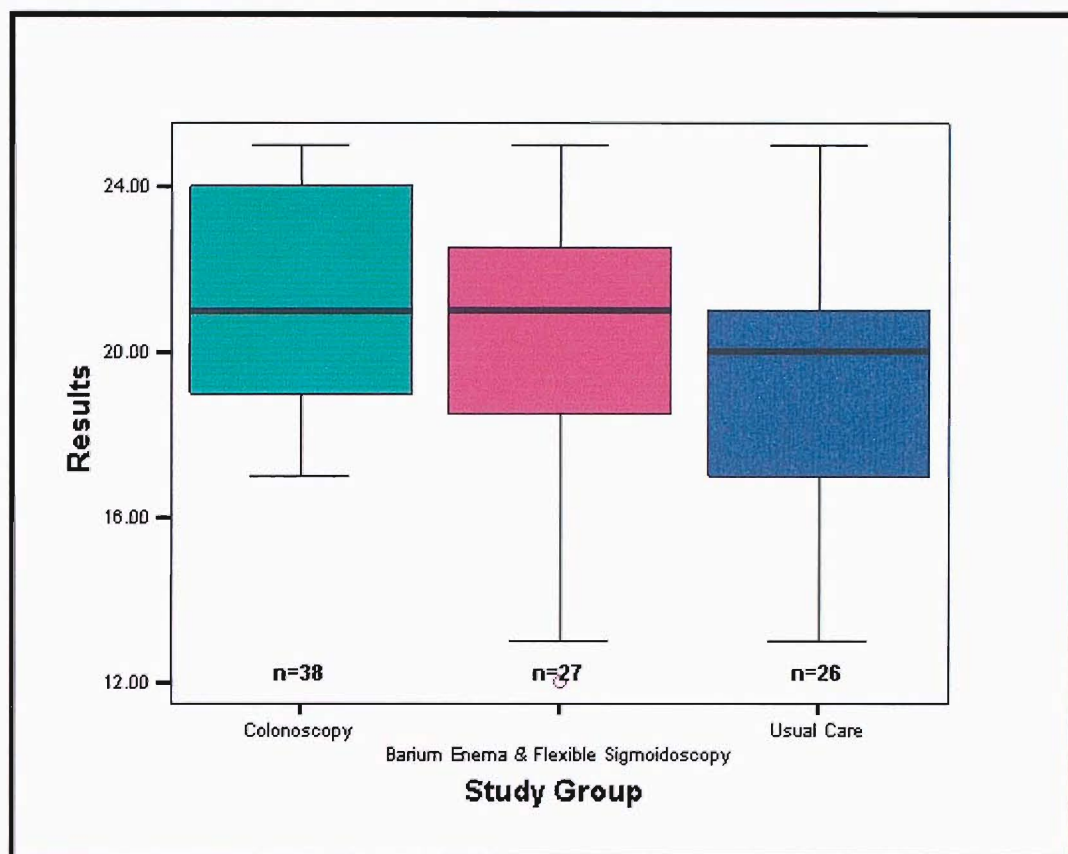


Figure 6.3.2.8c – Box plot of “Results” (Subscale 7 score) by group.

The scores for this dimension of satisfaction are distributed over the full range but only poorly conforms to a normal distribution; when broken down into the three groups it is apparent that scores for the “Colonoscopy” group are at the upper end of the range while the others’ scores are distributed throughout the range. The box plot (Figure 6.3.2.8c) supports this observation as the “Colonoscopy” group appear to demonstrate the highest level of satisfaction for this subscale followed by the “Barium Enema & Flexible Sigmoidoscopy”.

Using a Kruskal-Wallis Test (SPSS 10.1.0 for Windows) a non-parametric test for comparing three or more independent groups no significant difference in “Results” was identified ($p=0.108$).

Sub-analysis is underpowered but identifies a significant difference between “Colonoscopy” and “Usual Care” ($p=0.037$).

6.3.2.9 Disclosure (subscale 8 score)

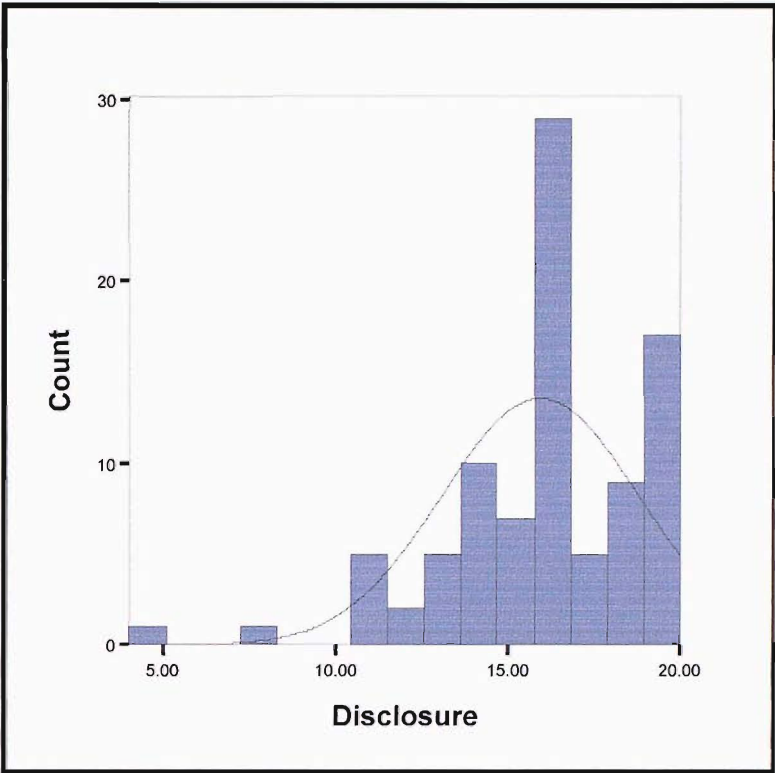


Figure 6.3.2.9a – “Disclosure” – Subscale 8 score of all study participants.

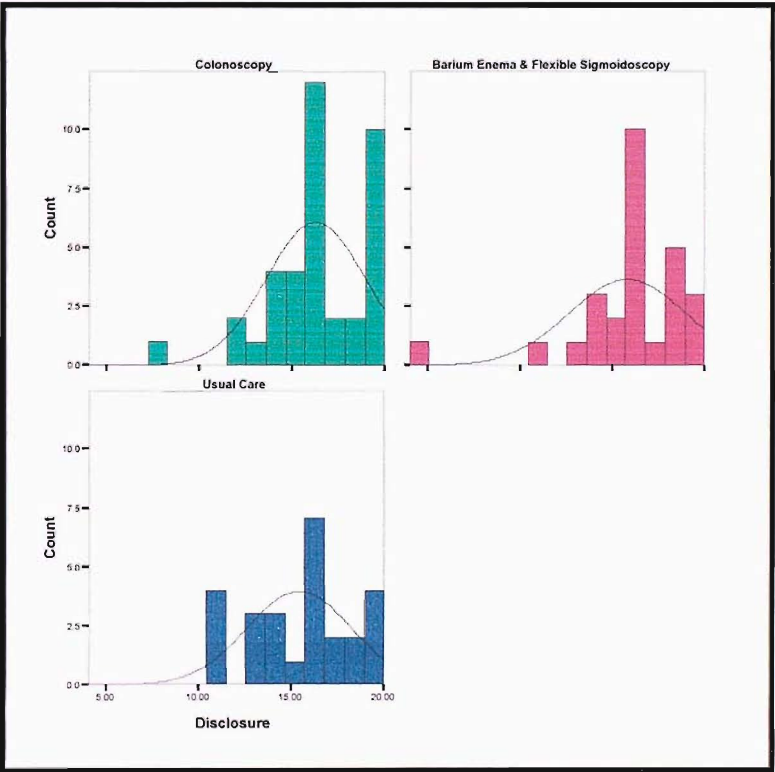


Figure 6.3.2.9b – “Disclosure” - Subscale 8 score by study group.

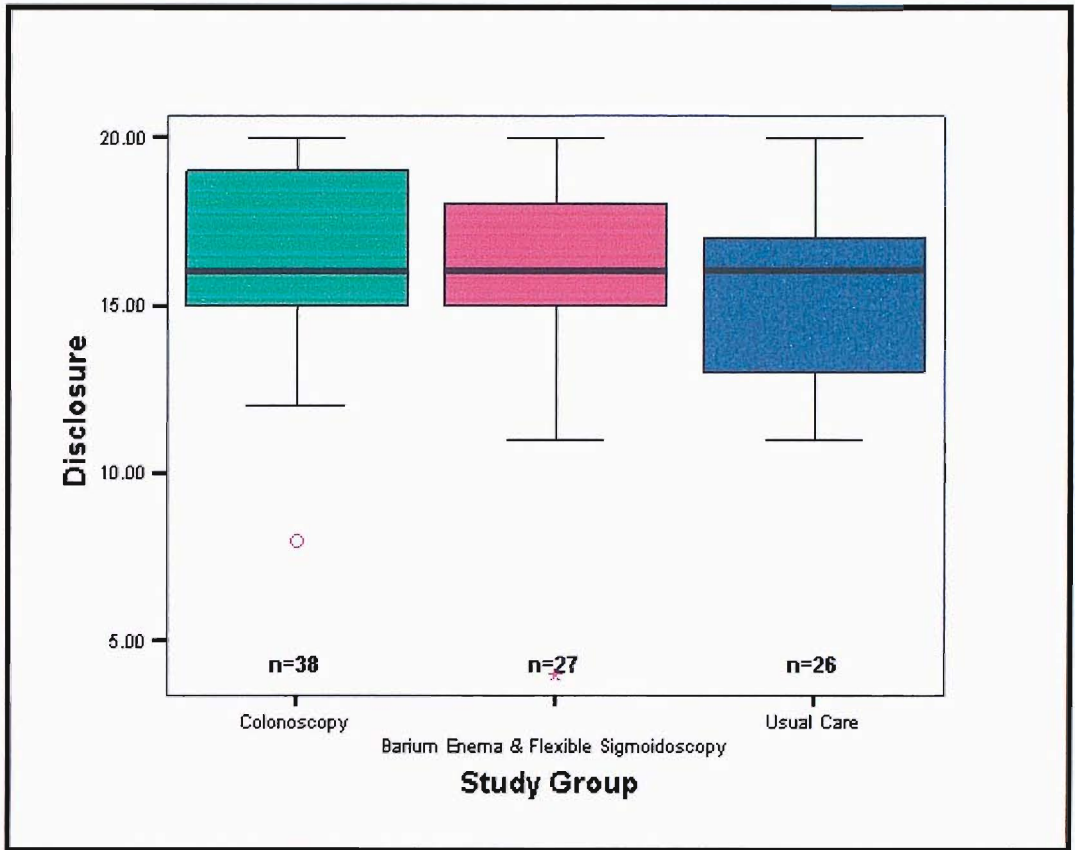


Figure 6.3.2.9c – Box plot of “Disclosure” (Subscale 8 score) by group.

The disclosure subgroup scores follow a normal distribution over the upper range of possible scores when charted for all study participants and by study group. The box plot (Figure 6.3.2.9c) suggests that despite sharing a median the score for the “Usual Care” group is lower than that of the other two.

Using a Kruskal-Wallis Test (SPSS 10.1.0 for Windows) a non-parametric test for comparing three or more independent groups no significant difference in “Disclosure” was identified ($p=0.469$). The statistical analysis was again underpowered.

There is one extreme (low) result in the “Barium Enema & Flexible Sigmoidoscopy” group. This 65-year-old female patient is the same that

scored the extreme (low) result for the “Understanding of Events” subscale. She was subject to investigations being cancelled at the time of attendance due to poor health of the patient’s part.

6.3.2.10 Preparation (subscale 9 score)

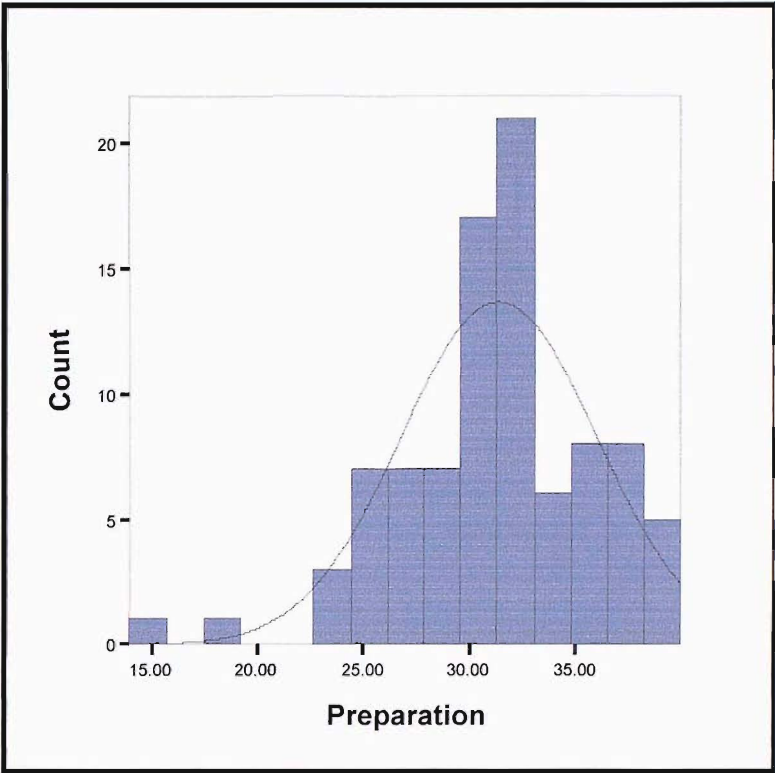


Figure 6.3.2.10a – “Preparation” – Subscale 9 score of all study participants.

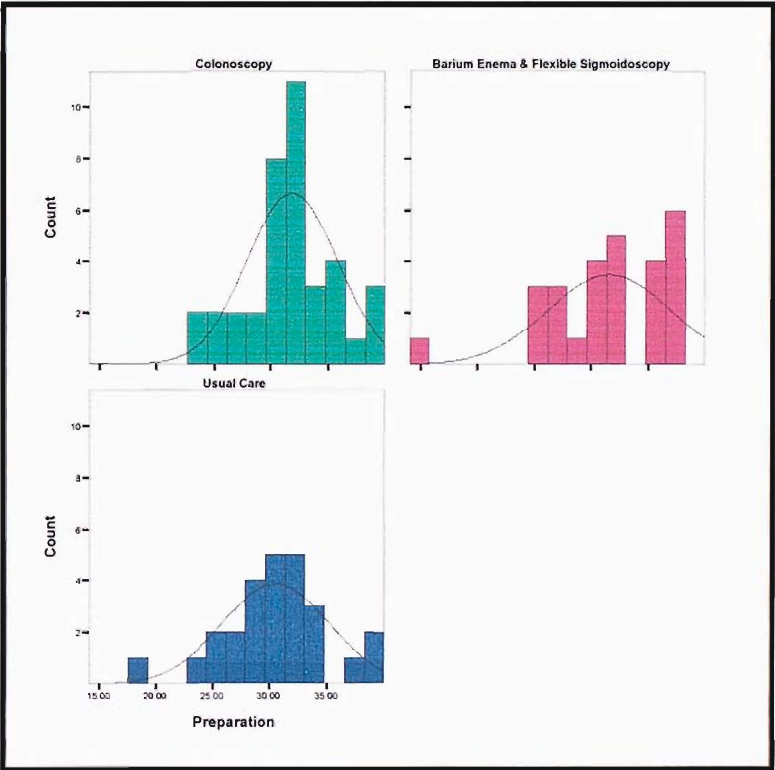


Figure 6.3.2.10b – “Preparation” - Subscale 9 score by study group.

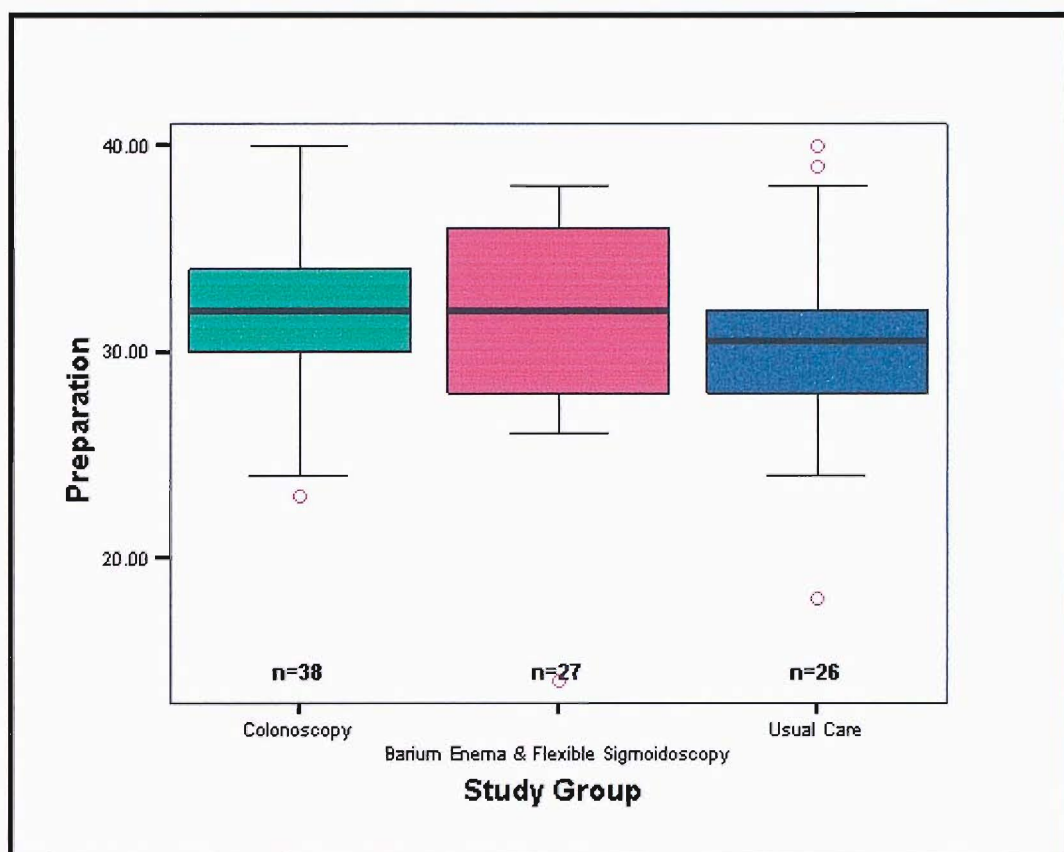


Figure 6.3.2.10c – Box plot of “Preparation” (Subscale 9 score) by group.

A box plot of this scales score (Figure 6.3.2.10c) indicates that the score for the “Usual Care” group is lower than the other two but the underpowered statistical analysis is unable to support or refute this with significant findings. Using a Kruskal-Wallis Test (SPSS 10.1.0 for Windows) a non-parametric test for comparing three or more independent groups no significant difference in “Preparation” was identified ($p=0.399$).

It is to be expected that patients in the “Colonoscopy” and “Barium Enema & Flexible Sigmoidoscopy” groups would display a higher level of satisfaction for the “Preparation” subscale as what was to be expected was covered in study information literature, at the face to face meeting, and by information sent out with appointment letters by the endoscopy and radiology departments. The

“Usual Care” group did not know what to expect beyond their next appointment.

6.3.2.11 Involvement/Control (subscale 10 score)

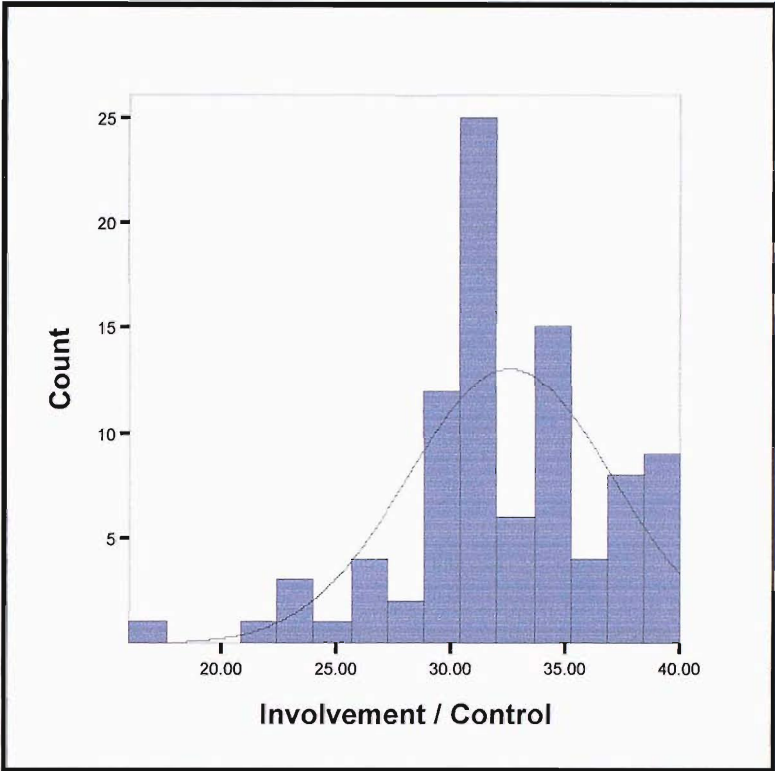


Figure 6.3.2.11a – “Involvement / Control” – Subscale 10 score of all study participants.

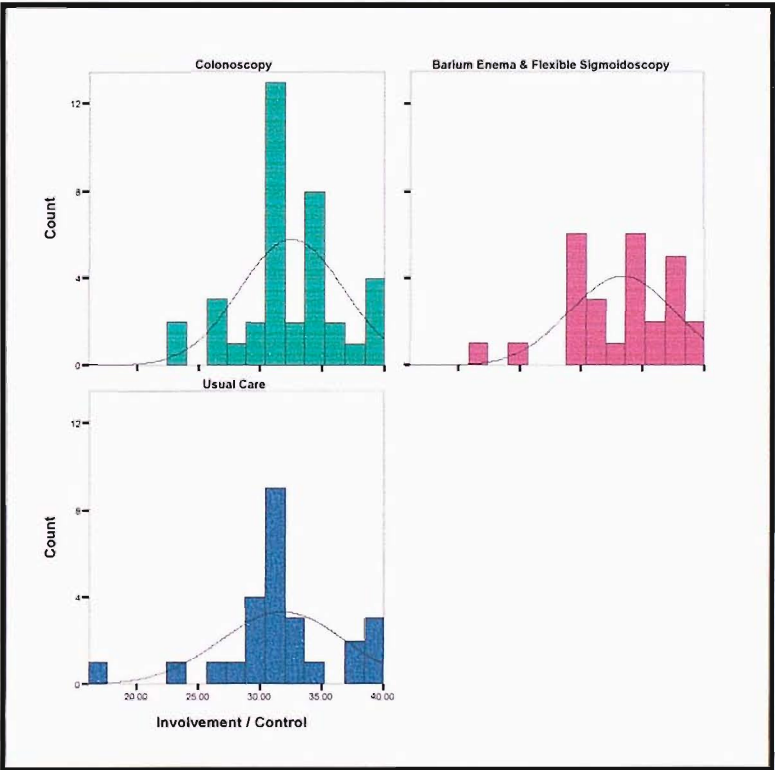


Figure 6.3.2.11b – “Involvement / Control” - Subscale 10 score by study group.

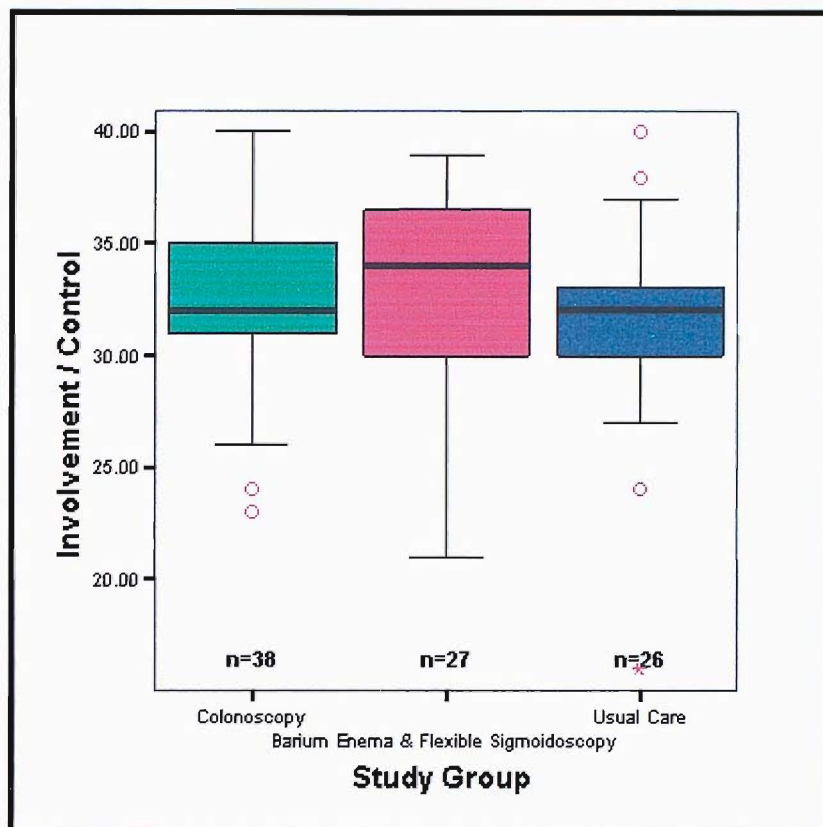


Figure 6.3.2.11c – Box plot of “Involvement / Control” (Subscale 10 score) by group.

The pattern of normal distribution at the upper end of the score scale was seen again here. Using a Kruskal-Wallis Test (SPSS 10.1.0 for Windows) a non-parametric test for comparing three or more independent groups no significant difference in “Involvement / Control” was identified ($p=0.387$).

The underpowered statistical analysis failed to identify a significant difference between the study arms but the box plot (Figure 6.3.2.11c) is suggestive of a higher level of satisfaction from the “Barium Enema & Flexible Sigmoidoscopy” group. This is surprising as patients in this group had all their investigations arranged by the researcher and beyond consenting to take part in the study (which could have seen them randomised to any of the three groups) had no involvement in what investigations they were sent for. The

“Usual Care” group were at least afforded the opportunity to discuss or questions about the planned investigations. It is clearly the patient’s impression of involvement/control that is important, rather than actual participation.

There was one extreme (low) value in the “Usual care” group; it was again returned by the 76-year-old female dissatisfied with her initial OPA.

6.3.2.12 Taken Seriously (subscale 11 score)

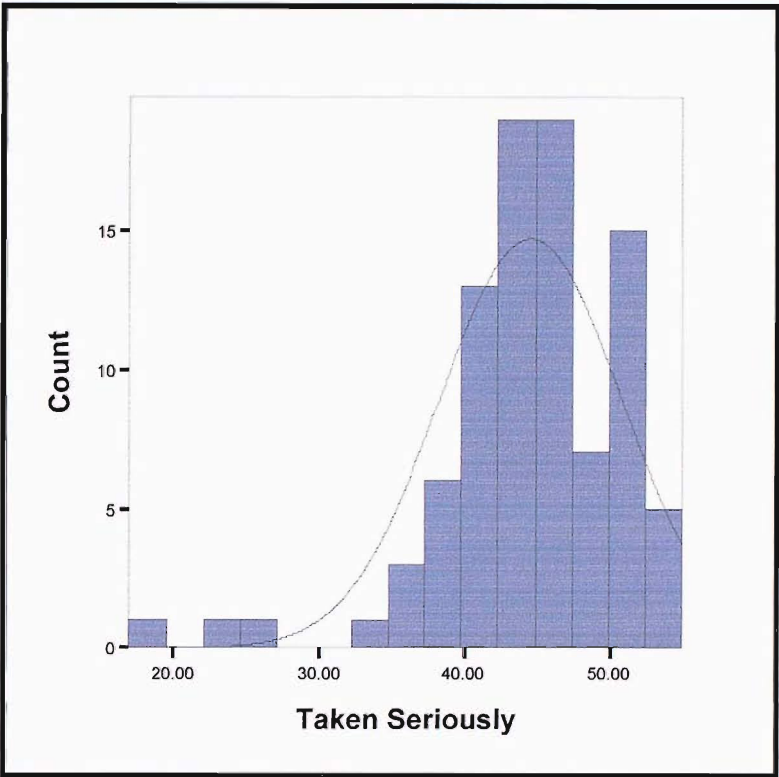


Figure 6.3.2.12a – “Taken Seriously” – Subscale 11 score of all study participants.

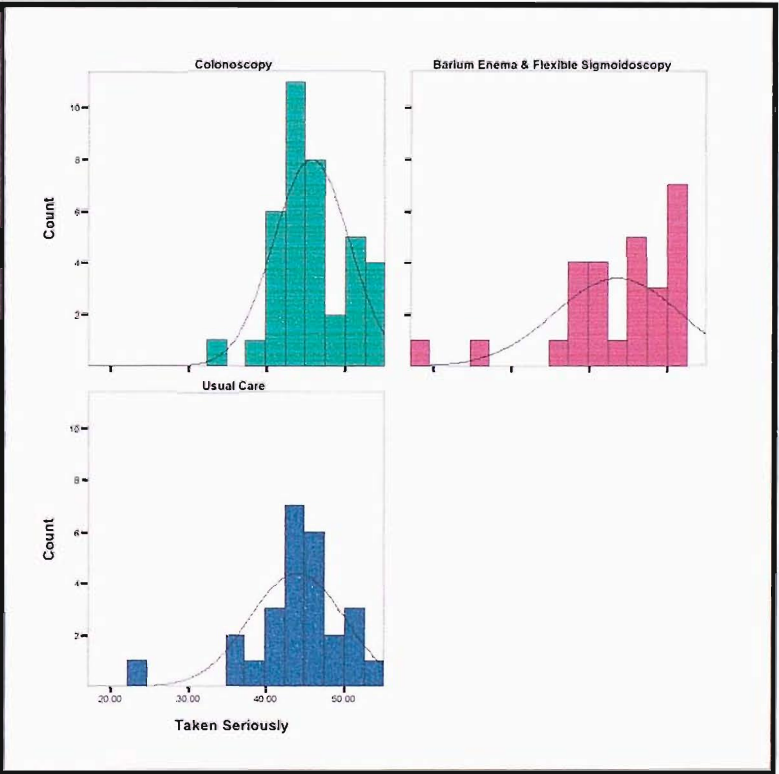


Figure 6.3.2.12b – “Taken Seriously” - Subscale 11 score by study group.

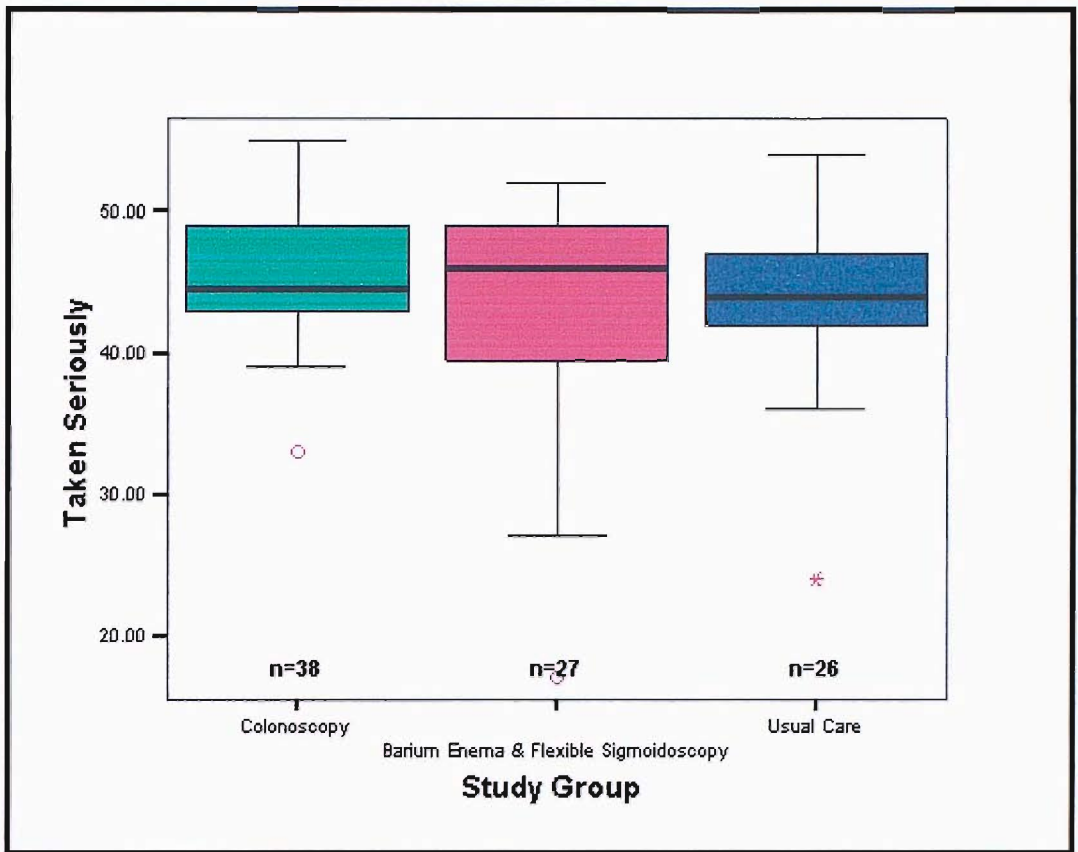


Figure 6.3.2.12c – Box plot of “Taken Seriously” (Subscale 11 score) by group.

The results follow the usual pattern of normal distribution at the upper end of the score range, demonstrated for all participants and by study arm (Figures 6.3.2.12a & 6.3.2.12b). A box plot of the scores (Figure 6.3.2.12c) fails to reveal any apparent trend and the underpowered statistical analysis revealed no significant differences. Using a Kruskal-Wallis Test (SPSS 10.1.0 for Windows) a non-parametric test for comparing three or more independent groups no significant difference in “Taken Seriously” was identified ($p=0.666$).

There was a single extreme (low) value in the “Usual Care” group, and it was the same 76 year old female patient as returned extreme low scores on previous occasions.

6.4 SECONDARY STUDY MEASUREMENTS.

While not considered as important as the primary study outcomes these measurements were taken into account during study design and set down as a study aim.

6.4.1 Number of hospital attendances

While it is not possible to calculate exact costs of investigation to the patient in terms of lost earnings (to patient or relative), travel costs etc; the number of visits made to hospital will supply an indirect indication. Physical visits to hospital were counted for the purpose of this analysis regardless of whether or not the purpose of the visit occurred.

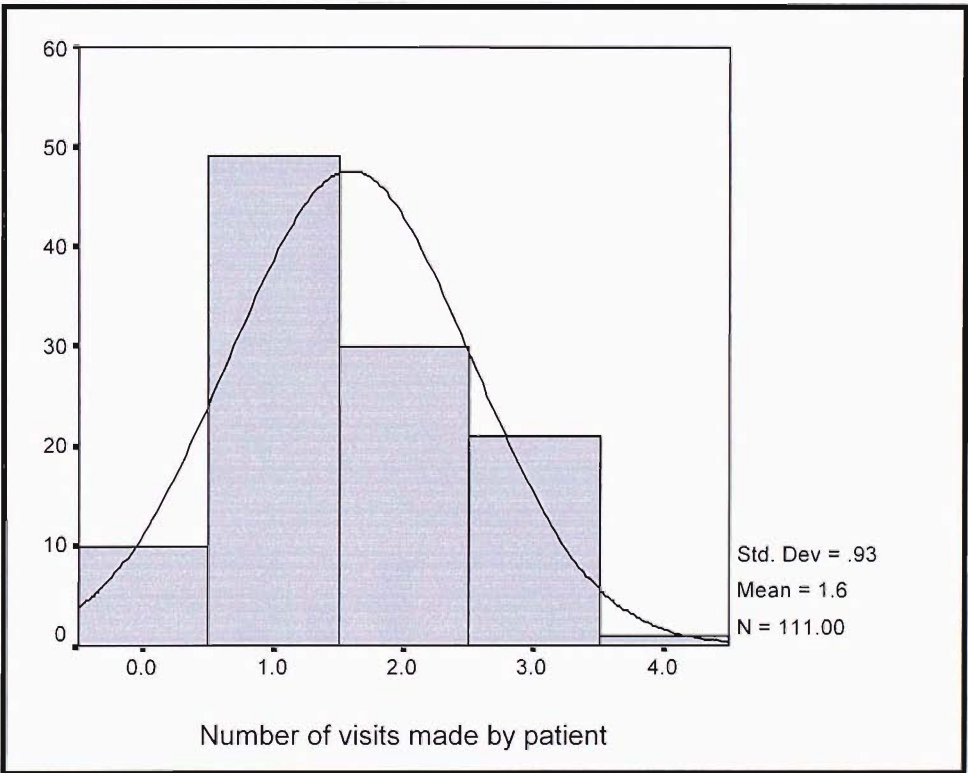


Figure 6.4.1a – Histogram showing number of visits made to hospital by all study participants.

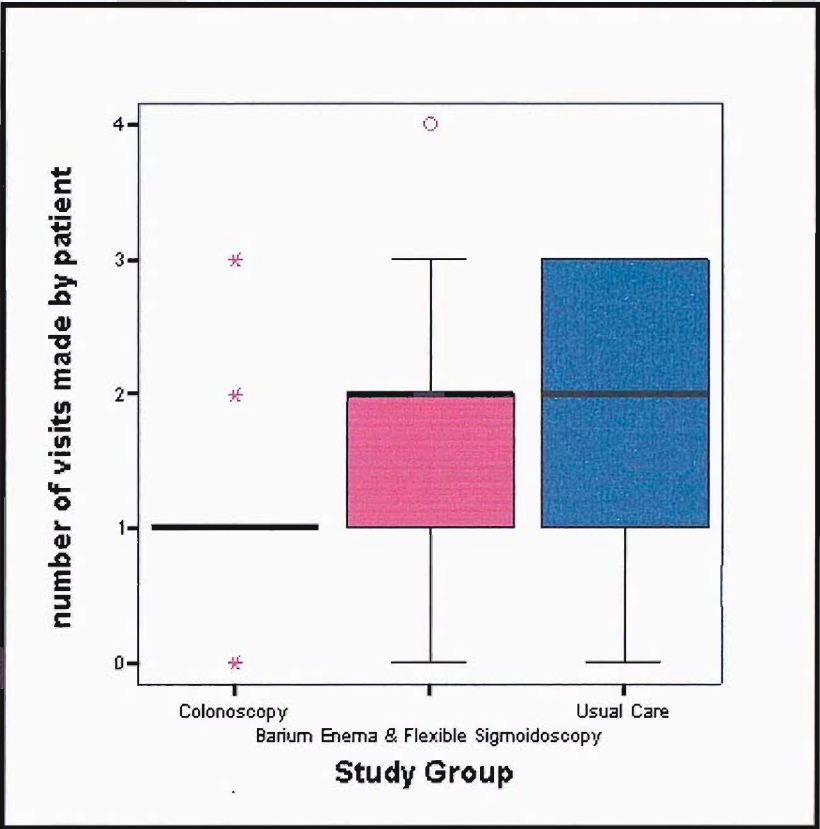


Figure 6.4.1b – Box plot of patient visits to hospital by study group.

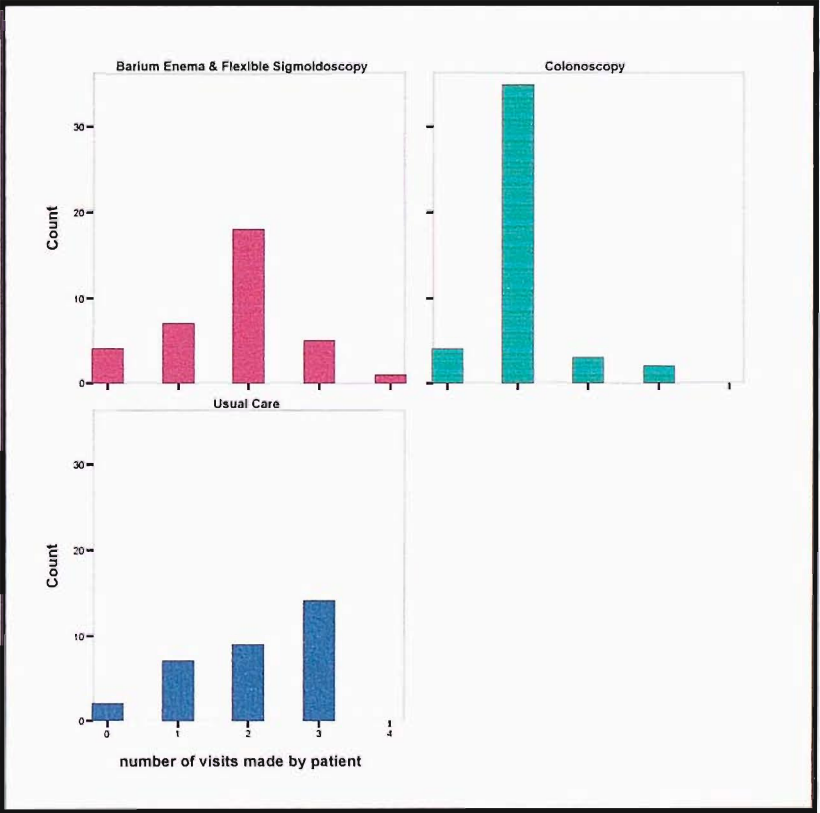


Figure 6.4.1c – Bar chart of patient visits to hospital by study group.

For the purpose of analysis this data was assessed as both parametric and non-parametric. Using Kruskal-Wallis Test (SPSS 10.1.0 for Windows) a non-parametric test for comparing three or more independent groups, and one-way ANOVA Test (SPSS 10.1.0 for Windows) for normally distributed data; a significant difference between the three groups was identified ($p < 0.000$ in both cases).

More detailed analysis using Mann-Whitney U Test for non-parametric data and 2-tailed T-test for parametric data showed p-values of less than 0.000 when comparing "Colonoscopy" to both "Barium Enema & Flexible Sigmoidoscopy" and "Usual Care"; but no significant difference between "Barium Enema & Flexible Sigmoidoscopy" and "Usual Care" ($p = 0.171$ on t-test and $p = 0.120$ on Mann-Whitney U).

6.4.2 Assessment of costs to the NHS

A top down economic analysis of the three different modes of investigation was undertaken from the perspective of the NHS. A societal perspective might have been preferable, taking into account, for instance, time spent by patients undergoing investigation and consequent loss of earnings, costs of travel for investigation etc. However, data on all of the variables that would have been required to undertake an analysis from that viewpoint was not available and its collection beyond the remit of the study. Neither was data from direct observation of the investigation being undertaken available. Rather, the cost of patient investigation was calculated by using the NHS 2001 reference costs (the most up to date at the time of analysis). It is important to consider also that not all NHS trusts submitted data towards these costs and that values used were mean average costs across all responding NHS trusts.

HRG code	Surgical Gastroenterology HRG label	Mean Average (£)
F05op	Colonoscopy with Biopsy or Therapy	138
F06op	Colonoscopy Examination Alone	127
F08op	Flexible Sigmoidoscopy with Biopsy or Therapy	121
F14op	Flexible Sigmoidoscopy Examination Alone	119
F15op	Barium Studies	120
F16op	Rigid Sigmoidoscopy with Biopsy or Therapy	110
F19op	Rigid Sigmoidoscopy	86
F24op	New Attendance with No Investigation or Procedure	61
F25op	Follow up Attendance with No Investigation or Procedure	51
Specialty code	Specialty	Mean Average (£)
100	First Outpatient Attendance General Surgery	98
100	Follow up Outpatient Attendance General Surgery	63

Table 6.4.2 – Abridged table of NHS 2001 reference costs.

When assigning a value to a “patient event” the most appropriate reference cost was used (see Table 6.4.2). Not all “patient events” were given a value in the reference costs; for example when planned events did not occur for some reason. For the purpose of analysis if a “patient event” did not occur and there was insufficient time to re-use the appointed clinical time the event was considered to have taken place (such as when a patient failed to attend, the event was cancelled on the day, there was an equipment failure); conversely if sufficient time was available to reassign the clinical time it was considered to have generated no cost.

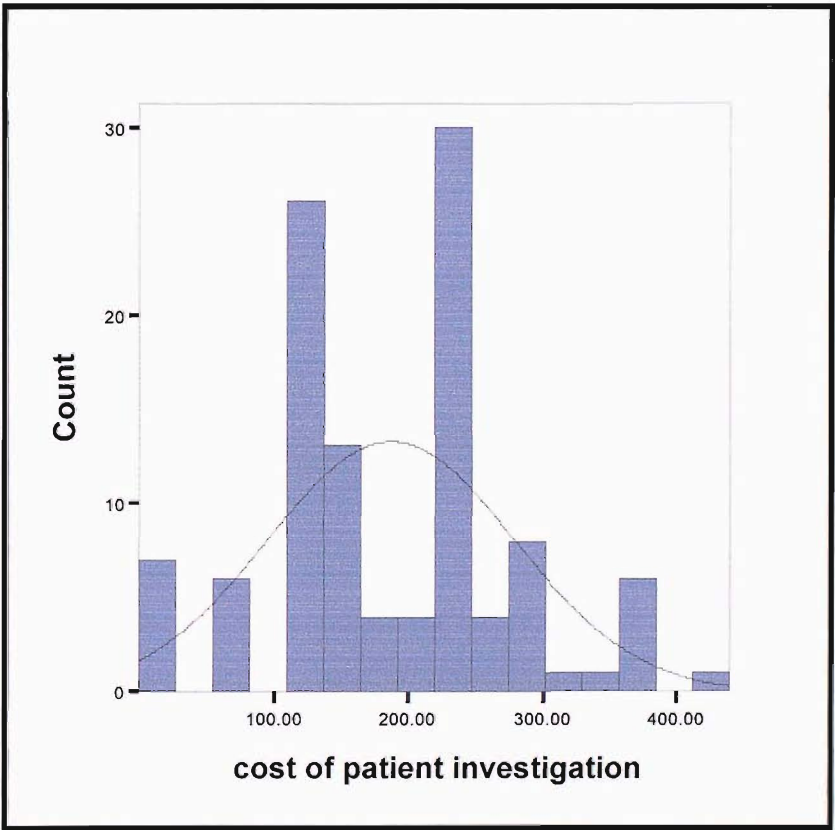


Figure 6.4.2a – Cost of investigation for all study participants.

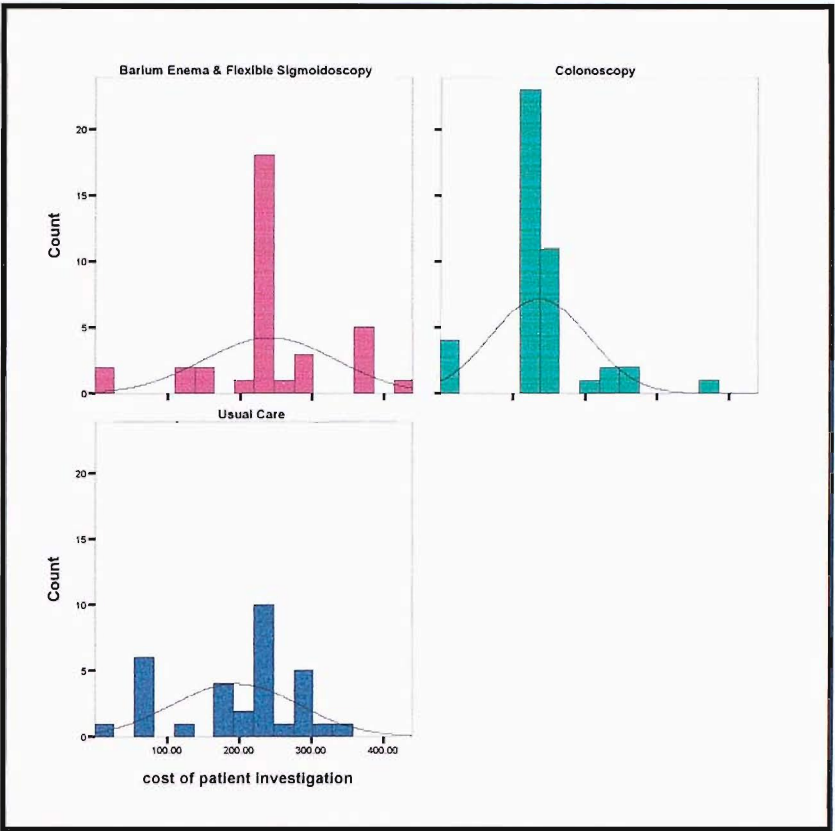


Figure 6.4.2b – Cost of investigation by study group.

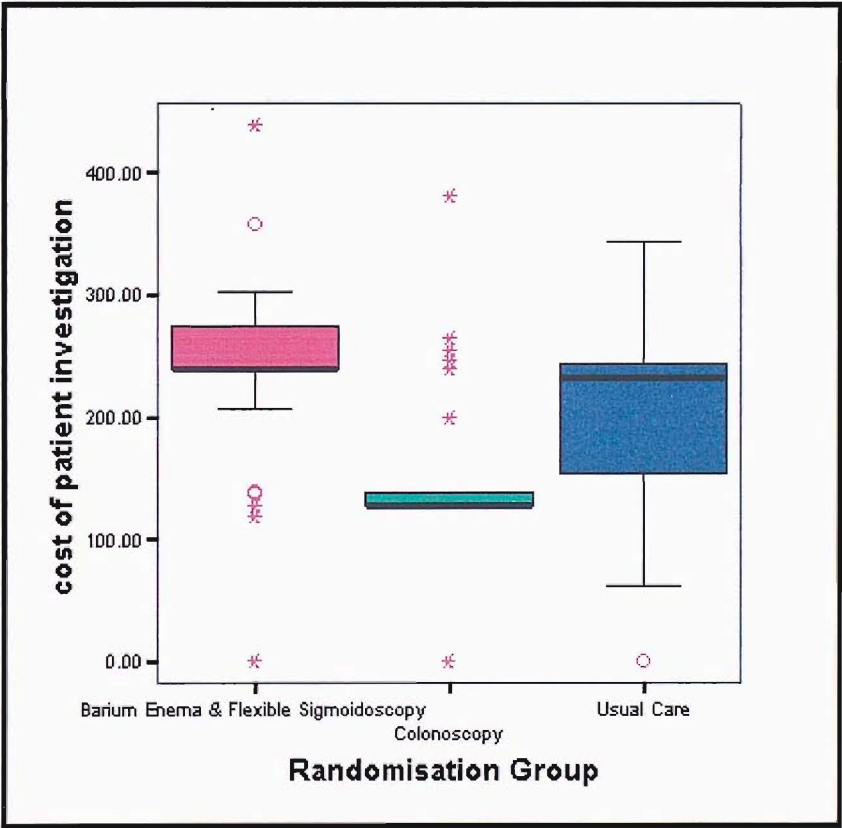


Figure 6.4.2c – Box plot of cost of investigation by study group.

For the purpose of analysis the data were analysed non-parametrically. Using a Kruskal-Wallis Test (SPSS 10.1.0 for Windows) a non-parametric test for comparing three or more independent groups, a significant difference between the three groups was identified ($p < 0.001$).

The study groups were then compared pairwise using Mann-Whitney U tests. A significant difference was demonstrated between all pairs; "Barium Enema & Flexible Sigmoidoscopy" to "Colonoscopy" ($p < 0.000$), "Barium Enema & Flexible Sigmoidoscopy" to "Usual Care" ($p = 0.005$), "Colonoscopy" to "Usual Care" ($p = 0.001$).

For greater accuracy in economic comparisons a technique of bootstrapping for the calculation of 95% confidence intervals would have to be employed. This is a specialised subject requiring purpose designed software and a computer system with a processing capacity exceeding that normally seen; as such this method of making economic comparisons is beyond the scope of this thesis.

6.5 TERTIARY STUDY MEASUREMENTS.

These measurements were only considered after study design was set and data collection commenced. As such they were not considered in study design and as such any conclusions drawn from them are of a lesser strength than those drawn from the primary and secondary measures.

6.5.1 Time to first hospital appointment.

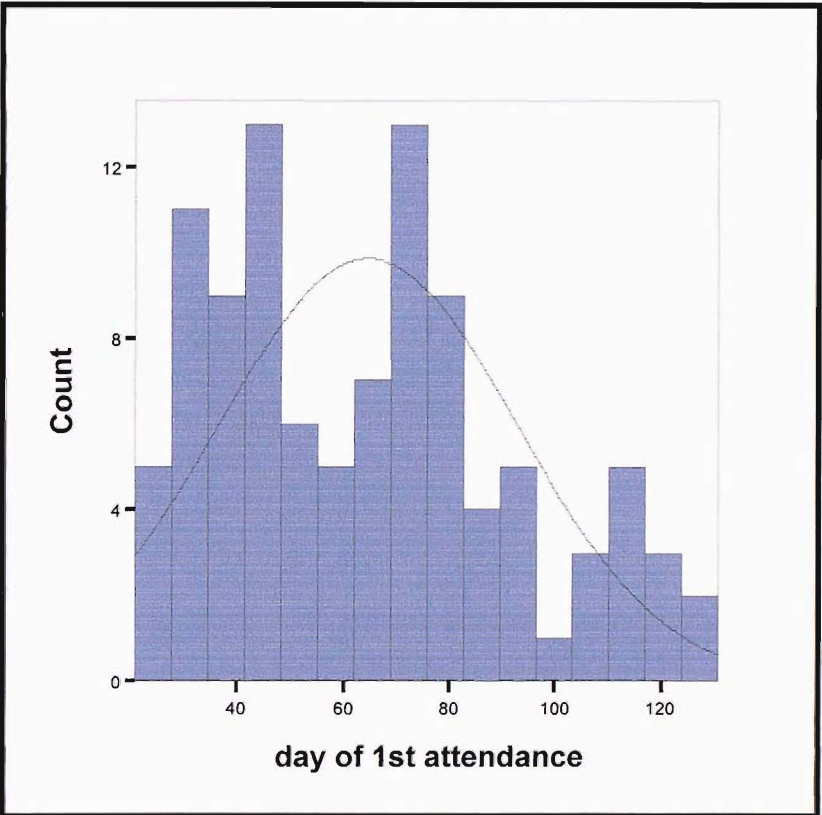


Figure 6.5.1a – Time (days) to first appointment for all study participants.

The first appointment is the point at which patient investigation actually commences. For this reason “time to first attendance” was analysed for significant differences between the three study groups.

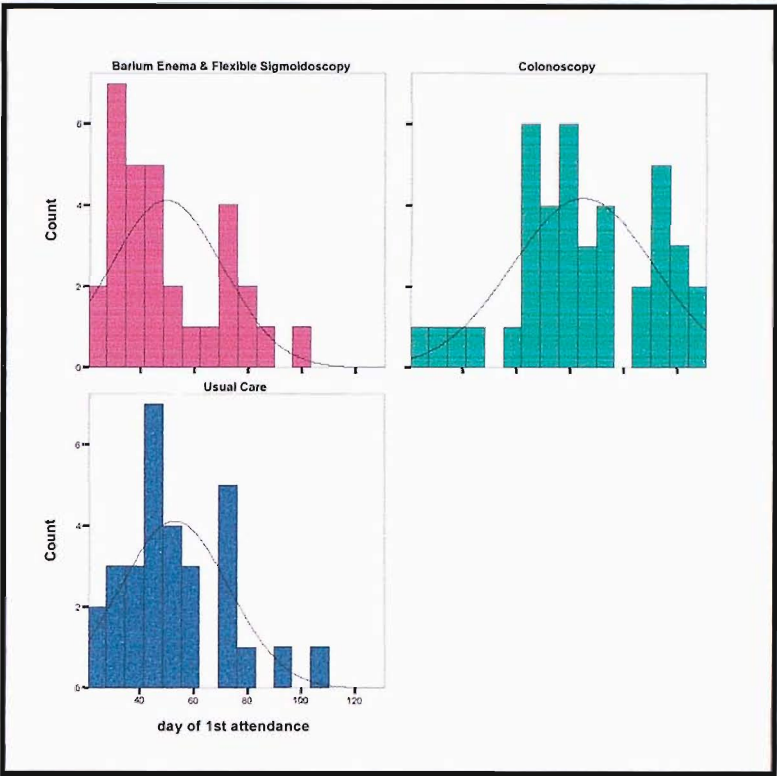


Figure 6.5.1b – Time to first appointment by study group.

Using a Kruskal-Wallis test (SPSS for Windows 10.1.0) there is a significant difference in ‘time to first appointment’ between the three study groups (p<0.001)

Study Group	Range	Mean	Standard Deviation	95% confidence interval	Median	Inter-quartile range
All	21-131	64.68	28.082	59.14-70.23	65.00	40.00
Colonoscopy	24-131	85.03	26.196	76.65-93.40	82.00	38.00
Barium Enema & Flexible Sigmoidoscopy	21-97	49.77	20.746	42.16-57.38	43.00	42.50
Usual Care	23-110	52.97	20.016	45.49-60.44	48.50	30.00

Table 6.5.1 – Descriptive statistics of “time to first appointment” for all patient groups.

Further analysis using Mann-Whitney U tests for comparing two independent groups of non-parametric data revealed a significant difference in time to first

attendance when comparing “Colonoscopy” to both “Barium Enema & Flexible Sigmoidoscopy” and “Usual Care” ($p<0.001$ in both cases). However when comparing “Barium Enema & Flexible Sigmoidoscopy” and “Usual Care” to each other there was no significant difference ($p=0.379$).

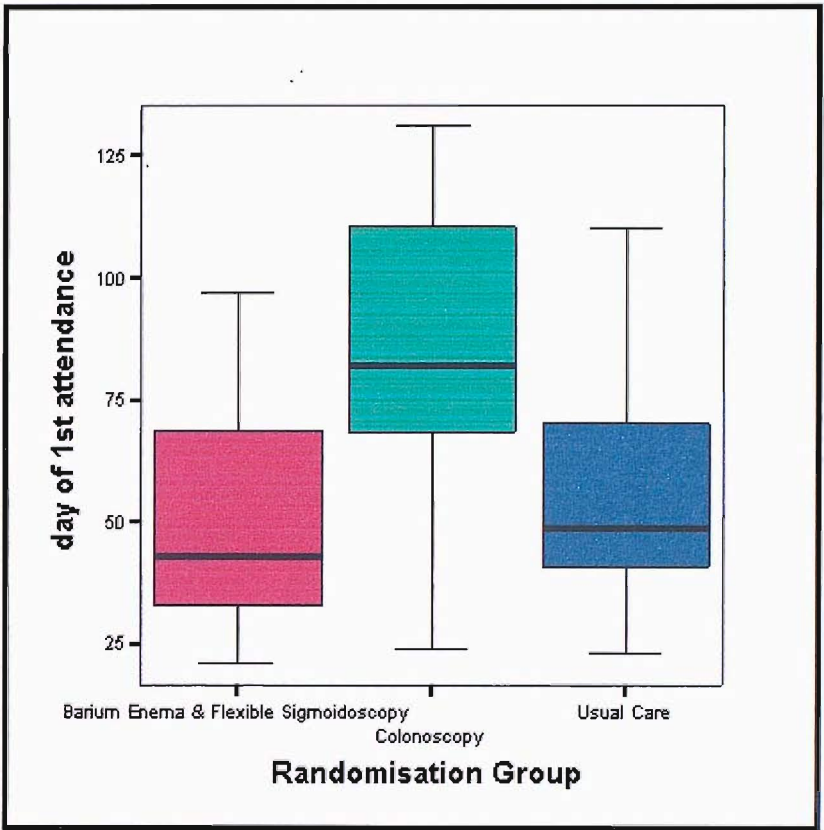


Figure 6.5.1c – Box plot of time to first appointment (days) by study group.

Being time data they lend themselves to survival analysis in much the same way as time to study endpoint does (see section 6.3.1.2). The Kaplan-Meier Survival plot clearly shows that patients in the “Colonoscopy” study group take longer than those in the other two groups to reach their first appointment at every level (see Figure 6.5.1d)

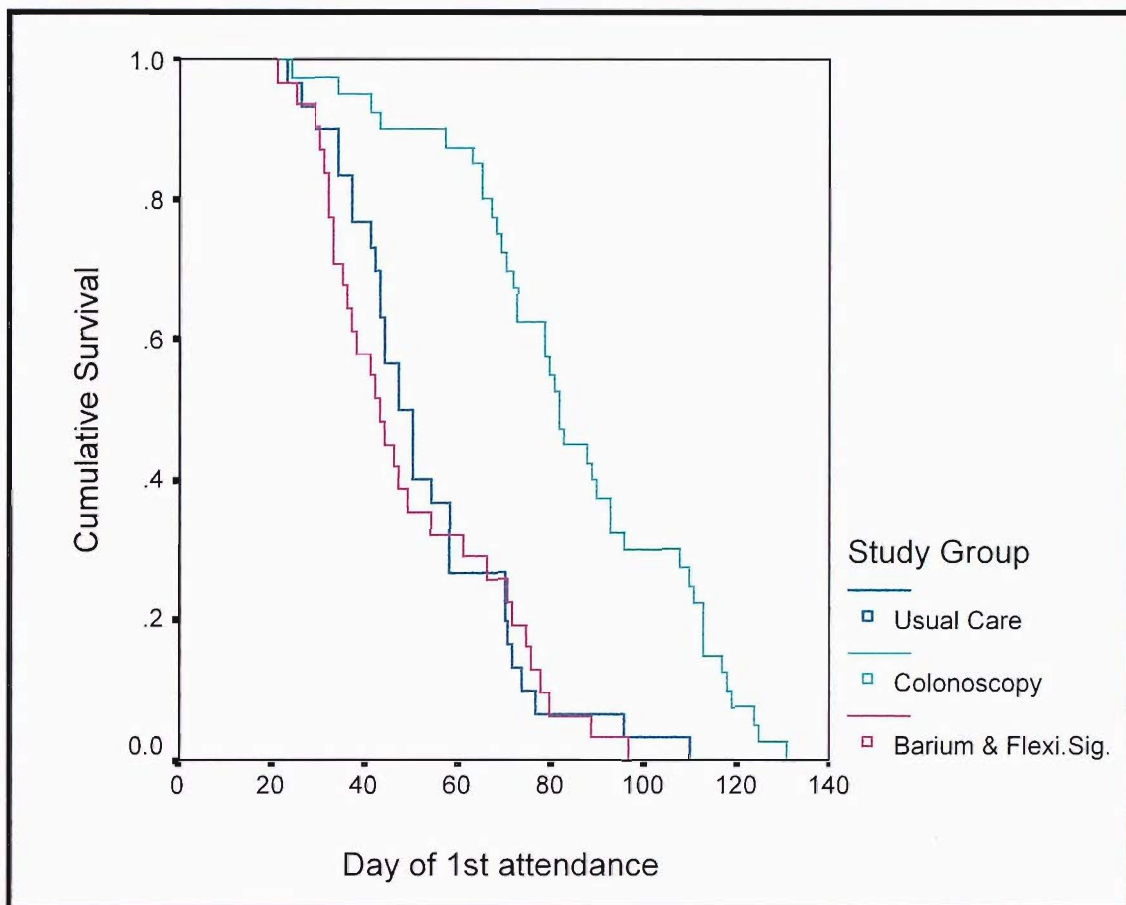


Figure 6.5.1d– Kaplan-Meier Survival plot of time taken for study participants to attend their first appointment.

6.5.2 Booked appointments & patient hospital attendances.

Rescheduling hospital appointments for whatever reason incurs a burden on the NHS (administrative at the least, wasted clinical slots at worst) and on the patient (anxiety, disappointment, lost earnings).

When comparing the number of appointments made with the number of patient attendances (using paired T-test) there was a significant difference across all study participants ($p < 0.001$), meaning there were a statistically significant number of cancellations. This significance continued when the groups were analysed separately, “Barium Enema & Flexible Sigmoidoscopy” $p < 0.001$, “Colonoscopy” $p = 0.001$, and “Usual Care” $p = 0.001$.

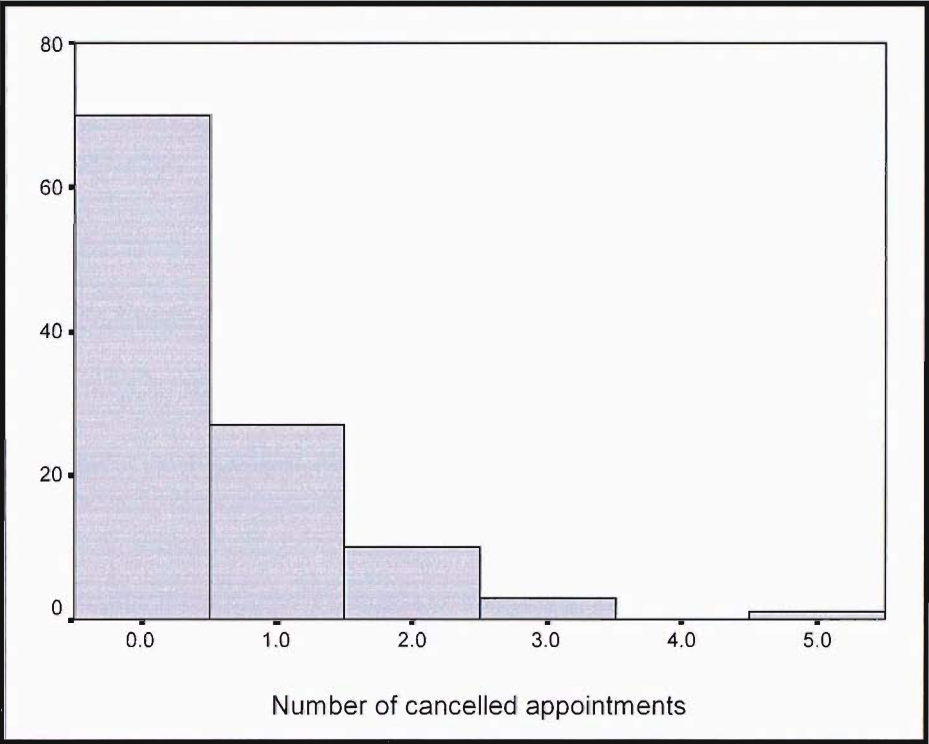


Figure 6.5.2a – Number of cancelled hospital appointments per patient across all study recruits.

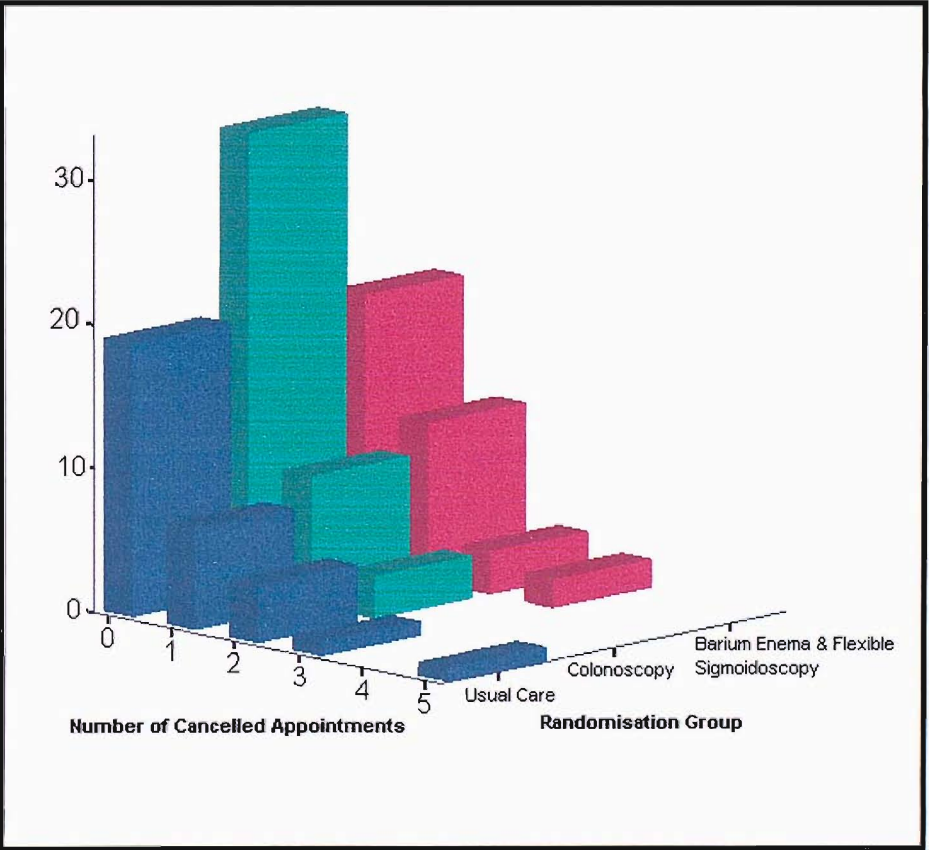


Figure 6.5.2b – Number of cancelled hospital appointments per patient by study group.

When comparing the three groups for number of cancellations (using a Kruskal-Wallis test, SPSS for Windows 10.1.0) no significant difference was identified ($p=0.172$).

When appointments are analysed independently of study group it is apparent that a colonoscopy appointment is the type most likely to be cancelled, and that the hospital and patients have an equal role.

Investigation	DNA (did not attend)	CBP (cancelled by patient)	CBH (cancelled by hospital)	Cancelled on day (patient/staff illness, equipment failure etc.)	Total
Colonoscopy	-	8	10	4	22
Flexible Sigmoidoscopy	4	5	1	2	12
Barium Enema	3	8	2	5	18
Outpatient Appointment	5	6	6	-	17

Table 6.5.2 – Cancelled appointments by type.

6.6 RETROSPECTIVE POWER CALCULATION

Due to its nature as “the time at which the patient was informed of...” the study end point was a novel concept and similar data are not collected as part of routine NHS book keeping. An attempt at gaining the data retrospectively from patient notes and records was also fruitless due to lack of documentation and an incomplete paper trail for patient events.

For these reasons it was not possible to perform a power calculation in order to set required recruitment. The study’s power was therefore calculated retrospectively using data collected during the study. Calculations were made using SAMPLESIZE v2.0 (Blackwell Sciences Ltd) for independent groups analysed by 2-sided t-test.

6.6.1 Power to identify a significant difference in - “Time taken for patient to reach study endpoint”.

Power equates to the percentage chance that a statistically significant difference will be identified given the available sample size ($0.9 = 90\%$); small samples will usually fail to identify small but significant differences between groups. During this study a standard significance level of 5% ($p=0.05$) or less was adopted as being significant.

Using these figures there was only a 2% chance of identifying a statistically significant difference in days to endpoint between the “Colonoscopy” and

“Flexible Sigmoidoscopy & Barium Enema” groups; a sample size of 71,100 would be required to have an 80% chance of identifying a difference.

Likewise, there was only a 4% chance of identifying a statistically significant difference in days to endpoint between the “Colonoscopy” and “Usual Care” groups; a sample size of 4,586 would be required to have an 80% chance of identifying such a difference.

There was also only a 3% chance of identifying a statistically significant difference in days to endpoint between the “Flexible Sigmoidoscopy & Barium Enema” and “Usual Care” groups; with a sample size of 6,361 being required to have an 80% chance of identifying a difference.

Groups Compared	P value	Power	Sample Size	Sample size required to have a power of 0.80
Colonoscopy vs. Barium Enema & Flexible Sigmoidoscopy	p = 0.843	0.02	29	71,100
Barium Enema & Flexible Sigmoidoscopy vs. Usual Care	p = 0.571	0.03	27	6,361
Colonoscopy vs. Usual Care	p = 0.681	0.04	27	4,586

Table 6.6.1 – Summary of study’s power to identify a statistically significant difference in “time taken for patient to reach study end point” between the three study groups.

6.6.2 Power to identify significant differences in expressed patient satisfaction.

Satisfaction Scale Compared	Study Groups Compared	P value	Power	Sample Size	Sample size required to have a power of 0.80
Overall Satisfaction	C vs. B	p = 0.549	0.18	27	178
	B vs. U	p = 0.383	0.11	26	363
	C vs. U	p = 0.122	0.10	26	386
Understanding of Events	C vs. B	p = 0.260	0.14	27	255
	B vs. U	p = 0.517	0.07	26	807
	C vs. U	p = 0.086	0.28	26	104
Anxiety	C vs. B	p = 0.015	0.66	27	37
	B vs. U	p = 0.329	0.24	26	123
	C vs. U	p = 0.191	0.19	26	160
Professionalism	C vs. B	p = 0.883	0.46	27	57
	B vs. U	p = 0.093	0.44	26	61
	C vs. U	p = 0.039	0.45	26	59
Confidence / Trust in Staff	C vs. B	p = 0.449	0.05	27	1,984
	B vs. U	p = 0.680	0.17	26	190
	C vs. U	p = 0.073	0.25	26	119
Substance of Consultation	C vs. B	p = 0.630	0.03	27	9,673
	B vs. U	p = 0.052	0.27	26	110
	C vs. U	p = 0.120	0.24	26	127
Mechanics	C vs. B	p = 0.659	0.05	27	1431
	B vs. U	p = 0.648	0.02	26	196,000
	C vs. U	p = 0.312	0.08	26	633
Results	C vs. B	p = 0.436	0.27	27	114
	B vs. U	p = 0.202	0.10	26	394
	C vs. U	p = 0.037	0.62	26	39
Disclosure	C vs. B	p = 0.728	0.08	27	598
	B vs. U	p = 0.409	0.07	26	919
	C vs. U	p = 0.229	0.20	26	159
Preparation	C vs. B	p = 0.952	0.04	27	3,584
	B vs. U	p = 0.335	0.11	26	360
	C vs. U	p = 0.171	0.20	26	159
Involvement / Control	C vs. B	p = 0.381	0.09	27	471
	B vs. U	p = 0.188	0.20	26	156
	C vs. U	p = 0.487	0.08	26	660
Taken Seriously	C vs. B	p = 0.509	0.18	27	185
	B vs. U	p = 0.872	0.02	26	5,881
	C vs. U	p = 0.406	0.19	26	160

Table 6.6.2 – Summary of study's power to identify a statistically significant difference in expressed patient satisfaction. (C= Colonoscopy, B = Barium Enema & Flexible Sigmoidoscopy, U= Usual Care)

6.6.3 Power to identify a statistically significant difference in number of hospital attendances between study groups.

When comparing the “Colonoscopy” group with the “Flexible Sigmoidoscopy & Barium Enema” group the study has a power of 0.76, a sample of 39 (as opposed to the 35 recruited) would be required to achieve a power of 0.8 (an 80% chance of identifying a statistically significant difference).

The study had a power of 0.26 to identify a difference between the “Flexible Sigmoidoscopy & Barium Enema” and “Usual Care” groups; a sample of 141 being necessary to reach a power of 0.8.

When comparing the “Colonoscopy” and “Usual Care” groups the recruited sample of 32 achieved a power of 0.98.

6.6.4 Power to identify a statistically significant difference in cost to the NHS between study groups.

When comparing the “Colonoscopy” group with the “Flexible Sigmoidoscopy & Barium Enema” group the study has a power of 0.9999 from the recruited sample of 35 patients.

The study had a power of 0.51 to identify a difference between the “Flexible Sigmoidoscopy & Barium Enema” and “Usual Care” groups; a sample of 62 being necessary to reach a power of 0.8.

When comparing the “Colonoscopy” and “Usual Care” groups the recruited sample of 32 achieved a power of 0.83.

6.6.5 Power to identify a statistically significant difference in time to first hospital attendance between study groups.

When comparing the “Colonoscopy” Group with both “Flexible Sigmoidoscopy & Barium Enema” and “Usual Care” groups the study has a power of 0.9999.

The power is only 0.08 when comparing “Flexible Sigmoidoscopy & Barium Enema” and “Usual Care” groups for a statistically significant difference.

While the recruited sample was 30 a sample of 639 is required to reach a power of 0.8.

6.6.6 Power to identify a statistically significant difference in the number of cancelled hospital attendances per patient by study group.

The study has a power of 0.41 when looking for a statistically significant difference between the “Colonoscopy” and “Flexible Sigmoidoscopy & Barium Enema” groups; a sample of 90 (c.f. the 35 recruited) to reach a power of 0.8.

The power is only 0.04 when comparing “Flexible Sigmoidoscopy & Barium Enema” and “Usual Care” groups; a sample of 4262 is needed.

“Colonoscopy” and “Usual Care” group comparisons have a power of 0.6 and would required a sample of 50 to reach a power of 0.8.

6.7 PATIENTS' FREE TEXT QUESTIONNAIRE RESPONSES.

The free text section of the questionnaire was provided mainly in order that patients could provide their opinion of the questionnaire; it also gave patients the ability to give feed back on the care they received. It was acknowledged that a questionnaire could not be omni-competent without being unacceptably long and it was necessary to ensure there was no common omitted facet to care that was identified in the free text feedback. It was also accepted that there would be issues that patients felt strongly about and would not feel satisfied with a Likert scale response.

Of the 111 recruited patients 95 reached study end point: all of these patients received the questionnaire by mail and had the opportunity to provide free text feedback. 91 questionnaires were returned and of these 65 contained free text feedback from the patients.

Patient feedback was evaluated by a process of phenomenological subjective analysis (as described in section 5.2.1.2). Patient feedback fell into the intended two groups –

1. Questionnaire feedback
2. Care / Research feedback

The comments on the questionnaire have been addressed in section 5.3.2.4. The comments on care received by the patients numbered eighty-nine; 81 of which grouped into one of 10 dimensions. These dimensions had similar though not identical themes to those dimensions identified during questionnaire development (see Figure 5.3.5.2). In trying to measure a

patient's satisfaction a questionnaire can raise issues that the patient has not previously considered, or influence the importance a patient apportions to an aspect of their care. As with many subjective phenomena the act of assessment/measurement changes the very thing it sets out to study. It is no surprise that the dimensions did not perfectly match those already identified.

Dimension	Negative Feedback	Positive Feedback
General Satisfaction	2	22
Preparation / Expectations	3	3
Waiting for Appointments	4	
Appointment	7	
Facilities	3	
Empathy of Staff	3	11
Discussion with Doctor	4	
Receipt of Results	4	
Information after Investigation	3	2
Treatment/Advice about ongoing symptoms	10	
Miscellaneous	1	7
TOTAL	44	45

Table 6.7 – Questionnaire free text patient feedback by dimension and polarity.

Patients providing free text feedback are again a self-selecting group (much in the same manner as patients completing the questionnaire at all, and those writing letters of complaint/thanks). The comments made by the patients are evenly matched positive for negative (see Table 6.7) and are not purely praising or critical.

The dimensions attracting the greatest number of comments were General Satisfaction, Empathy of Staff, and Treatment/Advice about ongoing symptoms.

The general satisfaction dimension attracted 24 comments. Twenty-two of these comments were positive, in the main taking the form of a simple statement of satisfaction (or an absence of dissatisfaction) or a statement of thanks to the staff. Two patients stated that they were dissatisfied, one indicating that they were pursuing a private consultation.

The Empathy of Staff dimension had 14 comments; eleven of which were positive praising staff for being friendly, kind, and caring. The three negative comments all related to the behaviour of doctors where a failure of communication and abruptness (*“in a hurry to leave me”*) seemed to be the main problem. A breakdown of the doctor patient relationship (no matter how brief the interaction is) can be extremely damaging and undermine the patients confidence in the entire process of investigation-

“I felt the doctor who did the tests on me was rough, flippant, uncaring and he was late. The nurse who was wonderful had to go looking for him. When he did appear he absolutely stank of cigarettes/smoke. When he administered the drug it hurt very much. I felt the force he used unnecessary.”

[Patient Comment from Questionnaire Free Text Feedback]

The Treatment/Advice about ongoing symptoms dimension attracted 10 comments, all of them negative. Patients' comments in this dimension focused on a lack of a diagnosis in light of normal investigations (and in some cases despite being informed of the diagnosis); and on the lack of treatment for their symptoms. All patients received information on investigation results and appropriate advice, the number of comments indicates a number of things. Firstly that the patients are not only concerned with what their

symptoms may suggest, “a clean bill of health” is not sufficient. Patients like a diagnosis or “label” for their symptoms. Secondly a proportion of patients require treatment or advice to control their symptoms, reassurances that they do not represent anything sinister does not suffice in all cases. Thirdly we still need to work on communication skills as either patients are not understanding all that they are told, or that they are not retaining it. This would support the use of printed advice/information sheets commonly (but not always) employed.

There were a number of key points raised by patients falling under other dimensions.

There were comments that some of the information sent to the patient was conflicting or inaccurate. Every effort had been made to ensure that research study literature did not contradict that used by the involved departments but where the study had a purely observational role it could not intervene or censor the information sent to patients.

There were two main issues with appointments raised in the free text feed back. Patients commented on the lack of opportunity to talk to the doctor (mainly at endoscopy) in order to go over what to expect or the findings of investigations. Patients also commented that where the planned procedure had been change they were not consulted (e.g. equipment failure meaning either a barium enema or colonoscopy was performed in lieu of the other, rather than needlessly putting the patient through a second bowel preparation for a rescheduled investigation). Participation in the decision to change would

clearly have been important to them even when there was little alternative and the decision made in their best interests; that or the reasons for the change to the planned procedure were not adequately explained to them.

Two patients commented that they had been in pain during their endoscopic examination.

The wait for results and the lack (or inadequacy) of information was also commented upon by a small number of patients. There were specific comments from two patients on how helpful the letter explaining the results had been –

“The follow up letter was necessary as I was still feeling the effects of the anaesthetic and did not fully understand the doctors statement”

“....and particularly appreciated receiving a letter fully explaining the results of the examination.”

This again reinforces the importance of written information (which can then be reviewed as many times as necessary) to the patient.

It was not unexpected that there were 4 comments criticising the wait for appointments, nor that there were 3 comments about the standard of facilities/conduct of other patients and visitors.

6.8 CLINICAL OUTCOMES AND DIAGNOSES

The clinical outcomes for the 111 study recruits are shown in Table 6.8. Of the 16 patients who withdrew before reaching study endpoint three had undergone some investigations which provided a working diagnosis though having failed to complete the patient pathway it is uncertain as to whether or not these would have been final diagnoses.

Clinical Outcome	Flexible Sigmoidoscopy & Barium Enema Group	Colonoscopy Group	Usual Care Group
Diagnosis			
Colorectal Cancer (CRC)		1(2%)	
Polyp	4(11%)	2(5%)	1(3%)
Diverticulosis & Polyp		2(5%)	1(3%)
Diverticulosis	13(37%)	16(36%)	7(22%)
Diverticulosis & Haemorrhoids		1(2%)	1(3%)
Haemorrhoids			1(3%)
Colitis / Proctitis			3(10%)
Infection		1(2%)	
Discharged with Reassurance			
	10(29%)	16(36%)	9(28%)
Need to Further Investigate			
Provisional Diagnosis	1(3%) – polyp		1 (3%) – polyp. 1 (3%) – CRC 1 (3%) - diverticulosis
No Diagnosis	1(3%)		1(3%)
Withdrew From Study			
Provisional Diagnosis	2(6%) – diverticulosis	1(2%) – polyps	
No Diagnosis	4(11%)	4(9%)	5(16%)

Table 6.8 - Clinical outcomes for study recruits.

There was one death within the study, an elderly lady in the “Colonoscopy” group. The patient had undergone her examination at which multiple small adenomas were identified throughout the colon and treated by snare excision. The patient became unresponsive immediately following the procedure despite reversal of sedation. She was admitted as an emergency medical admission but failed to regain consciousness, dying a little over 24 hours later. Post mortem examination identified global cerebral infarction as the cause of death.

No morbidity was reported within the study group through medical channels.

7 – DISCUSSION

7.1 KEY STUDY FINDINGS - A RETURN TO THE NULL HYPOTHESIS

The Null Hypothesis is stated in section 3.2. Given the results (section 6) and discussion of findings (section 7) here follows a direct response to the Null Hypothesis.

7.1.1 Time

The study failed to identify a statistically significant difference between the three study arms in “time to endpoint”. Although it was underpowered to achieve this comparison, however, time to end point was remarkably similar across all three study groups, and the small differences seen can be of no clinical importance.

7.1.2 Costs

7.1.2.1 Cost incurred by the NHS

There was a statistically significant difference in costs to the NHS when analysing money spent in order to get a recruit to end point between the three study groups.

As an outpatient investigation strategy “Barium Enema & Flexible Sigmoidoscopy” was more expensive than “Usual Care”, which in turn was more expensive than “Colonoscopy”.

7.1.2.2 Number of hospital visits made by the patient

The number of visits a patient was required to make to hospital during the process of investigation was assessed as an indirect measure of costs to the patient.

Patients in the “Colonoscopy” group made significantly fewer visits than those in the other two study groups. No statistically significant difference was identified between the “Barium Enema & Flexible Sigmoidoscopy” and “Usual Care” groups.

7.1.3 Outcomes

7.1.3.1 Patient satisfaction

The study failed to identify a statistically significant difference in general satisfaction between the three study groups.

7.1.3.2 The nature of study endpoint

Study endpoint was the point at which the patient was informed of diagnosis, discharge (with reassurance), or need for further investigation. There was no statistically identifiable difference in the nature of study end point.

7.2 PROBLEMS ENCOUNTERED

7.2.1 Execution of the study

The study was executed in line with the protocol outlined in section 4.0 and it was not necessary to modify the study protocol in order to accommodate unforeseen or omitted circumstances. There were, however, a number of aspects to study protocol which created difficulties.

7.2.1.1 Labour intensive.

The recruitment of patients was a labour intensive process. The regular checking for new referrals, application of inclusion/exclusion criteria, information mailing, and follow up telephone call was then followed by the arrangement of a face-to-face meeting with the potential study recruit. The meetings were conducted in the patients' homes, and so sufficient time had to be allowed for discussions of variable lengths (varying from 5 to 55 minutes) and time to travel between venues. The necessary safety margins (to avoid late/missed appointments thus jeopardising recruitment) resulted in a considerable amount of researcher time being wasted.

As the lack of funding limited the study to one researcher (myself) the study's scope was limited to a single unit despite initial optimism that recruitment would spread to at least one other centre. This in turn meant that patient recruitment was not enhanced by the inclusion in the study of a second recruitment site.

7.2.1.2 Long recruitment process

The protocol requirement that patients suitable for study recruitment be sent a patient information pack by post and be allowed 7-10 days to familiarise themselves with it meant that (by protocol) the quickest a patient could be recruited from detection was 7 days (arranging a face-to-face meeting on the day of telephone contact). In the event recruitment took between 7 & 32 days; the minimum of 7 days was because the patient initiated contact with the researcher (via the contact telephone number provided – see Appendix S), the maximum of 32 days was because the patient, while wishing to participate, wanted to see their GP first and so delayed the face-to-face meeting until after that appointment.

7.2.1.3 Patient information

Because potential recruits were invited to participate in a study that would involve randomisation to a number of potential investigations the volume and detail of information with which they were provided exceeded the norm. In addition to the patient information sheets distributed as part of the study protocol patients also received standard information appropriate to their care (see Appendices R S & T). This was the case whether or not a potential recruit agreed to participate.

A patient would normally receive standard literature offered by the departments in relation to the particular investigation they were due to undergo. The study patient information sheet contained an account of potential investigations/actions, what they might entail, and what their various

merits/weaknesses might be. A greater emphasis was also placed on the potential complications of the investigative modalities.

This resulted in “information overload” in a number of cases with the patients becoming confused or muddled: this became apparent at either the telephone contact or face-to-face meeting stage and all efforts were made to resolve any confusion. It was an important part of study’s patient information sheet development to ensure the contents did not contradict with information provided in standard patient information offered. Unfortunately there was no apparent means to reduce the study literature received by the potential recruits as it was the minimum deemed necessary to obtain informed consent.

7.2.1.4 Clerical error

Only one significant clerical error was identified and this resulted in a “Usual Care” group patient being sent for a colonoscopy in the first instance rather than an outpatient appointment. The patient was kept within the study and analysed on an intention to treat basis in much the same way that patients referred for one investigation but receiving another were (e.g. due to equipment failure).

7.2.2 Recruitment & sample size

As detailed in section 2.2.9 it was not possible to perform a power calculation and so determine a required sample size prior to commencing study recruitment. The data-sets held by the involved departments concentrated on waiting times for appointments / investigations. The issue of how long it takes

for a patient to reach a diagnosis is not taken into account for all patients in the NHS. While data exist on time elapsed between referral and diagnosis for patients entered onto cancer registries those patients with a diagnosis of benign disease (or no diagnosis) are subject to no such data collection. Even then the record is usually of when a clinical or histological diagnosis is made, not when the patient is informed.

As no data-set was held that would enable a power calculation to be made a retrospective note search was performed. However, it was not possible to identify patients from when they were referred but only from when they were first seen. Additionally, the note sets were incomplete, and the level of note keeping was not adequate to extract the required information.

7.2.2.1 Retrospective power calculations

A retrospective power calculation was performed for analyses made within the study using SAMPLESIZE v2.0 (Blackwell Sciences LTD). A desirable study power would be 0.8 to identify a difference with a p value of 0.05; that is to say an 80% chance of identifying a statistically significant difference (if statistical significance is set as the probability of the assessed values occurring by chance was 5% or less).

The calculations performed showed that the study was underpowered to identify the differences found, and the individual powers are discussed in the light of the results in the relevant sections.

However, there is an important difference between a statistically significant difference and a practically significant difference. A difference of half a day in mean time to reach study endpoint requires 71,000 patients to be treated in each study arm to reach statistical significance, but has no practical significance.

7.2.2.2 Recruitment shortfall

In the absence of a power calculation to guide recruitment the decision was made to recruit patients for a 12 month window. Recruitment was to begin at Lymington Hospital (New Forest) and then later expand to The Royal South Hampshire County Hospital (Southampton) if manpower allowed. In the event recruitment was limited to the single centre of Lymington Hospital for reasons discussed in section 7.2.

It was estimated that 450-600 potential recruits would be referred to Lymington hospital alone during the recruitment period. The estimate was based on new referrals of patients to surgical outpatients and the endoscopy unit with colorectal symptoms during the months of April & May 2001.

During the recruitment window only 180 patients were identified as eligible for recruitment; of these only 111 consented to participate, and 95 proceeded through the study to reach the study end point.

There are four main reasons why recruitment may have fallen so short of expectations-

1. Potential recruits were over estimated.
2. Potential recruits were not identified.
3. Inclusion/exclusion criteria were too severe.
4. Failure to gain informed consent.

In all these cases their relative contributions to the shortfall would have been clearer had the total number of new referrals been recorded; this was not done and is an error in the study design. A retrospective effort to trace all new referrals failed to locate patients by the data on which the referral was received, as such data was incomplete and so only an estimate at best. These figures have therefore not been used in this research.

7.2.2.2.1 Over-estimation of potential recruits

The estimate of potential recruits for the 12-month window was based on the experiences of only 2 months. It is well known that referral rates to any specialty are subject to variation. In addition to more predictable trends (such as seasonal variation and the effect of holiday periods) there are also sporadic fluctuations.

It may be that the referral rates in April/May are normally high when compared to the rest of the year, but there is no evidence to support this. It is also a possibility that referral rates during the period on which estimates were based were abnormally high, or that referral rates during the entire recruitment window were abnormally low. In the absence of total referral numbers it is not possible to comment.

7.2.2.2.2 *Failure to identify potential recruits.*

The 3 times weekly new referral check was strictly adhered to, and new referrals were identified before any action was taken. The three times weekly routine was broken on only three occasions; two episodes of annual leave on the part of the researcher, and the 2 month recruitment hiatus forced by researcher illness. The recruitment window was extended by 3 months to compensate for lost recruitment and it seems unbelievable that there was a massive influx of new referrals during the period of researcher injury; but in the absence of figures this can not be proved (however improbable).

7.2.2.2.3 *Inclusion / exclusion criteria*

The majority of new referrals either failed to meet the inclusion criteria, or having met the inclusion criteria were then ruled out by exclusion criteria. Again as a record of all new referrals was not kept it is not possible to quantify the impact of the inclusion/exclusion criteria. It was apparent to the researcher that a high number of potential recruits were being ruled out after application of study exclusion criteria.

No attempt was made to modify inclusion/exclusion criteria for two reasons. Firstly modifying the study protocol at such a profound level as who is included would have jeopardised the reliability of any conclusions drawn. Secondly the inclusion/exclusion criteria had been selected in order to minimise harm to potential recruits that over investigation or delayed investigation might inflict (e.g. for those with high risk symptoms). The application of inclusion/exclusion criteria was intentionally a box ticking

exercise; criteria had to be “fool proof” and so were inevitably tight. The introduction of researcher discretion or weighting was considered unacceptable.

7.2.2.2.4 Failure to recruit eligible patients

Only 111 of 180 eligible recruits consented to participate in the study (62%). The reasons for the 69 failed recruitments were varied.

It proved impossible to contact 5 patients within the time limit set by the study protocol following the mailing of study literature. Patient contact was attempted by telephone only, and a time of 7:30pm set as the latest socially acceptable time to be making such calls (no calls were made at the weekends except at patient request).

Attempts at contact were made regularly during the daytime on a daily basis (it later transpired that at least one patient had died before the referral on their part had been received!). There was little else that could be done to make contact by telephone short of writing to a patient with a contact number they could use but this would have resulted in an extension of the delay non-recruits experienced before their referrals were returned to the normal pathways for action. Telephone contact was considered essential in order to answer/address any of the patients' initial questions/concerns; it was also necessary to organise a mutually acceptable time for face-to-face meetings.

Eight potential recruits were lost during the break in recruitment due to researcher illness (section 6.1.1). Two had already been contacted by telephone, expressed an interest in participation, and an appointment arranged; the remaining 6 had not been telephoned and their opinions on participation are unknown. Clearly researcher injury was unforeseen and as there was only one researcher recruitment had to be halted, though patient tracking continued. Provisions in study protocol ensured that minimal disruption to patient care resulted from the disruption in recruitment with little or no inconvenience to the staff making the arrangements (section 4.2.3). The eight patients at the recruitment stage were seamlessly returned to the normal management pathways.

Eight patients transpired to have either been investigated by one or more of the modalities employed in the study in the previous year, or had been the subject of duplicate referrals and management had already been instigated in one form or another. It was therefore inappropriate to recruit them to the study.

Multiple referrals for a single complaint or condition on the part of a GP are clearly undesirable, as is the omission of pertinent information (such as recent investigation) in the referral letters. Such practice exposes patients to the risks of over investigation which can only be detrimental to their health, especially when associated with the potential risks seen with the investigative modalities employed in this study.

Seven patients did not want to participate in the study as they did not wish to have their symptoms investigated. Reasons varied from it being inconvenient due to self-employment, to the patient not considering their symptoms serious and so not wanting the inconvenience. All patients in this group were advised that their referral would be returned to the normal management pathways but that they should discuss their opinions with the referring doctor. Patients referred for investigation should be made aware of why the referral is being made, even if there is concern over the diagnosis, as part of good practice. The process can be time consuming but a deficient or absent explanation could result in a potentially treatable (or serious) condition being missed through ignorance as the patient declines investigation.

Six patients declined to participate as their short-lived symptoms had fully resolved and they did not wish to have any investigations. As with the above group their referrals were returned to the normal management system and they were advised to re-discuss matters with the referring doctor.

Over referral of patients with short-lived transient colorectal symptoms is an ongoing problem. As patients have become more aware of the possible significance of colorectal symptoms they are more likely to seek medical advice. Likewise with an ever tightening fervour for prompt referral and early diagnosis of potential malignancies coupled with an increasingly litigious medical system GPs are understandably less inclined to adopt a “watch and wait strategy”, instead referring patients on to a “higher authority” for decisions to be made.

Four patients declined to participate on the grounds that they had already or where due to shortly move out of the area served by the study facilities.

In some cases people do move at short notice but it would be preferred if patients were not referred if they stand little or no change of attending any of the appointments offered (or funding issues between trusts would limit their investigation). Unfortunately patients do continue to wait for outstanding appointments even when they have moved out of an area. They then run the risk of attending only to be told that things cannot progress further because they have moved and that they need to see their new GP for referral to the local unit (this is not a problem limited to the investigation of colorectal symptoms). This inevitably delays their care.

Seven patients declined participation citing health problems as the reason. In some cases the patient felt they were currently too unwell to undergo any investigations, others felt that they already had enough problems without becoming involved with anything else (such as a research study).

The patients' wishes were respected and beyond ensuring the patients understood what participation might involve no attempt was made to convince them to take part. This was done to ensure that a misunderstanding was not a key factor in the patients' decision (as was the case with at least one patient who then happily agreed to take part).

Five patients did not participate as they had elected to seek private care.

While private care offers an important and valid adjunct to NHS care it is unfortunate when patients are referred down both avenues with already stretched NHS resources invariably those being wasted (clerical as a

minimum but even up to patients repeatedly failing to attend for appointments or investigation).

The largest group sharing a common reason for turning down the invitation to participate in the study were the 9 patients who simply did not want to take part in any form of research. All received assurances that all methods and investigations were well established and that no new methods were being employed. Beyond that no effort was made to persuade them to participate and their referrals were returned to the main patient pool.

Some patients expressed that they simply did not want to take in anything that may involve extra effort on their part, but these were the minority. The majority simply did not feel comfortable participating in anything that might be construed as experimental. The phrase "Guinea Pig" was mentioned more than once. Other than ensuring there had not been a misunderstanding these patients' opinions have to be respected.

Of the remaining 10 patients who declined participation 5 did not offer a reason and one was not requested to avoid misinterpretation as being confrontational or pushy. The remaining 5 gave a variety of unique reasons (e.g. they were a member of staff).

In broad terms it can be considered that 13 of the 69 failed patient recruitments were not truly afforded the opportunity to participate. 30 should not have been referred due to desire for private care, recent investigation,

moving out of the area, or the patient not wanting investigation. Only 26 of the 69 failed recruits made reasoned decision that they did not want to participate in research and preferred to have their care managed through normal pathways.

7.3 INTERPRETATION OF FINDINGS

7.3.1 Continued relevance of study

The core subject of the study, that is the best management approach to address the large number of patients referred with “low risk” colorectal symptoms for further investigation, is no less relevant at the time of reporting (2004) than it was at the time of the study’s design and inception during 2001. The executive summary of the NHS Cancer Plan emphasised that new investment alone would not be sufficient to meet the stated aims. Existing services would need to be streamlined and new approaches required in order to optimise the use of the skilled workforce available [executive summary, NHS Cancer Plan].

The intervening 3 years have not seen the introduction of new investigative modalities for colorectal cancer, nor have they seen a revolution in service delivery. It has recently been announced that a National Screening programme for colorectal cancer will be introduced, but details of how it will be introduced, and in particular the resource implications, remain vague. During the same period our understanding of which symptom clusters should demand the promptest investigation (as they are most likely to herald colorectal cancer) has advanced little; and demands on investigative and diagnostic services continue unabated. An inquiry by the All-party Parliamentary Group on Cancer in the summer of 2004 was presented with testimony from the National Audit Office highlighting that data on how long

patients wait for diagnosis and treatment of cancer is only recorded for urgent referrals. The report went on to state that there is a –

“need to speed the flow of people initially referred non-urgently through the system [and] the best way to do this is to redesign the system so that everyone is seen quickly” [Meeting National Targets]

The study measurements of time, satisfaction, visit numbers and costs remain key issues within the delivery of healthcare. The patient centred endpoint of “when the patient is informed” seems even more important in today’s NHS of patient empowerment and PCT funding than it did at the study’s inception. The Department of Health driven “System Reform” which includes the Patient Choice agenda has gone further to place the patient and their desires at the centre of health care delivery. The target of offering patients a choice of 4-5 hospitals for the elective management of conditions requiring planned surgery by December 2005 seems optimistic, but time could see the strategy “rolled out” to other areas of healthcare. [System Reform] Patients’ choices, however, are likely to be emotional rather than evidence based. [Muir Gray 2004]

7.3.2 Population sample

The demographic make-up of the study group is important in that it must be a representative cross section of the population group that any conclusions drawn from the study are intended to benefit. There is no merit in embarking on a program of research and then applying its findings to a different group from that which enabled the findings to be made.

The full demographic details of patients recruited to the study are shown in Table 6.1.5. The median age of 67 with an inter quartile range of 58-78 means the study group is well matched to the population findings would be applied to (see Figures 1.1.2 a & b). The gender mix is 42 male (38%) to 69 female (62%)

The demographics of the non-participating (yet eligible to participate) group are also important to ensure that the recruited group was not self-selecting in terms of age and gender. Given that the mean age of the non-participant group is 67.5 and the inter quartile range 59-76; while the gender mix is 27 male (39%) to 42 female (61%) the selection (or exclusion) of a demographic sub-group does not appear to have occurred.

7.3.3 Randomisation

Randomisation of each patient to a study group was performed according to study protocol in all instances (see section 4.2.10). This employed a truly random (rather than pseudo-random) process to allocate study group; it was therefore possible to generate three significantly different populations.

The chance of this inequity occurring is ever present with random allocations but the chance reduces more times the randomisation process is performed.

As already indicated the number of patients recruited was less than the estimated number of recruits; at only 111 this relatively small number of recruits made the possibility of the randomisation process generating 3 significantly different groups a concern. If the study groups emerged as significantly different it would be difficult to make meaningful comparisons

without resorting to complex analytical methods of adjustment, and making non-parametric analysis of data, used extensively in this study, impossible.

Table 6.1.5 shows the make-up of the three groups in terms of numbers, gender and age.

It is unfortunate that there was disparity in group size. While in the majority of cases this is inconsequential, certain calculations (such as the retrospective power calculations) required matched group sizes and could only use the smallest sample size. However, analysis failed to identify a statistically significant difference between the three study groups in terms of age and gender, and we concluded that our analysis was valid.

7.3.4 Patient withdrawal from study

As detailed in section 6.2.1 there was no significant difference in the drop out rate between the three study groups. The stage at which a patient elected to drop out of the study (and reason where offered) cannot be reduced to a statistical comparison.

Sixteen recruited patients withdrew before reaching study end point – “patient informed of diagnosis, discharge (with reassurance), or need to further investigate”; five in the “Colonoscopy” group, six in the “Barium Enema/Flexible Sigmoidoscopy” group, and five in the “Usual Care” group.

7.3.4.1 Implications of patient withdrawal

7.3.4.1.1 *Expenditure and waste*

Sixteen patients failed to reach study endpoint at a cost of at least £1,820 (see Table 6.4.2):- even then the cost of clerical work and researcher time is not taken into account. Not all of this sum can be considered wasted, however, as the investigations/appointments the patients attended were with a purpose, but £1,032 was expended on investigations and appointments that were not used (2 outpatient appointments, 3 barium enema appointments, and 4 flexible sigmoidoscopy appointments). Nevertheless, it is the right of study participants to withdraw from research at any time and without prejudice to their treatment.

7.3.4.1.2 *Failure to fully investigate*

Of the 16 patients who withdrew before reaching study endpoint four had made arrangements in the private sector, and two had completed their investigations. Of the remaining 10, two withdrew due to ill health with full caring physician knowledge, one withdrew after part investigation with the knowledge and agreement of their GP, and one withdrew as their symptoms had fully resolved.

This left six symptomatic patients who apparently elected not to be investigated. These patients were not contacted beyond the point at which they withdrew and no attempt was made to trace them. It is possible that they also pursued care through alternative channels or were re-referred at a later date. The fact remains that these patients have not been optimally investigated on presentation. Study literature and the face-to-face discussion

with the researcher covered the reasons for investigation and possible diagnoses before the patients consented to participate, it is hoped that these patients' decisions were truly informed ones.

7.3.4.1.3 Did the wait for investigation have an effect on withdrawal?

Time taken is one of the primary study measurements and an ever-present factor in patient care and government targets. As we are told that time taken is of importance by myriad sources the length of time waited is bound to factor into decision making at some level.

Ten patients withdrew at the pre-investigation stage, of these two patients chose to pursue private care before any appointments were made. It is not known how long they were kept waiting to find out when their appointments might be, also patients invariably asked the researcher at the face to face meeting how long the process of investigation was likely to take and they were informed it would take weeks/months rather than days/weeks. These factors may have influenced these patients' decisions.

There was one withdrawal due to ill health leaving seven patients; of these one patient reported a resolution of symptoms, one elected for private care, three cancelled their appointments, and two simply failed to attend. The experiences of this group of seven indicates that they had already, or were due to wait, a longer than average time for their first appointment, with two falling between the 50th and 75th centiles, four between the 95th and 90th centiles, and the last beyond the 95th centile.

Of the four patients withdrawing during investigation one did so because of ill health, one after a barium enema and discussion with their GP had reassured them sufficiently, and a third who withdrew having had nothing abnormal found in outpatients, a normal colonoscopy and a normal ultrasound scan. The final patient attended an outpatient appointment before going private while awaiting a barium enema. The first appointment on day 96 was between the 75th and 90th percentiles and the patient was due to wait a further 3 weeks for an investigation. It is understandable if after a long wait the patient elected to take matters into their own hands by pursuing private care.

The two patients to withdraw from the study after investigation was completed were not typical with one dying and the other attending appointments that were cancelled on the day due to ongoing health problems. The final appointment, which the patient cancelled, was due to occur on day 147; 56 days after the last investigation.

All of the patients making a calculated decision to with withdraw from the study either had waited or were due to wait for a greater number of days than the norm. It would seem likely (though not proven) that the time waited influenced these patients' decisions to withdraw. There was no apparent weighting towards any study group.

7.3.5 Primary study outcomes

The primary study outcomes are those that the study was designed specifically in order to provide. In the absence of a power calculation it was

hoped that data collection from the year long recruitment window would be sufficient to show differences between the study groups. This was not the case, but the reasons why this might be so, in terms of the clinical importance of the differences observed, have already been discussed.

7.3.5.1 Time taken to reach study end point

As one of the simplest measurements and the importance of “timeliness” to patients and politicians alike, differences in time to end point could prove instrumental in the introduction of a policy of direct investigation; in the event the study failed to demonstrate neither a statistically significant difference, nor a clinically important one.

Although patient experiences were similar across the three groups for the majority of the study, patients in the “Usual Care” group took longer to reach end point at the upper extreme of patient experience. Survival analysis highlighted five cases in the “Usual Care” group as extreme values from the point at which the survival curves diverged.

A lack of resources in the NHS is not the only reason for diagnostic delay; two of these five extreme values are largely down to the patient involved (one cancelled four appointments and failed to attend another, while the other cancelled one and failed to attend one). A further patient cancelled one appointment herself before having one cancelled by the hospital. Another had an appointment cancelled by the hospital, the replacement taking 35 days,

and waited 42 days post investigation for histology results to become available. One patient had no cancellations for any reason.

It would not be unreasonable to expect that a patient sufficiently worried about their symptoms to seek medical advice, and whose GP was equally concerned enough to make a referral, would attend appointments whenever possible. This is clearly not the case. It is a hindrance to the delivery of their care that some patients can adopt a “pass the buck” attitude to responsibility for their own health.

7.3.5.2 Measurement of expressed patient satisfaction

The concept of patient satisfaction along with the design and development of the questionnaire has been detailed in sections 2.2.8 and 5.0, and is not covered again here.

The measurement of differences in satisfaction relies not only on a difference being present but also on the ability of the tool (questionnaire) to detect it. Comparisons in this instance were made across all groups, and directly between the groups, four comparisons in total. A summary of the retrospective power calculations for satisfaction comparisons is provided in Table 6.6.2. Because all of the comparisons are massively underpowered it is surprising that any statistically significant differences were identified. The sample sizes required to sufficiently power the comparisons are as a rule smaller than those required to achieve the same for “time to end point”.

The return rate of the questionnaire was 96% (91 of 95) which is beyond normal expectations [Streiner & Norman 1995] but what cannot be evaluated is the satisfaction of non-respondents. Reasons for not returning a questionnaire are diverse, from simple forgetfulness or not wanting to be bothered, to being so dissatisfied with care that withdrawal of co-operation as a means of “getting back” at what is considered inadequate.

The analysis of expressed satisfaction suffers greatly for being underpowered. None of the analyses have the desired power of 0.8; the majority are below 0.3 (see Table 6.6.2). Because the study is underpowered the chance of a statistical difference being identified even when one exists is very low. Only three of the 48 statistical comparisons identified a significant difference and at 6.25% this only just exceeds the 5% result expected to occur randomly (false positives).

Only apparent trends can be commented upon and those indicate that patients in the “Usual Care” group are the least satisfied with their care, while those in the “Colonoscopy” group are the most. This is perhaps surprising: although there was no difference in the time to endpoint across the three groups the “Colonoscopy” group had much longer waits before attending their first appointment.

It is important to note the questionnaire had a good response rate (despite the perpetual dilemma of what non-response may indicate); there was also a good spread of results between individuals indicating that the psychometric

tool was able to discriminate (to at least some degree) between differing experiences.

Separate analyses attempting to identify a correlation between satisfaction and other study measurements (e.g. days to end point, time to first attendance etc.) bore no fruit.

7.3.5.3 Free text patient Feedback

The free text section of the questionnaire is addressed in detail in section 6.7 and though these patient comments are not a measurable quantity they do offer insight into patient satisfaction and opinions that would otherwise be lost.

There are a number of key findings which should influence patient care

- A large proportion of patients desire a diagnosis and treatment for their symptoms, rather than reassurance that they do not represent sinister pathology.
- Patients value the opportunity to talk to a doctor face to face and discuss their symptoms.
- Patients dislike last minute changes even when made in their best interests.
- Patients like written information.

7.3.6 Secondary study outcomes

The secondary study measurements were intended from the study's inception but did not influence design.

7.3.6.1 Number of hospital attendances as an indication of patient costs.

It is not possible to place a cash value on the “cost” to the patient while going through the process of investigation as it may take many different forms.

Some costs such as earnings lost by the patient or accompanying relative, and travel, could have a cash value which could be calculated and counted but are beyond the limits of this study. Other costs such as anxiety, lost productivity, inconvenient/unpleasant investigation, and morbidity resulting from investigation are less tangible and defy a cash valuation.

The number of hospital attendances was selected as a yardstick of patient costs in order to enable a comparison between study groups (i.e. a relative rather than absolute comparison).

The number of hospital visits was assessed on an intention to treat basis and so includes the experiences of patients who failed to reach study endpoint.

The number of Hospital visits made ranged from zero (the ten patients who withdrew before any patient events had occurred), to four (a single patient in the “Barium Enema & Flexible Sigmoidoscopy” group).

The box plot showing attendances by study group (Figure 6.4.1b) reveals that patients in the “Colonoscopy” group made fewer visits to hospital – as was expected. The “Barium Enema & Flexible Sigmoidoscopy” and “Usual Care” groups share a common median though the “Usual Care” group appears to have more attendances. Statistical analysis identifies that there is a significant difference across the three groups ($p < 0.000$); more detailed analysis identifies that the “Colonoscopy” group has fewer visits than the other

two ($p < 0.000$) while there is no significant difference in attendances between the “Barium Enema & Flexible Sigmoidoscopy” and “Usual Care” groups. A lower number of attendances was expected for the patients in the “Colonoscopy” group and the research data confirms this. Patients in the “Barium Enema & Flexible Sigmoidoscopy” group were expected to need one or two visits (dependant on whether or not the investigations were co-ordinated to be performed on the same day), which proved to be the case. The “Usual Care” group were anticipated to need two or more visits. These expectations were supported in the study’s finding (see Figure 6.4.1c). The statistical comparison between “Barium Enema & Flexible Sigmoidoscopy” and “Usual Care” groups failed to prove significant but it was underpowered at 0.26 (a sample size of 141 in each arm would be needed to reach a power of 0.8).

7.3.6.2 Cost to the NHS

Calculations of costs to the NHS are based on the most suitable source material available – The NHS 2001 reference cost. These data are subject to their own shortcomings. The reference costs relied on the voluntary completion of data sets by NHS trusts and only half the trusts in England & Wales returned the information in time for inclusion. The reference material provides an average cost for events and a range (which tended to be wide); for the purpose of this analysis the average cost was used. Hospital visits also had to be matched as “best fit “ to the reference costs since they were not all encompassing.

Significant omissions in the reference costs are the cost of cancelling (or cancelling and rescheduling) an appointment, and more importantly the cost of a “DNA” (“did not attend” – the patient simply fails to keep their appointment). In order to compensate for these short falls appointments cancelled with sufficient time were considered not to have incurred a cost (the clerical work is not given a value in this analysis); appointments cancelled too late to reschedule and DNAs were priced as though the appointment/investigation had taken place, the main cost of these investigations being expenditure on man power rather than the use of equipment.

The findings of the cost analysis showed that the “Barium Enema & Flexible Sigmoidoscopy” pathway was the most costly with a mean expenditure of £241 (£290 per patient to reach study end point) and a range of £0-440. The second most costly was “Usual Care” with a mean expenditure of £195 (£231 per patient to reach study end point), the range of expenditure was £0-344. The least costly pathway was “Colonoscopy” with a mean expenditure of £137 (£154 per patient to reach study end point), and a range of £0-381. (see Figure 4.6.2c)

The difference in cost of investigation has funding implications with a difference of over £100 spent investigating a patient to the same ends between the most and least costly strategy. This is a subject worthy of further study, however, it has already been stated that a societal perspective on the

economic analysis would have been interesting. Ideally this should be undertaken outside the highly artificial context of a clinical trial.

7.3.7 Tertiary study outcomes

Tertiary measurements are those identified during the execution of the study as valid assessments of the patient experience. While not key to the study design or taken into account they were identified while data collection was ongoing, NOT once the data set was complete.

7.3.7.1 Time to first hospital appointment

The time taken for the first Hospital appointment to occur was considered important as it is a marker point in the patient pathway; up to this point the patient has been waiting for their investigation(s) to start, from this point on investigation is under way.

Statistical analysis identified a significant difference in time to first attendance between the three study groups with “Colonoscopy” taking significantly longer than “Flexible Sigmoidoscopy & Barium Enema” and “Usual Care” to deliver the first attendance. There was no significant difference between the “Flexible Sigmoidoscopy & Barium Enema” and “Usual Care” groups (see section 6.5.1)

The trend for patients in the “Colonoscopy” group to take longer to make their first hospital attendance is also demonstrated by survival analysis (Figure 6.5.1d).

It is best to consider this significant result in the light of other study findings. While patients in the “Colonoscopy” group require significantly fewer attendances to reach study end point they begin to do so significantly later (time to first attendance). The result is that there is no significant difference in time to end point between the three study groups though the patient journey, once started, is shorter in the “Colonoscopy” group.

The delay in time to first appointment for the “Colonoscopy” group can only be the result of the high level of demand on endoscopy facilities and services. If this could be rectified the “Colonoscopy” route is likely to prove –

- o Quicker
- o Less costly to NHS
- o Less costly to patient

The reality of freeing up endoscopy slots to expedite the investigation of patients in the non-fast track colorectal symptoms group is discussed in detail in section 7.3.8.

7.3.7.2 Appointment cancellations

The number of cancellations during the investigation of a single patient was also considered important. The “best use” of finite facilities does not include constant re-organisation. For the purpose of this analysis no differentiation was made between “DNAs” and appointments that the patient phoned to cancel (with or without adequate notice to reallocate the appointment).

For all study participants the number of booked appointments was compared with the number of hospital attendances using paired T-test, and the difference found to be significant. This difference continued to be significant when the three study arms were assessed separately.

Although this difference was significant analysis (using a Kruskal-Wallis test) failed to identify a significant difference between study arms.

This must be considered in light of the findings that patients in the “Colonoscopy” group were required to make fewer hospital attendances than those in the other two arms in order to reach study end point. The more hospital attendances a patient is required to make the greater the opportunity for cancellation, yet this did not occur. This suggests that patients in the “Colonoscopy” arm are particularly susceptible to cancellation. Appointment cancellation always involves some degree of cost; “Colonoscopy” is already significantly cheaper than the two other management strategies and if cancellations can be minimised (or abolished) the cost could be driven down further.

When the nature of an appointment and the number of cancellations is assessed independently of study group it appears that a colonoscopic examination is the most likely appointment to be rescheduled at either the hospital's or the patient's instigation.

7.3.8 Diagnostic outcomes

The study was not intended to, nor expected to, affect clinical outcomes. It set out to compare investigation strategies. Nonetheless the outcomes of these investigations are of interest and detailed in Table 6.8. Among the study participants (111) only 2 cases of colorectal cancer were identified; this was in keeping with expectations as patients were drawn from a population with “low risk” symptoms for colorectal cancer (in comparison to the “high risk” symptoms used to identify patients requiring a fast track two-week referral). A further 13 patients were found to have adenomatous polyps which were removed.

As discussed earlier study participants referred for colonoscopy had to wait longer than those referred through other channels before they reached their first hospital attendance. Once investigation was initiated, however, they progressed along the patient pathway at a quicker rate than those in the other groups, reaching study endpoint at the same time. Freeing up of endoscopy facilities in order to hasten the investigation of these patients is clearly desirable.

However, patients requiring investigation of colorectal symptoms do not exist in isolation from other patients in the NHS and there is competition for endoscopy services and facilities (e.g. planned surveillance or therapeutic colonoscopy, gastroscopy, and bronchoscopy to name but a few).

Prioritisation for any patient group would have to be justified, and backed by compelling evidence.

During the study period endoscopy services at the study site (Lymington Hospital) were used for a variety of purposes including the investigation of patients with Iron deficiency anaemia by “top & tail” endoscopy (colonoscopy and oesophagogastroduodenoscopy). A single physician performed all of these endoscopic examinations and a separate record of all findings was kept [Devane – personal correspondence]. These diagnoses are compared to the diagnostic findings made as a result of endoscopic examinations performed on study participants, the two groups having competed for endoscopy facilities.

Diagnosis	“Direct Investigation” study participants (54)	Iron deficiency anaemia patients(120)
Normal Investigation	21 (39%)	27 (23%)
Oesophagitis/Hiatus Hernia		18 (15%)
Gastritis/Gastric erosions		12 (10%)
Gastric Ulcer		9 (7%)
Gastric Polyps		2 (2%)
Gastric Cancer		3 (2%)
Duodenitis/Duodenal Ulcer		6 (5%)
Coeliac disease		1 (1%)
Colorectal Cancer	1 (2%)	18 (15%)
Polyps	9 (17%)	24 (20%)
Diverticular Disease	23 (43%)	40 (33%)
Angiodysplasia		1 (1%)
Infection (Spirochetes)	1 (2%)	
Colitis/Proctitis	3 (6%)	3 (2%)
Rectal Ulcer		1 (1%)
Haemorrhoids	1 (2%)	2 (2%)

Table 7.3.8 – Comparison of diagnostic yields from endoscopic examinations for patients in the “Direct Investigation” study group, and those undergoing investigation for iron deficiency anaemia.

The most dramatic difference between the two groups is the incidence of malignancy; only 2% (colorectal) in the study group, but 17% (2% gastric & 15% colorectal) in the iron deficiency anaemia group. Not only that but the rate of normal investigation in the study group was approaching twice that of the iron deficiency anaemia group (39% compared to 23%). If these figures are representative then it could be argued that patients fulfilling the study criteria should be given a lower priority rather than an elevated one when compared to patients with iron deficiency anaemia.

7.4 CONCLUSIONS

7.4.1 Which patients are suitable for direct investigation?

It is believed that the strict nature of the eligibility criteria played an influential roll in low recruitment, though in light of the retrospective power calculations it is clear that recruitment would never have reached sufficient numbers in the study setting.

The patient suitability criteria had several aims outlined in section 2.2.4: one of they key aims was to avoid the inappropriate investigation of patients which might result from an “automated” investigation process. In light of this it is concerning to note that nearly 15% of patients in the “Usual Care” study group were seen in the outpatient clinic only, and no further investigations considered necessary by the assessing surgeon. Had the same patients been randomised to either of the other study groups they would have been fully investigated as a matter of protocol. In order to see whether the assessing surgeon was correct it would be necessary to undertake a follow up study after a suitable interval (say 1-2 years), but that was outside the scope of this study.

The process of selecting which patients are suitable for a policy of direct investigation must be further examined before any widespread policy can be acted upon regardless of any favourable study findings.

7.4.2 The strain on endoscopic services

As discussed previously demands on endoscopic services are high and believed to be the main reason why a strategy of direct investigation failed to deliver on its main aim of reducing time to study end point. There were a number of study findings which support a demand for greater endoscopic services provision. An increase in facilities would appear to be the main answer to this as patients with these symptom clusters do not warrant prioritisation over other patients requiring endoscopic investigation.

7.4.2.1 Time to first appointment

Patients in the “Colonoscopy” study group had to wait consistently longer for their first hospital appointment than did those in the other two groups.

7.4.2.2 Fewer visits fails to deliver benefit

Although patients in the “Colonoscopy” group made statistically significantly fewer visits to hospital in the process of reaching study endpoint they did so at the same time as those patients in the other two study groups.

7.4.2.3 Colonoscopy appointments most likely to be cancelled

When analysed independently of study group a colonoscopy appointment was the appointment type most likely to be cancelled, with patients themselves and the endoscopy unit having an equal hand in the cancellations (see Table 6.5.2).

7.4.3 The assessment of patient satisfaction

During this study a psychometric tool in the form of a patient satisfaction questionnaire was developed and subjected to standard evaluation and validation techniques (see section 5.5). The questionnaire had an excellent response rate of 96%.

7.4.3.1 Measurement of satisfaction

While assessment failed to identify statistically significant differences in measured satisfaction a high level of response was provided; there was also considerable variation in response to the questions between individuals.

There was a trend towards greater satisfaction in the “Colonoscopy” group, and lesser satisfaction in the “Usual Care” group.

It did become apparent that it was a patients interpretation or recollection of events which was more important than what actually occurred.

7.4.3.2 Free text feedback

The section of the questionnaire allowing patients to express views and opinions (without a fixed structure) provided valuable insights.

7.4.3.2.1 General satisfaction

Comments on overall satisfaction were foremost with the majority (22) simply offering praise or thanks, and the minority (2) being critical of care.

7.4.3.2.2 *Empathy with staff*

Relations with staff were the next most numerous topic of comment. Again the majority were praising but all critical comments centred on the abruptness of doctors at consultations.

7.4.3.2.3 *Treatment / advice about ongoing symptoms*

All free text comments pertaining to care and advice were critical. Patients demonstrated that it is not only reassurance that they do not have cancer that they seek when complaining of colorectal symptoms. A proportion also want a diagnosis and advice as to how to deal with their symptoms (no matter how trivial they may seem). Failure to provide these leads to dissatisfaction.

- Patients like a diagnosis / label for their symptoms.
- Patients often desire a treatment for their symptoms rather than reassurance that they do not represent sinister pathology.
- Methods for improving patient's recollection of information and discussions are well received and effect satisfaction (see section 7.8.3)

7.4.4 Cancelled appointments

Cancelled appointments are a constant drain on NHS resources. If they are cancelled with sufficient notice and the appointment can be reallocated then they create a clerical burden at best. Last minute cancellations (or simple failure to attend on the part of the patient) waste clinical resources and have an impact beyond the care of the patient directly involved.

Appointments were cancelled by two different patient sub-groups: those withdrawing from the study / process of investigation and those who had appointments cancelled in the process of being fully investigated.

While not all appointment cancellations are down to the patient 39 of 71 appointments cancelled during the execution of the study were. There also appears to be a small subgroup of patients who continually failed to attend or cancelled appointments, one patient only attended two of seven booked appointments; all of the cancellations were due to the patient. This patient subgroup is seen at the extreme end of patient experience in term of days to end point.

7.5 IMPLICATIONS FOR CLINICAL PRACTICE

The aims of the study are stated in section 3.1 and amount to seeking to speed a patients progression through the process of investigation by reducing the number of appointments necessary to achieve this as a result of following a process of “Direct Investigation”; while maintaining or improving the patients satisfaction with the process.

7.5.1 Direct investigation by colonoscopy in comparison to usual care.

While reducing the number of appointments necessary to reach study end point there was no reduction in time taken to do so.

This process did significantly reduce the cost to the NHS of investigating the patient, and (by inference of the reduced hospital visits) reduced costs to the patient.

While there was no statistically significant difference in expressed satisfaction there was a trend towards greater satisfaction in the “Colonoscopy Group”.

7.5.2 Direct investigation by barium enema and flexible sigmoidoscopy in comparison to usual care.

There was no reduction in either the number of appointments necessary, or time taken, to reach study end point.

The cost to the NHS of investigating patients in the “Barium Enema & Flexible Sigmoidoscopy” was significantly higher than those in the “Usual Care” group. Cost to the patient remained unchanged.

There was no statistically significant difference in expressed satisfaction, though there was a trend for patients in the “Barium Enema & Flexible Sigmoidoscopy” group to express a lower level of satisfaction.

7.5.3 Implications and recommendations

If the economic assessment provided by this trial is correct, it seems to suggest that direct referral for colonoscopy is the way forward for investigation of patients presenting with low-risk symptom clusters. It provides an answer with the same timeliness as other investigative processes, requires fewer attendances by the patient, and is cheaper for the NHS. The initial wait for an appointment appears to have no effect on patient satisfaction, and would in any case likely be ameliorated by the introduction of more dedicated colonoscopy facilities.

Doubt is raised, however, by the fact that four of the 27 (14.8%) patients randomised to “Usual Care” were seen in outpatients and discharged with no further plan to investigate. If we accept a surgeons decision based on an outpatient consultation as the gold standard, this suggests that there would be an unacceptable level of over-investigation if direct investigation were to be introduced using methods and criteria used in this study. Exposing patients to unnecessary risk and needlessly using limited resources (in an already stretched system) is inexcusable. However, the “gold standard” may need to be established by further follow up studies of un-investigated patients.

There is clearly more work to be done before a process of Direct Investigation employing those techniques and criteria used in this study is introduced. Until more work is done to identify which patients are suitable for direct investigation clinical decision-making should remain the gatekeeper to investigation for “low risk” colorectal symptoms. While on face value surgical outpatients may seem an unnecessary step on the patient pathway it may have an important triage role to fulfil in weeding out those patients who require no further investigation and who would be exposed to unnecessary risk.

This major issue aside, investigation by colonoscopy is preferable to investigation by barium enema and flexible sigmoidoscopy. In addition to the benefits highlighted in section 2.2.5.2.2 investigation by colonoscopy is cheaper, requires fewer visits, and patients appear to express a higher level of satisfaction.

This does not mean that all patients in this clinical setting should be investigated by colonoscopy exclusively: facilities simply would not be able to cope. Until endoscopic services provision is substantially improved patients will continue to be investigated by both approaches, accepting that one has its disadvantages if the “greater good” is to be served.

7.6 IMPLICATIONS FOR FUTURE RESEARCH

7.6.1 Criteria for direct investigation

A process of direct investigation remains an attractive prospect for managing a subgroup of patients; the challenge at present is identifying which subgroup. The concept of selecting groups of patients based on their particular colorectal symptoms is not new, and is subject to much ongoing interest. The identification of which patients are most likely to harbour malignancy based on clinical symptoms and signs in order that their investigation be prioritised is the backbone of the NHS fast track (two week wait) system. The identification of which clinical features (almost always) provoke a clinical judgement to investigate could be included as a sub-analysis of such work. The follow up of those not investigated is of clear importance.

7.6.2 Patient satisfaction

The patient satisfaction questionnaire developed during this study could be used to compare outpatient management strategies within, or between, units (after a suitable period of validation).

As the questionnaire was developed from small group interviews performed in the general surgical outpatient setting it may also led itself to assessing patient satisfaction with other facets of surgical outpatient care (not just “low risk” colorectal symptoms). The questionnaire has already been used as a starting point for the assessment of patient satisfaction with breast care services. Each new clinical setting would require a process of revalidation.

7.6.3 Computer modelling of services

One of the limitations of effecting change in a clinical setting is that it is a time consuming and slow process. To first introduce a change, and then assess its impact can take months or years.

Although it has its routes in industry computer modelling can be used to reproduce the network of steps and services involved in a patients care (no matter how complex). The model may then be manipulated, and the projected effects are instantly provided.

The computer model is populated with data from individual patient experiences (not a table of means), this is because variation in experiences is a key part of planning services. Once populated, bottlenecks can be identified, and changes suggested. The changes that can be made are myriad, for example - including more booking clerks, changing the number of clinics (or appointments at each), endoscopy provisions (down to the number of scope washers), and so on. In this way multiple changes in service structure can be made and assessed in a short period time.

The process of modelling has progressed beyond “SIMcity™” and would require a hands on assessment of service provisions by a researcher (skilled in the technique) before they can be reproduced as a mathematical model and manipulation/modification can commence.

APPENDICIES

Appendix A	Sample “fast track” colorectal referral forms.....	274
Appendix B	Surveillance and Screening Guidelines Agreed Between Winchester & Southampton Colorectal Unites.....	276
Appendix C	Study Inclusion and Exclusion Criteria.....	277
Appendix D	Ethical Approval.....	278
Appendix E	General Practitioner Information Sheet.....	279
Appendix F	Patient Detail Record.....	280
Appendix G	Patient Study Record.....	281
Appendix H	Patient Information Sheet.....	282
Appendix I	Letter sent to Patients with whom the Researcher failed to make contact after being sent the Patient Information Sheet.....	285
Appendix J	Study Consent Form.....	286
Appendix K	Final Study Questionnaire.....	287
Appendix L	Questionnaire Cover Letter.....	290
Appendix M	Questionnaire Second Mailing Cover Letter.....	291
Appendix N	Test Re-test Questionnaire Cover Letter.....	292
Appendix O	Sample Topics used by Facilitator in Small Group Interviews.....	293
Appendix P	Face Value Questionnaire Dimensions.....	294
Appendix Q	Refined Questionnaire Dimensions.....	295
Appendix R	Standard Information sent out to Patients Undergoing Barium Enema Examination at Lymington Hospital.....	297
Appendix S	Standard Information sent out to Patients Undergoing a Colonoscopy at Lymington Hospital.....	298
Appendix T	Standard Information sent out to Patients Undergoing Flexible Sigmoidoscopy at Lymington Hospital.....	301
Appendix U	JAG guidelines for training in colonoscopy	303

SOMERSET COLORECTAL CANCER GROUP
REFERRAL FORM FOR PATIENTS SUSPECTED OF HAVING A HIGH RISK OF COLORECTAL CANCER

MPH FAX: 01823 342444
 Endoscopy Unit, Taunton & Somerset Hospital

YDH FAX: 01935 411186
 Yeovil District Hospital

Patient Details
 Surname _____
 Forename _____
 DOB: _____ Hosp No: _____
 Address: _____
 Telephone Number: _____

Referring GP Details:
 Name: _____
 Practice Stamp: _____
 Telephone Number: _____
 Fax Number: _____

Date of referral:

Should colorectal resection be necessary please indicate: ☐ Soonest available surgeon **OR**
☐ Preferred surgeon, please specify _____

HIGH RISK SYMPTOM GROUPS – REFERRAL CRITERIA TO FAST TRACK CARE
 Please tick all that apply

- ☐ Patient over the age of 65 years developing new rectal bleeding
- ☐ Patient aged 40-65 years with persistent bleeding > 6/52 without anal symptoms (e.g. pain, discomfort, soreness, itching, "piles")
- ☐ Patient aged over 40 years with persistent change in bowel habit (>6/52) with an increase in bowel frequency (with or without rectal bleeding), including wet wind.
- ☐ Unexplained iron deficiency anaemia (<10g with a low ferritin), with or without primary symptoms (e.g. pain, distension, abdominal mass, change in bowel habit)
- ☐ Palpable tumour on rectal digital examination
- ☐ Strong suspicion of colorectal cancer not meeting any of the above criteria. Please specify below:

**LOW RISK SYMPTOM GROUPS – PATIENTS SHOULD BE REFERRED IN THE USUAL WAY BY
 REFERRAL LETTER TO THE APPROPRIATE CONSULTANT**

RECTAL BLEEDING

- Rectal bleeding associated with perianal symptoms which include soreness, discomfort, itchiness, mucosal prolapse, pain and lumpiness.
- Bleeding associated with short, self-limiting changes in bowel habit, especially to a decrease in frequency of defaecation, hard stools and straining, but including short attacks of diarrhoea.
- Large volume self-limiting bleeds of bright red blood, separate from the stool.

CHANGE IN BOWEL HABIT

- Short attacks of decreased frequency of defaecation associated with hard stools and straining.
- Diarrhoea for less than 6 weeks.
- Recurrent attacks of diarrhoea with a complete return to normal bowel action between attacks without treatment.

LOWER ABDOMINAL PAIN

- Abdominal pain: with no abdominal mass, normal haemoglobin or not indicative of intestinal obstruction.

This is a pilot scheme to run up to 31 March 2000 when a major review will take place.

Charles Collins, Ian Eyre-Brook, Robin Kennedy, Clive Royle, Richard Welbourn and Tony Morkane.
 Somerset Health Authority, Taunton & Somerset Hospital and Yeovil District Hospital

SPECIMEN

Blankshire Cancer Network: Suspected Colorectal Cancer Referral Form

To make a referral, FAX this form to the Urgent Referral Team at the relevant hospital.
 If you wish to send an accompanying letter, please do so

Please ☒ corresponding box for which hospital referred to:

Hospital A: fax: _____ tel: _____	Hospital C: fax: _____ tel: _____	Hospital E: fax: _____ tel: _____
Hospital B: fax: _____ tel: _____	Hospital D: fax: _____ tel: _____	Hospital F: fax: _____ tel: _____

From: (use practice stamp if available):

Address: _____ GP's name: _____
 P.C.G. code: _____
 Tel no: _____
 Post code: _____ Fax no: _____
 Date of Referral: _____

Patient Details:

Name: _____ D.O.B: _____ Age: _____ Gender: m/f
 Address: _____ Tel no (home): _____
 Tel no (work): _____
 Post code: _____ New NHS No: _____
 Hospital No. (if known): _____
 Has the patient previously visited this hospital? Y / N
 Interpreter required? Y / N
 First language: _____

Referral Information (please ☒ boxes):

Primary symptoms:

Rectal Bleeding Yes ☐ No ☐
 Abdominal pain Yes ☐ No ☐
 Anal symptoms Yes ☐ No ☐
 Change in bowel habit Yes ☐ No ☐
 Increased frequency/looseness Yes ☐ No ☐
 Other _____

Systemic symptoms:

Weight loss Yes ☐ No ☐
 Tiredness/weakness Yes ☐ No ☐
 Symptoms of anaemia Yes ☐ No ☐

Examination:

Palpable abdominal mass Yes ☐ No ☐
 Palpable rectal mass Yes ☐ No ☐

Investigations:

Haemoglobin _____ g/dl Other _____

Comments/other reasons for urgent referral: _____

To be completed by the Data Team:

Date received: _____ Date 1st appointment booked: _____ Date of 1st appointment: _____
 Date 1st seen: _____ Specify reason if not seen at 1st appointment offered: _____
 Final diagnosis: Malignant / Benign: (please underline)
 Comments about this form and/or additional copies, phone: _____ fax: _____

WINCHESTER AND EASTLEIGH HEALTHCARE NHS TRUST
Suspected Colorectal Cancer – Two Week Wait Cancer Access Referral
FAX THIS FORM IMMEDIATELY TO 01962 825169

Patients name: DOB: Sex: GP details:
Hospital no: Surgery:
Home address:
Daytime phone:
Date of decision to refer: Phone:

Rectal bleeding for more than 6 weeks
Yes / No

Change of bowel habit to loose or more frequent for 6 weeks
Yes / No

Right sided abdominal mass or rectal mass
Yes / No

Iron deficiency anaemia without obvious cause*
Hb= MCV=

Both symptoms present
Yes / No

Age > 50
Yes / No

Treat symptomatically and review. If symptom recurs on stopping treatment then refer to surgical/medical outpatients in the usual way

Rapid access to Colorectal service
YES

Relevant medical history and current medication:

Appointments will be made in strict order of receiving this form with Mr RJS Lane / Mr AJG Miles
* Fe def anaemia = Hb<10 g/dl in women, 11 g/dl in men and MCV<80 or ferritin<6

For office use only
Appropriate ☐ Inappropriate ☐

Southampton NHS
University Hospitals and Community Health Services NHS Trusts
Fax: (023) 8082 5586
Email: uscref@suht.swest.nhs.uk
If you experience any problem sending this information, please telephone:
Tel: (023) 8082 5587

URGENT SUSPECTED COLORECTAL CANCER REFERRAL FORM

Name: Address: Tel no. Home: Work: Date of referral:

Sex: Date of birth: Hospital number: NHS number:

Registered GP Name: Surgery address: Tel no: Fax: e mail: Referring GP name (if different):

*If your preferred consultant is not available, this referral will be passed on to another member of the team in order to fulfil the two-week wait obligation

Barium Enema:
Done ☐ Normal ☐
Not done ☐ Abnormal ☐ Report enclosed ☐

Abdominal or Rectal mass:
Abdominal mass ☐ Position: _____
Rectal mass ☐

Rectal bleeding/Perianal symptoms:
Rectal bleeding and persistent change in bowel habit for at least six weeks ☐ Bright / Dark

Aged over sixty-five years
Rectal bleeding persistently with no perianal symptoms, with no evidence of benign disease ☐ Bright / Dark

Iron deficiency anaemia
No obvious cause and Hb<10g/dl in patients aged over forty years ☐

Dear Doctor:

For Hospital use only:
Surgical clinic ☐
Medical clinic ☐

The information contained in this facsimile is intended for the named recipients only
It may contain privileged and confidential information and if you are not an intended recipient you must not copy or distribute it. If you have received this facsimile in error, please notify us immediately by telephone on (023) 8082 5587
Version 5. 01/10/00

Appendix A

SURVEILLANCE AND SCREENING GUIDELINES AGREED BETWEEN WINCHESTER & SOUTHAMPTON COLORECTAL UNITS.

<i>Screening of asymptomatic relatives by family history</i>								
Disease	Lifetime Risk	Genetic Testing	Colon- oscopy	Flexi- sig	OGD	Age at initial screening	Surveillance colonoscopy	Surveillance flexi-sig
FAP/Gardners family 1 or more relatives affected	1 in 2	YES	No	YES	No	Puberty	5 yearly	Annual
Attenuated FAP family	1 in 2	YES	YES	No	YES	At diagnosis of relative	3 yearly	No
HNPCC family								
Colon Cancer in 3 or more relatives affecting 2 or more generations and 1 age <50	1 in 3	YES	YES	No	No	25 years	2 yearly	No
Colon Cancer in at least 2 relatives with 1 age <50 plus cancer of endometrium, urothelium, ovary, stomach* or pancreas in a 3 rd relative	1 in 3	YES	YES	No	No* *YES if gastric Ca in family	25 years	2 yearly	No
2 relatives colorectal cancer age less than 50 age 50 to 60 age greater than 60	1 in 3 1 in 10 <1 in 10	YES No No	YES YES No	No No No	No No No	5 years less than index case 5 years less than index case No screening	3 yearly 5 yearly No	No No No
1 relative colorectal cancer age less than 45 age greater than 45	1 in 10 <1 in 10					5 years less than index case No screening	5 yearly	No No
PLEASE NOTE: "relative" means first degree relative only (parent, sibling or child)								
Guidelines produced by collaboration between Winchester and Southampton Colorectal Units August 2000								

<i>Surveillance of patients after diagnosis</i>					
Disease	Lifetime risk	Interval to first investigation	OGD	Colonoscopy	Flexi-sig
FAP/HNPCC	100%	At diagnosis	5 yearly	2 yearly (until colectomy)	annual for IRA
Colorectal Cancer	5% at 5 years	Pre-operative		3-5 yearly	No
Adenomatous polyps					
1 or 2 polyps less than 1cm size	unknown	No surveillance		No	No
More than 2 polyps or 1 polyp greater than 1cm	unknown	3 years after removal repeated until 'clean colon'		5 yearly	No
Inflammatory Bowel Disease					
Total colitis	1 in 10	8 years of macroscopic pan-colitis		2 yearly	No
Limited proctocolitis	Unknown	15 years of macroscopic left sided colitis		No	5 yearly
Primary sclerosing cholangitis		At diagnosis of IBD		2 yearly (¹ early if also to or transplant)	No
Uretero-sigmoidostomy		10 years after surgery		No	3 yearly
Acromegaly		At diagnosis		3 yearly	No

STUDY INCLUSION & EXCLUSION CRITERIA

Patient ID No. **Inclusion / Exclusion Criteria for the Direct investigation of Colorectal Outpatients.****INCLUSION**

(tick one)

- ☐ *Change of Bowel habit*-..... change in frequency or consistency.
- ☐ *Rectal Bleeding*-..... blood either on or mixed with stool.
Patients over 65 with rectal bleeding and no perianal symptoms should have been fast tracked.
- ☐ *"Haemorrhoids"*-..... in combination with blood mixed with stool &/or change of bowel habit.
- ☐ *Change BH & Rectal Bleeding*
Patients with rectal bleeding & persistent change of bowel habit should have been fast tracked.

EXCLUSION

(cross all)

- ☐ *Age 45< or >90-*
- ☐ *Multiple co-morbidities*-..... may require discussion
- ☐ *Abdominal pain-*
- ☐ *Abdominal/Rectal mass-*
Patients with an abdominal/rectal mass should have been fast tracked.
- ☐ *"Exit Bleeding"*-..... fresh blood on paper only.
- ☐ *Perianal Symptoms*-..... pain, pruritis, soiling.

The "Fast Track" criteria referred to are those currently employed by Southampton University Hospitals & New forest Primary Healthcare Trusts. "Fast track" criteria are subject to change and differ between centres; for this reason there is overlap between the above inclusion/exclusion criteria and the "fast track" criteria.

LREC No.145/01

ETHICAL APPROVAL

SOUTHAMPTON & SOUTH WEST HANTS LOCAL RESEARCH ETHICS COMMITTEE

Chairman: Dr Audrey Kermode

Administrator: Mrs Clair Wright
Trust Management Offices
Mailpoint 18
Southampton General Hospital
Tremona Road
Southampton
SO16 6YD

Ref: CPW/DBL

Tel: (023) 8079 4912
Fax: (023) 8079 8678

15 June 2001

Mr Chris Newman
Surgical Research Fellow
Lymington Hospital
Southampton Road
Lymington SO41 9ZH

Dear Mr Newman

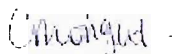
Submission No:145/01 – Randomised controlled trial to evaluate a direct referral service for investigation of patients with low risk symptom clusters suggestive of colorectal cancer, as against usual care.

Following the conditional approval and in response to your letter dated 12th June 2001, I am pleased to confirm full approval having received the amended Patient Information Sheet.

This approval was granted under Chairman's action by Mrs Clair Wright, and will be recorded by the Committee at their meeting in June.

This committee is fully compliant with the International Committee on Harmonisation/Good Clinical Practice (ICH) Guidelines for the Conduct of Trials involving the participation of human subjects as they relate to the responsibilities, composition, function, operations and records of an independent Ethics Committee/Independent Review Board. To this end it undertakes to adhere as far as is consistent with its Constitution, to the relevant clauses of the ICH Harmonised Tripartite Guideline for Good Clinical Practice, adopted by the Commission of the European Union on 17 January 1997.

Yours sincerely,



Mrs Clair Wright
Research Ethics Manager

New Forest
Primary Care Trust

Lymington Hospital
Southampton Road
Lymington
Hampshire
SO41 9ZH

Direct Investigation of Colorectal outpatients.

Tel: 01590 677011
Fax: 01590 671787

Study Title - Randomised controlled trial to evaluate a direct referral service for investigation of patients with low risk symptom clusters suggestive of Colorectal cancer, as against usual care.

Dear Doctor,

From October 2001 we will be evaluating three ways in which we can manage new routine colorectal referrals received at Lymington Hospital.

1. *Direct Investigation by Colonoscopy.*
2. *Direct Investigation by Flexible Sigmoidoscopy & Barium Enema.*
3. *Usual Care* (i.e. an outpatients appointment in the first instance, followed by investigation).

All three methods are accepted as safe, and are used to varying degrees throughout the NHS; there has however never been a valid comparison between the three in terms of acceptability to both patient and physician, and "best" use of resources. In order to compare these methods of patient management consenting patients will be entered into a randomised control trial.

Introduction

It is accepted across the west that around 25 patients with lower gastrointestinal symptoms will need to be investigated in order to find one with significant disease. Patients with certain combinations of symptoms and signs require full colonic investigation. We aim to investigate such patients directly on receipt of a referral letter (in accordance with a pre-defined protocol), as opposed to initiating investigations once patients have waited for and then attended an outpatient appointment.

Once the results of investigations are known those patients with a condition requiring treatment will continue their care from the outpatients department. Patients with either no pathology or pathology for which treatment is optional will be written to explaining this and offering them an outpatient appointment if they wish to discuss matters further, or they can refer back to their GP.

There has never been a formal evaluation of "Direct Investigation" as compared to traditional outpatient centred management of bowel symptoms. Although similar strategies have been employed at various centres the overall acceptability in terms of impact on delays, cost, and patient satisfaction has not been assessed. It is for this reason that consenting patients will be

randomised to one of the three investigative groups as part of a randomised controlled trial (to which ethical approval has been given).

It is hoped that this strategy of "Direct Investigation" will speed up the diagnostic process and reduce clinic waiting times for patients with significant problems. We anticipate a reduction in the time taken to diagnosis and subsequent management. We also expect a reduction in the number of visits a patient has to make to the Hospital to achieve this.

Most benefit will result from bypassing the first outpatient attendance in cases where the required investigation is clear from the referral letter. Patients mainly seeking reassurance that there is not a sinister cause for their symptoms may pass through the outpatient service without requiring an out patient appointment. It is important to stress that all patients will be offered an outpatient appointment.

Methods

New referrals to Lymington Surgical outpatients will be assessed for eligibility for inclusion by applying a set of criteria to information provided in the referral letter (agreed with the surgical consultant responsible for the patients). Non-eligible patients will be sent an outpatient appointment as part of usual care. Those eligible will be sent a patient information leaflet (attached) followed up by a telephone call. Patients consenting to participate in the study will be randomised to one of the three investigation groups.

No effort will be made to expedite any of these investigations beyond what is clinically indicated, they will be requested of and conducted by existing services. We will record the number and timings of hospital attendances. Once test results are known and the patient informed of diagnosis, discharged with reassurance, or told further investigations are needed we will circulate a postal patient satisfaction questionnaire.

What do you have to do?

This study should not affect your normal practice. A knowledge that this study is in place will be your main contribution to the study above your normal role in patient care, though it is possible that some patients may ask you about the study while deciding whether or not to participate. Referrals should continue to be made in the same manner and for the same symptoms as previously, research staff at Lymington will apply the eligibility criteria. As decisions are made purely on the detail provided in the referral letter the more information with which we are provided the better, particularly co-morbidities (we do not wish to send patients for unsuitable investigations).

Contact for further information-

Mr Chris Newman, Surgical Research Fellow
Available via Lymington Hospital switchboard- 01590 677011

Thank you for your time and help with this study

PATIENT DETAIL RECORD

Source

Consultant

No.

PATIENT DETAILS

NAME-

ADDRESS-

DATE OF BIRTH

TELEPHONE NO.

HOSPITAL NO.

GENERAL PRACTITIONER

PRACTICE

ADDRESS-

TELEPHONE NO.

Lymington Hospital
Southampton Road
Lymington
Hampshire
SO41 9ZJ

Tel: 01590 677011
Fax: 01590 671787

Direct Investigation of Colorectal outpatients.

You are being invited to take part in a research study. Before you decide whether or not to accept it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with friends, relatives and your GP if you wish. Ask us if there is anything that is not clear or if you would like more information. A member of the research team will telephone you to discuss any questions you may have (this will happen around one week after you receive this letter). Take time to decide whether or not you wish to take part.

Consumers for Ethics in Research (CERES) publish a leaflet entitled 'Medical Research and You'. This leaflet gives more information about medical research and looks at some questions you may want to ask. A copy may be obtained from CERES, PO Box 1365, London N16 0BW

Thank you for reading this.

What is the purpose of this study?

Hundreds of patients are seen in the Lymington surgical outpatient clinic every year having been referred by their General Practitioner. Many of these patients have symptoms that can be attributed to the large bowel, and some of them will need full investigation of the large bowel before we can be sure of the cause.

Some General Practitioners referral letters contain enough information about a patient and their symptoms for us to be certain that the patient needs full bowel investigation even before they are seen in clinic. We want to test a new way of arranging investigations for these patients.

When a GPs letter makes it obvious that the patient they are referring needs their large bowel fully investigated the patient will be offered these tests first, rather than waiting for a clinic appointment and then waiting for the test. We hope this will reduce the time taken to get from referral to test results, as well as reducing the number of times a patient needs to visit hospital.

Patients will not be sent for tests that are not needed. Patients going directly for tests will not get priority over other patients; they will simply have their tests requested earlier.

Why have I been chosen?

Your doctor (GP) has asked the surgeons at Lymington to see you because of some bowel symptoms. The information they provided in the referral letter leads us to believe you are one of a large number of patients who need their large bowel fully investigating before we can say what the cause of the symptoms might be. There are around 600 people referred to Lymington alone every year in a similar situation.

Do I have to take part?

It is up to you to decide whether or not to take part. If you decide to take part you will be asked to keep this information sheet for your reference and will be asked to sign a consent form (you will be given a copy). If you decide to take part you are still free to withdraw at any time and without giving a reason. This will not influence the standard of care you receive.

What will happen to me if I take part?

The research will run for 1 year, and if it is successful may continue as the normal way of running the outpatient clinic – you will only be involved for as long as it takes to investigate your symptoms.

Instead of being sent an outpatient appointment you will be randomly sent either-

1. **A Colonoscopy appointment-** This is a test where a doctor looks at the lining of the entire large bowel by passing a floppy telescope through the tail end. It involves a restricted diet for 2-3 days, and some special medicine on the day before the test to cause diarrhoea and clear the bowel. The doctor often gives an injection to make the patient drowsy during the test.
2. **A Flexible Sigmoidoscopy appointment & a Barium Enema appointment-** These are two separate tests, it is sometimes possible to conduct both at a single visit.
 - o A flexible sigmoidoscopy is another telescope test; this time the doctor only looks at the last bit of the bowel with a short floppy telescope. It involves a special medicine the day before the test to cause diarrhoea and clear out the last bit of bowel. Rarely an injection is given to make the patient drowsy.
 - o A Barium Enema is a special X-ray. Some special dye is introduced into the bowel by a soft tube passed into the tail end, followed by some air. The patient is then tipped on a table to move the dye around, and X-rays are taken. It does involve a restricted diet for upto 2-3 days, and some special medicine on the day before the test to cause diarrhoea and clear the bowel.
3. **An Outpatients appointment-** The patient is seen by the doctor in clinic, a history taken, and examination made. The doctors then requests any test that might be needed. In the case of people with your symptoms this will almost certainly be one of the two options above. This is an important group to which the above two must be compared in order to identify any benefits

You will be sent much more detailed information (as do all patients) once we know which test(s) you are going to have

What happens next depends on the result of the tests.

- If we find nothing wrong, or a condition which for which treatment is not required unless the patient wants it (such as treatment of piles) we will send you a letter explaining what was found and if there are possible treatments; we will also offer you an outpatient appointment to answer any questions or discuss treatments. You will not have to come to hospital to receive a normal test result.
- If we find anything that requires treatment or further investigation we will send you an outpatient appointment to discuss it.

Once you have been told the diagnosis, of the need to do more tests, or that the tests are normal we will ask you to complete a questionnaire that we will post to you. Your treatment will continue regardless of your answers, or if you choose not to complete the questionnaire.

What is a Randomised Trial?

Sometimes, because we do not know which way of organising a patients tests is best, we need to make comparisons. People are put into groups and then compared. The groups are selected by a computer that has no information about the individual (i.e. by chance). Patients in each group then have their tests organised in different ways and the results are compared.

What do I have to do?

Agreeing to take part and the completion of the questionnaire are the only differences to you between this research and the normal way of investigating patients. You will have to attend hospital and take the appropriate medicines for any tests, but no more so than if we were not involved with this research.

What is being tested?

We are trying to identify the best way to organise tests for hospital outpatients. The main aim is to reduce delays in reaching diagnosis as much as possible.

What are the alternatives?

The alternative is to attend an outpatient clinic. The patient is seen by the doctor, a history taken, and examination made. The doctors then requests any test that might be needed. Once the tests have been done and the results returned to the doctor they may write to you or send you a further appointment to discuss results.

Are there possible disadvantages and risks of taking part?

The possible disadvantage of this research is that a very small number of patients may be sent for tests (based on information in their doctor's letter) that would not be sent for tests if they were seen and examined by a surgeon in clinic. The information we use to select patients has been chosen in a way that should keep the chance of this happening very low. Decisions about tests cannot be right 100% of the time, either in studies or clinics.

The tests we use to investigate the bowel do have risks, as do all tests. The risk of complications for both groups of tests are roughly the same. Complications are seen in 1/10,000 tests, and very rarely even death can result (2/100,000 test).

What are the possible benefits of taking part?

We hope to prove that by sending appropriate patients directly for tests rather than attending a clinic first we will either be able to give them a diagnosis, or reassure them with a normal test result both quicker, and with less visits to hospital. We may be wrong, or may find that it is at the expense of patient satisfaction.

One third of patients entering the study will be managed the way all patients are managed at the moment, and as such may benefit very little on a personal level. They are no less important than the other two groups as without recording their experiences it would not be possible to detect any improvements.

What if new information becomes available?

There is ongoing research into which groups of people should have their bowel symptoms examined, and in what way. This study uses the best advice we have at present. It is unlikely that any results will become available and change normal practice during the running of this study. Should new information become available that suggests the study may not be the best course of action it will be discussed with the patient.

What happens when the research study stops?

We hope that if results are favourable that this system will become normal practice at Lymington. We will be surprised to see no benefits but if this where to occur the system would return to how it is at the moment; with all patients waiting for a clinic appointment before any tests are requested.

What if something goes wrong?

If you are unfortunate enough to experience a complication of the investigations then there are measures in place to treat you and minimise any damage done. All tests are used routinely within the day-to-day running of the hospital.

If you are harmed while taking part in this research project, there are no special compensation arrangements. If you are harmed due to someone's negligence, then you may have grounds for a legal action but you may have to pay for it. Regardless of

this, if you wish to complain about any aspect of the way you have been approached or treated during the course of this study, the normal National Health Service complaints mechanisms will be available to you.

Will my taking part in this study be kept confidential?

All information that is collected about you during the course of the research will be kept strictly confidential. Any information about you that leaves the hospital will have your name and address removed so that you cannot be recognised from it.

What will happen to the results of the research?

The results will be presented at medical conferences, and published in medical journals. If we can present a strong argument either in favour of or against this method of organising tests we may influence the way they are organised in other hospitals across the country.

Who is organising and funding the research?

This study is being organised by Mr. Smallwood (Consultant Surgeon) and Mr Newman (Surgical Research Fellow) with assistance from the Departments of Surgery and Public Health at the University of Southampton.
The study is funded by a grant from the South East Research and Development responsive grants scheme.

Who has reviewed the study?

This study has been reviewed and approved by The Southampton and Southwest Hampshire Local Research Ethics Committee.

Contact for further information-

Mr Chris Newman, Surgical Research Fellow

Available via Lymington Hospital switchboard- 01590 677011

Thank you for taking part in this Study.

LETTER SENT TO PATIENTS WITH WHOM THE RESEARCHER FAILED
TO MAKE CONTACT AFTER BEING SENT THE PATIENT INFORMATION
SHEET.

New Forest 
Primary Care Trust

Lymington Hospital
Southampton Road
Lymington
Hampshire
SO41 9ZH

Tel: 01590 677011
Fax: 01590 671787

Dear *To be personalised*,

You recently received a letter asking you to take part in a research program being conducted at Lymington Hospital following referral by your doctor.

Unfortunately I have been unable to make contact with you and as I do not wish to delay your appointment I will ensure your referral is dealt with in the normal way, not as part of any research.

I apologise for any confusion this may have caused.

Yours sincerely

Mr C Newman
Research Fellow to Mr Smallwood

STUDY CONSENT FORM.

New Forest 
Primary Care Trust

Patient Identification Number :

Lymington Hospital
Southampton Road
Lymington
Hampshire
SO41 9ZH

Tel: 01590 677011
Fax: 01590 671787

CONSENT FORM

Title of Project: Direct Investigation of Colorectal Outpatients.

Name of Researcher: Mr Christopher Newman
(Surgical Research Fellow to Mr Smallwood)

Please initial box

1. I confirm that I have read and understand the information sheet dated.....(version.....) for the above study and that I have had the opportunity to ask questions. ☐
2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected. ☐
3. I understand that sections of any of my medical notes may be looked at by responsible individuals from Lymington Hospital & the University of Southampton or from regulatory authorities where it is relevant to my taking part in research. I give permission for these individuals to have access to my records. ☐
4. I agree to take part in the above study. ☐

Name of Patient Date Signature

Name of Person Date Signature (if different from researcher)
taking consent

Researcher Date Signature

1 for patient, 1 for researcher, 1 to be kept with hospital notes

Patient ID No.

New Forest 
Primary Care Trust

Lymington Hospital
Southampton Road
Lymington
Hampshire
SO41 9ZH

Tel: 01590 677011
Fax: 01590 671787

DIRECT INVESTIGATION STUDY
PATIENT QUESTIONNAIRE

Please answer all questions. Questions are answered by circling a number to the right of each statement to indicate how much you agree or disagree with it.

For example-

	STRONGLY AGREE	AGREE	NO OPINION	DISAGREE	STRONGLY DISAGREE
☐ I prefer dogs to cats.	1	2	3	4	5

A space is provided at the end of the questionnaire for any comments you wish to make (either about questions or your hospital care). Please return this questionnaire in the stamped addressed envelope provided.

	STRONGLY AGREE	AGREE	NO OPINION	DISAGREE	STRONGLY DISAGREE
1. Firm decisions/plans were made at my appointment(s).	1	2	3	4	5
2. Discussions with the staff were open and honest.	1	2	3	4	5
3. I trust the doctor(s) I was seen by.	1	2	3	4	5
4. Hospital staff were friendly and polite.	1	2	3	4	5
5. I was involved with any choices which needed to be made about my care.	1	2	3	4	5
6. The doctors/nurses were interested in my problem and how to deal with it.	1	2	3	4	5
7. I found the process confusing.	1	2	3	4	5
8. I knew roughly when results would be available.	1	2	3	4	5
9. I was aware of what 'the plan' was, and so nothing came as a surprise.	1	2	3	4	5

	STRONGLY AGREE	AGREE	NO OPINION	DISAGREE	STRONGLY DISAGREE
10. What the test(s) would involve was accurately explained to me.	1	2	3	4	5
11. The reception staff were efficient.	1	2	3	4	5
12. At times my appointment(s) seemed rushed, not enough time was available.	1	2	3	4	5
13. I believe the doctor I saw was experienced in dealing with my kind of problem.	1	2	3	4	5
14. The doctor(s) seemed to think I was over reacting.	1	2	3	4	5
15. I felt my care was limited by budgets.	1	2	3	4	5
16. The wait for an appointment was short.	1	2	3	4	5
17. I was given the right amount of information for me.	1	2	3	4	5
18. The doctor seemed confident and sure of what they were doing.	1	2	3	4	5
19. Informing me of my test results did not seem to be a priority.	1	2	3	4	5
20. I felt like I was on a production line.	1	2	3	4	5
21. The standard of care I received matched what I had expected.	1	2	3	4	5
22. I would prefer a further opinion about my symptoms.	1	2	3	4	5
23. I was treated as an individual, not just another patient.	1	2	3	4	5
24. The staff explained my symptoms and the tests to me.	1	2	3	4	5
25. The doctor(s) listened to what I had to say.	1	2	3	4	5
26. I was given an adequate amount of information.	1	2	3	4	5
27. The staff I saw worked as a team.	1	2	3	4	5
28. I got what I wanted from my referral.	1	2	3	4	5
29. I felt comfortable asking the doctors questions.	1	2	3	4	5
30. Possible outcomes of my tests were explained.	1	2	3	4	5
31. I suspect information was held back from me.	1	2	3	4	5
32. The way the staff treated me helped me to relax.	1	2	3	4	5
33. I feel I was treated as my problem demanded, receiving neither too many nor too few tests.	1	2	3	4	5
34. The doctor(s) used too much jargon.	1	2	3	4	5
35. I was treated in a professional manner.	1	2	3	4	5

		STRONGLY AGREE	AGREE	NO OPINION	DISAGREE	STRONGLY DISAGREE
36	I believe I was given the same treatment as any other patient with my symptoms; my age/other medical conditions having no effect.	1	2	3	4	5
37	I was quickly informed when my appointment would be	1	2	3	4	5
38	The doctors/nurses knew what was planned and all worked towards that.	1	2	3	4	5
39	The doctors were able to give me a satisfactory diagnosis.	1	2	3	4	5
40	I feel there were questions left unanswered.	1	2	3	4	5
41	Explanations were made in terms I could understand.	1	2	3	4	5
42	I was able to discuss possible causes of my symptoms, and prognosis with the doctor.	1	2	3	4	5
43	I was left to dwell on my problem while waiting for appointments.	1	2	3	4	5
44	Explanations were clear and honest, making it easy to understand what was happening.	1	2	3	4	5
45	I had confidence in the doctors' abilities.	1	2	3	4	5
46	My appointment/tests were organised promptly.	1	2	3	4	5
47	I was kept waiting for my results/diagnosis.	1	2	3	4	5
48	My feelings and dignity were cared for.	1	2	3	4	5
49	The doctors were able to choose the best course of action.	1	2	3	4	5
50	My symptoms and concerns were taken seriously.	1	2	3	4	5
51	The timing of my appointment(s) was as convenient as could be expected.	1	2	3	4	5
52	I was able to ask about everything I was unsure about.	1	2	3	4	5
53	Things progressed too quickly for me.	1	2	3	4	5
54	I had to find things out for myself.	1	2	3	4	5
55	Staff were too busy/distracted to give me the attention I expected.	1	2	3	4	5
56	I have been preoccupied by thoughts about my hospital tests.	1	2	3	4	5
57	The way the doctor treated me made me feel better about things.	1	2	3	4	5
58	Waiting areas had sufficient seating and facilities.	1	2	3	4	5
59	I have not been reassured by the results of my tests.	1	2	3	4	5

		STRONGLY AGREE	AGREE	NO OPINION	DISAGREE	STRONGLY DISAGREE
60	Making/changing appointments was simple.	1	2	3	4	5
61	I was told several different conflicting things.	1	2	3	4	5
62	Waiting areas were comfortable and helped me to relax.	1	2	3	4	5
63	My life was "on pause" while waiting for my appointment.	1	2	3	4	5
64	Enough time was available for me when I attended appointments.	1	2	3	4	5
65	I am satisfied with the amount of information I received.	1	2	3	4	5
66	I didn't know what was happening or what would happen next a lot of the time.	1	2	3	4	5
67	I felt as though I was being fitted in at the hospitals convenience, rather than arrangements being made for me.	1	2	3	4	5
68	Overall I have been satisfied with the way in which I have been treated.	1	2	3	4	5
69	I am happy with the way in which I was informed of test results.	1	2	3	4	5
70	Possible diagnoses were discussed before the tests.	1	2	3	4	5
71	The possible causes of my symptoms worried me.	1	2	3	4	5
72	There were sufficient trained staff available.	1	2	3	4	5
73	I was informed of test results promptly.	1	2	3	4	5
74	I was told why tests were necessary.	1	2	3	4	5
75	The doctor(s) knew what was best for me and how to deal with things.	1	2	3	4	5
76	I feel I was given acceptable priority for my problem.	1	2	3	4	5
77	I found the need for tests worrying.	1	2	3	4	5
78	Parking at the hospital was a problem.	1	2	3	4	5
79	Tests were fully explained before hand so I knew what to expect.	1	2	3	4	5
80	The information I was given allowed me to prepare for what was to be done.	1	2	3	4	5
81	The medical staff were prepared and knew what I was there for.	1	2	3	4	5
82	The staff seemed more interested in the notes than in me.	1	2	3	4	5

QUESTIONNAIRE COVER LETTER

New Forest 
Primary Care Trust

Lymington Hospital
Southampton Road
Lymington
Hampshire
SO41 9ZH

Tel: 01590 677011
Fax: 01590 671787

Dear (TO BE PERSONALISED)

The attached questionnaire is the final part of the research study you kindly agreed to take part in when your GP referred you to the hospital for investigation of your bowel. You may already have finished your test(s), or be waiting for further tests or appointments, but it is important for us to find out what you are thinking now. Please complete the questionnaire now rather than waiting until you have had any more tests or appointments.

Please take time to read the questions and answer them as honestly as possible – once returned your answers will be anonymous, the number at the top of the questionnaire is only there so we know who has returned a questionnaire and who has not.

Your opinions form a very important part of this research; try to answer all of the questions. A space is provided at the end of the questionnaire if you have any comments you wish to make (either about the questions or your care at the hospital).

A stamped addressed envelope is included for the return of the questionnaire.

Thank you again for participating in this study.

Mr Chris Newman
Surgical Research Fellow

QUESTIONNAIRE SECOND MAILING COVER LETTER

New Forest 

Primary Care Trust

Lymington Hospital
Southampton Road
Lymington
Hampshire
SO41 9ZH

Tel: 01590 677011

Fax: 01590 671787

This is a second copy of the questionnaire as our records show we have sent one previously around 3 weeks ago but it has not been returned. It may have been lost on the way to you, on its way back to us, or you may not have had the chance to complete it. If you have recently returned the questionnaire please ignore this letter.

Dear (TO BE PERSONALISED)

The attached questionnaire is the final part of the research study you kindly agreed to take part in when your GP referred you to the hospital for investigation of your bowel. You may already have finished your test(s), or be waiting for further tests or appointments, but it is important for us to find out what you are thinking now. Please complete the questionnaire now rather than waiting until you have had any more tests or appointments.

Please take time to read the questions and answer them as honestly as possible – once returned your answers will be anonymous, the number at the top of the questionnaire is only there so we know who has returned a questionnaire and who has not.

Your opinions form a very important part of this research; try to answer all of the questions. A space is provided at the end of the questionnaire if you have any comments you wish to make (either about the questions or your care at the hospital).

A stamped addressed envelope is included for the return of the questionnaire.

Thank you again for participating in this study.

Mr Chris Newman
Surgical Research Fellow

TEST RE-TEST QUESTIONNAIRE COVER LETTER

New Forest 
Primary Care Trust

Lymington Hospital
Southampton Road
Lymington
Hampshire
SO41 9ZH

Tel: 01590 677011
Fax: 01590 671787

Dear (TO BE PERSONALISED)

A number of weeks ago you kindly completed a questionnaire connected to your recent bowel investigations. This was an early version of a questionnaire in development. We are writing to a number of patients a second time, as part of the new questionnaires development it is necessary to test its reliability over time.

The enclosed questionnaire is identical to the one you have already completed. I would be grateful if you could complete this questionnaire in accordance with your opinions now, please do not try to remember how you answered previously.

This is an important part of this research and will be the last time you are contacted concerning it.

A stamped addressed envelope is included for the return of the questionnaire.

Many thanks

Mr Chris Newman
Surgical Research Fellow

SAMPLE TOPICS USED BY FACILITATOR IN SMALL GROUP INTERVIEWS

Focus Group – Possible Issues

THEMES:

- Information
- Communication
- Involvement

- a) Access
- b) Administration
- c) Clinical
- d) Interpersonal
- e) Continuity

PATIENT PRIORITIES

1. Symptoms taken seriously
2. Patient felt listened to
3. See Doctor who is alert to symptoms
4. To feel in control
5. Feel that everything is well planned
6. To be treated politely and with compassion
7. Open discussion of issues
8. Confidence/faith in staff
9. Increased information availability
10. Felt reassured
11. Sufficient time/chances to ask questions

**SUMMARY OF FACE VALUE INTERNAL SCALES CONTAINED WITHIN
THE PATIENT SATISFACTION QUESTIONNAIRE.**

1. Anxiety/Effect on the Individual.

- 43 I was left to dwell on my problem while waiting for appointments.
53 Things progressed too quickly for me.
56 I have been preoccupied by thoughts about my hospital visits.
63 My life was "on pause" while waiting for my appointment.
71 The possible causes of my symptoms worried me.
77 I found the need for tests worrying.

2. Appointment Logistics.

- 12 At times my appointment(s) seemed rushed, not enough time was available.
51 The timing of my appointment(s) was as convenient as could be expected.
60 Making/changing appointments was simple.
64 Enough time was available for me when I attended appointments.
83 All my attendances at hospital were necessary and worth while.
85 There was a lot of waiting around at the time of appointments.

3. Timing/Waiting.

- 16 The wait for an appointment was short.
37 I was quickly informed when my appointment would be.
48 My appointment/tests were organised promptly.
47 I was kept waiting for my results/diagnosis.
73 I was informed of test results promptly.

4. Facilities/Staffing.

- 55 Staff were too busy/distracted to give me the attention I expected.
58 Waiting areas had sufficient seating and facilities.
62 Waiting areas were comfortable and helped me to relax.
72 There were sufficient trained staff available.
78 Parking at the hospital was a problem.

5. Interpersonal relations.

- 2 Discussions with the staff were open and honest.
4 Hospital staff were friendly and polite.
11 The reception staff were efficient.
29 I felt comfortable asking the doctors questions.
32 The way the staff treated me helped me to relax.
35 I was treated in a professional manner.
52 I was able to ask about everything I was unsure about.
65 The staff seemed more interested in the reason for my visit.
66 I did not like the doctor(s) I saw.
87 Some staff were arrogant/rude.

6. Information.

- 1 Firm decisions/plans were made at my appointment(s).
7 I found the process confusing.
9 I knew roughly when results would be available.
9 I was aware of what "the plan" was, and so nothing came as a surprise.
10 What the test(s) would involve was accurately explained to me.
17 I was given the right amount of information for me.
24 The staff explained my symptoms and the tests to me.
28 I was given adequate amount of information.
20 Possible outcomes of my tests were explained.
21 I suspected information was held back from me.
34 The doctor(s) saved too much jargon.
40 I feel there were questions left unanswered.
41 Explanations were made in terms I could understand.
44 Explanations were clear and honest, making it easy to understand what was happening.
54 I had to find things out for myself.
63 I am satisfied with the amount of information I received.
74 I was told why tests were necessary.
56 I didn't know what was happening or what would happen next a lot of the time.
60 I am happy with the way in which I was informed of test results.
70 Possible diagnoses were discussed before the tests.
75 Tests were fully explained before hand so I knew what to expect.
80 The information I was given allowed me to prepare for what was to be done.
84 I was given a thorough explanation of what the tests had shown and what this meant.

7. Confidence in care.

- 3 I trust the doctor(s) I was seen by.
8 The doctors/nurses were interested in my problem and how to deal with it.
13 I believe the doctor I saw was experienced in dealing with my kind of problem.
14 The doctor(s) seemed to think I was over reacting.
19 The doctor seemed confident and sure of what they were doing.
22 I would prefer a further opinion about my symptoms.
27 The staff I saw worked as a team.
38 The doctors/nurses knew what was planned and all worked towards that.
49 I had confidence in the doctors' abilities.
58 The way the doctor treated me made me feel better about things.
68 I have not been reassured by the results of my tests.
60 I was told several different conflicting things.
74 The doctor(s) knew what was best for me and how to deal with things.
81 The medical staff were prepared and knew what I was there for.

8. Considered as an individual.

- 5 I was involved with any choices which needed to be made about my care.
19 Informing me of my test results did not seem to be a priority.
20 I felt like I was on a production line.
23 I was treated as an individual, not just another patient.
28 The doctor(s) listened to what I had to say.
42 I was able to discuss possible causes of my symptoms, and prognosis with the doctor.
47 My feelings and dignity were cared for.
46 My symptoms and concerns were taken seriously.
66 I felt as though I was being treated in at the hospital convenience, rather than arrangements being made for me.

9. Equality/Fairness.

- 15 I felt my care was limited by budgets.
33 I feel I was treated as my problem demanded, receiving neither too many nor too few tests.
36 I believe I was given the same treatment as any other patient with my symptoms; my age/other medical conditions having no effect.
46 The doctors were able to choose the best course of action.
75 I feel I was given acceptable priority for my problem.

10. Expectations.

- 21 The standard of care I received matched what I had expected.
28 I got what I wanted from my referral.
39 The doctors were able to give me a satisfactory diagnosis.
87 Overall I have been satisfied with the way in which I have been treated.

REFINED QUESTIONNAIRE DIMENSIONS

REFINED INTERNAL SCALES
(overall $\alpha=0.7944$)1 UNDERSTANDING OF EVENTS ($\alpha=0.7325$)

- 7 I found the process confusing.
 22 I would prefer a further opinion about my symptoms.
 34 The doctor(s) used too much jargon.
 53 Things progressed too quickly for me.
 66 I didn't know what was happening or what would happen next a lot of the time.

2 ANXIETY ($\alpha=0.6939$)

- 43 I was left to dwell on my problem while waiting for appointments.
 56 I have been preoccupied by thoughts about my hospital tests.
 59 I have not been reassured by the results of my tests.
 63 My life was "on pause" while waiting for my appointment.
 71 The possible causes of my symptoms worried me.
 77 I found the need for tests worrying.

3 PROFESSIONALISM ($\alpha=0.8155$)

- 3 I trust the doctor(s) I was seen by.
 4 Hospital staff were friendly and polite.
 21 The standard of care I received matched what I had expected.
 28 I got what I wanted from my referral.
 32 The way the staff treated me helped me to relax.
 35 I was treated in a professional manner.
 36 I believe I was given the same treatment as any other patient with my symptoms, my age/other medical conditions having no effect.
 48 My feelings and dignity were cared for.
 49 The doctors were able to choose the best course of action.
 68 Overall I have been satisfied with the way in which I have been treated.
 75 The doctor(s) knew what was best for me and how to deal with things.

4 CONFIDENCE / TRUST IN STAFF ($\alpha=0.8328$)

- 1 Firm decisions/plans were made at my appointment(s).
 2 Discussions with the staff were open and honest.
 13 I believe the doctor I saw was experienced in dealing with my kind of problem.
 18 The doctor seemed confident and sure of what they were doing.
 25 The doctor(s) listened to what I had to say.
 27 The staff I saw worked as a team.

- 38 The doctors/nurses knew what was planned and all worked towards that.
 45 I had confidence in the doctors' abilities.
 57 The way the doctor treated me made me feel better about things.
 81 The medical staff were prepared and knew what I was there for.

5 SUBSTANCE OF CONSULTATION ($\alpha=0.7706$)

- 6 The doctors/nurses were interested in my problem and how to deal with it.
 17 I was given the right amount of information for me.
 23 I was treated as an individual, not just another patient.
 26 I was given an adequate amount of information.
 33 I feel I was treated as my problem demanded, receiving neither too many nor too few tests.
 50 My symptoms and concerns were taken seriously.
 64 Enough time was available for me when I attended appointments.
 65 I am satisfied with the amount of information I received.
 76 I feel I was given acceptable priority for my problem.

6 MECHANICS ($\alpha=0.7521$)

- 11 The reception staff were efficient.
 16 The wait for an appointment was short.
 37 I was quickly informed when my appointment would be.
 46 My appointment/tests were organised promptly.
 58 Waiting areas had sufficient seating and facilities.
 60 Making/changing appointments was simple.
 62 Waiting areas were comfortable and helped me to relax.
 72 There were sufficient trained staff available.

7 RESULTS ($\alpha=0.8101$)

- 8 I knew roughly when results would be available.
 39 The doctors were able to give me a satisfactory diagnosis.
 69 I am happy with the way in which I was informed of test results.
 73 I was informed of test results promptly.
 84 I was given a thorough explanation of what the tests had shown and what this meant.

8 DISCLOSURE ($\alpha=0.7533$)

- 31 I suspect information was held back from me.
 40 I feel there were questions left unanswered.
 54 I had to find things out for myself.
 61 I was told several different conflicting things.

9 PREPARATION ($\alpha=0.7576$)

- 10 What the test(s) would involve was accurately explained to me.
- 24 The staff explained my symptoms and the tests to me.
- 30 Possible outcomes of my tests were explained.
- 42 I was able to discuss possible causes of my symptoms, and prognosis with the doctor.
- 70 Possible diagnoses were discussed before the tests.
- 74 I was told why tests were necessary.
- 79 Tests were fully explained before hand so I knew what to expect.
- 80 The information I was given allowed me to prepare for what was to be done.

10 INVOLVEMENT/CONTROL ($\alpha=0.7992$)

- 5 I was involved with any choices which needed to be made about my care.
- 9 I was aware of what "the plan" was, and so nothing came as a surprise.
- 29 I felt comfortable asking the doctors questions.
- 41 Explanations were made in terms I could understand.
- 44 Explanations were clear and honest, making it easy to understand what was happening.
- 51 The timing of my appointment(s) was as convenient as could be expected.
- 52 I was able to ask about everything I was unsure about.
- 83 All my attendances at hospital were necessary and worthwhile.

11 TAKEN SERIOUSLY ($\alpha=0.7575$)

- 12 At times my appointment(s) seemed rushed, not enough time was available.
- 14 The doctor(s) seemed to think I was over reacting.
- 19 Informing me of my test results did not seem to be a priority.
- 20 I felt like I was on a production line.
- 47 I was kept waiting for my results/diagnosis.
- 55 Staff were too busy/distracted to give me the attention I expected.
- 67 I felt as though I was being fitted in at the hospitals convenience, rather than arrangements being made for me.
- 82 The staff seemed more interested in the notes than in me.
- 85 There was a lot of waiting around at the time of appointments.
- 86 I did not like the doctor(s) I saw.
- 87 Some staff were arrogant/rude.

SPARES

- 15 I felt my care was limited by budgets.
- 78 Parking at the hospital was a problem.

STANDARD INFORMATION SENT OUT TO PATIENTS UNDERGOING A BARIUM ENEMA EXAMINATION AT LYMINGTON HOSPITAL

Please Note

If you are diabetic: please telephone the X-ray Department for advice on medication when you receive your appointment. It may be necessary to change your appointment time.

Please telephone the X-ray department if you are unable to keep your appointment or have any queries about any medication you are taking.

Ladies, if there is any possibility that you may be pregnant please telephone before attending for your examination.

X-ray Department direct line:
01590 646251

Southampton Community Health Services **NHS**
NHS Trust

Having a Barium Enema

Southampton Community Health Services **NHS**
NHS Trust

ref K4142Y4M
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Southampton Community Health Services NHS Trust
November 2000

Lymington Hospital,
Southampton Road
Lymington, SO41 9ZH
Telephone 01590 677011

What is a Barium Enema?

It is an X-ray examination of the large bowel. Barium (a liquid that shows up on X-ray) is introduced into your back passage. This coats the wall of the bowel and a series of X-rays are then taken.

Is there any preparation before the examination?

It is important that your bowel is as empty as possible for the procedure to be successful. You will be sent an appointment and instructions about diet. Also a very strong laxative which will give you diarrhoea. It is important that you follow the instructions, especially the need to drink, to avoid becoming dehydrated. If, after you have received your instructions, you have any queries please ring the X-ray department.

Further Information

The laxative may make the skin around the back passage sore. Vaseline or Zinc and Castor oil cream may be helpful.

What happens when I arrive in the X-Ray Department?

Please report to the receptionist. If any personal details on your appointment letter are incorrect please inform the receptionist. You will be asked to take a seat in the waiting room. A member of staff will show you to a cubicle. You will be asked to undress and put on a white gown and dressing gown. Please bring your own dressing gown if you prefer. A basket is provided for your clothes. You should keep this with you. Please sit in the waiting room until you are called for your examination.

What is the procedure?

A tube is gently inserted into your back passage so that barium can be introduced. This coats the wall of the bowel and is drained off before some air is puffed in. The X-rays are then taken. You will be asked to lie in several different positions. You may experience some colicky pains. An injection may be given into a vein in your arm to help you relax your bowel. This may cause a temporary

blurring of your vision, usually for about half an hour. (If you have glaucoma please inform the staff before the procedure.)

How long does it take?

You should be ready to go home after about an hour. This varies from one person to another.

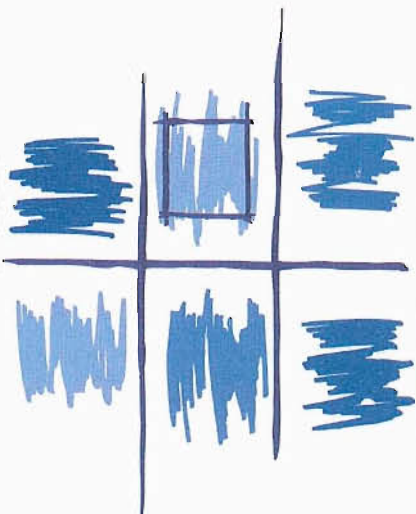
When will I know the results?

The results will be sent to your GP or Consultant within a week. When you receive your appointment for the examination please ring to make an appointment with your GP if you were referred by him/her or outpatient clinic if you have been referred by hospital consultant.

Are there any after effects?

Colicky pains which may be relieved by going to the toilet. Trapped air can usually be relieved by walking around and visiting the toilet again. It may take a day or two for your normal bowel habit to return. You are advised to drink plenty of fluids (at least three pints in 24 hours) to help clear the barium.

Having a Colonoscopy



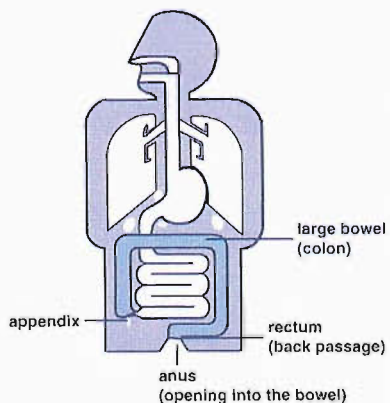
a guide to the test

You have been advised to have a colonoscopy to help find the cause of your symptoms. This leaflet has been prepared from talking to patients who have had the test. It may not answer all your questions so if you have any worries please don't hesitate to ask. The staff who are doing the test will be available to answer any queries. Not every hospital does things in exactly the same way.

What is a Colonoscopy?

Colonoscopy is a test which allows the doctor to look directly at the lining of the large bowel (the colon). In order to do the test a colonoscope is carefully passed through the anus into the large bowel. The colonoscope is a long flexible tube, about the thickness of your index finger, with a bright light at the end. Looking down the tube, the doctor gets a clear view of the lining of the bowel and can check whether or not any disease is present. Sometimes the doctor takes a biopsy - a sample of the lining for examination in the laboratory. A small piece of tissue is removed painlessly through the colonoscope, using tiny forceps.

It is also possible to remove polyps during the colonoscopy. Polyps are abnormal projections of tissue, rather like warts, which the doctor will want to examine in more detail.



What should you expect?

The preparation: To allow a clear view, the colon must be completely empty of waste material. If it is not, certain areas may be obscured and the test may have to be repeated. The hospital will give you detailed instructions about clearing the colon. It is important to take all of the laxative prescribed and also considerably increase your intake of clear fluids on the day before the examination, which will help clean the bowel.

When you come to the department, a doctor will explain the test to you and will usually ask you to sign a consent form. This is to ensure that you understand the test and its implications. Please tell the doctor or nurse if you have had any allergies or bad reactions to drugs or other tests. They will also want to know about any previous endoscopy you may have had, or of any other medical conditions which you suffer from and any medication which you may be taking. If you have any worries or questions at this stage don't be afraid to ask. The staff will want you to be as relaxed as possible for the test and will not mind answering your queries.

You will be asked to take off your trousers or skirt and to put on a hospital gown. You may also be asked to remove any jewellery or metal objects in case a special piece of equipment, called a diathermy unit, is used.

During the test: In the examination room you will be made comfortable on a couch, resting on your left side, with your knees slightly bent. A nurse will stay with you throughout the test. The doctor may give you a sedative injection to make you sleepy and relaxed. The nurse will probably attach a small device to your finger or thumb, in order to record your pulse rate and monitor your general condition during the examination. When the tube has been gently inserted through the anus into the large bowel, air will be passed through it to distend the colon to give a clearer view of the lining. This may give you some wind-like pains but they will not last long. You may feel the sensation of wanting to go to the toilet, but as the bowel is empty, there is no danger of this happening. You may pass some wind but, although this is embarrassing, remember the staff do understand what is causing it. It usually takes up to thirty minutes for the colon to be examined, but the test sometimes lasts longer. X-ray equipment may also be used. When the examination is finished, the tube is removed quickly and easily.

After the test

You will be left to rest in the unit for at least thirty minutes. You may feel a little bloated with wind pains but these usually settle quite quickly.

Going Home

If you are going home after the test it is essential that someone comes to pick you up. Once home, it is important to rest quietly for the remainder of the day. Sedation lasts longer than you think, so you should not:

- drive a car
- operate machinery
- drink alcohol

The effects of the test and injection should have worn off by the next day when most patients are able to resume normal activities.

When do I know the result?

In many cases the doctor will be able to tell you the results of the test as soon as you are awake. However, if a sample (biopsy) has been taken or polyps have been removed for examination, the results may take several days.

It is a good idea to have someone with you when you speak to the doctor after the test. Because of the sedation, many people find they forget everything that has been said to them. Details of the results and any necessary treatment should be discussed with your general practitioner or hospital specialist - whoever recommended you to have the test.

Written by Alison Hadley, formerly of the Middlesex Hospital, in collaboration with the Department of Gastroenterology at the Middlesex Hospital, and revised by Mr. Roger J. Leicester, OBE, Consultant Colorectal Surgeon, St. George's Healthcare N.H.S. Trust, London.

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**COLONOSCOPY
INFORMATION FOR PATIENTS**

WHAT IS A COLONOSCOPY?

A colonoscopy is a procedure which allows the Doctor to look down a long flexible tube at the lining of the large bowel, to establish if disease is present.

WHY IS IT BEING PERFORMED?

Colonoscopies are performed for the following reasons:-

To find the cause of bleeding from the bowel.

To find the cause of an altered bowel habit.

As a check if bowel disease runs in the family.

To check for causes of anaemia.

By looking directly at the bowel lining inflammation, tumours and polyps can be diagnosed and treated.

If the colonoscopy is not performed there is a risk that certain types of disease will grow beyond the point at which they can be properly dealt with, if not found early enough.

WHAT TO EXPECT

To allow a clear view, the colon must be completely empty of waste material. It is therefore important that the dietary advice is followed and the bowel preparation is taken as directed.

On admission to the Day Case Unit a nurse will take your details, your questions will be answered and the procedure explained to you.

The Doctor will see you and your consent obtained for the procedure. You will be given a sedative and a pain killer prior to the procedure. The nurse will stay with you throughout the colonoscopy.

When the colonoscope has been inserted into the large bowel, air will be passed through to distend the bowel for a clearer view. This may cause wind like pains but they should not last long.

It can take up to 30 minutes to examine the bowel but can sometimes take

BOWEL PREPARATION INSTRUCTIONS

To allow a clear view, the colon (larger bowel) must be completely empty of waste materials. If not, the test may have to be repeated. To avoid this, please follow the instructions carefully.

4 DAYS BEFORE COLONOSCOPY

Please stop any iron tablets, but continue with all other medications.

2 DAYS BEFORE COLONOSCOPY

Follow the low residue diet sheet.

DAY BEFORE COLONOSCOPY

Follow the diet sheet in the morning.

At 2pm take the first sachet of Pico lax. You can either dissolve the sachet into a pint of liquid and then drink, OR dissolve into a glass of water, and then drink a pint of liquid over about an hour. We do advise you to stay at home from now on.

DO NOT EAT AFTER 2PM, BUT DRINK AS MUCH AS YOU WISH FROM THE FLUIDS ALLOWED LIST

At 5pm take the second sachet. You should expect loose, frequent bowel actions. Some bowel cramping is normal.

FLUIDS ALLOWED

Black tea/coffee, lemon, sugar, glucose, honey allowed
Strained fruit juices or squash
Still, carbonated tonic water, Lucozade or lemonade
Sieved soup or consommé, weak stock cubes, Marmite, Bovril
Jelly without fruit
Alcohol may be drunk in moderation

PLEASE DO NOT TAKE ANY MILKY DRINKS

DAY OF COLONOSCOPY

Take the final sachet before 7am.

You may drink a small amount of clear fluids after this.

If at any stage you vomit the preparation, please contact the Day Case Unit for advice. You may take your usual medication unless for diabetes.

REMEMBER, YOU WILL BE GIVEN A STRONG SEDATIVE, DO NOT DRINK ALCOHOL, DRIVE, SIGN ANY IMPORTANT DOCUMENTS OR OPERATE MACHINERY FOR 48 HOURS AFTERWARDS

longer. Small pieces of the bowels lining maybe taken for analysis in the laboratory, this is called a biopsy.

Should a polyp be found it maybe possible to remove it.

POSSIBLE RISKS / COMPLICATIONS.

There maybe some pain or swelling of the abdomen after the procedure. This should settle after a few hours.

Bleeding may occur if a polyp is removed.

Very rarely the bowel maybe perforated or punctured.

WHAT HAPPENS AFTER THE PROCEDURE?

It will be possible to leave hospital a few hours after the procedure. The Doctor performing the colonoscopy will explain any findings and if any other appointment is necessary.

On discharge from the Unit you will be advised the following:-

Not to drive self home.

Not to operate any machinery e.g lawnmowers.

Not to sign any important documents.

Not to drink any alcohol.

When you get home, please rest, eat a light meal and have an early night.

You may feel a little uncomfortable and have wind for a day afterwards.

IF YOU HAVE ANY STRONG STOMACH PAINS OR BLEEDING FROM THE BACK PASSAGE:-

PLEASE CONTACT YOUR DOCTOR IMMEDIATELY

If you are at all worried, please ring direct to the Day Case Unit between 9 am and 5 pm Monday to Friday. Tel: 01590 646255.

References:- Keymed (1996) - Having a Colonoscopy, a guide to the test.
PatientWise (1996) - Medical and Health Information for patients.

D.C Aug 1999

DIET SHEET

	CHOOSE	AVOID
Breads and Cereals	White bread cakes, biscuits made with white flour White rice and pasta Processed breakfast cereals such as Rice Krispies, cornflakes and special k	Wholemeal bread, rice and pasta, grains or speciality breads Biscuits made with brown flour or with fruit and nuts Breakfast cereals such as oatbran, branflakes, muesli, weatibix, unprocessed bran or any containing fruit or nuts.
Fruit and Veg	Potatoes boiled or mashed, (not jacket) pumpkin, marrow, squash beansprouts, celery cucumber, lettuce, tomato, mushrooms peaches watermelon	All other fruit and vegetables
Dairy Products	Plain yoghurt, skimmed milk, soya milk, cottage cheese, plain block cheese, plain block butter, margarine, vanilla ice-cream, plain custard	Cheeses with added ingredients Thick milk shakes with fruit, fruit yoghurts
Protein Foods	Lean white meat or fish, eggs	beans, lentils, red meat, mince, lasagne, bolognese, any meat dish with vegetable filler
Drinks	Tea, coffee, water, plain milk drinks, soft drinks, strained fruit juices, clear soup	Alcohol Unstrained fruit juice
Miscellaneous	Jellies, sugar, honey, marmite, popcorn	Pies, quiches, pastry foods, jarts, marmalades, chutneys, pickles, peanut butter, dried fruit and nuts, fruit cakes

SOUTHAMPTON HEALTH SERVICES NHS TRUST

LYMINGTON HOSPITAL
Southampton Road,
Lymington,
Hampshire SO41 9ZM
Telephone: 01590 677011
Fax: 01590 671787
Website: www.scts.org.uk

LYMINGTON HOSPITAL DAY CASE UNIT

WELCOME TO THE DAY CASE UNIT

We hope your stay with us will be as comfortable as possible. The staff on the Unit are there to help you and to answer any queries you may have. Please do not hesitate to telephone the Unit to discuss any problems or concerns you may have.

ABOUT THE UNIT

The Unit is a purpose built unit with specialist facilities, equipment and staff undertaking day case admissions for a variety of investigations and treatments.

COMING TO THE UNIT

Please bring with you the following:

- Your admission letter
- Dressing gown and slippers if worn
- Glasses for reading
- Medicines and tablets (these will be returned to you)

DO NOT bring any items of great value or large sums of money as refreshments are provided and the nursing staff can do any phone calls to relatives.

PREPERATION

Please follow carefully any instructions you have received. This will help to ensure your procedure is a success the first time. Do shower or bath the night before or in the morning.

WE LOOK FORWARD TO MEETING YOU

We would like to draw to your attention the fact that we are a mixed sex ward. However our toilet facilities are completely separate.

Adult & Community Hospital Services

Southampton Community Health Services NHS Trust

LYMINGTON HOSPITAL
Southampton Road,
Lymington,
Hampshire SO41 9ZM
Telephone: 01590 677011
Fax: 01590 671787
Website: www.scts.org.uk

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Adult & Community Hospital Services

STANDARD INFORMATION SENT OUT TO PATIENTS UNDERGOING A
FLEXIBLE SIGMOIDOSCOPY AT LYMINGTON HOSPITAL.

Southampton Community
Health Services
NHS Trust



Lymington Hospital
Southampton Road
Lymington
Hampshire SO41 9ZH
Telephone: 01590 677011
Fax: 01590 671787
Website: www.schx.org.uk

Dear.....

Your appointment for..... has been made.

Please attend the Day Case Unit on..... at.....

Please follow the attached instructions carefully.

Please would you let us know if you are unable to keep the agreed appointment as soon as you are aware by telephoning the Day Unit on 01590-646255. This will mean we are able to re-allocate your operation slot, if we are given enough time.

Please let us know if there are any changes in your details or circumstances, i.e. Change of address.

Yours sincerely

Day Case Unit staff.



Adult & Community
Hospital Services

Southampton Community
Health Services
NHS Trust



Lymington Hospital
Southampton Road
Lymington
Hampshire SO41 9ZH
Telephone: 01590 677011
Fax: 01590 671787
Website: www.schx.org.uk

LYMINGTON HOSPITAL DAY CASE UNIT

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ABOUT THE UNIT

The Unit is a purpose built unit with specialist facilities, equipment and staff undertaking day case admissions for a variety of investigations and treatments.

COMING TO THE UNIT

Please bring with you the following: Your admission letter
Dressing gown and slippers if worn
Glasses for reading
Medicines and tablets (these will be returned to you)

DO NOT bring any items of great value or large sums of money as refreshments are provided and the nursing staff can do any phone calls to relatives.

PREPERATION

Please follow carefully any instructions you have received. This will help to ensure your procedure is a success the first time. Do shower or bath the night before or in the morning.

WE LOOK FORWARD TO MEETING YOU

We would like to draw to your attention the fact that we are a mixed sex ward. However our toilet facilities are completely separate.



Adult & Community
Hospital Services

BOWEL PREPARATION INSTRUCTIONS SIGMOIDOSCOPY

To allow a clear view, the sigmoid colon must be completely empty of waste materials. If not, the test may have to be repeated. To avoid this, please follow the instructions carefully.

4 DAYS BEFORE SIGMOIDOSCOPY

Please stop any iron tablets, but continue with all other medications.

2 DAYS BEFORE SIGMOIDOSCOPY

Follow the low residue diet sheet.

DAY BEFORE SIGMOIDOSCOPY

Follow the diet sheet in the morning.

At 5pm take the sachet of PicoLax. You can either dissolve the sachet into a pint of liquid and then drink, OR dissolve into a glass of water, and then drink a pint of liquid over about an hour. We do advise you to stay at home from now on.

DO NOT EAT AFTER 2PM, BUT DRINK AS MUCH AS YOU WISH FROM THE FLUIDS ALLOWED LIST

You should expect some loose, frequent bowel motions. Some bowel cramping is normal.

FLUIDS ALLOWED

Black tea/ coffee, lemon, sugar, glucose, honey allowed.
Strained fruit juices or squash
Still, carbonated tonic water, lucozade or lemonade
Sieved soup or consommé, weak stock cubes, Marmite, Bovril
Jelly without fruit
Alcohol may be drunk in moderation
PLEASE DO NOT TAKE ANY MILKY DRINKS

DAY OF SIGMOIDOSCOPY

You may drink of clear fluids ONLY

DIET SHEET

	CHOOSE	AVOID
Breads and Cereals	White bread cakes, biscuits made with white flour White rice and pasta Processed breakfast cereals such as Rice Krispies, cornflakes and special k	Wholemeal bread, rice and pasta, grains or speciality breads Biscuits made with brown flour or with fruit and nuts Breakfast cereals such as oatbran, branflakes, muesli, weetabix, unprocessed bran or any containing fruit or nuts
Fruit and Veg	Potatoes boiled or mashed, (not jacket) pumpkin, marrow, squash beansprouts, celery cucumber, lettuce, tomato, mushrooms peaches watermelon	All other fruit and vegetables
Dairy Products	Plain yoghurt, skimmed milk, soya milk, cottage cheese, plain block cheese butter, margarine, vanilla ice-cream, plain custard	Cheeses with added ingredients Thick milk shakes with fruit, fruit yoghurts
Protein Foods	Lean white meat or fish, eggs	beans, lentils, red meat, mince, lasagne, bolognese, any meat dish with vegetable filler
Drinks	Tea, coffee, water, plain milk drinks, soft drinks, strained fruit juices, clear soup	Alcohol Unstrained fruit juice
Miscellaneous	Jellies, sugar, honey, marmite, popcorn	Pies, quiches, pastry foods, jams, marmalades, chutneys, pickle, peanut butter, dried fruit and nuts, fruit cakes

JAG GUIDELINES FOR TRAINING IN COLONOSCOPY.

TRAINING IN COLONOSCOPY

As with OGD, in-service training is most important.

FACILITIES

1. The training unit should undertake at least 400 procedures a year.
2. Rotations should enable trainees to enhance their experience in units performing **more than** twice this number of procedures.

ENDOSCOPIC EXPERIENCE

Diagnostic

1. Most trainees in colonoscopy should have acquired basic endoscopic skills, usually by prior training in upper GI Endoscopy or Flexible Sigmoidoscopy. For trainees in Coloproctology, attendance at a JAG compliant Basic Skills Foundation or Flexible Sigmoidoscopy course to learn the background to safe endoscopy would be an alternative starting point.
2. Trainees should understand appropriate techniques of patient preparation, the mechanics of the procedure and its indications, limitations and the complications.
3. Each trainee should be able to perform at least 100 procedures within the course of a year and will be considered to have achieved a satisfactory level of competence when able to reach the caecum where indicated. It is expected that the caecal intubation rate should exceed 90% in those patients without stricturing or marked faecal contamination.
4. Trainees should also be able to demonstrate that they can intubate the ileum in at least 50% of procedures where indicated. Current data suggests that many trainees will need to perform more than 200 examinations to meet this criterion.

Therapeutic

5. Trainees should be competent in the techniques of hot biopsy, polypectomy, and treatment of colonic bleeding.
6. Trainees should be familiar with balloon dilatation of strictures and techniques to stop bleeding and treat angiodysplastic lesions.
7. Some trainees may wish to gain a higher degree of training in the more advanced techniques of dye spraying, tattooing, endoscopic mucosal resection and tumour debulking and stenting.

COURSES

1. Trainees should attend a Basic Skills in Colonoscopy course initiated by or compliant with JAG standards (JAG compliant course).
2. Trainees wishing to undertake more advanced techniques should attend an advanced colonoscopy course approved by JAG.

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