

Stepped treatment of older adults on laxatives. The STOOL trial

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and J Bond



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The research reported in this issue of the journal was commissioned by the HTA Programme as project number 98/32/99. The contractual start date was in October 2002. The draft report began editorial review in October 2006 and was accepted for publication in September 2007. As the funder, by devising a commissioning brief, the HTA Programme specified the research question and study design. The authors have been wholly responsible for all data collection, analysis and interpretation, and for writing up their work. The HTA editors and publisher have tried to ensure the accuracy of the authors' report and would like to thank the referees for their constructive comments on the draft document. However, they do not accept liability for damages or losses arising from material published in this report.

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Abstract

Stepped treatment of older adults on laxatives. The STOOL trial

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Objectives: To investigate the clinical effectiveness and cost-effectiveness of bulk-forming, stimulant and osmotic laxatives, and also of adding a second type of laxative agent in the treatment of patients whose constipation is not resolved by a single agent. Additionally, to define the meaning of constipation in older people from the perspective of GPs and older patients, and to investigate the use of prescribed and non-prescribed treatments for constipation in older people together with their adherence to prescribed treatments.

Design: A multicentre pragmatic, factorial randomised controlled trial with economic evaluation and qualitative study using in-depth interviews and focus groups with older people, GPs and community nurses.

Setting: General practices in north-east England.

Participants: People aged 55 years or over with chronic constipation living in private households.

Interventions: Six stepped-treatment strategies using three classes of laxatives: bulk, stimulant and osmotic preparations, singly and in combination.

Main outcome measures: The primary outcome was the constipation-specific Patient Assessment of Constipation – Symptoms/Patient Assessment of Constipation – Quality of Life. Secondary outcomes included EuroQoL 5 Dimensions, reported number of bowel movements per week, the presence/absence of the other Rome II criteria for constipation, adverse effects of treatment and relapse rates.

Results: Recruitment to the trial was difficult and the trial was closed after recruiting 19 participants. GP participants provided patient-centred definitions that focused on the idea of a change from the norm as

defined by the individual patient and ‘textbook definitions’ that focused on reduced frequency of defecation associated with a range of unpleasant sensations and other clinical symptoms. Nurses’ definitions of constipation included both a patient-centred perspective and the description of particular symptoms associated with constipation. Older participants defined constipation in terms of frequency of bowel movements and changes in normal bowel routine. Older participants perceived constipation as follows: linked to specific diseases, medical conditions or health problems; caused by the consumption of specific medications or surgical procedures; caused by diet or eating habits; part of the ageing process; due to not going to the toilet when having the urge to defecate; hereditary; caused by stress or worry; and caused by environmental exposure. GP participants suggested that constipation is due to changes in diet and lifestyle; the physiology and degenerative processes of ageing; and the iatrogenic impact of opiate medications. Nurse participants identified that constipation is linked to decreased mobility, decreased food intake, decreased fluid intake and consumption of certain medications. For many older people their constipation emerged as a problem over a period of time; for some the ‘condition’ had existed for many years. Self-management of constipation had typically been their first response to the symptoms and continued once professional help had been sought. Older participants had a wide experience of different management strategies and treatments for constipation, and at the time of the study had firm preferences about the laxatives they would use.

GP participants recognised the experience and use of laxatives of their patients. They exhibited strong personal preferences for different laxatives, often prescribing them in combination. Nurses were more likely than GPs to treat and prevent constipation using non-laxative measures; these included providing advice on appropriate dietary changes, increasing fluid intake and, if possible, encouraging exercise and mobility.

Conclusions: There is little shared understanding between patients and professionals about 'normal' bowel function with little consensus in general practice of the optimum management strategies for chronic constipation and the most effective strategies to use. Chronic constipation is seen as less important than other

conditions prevalent in general practice (e.g. diabetes) because it is not an agreed management target within national frameworks. Consequently, practitioners had little interest in constipation as a research topic. Patient preferences and the absence of patient equipoise formed an enormous barrier to the recruitment of patients in the implementation of this trial. Studies are needed to investigate different methods of recruitment within the constraints of current ethical guidelines on 'opting in' and to identify barriers and facilitators to recruitment to complex trials in general. Patient preference trials and natural cohort observational studies are also needed to investigate the effectiveness or cost-effectiveness of different laxatives and treatment strategies in the management of chronic constipation.



Contents

List of abbreviations	vii	5 Understanding the meaning of constipation	29
Note	viii	Overview	29
Executive summary	ix	Older people's experience of constipation	29
I Background	1	Health professionals' views on constipation	34
Introduction	1	Summary	38
What is normal bowel function and what is constipation?	1	6 Perspectives on the causes of constipation	39
Formal definitions of constipation	1	Overview	39
Lay perceptions of bowel function and constipation	1	Health beliefs and the causes of constipation	39
Prevalence of constipation among older people	2	GPs' perspectives on the causes of constipation	46
Impact of constipation on quality of life	2	Nurses' perspectives on the causes of constipation	47
Management of constipation	2	Summary	48
Summary	3	7 How older people manage constipation ...	49
2 Trial design	5	Overview	49
Overview	5	Life-course perspectives on the management of chronic illness	49
Objectives	5	Seeking professional advice	52
Health technologies being assessed	5	Summary	56
Study participants	6	8 The management of constipation by GPs and nurses	59
Sampling design and implementation	6	Overview	59
Methods of data collection	9	GPs' perspectives on the management of constipation	59
Blinding of outcome assessment	11	Nurses' perspectives on the management of constipation	72
Development and piloting of data-collection instruments	11	Summary	75
Methods of data analysis	12	9 Conclusions	77
3 Implementation of the trial	13	Understanding constipation	77
Introduction	13	The need for evidence	77
Preparation and implementation of the trial protocol	13	Implementation of the STOOL trial	77
Regulatory approval	13	Interpretations from the qualitative study	78
MREC approval	13	Conclusions	81
Primary care trust R&D approvals and LREC site-specific assessments	16	Recommendations for future research	82
Recruitment of practices and practitioners	18	Acknowledgements	83
Patient recruitment	20	References	85
Closure of the trial	22	Appendix I Trial protocol	89
Summary and implications	22		
4 Design of the qualitative study	25		
Background to the qualitative study	25		
Study objectives	25		
Study design	25		
Method	26		
Participant characteristics	26		

Appendix 2 Protocol amendments	101	Appendix 8 Topic guide for older-people interviews (qualitative study)	125
Appendix 3 Full patient information leaflet	103	Appendix 9 Topic guide for GP interviews (qualitative study)	127
Appendix 4 Brief patient information leaflet	109	Appendix 10 Topic guide for nurse interviews (qualitative study)	133
Appendix 5 Proposed economic evaluation	115	Health Technology Assessment reports published to date	141
Appendix 6 Patient information leaflet (qualitative study)	117	Health Technology Assessment Programme	157
Appendix 7 Health-professional information leaflet (qualitative study)	119		



List of abbreviations

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BNF	British National Formulary	NoReN	Northern Primary Care Research Network
CHSR	Centre for Health Services Research	OTC	over-the-counter
CONSORT	Consolidated Standards of Reporting Trials	P	patient
COREC	Central Office of Research Ethics Committees	PAC-QOL	Patient Assessment of Constipation – Quality of Life
CRB	Criminal Records Bureau	PAC-SYM	Patient Assessment of Constipation – Symptoms
CTA	clinical trial authorisation	PCT	primary care trust
DDX	Doctors' and Dentists' Exemption	PEG	polyethylene glycol
DFD	discomfort-free day	PI	principal investigator
EQ-5D	EuroQoL 5 Dimensions	PMS	personal medical services
EU	European Union	PW	participant's wife
GMS	General Medical Services	QALY	quality-adjusted life-year
I	interviewer	R&D	research and development
IBS	irritable bowel syndrome	RCT	randomised controlled trial
LREC	local research ethics committee	SfS	Support for Science
MHRA	Medicines and Healthcare Products Regulatory Agency	SSA	site-specific assessment
MREC	multicentre research ethics committee	STOOL	Stepped Treatment of Older adults On Laxatives
N	nurse	WTE	whole-time equivalent

All abbreviations that have been used in this report are listed here unless the abbreviation is well known (e.g. NHS), or it has been used only once, or it is a non-standard abbreviation used only in figures/tables/appendices in which case the abbreviation is defined in the figure legend or at the end of the table.

Note

In 1998 the HTA Programme produced a commissioning brief (HTA 98/32Rev) for a trial on the use of laxatives as treatment for chronic constipation in older people. The brief was based on recommendations of an HTA-commissioned systematic review which had found little evidence of the clinical effectiveness or cost-effectiveness of different prescribed laxatives in managing chronic constipation among older people.

The review did not propose a simple head-to-head comparison of different types of laxatives, but rather proposed a trial design that compared different types of laxatives within a stepped-treatment management protocol. The research questions identified in the commissioning brief (HTA 98/32Rev) were: what is the comparative cost-effectiveness of different types of laxatives (e.g. bulk-forming versus stimulant versus osmotic laxatives) in the treatment of elderly patients? And what is the cost-effectiveness of a stepped approach to the management of chronic constipation in which a single agent is prescribed alone before a combination of agents is tried?

In response to the commissioning brief the research team designed a complex randomised controlled trial investigating the cost-effectiveness of the stepped treatment of older adults on laxatives (ISRCTN11557289) (Chapter 2). In the research proposal the authors expressed concern about the viability of the design and proposed a large pilot or feasibility study. In line with HTA Programme policy at the time the researchers were commissioned to implement the full trial, but the HTA Commissioning Board invited them to design a qualitative study alongside the trial to investigate the definition and meaning of constipation among older people and health professionals and to investigate the use of different treatments (both prescribed and over-the-counter or non-prescribed treatments) by older people with constipation (Chapter 4).

Preparation for the trial (the development of research instruments; the production of documents and protocols; applications for regulatory, ethics and research governance approval; and the recruitment of practices to participate in the trial) started in September 2002. Ethics and research governance issues, challenges in recruiting practices and the willingness of only a handful of patients to participate (Chapter 3) influenced the research team's decision, made in consultation with HTA Programme, to close the trial prematurely in July 2005.

This report is therefore somewhat different from standard HTA reports of primary research. The report describes the background to the study and considers new evidence of the clinical effectiveness and cost-effectiveness of laxatives that has emerged since the publication of the earlier systematic reviews. The design of the trial and strategies used in its implementation to optimise practice and patient participation are presented. The barriers to successful implementation are examined. The majority of the report that follows is given over to the qualitative study that investigated the meaning of constipation and the use of different laxative treatments by older people for their constipation.



Executive summary

Background

Constipation may often be regarded as a trivial medical problem, but for people with chronic constipation the impact on their quality of life is considerable and the burden on healthcare resources, in terms of medical care visits, gastrointestinal-related procedures, laboratory tests and medications, is substantial.

Objectives

Trial

The aims of the Stepped Treatment of Older adults on Laxatives (STOOL) trial were:

- to investigate the clinical effectiveness and cost-effectiveness of bulk-forming, stimulant and osmotic laxatives
- to investigate the clinical effectiveness and cost-effectiveness of adding a second type of laxative agent in the treatment of patients whose constipation is not resolved by a single agent.

Add-on qualitative study

The aims of this study were:

- to define the meaning of constipation in older people from the perspective of GPs and older patients
- to investigate the use of prescribed and non-prescribed treatments for constipation in older people
- to investigate the adherence by older people to prescribed treatments for constipation.

Methods

Trial

Design

A multicentre pragmatic, factorial randomised controlled trial with economic evaluation.

Health technologies being assessed

Six stepped-treatment strategies using three classes of laxatives: bulk, stimulant and osmotic preparations, singly and in combination.

Setting

General practices in north-east England.

Participants

People aged 55 years or over with chronic constipation living in private households. Participants were identified as patients who had been prescribed laxatives three or more times in the previous 12 months, or with a recorded diagnosis of chronic functional constipation, or who had been prescribed a laxative continuously for the previous 12 months.

Outcome measures

The primary outcome was the constipation-specific Patient Assessment of Constipation – Symptoms/Patient Assessment of Constipation – Quality of Life. Secondary outcomes included EuroQoL 5 Dimensions, reported number of bowel movements per week, the presence/absence of the other Rome II criteria for constipation, adverse effects of treatment and relapse rates.

Qualitative study

In-depth interviews with older patients (target populations as for the trial) and their GPs, and focus-group interviews with practice and community nurses were undertaken using a purposive maximum variation sampling strategy (older people: variation by age, gender, socio-economic status, experience of constipation and use of different constipation treatments; health professionals: variation by age, gender, professional training, specialist interest and characteristics of the practice).

Results

Trial

Recruitment to the trial was difficult and the trial was closed after recruiting 19 participants.

Qualitative study

GP participants provided patient-centred definitions that focused on the idea of a change from the norm as defined by the individual patient and 'textbook definitions' that focused on reduced frequency of defecation associated with a range of unpleasant sensations and other clinical

symptoms. Nurses' definitions of constipation included both a patient-centred perspective and the description of particular symptoms associated with constipation. Older participants defined constipation in terms of frequency of bowel movements and changes in normal bowel routine.

Older participants perceived that constipation is linked to specific diseases, medical conditions or health problems; caused by the consumption of specific medications or surgical procedures; caused by diet or eating habits; part of the ageing process; due to not going to the toilet when having the urge to defecate; hereditary; caused by stress or worry; and caused by environmental exposure. GP participants suggested that constipation is due to changes in diet and lifestyle; the physiology and degenerative processes of ageing; and the iatrogenic impact of opiate medications. Nurse participants identified that constipation is linked to decreased mobility, decreased food intake, decreased fluid intake and consumption of certain medications.

For many older people their constipation emerged as a problem over a period of time; for some the 'condition' had existed for many years. Self-management of constipation had typically been their first response to the symptoms and continued once professional help had been sought. Older participants had a wide experience of different management strategies and treatments for constipation, and at the time of the study had firm preferences about the laxatives they would use.

GP participants recognised the experience and use of laxatives of their patients. They exhibited strong personal preferences for different laxatives, often prescribing them in combination. Nurses were more likely than GPs to treat and prevent constipation using non-laxative measures; these included providing advice on appropriate dietary changes, increasing fluid intake and, if possible, encouraging exercise and mobility.

Conclusions

Constipation means different things to different people. There is little shared understanding between patients and professionals about 'normal' bowel function. There is little consensus in general practice regarding the optimum management

strategies for chronic constipation and there is continuing uncertainty about the most effective strategies to use.

Chronic constipation is seen as less important than other conditions prevalent in general practice (e.g. diabetes) because it is not an agreed management target within national frameworks. Consequently, practitioners had little interest in constipation as a research topic.

Patient preferences and the absence of patient equipoise formed an enormous barrier to the recruitment of patients in the implementation of the STOOL trial. The successful involvement of patients and professionals in health technology assessments requires obvious uncertainty about treatment and management options and a clear interest in the topic by all parties.

The implementation of the Human Rights Act in the post-Alder Hey Inquiry environment and the increased stringencies resulting from the enactment of the EU Clinical Trials Directive have increased the barriers to health services research more widely. The implementation of research governance and ethical review processes in response to this new research environment has not allowed an appropriate balance between the rights of the individual and the collective rights of society, and typically does not involve a risk-based approach. Ethical guidance that opting-out recruitment strategies were too coercive and that recruitment of all participants should use opting-in strategies is a considerable barrier to study recruitment.

Recommendations for further research

The following studies could be undertaken in the future:

- studies to investigate different methods of recruitment within the constraints of current ethical guidelines on 'opting in'
- studies to identify barriers and facilitators to recruitment to complex trials in general
- patient preference trials and natural cohort observational studies to investigate the effectiveness or cost-effectiveness of different laxatives and treatment strategies in the management of chronic constipation.

Chapter I

Background

Introduction

Constipation may often be regarded as a trivial medical problem,¹ but for people with chronic constipation the impact of the condition on their quality of life is considerable^{2,3} and the burden on healthcare resources, in terms of medical care visits, gastrointestinal-related procedures, laboratory tests and medications, is substantial.⁴ In England and Wales constipation generated some 450,000 GP consultations per year in 1991–1992⁵ at an estimated cost of £4.5 million per year.⁶ The net ingredient cost in 2005 of prescriptions for laxatives was approximately £50 million per year in England.⁷

What is normal bowel function and what is constipation?

In clinical practice, frequency of normal bowel function ranges from three times per day to three times per week.⁸ Stool consistency is associated with whole gut transit time and is therefore considered a useful indicator of normal bowel function or the presence of constipation.^{9–11} Yet in everyday life constipation means different things to different people.^{12,13} Within clinical practice it remains largely a subjective diagnosis.¹⁴

Formal definitions of constipation

There is no universally accepted definition of constipation in clinical practice, although the following working definition has been proposed:¹⁴ “straining at passing stools for more than 25% of bowel movements” (p. 8). Others have used the frequency of bowel movements (fewer than three times per week) as an operational definition of constipation in clinical and epidemiological research.^{15,16} According to the Rome II criteria for functional constipation,¹⁷ a diagnosis of constipation requires two or more of the following symptoms to be present for at least 12 weeks, which need not be consecutive, in the preceding 12 months:

- straining in more than one in four defecations
- lumpy or hard stools in more than one in four defecations

- sensation of incomplete evacuation in more than one in four defecations
- manual procedures (e.g. digital evacuation or support of the pelvic floor) in more than one in four defecations
- fewer than three defecations per week.

Perhaps not surprisingly, there appears to be little agreement between self-perceived constipation and assessments based on the Rome II criteria.¹¹ In North America a systematic review of studies of the epidemiology of constipation¹⁸ reported that the prevalence of self-reported constipation was consistently higher than that defined by the Rome II criteria.¹⁷ It is estimated that, in addition to the 63 million North Americans who meet the Rome II criteria, some 50 million North Americans reported that they have constipation. The authors of the review speculated that these differences reflect lay perceptions of normal bowel function, in particular the absence of a daily bowel movement being described as ‘constipation’.

Lay perceptions of bowel function and constipation

Frequency of bowel evacuation

Few studies have reported lay perceptions of constipation, but infrequency in bowel evacuation is an often used lay criterion. In an early clinical study of 287 hospital outpatients in London, almost half considered constipation in terms of bowel movement infrequency. Women were more likely than men to report infrequency, although men were more likely to consider infrequency as harmful. About one-quarter of patients believed in the benefit of purgation.¹⁹ Multivariate analysis of a recent Japanese population survey of bowel conditions found that frequency of bowel movements was of highest importance to older people.²⁰ Similarly, an Australian qualitative study of 90 older people reported that frequency of evacuation (not defecating for a number of days; mode three or more days) was the most often cited description of constipation by study participants.¹³

Other lay criteria of constipation

When describing constipation, lay people also place emphasis on other symptoms such as

abdominal pain, straining,²¹ bloating,²² lack of satisfactory defecation²³ and not being able to defecate when feeling the urge.¹³ Both the Japanese population survey and the Australian qualitative study cited above highlight the range of factors that people take into account when defining constipation; they also indicate that the importance afforded to different symptoms, or combinations thereof, varies from patient to patient.

Prevalence of constipation among older people

Given the variation in definitions and perceptions of constipation, both in clinical practice and among the general population, it is not surprising that there is little agreement on the prevalence of the condition. Estimates of the prevalence of constipation in the general population of the UK range from 2% to 51.5%.^{9,10,24-26} In North America estimates range from 1.9% to 27.2%.¹⁸ The wide range of estimates reported in these studies reflects the variation in criteria used by clinicians and the public to define constipation and the different methods of data collection used to assess different criteria of constipation. However, there is some consensus that constipation (however defined) is more prevalent among older people, as reflected in consultation rates in British general practice. Data from the UK national survey of morbidity data in general practice⁵ show that consultation rates per 10,000 person-years for constipation range from approximately 75 for 45–64-year-olds, through 200 in the age group 65–74 years and 400 in the age group 77–84 years, to 600 in the age group 85 years or over. Peticrew and colleagues¹ conclude that “on the basis of surveys in the UK and USA, possibly about one-fifth of older people living in the community have symptoms of constipation” (p. 3).

Impact of constipation on quality of life

Studies reporting the relationship between quality of life and constipation have shown that people with constipation generally have impaired quality of life compared with the general population. The number of studies, particularly of older people, is, however, limited.¹⁸ In a sample of older people in the USA, functional bowel disorders, including constipation, had a negative impact on well-being and led to impaired daily living.² In interviews

with frail older people living at home, constipation was spontaneously mentioned by 45% of participants and was considered by 11% to be a major problem adversely affecting their quality of life.¹⁶ A Canadian study that assessed health-related quality of life [using the Short-Form (SF)-36 and SF-12] found statistical associations between health-related quality of life and the presence of constipation, but the clinical significance of these associations was unclear.²⁷

Management of constipation

Proprietary laxatives are the most common treatments for chronic constipation. Three classes of laxatives are in common use in the UK for the treatment of constipation: bulk, stimulant and osmotic laxatives. As reported in the HTA systematic review, there is limited evidence of either the clinical effectiveness or cost-effectiveness of laxatives prescribed for older people or for different management strategies combining classes of laxatives.^{1,28} The review found that interpretation and extrapolation of findings from clinical trials of the treatment of constipation in older people was limited by the lack of generalisability of existing studies; in particular, study populations were predominantly from long-term care institutions – hospitals, residential and nursing homes – and were therefore likely to be frailer and less ambulant than older people living at home. Inadequate sample size and probable lack of statistical power further limited interpretation and generalisability.

Most of the laxative trials reported were of single active treatments compared with placebo. Most found non-significant trends in bowel movements per week and non-significant trends in stool consistency and pain. A trial of the use of a stimulant laxative²⁹ and another of the use of an osmotic laxative³⁰ found significant increases in the mean number of bowel movements. Few comparisons of different classes of laxative have been made. However, in two good-quality trials,³¹⁻³³ a combination of bulk plus stimulant laxative was found to be more effective in improving stool frequency and consistency than osmotic laxative alone. The review also highlighted the lack of good cost-effectiveness data: there was no evidence that the more expensive preparations were any more effective than less expensive preparations.

A recent American systematic review of the efficacy and safety of routinely used therapies for chronic

constipation³⁴ established that there was a paucity of high-quality trials for the commonly used laxatives. Many of the trials were based on small sample sizes and lacked the power to establish the efficacy of individual agents. The authors of the review reported that intertrial comparisons or pooling of results in meta-analyses were not feasible because of the wide variations in definitions of constipation and the outcomes being assessed. The review did find good (grade A) evidence to support the use of polyethylene glycol (PEG) and tegaserod; PEG was more effective than lactulose. It also found moderate (grade B) evidence to support the use of lactulose and psyllium. The review found a paucity of evidence regarding other commonly used laxatives such as milk of magnesia, senna, bisacodyl and stool softeners.

A further conclusion of the HTA systematic review^{1,28} was that there exists little evidence-based guidance on what constitutes effective management more generally of constipation in older people. The authors of the review suggested that laxatives may not be the appropriate treatment for all people with constipation. In particular, they expressed the view that changes (“improvement”) in overall diet may be sufficient to prevent and treat the condition. However, they point to the lack of good-quality evidence showing that dietary interventions are effective. Petticrew and colleagues¹ proposed a stepped approach to the management of constipation. They suggested, as an example of a stepped strategy, first considering changes in diet. If unsuccessful, dietary supplements could then be tried. If changing diet and including dietary supplements showed no improvement in bowel habits, then cost-effective laxative treatments could be prescribed.

Based on the findings of that review, in preparing the original brief for the evaluation of the management of constipation in older people, the advisory panel to the HTA Programme proposed an additional step in the treatment strategy. This involved prescribing a single class of laxative (e.g. bulk or stimulant) in the first instance. If a single class of laxative failed to resolve the constipation the prescription of a second laxative from a different class was proposed (e.g. bulk plus stimulant). Although such a management strategy makes clinical sense, there existed limited evidence of its clinical effectiveness or cost-effectiveness or of its feasibility in clinical practice. To improve the evidence base, HTA finally

commissioned two independent randomised controlled trials (RCTs):

- to compare the clinical effectiveness and cost-effectiveness of different classes of laxative within a stepped management strategy (the subject of this report)
- to compare the clinical effectiveness and cost-effectiveness of practice-based educational interventions to change the diets of older people who have constipation with traditional medical management using laxatives (LIFELAX – Diet and lifestyle vs laxatives in the management of chronic constipation in older people; ISRCTN7388134).

Summary

In reviewing the meaning of constipation in the medical literature it was found that, among health professionals, there is little consensus on a formal definition of constipation. Experts in gastrointestinal medicine have produced formal criteria and guidelines for the assessment and management of constipation (the Rome II criteria), but few practitioners appear to use them. Moreover, constipation is viewed as a subjective diagnosis. Among clinicians there is consensus that there exists a wide variation between individuals in the normal frequency of bowel movements, ranging from three times per day to three times per week. Lay perceptions of constipation, as reported by a small number of studies, differ from professional criteria although frequency of bowel movements is a key component of constipation for the majority of older people. A fundamental question therefore still remains: what exactly is constipation?

The treatment and management of constipation have been both lay and professional concerns. The few existing studies of the management of constipation highlight the lack of good evidence concerning the use of different treatments. The HTA systematic review found that the clinical effectiveness and cost-effectiveness of most laxative treatments and management strategies were unknown. A recent American systematic review of the efficacy of different therapies for constipation echoes the conclusions of the HTA review. Studies investigating the meaning of constipation and different treatment strategies and clinical trials to evaluate the clinical effectiveness and cost-effectiveness of treatments remain to be done.

Chapter 2

Trial design

Overview

The Stepped Treatment of Older adults On Laxatives (STOOL) trial was designed as a pragmatic,³⁵ factorial, multicentred RCT conducted in the north-east of England to investigate the clinical effectiveness and cost-effectiveness of different laxatives and management strategies of chronic constipation in older people. The outcomes for people aged 55 years or more, registered with study practices, experiencing constipation and using prescribed laxatives, were to be compared for different stepped-management strategies of three types of laxative (bulk forming, stimulant and osmotic laxatives). The original protocol commissioned by the HTA Programme is reproduced in Appendix 1.

Objectives

The primary objectives for the study were:

- to investigate the clinical effectiveness and cost-effectiveness of bulk-forming, stimulant and osmotic laxatives when used singly
- to investigate the clinical effectiveness and cost-effectiveness of adding a second type of laxative agent in the treatment of patients whose constipation is not resolved by a single agent.

In addition, a secondary objective for the study was:

- to describe the adherence by patients to treatment protocols and to estimate its impact on cost-effectiveness.

Health technologies being assessed

Stepped treatment of constipation

Study participants were randomised to one of six stepped-treatment strategies (*Table 1*). Those participants who were not satisfied with their treatment outcome during or after 6 weeks on treatment had a second class of laxative agent added at step 2.

In line with recommendations from the Rome II group³⁶ regarding the design and conduct of trials in functional gastrointestinal disorders, a washout period after randomisation but before initiation of the first step laxative was initially proposed for the STOOL trial. Patients would be withdrawn from their current laxative for a period sufficient (2 weeks) for the effects of that drug on their bowel function to be negated.

Pharmacological agents

This study focused on three classes of laxatives: bulk, stimulant and osmotic preparations. The bulk laxative included in the study was isphagula husk (e.g. Fybogel[®] or Regulan). The stimulant laxative was senna and the osmotic laxative was lactulose or PEG (e.g. Movicol[®]).

Within each class, the choice of actual preparation (e.g. between Fybogel and Regulan) was at the discretion of the individual practitioner. It was envisaged that this latitude would encourage greater compliance with the protocol, and would allow GPs to comply with the recommendations of any practice-level or local formularies. It also allowed patients who were already taking a laxative in the class to which they were

TABLE 1 Individual laxative treatment strategies

Strategy	Step 1	Step 2
1	Bulk laxative	Combination of bulk + stimulant laxative
2	Bulk laxative	Combination of bulk + osmotic laxative
3	Stimulant laxative	Combination of stimulant + bulk laxative
4	Stimulant laxative	Combination of stimulant + osmotic laxative
5	Osmotic laxative	Combination of osmotic + bulk laxative
6	Osmotic laxative	Combination of osmotic + stimulant laxative

randomised to continue with their recognised formulation. Dosage was also at the discretion of the prescribing GP; this was to mirror normal clinical practice, whereby patients commonly receive differing doses depending on their body mass, age and frailty. Since STOOL was a pragmatic trial, the range of doses used in normal clinical practice was allowed. These decisions regarding latitude with respect to the choice of preparation and dosage were informed by discussion with the clinical members of the team (RB, RC and GR).

Study participants

Target population

The target population for the study comprised people aged 55 years or over with chronic constipation living in private households. The choice of an age cut-off of people aged 55 or over was made after due consideration of the morbidity statistics from general practice,⁵ which indicated that GP consultation rates for constipation take off in the 45–64-year age group and rise steadily with age. The exclusion of residents in long-term care reflected the different morbidity and lifestyle experience of long-term care residents. The study focused on a predominantly ambulant population able to attend a primary care clinic independently.

Inclusion criteria

The complexity of the Rome II criteria for functional constipation¹⁷ militates against their use in screening for chronic constipation. Moreover, the Rome II guidance advises that new cases of constipation (the ‘incident’ cases) should receive extensive investigation to determine the underlying cause of the constipation and rule out more sinister causes, before a diagnosis of functional constipation is made and laxatives are prescribed.

As a result, only ‘prevalent’ cases were identified and recruited. Participants were identified from general practice computerised patient records using search facilities in the practice software systems (i.e. EMIS, Torex, etc.) to select patients who fulfilled one or more of the following criteria:

- had been prescribed laxatives three or more times in the previous 12 months
- had been prescribed a laxative continuously for the previous 12 months
- had a recorded diagnosis of chronic functional constipation.

Exclusion criteria

The following patients were excluded:

- patients resident in long-term care institutions
- patients with inflammatory bowel disease, intestinal obstruction/bowel strictures, known colonic carcinoma, multiple sclerosis, known autonomic neuropathy, or any conditions contraindicative to the prescription of any laxative preparations included in the stepped treatment protocol
- patients on morphine and other potent opiate analgesics (as these are known to predispose to constipation)
- those with an inability to complete outcome assessments, even with assistance (e.g. major cognitive impairment, lack of understanding of English).

Consent

Multicentre research ethics committee (MREC) favourable opinion was granted following a number of iterations. For each individual centre (primary care practice), a site-specific assessment (SSA) was obtained from the appropriate local research ethics committee (LREC).

Written informed consent was obtained for all participants recruited to the trial. A full patient information leaflet (version 2, 5 March 2003) (see Appendix 3) and a brief information leaflet (version 1, 1 November 2002) (see Appendix 4) were provided to patients and their carers. Both leaflets followed Central Office of Research Ethics Committees (COREC) guidelines and included details about the reason for the trial and its aims, what participants would have to do if they agreed to take part, potential disadvantages of participation, and information about withdrawal from the trial. Patients (and their carers) were given time to consider the trial fully and ask any questions about the implications of the trial.

Sampling design and implementation

Recruitment

General practices in northern England were invited by letter to participate. It was estimated that the study would need to recruit 22–25 average-sized practices. The aim was to include practices from existing research networks, such as the Northern Primary Care Research Network (NoReN), but owing to the low take-up (see Chapter 3) other practices were also approached.

Two methods of participant recruitment (incident and prevalent cases) were considered during the planning phase of the study. However, as outlined above, it was decided that only prevalent cases would be recruited. Experience in practice suggested that there would be a risk of slow recruitment of incident cases, owing to the small number of such cases presenting per year in any one practice. Moreover, as already noted, incident cases, at least initially, were expected to be subject to more intensive medical investigation for the cause of the constipation (in line with Rome II guidance), which would militate against their inclusion in the trial. Therefore, the focus was solely on prevalent cases, retrospectively identified through computerised records of laxative prescriptions, as described above. Patients were initially screened by practice staff to remove identifiable study exclusions. Eligible participants were then invited to attend a nurse-led research clinic (led by a practice nurse) to discuss entry into the study.

In the original protocol (see Appendix 1) the nurse-led clinics were to be staffed by dedicated research nurses. This was not possible in practice because of resistance from general practice owing to a lack of space and the impracticality of research nurses being able to cover multiple practices in which there were few available slots to hold research nurse-led clinics. Under research governance some practitioners perceived that the research nurses would be employed within practices and they were unprepared to take on this additional responsibility.

Following informed consent, a base line assessment was completed (mainly by the nurse) and patients were randomised via the Centre for Health Services Research (CHSR) web randomisation service or telephone/secure fax alternative. Only at this point were personal details of recruited patients released to the research team.

Randomisation

Simple participant randomisation into one of six treatment strategies was used. Following the end of each baseline assessment session, practices were asked to access the CHSR web randomisation service, or to contact a designated member of the randomisation service by telephone/secure fax, and were informed about the allocated step 1 laxative treatment. The relevant GP or prescribing nurse then issued a prescription which was handed to the study participant.

To avoid GPs pre-empting the second step in the treatment regimen, initially the practice was

informed only of whether the patient had been randomised to receive a bulk, a stimulant or an osmotic laxative. Practices were informed of the second step treatment strategy only following the 5-week follow-up assessment or after a medical decision that a second laxative was needed before the end of step 1. Patients in whom constipation remained unresolved at this point were randomised to one of two 'add-in' laxatives (*Table 1*), from a class other than their initial medication.

Sample size

The study was powered to detect an effect size (mean difference divided by standard deviation at baseline) of 0.5 on a continuous measure of condition-specific quality of life Patient Assessment of Constipation – Symptoms (PAC-SYM) and Quality of Life (PAC-QOL).³⁷ This represents a moderate effect in quality of life assessment.³⁸ Participants were randomised to one of six treatment strategies. To allow for multiple comparisons, the sample size calculation was based on a significance level of 2.5% (rather than the usual 5%) and a power of 90% (rather than the usual 80%). Using these assumptions, standard sample size calculations indicated the need to recruit and retain 100 participants in each arm of the study (which yielded a total of 600 participants). In step 1, participants were being randomised to one of three laxative classes. The intention was to pool data from pairs of strategies (e.g. strategies 1 and 2 in *Table 1*), and to conduct three pairwise comparisons, to determine the relative effectiveness of the three classes of laxatives when taken alone. The intention was to have increased power for these comparisons.

Attrition was estimated at 40% (including both refusal to randomisation and loss to follow-up post-randomisation), based on prior experience of participation and loss to follow-up rates in other trials of older people in primary care, particularly those about 'embarrassing' topics. This meant that the target number of patients to be recruited was 167 participants in each arm of the trial, a total of 1002 participants.

An average practice list size of 8000 patients was assumed, with approximately 2800 patients in each practice in the age range relevant to this study. Estimates based on the most conservative figures (2%) for the prevalence of constipation^{24-26,39} and on applying a simple search on prescribing data to the records of one of the study investigators (GR) suggested that 40–45 patients meeting study eligibility criteria were

likely to be identified in the average practice. This suggested that 22–25 practices needed to be recruited.

Minimising bias and improving compliance

The risk of recruitment bias (i.e. patients being unwilling to enter the trial because they may have to change their laxative treatment) was recognised. The minimisation of attrition post-randomisation was given high priority by the research team. The practice nurses were asked to reinforce the importance of both adherence to treatment and completion of questionnaires and diaries. Up to two written reminders were used for participants who failed to return postal questionnaires. Regular telephone contacts were also used to remind participants to complete and return questionnaires and structured diaries.

An intention-to-treat analysis was proposed. Concordance with or adherence to treatment is a perennial challenge in the majority of intervention studies and it was therefore important to be able to estimate the extent of non-adherence by participants. This issue was addressed by collecting data about laxative use habits (including non-prescribed treatment) as part of a structured diary and in follow-up questionnaires.

It was envisaged that the commitment of GPs and practice staff would be crucial to the success of the study. At the beginning of the trial, educational events were used to introduce the study, including the stepped treatment protocol, to health professionals (GPs and practice nurses) from the participating practices.

Baseline and outcome measurement

Participants were followed up for 6 months from the date of randomisation. Follow-up data were captured through a daily self-completed structured diary; and telephone interviews and self-completed postal questionnaires at the end of step 1 (5 weeks post-randomisation), at the end of step 2 (9 weeks post-randomisation) and at 6 months (Tables 2 and 3).

Quality of life and clinical outcomes

The primary outcome, and the criterion upon which the sample size calculations were based, was disease-specific quality of life. The chosen measure of quality of life was the constipation-specific PAC-SYM/PAC-QOL,³⁷ which has been demonstrated to have good validity and reliability. Permission to use this instrument was granted by the owners of the scale (Janssen Pharmaceuticals) with the proviso that anonymised patient data (i.e. responses to quality of life questionnaires) be

TABLE 2 Baseline and outcome measures

	Measurement method	When	Where
<i>Primary outcome</i>			
Disease-specific quality of life: PAC-SYM/PAC-QOL	Self-completed postal questionnaire	End of step 1, end of step 2 and 6-month reassessment	Participant's home
<i>Secondary outcomes</i>			
EQ-5D	Self-completed postal questionnaire	End of step 1, end of step 2 and 6-month reassessment	Participant's home
Number of bowel movements per week	Self-completed diary	Daily for 6 months	Participant's home
Other Rome II criteria: straining at defecation, stool consistency, perceived incomplete evacuation	Self-completed diary	Daily for 6 months	Participant's home
Adverse events: abdominal pain, nausea, bloating, flatulence, diarrhoea	Self-completed diary	Daily for 6 months	Participant's home
Relapse rates: including repeat consultations	Self-completed diary; GP records	Daily for 6 months (diary); end of 6-month follow-up period (GP records)	Participant's home (diary); general practices (GP records)
EQ-5D, EuroQol 5 Dimensions.			

TABLE 3 Measuring treatment impact

Impact	Measure	When	Where
Costs to participants of the condition and its management	Telephone interview	End of step 1, end of step 2 and 6 month reassessment	Participant's home
Consultation rates and laxative prescriptions	GP records	End of 6-month follow-up period	General practices
Adherence with drug treatment	Health diary; telephone interview	Using different methods, at end of step 1, end of step 2 and 6-month reassessment	Participant's home
Patient satisfaction	Postal questionnaire	End of step 1, end of step 2 and 6-month reassessment	Participant's home
Health-related quality of life, including utility-based assessment of health state	Postal questionnaire	End of step 1, end of step 2 and 6-month reassessment	Participant's home

submitted to them for the purposes of further refinement of their instruments and development of population norms. The condition-specific measure of quality of life was supplemented by the generic, utility-based EQ-5D^{40,41} (Table 2).

Secondary clinical outcomes included the reported number of bowel movements per week, the presence/absence of the other Rome II criteria for constipation adverse effects of treatment and relapse rates (Table 2).

For the purposes of the economic evaluation, the researchers had also intended to assess the impact of the treatment on costs and health state utility (Table 3).

Methods of data collection

Table 4 shows participants' pathways through the trial, the clinical assessments completed and data-collection methods used at different points on the pathway.

Baseline assessment (T⁰)

The baseline assessment comprised a structured assessment of participants' health status through a short face-to-face structured interview and self-completed questionnaire. The baseline assessment was designed to be conducted mainly by a nominated practice nurse, and lasted for approximately 30–35 minutes. Given that many general practices were short of nursing time and staff, the researchers also allowed (with MREC approval) the use of a receptionist trained in the study protocol, provided that appropriate arrangements in terms of confidentiality and data protection were in place. Before the face-to-face

interview, eligibility for the trial was confirmed and written informed consent elicited.

The face-to-face interview comprised: questions about bowel habits and Rome II criteria for functional constipation;¹⁷ questions about use of prescribed and over-the-counter (OTC) laxatives; and a question about personal criteria for successful outcomes ("What would be a successful result of treatment of constipation for you?").

At the end of the interview, participants were asked to fill in a self-completed questionnaire to collect baseline measurements. This questionnaire comprised: questions about the participant's personal circumstances; the PAC-SYM/PAC-QOL and EQ-5D; structured questions about levels of mobility/physical activity and diet; and satisfaction with different characteristics of laxative treatment.

During the baseline assessment, a daily self-completion symptom and health diary (described below) was distributed and explained to participants.

Health diary

To minimise recall bias, data on bowel habits and symptoms based on the Rome II criteria¹⁷ were gathered by a structured health diary completed daily and returned monthly for 6 months. This diary was developed and piloted in parallel with the qualitative study. It was designed to capture information on the number of bowel movements, other Rome II criteria, adverse events, relapse rates, adherence to laxative therapy, out-of-pocket expenses associated with constipation and its management (to inform the economic evaluation). Based on experience from using similar diaries in research on falls in older people, it was

TABLE 4 Participants' pathways through the trial

Time (weeks)	Activity
	Eligible participants (i.e. three or more laxative prescriptions in the previous 12 months and/or with a recorded diagnosis of chronic functional constipation) identified from computerised practice notes Initial screen by practice to identify exclusions Invitation by practice to patient to attend nurse-led research clinic to discuss constipation; eligibility criteria confirmed
T ⁰	Nurse-led research clinic: informed consent completed; baseline assessment (baseline interview and self-completed questionnaire); start daily self-completed diary for 6 months
T ⁰⁻¹	Randomisation to treatment group using secure web-based randomisation service (or telephone/secure fax)
T ¹	Collect prescription and start step 1 agent (single laxative). Provisional appointment made for follow-up consultation
T ⁷	Step 1 reassessment – conducted by a researcher based in CHSR: <ul style="list-style-type: none"> • follow-up telephone interview 1 • postal questionnaire 1 If the participant was still experiencing symptoms of constipation (constipation unresolved), he or she was randomised to a second additional class of laxative
T ^{7-T⁸}	Receive prescription and start step 2 (combination of laxatives) where constipation unresolved on monotherapy
T ¹¹	Step 2 reassessment – conducted by a researcher based in CHSR: <ul style="list-style-type: none"> • follow-up telephone interview 2 • postal questionnaire 2
T ²⁷	6-month follow-up assessment – conducted by a researcher based in CHSR: <ul style="list-style-type: none"> • follow-up telephone interview 3 • postal questionnaire 3 Review of practice notes to abstract data on consultation rates and prescription patterns

expected that 90% of diaries would be returned completed.⁴²⁻⁴⁴

Postal questionnaires

Follow-up self-completion questionnaires, with up to two reminders for initial non-respondents, were sent by post to arrive at T⁶⁻⁷ (end of step 1), T¹¹ (end of step 2) and T²⁷ (6 months post-randomisation). These questionnaires contained the same items as the baseline self-completion questionnaire, notably the PAC-SYM/PAC-QOL^{37,45} and EQ-5D.^{40,41}

Follow-up telephone interviews

The follow-up telephone interviews were also administered at the end of step 1 (i.e. at 7 weeks post-randomisation), the end of step 2 (i.e. 11 weeks post-randomisation) and at 6 months post-randomisation. They focused on the participant's perceptions of the outcome/success of treatment, and on the use of healthcare resources, and out-of-pocket expenses associated with the use of those resources, including purchase of OTC

medication to manage constipation (the latter set of questions was designed to inform the economic evaluation). The interviews were conducted by a trained member of the research team based in CHSR.

To determine a participant's need for step 2 (combination therapy) of the intervention and to enquire about the extent to which their personal criteria for successful outcome had been fulfilled on the allocated single laxative treatment regimen, the following types of questions were asked during the step 1 reassessment:

- Do you feel that your constipation has been successfully treated by now?
- Are you satisfied with the control of your symptoms of constipation?

The definition of 'unsuccessful resolution of constipation' was based on the participant's subjective opinion at step 1 reassessment. Where necessary, step 2 treatment strategies were

implemented. For those participants proceeding to step 2, the same questions were asked at the 11-week follow-up (step 2 reassessment). To determine whether a relapse had occurred, the same questions were administered to all participants at 6-month follow-up.

Although structured interviews are the gold standard for the collection of a large volume of complex data,⁴⁶ the amount of data collected at follow-up was minimised, to contain the cost of data collection and to reduce respondent burden as much as possible. The use of self-completion questionnaires and telephone interviews to gather these data also allowed some blinding of outcome assessment, since the interviews and questionnaires were administered by members of the research team not otherwise involved in data analysis and who could be blinded to treatment allocation.

Medical records

Previous experience suggested that data on consultation rates and prescribed medication could be gathered most accurately and reliably from medical records. The intention, therefore, was to abstract such data about all study participants from practice-based medical records to a laptop computer at the end of the 6-month follow-up period. Based on experiences in previous primary care trials,^{47,48} for efficiency in data capture, it was proposed that this be done practice by practice at the end of the data-collection period. However, this activity was not completed owing to the premature closure of the trial.

Blinding of outcome assessment

Health technology assessment is essentially a pragmatic activity conducted in normal clinical practice, rather than an exploratory activity conducted in highly controlled laboratory settings. It follows that blinding doctors and study participants to treatment may not be desirable (even if practicable; which is not the case with different classes of laxatives, since their appearances and dosage mode are very different) since it distorts normal clinical practice. In contrast, blinding of outcome assessors is important because it minimises subjective bias towards a given treatment.

As a result, the research staff conducting the interviews and processing the postal questionnaires and diaries were not aware of the

participants' treatment allocations. Participants were encouraged to respond to questions without describing their treatment regimen. The use of self-completed and postal questionnaires assisted in minimising subjective bias. Another potential bias that was considered was the Hawthorne effect on participants of continuing discussion about the taking of medication. However, this was considered as a positive effect. It was expected to affect all strategy groups equally and to increase participant adherence to treatment regimens. It may, however, give a biased estimate of normal participant adherence to drug therapy.

Development and piloting of data-collection instruments

The measures of outcome and impact listed in *Tables 2* and *3* were selected because they were of known validity and reliability. These measures were brought together in five kinds of data-collection instrument: face-to-face interviews (baseline assessment), self-completed postal questionnaires (administered at the end of step 1 and step 2 and at 6-month reassessment), telephone interview (administered at the end of step 1 and step 2 and at 6-month reassessment), self-completed health diary (completed daily for 6 months) and data-abstraction protocol (GP records after 6-month follow-up completed). Only the self-completed diary was a completely new data-collection instrument that required development, validation and piloting. Each of the other instruments was formally reviewed independently by two members of the research team (JB and EM) and pretested with five participants recruited for the qualitative study.

The self-completed diary was developed from first principles. The qualitative interviews were used to generate a list of terms used by participants to describe symptoms of constipation. These were found to be very similar to the symptoms identified by the Rome criteria for constipation. A simple one-page diary for each day was created using the language of participants. In a series of cognitive interviews⁴⁹ participants were asked to describe what they understood by different diary items and iteratively refinements were made to question wording. As with the other research instruments, the final draft diary was formally reviewed independently by two members of the research team (JB and EM) and pretested with five participants recruited for the qualitative study who completed the diary for up to 28 days.

Methods of data analysis

Since randomisation was at the level of the individual patient, treatment groups were regarded as independent samples and the intention was to analyse them by using appropriate methods. Given the pragmatic design of the trial, an intention to treat analysis was proposed.

As the primary outcome (PAC-SYM/PAC-QOL score) was a continuous variable, linear modelling procedures were proposed for the analysis of the primary outcome.

Secondary outcome measures included binary, count and continuous variables. These were expected to be analysed using logistic, Poisson and normal regression procedures as appropriate. The analyses were intended to use standard methods for handling missing values⁵⁰ and to take into account the repeated observations on each patient. No interim analyses or additional subgroup analyses were planned or undertaken. Since the trial was closed with only 19 participants recruited, neither the proposed statistical analyses nor the proposed economic analyses (see Appendix 5) were undertaken.

Chapter 3

Implementation of the trial

Introduction

This chapter provides a narrative account of the challenges faced by the trial team during the implementation of the trial, which experienced low participation by practices and poor patient recruitment. In summary, some 367 practices in total were approached and invited to participate. Of these, 38 agreed to participate. However, only 26 practices participated in the training of practice staff in the study protocol and only six practices ever started to recruit patients to the trial. Of these, only three practices were still recruiting when the trial was closed. *Figure 1* is the CONSORT (Consolidated Standards of Reporting Trials) diagram for the trial. The CONSORT diagram is incomplete in that we were never able to get all of the six recruiting practices to provide accurate data about the number of eligible participants identified through the electronic search of morbidity and prescribing records, the number excluded after applying exclusion criteria, the number who did not respond to the invitation to participate or who failed to attend the baseline assessment clinic and the number who, at the baseline assessment, did not give informed consent to participate. As *Figure 1* shows, of 19 participants randomised, nine withdrew from the trial and one was lost to follow-up. Only nine of the 19 completed the trial.

Preparation and implementation of the trial protocol

The implementation of trials in general practice has always been more challenging than have been secondary care trials in hospitals or long-term care settings, because of the larger number of collaborating units necessary to achieve target sample sizes and because they take place in relatively uncontrolled environments. But the preparation and implementation of the STOOL trial also coincided with a period of considerable change within the NHS, in terms of both the emergence of a new research governance and ethics framework and the implementation of new primary care contracts.

Regulatory approval

This trial was initiated after publication of the European Union (EU) Clinical Trials Directive, but before its enactment into UK law. For that reason, although the trial met the criteria for a clinical trial of an investigational medicinal product, the authors were able to avail themselves of transitional arrangements with respect to obtaining regulatory approval from the Medicines and Healthcare Products Regulatory Agency (MHRA). Rather than needing to submit a full application, with supporting documents, for a clinical trial authorisation (CTA), they were allowed to apply instead for a Doctors' and Dentists' Exemption certificate (DDX). The DDX was issued and was then rolled over into a CTA on 1 April 2004.

MREC committee approval

An overview of the timeline for the trial is shown in *Figure 2*. Initial ethics application was submitted to the allocated MREC in February 2002. The committee was unable to approve the application without having sight of the finalised research instruments. Following the appointment of a trial manager in October 2002 the preparation of the relevant documentation was completed and the ethics application was resubmitted in December 2002. It was reviewed on 13 February 2003 and conditional approval was granted on 20 February 2003, subject to submission of some additional information and minor amendments to the trial documentation.

The documents concerned were amended and resubmitted to MREC for approval. On 15 April 2003, MREC considered the additional information and the revised documentation which had been submitted in response to the issues raised by the committee during the initial review. The committee then raised further concerns about the way in which the initial invitation of potential participants in the trial was planned. In particular, the committee felt that a prebooked appointment for participants to attend a practice-based research clinic could be coercive and suggested that patients

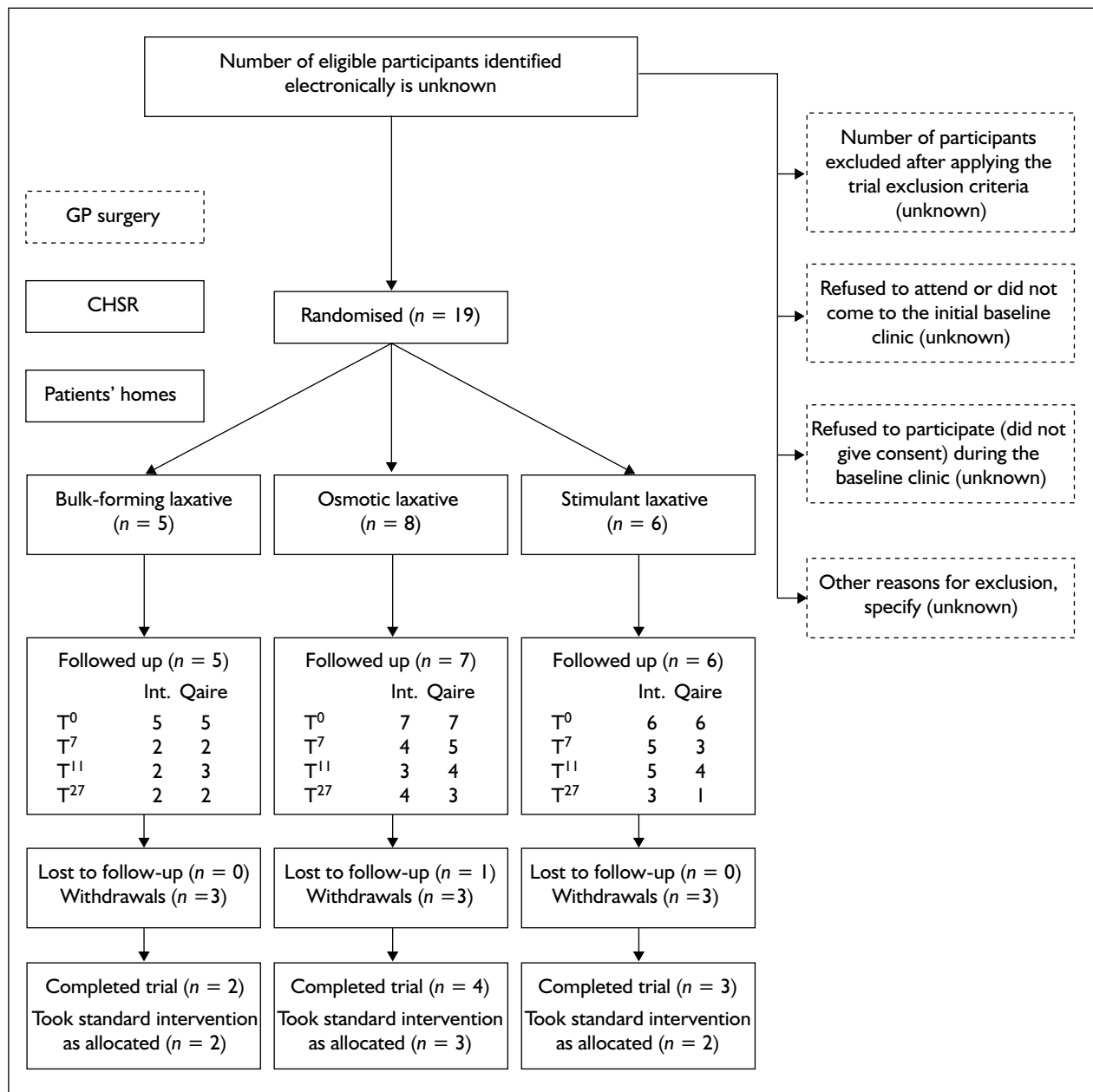


FIGURE 1 CONSORT flowchart for the trial

should be provided with a choice of whether or not to attend the prearranged appointment. It was suggested that participants should be given an option to opt out from the clinic. Therefore, it was agreed that a ‘Yes/No/Please change my appointment’ response slip should be enclosed with the invitation letter to potential participants.

The requested changes in the patients’ recruitment procedure were incorporated in the study recruitment strategy and a favourable opinion was finally granted on 29 May 2003, some 15 months after the initial application for review.

Some amendments to the protocol were sought from and (with the exception of the last one) approved by MREC (in some cases, only after considerable correspondence) during the course of the study (between December 2003 and March 2005): These comprised:

- Removal of the ‘washout’ period. Based on findings from the qualitative interviews and discussion at the first trial steering committee, it was felt that patients would be unwilling to undergo a 2-week washout period between randomisation and commencement of step 1



FIGURE 2 Timeline for the trial

laxative therapy. The researchers therefore decided to issue a 6-week prescription for the step 1 laxative, with the first two weeks of treatment being ignored in data analysis.

- Removal of T¹⁸ telephone interview (designed solely to collect economic data) and incorporation of the collection of these data into telephone interviews at the end of steps 1 and 2 (T⁶ and T¹¹) and at 6-month follow-up (T²⁷).
- Allowing patients to set personal goals to measure success, and to use these goals in deciding whether to proceed to step 2 laxative. Findings from qualitative research had shown that patients vary in their assessment of successful outcomes of the management of constipation, suggesting that a person-specific definition of 'success' would be most appropriate.
- Allowing the use of a practice receptionist, rather than a practice nurse, to recruit patients and conduct the baseline assessment. Although the general expectation was that a practice nurse would take on this role, in practices where staff workload precluded this approach, it was proposed that a receptionist trained in the study protocol could introduce the study, take informed consent and administer the baseline interview, provided appropriate arrangements were in place to ensure confidentiality and data protection.
- Allowing the use of district nurses, rather than practice nurses, to recruit patients and conduct the baseline assessment. This request was to accommodate the particular needs of one practice where workload precluded practice nurses or receptionists from carrying out these activities.
- In the original protocol, it was proposed to carry out an assessment of the cognitive function of potentially eligible patients. Since the anticipated prevalence of cognitive impairment was low, it was subsequently decided that this assessment could be omitted without detriment to the study, to reduce burden on nurses and patients.
- Amendment of trial exclusion criteria to exclude patients with multiple sclerosis or significant autonomic neuropathy, or those on morphine or morphine derivatives.
- Explicit recognition (following securing SfS funding) that practices would receive reimbursement for the time and out-of-pocket expenses involved in patient recruitment and assessment; this necessitated explicit mention of this reimbursement in the patient information leaflet.

- Submission for approval of final, piloted versions of self-completion questionnaires, telephone interview schedules and patient diaries.
- Allowing practice or district nurses to follow up, in a one-off short telephone call, the initial invitations to participate in those patients who did not return their response slip unprompted. The purpose of the call was to determine whether a prospective participant would or would not attend the clinic. This amendment was intended to minimise the incidence of non-attendance and to allow participating practices to utilise the time slots they had allocated for the trial activities in the most efficient way.

These amendments were also submitted to the MHRA, primarily for information.

Primary care trust R&D approvals and LREC site-specific assessments

Selection and recruitment of primary care trusts

Primary care trusts (PCTs) in north-east England, Yorkshire and Cumbria were allocated between the STOOL and the LIFELAX trials on the basis of proximity to Newcastle upon Tyne, with STOOL selecting the PCTs located somewhat farther away from Newcastle, including those in Cumbria, North Yorkshire and the East Riding of Yorkshire.

Initially, PCT research and development (R&D) approvals were sought from nine local PCTs: Newcastle; North Tyneside; Sunderland; Langbaugh; Durham Dales; Easington; Hartlepool; Middlesbrough; and Darlington. Owing to poor GP response and consent rate, the overall number of PCTs approached for managerial approval was subsequently increased from eight to 22. In total, PCT R&D approval was sought, at two different stages, from 14 additional PCTs: East Yorkshire; Yorkshire Wolds and Coast; West Cumbria; Eden Valley, Carlisle and District; Eastern Hull; West Hull; Selby and York; Doncaster Central; Doncaster East; Doncaster West; North Lincolnshire; North East Lincolnshire; and Rotherham.

Obtaining approvals: which comes first, the PCT or the LREC?

Favourable SSAs (from LRECs) and research governance managerial approvals (from PCT R&D

departments) were sought following the receipt of the initial favourable opinion from MREC. However, at the time of making these applications, it was unclear to all concerned whether PCTs should first give R&D approval for the study to proceed within their area in principle (before individual practices were approached) or whether LRECs first needed to conduct SSAs on potential practices (before the request for or granting of PCT R&D approval).

This led to confusion and delays in obtaining relevant approvals, as certain PCTs asked to be provided with evidence of MREC and LREC approvals before they would grant formal R&D approval, and some LRECs insisted on having the names and CVs of the local researchers [principal investigators (PIs)] before they could progress the site-specific assessments. Where PCTs did not wish individual practices within their area to be approached before R&D approval had been granted, this led to an impasse.

Eventually, this issue was clarified and it was agreed that MREC favourable opinion should be followed by PCT approval, recruitment of general practices and application to LREC for SSA (in that order) before patient recruitment could commence. This process, however, was time-consuming, resulting in significant delays with respect to the study patients' recruitment timetable.

Obtaining PCT R&D approvals

Obtaining R&D approval from participating PCTs took from 1 month to up to a year. Although in the majority of cases approvals were given within 30–40 days of application, disagreements with respect to who should be responsible for provision of indemnity for the study, long delays in issuing honorary contracts to members of the research team and, in one case, a request to sign a formal confidentiality agreement which contradicted some of the requirements of the research governance framework, resulted in extensive delays in obtaining approvals from several PCTs.

The excessive time required for issuing of honorary contracts, the lack of common conditions for their issue (e.g. lack of agreement over precisely which members of the team required an honorary contract) and the need for Criminal Records Bureau (CRB) and occupational health checks were all significant barriers to the initiation of patient recruitment. Although many trusts had granted their R&D approval before honorary contracts were issued and a verbal agreement was made to start the recruitment of

patients in a timely manner, on one occasion the issuing of R&D approval was delayed for almost a year until the honorary contracts with that PCT were finalised. This prevented the timely start of patient recruitment.

As should be clear from the description of the study protocol (Chapter 2), it was never intended that any members of the research team (with the exception of the qualitative researcher) should have face-to-face contact with patients. Indeed, the majority of the team were to have access only to anonymised data at most. Thus, the stipulations in respect of honorary research contracts appeared excessively cautious.

Obtaining LREC site-specific assessments

The requirements for SSAs by LRECs led to additional delays in the initiation of patient recruitment. As advised by COREC, LRECs treated each general practice recruited into the study as a separate site and required the submission of a separate SSA, accompanied by the CV of the GP taking on the role of PI for that site. Moreover, the process required that each local PI should himself or herself apply for an LREC number, complete and sign the relevant form and send it to the appropriate LREC. These stipulations created a number of difficulties as many GPs did not have readily available CVs, were unfamiliar with the LREC forms and processes and did not have sufficient time to carry out these tasks. To facilitate this process the authors therefore prepared and submitted the relevant applications on behalf of the participating GPs. However, it took a considerable amount of time and numerous reminders before the relevant CVs and signed forms were received from participating GPs and could be submitted to the relevant LRECs.

To reduce the time needed for SSA applications, an innovative approach was subsequently adopted using NoReN as a local research site for all participating practices within the geographical area covered by this network. The clinical director of NoReN (GR, a PI of the STOOL trial) agreed to act as PI for the purpose of the SSA.

To the best of the authors' knowledge, they set a precedent within the UK in using this approach, which allowed them to speed up the SSA process in the areas covered by NoReN. However, on one occasion this approach was challenged by an LREC as inappropriate and approvals were delayed for several months as a consequence. In addition, the directors of other GP research

networks did not agree to take responsibility as PI for the sites within their network's geographical area, which meant that the researchers had to submit individual applications for each local practitioner in those areas.

Recruitment of practices and practitioners

Recruitment of general practices for the STOOL trial proved much more difficult and slow than originally anticipated. Between June and August 2003, a total of 129 general practices, from the first five PCTs who approved the study, were approached to join the study by an invitation letter, followed by two reminders. Sixty-four general practices (49.6%) responded to the study invitation, of which only nine (7.0%) expressed interest in participating. To compensate for the poor GP response rate, a decision was taken to expand further the study catchment area, as described above. As a result, during the first year of general practice recruitment, a total of 367 general practices was approached, in several different waves. Only 15 general practices expressed interest in joining the study over this period, with only 12 (3.2%) providing formal consent to participate. Three practices withdrew immediately after receiving the full trial documentation and a request to sign a formal letter of agreement to recruit participants.

As a result of the extremely poor consent rate, a managerial decision was taken in February 2004 to suspend recruitment of practices to allow review and refinement of the recruitment procedures.

Barriers to recruitment of practices and practitioners

The researchers considered that it was imperative to ascertain the obstacles to recruitment to the STOOL trial in comparison to other studies and if possible to address these barriers. Feedback about the study and perceived barriers to recruitment were communicated through a variety of channels:

- informal feedback from GPs invited to take part in the study
- telephone interviews with GPs conducted by CHSR
- feedback from GP champions and research-active GPs
- feedback from health professionals, members of the extended research team and members of the trial steering committee

- feedback from PCT R&D managers and facilitators
- feedback from UK Trial Managers' Network
- telephone interviews conducted by NoReN staff with GPs, focusing on potential incentives for GPs to join the trial.

A wide range of interrelated factors that had discouraged GPs from participating in the STOOL trial was identified through these channels. Key issues were:

- lack of nursing time to perform the initial assessment, due to understaffing and heavy workload, including the preparation for the introduction of the new General Medical Services (GMS) contracts
- overcrowded premises and lack of consulting space for the initial baseline assessment
- lack of interest in research in general and in this research question in particular
- lack of incentives (remuneration perceived inadequate, lack of non-monetary incentives)
- changes in research governance regulations (current guidelines on patient confidentiality precluded the research team from approaching and recruiting patients directly)
- paperwork and documentation required for research governance purposes discouraged practitioners from taking part in research
- protocol amendment procedures were a barrier to flexible recruitment as changes and additions to the recruitment strategies were considered substantial amendments and required MREC favourable opinion before implementation
- perceived difficulties with changing the laxatives of long-term laxative users.

Results from telephone interviews with GPs

The detailed comments from GPs concerning barriers to recruitment to this trial and to participation in research in general are summarised below. For the most part, they echo the more general themes identified above, but some more specific issues were also raised.

General reasons

- GPs were under time constraints and had a heavy workload, resulting from pressure to meet government targets and preparation for the introduction of the new GP contract and other reforms.
- GPs felt overstretched and needed to draw a balance between their work commitments and their own quality of life.

- Respondents had teaching and training responsibilities, particularly for vocational training practices.
- Respondents were involved in other research activities and there was a lack of adequate staffing to support such requests. GPs reported that too many research activities were happening and that practices were overburdened with multiple requests to participate in research studies.
- Some respondents reported that it was practice policy not to participate in research.
- Respondents also reported that there was a lack of consensus among practice GPs regarding participation in this particular study, or in research more generally, or that they (as a practice or as individuals) had no interest in research.

Reasons related to the study topic and design

- Respondents felt the trial would be very disruptive to practice work.
- Respondents reported a shortage of nurses or nursing time, and therefore that their practice nurses were often overworked. They felt that a decision to join the study would put considerable additional strain on practice nurses. Some respondents highlighted that their practice could not spare any nursing appointments to carry out the baseline assessments.
- Some respondents felt that their premises were inadequately equipped to take on the additional work of the trial, particularly because of the lack of space for paperwork or of rooms for conducting the baseline assessments, or because of the inaccessibility of the premises to older people.
- Respondents predicted that any study involving older people would increase the practice workload (since it might provoke additional, not necessarily related, consultations).
- The trial was perceived by many respondents to be inadequately remunerated in relation to the time and work involved.
- Finally, a number of the respondents thought that the topic of the research was not inspiring.

Strategies for improving the recruitment of practices and practitioners

To compensate for the poor GP participation rate, a variety of different strategies was adopted, which included:

- expanding the study catchment area from eight to 22 PCTs

- raising awareness, by:
 - sending fliers about the study to relevant primary care research networks and research-active practices
 - asking R&D facilitators and managers in the participating PCTs to disseminate information about the trial via PCT newsletters and, where appropriate, by e-mail.
 - presenting an overview of the study at some of the relevant primary care research networks' conferences.
 - inviting simultaneously the senior partner, practice manager and lead practice nurse to join the study, to ensure buy-in by all stakeholders in the practice
 - identifying key research practices and targeting GP champions with a request to help with the study
- changing the protocol to minimise the extra workload for participating practices associated with trial activities, by:
 - reducing the number of the practice-based visits from two to one
 - reducing the originally planned time for the baseline assessment
 - introducing flexibility in respect of the conduct of the baseline assessment by allowing a trained receptionist to be used and by recruiting community nurses to help with the study
 - reviewing trial documentation used for practice and patient recruitment, and designing a shorter GP-friendly information sheet and study protocol, emphasising flexibility and reduced workload
 - using NoReN staff to telephone GPs, to identify opportunities for improving recruitment and explore practitioners' interest in payment per patient recruited instead of lump sum per practice
 - consulting and networking with professionals perceived to be in a position to help with recruitment (i.e. clinical advisors for the study, primary care academics, primary care nursing professionals, GP champions, primary care research networks, etc.).

Payment per patient recruited

The telephone interviews with GPs highlighted that the remuneration to the practice for participating in the study was inadequate with respect to the time and efforts needed to dedicate to the study. The researchers had initially provided for a lump sum payment to practices of £510 to recompense the practice for the time and out-of-pocket expenses of identifying eligible patients and approaching them to take part in the study.

Members of the extended research team and the trial steering committee also suggested that providing and advertising financial remuneration as payment per patient recruited might be a more successful recruitment strategy. This was supported by evidence in the literature and feedback from UK Trial Managers' Network.

In response, working through NoReN, the authors applied for and obtained SfS funding (widely known as ad hoc funding) from the Department of Health to cover the true cost to practices of patient recruitment. This allowed them to offer £79 per patient recruited, a figure estimated on the basis of full economic costs to practices of recruiting and assessing patients and delivering the trial intervention.

Resuming practice recruitment

Following this success in obtaining SfS funding, the researchers reapproached all those general practices that had previously refused to take part or had not replied to the initial invitation. Within a relatively short period (3 months in the summer of 2004) there was dramatically increased interest from general practices in taking part in STOOL. This brought the total number of practices who agreed to take part in the study to 38, of which 21 returned a formal letter of agreement to recruit participants.

As a result of achieving the projected number of practices needed for adequate patient recruitment, it was agreed that approaching new general practices from the geographically most distant PCTs in South Yorkshire would be put on hold.

Patient recruitment

Although the trial managed to meet its objectives in terms of number of general practices recruited into the trial, setbacks were encountered with negative implications for recruitment of patients.

During the period October 2004 to January 2005, 26 practices (out of the 38 who had agreed to participate) were trained in implementing the study protocol, and received the relevant study documents and materials. The remaining 12 practices either explicitly dropped out of the trial or repeatedly cancelled prearranged appointments for training and asked if they could postpone recruitment of patients to a later date.

A number of different strategies was tried to encourage patient recruitment in those practices

trained in the trial protocol. These included sending letters of encouragement to the relevant GPs (and to the practice nurses and practice manager, where appropriate) both from the study team and from the GP member of the study team (GR) who was also the clinical director of NoReN. In addition, practice staff were telephoned to discuss any problems they might be having with initiating recruitment of patients, and to offer help and support if needed.

However, these interventions did not achieve the desired results. Out of the 26 trained practices, only six started recruitment of patients, while the majority of practices repeatedly postponed the start of patient recruitment (albeit for a range of plausible and persuasive reasons) or explicitly withdrew from the study.

Reasons for delays in patient recruitment

A wide range of reasons was given by general practices for the delays in starting patient recruitment and for withdrawal. Many of these reasons reflected those provided by practices who did not want to participate in the first instance, as described above. They included:

- other commitments (e.g. heavy workload, flu immunisation, meeting GMS contract targets)
- loss or absenteeism of staff; staff maternity or sick leave; staff shortages or holidays
- moving premises or renovation of premises.

Lack of genuine interest in the trial also may have played some part. The researchers tried to encourage practices to start patient recruitment by reminding them that each patient recruited attracted a payment of £79 to the practice, and asked about their preferred way of payment and financial details. However, only six practices responded to the letter, which may suggest that the study was seen by some as low priority.

There were also some objective reasons for delays in site initiations, the majority of which were outside the authors' control, which included:

- Ethical and research governance issues: SSAs for two areas were delayed by 4 months owing to disagreements about the director of NoReN as the PI for all participating practices in those areas.
- Additional time was required for implementing changes in the recruitment strategy owing to the substantial amendment processes demanded by MREC.

- There were delays (3 weeks) in printing new trial documentation.
- There were numerous cancellations of prearranged appointments for training sessions (with dates agreed being postponed repeatedly).
- Negativity and reluctance were encountered in terms of arranging protocol training sessions for the remaining untrained general practices.
- A number of trained practices decided to postpone recruitment of patients for several months.
- Variable information technology (IT) skills and support in practices hindered identification of eligible participants.

Recruitment of participants

The first participant was recruited to the STOOL trial in January 2005. Poor response and lack of attendance at baseline assessment clinics were experienced in all active sites, resulting in three out of six active practices withdrawing from the study.

Experience from all active practices indicated that many eligible participants invited to attend a baseline assessment clinic did not return their response slip to indicate whether they would attend the prearranged baseline assessment clinic and did not turn up at the appointed time. For example, one GP, from one of the biggest practices taking part in the trial, reported that after setting up two recruitment clinics he had a 75% non-attendance rate, despite follow-up telephone calls made by his practice staff to the invited patients. The practice in question invited 15 patients in total, of whom only one agreed (reluctantly) to take part in the trial. Patient non-attendance with respect to specific prearranged baseline assessment clinics varied from 33% to 100% in some of the active sites.

This trend made it difficult for some practitioners to justify setting up subsequent clinics; they argued that that the payment of £79 per patient recruited did not cover the significant opportunity and financial cost of non-attendance at scheduled assessments and the subsequent 'wasted' appointments.

In an attempt to address the problem of low patient response and attendance, practices were advised to invite a few more patients per baseline assessment clinic than originally planned, in anticipation of less than 100% attendance rates, with the exact number to be based on their previous experience of non-attendance. It was also suggested that, following their usual practice, they

could follow up the initial invitation with a short telephone call to determine whether invited patients were considering attending the clinic. The follow-up telephone call option had not been included in the original MREC application, however, and the authors were advised to submit a notice of substantial amendment. The MREC was unable to give a favourable opinion of the amendment for the following reasons:

- The committee had not been provided with a telephone script that the nurse would use when trying to contact patients (the authors had not provided such a script, since they felt that the content of the call should be at the discretion of the nurse and in line with the practice's normal policy in respect of checking that patients were going to attend a prearranged appointment).
- The committee was concerned that the nurse would be unable to identify that he or she had contacted the correct person without breaching confidentiality.
- The committee was concerned that invited patients would not remember the original invitation letter and might therefore be unfamiliar with the study.

General practices opting out from the study or asking to postpone patient recruitment (often repeatedly and by several months), delays in site initiations, few eligible participants in some of the smaller single-handed practices (but also in one middle-sized practice), and poor patient response and consent all contributed to the poor patient recruitment.

The six active practices between them only managed to recruit a total of 19 study participants, of whom half withdrew from the study as a result of dissatisfaction with their allocated laxative treatment or side-effects associated with that treatment.

Barriers to recruitment of patients

Formal (telephone interviews with GPs) and informal contact with practices highlighted a number of reasons why older people were not participating in the trial. Although the following explanations are based largely on practice perceptions and accounts, some of these reasons were reported to practices by patients themselves.

- Patients with resolved bowel problems (at least by the patient's own definition) were captured by the trial inclusion criteria. These included patients who were not currently on laxative medication (but had had a diagnosis of

functional constipation at some time in the past or had a 'standing' repeat prescription for laxatives, which could be activated on an 'as needed' basis) and those who were settled on a particular laxative, which controlled their constipation to their satisfaction, and wished to stay on it.

- Practices suggested that older people tend to: lack interest in research in general; have poor concentration and understanding of what is required; have poor hearing; lack energy to fill in forms, in particular keeping a daily diary about their bowel habits for 6 months; have no access to a telephone for initial contact and follow-up interviews; be reluctant to or have difficulty in attending the practice for baseline assessment.
- Because of co-morbidity, a higher proportion of patients than that originally estimated by the research team failed to meet the trial inclusion criteria.
- Practices were reluctant to recruit more than 25–30 patients to the trial.

On reflection and discussion of these issues, the research team and the trial steering committee members felt that some of these issues could have been addressed if an enthusiastic and informed individual, ideally a member of the research team rather than a hard-pressed member of a primary care team, had been able to explain the study to potential participants and discuss the implications of participation. They concluded that many of the problems encountered were a direct consequence of the changes in research governance and ethical procedures that prevent members of the research team approaching patients directly, but instead place the burden of recruiting patients on busy primary care professionals.

Closure of the trial

Once it was clear that it was going to be difficult to recruit patients even within those participating practices actively recruiting, the closure of the trial appeared inevitable. Before making the final decision, however, the researchers revisited the sample size calculations. However, given the lack of interest from the majority of practices and the majority of eligible patients in the study protocol, it was difficult to see how the trial could ever recruit sufficient participants, even aiming at a more modest target of 620 (original target 1004) patients to be recruited, by accepting 70% power to detect the effect sizes specified in the protocol (see Chapter 2). Likewise, there was no evidence

that a simple head-to-head trial of the three classes of laxative (or even of two out of the three), and ignoring stepped management, would have been feasible, given the apparent preferences of patients for specific laxative types (in other words, lack of patient equipoise). In a meeting of the trial steering committee, it was accepted that it would not be viable to proceed with the trial and the formal procedure for closure (including notification of MHRA and MREC) was initiated in May 2005.

Summary and implications

The implementation of the STOOL trial appears to have been unsuccessful for a number of reasons. These are related both to procedural issues resulting from changes in ethical review and research governance processes, and to disappointingly poor levels of interest and response at both practice and patient level. The STOOL trial was running at a time of considerable change and uncertainty around ethical and research governance issues, following the report of the Alder Hey inquiry,⁵¹ the implementation of the European Human Rights Act⁵² and preparation for the enactment of the EU Clinical Trials Directive. At this time of uncertainty, guidelines for ethical committees became more prescriptive and committees became more risk averse. Guidance to researchers appeared inconsistent and inflexible, and the process of ethical review became increasingly bureaucratic and unresponsive. The publication of the Research Governance Framework⁵³ created similar challenges. Decisions at the local level often appeared contradictory to national advice. The imperative for researchers to have honorary contracts was particularly challenging because of the paucity of expertise and resources to implement the policy efficiently. The experiences in the STOOL trial are mirrored by those of other researchers undertaking studies in primary and community settings at a similar time.^{54–57}

In addition to the inevitable delays created by these developments, the STOOL trial found that changes in the way that non-invasive clinical research was to be implemented increased barriers to patient participation. The provision that patients should opt into the research, rather than opt out,⁵⁸ and the consequent transfer of responsibility for recruitment and consent to members of the primary care team, meant that the nature and objectives of the trial were never fully explained to many potential participants.

Individual practices were apparently unable or unwilling to take on the considerable extra workload that the opting-in provision creates. At the same time, ethics committees were not always willing to think creatively about how to balance the protection of the rights of potential participants against the need to evaluate interventions of unproven value, or to apply a risk-based assessment in judging whether an opt-in or an opt-out process would be more appropriate for a given study. Evidence of the decreased response rates and the biases resulting from opt-in as opposed to opt-out approaches^{59,60} appear to have been largely ignored by those responsible for determining and implementing policy, although debate persists^{58,61} on the adverse implications for trials, epidemiological and health services research.

The set-up of the STOOL trial also coincided with the introduction of the new GP contract. During the period of this trial practices were heavily

involved in setting up the necessary audit and information systems required to meet the quality targets associated with this contract. Moreover, the contract has very minimal incentives for research, and thus research-related activities were viewed by many GPs and their practice staff as an unwelcome distraction from the other demands of getting to grips with the contract. This was indeed a challenging period for any kind of research in primary care.

Specific barriers to the conduct of this trial that were identified by the GPs surveyed suggest that the opportunity costs to practices of participating in STOOL were too great in terms of time, practice resources and nursing capacity. For some the subject was insufficiently interesting. The barriers for patients are unclear, but GP participants suggested that their patients were not in equipoise and would be unwilling to switch from their preferred treatment regimen, particularly if it was currently being successful.

Chapter 4

Design of the qualitative study

Background to the qualitative study

Examination of the epidemiological, medical and social science literature highlighted few studies of constipation that had investigated the definition, meaning, experience and impact of constipation from the perspective of older people. It revealed that constipation as a chronic condition has not been the focus of social research and much of our understanding of constipation is drawn from the medical and epidemiological literature.

To inform the design and facilitate the implementation of the STOOL trial, the HTA Commissioning Board funded an add-on qualitative study which aimed to address the following research questions:

- How do GPs and older patients define constipation?
- What treatments do GPs routinely prescribe for constipation in older people? When and why do they prescribe different treatments?
- What are older patients' views of different treatments for constipation?
- How well do older patients adhere to prescribed treatments and what are the barriers and facilitators to adherence?
- What is the pattern of self-medication using OTC preparations by older people with constipation?

Study objectives

The primary objectives of the add-on qualitative study, therefore, were:

- to define the meaning of constipation in older people from the perspective of GPs and older patients
- to investigate the use of prescribed and non-prescribed treatments for constipation in older people
- to investigate the adherence by older people to prescribed treatments for constipation.

As a result of the early closure of the STOOL trial, the focus of the analysis reported in the remainder of this report is on the following questions:

- What does constipation mean to both older people and health professionals? What are the commonalities and differences in their definitions and understanding of constipation?
- How do patients experience constipation and how does constipation affect their daily lives?
- What are the likely barriers to participation in trials of constipation for both patients and health professionals?

Study design

This element of the research comprised a qualitative analysis of in-depth interviews with older patients and their GPs, and focus-group interviews with practice and community nurses.

The original protocol for the qualitative study proposed that only patients and GPs would be interviewed. However, given the role that nurses play in the management and treatment of constipation, interviews with a sample of practice and community nurses were also conducted.⁶²

Target population

The target population was people aged 55 years or over with chronic constipation living in private households in north-east England, and the GPs and practice and community nurses who provided their care. The target population of patients mirrored that of the main trial (see Chapter 2) and focused on a predominantly ambulant population able to attend a primary care clinic independently. The exclusion of residents in long-term care reflected the different morbidity and lifestyle experiences of long-term care residents.

Inclusion/exclusion criteria

Patients aged 55 years or over with three or more laxative prescriptions in the previous 12 months and living in the community were eligible for inclusion in the study. The exclusion criteria included residence in a long-term care institution and inability to communicate owing to deafness, aphasia, severe cognitive impairment or language difficulties. Participants were not excluded on the basis of cognitive impairment or ethnicity alone.

Sampling strategy

To facilitate comparative analysis, a purposive maximum variation sampling strategy was adopted.⁶³ The researchers aimed to recruit approximately 15–25 patients and 15–25 health professionals, since their experiences in other similar studies suggested that data saturation is typically achieved after 15–20.

The patient recruitment strategy aimed to achieve sample variation by age, gender, socio-economic status, experience of constipation and use of different constipation treatments. Health professionals were selected to achieve variation by age, gender, professional training, specialist interest and characteristics of the practice.

Participant recruitment

Patients were recruited from three practices in each of an urban (Sunderland) and a rural (Northumberland) area (i.e. six practices in total). Participants were identified and contacted by the practice from their patient lists, according to the study eligibility criteria described above. An opt-in recruitment procedure was used. Eligible patients were sent a recruitment letter from their GP, an information sheet about the research (see Appendix 6), a consent form and a reply-paid envelope (addressed to CHSR). Patients were invited in batches of 25, to enable interviewing to keep pace with recruitment and so that patients were not invited unnecessarily once the interview target had been achieved.

In total 101 patients were invited, of whom 28 (28%) consented, although four later asked to be withdrawn. Interviews with the remaining 24 patients were undertaken between September 2002 and July 2003.

Health professional recruitment

GPs and nurses at each of the six participating practices were identified and invited by letter [accompanied by an information sheet (see Appendix 7), a consent form and a reply-paid envelope] to take part in the study. Reminder letters were sent after 2 weeks and a follow-up telephone call was attempted where no reply was received. Altogether, 56 health professionals from the six general practices were invited to take part.

GPs

Thirty-three GPs from six practices were invited for an interview, of whom ten GPs from four practices agreed to participate and provided written consent. One GP later withdrew because of time pressure. Altogether, nine in-depth interviews

with GPs were undertaken, between September 2002 and July 2003.

Practice/community nurses

Twenty-two nurses from the same six practices were invited to participate; 17 agreed to group interviews (two to five nurses per group), which were undertaken between April and September 2003.

Ethics and R&D approval

Favourable opinion from the LRECs in Sunderland and Northumberland LRECs was obtained before recruitment of participants. PCT R&D approval was also obtained.

Method

In-depth or group interviews with patients and health professionals were conducted by an experienced qualitative researcher (CS). The interviewer used a topic guide, specific to the type of participant (see Appendices 8–10), to elicit systematically participants' accounts with respect to the main topics of interest. The interviewer also encouraged participants to voice their own concerns and thus identify new themes outside those covered by the topic guides. Topic guides were revised on an ongoing basis to reflect emerging issues. All interviews were digitally recorded and transcribed. The interview transcripts formed the formal data for interpretative analysis according to the precepts of constant comparison.⁶³ Transcripts were analysed using a generative thematic approach⁶⁴ aided by a qualitative software package (Atlas ti).

The analysis presented in this report is a descriptive analysis of the transcripts only. Since qualitative descriptive data are not generalisable, and given the small number of transcripts available (particularly of GP interviews), caution should be applied in generalising the interpretations provided by the authors.

Participant characteristics

Patients

In-depth qualitative interviews were completed with 12 women (median age 75 years, range 56–88 years) and 12 men (median age 72 years, range 56–81 years). None of the participants was in paid employment at the time of interview. Two-thirds of participants were married and living with their spouse at the time of the interview; in some

cases the spouse was present during the interview. Five women and three men were widowed and living alone.

General practitioners

In-depth qualitative interviews were completed with seven male and two female GPs (years of experience as a GP: 1, 3, 7, 8, 9, 13, 23, 29 and 31), working in four practices ranging in list size from 6400 to 9500 patients. None of the GPs interviewed described themselves as having a particular interest in gastrointestinal conditions. Two reported that they had a special interest in older people.

Nurses

Nurses participated in six focus-group interviews in six practices. The size of the focus group ranged from two to five participants. Of nurses participating in the focus groups, five were district nursing sisters, seven were community staff nurses, three were practice nurses, one was a student nurse and one was an auxiliary nurse. They had worked in their current general practices for an average of 10 years (range 4 weeks to 30 years) and had been in nursing for an average of 25 years (range 1–41 years).

Chapter 5

Understanding the meaning of constipation

Overview

In Chapter 1 the Rome II criteria for functional constipation were reviewed.¹⁷ How do these criteria relate to the way that older people understand and describe constipation? Are these the criteria used by health professionals in the diagnosis, treatment and management of constipation? This chapter presents an analysis of the qualitative data, using the transcripts of interviews and group interviews with participants to explore these questions.

Two meanings of constipation were provided by GPs: a patient-centred definition and a textbook definition; neither fully reflected the Rome II criteria. Patient-centred definitions focused on the idea of a change from the norm as defined by the individual patient, whereas textbook definitions focused on reduced frequency of defecation associated with a range of other unpleasant and clinical symptoms such as difficulty passing stools and hard stools. 'Chronic constipation' was not a term that GPs tended to use.

Nurses' definitions of constipation included both a patient-centred perspective and the description of particular symptoms associated with constipation. Person-centred definitions focused on changes to people's routines in terms of reduced frequency of bowel movements and the difficulties and discomfort experienced by older people in passing stools. In contrast to GPs, 'chronic constipation' is a term used by nurses in their practice.

The meaning of constipation to older patients was similar to the health professionals' patient-centred perspective. Frequency of bowel movements and changes in normal bowel routine were central to participants' definitions. They were very clear about what they perceived to be abnormal. This included the size, form and consistency of stools; difficulties and discomforts in passing stools; feeling 'blocked'; and unpleasant symptoms such as bloating and flatulence. While these aspects of bowel function are among those specified in the Rome II criteria, neither patients nor the health professionals caring for them were consistent or rigorous in

their perceptions of how frequently, for how long or in which combinations these symptoms and manifestations needed to be present to constitute 'constipation'.

What clearly emerges, however, from the different accounts of patients and health professionals is some common understanding of the general nature of constipation, but also considerable differences of perception among both patients and health professionals. Like many health problems managed in primary care, constipation means different things to different people.

Older people's experience of constipation

The majority of participants did not consider themselves to be 'constipated' at the time of interview. This perception was associated with the view that their current use of laxatives and other interventions for the management of their bowel function had much improved their bowel habits compared to past experience. The past experience of constipation was extremely vivid in their accounts and participants did not appear at all inhibited in describing what being constipated meant to them.

Health beliefs about constipation appeared very consistent among this group of participants, drawn from a particular generational cohort. For most of these participants, achieving a daily bowel movement was an important goal. For some, not achieving a daily movement meant they were 'constipated' from their perspective, although others were content with going every other day provided there was no discomfort. Not surprisingly, frequency, regularity and comfort of bowel movements are important factors in participants' perspectives on constipation. In addition to frequency and regularity, however, participants associated a number of problems that they had experienced over the years 'with their bowels' with constipation. In their accounts, they described both physical sensations and emotional feelings. These descriptions of their experiences provide different meanings of constipation that are summarised in *Box 1*.

BOX 1 Older participants' description or meaning of constipation

- Changes in normal bowel habits in terms of frequency (less often than normal) and regularity. Described by participants as “not being able to go to the toilet at all or as often as normal”. (Normal in this context being what has been typical for the individual concerned.)
- Experiencing a continual and often urgent urge to pass a stool without being able to do so. Described by participants as “can't or couldn't go”.
- Experiencing difficult or uncomfortable bowel movements, including the need for excessive straining, pain or soreness during bowel movement or rectal bleeding. Described by participants as “difficult to pass or go”, “have to strain” or “sore to pass”.
- Passing uncharacteristic stools that are too small, hard or compact. Described by participants as “just a little drop”, “sheep's droppings” or “hard”.
- Feelings of being blocked. Described by participants as “bunged up”, “not passing through” or “having a tight anus”.
- Feelings of inadequate or incomplete evacuation. Described by participants as “seems as though I can never finish”, “my bowel didn't empty” or “couldn't finish emptying my bowel”.
- Feelings of bloating, hard stomach, abdominal pain or flatulence. Described by participants as “stomach swells”, “bloating as if pregnant”, “hard stomach” or “stomach aches”.
- Feelings of tiredness and fatigue or general discomfort. Described by participants as “don't feel right”, “feel sluggish”, “lack of energy” or “you didn't feel you were firing on all four [cylinders]”.
- Dependent on laxative to produce a bowel movement. Described by participants as “not being able to go without laxatives”.

The meaning of constipation to older people

When asked to explain in their own words what they meant by constipation, participants used a number of terms, including: ‘not going’, ‘never been’, ‘can't go’, ‘could not go to the toilet’, ‘not going as often’, ‘missing’, ‘not passing waste’ and ‘bunged up’.

Interviewer (I): “What does constipation mean to you, how does it, if you say you're constipated, what do you mean by that?” Patient (P): “I mean I just can't go to the loo.” I: “You can't go?” P: “No.”

(Patient 15)

I: “Right, right. OK, right, so I mean for you, you know if I said to you right what do you mean when you're constipated what would you say, what does being constipated mean to you?” P: [*Laughs*] “Obviously that I've never been.” I: “That you just don't go.”

(Patient 6)

P: “I just don't go, that's it.” I: “It's more the fact that you don't go?” P: “I stop, aye.”

(Patient 1)

P: “It was mainly bouts where I didn't go at all, maybes 2 days, 3 days.”

(Patient 2)

P: “You can't go to the toilet.” I: “You can't go ...” P: “No and you go for days and days.” I: “Right, OK.”

(Patient 3)

“Well just you wanted to go to the toilet [a-ha], you know, but you just couldn't [you couldn't go], that was the main thing [mmm].”

(Patient 4)

“I basically wasn't going. I wasn't passing waste at all.”

(Patient 5)

I: “You know, when you say you're constipated, if you say ‘oh, I'm constipated’ what do you actually mean when you say that?” P: “I can't pass, my bowels aren't working properly.”

(Patient 23)

Most participants associated constipation with decreases in normal bowel frequency, but at least three groups of participants could be identified as having distinctive experiences: those who were unable to pass a stool despite having an urge to go (‘can't go’), those for whom there was an infrequent passing of stools (‘not going to the toilet’) and for those who missed a day without a bowel movement (‘not going as often’).

Differences were noted between the majority of participants who articulated their meaning of constipation as ‘can't go’ and those participants for whom constipation was simply ‘not going to the toilet’. The former group of participants commonly described their experience as wanting to go, having an urge to go and a sensation that there is a stool there waiting to be passed, but when they go to the toilet and try to pass a stool nothing happens (‘unable to pass a stool’). Alternatively, participants may pass inadequate (‘very little’) amounts of stool which do not alleviate the continuing urge to go and are often associated with a feeling of incomplete emptying of the bowels. Such unproductive attempts to have a bowel movement are usually followed by a constant urge or frequent urges to go. As a result participants make repeated visits to the toilet, vividly described as ‘going for tries’. These visits are usually accompanied by excessive straining.

Eventually, participants manage to move their bowels, but this is reported to be difficult and often painful.

For example, one participant in this category reported that, despite having the urge to go, when he does visit the toilet he is not able to move his bowels. The lasting urge to go prompts him to go backwards and forwards to the toilet, something that he describes as a nuisance. Eventually, however the obstructions are resolved and then he may move his bowels up to three or four times a day.

I: "Right, so you've got constipation, what do you get? I mean, is it that you are not going to the toilet; is it hard to go; how does it?" P: "Aye, you're sitting here and you are wanting to go [a-ha] and then when you do go you cannot. [Right, right.] You cannot use it and then you are back and forwards." I: "Do you get, when you say you want to go, are you getting the urge to go? [Aye.] You get the urge to go?" P: "You get the urge to go." I: "But when you get there ...?" P: "When you get there nothing happens." I: "Right, right, and have you got a sensation that there is something there waiting to be passed?" I: "Aye, yes, it's there because you do that maybe all day the day that could happen [right] and tomorrow morning you could go and clear the lot out [right, right, right]. In fact you might, the next day you might go three or four times. [Right.] Sometimes you might just need to go the once and then the next day you might go to the toilet and then back another couple of hours you are back again [right]. It's a bit of a nuisance. It depends where you are, it's a bit of a nuisance at times, but err ..."

(Patient 21)

In contrast, those participants (a smaller group) who articulated their notion of constipation mostly as 'don't go' or 'not going to the toilet' described their experiences not in terms of wanting to go or trying to go, but rather in terms of the length of time since they last had a successful bowel movement. Not going to the toilet was often associated with the absence of an urge to go. For example, one participant, who reported being dependent on laxatives for a bowel movement, felt that there was a stool waiting to be passed, but stressed that she does not have the urge to go. As a result she does not strain, but rather waits to get an urge to go before she visits the toilet to move her bowels.

P: "But the second ... for me to go a second time I feel I need to go but now that's the one that gives me the bother. [Right.] How I describe it is that, you know, people get an urge, oh I must go to the toilet. Well I don't. But I get a bearing down feeling and I need the toilet but I don't get that urge. So to me

without that urge I can't strain. If you get the urge you naturally strain at the same time. So I'm hanging about waiting. I'm needing to go, needing to go. I'm hanging about waiting to get an urge to actually go." I: "Right. So have you got a sensation that you've got something there waiting to be passed? [Yes, exactly.] Right, so you've got a sensation that there's something there waiting to be passed but you don't have the urge to go?" P: "That's it, that's it in a nutshell."

(Patient 22)

Such periods of bowel inactivity were associated with abdominal discomfort described as 'feeling uncomfortable', 'being full', or 'having a bloated, swollen or hard stomach'. Going for several days without a bowel movement was associated with a hardening of the stool and what some participants described as a 'blockage'.

Having a day or two without a bowel movement was one of the key meanings of constipation. This reflected the widespread perception among participants of what constituted a normal bowel routine and the preference for a regular (and mainly daily) bowel movement pattern.

P: "I think I would know simply because I hadn't had a bowel movement and started to feel er a bit sort of uncomfortable as though, you know, how it was all a bit full." I: "And when you say you hadn't had a bowel movement would that be for 1 day or missing 2 days or could it go on longer than that?" P: "Err, well, em, I would think of myself nowadays as constipated if I don't have a bowel movement for 1 day really, I always have found that being on holiday or being away in a different place tends to affect me in that way, I mean, we've just been away and I was really surprised that I had a day without a bowel movement and it was all to do obviously with all this different surroundings." I: "With having been away. OK, to you, when you say you're constipated do you mean that you haven't been for ...?" P: "Well, I think, I think I've got to look back rather a long way to when I would say I suffered more from constipation, and I would say it would have gone on 2 or 3 days in those days, but I think since we started having so many vegetables and fruit and so on really I have not had these long periods."

(Patient 17)

Participants in general did not acknowledge that variation in frequency of bowel movements may be normal or may reflect changes in diet or medication use. The strong imperative for having a regular, preferably daily, bowel movement meant for some participants that a day or two without a bowel movement was 'constipation'. This in turn may prompt some participants to attempt a bowel movement which may also be associated with unproductive excessive straining.

Difficulties with defecation were also strongly associated with ideas about constipation. Difficulties were predominantly described in terms of uncharacteristic hard stools or excessive straining. The passing of small sheep-dropping-like, or normal-sized but hard and compact, stools emerged as the main reason why participants experienced difficulties with defecation. Such stools were reported to be very difficult and hard to pass (in both senses of the word); this resulted in painful defecation and bleeding, which was especially common when participants reported that they had 'piles'. These difficulties were often associated with feelings of incomplete evacuation and frequent urges to go.

I: "You know, when you say you're constipated if you say, 'oh, I'm constipated', what do you actually mean when you say that?" P: "I can't pass, my bowels aren't working properly." I: "Right. And when they're not working properly is that that you can't go at all or is it difficult to go or how does it affect you?" P: "A bit of both. I find it difficult to go and then, if I can describe it, or my stools are more like sheep's dottle." I: "Right, some little pelley things?" P: "Aye, little pelley things. [Right.] Which are hard to pass. So that, you know, that's it really. And just that ... and then sometimes when I get the urge that I want to go and then nothing happens. Because I have to strain." I: "Right, so you get an urge like you want to go to the toilet but when you get there ...?" I: "It's very difficult."

(Patient 23)

Participants who described constipation in terms of frequency and regularity and/or difficulty with passing a stool gave further details in their accounts of how they knew when they were constipated. This broadens our understanding of the meaning of constipation. A general feeling of bowel discomfort was, for these participants, a clear indication that they were constipated.

I: "I'll come back to that. When you have been constipated or you are constipated how have you known when you're constipated?" P: "Well, em, I think I would know simply because I hadn't had a bowel movement and started to feel, err, a bit sort of uncomfortable as though, you know, how it was all a bit full."

(Patient 17)

In their accounts participants described how the experience of discomfort associated with delayed defecation was linked to various bowel 'symptoms' such as abdominal fullness, bloated stomach and 'feeling blocked'. Such 'symptoms' were used by some participants to explain both what happens when they are constipated and what constipation means to them.

I: "So what we're discovering is that constipation can mean different things to different people, so if I ask you what do you mean when you say you're constipated?" P: "Well, I feel sort of bloated and probably haven't been to the loo for several days." I: "Right, you get bloated and haven't been for several days? [Yes.] OK, and now would that be 2 days, 3 days, 4 days, 5 days, is there a usual number of days?" P: "Two to three I should think [2-3 days]. Three days I would be getting worried about it."

(Patient 10)

Feelings when constipated

Participants therefore reported experiencing a wide range of feelings or 'symptoms' when they were constipated (*Box 2*) and described how being constipated made them feel in themselves. Both physical sensations and emotions were included in their accounts.

The details that older people gave to explain their feelings when constipated often varied as much as their descriptions of what constitutes constipation. Sometimes they were vague, and feelings were described as a general sense of unwellness – feeling not right, out of sorts or uncomfortable. Such descriptions seem to imply that participants had difficulty in explaining exactly how they felt, but nonetheless knew that something was not right.

P: "I didn't feel I didn't feel right but whether ... whether that was a mental or a physical ... I mean, I just [right], I just didn't feel right about it." I: "You didn't feel right."

(Patient 5)

P: "Don't feel usual self." I: "Is there anything that you find you do more of when you're constipated than when you're not?" P: "Yes, be bad tempered. I am probably worrying about what's the matters with me, which is again my nature, no apart from that it, yes you don't, you don't feel your usual self, but I cannot think that it puts me back too much in either direction."

(Patient 12)

At other times, accounts were more focused and specific. The most common of these included feelings of bloated stomach, abdominal pain, the need for excessive straining and feelings of incomplete evacuation.

P: "I tend to where I've got every 5 days I can get rid of it [right], but afterwards it never feels as though I've really complete evacuation [does it not?] No, never [right]. I've managed OK, but [a-ha] I've always got a feeling that [a-ha] there's something else that wasn't a good passage that." I: "You never feel completely emptied." P: "Exactly." I: "Right, you feel that something there ..." [talking both at the

BOX 2 Symptoms experienced when constipated

Abnormal decrease in stool frequency (including missing a day)
 General discomfort/uncomfortable feeling (general and/or abdominal discomfort)
 Bloating/swelling of abdomen/abdominal fullness
 Wind/flatulence
 Sensation of stool building up/accumulation of stool and developing blockage of the colon
 Abdominal pain/cramps, commonly associated with decrease in stool frequency
 Continual urge to go but unable to move bowels
 Straining (excessively) at stools
 Feeling stool could not be passed/blocked
 Anorectal sensation that stool is there waiting to be passed
 Trying/going for tries continually
 Back-end discomfort/pain/soreness when passing (usually uncharacteristic and hard) stool
 Decrease in size of stool passed
 Uncharacteristic stools (e.g. sheep dottle, pelleted)
 Hard/solid stools
 Feeling of incomplete evacuation/insufficient defecation
 Bleeding from back passage
 Piles/haemorrhoids
 Loss of appetite
 Permanent or temporary loss of urge to go
 Feeling ill, sick, 'yuck' (nausea)
 Difficult to control and sudden/unexpected urge to go that may result in accidents/incontinence
 Diarrhoea (constipation alternating with diarrhoea)
 Physical sensation of tiredness and fatigue, lack of energy
 Impacted faeces needing hospital treatment

same time]. P: "I still something there to be passed away ... But it's never complete evacuation [no], I always come out of there with I'm pleased with that but [but yeah] I don't feel like I've had a complete evacuation."

(Patient 6)

"Erm, you're tired, you have the pain, pain's the worst. You can't go out, or you don't feel comfortable going out. You tend to lie about more, you know."

(Patient 3)

Other non-specific feelings reported by participants included tiredness or fatigue and, to a lesser extent, nausea.

"I think it did because, as I say, when you are that way you feel well not down but you don't feel as bright, well I didn't feel [a-ha] as bright and as up and running as I normally would. [Yes.] It was like it took the edge off you, you see, you were that bit lethargic at times."

(Patient 2)

"I've found that I feel very lethargic now and [do you?] there's jobs there's quite a few job I've got to do in the house, I say tomorrow [right] and tomorrow never comes."

(Patient 6)

P: "You just feel tired and ... well you don't feel right, do you? If you don't go to the toilet for 12 days?"

I: "Right. So did you feel kind of sluggish or ..."

P: "Yes. Just feel bad, I mean you feel sick, don't you?"

I: "Uh-huh. And did it make you feel tired or was it was it ..."

P: "Uh-huh. Tired and sick and fed up."

(Patient 3)

Emotional feelings that were associated with constipation included feeling agitated, worried, anxious, depressed, miserable, down, suicidal, apathetic, fed up, annoyed, grumpy and irritable. These feelings appeared to be linked to a range of health concerns and beliefs about the implications of an abnormal stool frequency for their health.

I: "Right, OK then, and how do you feel in yourself when you're constipated?" P: "Ooh, very slow and lethargic [do you?], can't be bothered with doing anything." I: "Right, so you feel quite sluggish and [ah yeah] lethargic, OK, and why do you think it makes you feel like that?" P: "I think it's just because I worry about it [you're worried] I know it's not right it's just not, it's abnormal really to be like that all the time [right], but this has been going on years now [right, right]."

(Patient 5)

"A couple of years ago I had a most dreadful, horrific and I did feel suicidal because [right], because I thought it was never, ever, and I this one particular friend I rang her and I said if you don't come and talk to me here I, I just don't know what I'm going to do and I really felt, em that this was, and she, you know talked, and then the next day, bless her, she went through a dreadful carry on with her husband and I was able to comfort her, you know." I: "Right,

right and was it ... ?” P: “I, I felt really, I could, if she hadn’t come and it’s an awful, ‘cause I do think it’s a weakness and people shouldn’t commit suicide, and you shouldn’t, your life’s given to you, it’s not yours to take sort of thing, you know [yeah], em, but em I felt, um, I cannot go on like this [right], and yet, em, that the pain then was really horrific, it was absolutely shocking, I’d had it all day, all day I’d had it, all day [right] and this this was about 10 o’clock at night when I rang her, you know [yeah], fortunately she doesn’t live too far away and she came but em it didn’t subside till well right round till morning.”

(Patient 11)

“Well I think once you don’t go to the toilet that’s it, well in my point of view [a-ha] if I don’t go to the toilet I just can’t do anything until I’ve been to the toilet [right], you know, I’ve got to go [right] because I’m frightened now.”

(Patient 4)

I: “Right, OK, when you have been constipated in the past how has it made you feel in yourself?” P: “Well when I’m occupied doing something you’re mind’s has something else to think about, if you’re sitting doing nothing then your mind immediately latches on to I wish I could go to the lavatory [right, OK], so it’s just, it’s just like anything when your mind isn’t occupied small things become major things.”

(Patient 8)

Some participants initially reported that they did not feel much different when constipated. However, on reflection or in response to more specific questions by the interviewer, these participants often described the same kinds of feelings and emotions as those spontaneously articulated by others.

Health professionals’ views on constipation

How do GPs define ‘constipation’?

From interviews with GP participants, two clear categories of definition emerged: patient-centred and textbook definitions. A number of GP participants used a patient-centred definition explicitly, stating that it was a change from the norm for each patient that triggered their definition and diagnosis of constipation. For the other GP participants, a more textbook definition underpinned how they defined constipation.

Patient-centred definition

The patient-centred definition centred on the idea of a change from the norm, where the ‘norm’ is interpreted as what is normal for that particular person.

“Whatever is not normal according to the patient ... So that they can be know still be normal but it’s new for them and it’s completely different so you can have what seems like a normal bowel habit but it’s new for them, so it is a change or obviously diarrhoea is a change or intermittent diarrhoea and constipation, anything that changes really.”

(GP 5)

This definition also included an acknowledgement that there is a ‘range of normality’ both among patients and within each particular patient.

“Well I think again it’s relative to that person, so eh, ehm, but I think within that person there is probably a range of normality, ehm, which err, which should be accepted. So, for example, for someone who goes every day, ehm, I wouldn’t be that unhappy if that frequency dropped down to three times a week [mmm]. For example, if they were taking medication for some undercurrent problem or if ehm, what I wouldn’t accept is other hallmark symptoms, like pain or like blood or a prolonged change [right] then one might get a little anxious.”

(GP 13)

Textbook definition

The textbook definition centred on the frequency of bowel movements. One GP participant commented that normal bowel frequency is anything from three times a day to once every three days; a comment that reflects expert opinion.⁶⁵ But he also acknowledged that he would take into account what is ‘normal’ for each patient (thereby recognising a more patient-centred definition, as described above). Others defined constipation as being less than three bowel movements per week, while others spoke of ‘loss of regularity’. In their definitions of constipation, all GP participants referred to a reduced frequency of bowel movement; in other words, a relative rather than an absolute criterion.

Most also referred to stool consistency in their definitions, commenting on the fact that, with constipation, patients experience difficulties passing stools or have stools that are hard. Additional factors mentioned by GPs included loss of regularity, increased pain, change in consistency of the stool, discomfort, abdominal pain, patients feeling sickly and bloated, and patients being ‘non-specific off legs, that is for want of a better word ... out-of-sorts, slight confusion, disorientation’. But it would appear to be reduced frequency of bowel movements that prompts the majority of patients to visit the doctor.

“Well, they might have bleeding if they have passed a hard stool [right, as well] or they might come in with

abdominal pain. Usually when they come in about that they come in with constipation and they just say 'I'm constipated, doctor' and it's usually about how often they've been." [It's usually about frequency?] Yes."

(GP 5)

Therefore, in their textbook definitions of constipation reduced frequency was 'often' associated with discomfort, with stools becoming firmer or harder in texture and more difficult to pass from the body and requiring the patient to strain excessively. However, the majority of GP participants put this into the context of what is and is not normal for each individual person and so their definitions also encompass a patient-centred element.

Chronic constipation

The commissioning brief for the STOOL trial focused on the term 'chronic constipation' and this term was therefore one that the research team used. However, when GP participants were asked whether 'chronic constipation' was a term they personally used, a range of responses was received, including that they did not use it at all or used it only sparingly. Some purposefully avoided the term 'chronic', while others used it only in relation to specific manifestations of the condition. Some commented that it was a term they associated more with constipation in children.

In particular, 'chronic constipation' was not a term they tended to use when speaking to patients. GP participants commented that they felt other terms were more appropriate, including: 'long-standing constipation', 'just gone on a long time', 'long-term constipation' and 'recurrent constipation'. Reasons for not using the term chronic constipation with patients varied. For some, constipation was not regarded as a disease in itself, but rather was seen as indicative of something else: another underlying condition or the use of certain medications. There was also a preference not to label diseases in general as 'chronic', but rather to try and move people on from this, while recognising that this does not always work.

"I don't usually talk to people about having chronic constipation . . . I think because starting off with people who first present, you're not expecting to get into that sort of situation apart from specific conditions. And you know, people who in a sense already have it, it's a matter of trying to educate and change, but sometimes you can't, but it becomes a sort of fact of life, but I try to avoid that. I don't think it's a disease in itself."

(GP 4)

In some localities the term 'chronic' is perceived by patients to be synonymous with 'bad' and 'severe' and is avoided by GPs for that reason.

"I don't seem to use that term . . . very occasionally I will say it, especially if somebody has come in and they've said 'Oh I've had constipation for ages'. I tend to use a lot of plain English. I just say 'had constipation for years' and things like that in my notes I don't tend to use many . . . [right, you wouldn't use . . .]. I mean 'chronic' if you say 'chronic' to a patient they just think that means bad, they don't think it means a long time [ah, right] in place name. 'Chronic, oh! It's chronic doctor' and it just means severe, so you've got to be careful what you say really. So I just tend to stick to long time; short time; bad; painful".

(GP 5)

Nonetheless, there were some situations in which GP participants deemed that it was indeed appropriate to use the term 'chronic'. These included in relation to patients experiencing constipation for more than a year, or where it was associated with impacted faeces.

"I think chronic constipation is only a term I would use where it is causing problems from faecal impaction, really."

(GP 10)

GP participants also described people whom they would describe as chronically constipated; these seemed to be long-term users of laxatives who were dependent on their laxatives to move their bowels.

"Yes we do have and we do treat people with chronic constipation. In some of those it's a habit so perhaps people have used laxatives all their lives, who require laxatives to move their bowels, on an ongoing treatment – I think they would come into that category. Even though, perhaps for them the current bowel movement is set in a pattern."

(GP 13)

"I mean obviously there are people who we still have in the system who are long-term users of laxatives, who have a chronic condition either because of whatever started it off or because they are habitual laxative users, but I mean I don't usually talk to people about having chronic constipation."

(GP 4)

Sharing a definition of constipation with older people

GP participants were asked whether they used a similar definition of constipation to their patients. Even before the interviewer posed this question,

three GP participants had already commented that they felt patients may well define constipation differently from themselves as clinicians, indicating an awareness of the difficulties inherent in using the term.

“I think what I understand by it and what the patient understands by it is often quite different.”
(GP 10)

“Em, well what I understand and what patients understand are probably two different things.”
(GP 13)

Most GP participants felt that their own definition of constipation would differ from that of an older person in some way. Half of the GP participants felt that older patients had an expectation influenced by long-standing cultural beliefs that they should move their bowels every day and hence if they did not do so they may perceive themselves as constipated. Older people were referred to by these GP participants as a homogeneous group and hence this perception was applied to all older patients.

“‘Doctor I only go every two days.’ – ‘Does it hurt?’ – ‘No.’ – ‘Is it soft?’ – ‘Yes.’ – ‘Do you bleed?’ – ‘No.’ – ‘Would you be aware of it if you were not thinking about it?’ ‘No.’ They think because their granny has told them that is not enough ...”
(GP 13)

Other GP participants were less inclined to see older people as a homogeneous group; this group consequently suggested that older people may have varying beliefs. Nevertheless, these participants recognised that some older people still believed that one should have a daily bowel movement.

“I think there’s a wide spectrum of views of older people. Some of the people have, you know, the old-fashioned view that you must go every day and that everything else is not normal, and some people will have being going once a week all their lives and consider that perfectly normal, and everything in between.”
(GP 5)

The use of the term ‘old-fashioned view’ in this quotation contrasts with the perspective of another GP participant who suggested that there had been a change over time away from the perception of the daily need for a bowel movement.

“I think there seems to be a lot less [sic] people coming along saying because I haven’t been every day.”
(GP 4)

How do practice and community nurses define ‘constipation’?

Accounts by practice and community nurses (nurse participants) of their definitions of constipation were similar to those of the GPs. Nurse participants’ definitions were less likely to have any grounding in the Rome II criteria, and the distinction between a patient-centred definition and textbook definitions was less clear-cut in this group of participants. Rather, their accounts focused on changes in a patient’s bowel routine (reduced frequency of bowel movements) and different ‘symptoms’ of constipation, such as hard and difficult to pass stools.

I: “Right, OK then, thanks, and just moving on to, ehm, looking at constipation, what, ehm, do you understand by the term constipation?” Nurse 1 (N1): “Now, come on, you’ve got that ehm nice little” [*laughing*]. N2: “Ehm, when you find out what their normal pattern is and then if it’s abnormal to that pattern and also description of the stool itself.” [I: Right, OK.] N2: “So it is not a sort of definition as such, but it is if they haven’t had their bowels moved for several days [right] and whatever the bowel content was beforehand.” I: “Right, OK, so you are looking at kind of stool consistency. [Yeah.] And would that be in terms of it being harder than usual or just different from usual?” N2: “Harder. We tend to use the Bristol Scale here.” I: “Ah, right, the Bristol Stool Form Scale? [Right, OK]. And you’ve mentioned not as frequent passage [of stool], so how [pause], have you got any idea how long somebody would have to have not been for before they would be considered constipated?” N2: “Well, it depends on them.” I: “It depends on what’s normal for them?” N2: “What’s normal for them.”
(Practice 2)

I: “No, no, OK thanks [papers shuffling], and what do you kind of understand by the term constipation? You know somebody, if that term is used, what do you understand by it, what do you think or what does it mean to you?” N1: “It usually means absence of a bowel movement.” I: “Right for a certain length of time or ...?” N1: “Ehm well everybody classes constipation as different [yes], so some people can go 3 days and be normal and others can go, you know miss a day going to the toilet, and they say they’re constipated [right], so we just tend to go by what the patient [right] what the patient classes themselves as ...” I: “Classes themselves as, so if it not the norm for them [yeah] that would be the definition, but it’s usually centred around frequency, is it of going?” N1: “Usually, I mean, the more complex cases they will ring and say I haven’t been for 8 days and I mean obviously 8 days is too long to go.” I: “Right, right, OK. And I mean is your, I mean would your definition be any different to that?” N2: “No.” I: “It’s similar? [Mmm.] Right, OK. And have you yourself got an opinion on what, ehm, is constipation, you said evidently 8 days would be too long, I mean would it,

when would it ... you know, is 1 day OK but 2 isn't or is 2 OK or 4 isn't or does it depend?" N1: "It just depends and again if the bowel motion is changed and it is hard – hard for them to push out and obviously to me that's constipation as well." I: "Right, so even if it was just a hard bowel movement without having missed a day that would still be ...?" N1: "I think you can start to think about it." ... N1: "It's where somebody can't pass a stool comfortably [right] and it isn't acceptable for them because constipation for one person might be different, you can't really put a time on it because somebody might just normally go every 3 days, 4 days [a-ha, a-ha], but it's when it's uncomfortable for them to pass it and they have to strain [right] and, you know." I: "So you've got an element of frequency in there and also, ehm [consistency], consistency and uncomfortableness passing a stool. Alright, is there anything else anybody would add to that?"

(Practice 3)

I: "Right, thanks for that, thanks. Ok, and I mean to you, what's your definition of constipation? How would you define constipation?" N2: "Constipation is, em, when a person isn't, is out of their normal bowel habit, routine [right], routine, when they haven't had a bowel motion, you know, in a, in a different way to what they would normally do [right, OK]. If, if they had their bowels open every 3 days and it's gone to every 5 or 6 days [mmm], well then" N1: "Like a change to the norm." N2: "... I would consider that a change, change to the norm" (N1/N2 speaking together). I: "And is that, is that your definition?" N2: "A change. Some, some people go twice a day, some people go once every 2 days or whatever [right], e-em" I: "So a change to what's normal?" N1: "Like a body change [for them?] For them, that's right." I: "In terms of becoming less frequent?" N2: "Yes, less frequent, yes." I: "Right, so a change in terms of becoming less frequent?" N2: "But, unless, unless there's the alternative where they've suddenly become having loose stools and are incontinent, of loose watery stools and then I've got to think, hang on here, are they constipated, and, truly constipated and are they having em, a by-pass of faecal overflow [right]?"

(Practice 6)

Chronic constipation

In contrast to the GPs, nurses commented that the term chronic constipation is one that is used in their practice. For some nurse participants, 'chronic constipation' is a long-standing problem that is not resolved after lifestyle advice and months of treatment, or is something that happens recurrently.

I: "Right, OK, and what would like chronic constipation mean to you – what would ...?" N1: "Somebody who has the problem over a long period of time – it's not just an acute thing that's happened as a one-off – it happens recurrently." I: "Right, so it

happens recurrently and would that be for like a certain number of weeks or months or ...?" N2: "It could be, sometimes we get patients who are constipated for maybe 3 or 4 weeks at a time and then they are OK and then you don't hear from them and then they come on the books again." I: "Right, OK, then, thanks." N2: "All depending on what their illness is." I: "Right then, OK, thanks, right." N2: "You know, it could mean that they are always prone to this problem."

(Practice 3)

For others, 'chronic constipation' was where the potential cause cannot be identified and the bowels are not likely to get better. Patients who were perceived as dependent on laxatives were also described as having 'chronic constipation'.

N3: "I think if it maybe had been a long-standing problem. [N1: mmm, mmm]" and even with advice and things it's still not." I: "Right." N3 and N2 (talking together): "Yeah, yeah, I would I... yeah is that" N1: "It could be dietary, it could be somebody who, it's their diet and they just will not change [mmm], you know, and I think even sometimes elderly people in particular who have, ehm, you know got into the habit of taking medications, often are resistant to them as they get older, the ones who took them for a clean-out when they were younger, you know, and things."

(Practice 6)

For some nurses the term 'chronic constipation' equals severe constipation.

N58: "It tends to be lactulose [right], but I have on a couple of occasions suggested Movicol for patients who I've thought had chronic, really bad constipation and for example, a lady with, em, dementia who, who was having really hard stools and was taking senna and lactulose with very little sort of ... , but the, but the ... what the thing was with this lady was that she was, em, frightened to sit on the toilet and frightened to pass this hard stool, so it was in a bit of a, em"

(Practice 4)

Sharing a definition of constipation with older people

Like most of the GP participants, the majority of nurse participants felt that their own definition of constipation appeared to differ from that of their patients. The following unanimity of response was experienced in most of the group interviews:

I: "Ok, thank you, right, I mean from your experience do you think an older person uses the same definition as you do when they're talking about constipation?" N1 and N2 (talking together): "No." I: "No, neither of you do?" N2: "No".

(Practice 2)

Some of the nurse participants commented that when old people speak to them about being constipated they usually use terms such as 'bunged up', 'haven't been' 'not going'. The vast majority of nurses, however, seemed to agree that for older people, constipation tends to focus around the notions of infrequency and, to a lesser extent, on difficulties passing stool, usually because the stool is hard, but also because of excessive straining or the need to strain.

I: "So do you find that older people are describing the constipation of not having gone for a day?" N1 and N2 (together): "Yes." I: "So it tends to be the frequency that they're focusing on [yes] rather than the stool consistency or anything like that?" N1 and N2 (together): "Yes."

(Practice 2)

I: "OK, right, OK thanks, OK. And if an older person is saying to you that they are constipated what kind of things can they mean by that?" N1: "Well usually they mean that they haven't been for their regular routine." I: "Right, right, so is it usually about not having gone at all rather than hard stools or pain, or does that come into it as well?" N1: "They don't often mention they've got hard stools, it is usually a case of 'I haven't been'."

(Practice 3)

N1: "Some, some people go twice a day, some people go once every 2 days or whatever [right], e-em" I:

"So a change to what's normal ...?" N1: "Like a body change ..." I: "... for them." N2: "For them, that's right." I: "In terms of becoming less frequent?" N2: "Yes, less frequent, yes."

(Practice 6)

Summary

What emerges from these different accounts of patients and health professionals is a common understanding of the general nature of constipation, but also considerable differences of perception among both patients and health professionals and between the various groups. Like many health problems managed in primary care, constipation means different things to different people. Even when health professionals are aware of formal methods of defining constipation, such as the Rome II criteria or the Bristol Stool Scale, they tend not to apply these methods in their clinical practice. Rather, they accept and work with patient-centred definitions. The implications of this diversity of perspectives for the implementation of constipation intervention studies are considered in Chapter 9. But first, this work turns to the question of what patients and professionals understand to be the causes of constipation (Chapter 6) and their management of constipation (Chapters 7 and 8).

Chapter 6

Perspectives on the causes of constipation

Overview

As shown in Chapter 5, there is considerable diversity of views about the definition and meaning of constipation within and between older people and health professionals. A similarly wide range of beliefs about the cause of constipation was apparent in the interviews with older people and health professionals.

Through the analysis of the interview transcripts, a number of broad categories was identified from the interviews with patients. They variously believed that constipation is: (1) linked to specific diseases, medical conditions or health problems; (2) caused by the consumption of specific medications or the result of particular surgical procedures; (3) caused by diet or eating habits; (4) part of the ageing process; (5) due to not going to the toilet when one has the urge to defecate; (6) hereditary; (7) caused by stress or worry; and (8) caused by environmental exposure.

GP participants provided a more focused but not dissimilar subset of explanations. They focused on the increased prevalence of constipation with age but suggesting that this was variously due to changes in diet and lifestyle, the physiology and degenerative processes of ageing, and the iatrogenic impact of opiate medications.

Nurse participants provided explanations for the causes of constipation that had commonalities with both the older people's perspectives and the more focused GP perspectives. They suggested that constipation is linked to decreased mobility, decreased food intake, decreased fluid intake and the consumption of certain medications.

Health beliefs and the causes of constipation

Within the behavioural and social sciences, particularly health psychology and medical sociology, a range of understandings and models has emerged to investigate the way in which individuals perceive their own health and the factors that they believe contribute to health and illness; see, for example, references 66–75. As

highlighted by one review,⁷⁶ a clear distinction has emerged among the lay population between health and disease and how ideas about causation of illness or disease are separated from lay perspectives on the maintenance of health.⁷¹ There is an apparent recognition that lifestyle behaviours are important for maintaining health, but lay understandings typically emphasise biological rather than behavioural causes of illness.^{66,67} Older people's accounts of health and illness in general (and in the focus of this report, constipation) are diverse because they are individual and social beings⁷⁷ and consequently are influenced by cultural, medical and social ideologies. Thus, for example, Chapter 5 showed how social mores of older generations influenced participants' perspectives of what was the 'normal' frequency of bowel movements. How did older participants explain the causes of their constipation?

Older people's beliefs about the causes of constipation

Older participants were asked to think about the causes of constipation and other bowel problems. For a minority, their initial reaction was that they were unable to specify a cause.

"No, no, none whatsoever. I just couldn't understand it myself how it just hit us like that [a-ha out of nowhere], I mean it had of been like a couple of days and trying to go [a-ha] and I couldn't [a-ha] I was just [a-ha] it hit us."

(Patient 4)

P: "Phew, no, I can't, I'll be honest, I just wouldn't." I: "You don't know? [No.] There's nothing when you look back you think on I wonder if it was that or I wonder if it was this?" P: "No, I've never. In fact I've never thought much about it really." I: "No, no. So you're not sure where it might have come from?" P: "I've no idea."

(Patient 13)

I: "OK then, right, thanks and do you have any, em, like idea that you might suffer from constipation?" P: "No, none, 'cause I eat, I think I eat a fairly healthy diet, lots of vegetables, fruit and salad and things like that." I: "Right, right, OK, have you ever asked the GP that you see why you might be constipated?" P: "Yes, well I don't know about why, I just tell him I am, you know, yes." I: "You are, right, right, does he give you any indication as to why? [No, no,] No, so

you've no real idea why this might have happened?"
P: "No, not particularly."

(Patient 10)

This last interview extract shows an example of a participant who was unable to suggest a cause for his or her own constipation, but was nonetheless able to offer an understanding of what might prevent bowel problems in general. In contrast the majority of older participants were able to offer a number of explanations of the causes and for some it was described as a combination of factors.

For example, a man aged 59 offered several different causes for the onset of his bowel problems. He thought that his "appalling" dietary habits during his working life were to blame for his problems with constipation and seemed to believe that not eating properly and regularly were the main reasons for his problems.

P: "Ehm, when I was working, again when you look back at the problems that I've got now, ehm, my diet habits were absolutely appalling. I mean I could be out of the house maybe 5 o'clock in the morning to travel across the west coast to work for a day, I'd have a cup of tea and during the course of the day I would rather work and get finished and get back home [right]. I would have half a sandwich, half a cup of tea and that would be it all day [right] until I got back [right]. So really speaking I didn't do myself any favours in that respect [a-ha, a-ha] but, ehm ... It could have been about ten ..." I (overlapping): "could have been about ten?" P: "... ten but I used to put it down to the lifestyle, not eating properly [right] and I thought it is possibly my fault [right], dodging meals and not taking regular meals and one thing and another, but er ... Ehm, as I say again, at the time I didn't put it down to being out of the norm. I just thought it was lifestyle and the fact, you know, the fact that I wasn't eating regularly or properly. ... As I said the only thing I can think of as I say for 24, 39, - I was 25 year [a-ha] as a field service engineer. As I say my diet was very poor, I used to eat basically to fit the job [yeah]. If I wanted to get back home at any time I would skip lunch, just get on with the job, finish the job and drive back home."

(Patient 2)

However, he also wondered whether ignoring the urge to go due to the nature of his work (a crane worker) and lack of available toilet facilities on site may also have contributed to his bowel problems.

P: "A lot of the times where you worked, i.e. you could be working on a crane stuck in the middle of nowhere [yes], there was no toilet facilities to use [right]. So the times when you wanted to go, you couldn't go [a-ha] and whether that was part of the problem I don't know." I: "Right, right. Do you think that might have

something to do with it that you sometimes you wanted to go but you had to kind of just ignore the urge did you?" P: "Well you had to basically, I mean as I say a lot of the places that you went to where cranes were on construction sites, and I mean I am going back about 20 year ago, you didn't have the toilet facilities that you have now [right]. You know, things have moved on vastly in the industry [right], those times as I say you know if you wanted to go for a pee sort of thing there was no problem, I mean if I wanted to use the toilet and there wasn't one there [yes] you basically had to override the idea and just try and get on with it like. ... And you know [a-ha] and when you did go obviously it was difficult but at the time you never, I never put it down to being like a medical complaint [no, no], I just thought it was the way I was running my life."

(Patient 2)

This participant linked his more recent bouts of constipation to his diagnosis of irritable bowel syndrome (IBS) and the consumption of certain medications that have constipating side-effects. This belief appeared to have been influenced by the opinion of medical professionals trying to investigate the underlying causes of his various health problems. This individual had been diagnosed with various conditions that may manifest themselves in terms of intermittent periods of constipation (e.g. IBS) or may cause stomach pain and discomfort (e.g. duodenal ulcer), symptoms which in the participant's mind are symptoms of constipation.

I: "Over the years, I mean looking back at the bowels now, how have your bowels been over the years?" P: "I went through a bad spell, ehm, again it must have been maybe 5 year ago and I used to get bouts of constipation, chronic diarrhoea and again they sent me for blood test and they found out the liver enzymes were high [right]. They referred me to hospital who reckoned the problem was I was taking eight co-codamols [a-ha] a day for the pain for the arthritis and that was affecting the liver and was causing the problem, so they've stopped the tablets, but to be on the safe side they sent me in for, ehm, to get the cameras down to look through the back body [right] and they found out I had duodenal ulcers [ah, right], so they cured those. But even then after that I used to go through bouts of constipation, bloatedness [a-ha], you could sit down at a night time and your tummy could be out here! [Would it, right] And again went back to the doctor's and went back through the notes and he seemed to think it could be irritable bowel. ... and he said, well obviously they seem to think you could have you know a touch irritable bowel so we'll go down that road and treat it [yes], if it doesn't work we will refer you back to the hospital. If you find you've got comfort we will just leave it as it is and I felt, you know, reasonably well."

(Patient 2)

Finally, this individual also felt that his general anxiety and worry had contributed to the deterioration of his constipation and aggravated existing bowel symptoms. This case example illustrates a common experience of older people and the variety of explanations that they may have for their constipation.

Among the older participants bowel problems and constipation rarely existed in isolation. Co-morbidity and the use of several medications were not uncommon. Participants were particularly likely to highlight painkillers and anti-inflammatory medications as one cause of their constipation.

There was also some uncertainty in some participants' minds about what caused constipation. This resulted in participants offering multiple, and sometimes contradictory, explanations during the course of an interview. For example, one man in his seventies had undergone various operations (apparently related to his bowel) for cancer, but exactly what sort of cancer he had been treated for remained unclear. When asked whether he had any idea as to the cause of his constipation he replied:

“Well, it's just because I have had cancer isn't it? It must have been, yeah.”

(Patient 1)

However, later on he contradicted himself and said that he did not think that his cancer and constipation are related:

I: “Right, OK, right ... so you mentioned before that, did you think the cancer that you had affected the constipation ... do you think that was the cause of it or do you think the two weren't related?” P: “No, I don't think they were related, no.”

(Patient 1)

Eventually it became clear that he had been diagnosed with cancer about 4 years before the interview. However, he felt he had been suffering from constipation since his thirties. This example

highlights potential difficulties that participants may have in recalling the chronology of the events that led to their constipation. It may also be the case that, when participants speculate about the cause of constipation, they refer to more recent bouts of symptoms as opposed to the original onset of constipation in the past.

Box 3 summarises participants' accounts of the causes of their constipation.

Links with coexisting disease or other health problems

Colon cancer, encephalitis, IBS, diverticular disease, bowel polyps and piles (haemorrhoids) were all mentioned by participants as a potential cause of their constipation and bowel problems. This is perhaps not surprising given that many participants reported experiencing these diseases or health problems.

“... and then it was only in, well in the latter years, well again I had a long period when things were fine [ah-ah], and then of course, I blame em haemorrhoids, I blame myself for haemorrhoids for me, don't I, because obviously I must have put on weight, I must have aggravated something, I've, I've started something off haven't I?”

(Patient 11)

Another woman in her seventies had been diagnosed with diverticular disease (diverticulitis) and assumed that this was what caused her constipation:

“I have no idea ... ah well, because I have bowel, what is it, diverticulitis ... so that causes it.”

(Patient 3)

When asked whether she was told that this was the cause of the constipation she replied:

“Well I think it must because it's not normal, is it?”

(Patient 3)

It is interesting to note the link between having haemorrhoids and suppressing the urge

BOX 3 Beliefs about the causes of constipation

Linked to specific diseases, medical conditions or health problems (e.g. IBS, haemorrhoids or cancer)
 Caused by the consumption of specific medications or resulting from surgical procedures
 Caused by diet or eating habits
 Part of the ageing process
 Due to not going to the toilet when one has the urge to defecate
 Hereditary
 Caused by stress or worry
 Caused by environmental exposure

to go made by the same female participant. She used to avoid straining and put off her urge to pass a stool because of painful haemorrhoids and fear of being hurt. This, in her opinion, is how her constipation had started. This example illustrates how lay strategies to manage haemorrhoidal pain, such as avoiding straining and suppressing the urge to go, may lead to constipation; this is a somewhat different experience from ignoring the urge to go due to social inconvenience or lack of readily accessible or acceptable toilets (see below).

“A-ha, I think it must have been when I had haemorrhoids and I was putting off when I went to the toilet because it hurt you then, I think that was part of it. [Right.] You know, you wouldn’t go because when you were straining, you were pulling them down and then they would hurt you [yeah], so I think that’s how I think that started.”

(Patient 3)

Another female participant wondered whether she had a tight anus which led to difficulties in passing stools:

P: “Well 2 days I would be constipated at 2 days [at 2 days] if I didn’t do anything about it [right, right, OK, that’s fine], I would have the greatest difficulty in evacuating it after that day [together].” I: “Right, because it would be a lot harder?” P: “Hard, yes, and I sometimes wonder if I’ve got a very tight anus.” I: “Ah, because you find it difficult to pass the waste through? [Yes, yes.]”

(Patient 19)

Medication side-effects

Constipation and bowel problems were also commonly believed to be caused by a number of different medications taken by study participants. General medicines, pain killers (e.g. codeine, co-codamol), anti-inflammatory drugs such as Voltarol[®], the cholesterol-lowering medication Lipitor[®], insulin and medications containing calcium were all mentioned among those believed to have led either to the onset or exacerbation of participants’ constipation.

“So, of course, I’ve been seeing the doctor and then had an X-ray and they discovered that was where what was causing all the acute pain. And also at the same time they discovered that there was a certain amount of osteoporosis which I never knew I had, you know, and of course then I was on such a high dosage of painkillers, that’s when I became so constipated. I mean I did have slight problems beforehand but nothing like that and of course with the painkillers they can be very constipating.”

(Patient 23)

One participant reported that at one time he used to take 20 different medications and suggested that taking too many medications may also explain part of his constipation.

Wife of participant (PW): “But I remember at the start you took so many pills, he was taking about 20.” P: “They blamed them at first.” PW: “And I think that that helped cause some of the constipation.”

(Patient 14 and wife)

Some participants connected the adding-on of or changes in their prescribed medication for another health condition with the exacerbation of symptoms of constipation.

I: “And if you look at your bowels over the years, so if you go back many years to childhood and your adulthood, did you have any problems with constipation then?” P: “I don’t think so, I can’t remember.” P: “And can you remember how long ago the constipation started?” P: “Well, I won’t say it was as soon as I took insulin but obviously before that, don’t know about constipation, but I found it more difficult sometimes to pass, but it certainly came on worse when I had the insulin.”

(Patient 20)

Participants also reported laxatives taken for constipation and the side-effects of prescribed medication taken for another disease may have opposite effects with respect to bowel activity. This was often seen as a balancing act between treating certain important health conditions with medications that may have constipating side-effects and trying to maintain normal bowel functioning and prevent constipation.

“Again I mean when you look at the two tablets they do different things for different complaints, I mean they seem to oppose each other but by keeping it the way it is [a-ha], taking those and the Fybogel, I’ve found it seems to keep things in check.”

(Patient 2)

P: “You see, when I got the codeine, the doctor says mind it might bung you up! But it was OK, it’s been alright, was it last week, I said or not long ago anyway, that I had a bit of difficulty, but I was taking codeine then of course. But the idea was to have a little bit stronger than the paracetamols for my toe, because I was having difficulty, but I don’t always, you see in the morning, I take an aspirin, so I don’t take codeine in the morning, I took one paracetamol and an aspirin. I take the aspirin because I had two slight strokes a long time ago now, 10, 12 years ago, and I still take them, but I don’t take them all together, you see.” I: “But you take your codeine when you want a little bit more of the pain relief?” P: Well it was at night mainly. I don’t know whether, it worked I suppose.” I: “Do you notice that when you do take the codeine,

you do get a little bit more bunged up?” P: “I hadn’t really ... but last week, it could have been that, because that’s when this left toe started, well was a bit painful.”

(Patient 20)

Diet and eating habits

Participants associated constipation with diet and poor eating habits. Specific dietary behaviour reported by participants as causes of their constipation included not eating much in the past, an irregular diet and missing meals, and a diet low in foodstuffs containing sufficient roughage. Others referred to the effects of particular foods on the bowel function.

P: “More loose, that’s the way to put it – more loose than it should have been anyway really. I thought, oh, by gum. But I did have the orange yesterday. I think another thing it depends on what your diet is it must be mustn’t it? Do you think it could be?” I: “It could be what you’re eating.” P: “I don’t know. I think sometimes you take, eat something and you think, you know, and the next day you haven’t been very much at all. Like I say, touch wood, I go the once, you know, like in the morning.”

(Patient 7)

“But, um, that might be due to the fact that, um, I ate slightly different things last week, um, I don’t know, and but other times, hopefully, if, you know, if I’ve taken medication on time, that I, I will have a bowel moment of sorts, yes, you know.”

(Patient 8)

“Aye, well I think it is a lot to do with what I’ve eaten. I think I should really – I’ve not mentioned it to the doctor X, I was going to see a dietitian and see if I could be put onto a diet [right]. You see the day there, I get my breakfast and sometimes I will not eat no more until 5 o’clock at night [yes]. You see if you are not eating regularly you cannot expect to be on a regular basis [right, right, a-ha]. You see, that’s what I said, the daughter said the same, if I could make it breakfast time, sort of lunch time [a-ha] and night time Because when I was coming in at night I was only eating my dinner I was only eating half of it or maybes some night I wouldn’t eat it at all [not at all?], aye, I think on the whole I was really doing a bad thing because we were living on sandwiches all the time – see we were on the tractors and when I was out contracting and you are self-employed [a-ha], I mean you are going to bash on and we were driving [yeah] and we used to have a box of sandwiches and a flask of tea in the cab and, er, we used to just eat the sandwich or a cup of tea as we were driving [a-ha] and I think that was not a good idea [right, right]. I think that would start nearly everything off.”

(Patient 21)

Diet poor in fibre was another common theme that emerged from the data and may reflect

participants’ awareness about health-promotion messages with respect to constipation.

I: “Right, right yeah, and when you look back into the past maybe when you were in forties and fifties did you have any idea then why you were getting constipated?” P: “Em, no, no, not really I felt it’s em perhaps it’s just one of those things [those things], I thought I might not be eating enough roughage [right, right] and that sort of thing.” I (picking up on an earlier comment): “Ah, ah, but more recently you think it’s because you’re perhaps less active?” P: “I’m much less active, yes I was a very active person.”

(Patient 19)

It appears that most participants were aware about the current professional advice and health-promotion messages regarding the benefits of a fibre-rich diet for maintaining healthy bowel functioning.

“Because of the food, you see, which though everything was wholesome and, er, well cooked but in those days it was always pies and puddings and home-made dinners and big stews and things, pies, pie crusts and all that see, and we were very well fed and very well looked after, I’m sure, but possibly we should have had less and more of roughage or more of cereals, or more of whatever they tell you to have now, yeah.”

(Patient 11)

As a consequence of these messages, a number of participants had made certain adjustments in their diet and perceived that their current diet was healthier as compared to the distant past. For example, one female participant commented that years ago people used to have unhealthy diets. She became a vegetarian later in her life; in her opinion this change was a great help and had made a big difference to her more recent experience of constipation.

P: “Well, I have wondered that, I mean, em, I mean years ago I think people had rather unhealthy diets and when I look back [*laughing*] at the kind of food we had I don’t know whether it was anything to do with that, I mean my father I remember was constipated, yes, and he at one time had these charcoal biscuits, I don’t know whether you’ve ever heard of those, but he brought home these charcoal biscuits one time, that’s sort of stuck in my mind that he was taking them because this was supposed to happen, and, em, I don’t know really I mean my father was person who had quite a few problems and might be a bit sort of nervous type of person, and whether that affected it I don’t know really, eh.” I: “Right, right, I mean would you say it would be more the diet-type factors than the family history, or, or do

you think it may be both?" P: "Well I mean in view of fact that it seemed to be greatly helped by my changing to a vegetarian diet when I was obviously a lot older, I think diet could have been relevant."

(Patient 17)

Advancing age

Advancing age was believed by some participants to be the cause of their constipation or deterioration in bowel health. Some felt that with advancing age there had been a slowing down of their overall body functioning and in particular their bowels.

P: "I mean, I don't, I try not to worry about . . . I mean, I don't worry about it, but every now and again you think, oh dear me, you know. I mean I realise as you get older you know things tend don't work as well as they did when you were in your twenties or thirties, but I mean that's just a fact of life, you know." I: "So it's not causing you kind of undue worry or concern?" P: "Oh, no, no, life's too short for things like that you just get on with it and I just think well, you know, it could be much worse."

(Patient 23)

I: "Have you got any idea why you suffer from constipation?" P: "I think, well it's just opinion, that I'm getting older and my bowel's getting a bit lazier and isn't working as efficiently." I: "So you do see this as part of the ageing process?" P: "I do, I may be wrong on that." I: "Why do you think you see it as part of the ageing process?" P: "I suppose because everything was normal as I say, up until I was about 50 and then just suddenly gradually gets not so good, you know? . . . I sometimes have difficulty especially at the minute, clearing my system. I go in the morning alright, then later in the morning and then probably later again in the day, you know, so when you're younger, you can go and clear your system and that's it, but I'm everything kind of sluggish."

(Patient 24)

Several participants linked the decline in their normal physical activity, due to ageing and ill-health, to the onset of their constipation or deterioration in their bowel habits. One man, for example, described himself as having been 'regular' all his working life and believed that his problems started after he retired. He felt that the fact he lost his daily routine and became less active may have contributed to his constipation.

"I can't think of anything really, I've never been a good breakfast eater, but whether it was the activity of work itself or whether it's just, er, getting into a habit of going every morning and maybe that helped, getting up and getting ready and getting out to work, maybe that, er, I've lost that routine, you see."

(Patient 6)

A female participant connected the onset of her constipation in the past with having inadequate roughage in her diet, but linked her more recent bowel problems with becoming less active and with getting older.

P: "Yes, I think it was there wasn't anything abnormal except a diverticulum, but I mean it wasn't bothering me. [it wasn't?] No." I: "No, right, did they say that, were they able to give you any causes as to what was causing the constipation?" P: "Emm. No I can't say they did, I had no conversation with the, eh, surgeon afterwards and, eh, I think probably just getting older and not as active as I used to be you see I couldn't go at the same pace." I: "ah, ah, what do you think's caused it, is it the less activity, I mean have you got any idea why you might suffer from constipation yourself?" P: "Em, I think probably partly because I'm not as active as I was, I mean I used to do an awful lot of walking and running and I cared for my mother, [she] was 94 when she died with Parkinson's disease and I was up and down the stairs like a machine [yeah, yeah] and that sort of thing [right], so even if it wasn't exercise outside it was inside." I: "Right, right, yeah, and when you look back into the past maybe when you were in forties and fifties did you have any idea then why you were getting constipated?" P: "Em, no, no, not really I felt it's em perhaps it's just one of those things [those things], I thought I might not be eating enough roughage [right, right] and that sort of thing." I: "Ah, ah, but more recently you think it's because you're perhaps less active?" P: "I'm much less active, yes, I was a very active person."

(Patient 19)

One male participant suggested that with becoming older he was not eating so much and thought that this may also have played a part in his more recent problems with constipation.

"I think that be a lot of causing my bowels not functioning every day. You see I used to go, when we were working steady and that, without fail you went every day [right] but since you stop and I've not eaten much [mmm]. I say to myself, well, if you are not eating well you cannot go to the toilet."

(Patient 20)

Ignoring the urge to go

A number of participants believed their constipation may be due to the fact that they suppressed their urge to pass a stool. For some this was to avoid haemorrhoidal pain (as discussed above), while for others it was because of the inaccessibility of suitable toilets owing to the nature of their work or a preference towards using their own toilet. One participant described it as laziness:

P: "The only thing I could think was laziness, you know, putting off going." I: "Did you find that was

something you did in the past, like lack of time to go to the toilet?" P: "Well, it shouldn't have been, you should always find time, but I don't know it just seemed to creep up on me." I: "So did it gradually get worse over the years?" P: "Oh yes, I think so." I: "It wasn't like a sudden thing that came up on you all of a sudden?" P: "No, oh, no." I: "It was building up over time?" P: "Yes."

(Patient 15)

Earlier in this chapter, the problems of the crane operator who attributed his constipation to the lack of toilet facilities at work were described. Other participants connected the start of their constipation with the suppressing of the urge to go while at work. For example, one woman described how she delayed going until she returned home because she was reluctant to use the toilets at work.

I: "Right, OK, thanks. I mean going back, kind of going back a little while first, go back to childhood, now you've mentioned already about when you were a child you didn't seem to have any, no problems with your bowels. In young adulthood, which I think you've mentioned, you started work. Do you think, is that when you see this pattern as having started?" P: "Definitely. That's when I feel it started." I: "Right, and why do you think you can link the two?" P: "Well my only reason is that I would put off going at work until I got home at night." I: "Was that because you didn't like using the public toilets?" P: "Using the public toilets, using the toilets at work." I: "Is that any public toilets? You only like your own, because some people do, you only like your own toilet or can you use toilets in other people's houses, but not toilets in the town or toilets in the shops?" P: "Well, I'm like that I think in other people's houses." I: "So you really just like going on your own?" P: "I do really." ... I: "Yeah, right, OK. So when you started work were you getting, I mean I don't know if you can remember but would you get an urge to stool but suppress it?" P: "Yes, I suppose I did. That's what I think happened." I: "Yeah, right. And do you see that as having contributed to the problem, to the constipation, the fact that you were putting it off?" P: "Yeah, that is my reason for it." I: "That's what you think was the cause of it?" P: "Yeah." I: "Right, OK, that's fine. Right. Have you ever explored that as a possible cause with the GP?" P: "Well, as I say, I did once say to him about that, but he thought that there was more to it than that."

(Patient 22)

Hereditary

A number of participants linked their constipation to a hereditary predisposition or a 'faulty gene'.

"Well, I was concerned, you know, I don't want to sound like a martyr, I thought I'll put up with the pain, but em, really it was because I knew that there was a history in the family of bowel problems and

knew how my mother had suffered and I knew how she used to tell me my, her father, my grandfather, suffered and so I thought well if this is a hereditary thing I had better get it checked, you know."

(Participant 8)

I: "All the time, OK then, right, thanks. Why do you think you might suffer from constipation, or have suffered, have you got any idea?" P: "Well me family has, me father was the same." PW (overlapping): "His father always was" I: "Right, right [yes]. Right, so do you think it's in your family?" P: "I think so."

(Patient 9)

Another male participant speculated that perhaps a "little faulty gene" in his system probably led to his constipation:

"Well I presume it's a little faulty gene somewhere [laughs] [right] in the system, there's a little something in the system, er, these kind of things that creep up on you and I suppose thinking back the first couple or three times it happens to you, you think what's going on here [right] and then gradually you accept it as being the normal [right] the norm."

(Patient 12)

Worry and stress

A few participants linked their constipation to psychological causes such as worries and stress. A male participant who suggested various causes for his bowel problems, including having IBS, felt that during periods when he was uptight or was worried his bowel problems become worse.

"I don't know whether it could be me, but I get the impression that if I got uptight, if I had a lot of worry [a-ha] that could make the problem worse as well [right]. Now I don't know whether that is part of being constipated or part of something else [a-ha] which could have linked with what they thought was the, ehm, irritable bowel [right, right], but that's something else I've found, if I had major problems whereby where work was going wrong or things like that [a-ha] that would sometimes [right] throw me."

(Patient 2)

Another man recalled that his doctor suggested that part of his bowel problems might be illness or stress related:

"You know, I mean, he did say, he said all along any of these problems I've had... could have been related to the illness [yeah] or stress related."

(Patient 5)

Environmental exposure

Other less prominent suggestions about the cause of constipation included exposure to occupational hazards such as "chemicals":

“Another thing that could have been wrong with me was that we were working with some funny chemicals [right] and there were some fellows died with them.”
(Patient 21)

GPs' perspectives on the causes of constipation

As illustrated above, older participants' beliefs about the causes of constipation are varied and complex. In contrast, the views of GP participants were more focused. From the interview transcripts, three main factors were identified as causing constipation in older people: diet and lifestyle, physiology and degenerative processes, and concomitant medication.

Diet and lifestyle

GP participants commented that the diets of some older people may be poor, in that they may not eat foods that are regarded as helpful to the bowels or they simply may not eat very much at all. It was also recognised that older people may not drink adequate quantities of fluids as they may be concerned about getting to the toilet in a timely manner. Fluid intake was sometimes mentioned separately from diet. In terms of lifestyle, they deemed exercise as important to healthy bowels, but recognised that some older people may become less mobile because of other health problems. Reduced mobility was identified as a contributory factor in the causes of constipation.

“I think it's dietary and I think it's exercise. I think that, especially if they live alone they don't cook properly for themselves. I think that even if they do cook properly for themselves that they naturally look for convenience foods that they can prepare easily that are often very low fibre. I think that they take less exercise.... I mean, I think that, I don't think there is an illness causing this. I think it's about, you know, timing again when you go into it, you know, they've never eaten vegetables in their life.”

(GP 6)

I: “Do you think more fluid and diet or do you think both play a part?” GP: “Both play a part. But I think, I don't think a lot of older people eat just as well as younger people so when I am the question sort of was ‘Well as people get older why does it develop?’ and I think often, some people eat badly you know, if they cannot prepare vegetables, they eat out of tins. A lot of the time younger do that as well, whereas I think younger people drink more than older people do.” I: “Right, so fluid is obviously an important one, right OK then, thanks. I mean do you try to establish what the cause is as a kind of...?” GP: “It depends on how new it is. If they say ‘Look I've been constipated all my life and it's got a bit worse’ – no. But if you know

it's just been the last month or so, you always ask them well has anything changed in the last month and you ... diet habits mainly they've changed.”
(GP 5)

Physiology and degenerative processes

A number of GP participants felt that as people got older so the bowels ‘slowed down’ and the slower transit time could be a factor in constipation. Other health problems may also come into play and either add to the bowel problems or result in the prescription of medication which has a constipating effect (see below).

“Well, maybe bowel pathology, it may be, it may just be sort of physiological almost in that the bowel slows down as they get a bit older. There may be bowel pathology such as diverticular diseases or bowel cancers, or it may be metabolic problems such as hypothyroidism.”

(GP 10)

“Normal pattern of ageing ... and part of the ageing process giving them osteoarthritis and etc., etc., hence medication But normal part of the ageing process.”

(GP 5)

“They tend to get slower bowel transit time, whether that counts, but again sometimes that isn't constipation that you can sort of say well that's a change, but if they're not getting hard motions that doesn't necessarily matter.”

(GP 4)

Medication

The majority of older participants were taking prescribed medications for other health problems. As we have seen above, concomitant medication use was an important explanation for older participants and one that was also recognised by GP participants. There was an acknowledgement that medications, whether prescribed or bought OTC, could contain ingredients known to contribute to or exacerbate constipation.

“Other medications that we put people on, all sorts of things. Usually some of them use codeine, plus other things, if they're on anticholinergic, unstable bladders, all cause constipation.”

(GP 5)

“Yes I wouldn't say I always succeed but I do try and find out [the cause] because often it is about, you often again, find out about over-the-counter medications, that people are saying ‘Oh, I'm taking Solphadol, ever since I found Solphadol, a wonderful thing.’ Which paracetamol and codeine preparations they are buying themselves and that they are not realising that this is what is having an effect.”

(GP 6)

In addition, one GP participant commented that there is a tendency to get older people off non-steroidal medication in order to avoid potential heart or renal failure. As a result, GPs tend to prescribe opiate-based analgesics accompanied by a prescribed laxative to counteract the expected constipating side-effects.

“We would rather have them on an opiate with a laxative than we would on a non-steroidal and get heart failure and renal.”

(GP 5)

Nurses' perspectives on the causes of constipation

Nurse participants had a clear and unanimous view about the causes of constipation in older people. Four causes were consistently mentioned in each of the focus group interviews: a poor diet, insufficient fluids, a lack of exercise or immobility and the constipating effects of medicines taken for other conditions. The following extracts from the focus-group interviews clearly illustrate the views of nurse participants and provide explanations of why older people experience poor diets, consume insufficient fluids and have insufficient exercise, and detail about the constipating influences of different medications.

Diet

N64: “But it is getting them to go ... , use the senna but, again they become dependent on, then it's ... , they're not eating the right foods. If they were to eat maybe a healthier diet and more fluid in their diet, then they wouldn't have constipation. So, it comes down to education but, you know, to take it in”

N61 (talking over): “But it's quite difficult for the elderly though that's at home because I mean they cannot boil pans of brussel sprouts and things, home-helps are going in and they're just doing em, things into the microwave you know so the diet's ... , is em, not probably as good” N58: “... I think a lot of convenience foods they use now.”

(Practice 4)

Fluids

I: “I mean, do you see constipation in older people as being something which can be alleviated, or do you see it as a chronic condition in the older age group?” N59: “In the age group I see it's” N60: “Well, to me I ... to me it's, a lot of it is fluids.” I: “Right, and if you can get the fluids right do you” N60: “Really, everyone is, has got a moderate dehydration.”

I: “Right, right. And I mean is that something that you see you can, you can tackle or does it tend to persist, that that's the way you know that they are?” N60: “Well, it's it's all down to em expectations. My

expectations are that someone can have fluids you know every hour, every hour and a half but the reality is we have people living in the community who will have three visits a day by carers, if they've got problems with a slight incontinence problem they stop drinking after 5 o'clock at night, they haven't got up till 9 o'clock in the morning and they've virtually had three drinks in a day.”

I: “Yeh, so it's a, it's a realism side ... to get yeah, sure.” N60: “It's the, you know this is care in the community but I, yeah,” I: “No, I know, ... so the ideal this is reality, you could, you can tell them.” N60: “That's, that's right.”

I: “To drink eight glasses but you can't, there's no way.” N60: “That, that's right, I mean [yeah, I understand] ... am I going to be there at night to help them onto the commode? To make them a drink and you know.”

(Practice 6)

Exercise

Lack of exercise was mentioned by all focus groups, but there was little discussion on this topic because of a high level of consensus between participants.

“And they don't move around as much, they're ... , you know, they're reliant on cars and”

(Nurse 64, Practice 4)

N60: “Because if they can manage to be mobile, they can manage to make themselves a cup of tea, they can go to the toilet, you know, so” N59: “They can go for a walk, so they're more active” N60: “That's right, they can get to the chemist” I: “Okay, so it's related to them, that their health.” N60: “It is to their health, rather than their age.”

(Practice 6)

But the following comment puts immobility and lack of exercise into another context – the inability to use the toilet in concert with the urge to defecate.

“N12: “Well that's right, and then you've got a lot of people who, you know, if they are disabled and they are relying on a home-help to go in, and I mean you have to think, you know if you had to ... you know, if somebody was taking you to the toilet and you had 10 minutes to perform or 5 in fact, then you were stressed and sat in a chair and couldn't move, you know there is a lot of constipation caused that way as well [right, right, ok], you know, mmm. I mean, you cannot go to order and I think that is a big ... that is a big thing in today's world [right, right] – it's the everybody is in a hurry and a rush and even I think in nursing homes, rest homes, you know, if you don't give people privacy and comfort and enough time to move their bowels then you are going to get problems, you know.”

(Practice 3)

Medication

Medications implicated in causing constipation were discussed more fully in each group, as the following example illustrates.

N60: “Well, a lot of them are on er, on painkillers [constipating medication?], so anything with the codeines in, it em ... [right]”. N59: “The MSTs are another one.” N60: “... the opioids, the opioids [right], em, we’re going a step further then [right], you know, they, they have to be on a strong stimulant.” I: “Right, and what did you mention, MST there ... ?” N60: “Morphine sulphate, I did ... it’s one of the ... opioids [overlapping voices] for certain severe pain ... intractable pain or terminally ill.”

(Practice 6)

Summary

The accounts of participants in this chapter have described the different perspectives of older

people, GPs and nurses on the causes of constipation. There was a lot of commonality among the three groups of participants. Diet and lifestyle and the iatrogenic effects of medications were common themes in all participants’ accounts. As with understanding the meaning of constipation, an understanding of different perspectives about the causes also helps us to understand the challenges of managing constipation from the perspectives of older people and the health professionals involved. In the next chapter, older participants’ accounts are used to describe the complexity of managing constipation in this age group, including how older people themselves self-manage their condition. Chapter 8 reviews the accounts of GP and nurse participants regarding their management of constipation in older people.

Chapter 7

How older people manage constipation

Overview

This chapter reports older participants' accounts of their experience of self-management and medical management of constipation. For many older people, their constipation emerged as a problem over a period of time and for some the 'condition' had existed for many years. Self-management of constipation had been their first response to the symptoms and continued even after professional help had been sought. Older participants had a wide experience of different management strategies and treatments for constipation and at the time of the study had firm preferences about the laxatives they would use (irrespective of whether they were completely effective).

Life-course perspectives on the management of chronic illness

Like most chronic illness, the management of constipation is a process and not an event. Using a life-course approach, this process was examined from the perspectives of older participants, starting with their recalled experiences of constipation during childhood and the ways in which it was managed.

Childhood constipation

Several older participants recalled early episodes of constipation. Occasional bouts of constipation in their childhood were usually managed by parents and significant others, who administered predominantly herbal and stimulant OTC laxatives. Syrup of figs, senna (boiled senna leaves) and chocolate-covered Ex-Lax[®] appeared to be the most commonly used OTC laxatives to address childhood constipation. Other OTC laxatives used in early years of life included castor oil, cascara and liquid paraffin. These medicines were usually taken occasionally on an as-needed basis. Contact with health professionals for childhood constipation was never mentioned by participants, although this may be due to poor or selective recall.

I: "Right, right, but I mean was there any particular reason in the past why you decided to stick to your own over-the-counter ...?" P: "No, this was when I

was young, I think my mother probably bought them for me too." I: "Right, right, was, I mean was it something that you kind of associated with going to see the GP about or not, or was it something ...?" P: "Not really, no." I: "No, you would just manage to take something yourself." P: "Yes, exactly."

(Patient 10)

"I can remember on the odd occasion being constipated and my mother giving me a dose of syrup of figs, much to my horror [right], which seemed to do the trick or a dose of liquid paraffin, but I mean it wasn't a constant thing."

(Patient 19)

"No. I think the name senna, it would maybe be something that would be taken years and years ago, you know I'm going back 60 years, I seem to remember my mother putting leaves in something and boiling them up or something like that. And I remember it was senna, and having senna tablets, it seems a bit more customer friendly than anything that's manufactured, like Ex-Lax or something like that."

(Patient 20)

P: "Oh I can remember as a child, I remember when I was staying with my grandparents in London, I think I went for 6 days, and of course it was like an atomic bomb when I went, you know, everybody in the house was pleased, you know [right, right, right], but em, it wasn't usually as bad as that [no, no, no]." I: "But if you look back over your life can you, do you feel that you were constipated as, as a child or adolescent?" P: "Just as a child I think, in adolescence it was better, in my teenage days it got better." I: "It got better? [It got better, yes.] Right, OK, and in those years was it managed by, you know your mother just buying over-the-counter stuff or home remedies, or were you actually getting any regular medication?" P: "No, I don't think so, I think I used to take Ex-Lax of all things, if you've ever heard of it, chocolate [chocolate laxative], that's it, I used to take that, yes." I: "Right, OK, was that as a child?" P: "I think so, yes, and then I tried Senokot, you know, like tea." I: "Right, OK, right, em, so after childhood and teenage-hood were you, and you said you had your children, and your bowels were all right then?" P: "Ah, ah, absolutely fine."

(Patient 10)

I: "And when you look back over the years, you know, if we look right back like to childhood, how were your bowels when you were a child?" P: "From what I can remember I was constipated." I: "You were constipated? [Yes.] And did you use any remedies at

that point, when you were little?" P: "I used to get syrup of figs, or castor oil occasionally, but the taste of that, I mean, that's how I remember it I suppose, I don't suppose I got it that often." I: "Did you get like a weekly dose of it or fortnightly dose? Can you remember? P: "Oh, I don't think so, I mean it's just ..." I: "Now and again?" P: "Now and again."

(Patient 16)

"Well, that isn't the reason that I wouldn't try the chemist. I think you hear about syrup of figs and things like that, but I suppose, in the far past, we had syrup of figs, you know when I was just a laddie, that was a long time ago, I seem to remember that, but when you're younger, not normally, you don't have problems like that, of course some people do, but I hadn't really, I can't remember ever being that bad."

(Patient 20)

While most participants who recalled using OTC laxatives during their childhood reported that they were used just occasionally (when required), some reported that they were given a weekly laxative dose by their parents. One female participant, for example, recalled that after an incident of undefined bowel problems she was given a laxative regularly every Sunday. Such a regular weekly administration of a laxative by parents may have been linked to the popular belief at that time that regularly cleaning the bowels carries health benefits and is good for general health.

"Oh, I daresay, now I can tell you this that when I was, just before I started school, I had trouble then, and I said to my mother, there's something wrong you know I can't, and she said oh you're alright, there was quite a few of us in the family of course, and she said just lie on the bed and I'll have a look, which she did and she said oh you're alright, and I can remember saying you're alright [right], and I thought I'm alright [and was that], I shall have to be alright [and was that, was that piles again?] that was, well I don't know I was 5 year old, how do I know? ... How do I know, 5 year old what it was and I didn't, and it's funny [hm-hm] because 5 or 6 year old, I remember going to school that particular day and not being able to sit down [no] and I stood at the back of the class [right] and I thought there's something wrong you know [and between that] and then she used to give me, um, oh some horrible abrasive thing er in water, I don't know what it was, I know it was pretty foul [right], she used to give me that every Sunday morning [so it was a weekly dose of laxative], it was, it was [right] every Sunday morning, but I can remember from then on suffering like that [uh-uh] and then, em, things seems to settle down [uh-huh] now whether or not because you suddenly [hm-hm], your taste buds change [uh-huh] you know what you can eat [and what you can't] and what you can't eat, your mother says eat that and

you do [yes, yeah] and [hm-hm] then you think, when you're older [right], I don't really like that."

(Patient 11)

Another female participant also mentioned that she probably had a weekly dose of syrup of figs in the past. However, she was unsure and admitted that it was difficult for her to recall that long ago.

I: "That's right, OK. Right. That's fine. And you mentioned that you always kind of kept senna in anyway. Is that over the years?" P: "Well, that's right. You start off, you know syrup of figs, then it was Cascara Evacuant. So I mean just one of those things that you grow up with." I: "And did you find, you know, like all these, you know the ones like syrup of figs and senna, did you used to kind of use them regularly in the old days? Did you have a weekly dose or anything?" P: "I can't remember. Probably got a weekly dose of syrup of figs. I honestly can't remember." I: "That's alright. But, I mean, you know, in your adult life you haven't taken a weekly dose?" P: "Oh no, no, no, no. I've even got some castor oil. Or liquid paraffin." I: "That was the other one, that's right." P: "So I've got some liquid paraffin in the medicine cabinet." I: "Are those the sort of things you would consider taking now? The syrup of figs and liquid paraffin or do you tend not to buy ... ?" P: "I think occasionally I've taken liquid paraffin but I can't remember what the result was. I just have it in the house."

(Patient 23)

Constipation during adulthood

During early adulthood, constipation or bowel problems tended to occur rarely or may not have been perceived as a health problem requiring medical attention. Occasional constipation appeared to have been tolerated, without significant impact on daily life, and more or less 'successfully' managed with occasional use of OTC laxatives.

"And you know [a-ha] and when you did go obviously it was difficult, but at the time you never ... I never put it down to being like a medical complaint [no, no], I just thought it was the way I was running my life ... You used to get the feeling as if your stomach was hard, you felt as if you wanted to go to the toilet but you couldn't [right] and, ehm, eventually you start to get stomach aches – that's when I used to go to see the chemist and get laxative and take it, and normally that used to do the job. Ehm, as I say again at the time I didn't put it down to being out of the norm. I just thought it was lifestyle and the fact, you know, the fact that I wasn't eating regularly or properly."

(Patient 2)

"I suppose thinking back the first couple or three times it happens to you you think what's going on here? [right] And then gradually you accept it as being the normal [right], the norm." I: "Do you think

that's what you did, you got used to that happening and, and ... ?" P: "The thing was it's never been, its never been a sort of enormous pain or anything like that, it's been a huge inconvenience, it's been painful for a short period of time [yeah] and upset my bottom [uh-huh], and, but no, that's apart from that ..."

(Patient 12)

Use of OTC laxatives

It is important to note that many common laxatives, including stimulant, bulk-forming and osmotic preparations, are readily available as OTC medication from pharmacies and (in some cases) health food shops. Therefore, individuals with constipation do not need a GP or nurse to act as gatekeeper as would be the case with prescription-only medication. Of course, there may be a financial benefit to those aged 60 and over, who are exempt from prescription charges, having laxatives prescribed rather than purchasing them OTC. This potential cost saving needs, however, to be set against the opportunity cost of consulting a GP or practice nurse, and should be viewed in the broader context of factors facilitating or inhibiting consultation.

Older participants reported that, during early adulthood, the use of OTC laxatives was again mainly on an 'as required' basis. They also reported that they tended to use one OTC laxative at a time instead of a combination of various laxative medications.

"The only time I have ever taken anything I have bought from a chemist was when I have actually needed it [right]. Ehm, since been on er the Fybogel. I just take them as a matter of course [right]. Every day on a morning, one a day, and truthfully I have never tried to come off it [no], I just took it as being something there [yes], just like a preventer which means it will keep it in check."

(Patient 2)

Participants reported that they typically used OTC laxatives during early adulthood and during middle age to address occasional bouts of constipation or the slowing down in bowel functioning. For most participants this meant when they had gone for a day or couple of days (up to maximum of 3 days) without a bowel movement, or to relieve symptoms of constipation such as stomach cramps or bloating. It was sometimes difficult, however, for participants to remember and explain why and under what circumstances they used OTC laxatives during early adulthood. Some speculated and gave less specific explanations such as "I wouldn't have been to the toilet" or "I was not going very well".

I: "Just the chocolate ones, OK – and what was the reason you tried that one?" P: "This was a long time ago, well I wouldn't have been to the toilet so you try anything, you know."

(Patient 3)

I: "OK, then. The Ex-Lax that you've got how did you come across them? Because you've bought them yourself, haven't you?" P: "I've bought them before and occasionally when I was a bit, well I wasn't constipated, but I wasn't going very well and I just bought some of them. Oh, years ago now."

(Patient 14)

Others were more specific and suggested that missing a certain number of days without a bowel movement and the discomfort that this caused were the main reasons that made them to go to the chemist and buy an OTC laxative.

"Well, if you miss a couple of days you just think, oh I'll buy some of this, you know [right, OK], like you do at the chemist."

(Patient 3)

"Once, you know like, I wouldn't go more than 2 days [right], I wouldn't let myself go for more than 2 days to go to the toilet [right], I would take something [you would take something], yeah."

(Patient 4)

Another participant recalled that after 3 days without a bowel movement in the past he would not feel particularly well and would usually get stomach pains and a hard stomach. This would make him go and buy OTC laxatives to 'sort himself out' and get 'back on form'. He recalled that at the time this self-management strategy was usually sufficient to resolve his bowel problems.

"Just the fact, as I say, I'd never been for maybes 3 days and you used to get pains in the stomach and you didn't feel particularly well, you didn't feel particularly hunger [right], and I used to go and pick something to get myself like sorted out and get myself somewhere back on form ... You used to get the feeling as if your stomach was hard, you felt as if you wanted to go to the toilet but you couldn't [right] and, ehm, eventually you start to get stomach aches – that's when I used to go to see the chemist and get laxative and take it and normally that used to do the job."

(Patient 2)

However, it emerged from participants' accounts that not everyone tried self-management with OTC laxatives before they discussed the problem with their GP. Some participants reported that they had never bought OTC laxatives, but instead always relied on professional advice when they became constipated. These individuals had

concerns about the potential harmful effect of self-treatment and trusted to professional expertise.

“I think that, er, you should, you shouldn’t put things into your body if you don’t know what you’re putting in [right, OK], I mean, you know [right], you wouldn’t put stuff on your body if you didn’t know what it was, would you, you wouldn’t, so why put it in? [OK] No, if the doctor thinks you need it in [right] that’s fine with me [but you wouldn’t do it yourself], no, no, no, no, no.”

(Patient 11)

I: “Why do you think you’ve chosen to go the medical route, rather than the over-the-counter route? Maybe there isn’t a reason but” P: “There isn’t, if you have a problem, you go to the doctor’s.” I: “So that’s your kind of thinking, you would rather go to the doctor’s than ... ? [Definitely, yes.] Is there any reason why you would feel happier going to the doctor’s than buying something yourself?” I: “I’ve always been a believer in taking professional advice.”

(Patient 24)

Some participants worried that self-management using OTC laxatives might have had a negative effect on other chronic conditions. One male participant, for example, articulated his worries about the effect on his diabetes. When he became constipated he went to his GP rather than buying something himself. In this case, reliance on professional expertise and avoiding the use of OTC laxatives seemed to be influenced by his desire to avoid any potential nutritional or medication risk.

“I’m a diabetic, you see. But I know you can’t just have anything. So that would be the reason. [Because of your diabetes.] It’s the same with everything, when you’re diabetic, you tend to think that way a bit.”

(Patient 20)

Self-management of ‘uncontrolled’ constipation

Some patients described how they managed periods of ‘uncontrolled’ constipation (i.e. constipation not responding satisfactorily to an initial self-management strategy). This often involved experimenting with different OTC laxatives and/or changing the laxative dose to find the right balance between being constipated and ‘going too much’. Stimulant OTC laxatives appeared to be the most common type of laxatives used at such times, although participants reported unpleasant side-effects such as frequent urges to go, which were difficult to suppress, stomach pain, loose stools or diarrhoea. Despite this, some participants continued to be reluctant to seek medical help and instead persisted in experimenting with OTC laxatives.

“I struggled on for years with bad stomachs rather than go to the doctor’s and actually, when I went, it was the camera, a month’s antibiotics and like anti-acid tablets and things were cured [yeah, yeah]. And you think, years of suffering for what?”

(Patient 2)

Seeking professional advice

Eventually, all participants had sought advice from their GP about their constipation. [Of course, only those individuals with multiple prescriptions for laxatives were included in these interviews (see Chapter 4), so by definition, all were consulters; other individuals with similar symptom experiences may have continued to self-manage and never consulted.]

The decision to consult may have been triggered by an alarming symptom (such as bleeding or pain), an unusually long time without a bowel movement or a realisation that OTC laxatives were no longer helping. For some, bowel problems were first raised in the context of a consultation that was (ostensibly at least) about something else. Contact with the GP often led to investigations for the underlying cause of the condition and experimentation with different laxatives to determine the optimum treatment.

I: “OK right, thanks, and how often do you see your GP now about your bowel condition? I know it is very difficult that when you see him about a lot of things to separate them, but” P: “At the moment, um, er, I’m not seeing him, I don’t have any review appointments coming up [right] because we’ve reached the stage where, er, I’m not going to see any more specialists, you know [right], but prior to that, of course, I was, not that I would say I was never away from the place, but it was regular appointments, and of course, in-between trying out, different you know medications [right, right] and things.”

(Patient 8)

For many participants there was no real ‘crisis point’ precipitating consultation, but for others constipation developed relatively rapidly, for example following an operation or changes to other medications, and this sudden change was a trigger for action.

I: “Did, em, did the doctor suggest constipation might be a side-effect before the constipation had actually happened?” P: “As soon as the hospital had given me these they said that constipation can result from these, I was warned in advance.” I: “Right, right, warned in advance, OK, right, thanks.”

(Patient 18)

“Well that started over 18 months ago now. It was discovered that I had two crushed vertebrae at the bottom of the lumbar regions, 1 and 2, I think they described them as. And I think that was caused by a few months previously – I sat rather hard on me bottom on my front doorstep, there was some ice, and I was making sure my husband was OK because he had a stroke 7 years ago, and I said be careful, I think it’s slippery and the words weren’t out of me mouth before I went down, like that on my bottom, feet straight out. At the time, apart from cutting me head on the porch corner, I didn’t feel anything. [Did you not?] No, not a thing. And then as I say, a few months afterwards I started getting sciatica and then it just got worse and worse until the pain became so acute I just didn’t know what it was. So, of course, I’ve been seeing the doctor and then had an X-ray and they discovered that was where what was causing all the acute pain. And also at the same time they discovered that there was a certain amount of osteoporosis which I never knew I had, you know, and of course then I was on such a high dosage of painkillers that’s when I became so constipated. I mean, I did have slight problems beforehand, but nothing like that, and of course with the painkillers they can be very constipating.”

(Patient 23)

Changing laxatives

Older participants reported that they rarely remained on the laxative initially prescribed by their GP or a hospital doctor. Prescriptions were changed by GPs or by hospital doctors because the laxative did not work to their satisfaction, produced unacceptable side-effects or did not match the preferences of participants. Their GPs tried participants on various different types of laxative (with duration of therapeutic trials ranging from trying them only once to prescribing the laxative for periods of up to 4 months) to see which product or combination of products worked best for that particular patient. Altering the dose upwards was reported to be common practice. This sometimes resulted in participants going too often or having loose stools, and the need for subsequent downward readjustment or a change to another laxative.

Once the initial approach to their GP had been made, participants appeared to feel more confident in contacting the doctor if treatment was perceived as inadequate for whatever reason. They also seemed to have overcome any initial embarrassment and concerns that they had about seeking professional advice.

I: “In the past does it tend to be you asking them to change it, rather than them saying we’ll change it?” P: “It would have been me.” I: “It would have been you?”

[Yes.] For reasons like ...” P: “Probably pained or didn’t work or wasn’t happy with it for whatever reason.”

(Patient 22)

I: “So how long did you try that for, can you remember, was it a few weeks or a few months?” P: “Oh I would say 3, 4 month [3 or 4 months] it wasn’t working I could tell, so I told them [right] and then he prescribed Senokot [Senokot, right so] and the last time [a-ha] was the suppositories, that was the only thing that worked [that’s working right], after an effort, mind.”

(Patient 6)

I: “Yeah, I mean did you go back to the doctor’s if you’d been hadn’t gone for 8 or 9 days?” P: “Ah, yeah, and that’s when they prescribed Senokots.” I: “And they gave you the Senokot, right, and so did you take the lactulose ...?” P: “Well, it made it a little easier for a while [right, a-ha] but it was still 7, 8, 9 days you see [right, right, OK], it was easier but there was still that gap of time.” I: “Big gap, so did you take the lactulose and the Senokot together or just one or the other?” P: “I ended up taking them both together.”

(Patient 6)

I: “Right, right. So has the doctor ever changed the laxative?” P: “No, he hasn’t. Except when he couldn’t get this orange stuff he changed us to senna.” I: “Right. So have you only had the two, you’ve had the orange stuff and the senna and the lactulose you’ve had for a long time? [Yeah, yeah, yeah.] Right, and have you had other ones apart from those three? Any other laxatives apart from those three? [No, no, no.] Just those three?” P: “That’s right, yeah.”

(Patient 7)

I: “And what happened after 4 months?” P: “And, em, I was, it was, em, I was going to, I think it was the hospital that changed it actually, yeah. I know yes, I was on, I think I was having to take Fybogel three times a day and lactulose twice. [Right.] And on another appointment, you know, the doctor said, and I said well I can’t stop, and he said I think we’re giving you too much Fybogel here, he said, em, reduce the Fybogel and continue with the lactulose, he said, and see what happens, well then, of course I went not back to square one, but things became difficult then again. [Right, right.] And then after that I was put on co-danthrusate.”

(Patient 8)

I: “Were you on that for a little bit, were you, or quite a while?” P: “For a while I would say. And all of a sudden when I’d come to order a bottle, then said, oh well, there’s a change, you don’t get that now, and you get this, and that was the senna.” I: “And did you ask your GP at all why they’d changed it?” P: “I don’t think I did. Because you see, then I could ring my surgery and they’d telephone the prescription through to [name of] chemists and I just went and got it ... It hasn’t been my custom just to go down to the doctor’s for anything, but obviously when you’re

diabetic you do have things, that not exactly go wrong, but that you may be thinking about and wondering if this has anything to do with diabetes and should you go? You know, here people say you should go to the doctor's." I: "Yes, you've got to be a bit more careful haven't you? [That's right] ..."

(Patient 20)

P: "Aye, no, there was a different one as well [right], there was lactulose and different ones. And that's where Dr [name] said if they are no good try something else and he was trying different things [right] and they didn't seem to be working." I: "No – how long were you trying all these different things for – were you trying them for a few weeks at a time or a few days at a time?" P: "Oh, maybe a month." I: "Right, on each one?" P: "Each one, that's what Dr [name] says, we will give it time to see if ... try it for at least 14 days, he says [right], really, or 15 days to let it go through your system [a-ha], but I used to be on it for about a month and then it just got to back usual again [yeah, right, right, OK]."

(Patient 21)

Controlling constipation

At the time of the study, the vast majority of participants perceived that their constipation was adequately controlled, or they were not constipated (at least according to their own definitions), despite unanimously admitting that they needed laxatives to maintain their bowel functioning. They had identified acceptable and 'effective' (if not always optimal) solutions for the management of their specific bowel problems. Their main aim was to maintain, what was for them, 'normal' regularity of bowel movement and of stool consistency and avoidance of unpleasant symptoms and of undesirable side-effects of medication (such as diarrhoea). In this way, they minimised the incidence and severity of constipation, and as a consequence their quality of life and daily routine were maintained.

For example, a female participant, aged 73, commented that she would try any laxative, including those tried in the past, as long as they worked. Although laxative effectiveness seemed to be the dominant factor influencing adherence to current treatment, avoidance of unpleasant side-effects was also important. This 73-year-old had found previously that using OTC Ex-Lax was "too severe" and required frequent visits to the toilet; she commented that it was not suitable for long-term treatment of constipation. She had also tried prescribed Fybogel and Senokot, but had found them insufficiently effective. This individual found that lactulose was more effective than previously used laxatives, describing it as "brilliant, the best laxative" she had ever tried.

Once a laxative regimen that was more or less consistent with a participant's own preferences was identified, the majority of participants preferred to stick with that regimen and avoid further experimentation. Once this point had been reached, contacts with their GPs regarding the management of constipation were limited and were usually only to collect repeat prescriptions or for another unrelated reason.

I: "Right, OK then, thanks, right. I mean how often would you see your GP now about your constipation?"

P: "Truthfully, never!"

(Patient 2)

I: "And how often do you see the GP now about your constipation?" P: "I don't, I don't I mean since the nurse since I got rid of it with the Movicol, which would be about 5 months ago [ahah], em when I've got no Movicol left I just 'phone the surgery and get a repeat prescription, so I don't go and see him."

(Patient 18)

P: "Well I have, err ... about every 3 months." I: "About every 3 months?" P: "Yes, regular. But if I need to go like when I was bad I just 'phone up and you get an immediate appointment. You know, the same day."

(Patient 3)

I: "How often do you see your GP now about the constipation?" P: "Well, I wouldn't say that I'd been for years to see him about the constipation." I: "So you just keep getting the repeat prescription?" P: "Yes, that's right."

(Patient 24)

I: "Does the constipation get mentioned when you are up there or, or ... ?" P: "No, I just telling him the senna is doing alright." I: "Right, OK then. Do you see your doctor about your constipation at all?" I: "Not now, I don't, no." I: "You just get repeat prescriptions of senna?" P: "That's right." I: "And do you go every now and again for a review of all your tablets?" P: "Well, they review them. Because when I get the actual prescription form, attached to it, there's a list of things."

(Patient 21)

I: "So can you remember, would it have been the doctor or the nurse or the hospital who first suggested laxatives to you?" PW: "It was the doctor." P: "Was it? I'm not really sure because I'd been constipated." I: "Right. So it would have been the GP coming out and sorted that out? OK." P: "Because when I was constipated I was telling him together with the district nurses and they decided to put me on laxatives." I: "Right, OK, right. And do you discuss your constipation with your doctor very often now?" P: "No. I just take them and be content. As long as I'm able to go at all." I: "Right, OK. As long as you go." P: "As long as I can keep going I never mention anything."

(Patient 14)

While some were fully content with their laxative regimens and the current control or prevention of their constipation, others acknowledged that full treatment success had not been achieved. A female respondent commented that the treatment is unlikely ever to resolve her constipation. Nevertheless, her laxatives helped to prevent constipation (bowel problems) and its consequences from recurring, which she regarded as successful management. It appeared that she would be willing to try new, 'better', laxatives if they were available. However, because she was reluctant to make a visit to her GP and be examined she was prepared to stay on her current medication.

I: "Right, OK thanks, and do you feel that those two laxatives have been successful in resolving your problem? [Yes I do.] You do, right [I do], and when we talk about resolving the problem ... ?" P: "It can never resolve it can it? I: "Right, I was going to come onto that [oh sorry], no, when I [*laughing* – sorry], no, that's great, that's really good, it's not resolving it, but do you think it's preventing it?" P: "Oh it's helping me, oh it's preventing it [right] and it's given me peace of mind right, and I can live every day, you know what I mean [right], I think I'll be alright today [right, right, OK], and the days it's not is my own fault for what I've eaten, well that's how, that what you say [ah, I know that], you know that OK [I know that]." I: "What do you see as a successful laxative, what do regard as a successful laxative?" P: "Well I can only go by what I what I am taking you see [that's right], I can only go by that [hmm], I mean what would help other people I don't know." I: "You don't know, but do you regard what you've got is successful for you?" P: "Well, I would say so [right], I mean if [*laughs*] if there's anything better then I'll have it, er, but I won't have it because I'm not going to be examined and I'm not going to talk about it [no, no] to the doctor, I'm just going to [right, right] keep on hoping he's going he says right, right, you know [right, OK, right]."

(Patient 11)

A male participant also commented that his laxative treatment had helped, but had not been 100% successful. Nevertheless, he acknowledged that to some extent it was easier now compared to the past because he managed to control the severity of his back-end pain.

I: "But the Fybogel and the Docusate. Do you think they've been successful in resolving the constipation?" P: "I suppose to a point. I don't say they're 100% successful but I would think they obviously do help." I: "Right, so you see them as helping?" P: "As a help but not 100%." I: "Right, OK. Right. So I mean do you regard that at the moment your constipation's successfully managed or not?" P: "Again not 100% no,

no." I: "If you look back can you see an improvement over time? Is it better now than it has been or is it about the same?" P: "To be honest, about the same I would think." I: "It hasn't really improved?" P: "No. I mean it's a bit easier now because my back isn't quite as painful."

(Patient 21)

It was commonly mentioned that routine laxative treatment, taken strictly as prescribed, did not always work. Several participants described a range of different, sometimes complex, strategies to address their individual circumstances and to achieve their desired outcome of 'normal', regular and comfortable bowel movements. Increasing or decreasing the dose of a laxative gradually, adding on and switching laxatives, temporarily discontinuing a prescribed laxative, and using OTC laxatives alongside prescribed laxatives or as a single treatment were all strategies used to manage the fact that prescribed laxatives were not always 100% effective.

Even those participants who were not fully satisfied with their current (prescribed) laxative management seemed to be reluctant to make a visit to their GP to discuss alternative treatment and tended to plod on, making use of various OTC laxatives or experimenting with a range of previously known laxatives and different doses, as described above. A perceived or an actual lack of any available alternative, reluctance to visit the GP because of fears of tests or clinical examination, and the ability to control, albeit suboptimally, the severity of episodes of constipation together explain some of the participants' reluctance to seek another management strategy. In addition, some felt that even ineffective laxatives (ineffective in terms of their personal preferences regarding frequency and consistency of bowel movements) might still help in some way to clean their bowels.

I: "Have you had a word with the GP about that you don't feel they work terribly well?" P: "Well, there is nothing else is there?" I: "Is there not, is there nothing he can offer you?" P: "I mean he's got another one, a bottle, but I'm not, er, so sure about that, no." I: "Have you tried it? [No]."

(Patient 1)

"No [no], because I've been going that long about it [right, right], I think they've given me everything they can."

(Patient 6)

"They tried everything else, you know, nurses, enemas, different prescriptions, so that was the only alternative. Couldn't go on."

(Patient 3)

P: "Well I don't know what the hell it is for [laughs]. I take that and I think it's only another, I don't know, it doesn't have any effect. [It doesn't, it doesn't work?] No, it doesn't work [right, right]. If I took that by itself that's what I mean [right], it's a waste of time, it's a waste of time. I still take them but that's what I think about them." I: "Right, right, right. So you said that you still take them – do you always take them or do you sometimes not bother taking them?" P: "Oh no, I still take them. I get them so I take them then." I: "You always take them, right, OK." P: "Yeah, because I thought they might clean your bowels out or whatever it is, but er, yeah."

(Patient 1)

It is notable that participants typically did not discuss with their GPs the use of additional OTC laxatives or other strategies (e.g. dose adjustment) for managing ineffective prescribed laxatives. It seems that many participants had taken the management of constipation into their own hands.

I: "So have you mentioned to the GP that you are trying the fruit cubes? Have you ever mentioned to the GP?" P: "Na, na, I just get on with it."

(Patient 1)

I: "You wouldn't make the special journey just for your constipation?" P: "No, it's not worth it." I: "It's not worth it? Why do you think it's not worth it?" P: "Why do I think?" I: "Why do you think it's not worth it?" P: "Because he suggested milk of magnesia and syrup of figs, he does his best, but a friend gave me this [Elinimase] ..."

(Patient 16)

I: "Right, right, OK, thanks right, and so you've been seeing your GP about your constipation for the last 3 years, is that right?" P: "Well I don't see him on a regular basis, I mean I went about it and had a sigmoidoscopy and, em, I haven't seen him about it since except that [you haven't, right?]. I was there having something else done, oh about my face that's right, I had some treatment to my face because of sun damage [ah right, right] to my skin and I said to him because he is a new GP, because my Dr [name] is sort of slowing down now, so I saw this Dr [name] I think his name was, and he said how was I, and I said I was taking this, em, Fybogel and I don't think much of it quite frankly, and he said why don't you try senna, well I mean I had tried senna and I was taking senna, I didn't say that at the time, but he said why don't you take senna, so I said well, yes I'm going to do that [right, right], so I ditched the em, well I have ordered it anymore it's still on my notes so I could get it if I wanted it." ... I: "Suits you alright, OK, do you ever, em, kind of adjust the dosage?" P: "Well, I have tried that, but I find that three is not as good as four, lets put it like that [right, right], you know, I mean I know when I buy it at Boot's they say to me, you know you just take this on an occasional basis, well rather than go into an explanation I say to them, Oh yes I know,

but I mean that I know the doctor knows that I'm taking it, I don't think he knows how much I'm taking, mind." I: "Right, right, so was that when you saw Dr [name], he didn't think much of the Fybogel and he suggested the senna. Since then are the GPs aware that you are on senna now – do you think ... ?" P: "Shouldn't think so, no." I: "You don't think they know?" P: "It wouldn't be written down in my notes [no, no], he didn't say 'I'll prescribe it for you' or anything like that."

(Patient 19)

Nonetheless, some participants commented that they would actively seek medical help if their constipation became bad; for most participants this meant an abnormally long period without a bowel movement or recurrence of persistent symptoms that were difficult to tolerate and did not respond to the types of 'adjustment' strategies described above.

I: "Right, OK, that's fine, so how often do you see your GP about your diverticulitis?" P: "No, I don't see anybody [you don't], no." I: "OK, so I mean you'd only really go if you had a flare-up presumably." P: "I would go if it looked as if I had a problem, but I haven't really at the moment."

(Patient 17)

"Well, now I don't see him about it, I just get the regular medication unless it was bad, like when it was 12 days I went and then, err, he sent the nurse in and the nurse came in 4 days and it was decided, well it was enough, you can't keep having enemas, so I was admitted to the hospital. They're very good, I have good doctors."

(Patient 13)

Summary

This chapter has provided a rich account of the experiences of managing constipation from the perspectives of older participants. By taking a life-course perspective, the analysis highlights that constipation for many older people is not necessarily a recent phenomenon. In clinical terms it is truly a chronic condition that has affected some participants for many years. Building on participants' accounts of the meaning and causes of constipation, this chapter shows how the interpretation of normal bowel movements and the beliefs around regular bowel movements have influenced the use of OTC laxatives and other remedies throughout the life-course experience of 'constipation'. People in general, but particularly this generation of older people, have staunch beliefs about their bowel habits and have been strongly influenced by

their families and social networks. Older participants sought professional advice from a variety of sources, including pharmacists, as well as GPs and nurses. Self-management usually continued even after treatments were being prescribed by health professionals. But the overriding feature of these accounts was the

strong preferences that many older participants had for specific prescribed laxatives, OTC laxatives and other remedies. This suggests that this group of patients is not in equipoise about laxative use and helps to explain the difficulties experienced in recruiting patients to the STOOL trial.

Chapter 8

The management of constipation by GPs and nurses

Overview

GP participants recognised the experience and use of laxatives of their patients. There exists no clear guidance on laxative prescription and GP participants presented different patterns of laxative prescription, often with strong personal preferences. Participants prescribed the four main types of laxatives (bulk-forming, stimulant, osmotic and faecal softeners) for constipation, but did not perceive these as closed categories and often prescribed them in combination. Ispaghula husk was the most widely prescribed. It was perceived as acceptable to patients, effective, inexpensive and 'natural'. It was prescribed for healthy bowel maintenance and long-term use. Osmotic laxatives were widely prescribed, but not perceived as suitable for long-term use; typically, they were prescribed for constipation that had been caused by opiate use. Osmotic laxatives were prescribed less often, but some participants were moving towards prescribing this class of laxative more often. The emergence of new agents such as Movicol may be changing participants' preferences for different laxatives.

In contrast to GPs, nurse participants' management of constipation was not laxative driven. They were more likely than GPs to treat and prevent constipation using non-laxative measures, including the provision of advice on appropriate dietary changes, increasing fluid intake, and, if possible, encouraging exercise and mobility. The management goals were often to get patients off laxatives; but if a laxative was required then it appeared that the first choice for the vast majority of nurses was Movicol.

GPs' perspectives on the management of constipation

Although lifestyle advice was an important part of GP participants' management armoury, it was the prescribing of laxatives that dominated their management of constipation. So what were GP participants prescribing at the time of the qualitative interviews (2002–2003)?

What laxatives did GPs prescribe?

During interviews, participants were shown lists of laxatives that were allowed to be prescribed on the NHS and were listed in the British National Formulary (BNF). The lists shown to participants were developed using the categories and laxatives listed in the HTA Programme's systematic review of the effectiveness of laxatives and expanded in *Effective Health Care Bulletin*.^{1,78} The developed lists were not comprehensive and did not include every available trade-name laxative. However, the lists covered those that are commonly used and were presented in four broad categories: bulk-forming laxatives, stimulant laxatives, osmotic laxatives and faecal softeners. Each category was divided into subgroups of laxatives, with examples given for each (*Table 5*).

GP participants were asked which laxatives they prescribed for older people for constipation. Certain laxatives were reported by participants to be prescribed for anyone with constipation. Fybogel and senna, for example, were widely used in all age groups. Certain laxatives were targeted at specific groups: docusate was mentioned by GP participants as being prescribed more often to older people than to younger adults, while co-danthramer and co-danthrusate were largely reserved for people who were terminally ill and those patients with cancer or on morphine. In terms of intended length of use, docusate sodium, Fybogel and lactulose were perceived as safe and therefore suitable for long-term maintenance and prevention of constipation, while senna and stimulant laxatives were in general seen as short-term solutions for resolving acute episodes of constipation. Some GP participants no longer prescribed the two listed faecal softeners: liquid paraffin and Fletcher's arachis oil (enema).

Although all GP participants were familiar with the main groups of laxatives presented to them on the list (i.e. bulk, stimulant, osmotic and faecal softeners), a few participants thought in terms of 'bulk, stimulant and softeners', rather than 'bulk, stimulant and osmotic' (equating osmotic and softeners).

TABLE 5 Laxatives prescribed on the NHS

Bulk-forming laxatives	Stimulant laxatives	Osmotic laxatives	Faecal softeners
Bran	Bisacodyl	Lactitol	Arachis oil
Trifyba [®]	Bisacodyl tablet	Lactitol	Paraffin
Ispaghula husk	Bisacodyl suppository	Lactulose	
Fybogel [®]	Dantron (danthron)	Lactulose	
Konsyl [®]	Co-danthramer	Macrogols	
Isogel [®]	Co-danthrusate	Movicol [®]	
Regulan [®]	Docusate sodium	Magnesium salts	
Methylcellulose	Dioctyl [®]	Magnesium hydroxide mixture BP	
Celevac [®]	Docusol [®]	Phosphates (rectal)	
Sterculia	Fletchers' Enemette [®]	Carbalax [®]	
Normacol [®]	Norgalax micro-enema [®]	Fleet [®] ready-to-use enema	
Normacol Plus [®]	Glycerol	Fletchers' phosphate enema [®]	
	Glycerol suppositories BP	Sodium citrate (rectal)	
	Senna	Micolette micro-enema [®]	
	Senna	Micalax micro-enema [®]	
	Manevac [®]	Relaxit micro-enema [®]	
	Senokot [®]	Sorbitol	
	Sodium picosulphate	Epsom salts	
	Sodium picosulfate		
	Dulco-lax [®]		

"I tend to think bulk laxatives, stimulant laxatives and stool softeners, actually, and I suppose I would class the osmotic in with the softeners."

(GP 10)

It thus appeared that many GP participants did not place laxatives in closed categories, but rather acknowledged that one type of laxative could have more than one property. For example, a bulk laxative such Fybogel was perceived as a softening as well as a bulking agent, while osmotic laxatives were regarded as softening agents as well as preparations that attracted water to the stool. However, stimulant laxatives, with the exception of docusate sodium, were regarded as having a more narrow action; in other words, senna only stimulated; it did not soften the stool.

The way in which GP participants talked about laxatives highlights the way that they perceived their properties.

"Many of them are already taking senna of some sort and therefore I'd give them some sort of softening agent and my first line of call would be lactulose. And I would say 'keep taking your senna for a few days because the lactulose will take a week or two to go into the system and through the system'."

"I would be talking about Fybogel and often I would use Fybogel as my bulking-softening agent."

(GP 6)

"I seldom use softeners ... I presume if we use the osmotic ones or the Fybogel type or bulk-forming agents, we will help some of the problem."

(GP 5)

Experience of prescribing bulk-forming laxatives

All GP participants reported that they would prescribe ispaghula husk, and a number commented that they would *only* prescribe ispaghula husk from those listed on the bulk-forming list. This preparation was prescribed either generically or specifically as Fybogel, which was the most commonly prescribed ispaghula husk branded preparation. Indeed, even when prescribed generically, an ispaghula husk preparation may well be dispensed by the pharmacist as Fybogel. Isogel and Regulan were mentioned less frequently, and Konsyl was not mentioned at all.

"I prescribe Fybogel, Regulan, Celevac, Normacol, but I think in that sort of order."

(GP 13)

"The only one I would prescribe out of that lot (bulk laxative list) is basically Fybogel, and I would often give it as ispaghula husk, and so some people do get Isogel and Regulan, but in fact that would automatically change to ispaghula husk under our computer system."

(GP 6)

"Fybogel, that's the only one out of that ... ispaghula husk, the generic really."

(GP 5)

"It depends on what the chemist actually gives for these, I think most of them probably get Fybogel."

(GP 4)

Methylcellulose was not commonly prescribed, but when it was used it tended to be prescribed as the

branded Celevac. Two GPs mentioned prescribing sterculia (both as the branded Normacol), but even then this was described as “fairly rare” or placed at the bottom of a list. None of the GP participants said that they prescribed bran. One participant suggested that his not doing so was linked to his own dislike of bran.

“I tend not to use the bran ones unless people have come wanting that, erm and I can’t really say why, it’s probably because I’m not fond of bran myself, I don’t think I’d be fond of any of these frankly [*laughs*], but, er, I don’t actually prescribe the bran ones.”

(GP 4)

Experience of prescribing stimulant laxatives

Stimulant laxatives were prescribed by all GP participants, but a number of comments made indicated that they preferred to use them for short periods only, as it was felt that longer term use of stimulants could cause problems. For example, one participant explained that over time the dose of senna needs increasing to maintain the same results. Another was concerned about “bowel habituation” and others spoke more generally about “the potential problems of long-term stimulant laxative use”.

“I dislike people on stimulants long term and I think from the co-danthrusate of 10 years ago where people almost got physically addicted to them, that their bowels wouldn’t move without a stimulant and therefore I very much try and keep senna as something, and even if they are on it long term, they use it intermittently and that they use their bulking agent as the method to move things forward.”

(GP 6)

“If it’s possible to avoid stimulant laxatives then it may prevent people going on getting sort of bowel lethargy and having problems there.”

(GP 4)

Senna was prescribed by all GP participants, although it was highlighted that, ideally, they preferred people not to be on senna long term. Two mentioned using senna for acute constipation as it was felt to be quick acting. It was also acknowledged that some people were on senna longer term (e.g. those taking co-codomol), even though this was not an ideal situation.

“I mean, every time they stop and they run into problems then you have to use it regularly.”

(GP 5)

One participant commented that when he does prescribe senna for longer term use he prefers his

patients to use it on an ‘as needed’ basis rather than continually. Under such circumstances senna may be prescribed alongside another laxative that is to be used continually.

Docusate sodium was frequently prescribed. Co-danthramer and co-danthrusate were frequently described as laxatives used with terminally ill people, those with cancer or those taking morphine. Bisacodyl and Manevac appear to be prescribed less frequently than senna, docusate sodium and co-danthramer.

“Right, the docusate we prescribe now ... the senna we prescribe and as I say we will have a handful on co-danthramer, that is nearly always after secondary care, ehm, literally I think you’d be talking about five or six people in the practice. I think you would find the greatest proportion was senna. I would think that the next greatest proportion would be docusate and while there might be a tiny proportion on the others, this is purely we are talking about the elderly aren’t we? ... Then I can’t think that there is anybody on the others.”

(GP 6)

“I mean, in cancer patients we would, we would often use co-danthrusate ... I could, yeah, I could sometimes use co-danthramer and occasionally bisacodyl. Again, it would depend on what had gone before, what had proved effective. Glycerol suppositories, but senna would come top and then these others would come less frequent.”

(GP 13)

“[Senna]. I use docusate fairly frequently, I use co-danthramer and co-danthrusate in terminal illness, ehm, I think that is probably it really.”

(GP 10)

Although still used occasionally, the Enemette and micro-enemas were mentioned less frequently. Sodium picosulphate was regarded as a ‘bowel prep’ and was not prescribed as a laxative, but rather as a preparation used in hospitals or to prepare for going into hospital for an examination of the colon.

Experience of prescribing osmotic laxatives

From the presented list, all GP participants reported prescribing lactulose. It was typically regarded as a safe but not particularly good laxative, and changing patterns in its use over time were noted, as discussed below. Movicol was increasingly being prescribed by some participants, but rarely used by others. Only one participant mentioned magnesium salts, and he would suggest to patients that they buy this as an OTC medication rather than prescribe it. Microlax was the most frequently mentioned of the enemas,

although phosphate enemas, specifically Fletcher's enema, were also mentioned.

The decline of lactulose and the rise of Movicol

As already noted, all GP participants mentioned prescribing lactulose, but only two participants reported continuing to prescribe lactulose over time, without mentioning any change in that time.

"Again, it has a long-standing record of acceptability ... to patients ... many of their mates have been on it, or friends, family, God knows what, it's part of the culture."

(GP 5)

However, the majority of GP participants reported prescribing less lactulose than they had done in the past; this trend was observed across all practices participating in the study. There was an overall sense that lactulose was declining as the most prescribed osmotic laxative, although it was still used and prescribed if people wanted it or had it before. The reasons given for prescribing less lactulose than in the past included the following.

- Lactulose was no longer considered as effective as it once was.
- Lactulose was regarded as a very expensive laxative. Senna was described as 'pennies', while lactulose was described as 'pounds' for the benefit achieved.
- Lactulose was no longer on practice formularies (mainly due to cost).
- Hospitals did not use it (except for pregnant women), so very few people were discharged from hospital on it.
- Movicol was regarded as more effective than lactulose (at least according to nurses).
- Research publications say that it is not very good.

Among the osmotic laxatives, it was reported that Movicol was increasingly being prescribed. However, this trend appears to be happening in only two of the practices participating in the qualitative study, with the other two reducing their use of lactulose but not increasing their use of Movicol.

The trend towards Movicol was identified by GP participants as a nurse-led initiative, particularly, but not exclusively, by those participants who were increasingly prescribing Movicol. However, none of the GPs had a sense of whether or not it was effective, as it was perceived as a relatively new laxative and not one that they had a great deal of

experience working with. There was some cynicism among GP participants that the nurses may have been influenced by pharmaceutical representatives, but GP participants nonetheless appeared to cooperate with the nurses' requests to prescribe Movicol.

"I have used the Movicol a few times, but I've only used it a few times, I haven't really got a good grip on how good it is."

(GP 4)

"I use lactulose less frequently now and Movicol I am using a little bit more of ... lactulose is no longer on our practice formulary mainly because of cost, Movicol is something I'm being asked to prescribe more by the district nurses, although it's not something that, you know, I've got much experience of myself."

(GP 10)

"Talking about nursing practice, what's in favour at the moment, it's quite interesting, is Movicol. I think the reps have been out in force, they've hit the nurses so I think we're now prescribing. I mean it will be quite interesting to look at the evidence base for that ... oh this patient needs Movicol, you know, it moves mountains [*laughs*]."

(GP 13)

"I mean the only one we would prescribe there by right, there is a change here, we would prescribe lactulose. But our nurses would prescribe Movicol. And we are therefore now prescribing Movicol and that is a nurse-led initiative ... and that's a recent innovation ... they claim that it is better than lactulose and that it is – the patients can titrate it better. I mean I am not convinced, I mean if you want me to be cynical, it perhaps that the drug reps have a good chat with them [*laughs*]."

(GP 6)

Enemas

Some GP participants regarded enemas more as the domain of district nurses, rather than of doctors. Enemas were also used occasionally as treatment for acute episodes of constipation and were typically described as 'one-off' treatments, rather than a regular way of managing constipation.

"I tend to pass it [enemas] on to the nurse, 'cause you usually haven't got it with you at the time so, what you tend to do, it's usually on house call, write a prescription, the family goes and gets the prescription and then the nurse will go and give them."

(GP 4)

"A lot of the enemas I have had experience with have been through the district nurses, but when I do prescribe them it's usually because I have been asked to prescribe a specific agent, so I've used, er, Fletcher's enema and phosphate enemas and

MicroLax, but it's not something I take the initiative to prescribe usually."

(GP 10)

"And so the MicroLax I would carry in my bag, if I got to a situation where somebody was completely chock-a-block I would be – I'm told by the nurses I've got to have that in my bag, so that they don't have to come out after me [*laughs*]."

(GP 13)

"The MicroLax micro-enemas are prescribed on a one-off basis, very, very occasionally for somebody ... and some of these like the Fletcher's enemas that the nurses may use, but in an acute situation, really postoperative, something like that, they would not be used as a routine."

(GP 6)

GPs' perspectives on older patients' preferences

GP participants were asked whether older people had a preference for a certain laxative. The majority of participants expressed the view that older people do indeed have a preference for a certain laxative, while others believed that older people have no particular preferences. Answers were often qualified.

Older people have a preference

There was no consistency of opinion among GPs regarding their perceptions of patient preferences among older people. No single laxative was identified as being preferred by older people, but participants who perceived a preference did provide reasons as to why they thought that older people preferred the specific laxative they suggested. Senna was seen to be preferred by some patients as it was believed by those patients to be effective, providing 'a good clean-out' and having immediate results.

"Older people like stimulants best because they work, they are little and therefore easy to take. Stimulant laxatives also work quicker than lactulose and Fybogel, but not massively different."

(GP 5)

It was generally perceived that patients preferred laxatives in tablet form.

"I think they prefer a tablet rather than having to mix up a drink that goes all gloopy."

(GP 10)

Others perceived that lactulose was preferred by patients because it was easy to take, had no unhelpful side-effects and because these patients had been influenced by their friends. Similarly, a patient preference for Fybogel was reported by

another GP participant who felt that some of the older people were influenced by informal networks and the local chemist.

Although most participants felt that patients had preferences, two GP participants felt that any such preferences were dictated largely by external factors and that these factors change over time. For example, people might, at a given time, express a preference for a laxative with which they are familiar because they have had it before and have found it effective. However, their familiarity is based on what the GP has previously prescribed for them; as practice prescribing habits change over time, preferences may follow accordingly. For example, the pharmaceutical advisor will influence what a GP prescribes and this will, in turn, influence what a person becomes familiar with. It was also acknowledged (as already noted above) that pharmacists can influence people's preferences: they can recommend or stock certain laxatives with which people then become increasingly familiar (through OTC purchases and through supply of a particular branded product in filling a prescription), and these familiar products are then requested more frequently. Informal networks of family and friends and advertising also play a part in the process of increasing public knowledge about certain laxatives. Hence, preferences that people express are dynamic and shaped by a complex network of external factors.

"I think personally it depends on our prescribing habits in the practice. If we use a lot of bulk-forming agents they come back and ask for it because somebody's used it before, prescribed before and they use it and they find it works alright. They might use it on [an] infrequent basis, and equally if we use a lot of stimulants they would probably come back for a similar thing. So very often, actually, influenced by us. Secondly, influenced by the pharmacist, where they buy over-the-counter medications. They find certain things work, they come back, ask for a similar thing again Actually, the prescribing, really it's written by a pharmaceutical adviser. When we change people from lactulose to Fybogel, they are happy with Fybogel. So maybe [they] equally work, all these things, yeah."

(GP 5)

"Yes, I mean some people come and they want something either 'cause they've had it before and know it works or they prefer to take it, I mean some people don't like granules, some people prefer to have a medicine or a tablet or, you know, so I mean there's definitely preference, yeah I think it moves on, I think there was a definite spell and it's difficult to say when it was ... certainly 15–20 years ago or up until reasonably recently we were prescribing lots of lactulose, it was popular ... and prior to that it was

liquid paraffin emulsion which lots of people had and nobody, I mean we don't prescribe it very much at all now, in fact my last patient who was a frequent consumer of it died aged eighty-something, she used to have a litre a month when I first met her in 1975. So I think I mean there's definite both patient favourites and the sort of thing that trip off doctors' pens favourites, and the two often, and advertising I think works as well so I think that, er, you know, if something seems to be effective then people say I've had that from the doctor, other people buy it from the chemists."

(GP 4)

One GP participant felt that there was no overriding group preference identifiable, but rather the category of 'older people' was made up of individuals with individual preferences.

"I think it's ... no I think it's very individual that. I think you can see the same 'person' as three different people and get three different answers, in that one is buying senna from the chemist, one is very happy to take one glass of Fybogel orange each day and one likes their lactulose, and I'm not convinced that there is a group preference, I think it's about an individual preference."

(GP 6)

Older people have no preference

A few GP participants felt that older people did not have any particular preference. One participant described people as being "passive" and prepared to go along with the preference of the GP.

"On the whole, there's a proportion who have no preference, and then you've got some people with some very odd views."

(GP 5)

It would appear from these data that GP participants have not identified one overriding preference that older people express. Rather, the GPs' perceptions of patient preferences are that these are varied or are individualised. Preferences change over time and are influenced by what happens within general practices. There is a flow of information among GPs, patients, nurses, pharmacists and significant others in different directions, all of which influence people's preferences.

Rationale for prescribing one laxative over another

GP participants were asked about their rationale for their choices of laxatives. Their responses suggested that their choice would often depend on the circumstances of individual patients. For

example, stimulants might be regarded as unsuitable for someone with constipation and bowel ischaemia, or Fybogel may be seen as useful for someone with constipation and diverticular disease. However, in the interviews the researchers sought to move beyond the scenarios where the choice of laxative was clear-cut and tried to unravel why participants preferred particular laxatives over others, and the factors that affected their decision-making process.

There are no national guidelines for the use of laxatives with older people, although it was mentioned that in paediatrics there is a suggested route to take when managing the condition, moving along in a 'logical' way from one laxative or strategy to another. However, among the GP participants it was more a case of participants using what they were familiar with and adding in a co-treatment or changing a laxative as the results suggested.

Initially, all the GP participants offered reasons for their choice of treatment. However, some commented that there was really no particular reason as to why they chose what they did, or commented that, on reflection, perhaps they ought to use other laxatives more often than they did currently.

"There should be a logic, I suspect there isn't ... it's just what I decide. I don't have an academic reason why I do it."

(GP 6)

"[Fybogel] probably should be [used as first line treatment] more than it is, to be honest. Yeah, I think I probably under-prescribe bulk laxatives, yeah, probably I think I should be using that more of a first line than I do."

(GP 10)

One participant suggested that some of his GP colleagues may feel 'threatened' by an interview which asked about how constipation was managed.

"Sometimes people feel threatened in a way if they don't have any structures, just do anything they like and everyday it changes. It's very difficult. But that's what you want to find out."

(GP 5)

The reasons offered by participants for the choices of specific laxatives included:

- external pressures on GPs to prescribe particular laxatives
- personal preference of individual GPs
- GPs' beliefs about the qualities and properties of laxatives, which cause them to regard some

laxatives as more suitable for prescribing than others in particular circumstances.

External pressures to prescribe particular laxatives

Patient preference

GP participants had experience of patients coming and requesting certain laxatives. As already discussed, they felt that patients were influenced by their own informal networks (family, friends) as well as advertising and recommendations by local pharmacists. Participants commented that they may prescribe what a patient requests if there is no valid reason for not doing so. This stems from a belief that a patient will be more likely to use a preparation that they have requested. Better adherence can mean a more successfully managed patient and, in turn, fewer repeat consultations.

“If it was working, yes, and I satisfied myself on the history that there wasn’t anything else going on ... just because if it’s working it’s, you know, they’re happy and I’m happy, one consultation rather than two or three.”

(GP 4)

Similarly, if a patient requested a bulk laxative, these were regarded by some participants as little more than a dietary-fibre supplement and therefore ‘harmless’; for that reason, the GP was likely to acquiesce with the request and prescribe a bulk laxative.

However, GP participants did comment that, if they did not agree that a patient was constipated and in need of a laxative, they would try to reassure the patient that their current bowel pattern was within a ‘normal range’, rather than prescribe a laxative. Diet and lifestyle advice might be offered at this stage. However, as one participant said, if a patient continued to insist that they wanted a laxative then he would just prescribe a bulk-forming preparation.

“Sometimes when you explain to them they are alright, if they insist then we will probably use bulk-forming agents because it comes to no harm ... Usually they are alright after you take a proper history and examine them – if you didn’t look at them they wouldn’t be satisfied ... when you talk to them you can judge whether the person actually will take your advice, if not, if they insist then we just give it to them.”

(GP 5)

Finally, GP participants also mentioned that a patient may come and request a laxative that they are already buying as an OTC medication but are

finding costly. If a patient is entitled to a free prescription under the NHS (currently all those aged 60 and over, and some other categories of patient are exempt from prescription charges), the GP may agree to prescribe the medication.

“If people ask for it, I mean sometimes people have bought them over the counter and said, ‘you know, have you any of this, this is great, keeps me regular, but, you know, it’s costing me a lot of money, I’m entitled to free prescriptions’, so I just give it to them.”

(GP 4)

Prescription formularies

During the course of the interviews, some GP participants mentioned that their particular practices had pharmaceutical advisors whose role was to review and if necessary recommend changes in what the doctors prescribed. Advisors’ recommendations may be influenced by research findings (e.g. effectiveness, potential side-effects), by cost considerations or by the marketing of a new drug. They would then make recommendations to the practice about which drugs should be given precedence and these recommendations may be written into guidelines for doctors to follow or incorporated into a practice formulary.

Some, but not all practices, appeared to have their own formularies. One participant spoke of having a ‘very loose’ practice formulary and another stated that their practice now had a personal medical services (PMS) formulary which had replaced the practice one. Participants spoke of local formularies, district formularies, central formularies and area formularies. However, it was sometimes difficult to establish exactly which sort of formularies influenced each practice.

“What I tend to do is I use the BNF, and any, you know, sort of guidance there is and we have a formulary for the area now which fits really most of what you need ... well we have a practice formulary and, it’s slightly complicated, we’ve had a practice formulary from about 1985 and it’s a sort of picking list on the computer now. Now that everywhere has produced sort of area forms, we’ve got a PMS formulary, we decided it would be silly to continue to do our specific practice one. So we’ve now gone on to having the PMS formularies as the picking list on the computer, but we apply, if you like, our own formulary for specific conditions, erm, just on what we agree to use out of what’s there. We haven’t got anything specific for that on laxatives, we just use this one.”

(GP 4)

Hence, GPs at any particular practice will have a number of laxatives that they are able to prescribe.

However, there were comments from participants that laxatives are not an area that pharmaceutical advisors tended to address very frequently, if at all.

Cost considerations also played a part in what laxatives were prescribed. One comment was made that the advice given by the pharmaceutical advisor on what laxatives to prescribe is based entirely on cost. A participant at a dispensing practice commented that they had to be cost-effective and tended therefore to prescribe what they stocked in the dispensary.

The following quotations help to illuminate some of the external influences on GPs' decision-making.

"We tend to depend a lot actually on the Fybogel type of bulk-forming agents. Reason was because a few years ago the pharmaceutical advisor was saying lactulose was expensive so we started it around... There's no guidance recently on prescribing laxatives. That was 6 or 7 years ago, when the old one, the pharmaceutical advisor, he was interested more in cost than clinical effectiveness. He'd just say, 'oh, lactulose is costing too much money, can you swap to this?' and recently there's been no guidance at all, the guidance is on other drugs."

(GP 5)

"It's [lactulose is] safe, without any big problems, but I think I've picked up from our guidelines that we've had sort of locally for about 3 years now that it's not very effective... there has been a move in the last 3 or 4 years in relationship to the guidelines, in relationship also to the nursing practice, because nurses make prescribing decisions which the doctors appear to be taking responsibility for, but it's the nurses that are doing this – they are out in the district, they are suggesting treatments, and in whatever influences them from their evidence-based perspective, lactulose is regarded as not friendly any more. And that has therefore influenced the doctors. So if you take these two things – the prescribing guide that is sort of written for doctors, by doctors, and then the change in nursing practice – you're getting a message quite clearly that it's much lower down the order."

(GP 13)

"Like most formulary decisions we have regular meetings about our formulary and we talk about things and we, you know, like everybody was quite happy that what we needed was a bulking agent and that there is not much advantage in any of the others, and that therefore we would use the simplest ispaghula husk."

(GP 6)

"Lactulose is no longer on our practice formulary, mainly because of cost."

(GP 10)

"I mean, we are a dispensing practice so all dispensing practices have to be fairly cost-effective, and therefore we limit what we dispense, and therefore what we prescribe because of the limitations of the business, so you know, Fybogel is what we keep on the shelves, and when you do that you tend then to do it for your prescribing patients as well."

(GP 13)

GP participants from two of the four practices reported that their practice never entertained pharmaceutical company representatives and so could not be influenced by their promotions. Participants from the other two practices commented that it was the nurses who saw pharmaceutical company representatives. They commented that the nurses were influenced by them and they felt that the influence of pharmaceutical representatives was behind the nurses' endorsement of Movicol, discussed above.

Hospital discharge

When a patient is referred to hospital for follow-up investigation about their constipation, or when a person is discharged from hospital, they may be given a prescription of a laxative. In these circumstances, GP participants tended to continue to prescribe the laxative prescribed by the hospital.

"There's two things that have happened here. One, it [Fybogel] is now the recommended thing in [district's] formulary and that has influenced me. Secondly, the hospital seems to be using it a great deal, so quite a few patients are coming out on it."

(GP 6)

"If you send someone for an investigation or whatever, the consultant or the operating doctor who's done the test might recommend something."

(GP 4)

Practice and community nurses

As reported above, the use of Movicol in some practices is a nurse-led initiative that is reported to influence practice prescribing patterns. Nurses are also involved in the administering of enemas prescribed by the GPs. However, when visiting people in the community, nurses may also identify a patient as requiring a laxative and request the GP to prescribe a certain medication.

Personal preference of individual GPs

It would appear that GP participants had used certain laxatives for many years and felt comfortable prescribing them. Often they were the laxatives that they had experienced using during their medical training and they continued to use them in general practice.

“Just familiarity really I think probably it originated in my old training practice when I was training probably; I think I’ve just carried on.”

(GP 4)

“I think it probably is in the practice formulary, but it’s mainly just habit ... just going back to as long as I have been prescribing really, it’s the only bulk laxative I’ve ever really used ... it certainly goes back to house officer days.”

(GP 10)

“Well it’s in our local formulary and again it’s in the formulary and it’s habit. I mean that is something that I’ve grown up with – Fybogel or the generic equivalent.”

(GP 13)

“I think they are fairly standard treatments and that goes well back into hospital training and before.”

(GP 5)

Occasionally, participants’ own opinions on whether a laxative is perceived to be palatable comes into play. As reported above, one participant did not prescribe bran-based laxatives owing to his own dislike of bran.

GP participants also considered whether older people would find a laxative palatable and acceptable. When referring to Fybogel, some participants described it as being much like a dietary supplement of bran: it was deemed ‘natural’. One participant also felt that older people would regard senna as ‘natural’.

“It’s [senna is] well known to patients, patients perceive it as being a natural remedy because it’s been marketed that way and it goes way, way back. It’s acceptable to patients and it’s cheap. It works and it’s acceptable so it fulfils all the categories for good medication.”

(GP 5)

Participants felt that some laxatives may be more appealing to patients than others and that this, in turn, may affect how well they adhere to the suggested treatment. A factor mentioned by several GP participants was how easy a laxative is to use. Taking a tablet or a spoonful of lactulose might be easier to manage than having to open and mix sachets of Fybogel or Movicol. A drink may be seen as more palatable than having to swallow one or more spoonful or granules (e.g. Normacol).

“If I’m honest, my first choice is lactulose. I think it’s a very effective agent. I think people find it relatively acceptable to use and so on. And I think it’s very nicely titratable, so they can take more or less as they need to.”

(GP 6)

“Manevac I seldom use it, it’s actually loads of granules – because sometimes people are frightened, there’s a whole spoonful of granules needed to put in the mouth.”

(GP 5)

In addition to how easily a laxative can be taken, GP participants considered potential side-effects of the laxatives they used. As mentioned previously, there was some concern over using senna long term. One participant noted that lactulose is known for causing wind, and for a patient who was already suffering from wind or who found that lactulose caused wind, Fybogel would be suggested as an alternative.

When compared to alternatives, the GP participants’ avowed preference is typically favoured because it is perceived as having certain qualities which the GP regards as appropriate to the situation. The stimulant laxatives in general, and senna in particular, were identified as being less suitable for long-term use. They were linked by participants to the need for an ever-increasing dose to promote the same effect, and to risks of megacolon, bowel lethargy, cramps, and the possibility of addiction and abuse. However, despite these reservations, senna was still a widely used laxative. Nonetheless, one participant who chose to prescribe Fybogel or lactulose compared these to senna and commented that the former preparations were ‘safer’.

Routine management of constipation

In the interviews, participants were presented with a number of case scenarios and asked to consider how they might routinely deal with such cases. The first scenario was designed to investigate how GPs initially managed constipation in a patient for whom this was a new (incident) condition, in that they had not consulted about this before.

“A 65-year-old female patient comes to see you, complaining that she is constipated. She has not consulted about this before and has no other major health problems. What might you do in such a case?”

GPs were also given the same scenario featuring a 45- and an 85-year-old female patient and again asked how they would manage it. (These scenarios were also included in the nurse focus-group interviews.)

Managing a 65-year-old patient

The processes that participants described in response to this first scenario shared many similarities. For example, there was a concern to rule out sinister causes; this dictated a need to

establish how long the constipation had been going on for, and highlighted the importance of a physical examination of the patient by abdominal and rectal examination. However, there were other actions that were not mentioned consistently by participants, but rather were mentioned by two or three GPs only. These included, for example, looking at a patient's medication for constipating effects and performing blood tests. However, although looking for agents that have constipating effects and performing blood tests were not mentioned consistently in response to this question, this does not mean that the GPs who did not mention these things did not do them; they might simply have omitted to mention them under the interview conditions. Regardless of this, what the data describe is the process that GPs go through when faced with managing a constipated patient and the importance that they attach to certain aspects of this process.

The range of factors that can be identified from participants' accounts of the process of dealing with a 65-year-old woman presenting with constipation consists of:

- taking a detailed patient history
- considering whether the 'constipation' a person presents with constitutes a change in bowel habit (see below); such an assessment requires a consideration of a number of other factors in this list
- giving consideration to the duration of the problem
- establishing whether the change experienced was sudden or recent or whether it had been building up gradually over a long period, sometimes years
- searching for triggers as to the cause of the constipation
- considering the general health of the patient
- considering the role other medications may be playing in the constipation (prescribed, but also OTC medications)
- considering the patient's appetite and diet
- considering the patient's mobility
- considering whether other gastrointestinal problems exist
- performing physical examinations, both abdominal and rectal
- performing blood tests to check for thyroid function, and faecal-occult blood tests
- looking for 'red flags' which may suggest sinister causes, including weight loss and bleeding
- ruling out sinister causes by further investigations including (possibly) hospital-based tests

- discussing treatment options (e.g. diet and lifestyle changes and prescribing laxatives)
- acknowledging that this process of ruling out sinister causes and establishing treatment process takes time and will involve repeat consultations.

It is clearly evident that these categories are not mutually exclusive; while one participant may mention the importance of considering a patient's general health and another may describe looking for any signs that his or her appetite had diminished, in doing so both are collecting background information. Indeed, 'taking a patient's history', which was mentioned by all but one participant, may well include a consideration of a multiplicity of the above factors.

Managing an 85-year-old patient

GP participants were offered the same scenario, but for a woman of 85, rather than 65. Participants' accounts suggested that the process that GPs would go through when presented with an 85-year-old patient would be the same as that for a 65-year-old, and that age itself would not make a difference to the way that they would manage the situation. The same type of investigation and questioning would be carried out to establish the cause and whether there was a change in bowel habit. One participant commented that bowel function may be slower within this older age group, but nonetheless his way of managing the situation would be the same. Another made the point that, although a person may be 85 years of age chronologically, they may be the same as a 70-year-old biologically and therefore should be treated the same.

"I think broadly my management would be the same – I mean there may be individual patient characteristics that would make you either more or less likely to investigate them thoroughly, but broadly speaking, if everything was otherwise identical apart from age, then I would treat them the same."

(GP 10)

"I think if there was no other difference but age then I would just deal with it exactly the same, erm, allowing for that you know that bowel function will tend to be slower with age, but nonetheless if it's somebody who is presenting exactly the same thing, I don't think I would do anything differently. If it's somebody who is much older and has different, you know, other illnesses of which I know, or there are other actors involved, then I might well take those into account – but not specifically the age."

(GP 4)

"Again, depending on the scenario I would still think, well, that's a change in bowel habit, but if I can

explain it by a variety of things, I would be less anxious. If the person was ambulant and getting around OK, but there wasn't a lot of other medication, I would treat them rather like a 65-year-old. Because we get a lot of 85-year-olds through the door here, independent, perfectly fit. Chronologically they are 85 but biologically they are 70, so I would treat them very much the same way. It depends on how much I can reduce my personal anxiety."

(GP 13)

Thus, in terms of treatment, the majority of GP participants would treat constipation in the same way, although two did point out some things that they may do differently. One felt that he would be less inclined to push dietary advice, seeing older people as less likely to change their eating habits.

"I don't think dietary advice is going to make that much, they're going to be so much further set, I don't think it would change that much."

(GP 5)

Another commented that what he would prescribe depended on the circumstances of the older person; for example, a spoonful of medicine such as lactulose may be easier for someone living alone to take, rather than a sachet that required opening and mixing, and therefore required greater dexterity.

Two participants commented that people of an older age who were in nursing homes were less likely to cause anxiety to GPs. First, the causes of constipation in a nursing home may be more obvious: less mobility, "the diet is sort of quite iffy" or patients may be on an increased number of drugs. Secondly, those living in nursing homes are given their drugs by the staff and therefore the staff would be responsible for mixing sachets, so these preparations could be used.

Managing a 45-year-old patient

The majority of GP participants reported that their anxiety about there being something sinister was reduced in this younger age group. However, one GP felt that constipation in anyone over 40 raised suspicions. Initial questioning would follow the same process as for a 65-year-old in trying to identify a cause of the constipation and its duration, and then assessing whether there were any 'red flags' present that would increase concern.

Differences were apparent in how some participants might manage a 45-year-old as opposed to a 65-year-old patient. Dietary advice would be given more emphasis in this age group.

Some participants appeared more able to take time in deciding whether to prescribe or investigate the complaint, and may choose to give dietary and exercise advice and then review the patient again at a later date. However, if after review, there was no progress they may choose to investigate further. One GP participant explicitly stated that he was less comfortable prescribing laxatives in a younger age group in case the patient ended up on them long term.

"I would be less likely to refer for investigation in the initial stage if they were younger, just because the likelihood of it being anything serious is less."

(GP 10)

"I think my instinctive anxieties are sort of reduced at that age because the chances of there being something pathological I think are probably smaller. I think they are not nil, but they are smaller. However, people just don't get constipated, I don't think, so what is it that's a factor? – and if it's explainable, fine. If it's not explainable and it's out of the blue I'd probably want to review them. I might not do investigations, I probably just want to review them with some advice about diet, exercise, over-the-counter stuff and further down the line, if we weren't getting any progress then I would think about possibly doing similar sorts of investigations."

(GP 13)

Constipation and changes in bowel habits

GP participants were concerned to distinguish between 'constipation' and 'a change in bowel habit'. A change in bowel habit could mean a change to increased frequency or decreased frequency, or indeed any change, such as alternating constipation and diarrhoea. A change in bowel habit could be indicative of something more sinister and therefore warranted further investigation. However, deciding when a bowel habit had changed was not straightforward. Constipation was regarded by the GP participants as being a symptom, rather than an illness. At times, participants struggled to explain how they made the distinction between diagnosing presenting symptoms as 'constipation' or 'a change in bowel habit'. Indeed, constipation is a point on the continuum of 'a change in bowel habit'.

The following considerations were mentioned by GP participants when they were deciding whether a patient's symptoms constituted a change in bowel habit or constipation. However, it is the combination of these factors, their severity and the context in which they appear that gives them meaning.

- Reduced frequency of passing a stool, outside the range of what is considered normal for the patient.
- A change that had not occurred previously, and is therefore a new change for that individual.
- The duration of the constipation: had it lasted for only a few days, or a few weeks? If the change had persisted over a number of weeks, then this was more indicative of a change in bowel habit. If someone reported that they passed stools infrequently but this pattern had persisted for years already, then a GP may decide not to investigate, as it was not classed as a 'change'.
- The presence of 'red flag' or 'alarm' symptoms such as bleeding or weight loss accompanying the constipation was regarded as warranting further investigation.
- Sudden-onset constipation where someone became acutely constipated could be indicative of a blockage and require further investigation. However, it could have a less sinister cause, such as a dietary or lifestyle change.
- Participants remarked that it is therefore important to try to establish the cause of the constipation, for example change of medication, diet or lifestyle. When there is no obvious cause, suspicions are heightened.

The following quotations illustrate the process that participants go through to make the distinction between constipation and change in bowel habit.

"Right, I think the first thing is that if this a change in bowel habit and you treat it, not really as constipation but as a change in bowel habit, and as change in bowel habit you have to first rule out any significant cause, i.e. cancer of the colon, as a cause for this change in bowel habit which, so there is this care that needs to be taken, in not just seeing it, as I say, because constipation is a symptom not an illness. And to rule out the, any more significant illness, so it needs a full abdominal examination, it needs a rectal examination. If there is further cause for concern it may need investigation by the unit at the local hospital, and who, and so on. But it may well be that with a slower change to a slower bowel action and a firmer bowel action over a period of time with nothing to find on examination and so on – that therefore one would treat it as constipation I don't know, there are some factors that make, that I somehow allow myself to think I am going to treat this as constipation, not as a change in bowel habit. I think it may well be, I think it is to do with past history, even a woman in her sixties, you know, if she's had no previous history of constipation that you've got to look for the cause, and I would look for the cause before all else. If, however, she is somebody who came in and said, 'I often get like this – 2 or

3 years ago I was like this', I would be less concerned."

(GP 6)

"Yes, if she's come in because, if she'd say, right, 'normally doctor I go the toilet every second day, but for the last few months I've only been going once a week' [right] or it's harder, then I would want to investigate that, but if she'd come to see me with constipation, say, say if she'd come to see me about something else or medication and she brought this up, so actually that bowel habit had been the same for 5 or 10 years I wouldn't investigate then."

(GP 4)

"Well, the constipation may be a change in bowel habit, but if it's an ongoing problem, has been the same for years then I would not be overly concerned and probably wouldn't initially refer on. But if the constipation is relatively recent then I would be more sort of circumspect about it and if I had concerns I would, in that situation, refer for further investigation."

(GP 10)

"I think it's always, I mean I think the best thing is people, you know, is the way people actually refer to it, because you talk to somebody about constipation and you ask what the motions are like and they say, 'well I've always been like this', I think they're usually probably right. So sometimes, you know, people are presenting and they say I've always dealt with this before and either they've just mentioned it or they are somebody who has been self-medicating. There are other people who I think very definitely get a message that this is quite unusual for them ... yes, it's out of the ordinary, it's not something that they've been used to. I mean, there's some people who'll say, 'I know that if I do such and such I'll always get constipated' and other people say, 'I've never had anything like this before', and then there's the shades between that [*laughing*]."

(GP 4)

In the interviews, the management approaches adopted and described by GP participants were clearly aimed at trying to reduce their own anxieties and to satisfy themselves that they had not overlooked any potential malignancies or bowel cancers.

"The main thing in my mind is to exclude a significant bowel problem, particularly a bowel cancer, beyond that, I probably tend to treat it as constipation."

(GP 10)

"Constipation is sort of that big, you know, the size of a big balloon, bowel cancer is, you know, the size of a tennis ball, so you can't refer absolutely everybody for investigations. So you have to have some sort of sieve, which ensures that you don't miss the odd number of tennis balls."

(GP 13)

The 'sieve' that was referred to in the above quotation appeared to operate on two levels. Level 1 included looking for a cause that could explain the constipation, such as medication increase or change, dietary change, decrease in exercise or fluids, which would therefore allow GP participants to manage the problem as constipation. Level 2 was a consideration of whether the constipation with which a person presented constituted a change in bowel habit and should therefore be investigated and managed as such; this included being aware of 'red flags', 'hallmark symptoms' and 'alarm symptoms', such as pain, blood, weight loss, duration and severity.

"If you can understand, or if I can understand why that person is constipated, and they are constipated because, as opposed to there is no clear reason why they should be so, it might be cancer ... it's sort of slightly unusual if there is no trigger to it, like dropped exercise, taking something over the counter, change in diet. If there is nothing happening there and it's been going on for, let's say, a month, but there were no other sort of symptoms like bleeding or weight loss, I would wonder what was going on and would classify that as a sort of change of bowel habit – so I would examine them, I would do a rectal examination. I would probably do some baseline bloods as well."

(GP 13)

"... at what point, at what point do I just accept that this is constipation? ... I look for other factors that might cause constipation; I look at their dietary history; I look at their exercise history and so on, but if it is a change in bowel habit, it is change in bowel habit and first that has to be investigated, and only if it is something that has been repetitive throughout their life – and it usually is, in reality. Obviously with other symptoms, so if they say I am going very infrequently, passing much harder motions and there is blood there, then obviously that puts it straight up, even though it could still be caused by nothing more than constipation."

(GP 6)

However, the two levels were clearly linked and if red flags were present, even if there was an 'obvious cause' of the constipation, then further investigation would be carried out.

First line treatments

GP participants were asked about their first line treatments for constipation. However, it is recognised that this was dependent on a host of other factors, many of which have been addressed above in the reporting of the participants' accounts of the routine management of constipation and factors influencing their choices

of laxatives. First line treatments could vary depending on factors, including:

- symptoms with which the patient presented
- the patient's former bowel history
- the patient's general health
- prescribing preferences of the GP
- presence or absence of red flags and warning symptoms, and subsequent management.

However, taking as a given that GPs had considered all the information provided by the patient and had reached the point where treatment was considered appropriate, the first line treatments chosen by GPs vary. In some instances advice is the first line treatment, rather than any prescription laxative. The findings presented above illustrate how first line treatments may differ considerably depending on the context in which patients present with symptoms of constipation. For example:

Context 1: A patient may present with pain and be very uncomfortable, and may not have passed a stool for several days. An examination may reveal hard stools in the rectum and in such a case senna may be prescribed as a short-term emergency treatment measure to get a person moving. In cases where someone is very bunged up an enema or suppositories may be prescribed.

Context 2: Constipation is mentioned 'on the back of' a consultation about another matter, is not deemed by the GP to require immediate treatment with laxatives and is not causing the patient much concern or discomfort. Diet and lifestyle advice only may be given in such a case.

In summary, the following themes emerged from data about first line treatment:

- All participants mentioned giving diet and lifestyle advice, but the emphasis given to this advice varied (see below).
- All participants mentioned using senna, but the timing of the use of senna varied considerably (see below).
- For longer term treatment, Fybogel and lactulose were popular choices.
- Co-treatments (combining laxatives) were often used at the very start of treatment to produce an immediate result, or considerably later in the treatment process when single laxative treatment was proving insufficient or ineffective.
- Changing or reducing constipating medication (where possible) was mentioned by two GPs (from the same practice) as a first line of treatment.

Diet and lifestyle advice as first line management

All GP participants acknowledged the importance of diet and lifestyle advice when first treating constipation, but the emphasis given to this varied among participants. It was reported that participants considered diet and lifestyle advice differently according to the situations with which patients present to GPs (as already discussed with respect to younger and older patients).

However, various ways of using diet and lifestyle advice within the treatment regime for constipation emerged. The majority of participants emphasised the importance of diet and lifestyle to their patients, but at the same time prescribed laxatives alongside this advice.

“Usually a combination of them both, I would advise her about dietary fibre and increasing fluid intake, but I would probably prescribe as well.”

(GP 10)

However, some participants distinguished between their patients in terms of whether dietary advice or a laxative should be used as the first line treatment. If the fibre content of a patient's diet was felt to be inadequate and it was felt that the patient was able to increase this via their diet, then dietary advice only may be given. However, if dietary fibre was felt to be already adequate, then laxatives could be a first line treatment.

“It depends, erm, I mean if somebody comes in and says, ‘I’m really uncomfortable’ and [I] examine them and find they’ve got very hard stools, you know it, so if somebody’s come in and really saying, ‘I need something done now’, then I would examine them there and then and would prescribe. If somebody has said, ‘I’m just concerned because it’s getting a bit difficult to go’ or ‘I’ve been OK but I’m sore, I’m getting anal fissures’, something like that, I would probably prescribe. But if it’s, erm, whereas these things often come in on another consultation so they haven’t come saying, ‘I desperately need something’, it’s while you’re talking about something else they say and ‘I’ve also been a bit constipated’, I would then tend just to give advice.”

(GP 8)

One GP emphasised that diet and lifestyle is of paramount importance in the treatment of constipation and appeared to use diet and lifestyle advice exclusively as the first line treatment. Information pamphlets were given out by this GP.

“The first thing I talk about is lifestyle ... we have a little pamphlet, the practice, which talks about high fibre, higher fibre diet, plenty of fluid and exercise ... and the first line treatment would be ‘you

need to try this first’ ... I will tend first to give them our pamphlet and say, ‘this is the best way of curing it’, because it is really about diet.”

(GP 6)

As a contrast, another participant felt that giving dietary advice was “blowing against the wind” in many cases and although he would offer this advice he looked towards laxatives as the main first line of treatment, accompanied where appropriate by a change in constipating medication. However, dietary change, where it was possible to implement, was regarded more as a preventive measure than as a treatment.

It is evident from these data that GP participants described many different ways of managing and treating constipation.

Nurses’ perspectives on the management of constipation

Nurse participants (practice and district nurses) reported that contact with older people with constipation was often initiated by GP referral. This usually happened when an older patient required an enema. Nurse participants reported that a large number of contacts with constipated patients occurred in care homes (residential and nursing), from where carers may call nurses and request a visit. The third type of contact with constipated older patients reported was self-referral by a patient or family member. This was more likely to happen where patients had been seen regularly by nurses.

Nurse participants were asked how they responded to patients who presented with constipation. As with GP participants, it was noted that this was context dependent and influenced by a number of different factors. The factors considered by nurse participants included whether a patient was ambulant, resident in a care home, impacted or having ordinary constipation, or considered at risk for constipation (see below), where a potential cause could not be identified or where constipation complaints were attributed to older people obsessed with their bowels.

Chapter 7 reported nurse participants’ views on the main causes of constipation in this age group: lack of exercise, poor diet, inadequate fluid intake and constipating medications. In managing older people with constipation, these were considered important risk factors among older people in general, to be taken into

account when assessing patients and ‘treating’ constipation.

I: “Right, and do you have people who you go in to see specifically about constipation?” N2: “No, not as a rule. But, if it’s a problem I’ll ... it tends to be, well it can be happened with a lot of things [mmm]. With the elderly people it’s part of our assessment when we see anybody for the first time, part of activities of daily living, and it’s one of the questions I would be asking. So when I see people for the first time I would be asking, you know, what’s their normal bowel habit ... ‘cause what’s normal to them isn’t normal to me [mmm], and are they having any problems that way, and we start and go through the other things of daily living which can affect constipation, which are, er, reduced fluid intake and dietary fibre, which tends ... which I would say are the main causes of constipation in the elderly. [Right, OK.] E-em, and we have to go through those first and I usually find that they’re not, they don’t have many fruit or vegetables, things you would normally associate with fibre, and they nearly always have a reduced fluid intake. They’re not taking the required amount of fluids so they, that’s often the case. [Right.] So that would be my first line, the first diagnosis that there was a problem there and the treatment, I would first of all go onto that unless it was, em, quite an acute problem and they were in discomfort, and then I would have to take it one fur ... one step further, and examine them abdominally and rectally, if, if they give me their consent [uh-uh], which is what we have to do now [right], digital rectal examination, you have to have the patient’s consent. [Right, OK.] And I would perform that and, er, make a, a diagnosis on that and [right] then take it further.”

I: “Right, so usually the people that you see you’re seeing for another reason, and constipation is part of the management, like overall management of them?” N2: “It is with, with the elderly. Also, em, th ... , em, multiple medication, you know [yeah], can cause, a lot of people, em, are having painkillers and anything with the codeine in causes constipation. And they’re unaware of that, so sometimes I can go for something unrelated but that problem is there. That’s often not the one [right] thing that you go for first.”

(Practice 6)

When dealing with someone born in the 1920s and 1930s – the ‘between the wars generation’ – other considerations come into play: increasing immobility in later life, whether patients hold a strong belief that they should move their bowels daily and as a consequence have been regular laxative users and whether, because of long-term laxative use, they have become ‘resistant’ to or dependent on laxatives. For postoperative patients and the terminally ill, reduced mobility, the increased likelihood of the concomitant use of painkillers and other constipating drugs, and the

potential for inadequate food and fluid intake are all risk factors that nurse participants look out for when first assessing patients.

“Well, it’s, it’s the other thing it’s the other things, like, like immobility. If people have come out of hospital [yeah] following surgery, em, you know, they, they’re often immobile, they’re not having their normal lifestyle, so you’ve got to allow some changes for that. E-em, they may not have been eating if they’re nauseated, you know, and on, so how can they have the normal bowel routine [movement, right, right] if, if they’re nauseated, you know.”

(Nurse 60, Practice 6)

In the focus-group interviews nurse participants emphasised the importance of responding to identified risk factors and highlighted different management strategies for older people generally and those who were terminally ill or recently discharged from hospital.

Community-dwelling older people

For older people living in their own homes, those who were self-referred or those who were already seeing the nurse for some other condition, nurse participants were generally reluctant to prescribe laxatives immediately as a first line of treatment, unless the person was impacted or felt very uncomfortable.

I: “No, OK, thanks, right. And how likely is it that, ehm, that at an initial consultation that an older person would be given a prescription at that stage? I mean you have mentioned diet and lifestyle, but nobody has mentioned prescription yet – is diet and lifestyle like your first line of, ehm, treatment almost, or would you tend to go for a prescription?” N1: “Well it depends, patient is like, if they are very, very uncomfortable [mmm] and they just can’t go and they haven’t been for a while, then sometimes you do need to discuss it with their GP [right]. ... and get them something to take orally, you might have to give them an enema or suppositories to relieve the constipation, but certainly after that you would be looking to not giving them long-term medication, but looking at, er, you know, re-educating them on fluids and diet and [right], you know, lifestyle [yeah] as [names of other participants] said, you know”.

(Practice 6)

It would appear, then, that nurse participants try to treat and prevent constipation in ambulant older people with predominantly non-laxative measures. This commonly included providing advice on appropriate dietary changes, increasing fluid intake and, if possible, encouraging exercise and mobility. Prune juice was repeatedly mentioned as a very effective, successful and

widely used non-laxative measure for addressing constipation. Participants reported that prune juice was effective even in impacted patients and was useful for long-term maintenance of bowel regularity.

N2: "We actually, ehm, don't use laxatives immediately. [Right.] We've discovered that if you increase the fluids, ehm, look at the diet and give them prune juice. [Ah, right.] We've started prescribing prune juice, well obviously you can't prescribe it, but we actually tell people to get it, and we start people off on prune juice and tell them to get it. [Get it, right.] And it's wonderful." N1: "It's wonderful." ... "So you might give them, er, you might just prescribe you know, if they're actually impacted they might need something for a couple of days [right], you know, until we get them established [mmm]. But it wouldn't be a case of them then taking laxatives for ever [no, no] – it would be a short-term measure to ... like an enema or something [aha] And you might just give them a short course of a laxative just to, ehm, you know, clear them high up [right] and things like that, but just a short course, and then, ehm [right]." N2: "That's actually my first line of attack now is the prune juice." N1 (overlapping): "Mmm, but if you actually give them like a good glassful to get them started" N2 (overlapping): "You need a full beaker full." N1: "... a full tumbler full [ah right] to get them started off and it's surprising how" N2 (overlapping): "... and then once they get going" N1: "... and then once they get going" N2 (overlapping): "... at breakfast a glass to keep them regular."

(Practice 2)

If a laxative was needed, it appeared that the first choice among nurse participants would be Movicol, as this was considered a very effective laxative that 'never' fails. Nonetheless, Movicol was used mostly as a relatively short-term laxative, because of considerations about cost. The long-term management aim of nurses was to get older patients off laxatives.

Older people whose bowels were impacted

Nurse participants reported that older people whose bowels were impacted would normally be encountered as referrals from the GP to the nurse with a request to perform an enema. Patients would be expecting an enema since this would have been what the GPs had told them would happen. For this group of patients, an enema and advice on drinking a daily glass of prune juice would be the first line treatment advocated by nurse participants. Fletcher's phosphate enema (a softener) would be nurse participants' first choice of preparation in these circumstances, as it does not require optimum fluid intake. If that did

not work, then participants would advocate the use of Microlax, but this osmotic laxative requires that patients are drinking adequate fluids. As highlighted in Chapter 6, many older people who are seen by nurse participants are not consuming an optimum amount of fluids. For others who have impacted bowels, nurse participants would use laxatives in the short term to clear the bowels. Future management would, once again, include diet and lifestyle modification.

Nurses' perspectives of different laxatives

The focus-group interviews with nurses provided different accounts of their laxative preferences from those provided by GP participants, and highlighted the complexity of the management of constipation in primary care. In responding to the voices of nurse participants, one should be cautious about generalising to all older people with constipation, since the caseloads of nurse participants are more likely to consist of older people with complex health needs and those who are most disabled. However, their comments, like those of their GP colleagues, reflect much that has been described by older people themselves and reported in Chapter 7.

Experience of bulk-forming laxatives

Fybogel (ispaghula husk) was the most widely discussed bulk-forming laxative mentioned in the focus-group interviews, reflecting the wider use of this product in this branded form among participating practices. Participants were concerned that, in order to be effective, Fybogel required good fluid intake and required that people were active, lifestyle factors not always observed in older adults. Nurses also reported that there was not good adherence because patients found its preparation and consumption difficult. As a result, and in contrast to GP participants, nurse participants reported that Fybogel is not commonly prescribed by nurse prescribers, because older people dislike it and find it 'gloopy' and unpleasant to take. Participants further claimed that, although Fybogel was prescribed by GPs and was on repeat prescriptions, patients did not use it and their "cupboards were full with it".

I: "Well, which ones [laxatives] would you have prescribed first and then which would you perhaps recommend for being prescribed – are there ones on there that you are able to prescribe?" N1: "There are only, ehm ... [N2: the Fybogel] ... the Fybogel and you have to prescribe it as, ehm, the isp ... ispaghula." I: "Right, so that is the one that you are able to prescribe?" N1: "That's the one that we are able to prescribe." I: "And is that the one that you would tend

to use?” N1 and N2 (in unison): “No.” I: “Is it not, right?” N2: “Older people hate it [N1: hate it] [ah, right, OK]. Find it very difficult to take.” I: “Right, this is where you dissolve it in a glass and drink it down?” N1 and N2 (in unison): “Yeah, yeah.” N1: “And you don’t get the compliance with it.” I: “Right, so you don’t really tend to go with bulking ones, OK. And you wouldn’t recommend another one off that list was prescribed by the GP, that’s just not the kind, the type of laxative that you would generally use?” N1 and N2 (in unison): “No, no.” I: “Right, OK, that’s fine, and the main reason for that would be the compliance, the people not liking taking it. And have you had, have you kind of experience that where it has been prescribed and it hasn’t been liked?” N1 and N2 (in unison): “Yes, yes.” N1: “We can go and find cupboards full of it – they regularly go and get their prescription every month because ... [N2: the doctor has says they have to have it] ... the doctor says they have to have it – but they don’t ... [they don’t take it.] ... it’s surprising how many boxes when people are clearing out that they bring back.”

(Practice 2)

Experience of stimulant laxatives

Stimulant laxatives were not discussed in any detail within the focus groups. There was a shared view among nurses that sometimes stimulants caused ‘gripping’ pains and discomfort, and that some patients avoided them for this reason. Senna was nevertheless recognised as a stimulant laxative that was prescribed to and found acceptable by some patients. Nurse participants recognised that some older patients preferred to take tablets rather than powders or ‘gooey’ drinks. Senna is marketed as a natural laxative, something that also attracts some patients. Other stimulant laxatives that are favoured by older patients are co-danthramer and co-danthrusate. Nurse participants reported that some older patients prefer these laxatives to lifestyle changes.

Experience of osmotic laxatives

Of all the osmotic laxatives, Movicol was the most widely discussed in the focus groups. Participants

were extremely positive about the acceptability of this agent to patients, and suggested that it was reliable and more effective than other types. Participants recognised that it was an expensive agent, but still indicated a strong preference for it over other preparations of the same class and over laxatives from different classes.

Beliefs in the effectiveness of lactulose were not as positive, and participants were not keen on their use with older people because of the need for an optimum fluid intake, as discussed above. Nurse participants perceived that lactulose was prescribed a lot by GPs, although this was not borne out in the GP interviews.

Summary

This chapter highlights that GPs’ and nurses’ management of constipation was often influenced by the self-management practices and beliefs of patients, although GP and nurse participants also had their own preferences of management strategies and particular laxatives (often within the guidance and constraints of their local formularies). Although providing dietary and lifestyle advice in certain circumstances, GP participants routinely prescribed and experimented with different combinations of laxatives. Although there was only a small number of interviews with GPs, it was evident that a range of management strategies was used by participants, with little clear consensus on the optimum strategies. Nurses were often referred patients by GPs to perform enemas. There was a stronger consensus in the nurse focus groups that diet and lifestyle advice was very important, particularly about fluid intake, but where nurses prescribed laxatives there was a preference for Movicol.

Chapter 9

Conclusions

Understanding constipation

There is little consensus in the medical literature of an explicit definition of constipation. Expert definitions of constipation exist within the Rome II consensus statements on functional constipation.⁶⁵ According to these criteria, a diagnosis of constipation requires two or more of the following symptoms to be present for at least 12 weeks, which need not be consecutive, in the preceding 12 months:

- straining in more than one in four defecations
- lumpy or hard stools in more than one in four defecations
- sensation of incomplete evacuation in more than one in four defecations
- manual procedures (e.g. digital evacuation or support of the pelvic floor) in more than one in four defecations
- fewer than three defecations per week.

Few practitioners, however, appear to apply the Rome II criteria in their clinical practice; instead, constipation is typically viewed as a subjective diagnosis.¹⁴ Nonetheless, among clinicians there is some consensus that there exists a wide variation between individuals in the normal frequency of bowel movements, ranging from three times per day to three times per week.⁸

The perceptions of older people reported by a small number of previous studies suggest that lay definitions of constipation differ from professional criteria.¹¹⁻¹³ Frequency and ease of bowel movements, however, remain key components of constipation for the majority of older people.

The need for evidence

The 1997 HTA 'Systematic review of the effectiveness of laxatives in the elderly'¹ concluded that there was limited evidence of the clinical effectiveness or cost-effectiveness of laxatives prescribed for older people in primary care. The review reported the paucity of good-quality studies comparing the outcomes of different classes of laxative (bulk-forming, stimulant or osmotic) or of different types of laxatives within classes. The brief

updating of the literature, reported in Chapter 1, suggests that the situation had not changed in 2005 and that there continues to be scant evidence from studies regarding the clinical effectiveness or cost-effectiveness of the use of laxatives among community-dwelling older people. The following research recommendations were proposed in the original review:

- "Research into the effectiveness of overall dietary change (including increased fluid intake) in the treatment of constipation in the elderly."
- "Trials of other bulk-forming and fibre-containing food supplements."
- "Intra-class comparisons of bulk laxatives."
- "Intra-class comparisons of stimulant laxatives."

Studies investigating the meaning of constipation and different treatment strategies and clinical trials to evaluate the clinical effectiveness and cost-effectiveness of treatments remained to be done.

Implementation of the STOOL trial

The STOOL trial was designed as a pragmatic,³⁵ factorial, multicentred RCT to investigate the cost-effectiveness of different laxatives (used singly and in combination) and management strategies for chronic constipation in older people. The outcomes for people aged 55 years or more, registered with study practices, experiencing constipation and using prescribed laxatives, were to be compared for different stepped management strategies of three types of laxative (bulk-forming, stimulant and osmotic laxatives). The trial was unsuccessful in recruiting patients on laxatives to the trial and experienced considerable difficulties in encouraging general practices to participate fully. Why was this the case?

Although speculative and based on the experience and beliefs of the research team and collaborating practitioners, the changing climate of research since the year 2000 has created considerable barriers to complex trials of 'routine' interventions. This trial provides an example of

the impact that the report of the Alder Hey Inquiry,⁵¹ the implementation of the European Human Rights Act⁵² and the enactment into law of the EU Clinical Trials Directive have had upon the health services research community.

Ethics committees and NHS trusts, faced with the introduction of a more prescriptive and bureaucratic framework, were unable to respond to the increasing workload generated within the envelope of resources provided. Local responsibility for the implementation of research governance led to variations in procedures across study sites. In some cases, there was rigid interpretation, and sometimes overinterpretation, of national guidelines. Trust research management and governance staff and ethics committees became more risk averse and were apparently unable to reflect on the processes that they were implementing. As a result, guidance to researchers appeared inconsistent and inflexible and the process of ethical review and R&D approval became increasingly bureaucratic and unresponsive. The imperative for researchers to have honorary contracts was particularly challenging because of the paucity of expertise and resources to implement the policy efficiently. The authors' experiences in these respects are echoed by other researchers conducting multicentre studies (trials and epidemiological studies), particularly those involving primary care, at a similar time.⁵⁴⁻⁵⁷

In addition to the inevitable delays created by these developments, the STOOL trial found that changes in the way that non-invasive clinical research was to be implemented increased barriers to patient participation. The provision that patients should opt into the research, rather than opt out, meant that the nature and objectives of the trial were never fully explained to many potential participants. Individual practices were unable or unwilling to take on the considerable extra workload that the opting-in provision creates. At the same time, the ethics committee was not always willing to think creatively about how to strike an appropriate balance between the need to protect the rights of potential participants and the need to evaluate interventions of unproven value. As with the attempts to negotiate the jungle of research bureaucracy, the authors' experiences with the negative impact, in terms of lower participation rates and biased achieved samples, of the opt-in approach have been described by others.^{59,60} Debate persists^{58,61} on the adverse implications for trials, epidemiological and health services research.

At the time of writing both ethical review processes and research governance have become less challenging, partly because both sides have learnt to 'play the game', but also because of important strategic changes to these processes that have made them more streamlined and responsive to the research community's concerns.

Specific barriers that were identified by surveyed GPs suggest that the opportunity costs to practices of participating in STOOL were often considered too great in terms of time, practice resources and nursing capacity. For some, the subject was insufficiently interesting. The barriers for patients were unclear from the informal survey data, but GP participants suggested that they (the patients) were not in equipoise and would be unwilling to switch from their preferred treatment regimen, particularly if it was currently perceived by the patient as being successful. Some of the patients who did agree to take part in the study and switched to a trial laxative later decided to withdraw completely from the trial or stayed in the trial but switched back to their pretrial laxative, owing to either side-effects (diarrhoea) of the new agent or its perceived lack of effectiveness.

Interpretations from the qualitative study

Analysis of data from the qualitative study of patients on laxatives, GPs, and community and practice nurses provided a clearer picture of some of the difficulties experienced in recruiting both practices and patients.

What is constipation?

Previous studies^{8,11-13} have suggested that constipation has been a difficult condition to define in clinical practice, with implications for how it is operationalised in epidemiological and evaluative research. The accounts of participants in the qualitative study reinforce this view and go some way to helping us understand why constipation is such a complex condition to define, classify, diagnose and treat.

Two meanings of constipation were provided by GPs: a patient-centred definition and a textbook definition; neither fully reflected the Rome II criteria, although both contained elements of those criteria. Patient-centred definitions focused on the idea of a change from 'normal' bowel function as defined by the individual, whereas 'textbook' definitions focused on reduced frequency of bowel movements, associated with a range of

other unpleasant signs and symptoms such as bloating, difficulty passing stools and hard stools.

Nurses' definitions of constipation also included both a patient-centred perspective and descriptions of particular signs and symptoms associated with constipation. Person-centred definitions focused on changes to people's routines in terms of reduced frequency of bowel movements and difficulties and discomfort experienced by older people in passing stools. Although the perspectives of GPs and nurses appear somewhat similar, in practice nurses adopted a more patient-centred approach than that described by GP participants.

The meaning of constipation to older patients was similar to the health professionals' patient-centred perspective. Frequency of bowel movements and changes in normal bowel routine were central to participants' definitions, with the interpretation of 'normal' being quite individualised and shaped by expectations and experiences. Participants in this study were very clear about what they perceived to be 'abnormal', including the size, form and consistency of stools, difficulties and discomfort in passing stools, feeling blocked and unpleasant symptoms such as bloating and flatulence.

What emerges from the different accounts of patients and health professionals is a common understanding of the general nature of constipation, but also considerable differences of perception within and between patients and health professionals. A key area of difference is in the interpretation of 'normal' frequency of bowel movements. Many older people believe that 'being regular' requires a daily successful bowel movement, success being the passing of 'normal' stools without difficulty or discomfort. This contrasts with the health professionals' perception that 'normal' frequency can be anything from three times per day to three times per week, depending on the individual and their life-course experience of defecation. This difference in the interpretation of normal frequency clearly influences the way in which patients manage what they perceive as constipation, as well as professionals' responses to their requests for help and the way in which they as doctors and nurses manage and treat 'constipation'. It also has major implications for the way that constipation is defined and operationalised in epidemiological and evaluative studies. The application of formal definitions, such as those incorporated into the Rome II criteria¹⁷ or even the modified Rome III criteria,⁷⁹ is likely to be challenged by

professionals and patients alike, and may be over-restrictive in identifying those who seek management for constipation.

Causes of constipation

There is a range of beliefs and scientific explanations about the causes of constipation. Through the analysis of the transcripts of interviews with older people, several broad themes were identified. It was variously believed that constipation is: (1) linked to specific diseases, medical conditions or health problems; (2) caused by the consumption of specific medications or results from particular surgical procedures; (3) caused by diet or eating habits; (4) part of the ageing process; (5) due to not going to the toilet when one has the urge to defecate; (6) hereditary; (7) caused by stress or worry; and (8) caused by environmental exposure.

GP participants provided a more focused subset of explanations than did patients, focusing on the increased prevalence of constipation with age, but emphasising that this was most often due to changes in diet and lifestyle, the physiology and degenerative processes of ageing, and the iatrogenic impact of opiate medications. Nurse participants provided explanations for the causes of constipation that drew upon both older people's perspectives and the more focused GP perspective. They identified that constipation was linked to decreased mobility, decreased food intake, decreased fluid intake and the consumption of certain medications. Although they articulated their views somewhat differently, there nonetheless appears to be considerable overlap between the beliefs of older people and those of health professionals.

Self-management of constipation by older people

From the accounts of older people a picture emerges of constipation often being a 'problem' for a large part of their lives that had often been managed 'informally' by the participants within their own social networks of family and friends. Self-management of constipation included the purchase of OTC laxatives, herbal remedies and dietary supplements, as well as changes to diet and lifestyle. These strategies were used to maintain regular bowel movements or to prevent and treat constipation.

Although self-management was most often the first response to the symptoms, participants usually continued to take OTC laxatives and other agents once professional help had been sought.

Older participants had a wide experience of different management strategies and treatments for constipation, and at the time of the study had firm preferences about the laxatives they would use (irrespective of whether they were wholly effective).

GP management of constipation

GP participants recognised the experience and widespread use of laxatives among their patients. Participants identified the absence of clear guidance on laxative prescription. They presented different patterns of laxative prescription, with strong personal preferences. Overall, GP participants prescribed the four main types of laxatives (bulk-forming, stimulant, osmotic and faecal softeners) for constipation, but did not perceive these as closed categories. They often experimented with prescribing different combinations of laxatives, readily changing preparations when patients reported that a particular product had no effect. Ispaghula husk was the most widely prescribed. It was perceived as acceptable to patients, effective, inexpensive and 'natural'. It was prescribed for healthy bowel maintenance and long-term use. Stimulant laxatives were widely prescribed, but not perceived as suitable for long-term use, and were mainly prescribed for constipation that had been caused by opiate use. Osmotic laxatives were prescribed less often, but some GP participants were moving towards prescribing them more frequently. The emergence of new agents such as Movicol may be changing participants' preferences for different laxatives.

Nurses' management of constipation

In contrast to GPs, nurse participants' management of constipation was not laxative driven. Study participants were seeing a subset of the patients seen by GPs, focusing on those who were less mobile and frequently frailer. They were more likely than GPs to treat and prevent constipation using non-laxative measures that included providing advice on appropriate dietary changes, increasing fluid intake and, if possible, encouraging exercise and mobility. Their management goals were often to get patients off laxatives; but if a laxative was required, then it appeared that the first choice for the vast majority of nurses was Movicol.

Implications of qualitative data

The rich descriptions of the meaning, causes and management of constipation by study participants highlight a number of implications for the assessment of interventions for the prevention and treatment of constipation.

For older participants constipation was not necessarily a recent phenomenon, but rather a 'chronic' condition that had affected some participants for many years. Older participants had staunch beliefs of what constituted regular and normal bowel movements, and these beliefs had been strongly influenced by their families, social networks and the wider culture. How older participants defined constipation and its causes influenced the use of OTC laxatives and other remedies throughout the life-course experience of 'constipation'. Older participants sought professional advice from a variety of sources, including pharmacists, as well as GPs and nurses. Self-management usually continued once professional treatments were being prescribed. The overriding feature of these accounts was the strong preferences that many older participants had for specific prescribed laxatives, OTC laxatives and other remedies. This suggests that this group of patients is not in equipoise about laxative use and helps to explain the difficulties experienced in recruiting patients to the STOOL trial. In addition, although recognising that they needed laxatives to manage their bowel habit to their satisfaction, the majority of participants in the qualitative study did not consider themselves to be 'constipated' at the time of interview. If those invited to participate in the trial shared this perception, they may have considered themselves ineligible for the trial, and this may provide a further explanation for the lack of willingness to participate.

GPs' and nurses' management of constipation was often influenced by the self-management practices and beliefs of patients, although GP and nurse participants also had their own preferences regarding management strategies and particular laxatives (within the guidance of their local formularies). GP participants routinely prescribed and experimented with different combinations of laxatives, and a range of management strategies was used by participants, with little clear consensus on the optimum approach. There appeared to be more uncertainty among GPs about the effectiveness of different strategies or laxatives, but their own strong preferences, and their unwillingness to go against patient preferences, probably militate against the willingness of some GPs to enter their patients into trials of laxatives.

The barriers to practitioner and patient participation in this trial reflect those identified by Prescott and colleagues⁸⁰ as limiting the quality, number and progress of randomised controlled

trials, in their systematic review of literature covering the period 1986–1996. More recently, King and colleagues,⁸¹ in another HTA review, have highlighted the impact of preferences on participation rates, while Robinson and co-workers⁸² have identified that many individuals query the possibility of individual equipoise and the value of random allocation to treatment strategies. Those findings, coupled with the findings from the STOOL trial, indicate that deep-rooted social practices and staunch preferences have considerable implications for the way that evaluative studies and complex trials are designed. They indicate the need for the health services research community to develop further the methods of patient-preference trials and naturalistic observational studies. Future participant engagement in traditionally designed clinical trials of laxatives and their management is highly unlikely.

GPs often referred patients to nurses, requesting that they perform enemas. Nurses presented a more patient-focused perspective than GPs and claimed to understand better the behaviour and management preferences of patients. Nurses may be more effective collaborators in constipation research and may be better at recruiting patients to trials. However, the range of patients seen by nurses is more limited, with a focus on less mobile and frailer patients. There was a strong consensus in the nurse focus groups that diet and lifestyle advice was very important, particularly about fluid intake. Research on diet and lifestyle interventions may be more attractive to nurses than traditional medical interventions. If harnessed, this level of enthusiasm may be helpful in the recruitment and retention of participants to trials of non-pharmacological interventions such as LIFELAX.

Conclusions

Constipation means different things to different people. There is little shared understanding between patients and professionals about 'normal' bowel function. There is also little consensus in general practice of the optimum management strategies for chronic constipation and continuing uncertainty about the most effective strategies to employ across the board.

Chronic constipation is seen as less important than other conditions (such as diabetes) that are prevalent in general practice. This is because it is not an agreed management target and does not figure prominently in national frameworks. Consequently, practitioners had little interest in

constipation as a topic of research. The practice implications of this research are unclear, although greater efforts could be made by GPs to understand the patient's perspective of symptoms of constipation.

Patient preferences and the absence of patient equipoise (indifference of a rational, informed patient with respect to the choice between two or more treatment strategies) was an enormous barrier to the recruitment of patients in the implementation of the STOOL trial.

The successful involvement of patients and professionals in health technology assessments requires obvious uncertainty among all parties about treatment and management options and their clear interest in the topic. The implementation of the Human Rights Act in the post-Alder Hey Inquiry environment, and the increased stringencies resulting from the enactment of the EU Clinical Trials Directive, have increased the barriers to health services research more widely.

The implementation of research governance and ethical review processes in response to this new research environment has not allowed an appropriate balance between the rights of the individual and the collective rights of society. There is an apparent lack of risk-based assessment and risk-management strategies in implementing research governance and ethical review processes. Ethical guidance that opting-out recruitment strategies were too coercive and that recruitment of all participants should use opting-in strategies is a considerable barrier to participant recruitment, particularly of prevalent as opposed to incident cases.

The Department of Health has established an appropriate framework and set of guidelines for ethical review and research governance. Following on from this and from the findings of this research, we suggest that:

- participants in this process, researchers, ethics committees and NHS trust officials learn from the experiences of the past few years and do not repeat mistakes during their continued implementation of the research governance framework for health and social care and other public-policy research
- there are robust auditing procedures and a central point for arbitration in place to ensure consistency of response to ethical and governance issues

- adequate resources and training are provided to support efficient implementation of these processes
- funders work with the research community to review the opt-in guidelines (and to consider the use of opt-out approaches in certain circumstances), to increase participant involvement in research while protecting the public and respecting their confidentiality and human rights.

We suggest that research funders and health service and public health researchers investigate different methods of recruitment within the constraints of current ethical guidelines on opting in, and assess the impact of different strategies on participation rates and biases.

It would be helpful if research funders, in partnership with the NHS, were able to ensure that adequate resources (in terms of finance, time, space and personnel) are made available to support NHS providers and to cover the additional costs of research-related activities during the implementation of clinical trials and other high-quality studies. It is important that such resources are not the preserve of selected providers or trusts, but are also accessible to primary healthcare teams.

We suggest that the HTA Programme and other funding bodies who support complex clinical trials should ensure that, in both commissioned and non-commissioned studies, a full understanding of the current behaviours and practices of potential users and providers of interventions is established before the implementation of the trial. This might be achieved by funding pilot and developmental trials, or qualitative and survey research of potential barriers to and facilitators of trial participation.

The evidence-based research community needs to recognise that RCTs are not always feasible in the context of some complex interventions and that

further methodological research is required to develop other methods of health technology assessment. These should include:

- the development of patient preference trials
- greater use of qualitative studies within trials to investigate the process of intervention
- the development of naturalistic observational studies.

We suggest that the HTA Programme, through the Methodology Panel, consider funding qualitative research and/or surveys to identify barriers and facilitators to recruitment to complex trials in general.

Recommendations for future research

There still remains a lack of clear evidence of the clinical effectiveness or cost-effectiveness of different laxatives and treatment strategies in the management of chronic constipation. The HTA Programme should revisit this topic and commission a patient preference trial or natural cohort observational study to investigate this further. Published recommendations for the design and conduct of trials in functional gastrointestinal disorders³⁶ may be difficult to implement. Rather, study design should reflect the context and reality of contemporary general practice, reflecting the various barriers and constraints to participation at practice, practitioner and patient levels.

Self-management strategies, including but not exclusively the use of OTC medication, are an important component in the management of chronic constipation. With the growing emphasis on encouraging patients to share responsibility for the management of their health and of acute and chronic conditions, further research – both descriptive and evaluative – on this topic is warranted.



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Contribution of authors and team members

Contribution to the study

Roger Barton (Professor of Clinical Medicine, Newcastle University and Director of Research, Northumbria Healthcare Trust) developed the

protocol and provided clinical advice throughout the study. John Bond (Professor of Social Gerontology and Health Services Research) was the lead investigator. He was responsible for the overall management of the study, developed the protocol and prepared the report for publication. Richard Curless (Consultant Physician) developed the protocol. Elaine McColl (Director, Newcastle Clinical Trials Unit) developed the protocol, project managed the study and prepared the report for publication. Svet Mihaylov (Senior Research Associate) was the trial manager and main researcher on the project. He was responsible for the day-to-day management of the trial and recruitment of practices and patients to the trial. He was also responsible for the analysis of qualitative data and prepared the report for publication. Greg Rubin (Professor of General Practice and Clinical Director of NoReN) developed the protocol, provided clinical advice and managed the relationships between the study team and general practice. Cathy Stark (Research Associate – qualitative researcher) managed the qualitative study, undertook the interviews with patients and health professionals, undertook qualitative analysis of the interview transcripts and prepared the qualitative analysis for publication. Nick Steen (Principal Research Associate – statistician) developed the protocol and provided statistical advice throughout the trial. Alessandra Vanoli (Senior Research Associate – health economist) developed the protocol for the economic evaluation.

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Contribution to the report

John Bond wrote the final report, Elaine McColl edited the report, Svet Mihaylov prepared drafts for Chapters 1–8, Cathy Stark prepared drafts for Chapters 5–8 and Alessandra Vanoli

prepared a draft of Appendix 5. All members of the project team were responsible for critical review of the report and comments were also received from members of the trial steering committee.



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Appendix I

Trial protocol

This appendix reproduces the original trial protocol that was submitted as a research proposal to the HTA programme. Changes to this protocol are summarised in Appendix 2.

STOOL – Stepped Treatment of Older adults On Laxatives

Background

The nature and prevalence of constipation

Constipation is often regarded as a trivial medical problem, but generates 450,000 GP consultations per year in England and Wales^{p1} at an estimated cost of £4.5 million per year.^{p2} The net ingredient cost of prescription laxative items is approximately £43 million per year in England.^{p3}

Constipation is largely a subjective diagnosis and there is no universally accepted definition.^{p4} Moriarty and O'Donaghue have proposed as a working definition: "straining at passing stools for more than 25% of bowel movements". The frequency of normal bowel function ranges from three times per day to three times per week,^{p5} with a frequency of less than three times per week being used as an objective clinical definition of constipation.^{p6,p7} Stool consistency has been highlighted as a good correlate of whole gut transit time and a useful indicator of the presence of constipation.^{p8-p11} According to the revised Rome criteria for functional constipation,^{p12} a diagnosis of constipation requires two or more of the following symptoms to be present for at least 12 weeks, which need not be consecutive, in the preceding 12 months:

- straining in at least one in four defecations
- lumpy or hard stools in at least one in four defecations
- sensation of incomplete evacuation in at least one in four defecations
- sensation of anorectal obstruction in at least one in four defecations
- manual manoeuvres necessary (e.g. digital evacuation, support of the pelvic floor) in at least one in four defecations
- three or fewer defecations per week.

Lay people, however, emphasise symptoms such as abdominal pain, straining^{p13} and bloating.^{p14} Probert and colleagues^{p15} have shown a lack of agreement between self-perceived constipation and objective assessments based on the Rome criteria.

Constipation has been demonstrated to have an adverse effect on perceived quality of life. Patients with chronic constipation have reported lower scores on the Psychological General Well-Being Index than a general healthy population, and symptom severity was correlated negatively with perceived quality of life.^{p16} In a sample of older people, functional bowel disorders, including constipation, had a negative impact on well-being and led to impaired daily living.^{p17} In interviews with frail older people living at home, constipation was spontaneously mentioned by 45% of informants, was considered to be a major problem by 11% and adversely affected quality of life.^{p7}

Estimates of the prevalence of constipation in the general population of the UK range from 2% to 51.5%, depending on the definition used;^{p8,p9,p18-p20} applying the Rome criteria, Probert and colleagues^{p15} estimated the prevalence to be 8.2% in women aged 25–69 years. The prevalence is highest among women.^{p8,p9,p20,p21} Constipation also appears to be a greater problem among older people, with a number of surveys reporting the prevalence of straining at stool and/or self-reported constipation to be in the range 20–25% for older people living at home.^{p9,p22-24}

Data from the UK national survey of morbidity in general practice,^{p1} show that the overall consultation rates per 10,000 person-years for constipation range from approximately 75 for the 45–64 age group, through 200 in the age group 65–74 and 400 in the age group 75–84, to 600 in the age group 85 or over. For a GP with a list size of 2000, these rates translate into approximately 12 consultations per annum per patient aged 55 and over.

Management of constipation in older people

The HTA systematic review of the effectiveness of laxatives used by older people^{p25} found limited

evidence of clinical effectiveness of management strategies for constipation:

- Trials of the treatment of constipation in older people were limited in number. Generalisability was limited by the fact that most trial participants were hospitalised or resident in residential or nursing homes (and therefore likely to be frailer and less ambulant than older people living at home). Sample size and the probable lack of statistical power also limited interpretation and generalisability.
- Most trials of single active treatments versus placebo or normal diet reported non-significant trends in bowel movements per week and non-significant trends in stool consistency and pain. Marchesi^{p26} reported a significant increase in the mean number of bowel movements using a stimulant laxative, while Vanderdonck and colleagues^{p27} found a significant increase with the use of an osmotic laxative.
- Few good quality direct inter- or intra-class comparisons for different laxatives had been carried out. However, in two good-quality trials^{p28-p30} a combination of a bulk plus stimulant laxative was found to be more effective in improving stool frequency and consistency than osmotic laxative alone.
- The cost of treatment with laxatives varies widely and there exists no evidence that the more expensive preparations which are becoming more widely used are more effective.

The research brief

The commissioning brief (HTA 98/32Rev) specifies the key research question: “What is the comparative cost-effectiveness of the different types of laxatives (e.g. bulk-forming v stimulant v osmotic laxatives) in the treatment of elderly patients with chronic constipation?” Good clinical practice, as recommended by the HTA review,^{p25} is to use a stepped approach to the management of chronic constipation. That is, single agents should be prescribed alone before a combination of agents is prescribed.

The research questions addressed by this study

We propose a simple stepped trial of laxative treatment of chronic constipation in older people with comparisons of individual treatment strategies, to address the following key questions:

- What is the comparative clinical and cost-effectiveness of bulk-forming, stimulant and osmotic laxatives?

- What is the comparative clinical and cost-effectiveness of using combinations of bulk-forming and stimulant laxatives; bulk-forming and osmotic laxatives; and stimulant and osmotic laxatives?

Given that the clinical effectiveness of these agents will be influenced by patient adherence to treatment protocols, a secondary question is:

- How do patients use laxatives?

Objectives

- To investigate the clinical and cost-effectiveness of bulk-forming, stimulant and osmotic laxatives.
- To investigate the clinical and cost-effectiveness of adding a second type of laxative agent in the treatment of patients whose constipation is not resolved by a single agent.
- To describe the adherence by patients to treatment protocols and to estimate its impact on cost-effectiveness.

Plan of investigation

Trial design

The trial will take the form of a pragmatic^{p31} factorial randomised trial of different forms of stepped pharmacological treatment of constipation with an economic evaluation. Study participants will be randomised to one of six ‘stepped’ treatment strategies (*Table P1*):

Setting

General practices in Northern and Yorkshire Region and the homes of older people from these practices.

Health technologies being assessed

Stepped treatment of constipation

Study participants will be randomised to one of six stepped treatment strategies (see *Table P1*). At step 1, participants will be given one of three classes of laxatives following a washout period of 2 weeks. After 4 weeks, at step 2, participants will be reassessed and if constipation has not been successfully resolved will have a second class of agent added.

Pharmacological agents

This study focuses on three classes of laxatives: bulk, stimulant and osmotic preparations. Bulk

TABLE P1 Individual laxative treatment strategies

Strategy	Step 1	Step 2
1	Bulk laxative	Combination of bulk + stimulant laxative
2	Bulk laxative	Combination of bulk + osmotic laxative
3	Stimulant laxative	Combination of stimulant + bulk laxative
4	Stimulant laxative	Combination of stimulant + osmotic laxative
5	Osmotic laxative	Combination of osmotic + bulk laxative
6	Osmotic laxative	Combination of osmotic + stimulant laxative

laxatives accounted for 25% of prescribed items (27% of total prescribing costs) in January–March 1996.^{p25} Stimulant laxatives accounted for 34% of items (44% of cost) and osmotic laxatives accounted for 41% of items (29% of cost). Since the HTA review,^{p25} ‘expensive’ stimulant laxatives, co-danthramer and co-danthrusate, have been given a limited licence for use only in terminally ill patients^{p32} and therefore the relative costs of stimulant laxatives may be less than in 1996. The bulk laxative to be included will be isphagula husk. The stimulant laxative will be senna and the osmotic laxative will be lactulose. As this is a pragmatic trial, within each class, the choice of actual preparation (e.g. between Fybogel[®] and Regulan[®]) will be at the discretion of the individual practitioner, although a ‘picking’ list ordered by cost will be provided. It is felt that this latitude will encourage greater compliance with the protocol.

Target population

People aged 55 or over with chronic constipation living in private households. The choice of an age cut-off of people aged 55 or over has been made after due consideration of the morbidity statistics from general practice^{p1} which show that GP consultation rates for constipation take off in the 45–64 age group and rise steadily with age. The exclusion of residents in long-term care reflects the different morbidity and lifestyle experience of long-term care residents. We will focus on a predominantly ambulant population able to independently attend a primary care clinic.

Inclusion criteria

The complexity of the Rome criteria militates against their use in screening for chronic constipation. The Rome criteria suggest that new cases of constipation (the ‘incident’ cases) should receive extensive investigation to determine the

underlying cause of the constipation before laxatives are prescribed. This trial will therefore identify and recruit only ‘prevalence’ cases. Participants will be identified from general practice computerised patient records using a standard software ‘query’ to identify patients prescribed laxatives three or more times in the previous 12 months.

Exclusion criteria

- Patients resident in long-term care.
- Patients with inflammatory bowel disease, intestinal obstruction/bowel strictures, known colonic carcinoma, and conditions contraindicative to the prescription of any laxative preparations included in the stepped treatment protocol.^{p33}
- Inability to complete outcome assessments, even with assistance (e.g. major cognitive impairment, lack of understanding of English).

Outcome measurement

Follow-up period

All participants will be followed up for 6 months from the date of randomisation.

Clinical outcomes

The primary clinical outcome, and the criterion upon which the sample size calculations have been based, is the reported number of bowel movements per week at the end of each step (6 and 10 weeks after randomisation) and at 6 months’ follow-up. Secondary clinical outcomes include the presence/absence of the other Rome criteria for constipation; adverse effects of treatment (although some of these may also be symptoms of constipation); and relapse rates (*Table P2*).

In addition to the measurement of these clinical outcomes, the impact of the treatment on costs and quality of life will be assessed (*Table P3*).

TABLE P2 Clinical outcome measures

	Measurement method	When	Where
<i>Primary clinical outcome</i>			
Number of bowel movements per week	Self-completed diary	Weekly for 6 months	Participant's home
<i>Secondary clinical outcomes</i>			
Other Rome criteria: straining at defecation, stool consistency, perceived incomplete evacuation	Self-completed diary	Weekly for 6 months	Participant's home
Adverse events: abdominal pain, nausea, bloating, flatulence, diarrhoea	Self-completed diary	Weekly for 6 months	Participant's home
Relapse rates: including repeat consultations	Self-completed diary; GP records	Weekly for 6 months (diary); end of 6-months follow-up period (GP records)	Participant's home (diary); general practices (GP records)

TABLE P3 Measuring treatment impact

Impact	Measure	When	Where
Costs to participants of the condition and its management	Self-completed questionnaire; health diary; telephone interview; postal questionnaire	Using different methods, at least monthly for 6 months	Participant's home
Consultation rates and laxative prescriptions	GP records	End of 6-month follow-up period	General practices
Adherence with drug treatment	Health diary; telephone interview; postal questionnaire	Using different methods, at least monthly for 6 months	Participant's home
Patient satisfaction	Postal questionnaire	End of 6-month follow-up period	Participant's home
Health-related quality of life	Postal questionnaire	End of 6-month follow-up period	Participant's home

Economic evaluation

Perspective of the study

An individual participant perspective and public sector budget perspective will be used, and particular emphasis will be given to the subsets of costs and effects relevant to address the health service perspective at a macrolevel. The societal perspective will not be considered since productivity costs are not relevant because of the nature of the clinical condition; similarly, impact on other family members can be neglected without introducing any relevant bias.

Measure of benefits used and type of study

Considering all the measures of effectiveness estimated within the clinical trial, a

cost-consequences analysis will be outlined. A cost-effectiveness analysis will be conducted on the basis of the number of bowel movements per week.

Resources data collected within the trial and costing methods

NHS resources will include the use of drugs and primary care services. These data will be collected through extraction of data from medical records of trial participants. Costs related to the use of medication and health services will be assigned using national published data.^{p33,p34} These will be supplemented with data derived through telephone interviews and postal questionnaires, which will seek to collect information about the patients' expenses on over-the-counter prescriptions and other expenditure relating to the management of constipation. Where possible,

participants will be asked to report costs and quantities separately.

Synthesis of costs and outcomes

If there is not statistically significant evidence that one strategy is more effective than another, a cost-minimisation framework will be used and the less expensive strategies recommended. If one strategy appears to be more effective and less costly than comparators, it will be recommended. If one strategy appears to be more effective but more expensive than comparators, estimates of incremental cost-effectiveness ratios will be generated and compared. A judgement will be required in a policy-making context to establish whether the additional benefits warrant the additional costs. In any case, recommendations will be made taking into account the issues of the generalisability of the results.

Sensitivity analysis

A sensitivity analysis will be carried out to test the robustness of the result to any variations in the key data inputs to the study, such as the price of medicines, in order to address the issues of both uncertainty in assumptions, methods and data, and the generalisability of the results.^{p35} Moreover, a sensitivity analysis taking account of differences in resource use which are practically significant (i.e. potentially costly), but which have not been shown to be statistically significant, will also be undertaken.

Clinical assessments and methods of data collection

Participants' pathways through trial

Table P4 shows participants' pathways through the trial.

Base-line assessment (T⁰)

The baseline assessment will comprise a structured assessment of participants' health status through face-to-face interview with a research nurse. The assessment will include cognitive function,^{p36} activities of daily living,^{p37} Rome criteria for functional constipation^{p12} and medication use (both prescribed and OTC). Eligibility to the trial will be confirmed. At the baseline assessment participants will be invited to complete a self-completed questionnaire to collect baseline measurements to be repeated by postal questionnaire at 10 weeks and 6 months (see Table P2). A weekly self-completed health diary will be distributed and explained to participants (see Table P2).

Health diary

To minimise recall bias, data on bowel habits based on the Rome criteria^{p12} will be gathered by a structured health diary completed weekly and returned monthly for 6 months; experience using similar diaries in research on falls in older people suggests that 90% of diaries will be returned completed.^{p38}

TABLE P4 Participants' pathways through the trial.

Activity	
1	Potential participants identified from computerised practice notes using simple query to flag individuals receiving prescriptions for constipation (three or more in previous 12 months)
2	Initial screen by practice to identify exclusions
3	Invitation by practice to patient to attend nurse-led research clinic to discuss constipation; eligibility criteria confirmed
4	T ⁰ Nurse-led research clinic-trial consent completed; baseline assessment (structured interview and self-completed questionnaires); withdrawal from medication for 2 weeks; start daily self-completed diary for 6 months
5	Independent randomisation to treatment strategy group
6	T ² Collect prescription and start step 1 agent (single laxative)
7	T ⁶ Nurse-led research clinic reassessment (structured interview and self-completed questionnaires); receive prescription and start step 2 (combination of laxatives) where constipation unresolved
8	T ¹⁰ Nurse-research clinic reassessment (telephone interview and postal questionnaires)
9	T ¹⁸ Telephone interview (economic data)
10	T ²⁶ Telephone interview (economic data), postal questionnaire (6-month outcomes)
11	Review practice notes to abstract data on consultation rates and prescription patterns

Six-week assessment (T⁶)

The 6-week assessment will comprise a structured assessment of participants' health status through face-to-face interview with a research nurse. The assessment will focus on bowel function and include the Rome criteria for functional constipation^{p12} and medication use. Unsuccessful resolution of the constipation at T⁶ will be identified and step 2 treatment strategies implemented.

Follow-up questionnaires

Follow-up questionnaires using up to two reminders will be sent at T¹⁰ and T²⁶. Data to be collected will include Rome criteria for functional constipation,^{p12} health-related quality of life,^{p39} medication use, out-of-pocket expenses and other resource-use data. Although structured interviews are the gold standard for a large volume of complex data,^{p40,41} we will minimise the data to be collected at follow-up in order to contain the cost of data collection. This will also allow some blinding of outcome assessment. In a recently completed unpublished trial with ambulant cognitively normal older people with angina, we achieved a response rate in excess of 70%, which suggests that non-response bias will not be a significant problem.

Telephone interviews

The telephone interview will act as a reminder for the return of health diaries and to collect more detailed data for the economic analysis. These will be relatively short interviews and data will be recorded directly onto a database by the interviewer. Other resource-use information will be collected from practice medical records.

Medical records

Data about all study participants will be abstracted from medical records and entered onto a laptop computer following the 6-month outcome. For efficiency in data capture this will be done practice by practice at the end of the data-collection period. Experience suggests that data on consultation rates and prescribed medication can be gathered most accurately and reliably from medical records.

Blinding of outcome assessment

Health technology assessment is essentially a pragmatic activity conducted in normal clinical practice, rather than an exploratory activity conducted in highly controlled laboratory settings. It follows that blinding doctors and study participants to treatment is not desirable (even if practicable – which is not the case with different classes of laxatives) since it distorts normal clinical practice. In contrast, blinding of assessors is important because it minimises subjective bias

towards a given treatment. All research staff conducting interviews or processing postal questionnaires and diaries will be blind to the random allocation of treatments to participants. The weakest link in our approach to the blinding of outcome will be at the 6-week assessment when the research nurse is likely to learn the treatment received by participants from participants themselves. Participants will be encouraged to respond to questions without describing their treatment regimen. The use of self-completed questionnaires at the two assessment visits will also assist in minimising subjective bias.

Another potential bias to be considered is the Hawthorne effect on participants of continuing discussion about the taking of medication. However, this should be considered as a positive effect. It should affect all strategy groups equally and will increase participant adherence to treatment regimens. It may, however, give a biased estimate of normal participant adherence to drug therapy.

Sampling design and implementation

Recruitment

General practices in the Northern and Yorkshire Region will be invited by letter to participate. We estimate that we will need to recruit 22–25 average-sized practices. We will seek to include practices from existing research networks, but may need to supplement with other practices, depending on take-up. Two methods of participant recruitment were considered: incident and prevalent cases. For the present study prevalent cases only will be considered. Experience in practice suggests that in addition to slow recruitment due to the small number of incident cases per year in any one practice, incident cases would, at least initially, be subject to more intensive medical investigation for the cause of the constipation, which would militate against inclusion in the trial. Prevalent cases will be retrospectively identified through computerised records. The practice will do an initial screen to remove identifiable study exclusions and invite eligible participants to attend a nurse-led research clinic to discuss entry into the study. Following informed consent, a baseline assessment will be completed and basic demographic information for those participants still eligible will be provided to an independent randomisation service at Newcastle. Access to this service can be by telephone, World Wide Web or secure fax. The randomisation service will hold a master participant index, randomise to first step treatment

and inform the appropriate GP. The GP will invite the patient to collect their prescription after a 2-week washout period.

Randomisation

Simple participant randomisation into one of six treatment strategies will be used. Randomisation will be done using an independent telephone (or World Wide Web) service in Newcastle. To avoid GPs pre-empting the second step in the treatment regimen, initially the practice will be informed only of whether the patient has been randomised to receive a bulk, a stimulant or an osmotic laxative. Practices will be informed of the second step treatment strategy following the 6-week assessment. This will be the randomised combination where the constipation remains unresolved.

Sample size

Participants will be randomised to one of six treatment strategies. The primary outcome measure is the number of bowel movements per week, which in this population has a standard deviation of approximately 2²⁵. In order to have 90% power to detect a mean difference of one bowel movement per week between any two-treatment strategies, assuming a 5% significance level, it is necessary to finish up with 85 patients per group (a total of 510). If we assume an attrition rate of 40% we need to recruit a total of 850 subjects.

Initially, subjects will be randomised to one of three drugs. We will therefore be able to pool data from pairs of strategies to determine the relative effectiveness of the three types of drugs when taken alone. Comparing two groups of 170 subjects will give us 90% power to detect a difference of 0.71 bowel movements. We will also have 90% power to detect a difference of 18% in the proportion of patients successfully managed using a single drug. Both these calculations assume a significance level of 5%.

Strategies for improving compliance

The commitment of GPs and practice staff will be crucial to the success of the study. At the beginning of the trial educational events will be used to introduce the study protocol, including the stepped treatment protocol, to health professionals from the participating practices. Research nurses will reinforce the importance of adherence to the study protocol. A regular newsletter to practices will report on their relative performance and progress in the study.

Methods of data analysis

Since randomisation is by individual participant to treatment strategy, treatment groups can be

regarded as independent samples and analysed using appropriate methods. The primary outcome measure takes the form of a count – the number of bowel movements per week – so treatment strategies will be compared using Poisson regression. Secondary outcome measures include both binary and continuous variables. These will be analysed using logistic and normal regression procedures as appropriate. Analysis will be on an intention-to-treat basis. No interim analyses or additional subgroup analyses are planned.

Stakeholder involvement

In line with guidelines on consumer participation^{P42} we will set up a user panel to provide input into this study. We will invite participating practices to join a separate professional stakeholder panel to advise on the implementation of the trial and help with dissemination of study recommendations locally.

Pilot study

This is a complex trial, which will require appropriate pilot work. Two types are necessary.

Development and testing of data-collection methods

Although most of the instruments which we propose to use in this trial have been used successfully in previous studies, it will be necessary to test the efficacy of different interviews and self-completed questionnaires. In particular, we will need to develop structured questions in both interview and self-completed format of the Rome criteria for functional constipation. Questionnaires will be developed with a user group of older people and tested on an independent sample of older people using cognitive interviewing techniques.^{P43}

Pretest study

We will use the practice of one of the applicants and randomly select a second practice in which to rehearse the full protocol prior to beginning the main study. If there are no major changes to protocol these data will be pooled with the main study if we have difficulty in reaching our target sample size.

Study timetable

Key milestones

Trials of complex interventions in primary care are often difficult to coordinate because of geographical spread and the involvement of a large number of small organisations. We have

TABLE P5 Key milestones

Month	Activity or comment (key milestone in bold)
-6	Funding agreed. Apply for MREC approval. Recruit pilot study practices. Advertise research staff
-3	Apply LREC approval
1	Ethical approval confirmed. Agreement of pilot study confirmed. Activate funding. Appoint research staff. Advertise for research nurses
2	Recruit practices. Develop questionnaires and other data collection instruments. Commission software query programme
3	Appoint and train one nurse. Test recruitment method in first practice
4	Test recruitment method in second practice
6	Appoint and train nurses. Progress report to HTA
7	Start recruitment of participants
12	Recruited 212 participants. Progress report to HTA
18	Recruited 424 participants. Progress report to HTA
24	Recruited 636 participants. Progress report to HTA
30	Finish participant recruitment. Progress report to HTA
37	Complete abstraction of medical records and close follow-up survey
38	Begin analysis of health diaries, economic data; follow-up survey and medical records. Begin reports and papers
40	Complete analysis of baseline data
42	Complete analysis of health diaries. Progress report to HTA
44	Complete analysis of follow-up survey and medical records
46	Complete economic analysis
48	Complete reports and papers. Final report to HTA

therefore taken the view that it would be sensible to recruit over 2 years rather than 12 months, which would allow us to focus on a small number of practices at any one time to achieve an average recruitment of 35 per month. Although this would increase the length of the trial, we anticipate that this would only increase the overall cost of the trial marginally. (Routine 6-monthly reports to HTA are excluded unless coincident with other key milestones.) *Table P5* shows the key milestones.

Expertise (including trial management)

The research team draws on all the necessary clinical (primary health care, geriatric medicine and gastroenterology) and health services research (economics, sociology, social gerontology and statistics) expertise. CHSR is a member of the MRC HSR Collaboration and has substantial experience of designing and executing complex trials and evaluating interventions in primary care and older people. Professor Bond (JB) is a sociologist with 30 years of researching practice and policy issues of concern to older people. He has successfully managed several studies of older people including complex trials. In addition to project management experience, he brings a special interest and expertise in assessing outcomes and quality of life in older people. He will have overall responsibility for the study.

Ms McColl (EM) is a generic health services researcher qualified in both economics and statistics with 15 years' experience of doing research in primary care, including the project management of complex trials. She holds a National Primary Care Career Scientist award with a particular remit for outcome assessment and management of chronic disease. Dr Steen (NS) is a statistician in CHSR with considerable experience of analysing complex data sets. NS will be the project statistician and will be responsible for the management of the database manager and statistical input to the trial. Ms Vanoli (AV) is a health economist in CHSR with experience in the design and critical appraisal of economic evaluations, and in the collection and analysis of economic data. She is currently involved in RCTs of interventions for older people and antiepileptic drugs. AV will be responsible for the economic evaluation in this study. Professor Rubin (GR) is a practising GP, with a particular expertise and interest in gastroenterology; he is secretary of the Primary Care Society for Gastroenterology and is a member of the Steering Group of NoReN (primary care network). He will be responsible for liaising with primary care organisations within the Northern and Yorkshire Region. Dr Curless (RC), an elderly care physician, and Professor Barton (RB), a consultant gastroenterologist, have a research interest in luminal gastrointestinal disease, as well as clinical experience in chronic constipation. They have recently completed a

prevalence survey of gastrointestinal symptoms in older people consulting primary care.^{P44}

Justification for support requested

The proposed study will take 48 months. Implementing complex trials in primary care requires considerable organisation and coordination. We have therefore planned to recruit participants over 2 years rather than 1 year, to ensure that the study recruits target sample size. The following support is requested.

Staff

Senior Research Associate (trial coordinator) [1.0 whole-time equivalent (WTE) for 4 years]. The person to be appointed will manage the trial on a daily basis.

Ms Vanoli (senior health economist) (0.2 WTE in year 1; 0.1 WTE in years 2 and 3; 0.4 WTE in year 4). She will undertake the economic evaluation.

Dr Steen (project statistician) (0.2 WTE in year 1; 0.1 WTE in years 2 and 3; 0.4 WTE in year 4). He will be responsible for the supervision of the randomisation service, data management and statistical analysis of the trial.

Project secretary (0.6 WTE for 4 years). She/he will be responsible for production of data collection instruments, the management of the study administrative database and the management of health diaries and outcome questionnaires, and will perform general administrative and secretarial duties on behalf of the project team.

Database manager (0.1 WTE for 2 years and 0.2 WTE for 2 years). She/he will be responsible for preparing questionnaires for data processing, writing validation and analysis programmes and producing data for other members of the project team.

Two research nurses (0.5 WTE for 3 years). They will be responsible for holding practice-based research clinics for baseline assessment and reassessment of study participants. They will also be responsible for the manual abstraction of data from primary medical care records at the end of the recruitment period.

Non-staff costs

Travel and subsistence: cost of travel to pilot-study participants' homes for development of research instruments, travel for nurses to practice premises, support for visiting advisors and to attend national and international conferences.

Consumable and data-collection costs: cost to print research instruments; to distribute health diaries and outcome questionnaires; and undertake telephone interviews. Equipment 'rental' costs, which includes the direct costs to the study of computers, printers and software and calculated on a standard algorithm for WTE staff working on the study. Direct costs of printing, postage and telephone are requested.

Exceptional items: CHSR will provide an independent telephone randomisation service. The CHSR is a self-supporting research Centre in the University with limited Higher Education Funding Council (HEFC) support. Professor Bond, who is expected to recover some of his time costs in research applications on a consultancy basis (10 days per annum), will provide overall project management. Resources are needed to contract out computer software writing of queries for electronic medical records and to provide administrative support to practices for the review of medical notes prior to recruitment and participant consent.

We have closely reviewed each item of expected expenditure in line with our considerable experience of doing studies of this kind. These are the direct costs of the study, which will ensure that neither the NHS nor universities will be inappropriately subsidising the study.

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Appendix 2

Protocol amendments

All protocol amendments were approved by the trial steering committee and MREC and reported to HTA trial monitoring team.

December 2002

- Disease-specific quality of life as measured as PAC-SYM/PAC-QOL was specified as the primary outcome. The number of bowel movements per week was specified as a secondary outcome.
- Changes in research governance militated against the proposed use of a research nurse to recruit data in practices. Recruitment was therefore done by practice nurses working in the sampled practices.
- The 6-week reassessment originally planned as an interview in the practice was changed to a telephone interview with a member of the research team.

April 2004

- The planned washout period was removed from the protocol following advice from the trial steering committee.

- The 18-month follow-up economic telephone interview was omitted to reduce the burden of data collection on participants.
- Changes were made to the definition of a successful outcome after step 1 to reflect participants' treatment goals.
- Practice receptionists were included to recruit and undertake baseline assessments where a practice nurse was not available.
- The cognitive function assessment at baseline was omitted to reduce the burden on participants.

October 2004

- Exclusion criteria were increased to exclude people with multiple sclerosis and significant autonomic neuropathy and patients on morphine or morphine derivatives.

Appendix 3

Full patient information leaflet

STOOL

Stepped Treatment of Older adults On Laxatives

A study about comparing three different medicines for treatment of constipation in older people



We would like to invite you to take part in our research study comparing the effect of three different types of medicines for treatment of constipation.

Before you decide whether or not to take part, it is important for you to know why the research is being carried out and what it will involve for you should you decide to join in the study. Please take time to read this leaflet carefully – it answers many of the questions you may have. If you wish, you can show the leaflet to your family and friends and discuss it with them. If there is anything you are not clear about, or if you would like any more information about the study and what it means for those who take part, please ask one of the research team – our contact details can be found at

the end of this leaflet. The research office can also put you in touch with an independent consumer representative, who can provide advice on your rights with respect to taking part in research.

Please take plenty of time to decide whether or not you wish to join this study – you do not need to make up your mind ‘on the spot’. In the accompanying letter your GP has suggested an appointment date for you to talk to a nurse at your doctor’s surgery. The nurse will explain the study in more detail and will be happy to answer any questions you may have. However, if the date or the time is not convenient for you, please ring the practice to make an appointment at a suitable time.

Thank you for taking the time to consider this study.

Who is doing this study?

We are a team of researchers based at the Centre for Health Services Research at the University of Newcastle upon Tyne. This study is funded by the National Health Service. We are working with many of the general practices in northern England.

Why are you doing this study and what do you want to find out?

Constipation is a common and often bothersome problem in adults in the United Kingdom, particularly amongst those aged 55 and over.

Constipation is often treated by prescribing laxatives. Laxatives are drugs designed to relieve constipation. There are different types of laxatives that work in different ways. However, there is still little knowledge about which laxative or combination of laxatives is best to treat older people with constipation.

Our research is about comparing three different types of laxatives for treatment of constipation in older people to see which is best.

How and why have I been chosen?

You have been chosen to take part because, according to your medical records, you have consulted your GP about constipation and are in the correct age group for the study.

We need about 1000 people with constipation, both men and women, aged 55 and over and will be selecting patients from a number of general practices in northern England.

Do I have to take part?

No, it is entirely up to you whether you take part. We would like you to take your time, to read this information sheet and to think about the study. We would very much like you to help us, but if you decide not to take part in the study, that's fine.

The care that you get from your GP's surgery will not be affected by your decision and no one will put pressure on you to take part.

To help us with future studies, we would like to ask you a few questions about why you have decided not to take part. But if you don't want to give a reason, you don't have to.

Can I say 'Yes' now and change my mind later?

Yes, you can. Even if you say 'yes' now you can leave the study at any time. You are not committing yourself to the study forever, and if you decide to leave, it will not affect the care you get from your doctors and nurses.

What do I have to do if I decide to take part in the study?

If, after you have read about the study, you would like to take part then we will need you to sign a consent form. You will need to do this at your surgery, as it needs to be countersigned by a nurse or a doctor.

After signing a consent form, you will be assigned to 1 of 6 different treatment groups. Initially each group will be given 1 of 3 different laxatives. If after six weeks your constipation does not improve, you will be given a second laxative to take in combination with the first one.

The choice of who is in which group will be made by a computer. The computer knows nothing about the individuals concerned. This means that we get a good mix of people in each group. It also ensures that the choice is made by chance (like pulling names out of a hat or drawing the balls in the National Lottery). This method is called 'randomisation'.

Can I or my GP choose the group I will be in?

No, it is not possible for you or your doctor to choose the group that you will go into. This is because we have to make it as fair as possible for all patients. You will have equal chance of one in six (17%) of being allocated to each one of these six groups. Each group will be prescribed one of three types of laxatives, Ispaghula Husk; Senna; Fybogel/Regulan or Movicol. You may have taken some of these medicines to relieve your constipation in the past and some may be new for you. You will be asked to take the prescribed medicine regardless of whether you have experience with it or not.

If you do not wish to be included in the study, you should tell your doctor. He or she will then treat your constipation in whatever way you and the doctor think is best for you. If you do decide that you would rather not take part in the trial, we would still like your permission for us to look at your medical records to see how your constipation is managed. However, if you don't want to be in the trial and don't want us to look at your records, we will respect that decision.

What will happen next if I decide to take part in the study?

• Face to face interview and self completion questionnaire

Regardless of which group you are chosen for, you will be interviewed by a nurse at your doctor's surgery and asked to fill in a short questionnaire when you join the study. If you need any help, the nurse will be there to assist you with the questionnaire.

- **Health diary**

After you fill in the questionnaire the nurse will give you a health diary and will explain how to fill it in. The diary asks about your bowel habits and the use of laxatives. Throughout the study we will ask you to complete the health diary daily and to return it to us on a monthly basis for six months. This will take very little time for you to fill in. We will provide you with full instructions of what you need to do during your first visit to your GP surgery.

- **Step 1**

You will be prescribed a single laxative by your GP and you will be asked to take it for six weeks. If your constipation is not better by then, you will be advised to make an appointment and visit your GP again. During that visit a second laxative will be added on to your original laxative prescription.

- **First telephone interview and postal questionnaire**

Towards the end of **Step 1** a fully trained member of our research team will contact you by phone to see how you are getting on. He or she will interview you on the phone, asking questions about any out of pocket expenses and contacts you have had with health care professionals in order to help manage your constipation. After the interview we will encourage you and ask you to complete a short postal questionnaire which we will have sent you several days in advance. The postal questionnaire will ask questions about your quality of life and will be similar to the one you will have completed when you first visited your GP surgery and saw the nurse. When you fill in the questionnaire we would appreciate if you could return it to us in the prepaid envelope provided within two weeks following the telephone interview.

- **Step 2**

If you still feel that your constipation has not been successfully resolved after six weeks of treatment, a second laxative will be added and you will be asked to take a combination of two laxatives for four weeks. You will need to pick up this new prescription from your GP.

- **Second follow-up telephone interview and postal questionnaire**

At the end of **Step 2**, the research team will send you a second questionnaire by post and will contact you again by phone for a short telephone interview. The interview will ask similar questions as the first telephone interview. After the interview we will check with you whether you have received the second postal questionnaire and will ask you to fill it in and return it to us in a prepaid envelope within two weeks following the second telephone interview.

Final postal questionnaire

Six months after the start of the study we will contact you again by phone for a short telephone interview. You will also receive a third postal questionnaire which we will ask you to complete and return to us in a prepaid envelope within two weeks after the date of receiving it.

Do you need to see my medical records?

Yes. At the end of the study we will need to look at your medical records. From them we will be able to extract some more information about how often you have visited your GP and the treatment you have received from your doctor related to constipation. This is mainly needed to help us with the analysis of the results. We are not interested in any other aspects of your health or medical care – just consultations about constipation and treatment for that problem.

Will I have to have any special tests or investigations if I take part?

No, the study does not involve any blood tests, colonoscopies or any other investigations. However, if your own doctor thinks you need a test or other investigation, you will be able to have it, without affecting your ability to take part in this study.

Will there be any lifestyle restrictions, or anything I won't be allowed to do if I take part?

No, you will be free to take part in all your normal activities at home and at work. You can eat your normal food.

Will I get paid for taking part in the study?

No, we are not paying anyone to take part in the study. Your doctors and nurses do not get any extra money for including you in this study. Paying people often puts undue pressure on them – that is why we are not doing it.

What are the likely benefits of taking part in the study?

There may not be a direct benefit for you personally as a result of this study. The potential benefit is that the treatment you will receive may prove to be more effective than the treatment for constipation you have received so far. However, this cannot be guaranteed.

In the long-term, we hope that the information we get from this study may help us to treat future patients with constipation better.

What are the possible disadvantages and risks of taking part?

We hope that all treatments will help you and do not think that there are any significant disadvantages or risks in taking part in the study.

Because we are not trying out any new laxatives in the study, your doctor will be able to tell you of any known side-effects for any of the laxatives they may prescribe. However, like any medicines, laxatives can have unwanted side-effects in some patients such as abdominal discomfort, bloating, flatulence etc. The likelihood and nature of these side-effects varies with the type of laxative but in general they are mild to moderate in intensity.

I have private health insurance. Do I need to tell my insurer if I decide to take part in the study?

If you decide to take part in the study, it is most unlikely that it will affect any private health insurance that you may have. However, you should let your insurer know that you are taking part in the study.

How long does the study go on for altogether?

Although each individual person will only be followed up for at most six months, it will take some time to get 1000 patients into the study. And we will also need some time at the end to analyse all the information we will be getting from the interviews, questionnaires and health diaries. The study lasts for four years altogether – we should have the final results in December 2006.

What will happen to the results from the study?

At the end of the study, the research team will write a report of the results for the NHS.

After that, we will write articles about the findings for publication in magazines, so that other health workers and carers read and apply what we have learned from this study in their practice.

In all the reports that we write, we will take great care that no individual patient can be identified. All the information the research team have about you will be kept private.

Has anyone checked out this study to see if it is alright?

When we applied to the NHS for money to do this research, our plans for the study were examined by other researchers to confirm that they were scientifically sound.

The study has also been reviewed by The South-West Multi-Centre Research Ethics Committee. This committee is responsible for ensuring that medical research going on is ethical and fair to study participants like yourself.

Will what I tell you be kept private?

Only the research team who will be running the study, and collecting and analysing information from study participants, will know who is in this study. We are all bound by a written code of confidentiality. This means that we must take great care to prevent anyone from outside the research team seeing any personal information about you, and we must not tell anyone else what you say. So all the information the research team has about you (e.g. from the interviews, questionnaires and examining your medical

records) will be kept private. Any information about you which leaves the surgery will have your name removed so that you cannot be identified from it.

One issue that we need to draw to your attention is that the owners of the copyright of the Quality of Life questionnaire we intend to use in our study, Jansen Pharmaceuticals Ltd., have asked us to provide them with the participants' responses to the questionnaire for the purposes of further improvement of their instruments. However, these data will be fully anonymised and no individual patient or practice will be identifiable at any time. On your questionnaire, you are only identified by a number. Only people in our office will know who the questionnaire came from.

We want to reassure you that anything you tell us will be kept secret. We will not tell anyone what you have said unless you ask us to. We will not give your contact details to anybody and nobody else will contact you by any means after the end of the study.

Will anyone else know I am in this study?

Local GPs know that this study is going on. We have written to all practices to tell them of our work. Only your own GP's surgery will know that you personally are in the study.

How can I get more information about the study?

Please feel free to contact a member of the research team if you would like some more information about the study, or if you have any questions you want answered. Our phone numbers are shown below. You may contact us right through the study. It's best to call during office hours (9.00 a.m. – 12.30 p.m. and 1.30 p.m. – 5.00 p.m.) but we do have an answer machine switched on when we are out of the office. If you prefer to write to us, our address is also shown below.

Research staff contact details

Dr Svet Mihaylov (Trial coordinator)
Project secretary

0191 222 7249
0191 222 7894

Centre for Health Services Research
School of Population & Health Sciences
University of Newcastle upon Tyne
21 Claremont Place
Newcastle upon Tyne
NE2 4AA

Appendix 4

Brief patient information leaflet



STOOL

Stepped Treatment of Older adults On Laxatives

PATIENT INFORMATION LEAFLET

Centre for Health Services Research
School of Population and Health Sciences
University of Newcastle upon Tyne
Newcastle upon Tyne NE2 4AA

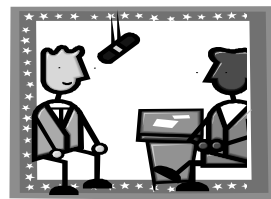
What will we ask you to do if you agree to take part in our study?



Visit us at your GP surgery: Initially we will invite you to talk to a nurse at your GP surgery. The nurse will be able to answer all the questions you may have about the study and check whether you are suitable to be included in the study.



Signing a consent form: If you are happy to take part in the study we will ask you to sign a consent form to confirm your agreement in writing. If you would prefer not take part in the trial, we would still like your written permission for us to look at your medical records to see how your constipation is being managed. Of course, you are free to refuse us permission, if you would prefer we did not look at your records.



Face to face interview: After you have signed the consent form, the nurse will need to conduct a short interview with you. The interview will take about 15-20 minutes and will be about your experiences of constipation.



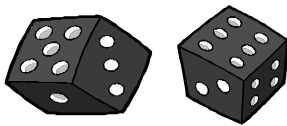
Filling in a questionnaire:

After the interview the nurse will give you a short questionnaire that asks about your health in general and about your constipation. If you need any help filling in the questionnaire, the nurse will be there to assist you.



Health diary: At the end of this visit, the nurse will give you a health diary and will provide you with full instructions of what you need to do with it. The diary asks about your bowel habits.

Throughout the study, we will ask you to complete the health diary **each day**. Each diary lasts for one month. We will ask you to return it to us each month. We will need you to complete and return the health diaries to us for a period of six months.



Randomisation: Then you will be assigned to 1 of 6 different treatment groups. Initially each group will be given 1 of 3 different laxatives. The choice of who is in which group will be made by a computer. The computer knows nothing about the individuals concerned. This means that we get a good mix of people in each group. It also ensures that the choice is made by chance (like pulling names out of a hat or drawing the balls in the National Lottery). This method is called '**randomisation**'.



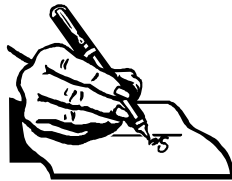
Step 1: You will be prescribed your first (Step 1) single laxative and you will be asked to take it for 6 weeks. If your constipation is not better by then, you will be advised to make an appointment and visit your GP again. During that visit a second laxative will be added on to your original laxative prescription.

First telephone interview and postal questionnaire: At the end of **Step 1** a trained member of our research team will contact you by phone to see how you are getting on. He or she will ask you questions about any out of pocket expenses and contacts you have had with health care professionals in order to help manage your constipation. After the interview we will encourage you and ask you to complete a short postal questionnaire which we will have sent you several days before we ring you. The postal questionnaire will ask you about your quality of life and will be similar to the one you will already have completed when you visited your GP surgery and saw the nurse. We will ask you to return it to us in a prepaid envelope within 2 weeks of the telephone interview.

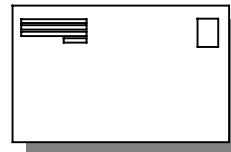
First telephone interview



Filling in a postal questionnaire



Return the questionnaire to us by post



Step 2: If you still feel that your constipation has not been successfully resolved after six weeks of treatment, a second laxative will be added and you will be asked to take a combination of two laxatives for four weeks.

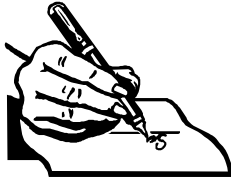
You will need to pick up this new prescription from your GP.

Second telephone interview and postal questionnaire: At the end of **Step 2**, we will send you a second questionnaire by post and will contact you by phone for a short telephone interview. The interview will ask similar questions as the first telephone interview. After the interview, we will ask you to fill in the second postal questionnaire and return it to us in a prepaid envelope within 2 weeks of the telephone interview.

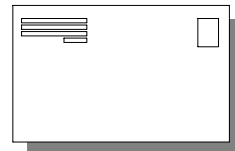
**Second telephone
interview**



**Filling in a postal
questionnaire**



**Return the questionnaire
to us by post**



Follow-up postal questionnaire at 6 months: 6 months after the start of the study we will contact you again by phone for a short telephone interview. You will also receive another questionnaire by post and be asked to fill it in and return it to us within 2 weeks.



Examining your medical records: At the end of the study we will need to look at your medical records. From them we will be able to extract some more information about how often you have visited your GP and the treatment you have received from your doctor related to constipation. This is needed to help us with the analysis of the results.

Thank you for reading this information leaflet!



Research staff contact details

Dr Svet Mihaylov (Trial coordinator)

0191 222 7249

Project secretary

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Appendix 5

Proposed economic evaluation

Perspective of the study

The researchers intended to use both an individual participant perspective and public-sector budget perspective with particular emphasis given to the subsets of costs and effects relevant to address the health service perspective at a macrolevel. Given the nature of the clinical condition and the age group of patients, productivity costs were deemed not to be relevant and therefore the societal perspective was not considered. Similarly, impact on other family members could be neglected without introducing any relevant bias.

Measure of benefits used and type of study

Considering all the measures of effectiveness estimated within the clinical trial, the researchers intended to outline a cost–consequences analysis. A cost-effectiveness analysis was proposed to be conducted on the basis of the number of bowel movements per week and on the utility-based measure of health state, applying societal values derived from a community-based population.⁸³

Although quality of life is an important indicator of benefit in the treatment of constipation, and is the primary outcome measure in this study, none of the currently available condition-specific measures yields a unique quality of life score (i.e. a utility or preference). Therefore, a comparison/synthesis of costs and outcomes based on each of the separate quality of life dimensions in these profile measures would have been methodologically invalid. For this reason, a utility-based index measure, the EQ-5D,^{40,41} was proposed to facilitate calculation of quality-adjusted life-years (QALYs). The authors were, however, aware of the concerns about the use of QALYs in devising resource allocation strategies between different age cohorts.^{84,85} Therefore, they aimed to develop or apply already existing ‘corrective’ measures to the prospective results, so that the findings did not have unfavourable implications for the funding of health technologies for older people.

Furthermore, it was anticipated that the EQ-5D might not be sensitive enough to detect differences in the population being studied. Therefore, alongside this utility-based measure, it was proposed to calculate discomfort-free days (DFDs) as a new measure of outcome. This measure included the impact on patients’ well-being of unwanted symptoms due both to constipation and to treatment side-effects. It would have been a crude but meaningful measure of the patients’ perceived effectiveness of treatment. DFDs were proposed to be derived through the self-completed structured diaries, in which patients were asked to report the overall impact of both the symptoms of constipation and side-effects of the laxatives on their well-being. Severity of impact was proposed to be graded in levels, and the number of days spent in each level of discomfort calculated. The researchers believed that the comparison of DFDs with EQ-5D utilities would have represented a useful addition to the body of knowledge on the assessment of cost-effectiveness in trials where the main impact is expected to be on palliation of symptoms and improvement of the quality of life, rather than on extension of life. They also sought to develop scenarios based on symptoms of constipation and condition-specific quality of life, and to use standard gamble and time trade-off techniques to establish utilities for the defined health states. This valuation exercise was proposed to be conducted on a small sample of participants, using common states defined by symptom diary and PAC-SYM/PAC-QOL responses from the early phases of the trial.

Resources data collected within the trial and costing methods

NHS resources proposed to be included comprised the use of drugs and primary care services. It was proposed to collect this information through extraction of data from medical records of trial participants (see Chapter 2). Costs related to the use of medication and health services were to be assigned using national published data.^{86–88} The researchers also intended to supplement the above data with data derived from telephone interviews and postal

questionnaires, which sought to collect information about the patients' expenditure on OTC medications and other items relating to the management of constipation. Where possible, it was planned to ask participants to report costs and quantities separately.

Synthesis of costs and outcomes

In the eventuality that the trial results were not able to demonstrate statistically and clinically significant evidence that one strategy was more effective than another, the intention was to apply a cost-minimisation framework and to recommend the less expensive strategies. If one strategy, however, appeared to be more effective (clinically) and less costly than comparators, it would be recommended. If one strategy had appeared to be more effective but more expensive than comparators, estimates of incremental cost-effectiveness ratios would have been generated

and compared. A judgement would then be required in a policy-making context to establish whether the additional benefits warrant the additional costs. In any case, recommendations would have been made taking into account the issues of the generalisability of the results.

Sensitivity analysis

A sensitivity analysis was proposed to test the robustness of the result to any variations in the key data inputs to the study, such as the price of medicines, to address the issues of both uncertainty in assumptions, methods and data, and the generalisability of the results.⁸⁹ It was also intended to conduct a sensitivity analysis that took account of differences in resource use which were practically significant (i.e. potentially costly), but which had not been shown to be statistically significant.

Appendix 6

Patient information leaflet (qualitative study)

Information Sheet for STOOL Research Project

We would like you to take part in a research study about constipation and the use of laxatives. Constipation is a common and often bothersome problem in adults in the UK, particularly amongst those aged 55 and over. Our research aims at finding out more about how constipation affects people and what treatments they have tried to help their constipation.

The research is being carried out by a team of researchers at the Centre for Health Services Research at Newcastle University. Many of the GPs in this area are helping us find participants for our research. This is why you have been sent a letter from your GP.

If you do decide to participate, our researcher Cathy Stark, will come and talk to you about your experiences. This interview can be arranged at a time and place to suit you. You may prefer to be interviewed in your own home or at the surgery or at the University in Newcastle. During the interview you will be asked about how constipation affects you and the symptoms you experience, and also about what you think of the laxatives you have tried. You do not have to answer any questions that you do not want to. Everything that you tell Cathy will be kept private; we will not tell anyone outside the research team what you say.

If you would like to talk to Cathy Stark about the research before making up your mind whether to participate, please phone **(0191) 222 7249 Monday to Wednesday, during office hours. If no-one is available please phone (0191) 222 7045 and leave a message with the secretary or on the answer phone.** Cathy can ring you back to save you the cost of the call. Please telephone Cathy for information about the research and not your GP.

If you would like to take part in the research please fill in the consent form and return it in the envelope provided. Cathy will then contact you to arrange an interview. We will also send you an information leaflet with more details about the research.

Thank you.

Appendix 7

Health-professional information leaflet (qualitative study)

**University of Newcastle upon Tyne
Centre for Health Services Research**



STOOL

Stepped Treatment of Older adults On Laxatives

Information Leaflet for Nurses

January 2003

What is the STOOL Project?

The STOOL Project is a qualitative study which aims to find out about nurses' experiences of dealing with constipation in older adults and, where applicable, nurses' experiences of prescribing laxatives for older people with constipation. We would like to talk to a variety of nurses attached to each GP surgery included in our study sample.

We also want to learn more about older people's experience of constipation and laxative use. We will be collecting the views of nurses, GPs and older people during this study.

This small qualitative study is part of a larger randomised control trial (RCT) which has been set up to find out about the comparative clinical and cost effectiveness of using different categories of laxatives, singly and then in combination. STOOL stands for Stepped Treatment of Older adults On Laxatives.

The qualitative study is important in helping us understand more about how patients experience constipation and use laxatives and how nurses manage these patients. An increased understanding of these issues will help us refine the questions we ask during the RCT.

Who is running the study?

The study is being undertaken by a group of researchers from the Centre for Health Services Research, Newcastle University. We are working closely with local clinicians from primary and secondary care.

Who is funding the research?

The research is funded by the National Health Service (Research and Development) under a research programme called Health Technology Assessment.

Why is the research important?

Many questions in constipation research have been addressed inadequately, or not at all. It remains unclear which laxative agents offer the best combination of efficacy, low incidence of adverse effects, acceptability and cost. We want to know about how nurses deal routinely with constipation in older adults. Where applicable, we also want to know whether nurses have a preference for prescribing a certain type of laxative for older people, and why this is. We will also be asking GPs similar questions. It is also important to learn more about how patients define constipation and whether they have a preferred treatment and how easy or difficult patients find adherence to prescribed treatment. The literature suggests that patients and health professionals may not define constipation in the same way, and that these differences may affect consultation patterns and compliance with therapy.

Is constipation worth investigating?

Yes. Constipation is a common and bothersome problem, especially for older people. Estimates of the prevalence of constipation in the general population of the UK range from 2% to 51.5%, depending on the definition used. It appears to be more common in women than men. In elderly people living in the community, approximately 20-25% have symptoms of constipation. Propensity to consult increases with age - for a GP with an average list size of 2000, approximately 12 patients aged 55 and over will consult about constipation each year. Overall, constipation generates 450,000 GP consultations every

year in England and Wales, at an estimated cost of £4.5 million per year.

What are you asking me to do?

We would like to invite you to take part in an interview with a researcher from our team. This would be a one-to-one, face-to-face interview and can be arranged at a place and time that is convenient to you, such as your surgery premises. It is estimated that the interview will take about 30 minutes, but it may be longer or shorter depending on how much you want to say.

We would like to tape record the interview so that the researcher does not have to make notes during the interview, and can concentrate on what is being said.

What will I be asked about?

You will be asked about your experiences of dealing with constipation in older adults (aged 55 and over). We want to find out which laxatives, if any, are routinely used and whether you have a preference for prescribing or recommending a particular laxative and why this is so. Also we are interested in your opinions about combining laxatives and whether you regard this as an effective treatment.

What will happen to the information you collect?

The taped interview will be transcribed and analysed. The information collected will be confidential to the research team. The interview will be given a code number and no names will be used on the transcript to assure anonymity.

The study will be published by the Department of Health as a Health Technology Assessment Report. These reports are made widely available to other bodies responsible for the

administering and funding of NHS services. A summary of findings will be made available to all participants.

What do I do now?

We would very much like you to take part in the research. Please fill in the attached consent form to indicate whether or not you are willing to take part. If you are willing, please indicate a convenient time for our researcher to telephone you in order to set up an interview. Please return the consent form in the envelope provided within two weeks from the date of this letter.

If you would like to talk to someone about the research in more detail please telephone Cathy Stark on the telephone number given at the end of this brochure.

Thank you for your time.

For further information please contact:

Dr Cathy Stark
STOOL Project
Centre for Health Services Research
University of Newcastle upon Tyne
21 Claremont Place
Newcastle NE2 4AA
Tel: 0191 222 7249 (Monday to Wednesday 8.30am - 4.30pm)
Or 0191 222 7045 at other times for secretary or answer phone.

Appendix 8

Topic guide for older-people interviews (qualitative study)

[Revised May 2003]

Preamble about the study
Check have consent
Permission to tape
Assurance of confidentiality

Topic: General health

Sample questions:

Can you tell me about your general health?
How would you rate your general health?
Any conditions, any ongoing or intermittent health problems?
Any problems in the past?
Mobility?
Eating habits?
Medication – regular (co-codamol, blood pressure, etc.) and what is it for?

Topic: Defining constipation

Understanding the term constipation

Experience of associated symptoms.

You have been included in this study because you have experienced constipation. Constipation can mean different things to different people.

- Can you tell me what **YOU** mean when you say you are constipated?
(haven't opened bowels for some days; pass hard or small stools; have to strain; other)

How do you know when you are constipated?

What symptoms do you have when you are constipated?
(pain, bloating, headache)

How do you feel in yourself when you are constipated?
(irritable, sluggish, anxious)

Why do you think you feel like this?

- Do you see yourself as constipated at the moment?
Why is that/isn't that?
- When was the last time you were constipated?
What happened then – why do you say you were constipated?
- How often do you become constipated?

How have your bowels been over the years?
(childhood, young adulthood, middle age, etc.)

How long do you think you have been suffering with constipation?
(all your life, many years, only two years or so, etc.)

Topic: Normal bowel habit and bowels over time

What is your usual pattern for opening your bowels at the moment?

How happy are you with your current bowel opening pattern?

Why is that?

Ideally, what bowel opening pattern would you like to have?

Why is that?

- What do you consider is a 'normal' bowel pattern?
Why do you say this?

Do you consider that you have a 'normal' bowel habit?

Do you feel it's important to have regular bowel routine?

Why do you say that?

Topic: Constipation and daily life

Do you think being constipated affects your daily life?

In what way?

Are there things that you can't do when you are constipated that you normally do?
(go to work, go out, socialise)

Are there things that you avoid doing when you are constipated?

(going out, eating out, socialising)

Why do you avoid these things?

Are there things that you do when you are constipated that you don't normally do?
(stay near toilet, go regularly for tries to toilet)

Could you tell me how being constipated affects you during an average day?

Topic: Constipation and health beliefs

Why do you think you suffer from constipation?

Do you think being constipated affects your health?

In what way?

Does being constipated cause you concern?

Why is this? What is it that worries you?

Have you raised these concerns with your GP?

Appendix 9

Topic guide for GP interviews (qualitative study)

[Revised 18 February 2003 following laxative classification review]

Preamble

What research is about

In-depth study of GPs' experiences of older people who self-report with constipation. Interested in learning more about GPs' experiences of different treatments for constipation.

Topic: Definition of constipation (GP definition)

What do you understand by the term constipation?

What criteria do you use to define constipation?

- frequency of passing stools
- difficulty passing stools (straining)
- consistency of stool
- associated symptoms (bloating, pain, etc.)
- change in bowel habit
- other

Do you ever use the term 'chronic constipation'? If so, what do you mean by it?

If never used, any reason why not?

Topic: Difficulties with definitions

Defining constipation in older people

(for purpose of this study definition of older people = age 55+)

From your experience, do you think that older people use the same definition as you do?

When an older person reports that they are constipated, what do they usually mean by this?

From your experience, when an older person presents with constipation, what symptoms do they usually describe and present with?

What symptoms do you usually ask them about?

Topic: Dealing routinely with constipation older patients

I would like to describe a scenario to you and then ask you how you might routinely deal with it.

A 65-year-old female patient comes to see you complaining that she is constipated. She has not consulted about this before and has no other major health problems.

What might you do in such a case?

Explore:

Do you apply any formal criteria to assess if patient is constipated [e.g. Rome II, Manning Scale (IBS), Bristol Stool form]?

Would the patient be given a prescription at initial consultation?

Would a follow-up appointment be suggested (always, only if no improvement, only if condition was felt to have worsened, other)?

If the patient was older, say 85, would your way of dealing with it be any different?

Why not?

In what way?

If the patient was in their 40s instead of in their 60s would your approach be different?

Why not?

In what way?

Change in bowel habit versus constipation

You have mentioned change in bowel habit, which sounds like it is different from constipation.

How are you using these terms?

How do you distinguish between the two – when does constipation become a change in bowel habit?

Topic: Routine prescriptions

What would you routinely prescribe for constipation in an older person?

What type of laxative do you regard this to be?

How do you regard this as working on the body?

What factors, if any, influence your choice of treatment?

What type of laxative is routinely prescribed (bulk, osmotic, stimulant)?

Why would you choose this particular treatment?

(explore: effectiveness, ease of use, side-effects, costs)

Do you believe this particular treatment to be effective?

On what evidence do you base this judgement?

Under what circumstances would you prescribe something other than this laxative?

Do you find that older people have a preference for a certain type of treatment for constipation?

What is this preference (prescribed laxative, lifestyle advice)?

Is there a preference expressed for a particular laxative or certain category of laxative? Which? Why do you think this is?

Would you prescribe their preferred laxatives if they requested it?

Why, why not, what factors would be taken into account?

Topic: Deciding not to prescribe a laxative

Are there circumstances when you wouldn't prescribe a laxative for an older person complaining of constipation?

When might this occur?

Do you feel that older people want to be prescribed a laxative when they consult with constipation – is this their expectation? Why do you think this? Does it vary?

If so, how is this managed in the consultation?

Topic: Other treatments and investigations

OTC medications

In your experience, are OTC medications something which most people consulting with constipation have tried, or do people tend to come to you as first port of call?

Is self-treatment for constipation something you would ask a patient about when they present with constipation?

Why/why not?

What would you ask about?

First point of contact (FPOC) versus not first point of contact (NFPOC)

Where do you see yourself in the process of a person consulting about constipation – would they come to your first or do you think would have seen a community nurse or pharmacists? Any perception of this?

Bowel diary

Are patients asked to keep a diary of their bowel function (routinely/under what circumstances)?

Follow-up investigations

Are patients ever referred for follow-up investigation?

What would lead you to request further investigation (routinely, under what circumstances)?

Topic: Causes of constipation in older people

Is constipation something which you think affects people more as they get older?

Why/why not do you believe this to be the case?

What is your understanding of the causes of constipation in the elderly?

- decreased mobility
- lack of exercise
- decreased calorie intake
- decreased fluid intake
- constipating medications
- other chronic conditions (and associated medications)

Do you try and identify the cause of constipation in an elderly patient?

Does the suspected or established cause of constipation have an effect on how you manage the consultation (e.g. would it affect whether you prescribe and/or what you prescribe)?

Are lifestyle factors relating to constipation ever discussed with older people?

Why not? or

Which factors, what is said or recommended?

Do you view constipation in older people as a chronic condition or one which can be alleviated? Why do you say this?

Topic: GPs' experience of prescribing different categories of laxative

Categories of laxative

I would like to ask you your opinions about and experience of prescribing the main types of laxatives.

According to literature, usually divided into:

- bulk/fibre laxatives
- stimulant
- osmotic.

Are these categories that you find yourself working with and thinking in?

Why is that the case/not the case?

Any others that you use?

Where do softeners fit in to this classification, if at all?

List of main preparations attached to enable researcher to show GP which laxative is being discussed. List of laxatives found in BNF.

Bulk/fibre laxatives (bran, ispaghula husk, methylcellulose, sterculia)
(increasing fibre, increasing weight, increasing water-absorbent properties of stool)

Show sheet

Can I ask what you might routinely prescribe for an older person?

Do you see the laxatives you have identified as bulking agents?

Why do you regard this as suitable/not suitable for an older person?

In your opinion, how does a bulking agent work?

Why would you choose this one rather than another (what factors do you take into account – cost, ease of use, effectiveness, lack of side-effects)?

In addition to the above, are there any other factors which influence your decision to prescribe certain bulk laxatives (pharmaceutical promotions, research outcomes, recommendations from others, practice or district formularies, patient preference)?

Stimulant laxatives (bisacodyl, senna, danthron, ducusate sodium)
(stimulation of colonic nerves to increase intestinal motility, stimulate production of water and so some osmotic properties)

Show sheet

Can I ask what you might routinely prescribe for an older person?
Do you see the laxatives you have identified as stimulant agents?
In your opinion, how does a bulking agent work?
Why do you regard this as suitable/not suitable for an older person?

Why would you choose this one rather than another (what factors do you take into account – cost, ease of use, effectiveness, lack of side-effects)?

In addition to the above, are there any other factors which influence your decision to prescribe certain stimulant laxatives (pharmaceutical promotions, research outcomes, recommendations from others, practice or district formularies, patient preference)?

Osmotic laxatives (magnesium salts, lactulose, lactitol)

Show sheet

Can I ask what you might routinely prescribe for an older person?
Do you see the laxatives you have identified as osmotic agents?
In your opinion, how does an osmotic agent work?
Why do you regard this as suitable/not suitable for an older person?

Why would you choose this one rather than another (what factors do you take into account – cost, ease of use, effectiveness, lack of side-effects)?

In addition to the above, are there any other factors which influence your decision to prescribe certain stimulant laxatives [pharmaceutical promotions, research outcomes, recommendations from others (who), practice or district formularies, patient preference]?

Topic: Changing treatments and use of co-treatments

Changing treatments

When might you change a patient's prescription from one laxative to another?
Is it usual that a patient might be prescribed a second and different laxative?

Do you have an order in which you prefer patients to try laxatives?
(i.e. would you prescribe different types of the same category of laxative, e.g. an ispaghula husk preparation followed by a sterculia preparation – both bulk laxatives; or would you tend to move from one category to another, e.g. from bulk to osmotic or stimulant?)
Why do you prefer to try laxatives in this particular order?
What is the rationale for this?

Use of co-treatments

When treating older people for constipation do you routinely prescribe more than one laxative?
If so, why is this?
If not, why not?

When might you consider using co-treatments or more than one laxative?
What co-treatments, if any, do you have experience of prescribing for older people?

Why did you decide to combine these particular treatments [pharmaceutical promotions, research outcomes, recommendations from others (who), patient preference, cost, ease of use, effectiveness, lack of side-effects]?

How effective do you believe these co-treatments have been?

Why do you say this?

Topic: Background of GP and practice

I would like finish by asking you a little bit about yourself and the practice

Characteristics of the practice

Number of GPs

Number of patients on list

Inner-city area, rural area

Teaching or non-teaching practice

Time GP has been at practice

Year of GP's medical qualification

Any one in practice with particular interest in elderly or gastrointestinal conditions

Question we've added in to help us understand better how to advertise our RCT

Which mail bases they use and why

Other resources that do find informative – help to inform us where to target advertisements of the trials

Conclusion

Is there anything else that you would like to add about your experience of treating older people presenting with constipation?

Anything you would like to ask?

Thanks, etc.

Appendix 10

Topic guide for nurse interviews (qualitative study)

[Revised 18 February 2003 following laxative classification review]

Preamble

What research is about

In-depth study of nurses' experiences of older people who describe themselves as constipated. Interested in learning more about nurses' role and experiences of treating constipation

Our definition of an older person is age 55 and over

We are interested in community-dwelling older people, rather than those in long-term nursing or residential care

Topic: Nurses' role in managing and treating constipation

Nurses' general role

Could you tell me a little bit about your role as a nurse in general terms –

Are you practice based?

Are you community based – visiting older people in their home?

Do you have regular patients that you see?

Does the GP ask you to see someone *after* the GP has seen them or can it be before?

Prescribing role

Do you prescribe at all?

Do you work within any limitations?

Restricted compared to GPs?

Practice formularies?

Nurse formularies?

Contact with older people

Under what circumstances have you come into contact with older people?

Under what circumstances have you come into contact with older people with constipation?

What role do you think you play as a nurse in managing constipation in older people?

How do you become involved in management of older patients?

Asked by GP first

Constipation disclosed when go for other reasons

Sent out for impaction, enemas, etc.

Topic: Definition of constipation (nurse definition)

What do you understand by the term constipation?

What criteria do you use to define constipation?

frequency of passing stools

difficulty passing stools (straining)

consistency of stool

associated symptoms (bloating, pain, etc.)

change in bowel habit

other

Do you ever use the term 'chronic constipation'? If so, what do you mean by it?

If never used, any reason why not?

Topic: Difficulties with definitions

Defining constipation in older people

(for purpose of this study definition of older people = age 55+)

From your experience, do you think that older people use the same definition as you do?
When an older person reports that they are constipated, what do they usually mean by this?

From your experience, when an older person presents with constipation, what symptoms do they usually describe and present with?

What symptoms do you usually ask them about?

Topic: Dealing routinely with constipation in older patients

I would like to describe a scenario to you and then ask you how you might routinely deal with it.

A 65-year-old female patient comes to see you complaining that she is constipated. She has not consulted about this before and has no other major health problems.

What might you do in such a case?

Explore:

Do you apply any formal criteria to assess if patient is constipated [e.g. Rome II, Manning Scale (IBS), Bristol Stool form]?

Would the patient be given a prescription at initial consultation?

Would a follow-up appointment be suggested (always, only if no improvement, only if condition was felt to have worsened, other)?

If the patient was older, say 85, would your way of dealing with it be any different?

Why not?

In what way?

If the patient was in their 40s instead of in their 60s would your approach be different?

Why not?

In what way?

Change in bowel habit versus constipation

You have mentioned change in bowel habit, which sounds like it is different from constipation.

How are you using these terms?

How do you distinguish between the two – when does constipation become a change in bowel habit?

Topic: Routine prescriptions

What would you routinely prescribe (recommend) for constipation in an older person?

What type of laxative do you regard this to be?

How do you regard this as working on the body?

What factors, if any, influence your choice of treatment?

What type of laxative is routinely prescribed (bulk, osmotic, stimulant)

Why would you choose this particular treatment?

(explore: effectiveness, ease of use, side-effects, costs)

Do you believe this particular treatment to be effective?

On what evidence do you base this judgement?

Under what circumstances would you prescribe (recommend) something other than this laxative?

Do you find that older people have a preference for a certain type of treatment for constipation?

What is this preference (prescribed laxative, lifestyle advice)?

Is there a preference expressed for a particular laxative or certain category of laxative? Which? Why do you think this is?

Would you prescribe their preferred laxatives if they requested it?

Why, why not, what factors would be taken into account?

Topic: Deciding not to prescribe a laxative

Are there circumstances when you wouldn't prescribe (recommend) a laxative for an older person complaining of constipation?

When might this occur?

Do you feel that older people want to be prescribed a laxative when they consult with constipation – is this their expectation? Why do you think this? Does it vary?

If so, how is this managed in the consultation?

Topic: Other treatments and investigations

OTC medications

In your experience, are OTC medications something which most people you deal with constipation have tried, or do people tend to come to you or their GP as first port of call?

Is self-treatment for constipation something you would ask a patient about when they present with constipation?

Why/why not?

What would you ask about?

FPOC versus NFPOC

Where do you see yourself in the process of a person consulting about constipation – would they come to you first or do you think would have seen a community nurse or pharmacists? Any perception of this?

Bowel diary

Are patients asked to keep a diary of their bowel function (routinely/under what circumstances)?

Follow-up investigations

Are patients ever referred for follow-up investigation?

What would lead you to request further investigation (routinely, under what circumstances)?

Is this something that you as a nurse may do, or is it done in collaboration with GP?

Topic: Causes of constipation in older people

Is constipation something which you think affects people more as they get older?

Why/why not do you believe this to be the case?

What is your understanding of the causes of constipation in the elderly?

decreased mobility

lack of exercise

decreased calorie intake

decreased fluid intake

constipating medications

other chronic conditions (and associated medications)

Do you try and identify the cause of constipation in an elderly patient?

Does the suspected or established cause of constipation have an effect on how you manage the consultation (e.g. would it affect whether you prescribe and/or what you prescribe)?

Are lifestyle factors relating to constipation ever discussed with older people?

Why not? or

Which factors, what is said or recommended?

Do you view constipation in older people as a chronic condition or one which can be alleviated? Why do you say this?

Topic: Nurses' experience of prescribing different categories of laxative

Categories of laxative

I would like to ask you your opinions about and experience of prescribing (recommending) the main types of laxatives. According to literature, usually divided into:

- bulk/fibre laxative
- stimulant
- osmotic.

Are these categories that you find yourself working with and thinking in?
Why is that the case/not the case?

Any others that you use?
Where do softeners fit in to this classification, if at all?

List of main preparations attached to enable researcher to show nurse which laxative is being discussed.
List of laxatives found in BNF.

Bulk/fibre laxatives (bran, ispaghula husk, methylcellulose, sterculia)
(increasing fibre, increasing weight, increasing water-absorbent properties of stool)

Show sheet

Can I ask what you might routinely prescribe/suggest for an older person?
Do you see the laxatives you have identified as bulking agents?
Why do you regard this as suitable/not suitable for an older person?
In your opinion, how does a bulking agent work?

Why would you choose this one rather than another (what factors do you take into account – cost, ease of use, effectiveness, lack of side-effects)?

In addition to the above, are there any other factors which influence your decision to prescribe/suggest certain bulk laxatives (pharmaceutical promotions, research outcomes, recommendations from others, practice or district formularies, patient preference)?

Stimulant laxatives (bisacodyl, senna, danthron, docusate sodium)
(stimulation of colonic nerves to increase intestinal motility, stimulate production of water and so some osmotic properties)

Show sheet

Can I ask what you might routinely prescribe for an older person?
Do you see the laxatives you have identified as stimulant agents?
In your opinion, how does a bulking agent work?
Why do you regard this as suitable/not suitable for an older person?

Why would you choose this one rather than another (what factors do you take into account – cost, ease of use, effectiveness, lack of side-effects)?

In addition to the above, are there any other factors which influence your decision to prescribe certain stimulant laxatives (pharmaceutical promotions, research outcomes, recommendations from others, practice or district formularies, patient preference)?

Osmotic laxatives (magnesium salts, lactulose, lactitol)

Show sheet

Can I ask what you might routinely prescribe for an older person?

Do you see the laxatives you have identified as osmotic agents?
In your opinion, how does an osmotic agent work?
Why do you regard this as suitable/not suitable for an older person?

Why would you choose this one rather than another (what factors do you take into account – cost, ease of use, effectiveness, lack of side-effects)?

In addition to the above, are there any other factors which influence your decision to prescribe certain stimulant laxatives [pharmaceutical promotions, research outcomes, recommendations from others (who), practice or district formularies, patient preference]?

Topic: Changing treatments and use of co-treatments

Changing treatments

When might you change/recommend change a patient's prescription from one laxative to another?

Is it usual that a patient might be prescribed a second and different laxative?

Do you have an order in which you prefer patients to try laxatives?
(i.e. would you prescribe different types of the same category of laxative, e.g. an ispaghula husk preparation followed by a sterculia preparation – both bulk laxatives; or would you tend to move from one category to another, e.g. from bulk to osmotic or stimulant?)

Why do you prefer to try laxatives in this particular order?

What is the rationale for this?

Use of co-treatments

When treating older people for constipation do you routinely prescribe (is it common) more than one laxative?

If so, why is this?

If not, why not?

When might you consider using co-treatments or more than one laxative?

What co-treatments, if any, do you have experience of prescribing for older people?

Why did you decide to combine these particular treatments [pharmaceutical promotions, research outcomes, recommendations from others (who), patient preference, cost, ease of use, effectiveness, lack of side-effects]?

How effective do you believe these co-treatments have been?

Why do you say this?

Topic: Background of nurse and practice

I would like to finish by asking you a little bit about yourself and the practice

Characteristics of the practice

Number of nurses

Number of patients on list – how does this relate to nurses?

Inner-city area, rural area

Teaching or non-teaching practice

Time nurse has been at practice

Year of nurse's medical qualification

Any nurse in practice with particular interest in elderly or gastrointestinal conditions

Question we've added in to help us understand better how to advertise our RCT

Which mail bases they use and why

Other resources that they do find informative – help to inform us where to target advertisements of the trials.

Conclusion

Is there anything else that you would like to add about your experience of treating older people presenting with constipation?

Anything you would like to ask?

Thanks, etc.

Laxative classification

<i>Bulking agents</i>	
Bran	Trifyba Fibraform
Ispaghula husk	Fybogel Konsyl Isogel Regulan
Methylcellulose	Celevac
Sterculia	Normacol Normacol plus
(also Metamucil, psyllium, glucomannan fibre)	
<i>Stimulant laxatives</i>	
Bisacodyl	Bisacodyl tablet/suppository
Dantron (danthron)	Co-danthramer Co-danthrusate
Docusate sodium	Diocyl Docusol Fletchers' Enemette Norgalax micro-enema
Glycerol	Glycerol suppositories
Senna	Senna Manevac
Sodium picosulfate Sodium picosulphate	Sodium picosulfate Dulco-lax
<i>Osmotic laxatives</i>	
Lactitol	Lactitol
Lactulose	Lactulose
Macrogols	Movicol
Magnesium salts	Magnesium hydroxide mixture BP Liquid paraffin and magnesium Hydroxide oral emulsion BP
	Phosphates (rectal) Carbalax Fleet ready-to-use enema Fletchers' phosphate enema
Sodium citrate (rectal)	Micolette micro-enema Micalax micro-enema Relaxit micro-enema
(also sorbitol, epsom salts)	
<i>Faecal softeners</i>	
Arachis oil	Fletchers' arachis oil retention enema
Liquid paraffin	Liquid paraffin oral emulsion



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No. 1

Clinical and cost-effectiveness of donepezil, rivastigmine and galantamine for Alzheimer's disease: a rapid and systematic review.

By Clegg A, Bryant J, Nicholson T, McIntyre L, De Broe S, Gerard K, *et al.*

No. 2

The clinical effectiveness and cost-effectiveness of riluzole for motor neurone disease: a rapid and systematic review.

By Stewart A, Sandercock J, Bryan S, Hyde C, Barton PM, Fry-Smith A, *et al.*

No. 3

Equity and the economic evaluation of healthcare.

By Sassi F, Archard L, Le Grand J.

No. 4

Quality-of-life measures in chronic diseases of childhood.

By Eiser C, Morse R.

No. 5

Eliciting public preferences for healthcare: a systematic review of techniques.

By Ryan M, Scott DA, Reeves C, Bate A, van Teijlingen ER, Russell EM, *et al.*

No. 6

General health status measures for people with cognitive impairment: learning disability and acquired brain injury.

By Riemsma RP, Forbes CA, Glanville JM, Eastwood AJ, Kleijnen J.

No. 7

An assessment of screening strategies for fragile X syndrome in the UK.

By Pembrey ME, Barnicoat AJ, Carmichael B, Bobrow M, Turner G.

No. 8

Issues in methodological research: perspectives from researchers and commissioners.

By Lilford RJ, Richardson A, Stevens A, Fitzpatrick R, Edwards S, Rock F, *et al.*

No. 9

Systematic reviews of wound care management: (5) beds; (6) compression; (7) laser therapy, therapeutic ultrasound, electrotherapy and electromagnetic therapy.

By Cullum N, Nelson EA, Flemming K, Sheldon T.

No. 10

Effects of educational and psychosocial interventions for adolescents with diabetes mellitus: a systematic review.

By Hampson SE, Skinner TC, Hart J, Storey L, Gage H, Foxcroft D, *et al.*

No. 11

Effectiveness of autologous chondrocyte transplantation for hyaline cartilage defects in knees: a rapid and systematic review.

By Jobanputra P, Parry D, Fry-Smith A, Burls A.

No. 12

Statistical assessment of the learning curves of health technologies.

By Ramsay CR, Grant AM, Wallace SA, Garthwaite PH, Monk AF, Russell IT.

No. 13

The effectiveness and cost-effectiveness of temozolomide for the treatment of recurrent malignant glioma: a rapid and systematic review.

By Dinnes J, Cave C, Huang S, Major K, Milne R.

No. 14

A rapid and systematic review of the clinical effectiveness and cost-effectiveness of debriding agents in treating surgical wounds healing by secondary intention.

By Lewis R, Whiting P, ter Riet G, O'Meara S, Glanville J.

No. 15

Home treatment for mental health problems: a systematic review.

By Burns T, Knapp M, Catty J, Healey A, Henderson J, Watt H, *et al.*

No. 16

How to develop cost-conscious guidelines.

By Eccles M, Mason J.

No. 17

The role of specialist nurses in multiple sclerosis: a rapid and systematic review.

By De Broe S, Christopher F, Waugh N.

No. 18

A rapid and systematic review of the clinical effectiveness and cost-effectiveness of orlistat in the management of obesity.

By O'Meara S, Riemsma R, Shirran L, Mather L, ter Riet G.

No. 19

The clinical effectiveness and cost-effectiveness of pioglitazone for type 2 diabetes mellitus: a rapid and systematic review.

By Chilcott J, Wight J, Lloyd Jones M, Tappenden P.

No. 20

Extended scope of nursing practice: a multicentre randomised controlled trial of appropriately trained nurses and preregistration house officers in pre-operative assessment in elective general surgery.

By Kinley H, Czoski-Murray C, George S, McCabe C, Primrose J, Reilly C, *et al.*

No. 21

Systematic reviews of the effectiveness of day care for people with severe mental disorders: (1) Acute day hospital versus admission; (2) Vocational rehabilitation; (3) Day hospital versus outpatient care.

By Marshall M, Crowther R, Almaraz-Serrano A, Creed F, Sledge W, Kluiters H, *et al.*

No. 22

The measurement and monitoring of surgical adverse events.

By Bruce J, Russell EM, Mollison J, Krukowski ZH.

No. 23

Action research: a systematic review and guidance for assessment.

By Waterman H, Tillen D, Dickson R, de Koning K.

No. 24

A rapid and systematic review of the clinical effectiveness and cost-effectiveness of gemcitabine for the treatment of pancreatic cancer.

By Ward S, Morris E, Bansback N, Calvert N, Crellin A, Forman D, *et al.*

No. 25

A rapid and systematic review of the evidence for the clinical effectiveness and cost-effectiveness of irinotecan, oxaliplatin and raltitrexed for the treatment of advanced colorectal cancer.

By Lloyd Jones M, Hummel S, Bansback N, Orr B, Seymour M.

No. 26

Comparison of the effectiveness of inhaler devices in asthma and chronic obstructive airways disease: a systematic review of the literature.

By Brocklebank D, Ram F, Wright J, Barry P, Cates C, Davies L, *et al.*

No. 27

The cost-effectiveness of magnetic resonance imaging for investigation of the knee joint.

By Bryan S, Weatherburn G, Bungay H, Hatrick C, Salas C, Parry D, *et al.*

No. 28

A rapid and systematic review of the clinical effectiveness and cost-effectiveness of topotecan for ovarian cancer.

By Forbes C, Shirran L, Bagnall A-M, Duffy S, ter Riet G.

No. 29

Superseded by a report published in a later volume.

No. 30

The role of radiography in primary care patients with low back pain of at least 6 weeks duration: a randomised (unblinded) controlled trial.

By Kendrick D, Fielding K, Bentley E, Miller P, Kerslake R, Pringle M.

No. 31

Design and use of questionnaires: a review of best practice applicable to surveys of health service staff and patients.

By McColl E, Jacoby A, Thomas L, Soutter J, Bamford C, Steen N, *et al.*

No. 32

A rapid and systematic review of the clinical effectiveness and cost-effectiveness of paclitaxel, docetaxel, gemcitabine and vinorelbine in non-small-cell lung cancer.

By Clegg A, Scott DA, Sidhu M, Hewitson P, Waugh N.

No. 33

Subgroup analyses in randomised controlled trials: quantifying the risks of false-positives and false-negatives.

By Brookes ST, Whitley E, Peters TJ, Mulheran PA, Egger M, Davey Smith G.

No. 34

Depot antipsychotic medication in the treatment of patients with schizophrenia: (1) Meta-review; (2) Patient and nurse attitudes.

By David AS, Adams C.

No. 35

A systematic review of controlled trials of the effectiveness and cost-effectiveness of brief psychological treatments for depression.

By Churchill R, Hunot V, Corney R, Knapp M, McGuire H, Tylee A, *et al.*

No. 36

Cost analysis of child health surveillance.

By Sanderson D, Wright D, Acton C, Duree D.

Volume 6, 2002**No. 1**

A study of the methods used to select review criteria for clinical audit.

By Hearnshaw H, Harker R, Cheater F, Baker R, Grimshaw G.

No. 2

Fludarabine as second-line therapy for B cell chronic lymphocytic leukaemia: a technology assessment.

By Hyde C, Wake B, Bryan S, Barton P, Fry-Smith A, Davenport C, *et al.*

No. 3

Rituximab as third-line treatment for refractory or recurrent Stage III or IV follicular non-Hodgkin's lymphoma: a systematic review and economic evaluation.

By Wake B, Hyde C, Bryan S, Barton P, Song F, Fry-Smith A, *et al.*

No. 4

A systematic review of discharge arrangements for older people.

By Parker SG, Peet SM, McPherson A, Cannaby AM, Baker R, Wilson A, *et al.*

No. 5

The clinical effectiveness and cost-effectiveness of inhaler devices used in the routine management of chronic asthma in older children: a systematic review and economic evaluation.

By Peters J, Stevenson M, Beverley C, Lim J, Smith S.

No. 6

The clinical effectiveness and cost-effectiveness of sibutramine in the management of obesity: a technology assessment.

By O'Meara S, Riemsma R, Shirran L, Mather L, ter Riet G.

No. 7

The cost-effectiveness of magnetic resonance angiography for carotid artery stenosis and peripheral vascular disease: a systematic review.

By Berry E, Kelly S, Westwood ME, Davies LM, Gough MJ, Bamford JM, *et al.*

No. 8

Promoting physical activity in South Asian Muslim women through 'exercise on prescription'.

By Carroll B, Ali N, Azam N.

No. 9

Zanamivir for the treatment of influenza in adults: a systematic review and economic evaluation.

By Burls A, Clark W, Stewart T, Preston C, Bryan S, Jefferson T, *et al.*

No. 10

A review of the natural history and epidemiology of multiple sclerosis: implications for resource allocation and health economic models.

By Richards RG, Sampson FC, Beard SM, Tappenden P.

No. 11

Screening for gestational diabetes: a systematic review and economic evaluation.

By Scott DA, Loveman E, McIntyre L, Waugh N.

No. 12

The clinical effectiveness and cost-effectiveness of surgery for people with morbid obesity: a systematic review and economic evaluation.

By Clegg AJ, Colquitt J, Sidhu MK, Royle P, Loveman E, Walker A.

No. 13

The clinical effectiveness of trastuzumab for breast cancer: a systematic review.

By Lewis R, Bagnall A-M, Forbes C, Shirran E, Duffy S, Kleijnen J, *et al.*

No. 14

The clinical effectiveness and cost-effectiveness of vinorelbine for breast cancer: a systematic review and economic evaluation.

By Lewis R, Bagnall A-M, King S, Woolcott N, Forbes C, Shirran L, *et al.*

No. 15

A systematic review of the effectiveness and cost-effectiveness of metal-on-metal hip resurfacing arthroplasty for treatment of hip disease.

By Vale L, Wyness L, McCormack K, McKenzie L, Brazzelli M, Stearns SC.

No. 16

The clinical effectiveness and cost-effectiveness of bupropion and nicotine replacement therapy for smoking cessation: a systematic review and economic evaluation.

By Woolcott NF, Jones L, Forbes CA, Mather LC, Sowden AJ, Song FJ, *et al.*

No. 17

A systematic review of effectiveness and economic evaluation of new drug treatments for juvenile idiopathic arthritis: etanercept.

By Cummins C, Connock M, Fry-Smith A, Burls A.

No. 18

Clinical effectiveness and cost-effectiveness of growth hormone in children: a systematic review and economic evaluation.

By Bryant J, Cave C, Mihaylova B, Chase D, McIntyre L, Gerard K, *et al.*

No. 19

Clinical effectiveness and cost-effectiveness of growth hormone in adults in relation to impact on quality of life: a systematic review and economic evaluation.

By Bryant J, Loveman E, Chase D, Mihaylova B, Cave C, Gerard K, *et al.*

No. 20

Clinical medication review by a pharmacist of patients on repeat prescriptions in general practice: a randomised controlled trial.

By Zermansky AG, Petty DR, Raynor DK, Lowe CJ, Frementle N, Vail A.

No. 21

The effectiveness of infliximab and etanercept for the treatment of rheumatoid arthritis: a systematic review and economic evaluation.

By Jobanputra P, Barton P, Bryan S, Burls A.

No. 22

A systematic review and economic evaluation of computerised cognitive behaviour therapy for depression and anxiety.

By Kaltenthaler E, Shackley P, Stevens K, Beverley C, Parry G, Chilcott J.

No. 23

A systematic review and economic evaluation of pegylated liposomal doxorubicin hydrochloride for ovarian cancer.

By Forbes C, Wilby J, Richardson G, Sculpher M, Mather L, Reimsma R.

No. 24

A systematic review of the effectiveness of interventions based on a stages-of-change approach to promote individual behaviour change.

By Riemsma RP, Pattenden J, Bridle C, Sowden AJ, Mather L, Watt IS, *et al.*

No. 25

A systematic review update of the clinical effectiveness and cost-effectiveness of glycoprotein IIb/IIIa antagonists.

By Robinson M, Ginnelly L, Sculpher M, Jones L, Riemsma R, Palmer S, *et al.*

No. 26

A systematic review of the effectiveness, cost-effectiveness and barriers to implementation of thrombolytic and neuroprotective therapy for acute ischaemic stroke in the NHS.

By Sandercock P, Berge E, Dennis M, Forbes J, Hand P, Kwan J, *et al.*

No. 27

A randomised controlled crossover trial of nurse practitioner versus doctor-led outpatient care in a bronchiectasis clinic.

By Caine N, Sharples LD, Hollingworth W, French J, Keogan M, Exley A, *et al.*

No. 28

Clinical effectiveness and cost – consequences of selective serotonin reuptake inhibitors in the treatment of sex offenders.

By Adi Y, Ashcroft D, Browne K, Beech A, Fry-Smith A, Hyde C.

No. 29

Treatment of established osteoporosis: a systematic review and cost-utility analysis.

By Kanis JA, Brazier JE, Stevenson M, Calvert NW, Lloyd Jones M.

No. 30

Which anaesthetic agents are cost-effective in day surgery? Literature review, national survey of practice and randomised controlled trial.

By Elliott RA Payne K, Moore JK, Davies LM, Harper NJN, St Leger AS, *et al.*

No. 31

Screening for hepatitis C among injecting drug users and in genitourinary medicine clinics: systematic reviews of effectiveness, modelling study and national survey of current practice.

By Stein K, Dalziel K, Walker A, McIntyre L, Jenkins B, Horne J, *et al.*

No. 32

The measurement of satisfaction with healthcare: implications for practice from a systematic review of the literature.

By Crow R, Gage H, Hampson S, Hart J, Kimber A, Storey L, *et al.*

No. 33

The effectiveness and cost-effectiveness of imatinib in chronic myeloid leukaemia: a systematic review.

By Garside R, Round A, Dalziel K, Stein K, Royle R.

No. 34

A comparative study of hypertonic saline, daily and alternate-day rhDNase in children with cystic fibrosis.

By Suri R, Wallis C, Bush A, Thompson S, Normand C, Flather M, *et al.*

No. 35

A systematic review of the costs and effectiveness of different models of paediatric home care.

By Parker G, Bhakta P, Lovett CA, Paisley S, Olsen R, Turner D, *et al.*

Volume 7, 2003

No. 1

How important are comprehensive literature searches and the assessment of trial quality in systematic reviews? Empirical study.

By Egger M, Jüni P, Bartlett C, Holenstein F, Sterne J.

No. 2

Systematic review of the effectiveness and cost-effectiveness, and economic evaluation, of home versus hospital or satellite unit haemodialysis for people with end-stage renal failure.

By Mowatt G, Vale L, Perez J, Wyness L, Fraser C, MacLeod A, *et al.*

No. 3

Systematic review and economic evaluation of the effectiveness of infliximab for the treatment of Crohn's disease.

By Clark W, Raftery J, Barton P, Song F, Fry-Smith A, Burls A.

No. 4

A review of the clinical effectiveness and cost-effectiveness of routine anti-D prophylaxis for pregnant women who are rhesus negative.

By Chilcott J, Lloyd Jones M, Wight J, Forman K, Wray J, Beverley C, *et al.*

No. 5

Systematic review and evaluation of the use of tumour markers in paediatric oncology: Ewing's sarcoma and neuroblastoma.

By Riley RD, Burchill SA, Abrams KR, Heny D, Lambert PC, Jones DR, *et al.*

No. 6

The cost-effectiveness of screening for *Helicobacter pylori* to reduce mortality and morbidity from gastric cancer and peptic ulcer disease: a discrete-event simulation model.

By Roderick P, Davies R, Raftery J, Crabbe D, Pearce R, Bhandari P, *et al.*

No. 7

The clinical effectiveness and cost-effectiveness of routine dental checks: a systematic review and economic evaluation.

By Davenport C, Elley K, Salas C, Taylor-Weetman CL, Fry-Smith A, Bryan S, *et al.*

No. 8

A multicentre randomised controlled trial assessing the costs and benefits of using structured information and analysis of women's preferences in the management of menorrhagia.

By Kennedy ADM, Sculpher MJ, Coulter A, Dwyer N, Rees M, Horsley S, *et al.*

No. 9

Clinical effectiveness and cost-utility of photodynamic therapy for wet age-related macular degeneration: a systematic review and economic evaluation.

By Meads C, Salas C, Roberts T, Moore D, Fry-Smith A, Hyde C.

No. 10

Evaluation of molecular tests for prenatal diagnosis of chromosome abnormalities.

By Grimshaw GM, Szczepura A, Hultén M, MacDonald F, Nevin NC, Sutton F, *et al.*

No. 11

First and second trimester antenatal screening for Down's syndrome: the results of the Serum, Urine and Ultrasound Screening Study (SURUSS).

By Wald NJ, Rodeck C, Hackshaw AK, Walters J, Chitty L, Mackinson AM.

No. 12

The effectiveness and cost-effectiveness of ultrasound locating devices for central venous access: a systematic review and economic evaluation.

By Calvert N, Hind D, McWilliams RG, Thomas SM, Beverley C, Davidson A.

No. 13

A systematic review of atypical antipsychotics in schizophrenia.

By Bagnall A-M, Jones L, Lewis R, Ginnelly L, Glanville J, Torgerson D, *et al.*

No. 14

Prostate Testing for Cancer and Treatment (ProtecT) feasibility study.

By Donovan J, Hamdy F, Neal D, Peters T, Oliver S, Brindle L, *et al.*

No. 15

Early thrombolysis for the treatment of acute myocardial infarction: a systematic review and economic evaluation.

By Boland A, Dundar Y, Bagust A, Haycox A, Hill R, Mujica Mota R, *et al.*

No. 16

Screening for fragile X syndrome: a literature review and modelling.

By Song FJ, Barton P, Sleightholme V, Yao GL, Fry-Smith A.

No. 17

Systematic review of endoscopic sinus surgery for nasal polyps.

By Dalziel K, Stein K, Round A, Garside R, Royle P.

No. 18

Towards efficient guidelines: how to monitor guideline use in primary care.

By Hutchinson A, McIntosh A, Cox S, Gilbert C.

No. 19

Effectiveness and cost-effectiveness of acute hospital-based spinal cord injuries services: systematic review.

By Bagnall A-M, Jones L, Richardson G, Duffy S, Riemsma R.

No. 20

Prioritisation of health technology assessment. The PATHS model: methods and case studies.

By Townsend J, Buxton M, Harper G.

No. 21

Systematic review of the clinical effectiveness and cost-effectiveness of tension-free vaginal tape for treatment of urinary stress incontinence.

By Cody J, Wyness L, Wallace S, Glazener C, Kilonzo M, Stearns S, *et al.*

No. 22

The clinical and cost-effectiveness of patient education models for diabetes: a systematic review and economic evaluation.

By Loveman E, Cave C, Green C, Royle P, Dunn N, Waugh N.

No. 23

The role of modelling in prioritising and planning clinical trials.

By Chilcott J, Brennan A, Booth A, Karnon J, Tappenden P.

No. 24

Cost-benefit evaluation of routine influenza immunisation in people 65-74 years of age.

By Allsup S, Gosney M, Haycox A, Regan M.

No. 25

The clinical and cost-effectiveness of pulsatile machine perfusion versus cold storage of kidneys for transplantation retrieved from heart-beating and non-heart-beating donors.

By Wight J, Chilcott J, Holmes M, Brewer N.

No. 26

Can randomised trials rely on existing electronic data? A feasibility study to explore the value of routine data in health technology assessment.

By Williams JG, Cheung WY, Cohen DR, Hutchings HA, Longo MF, Russell IT.

No. 27

Evaluating non-randomised intervention studies.

By Deeks JJ, Dinnes J, D'Amico R, Sowden AJ, Sakarovich C, Song F, *et al.*

No. 28

A randomised controlled trial to assess the impact of a package comprising a patient-orientated, evidence-based self-help guidebook and patient-centred consultations on disease management and satisfaction in inflammatory bowel disease.

By Kennedy A, Nelson E, Reeves D, Richardson G, Roberts C, Robinson A, *et al.*

No. 29

The effectiveness of diagnostic tests for the assessment of shoulder pain due to soft tissue disorders: a systematic review.

By Dinnes J, Loveman E, McIntyre L, Waugh N.

No. 30

The value of digital imaging in diabetic retinopathy.

By Sharp PF, Olson J, Strachan F, Hipwell J, Ludbrook A, O'Donnell M, *et al.*

No. 31

Lowering blood pressure to prevent myocardial infarction and stroke: a new preventive strategy.

By Law M, Wald N, Morris J.

No. 32

Clinical and cost-effectiveness of capecitabine and tegafur with uracil for the treatment of metastatic colorectal cancer: systematic review and economic evaluation.

By Ward S, Kaltenthaler E, Cowan J, Brewer N.

No. 33

Clinical and cost-effectiveness of new and emerging technologies for early localised prostate cancer: a systematic review.

By Hummel S, Paisley S, Morgan A, Currie E, Brewer N.

No. 34

Literature searching for clinical and cost-effectiveness studies used in health technology assessment reports carried out for the National Institute for Clinical Excellence appraisal system.

By Royle P, Waugh N.

No. 35

Systematic review and economic decision modelling for the prevention and treatment of influenza A and B.

By Turner D, Wailoo A, Nicholson K, Cooper N, Sutton A, Abrams K.

No. 36

A randomised controlled trial to evaluate the clinical and cost-effectiveness of Hickman line insertions in adult cancer patients by nurses.

By Boland A, Haycox A, Bagust A, Fitzsimmons L.

No. 37

Redesigning postnatal care: a randomised controlled trial of protocol-based midwifery-led care focused on individual women's physical and psychological health needs.

By MacArthur C, Winter HR, Bick DE, Lilford RJ, Lancashire RJ, Knowles H, *et al.*

No. 38

Estimating implied rates of discount in healthcare decision-making.

By West RR, McNabb R, Thompson AGH, Sheldon TA, Grimley Evans J.

No. 39

Systematic review of isolation policies in the hospital management of methicillin-resistant *Staphylococcus aureus*: a review of the literature with epidemiological and economic modelling.

By Cooper BS, Stone SP, Kibbler CC, Cookson BD, Roberts JA, Medley GF, *et al.*

No. 40

Treatments for spasticity and pain in multiple sclerosis: a systematic review.

By Beard S, Hunn A, Wight J.

No. 41

The inclusion of reports of randomised trials published in languages other than English in systematic reviews.

By Moher D, Pham B, Lawson ML, Klassen TP.

No. 42

The impact of screening on future health-promoting behaviours and health beliefs: a systematic review.

By Bankhead CR, Brett J, Bukach C, Webster P, Stewart-Brown S, Munafa M, *et al.*

Volume 8, 2004

No. 1

What is the best imaging strategy for acute stroke?

By Wardlaw JM, Keir SL, Seymour J, Lewis S, Sandercock PAG, Dennis MS, *et al.*

No. 2

Systematic review and modelling of the investigation of acute and chronic chest pain presenting in primary care.

By Mant J, McManus RJ, Oakes RAL, Delaney BC, Barton PM, Deeks JJ, *et al.*

No. 3

The effectiveness and cost-effectiveness of microwave and thermal balloon endometrial ablation for heavy menstrual bleeding: a systematic review and economic modelling.

By Garside R, Stein K, Wyatt K, Round A, Price A.

No. 4

A systematic review of the role of bisphosphonates in metastatic disease.

By Ross JR, Saunders Y, Edmonds PM, Patel S, Wonderling D, Normand C, *et al.*

No. 5

Systematic review of the clinical effectiveness and cost-effectiveness of capecitabine (Xeloda®) for locally advanced and/or metastatic breast cancer.

By Jones L, Hawkins N, Westwood M, Wright K, Richardson G, Riemsma R.

No. 6

Effectiveness and efficiency of guideline dissemination and implementation strategies.

By Grimshaw JM, Thomas RE, MacLennan G, Fraser C, Ramsay CR, Vale L, *et al.*

No. 7

Clinical effectiveness and costs of the Sugarbaker procedure for the treatment of pseudomyxoma peritonei.

By Bryant J, Clegg AJ, Sidhu MK, Brodin H, Royle P, Davidson P.

No. 8

Psychological treatment for insomnia in the regulation of long-term hypnotic drug use.

By Morgan K, Dixon S, Mathers N, Thompson J, Tomeny M.

No. 9

Improving the evaluation of therapeutic interventions in multiple sclerosis: development of a patient-based measure of outcome.

By Hobart JC, Riazi A, Lamping DL, Fitzpatrick R, Thompson AJ.

No. 10

A systematic review and economic evaluation of magnetic resonance cholangiopancreatography compared with diagnostic endoscopic retrograde cholangiopancreatography.

By Kaltenthaler E, Bravo Vergel Y, Chilcott J, Thomas S, Blakeborough T, Walters SJ, *et al.*

No. 11

The use of modelling to evaluate new drugs for patients with a chronic condition: the case of antibodies against tumour necrosis factor in rheumatoid arthritis.

By Barton P, Jobanputra P, Wilson J, Bryan S, Burls A.

No. 12

Clinical effectiveness and cost-effectiveness of neonatal screening for inborn errors of metabolism using tandem mass spectrometry: a systematic review.

By Pandor A, Eastham J, Beverley C, Chilcott J, Paisley S.

No. 13

Clinical effectiveness and cost-effectiveness of pioglitazone and rosiglitazone in the treatment of type 2 diabetes: a systematic review and economic evaluation.

By Czoski-Murray C, Warren E, Chilcott J, Beverley C, Psyllaki MA, Cowan J.

No. 14

Routine examination of the newborn: the EMREN study. Evaluation of an extension of the midwife role including a randomised controlled trial of appropriately trained midwives and paediatric senior house officers.

By Townsend J, Wolke D, Hayes J, Davé S, Rogers C, Bloomfield L, *et al.*

No. 15

Involving consumers in research and development agenda setting for the NHS: developing an evidence-based approach.

By Oliver S, Clarke-Jones L, Rees R, Milne R, Buchanan P, Gabbay J, *et al.*

No. 16

A multi-centre randomised controlled trial of minimally invasive direct coronary bypass grafting versus percutaneous transluminal coronary angioplasty with stenting for proximal stenosis of the left anterior descending coronary artery.

By Reeves BC, Angelini GD, Bryan AJ, Taylor FC, Cripps T, Spyt TJ, *et al.*

No. 17

Does early magnetic resonance imaging influence management or improve outcome in patients referred to secondary care with low back pain? A pragmatic randomised controlled trial.

By Gilbert FJ, Grant AM, Gillan MGC, Vale L, Scott NW, Campbell MK, *et al.*

No. 18

The clinical and cost-effectiveness of anakinra for the treatment of rheumatoid arthritis in adults: a systematic review and economic analysis.

By Clark W, Jobanputra P, Barton P, Burls A.

No. 19

A rapid and systematic review and economic evaluation of the clinical and cost-effectiveness of newer drugs for treatment of mania associated with bipolar affective disorder.

By Bridle C, Palmer S, Bagnall A-M, Darba J, Duffy S, Sculpher M, *et al.*

No. 20

Liquid-based cytology in cervical screening: an updated rapid and systematic review and economic analysis.

By Karnon J, Peters J, Platt J, Chilcott J, McGoogan E, Brewer N.

No. 21

Systematic review of the long-term effects and economic consequences of treatments for obesity and implications for health improvement.

By Avenell A, Broom J, Brown TJ, Poobalan A, Aucott L, Stearns SC, *et al.*

No. 22

Autoantibody testing in children with newly diagnosed type 1 diabetes mellitus.

By Dretzke J, Cummins C, Sandercock J, Fry-Smith A, Barrett T, Burls A.

No. 23

Clinical effectiveness and cost-effectiveness of prehospital intravenous fluids in trauma patients.

By Dretzke J, Sandercock J, Bayliss S, Burls A.

No. 24

Newer hypnotic drugs for the short-term management of insomnia: a systematic review and economic evaluation.

By Dündar Y, Boland A, Strobl J, Dodd S, Haycox A, Bagust A, *et al.*

No. 25

Development and validation of methods for assessing the quality of diagnostic accuracy studies.

By Whiting P, Rutjes AWS, Dinnes J, Reitsma JB, Bossuyt PMM, Kleijnen J.

No. 26

EVALUATE hysterectomy trial: a multicentre randomised trial comparing abdominal, vaginal and laparoscopic methods of hysterectomy.

By Garry R, Fountain J, Brown J, Manca A, Mason S, Sculpher M, *et al.*

No. 27

Methods for expected value of information analysis in complex health economic models: developments on the health economics of interferon- β and glatiramer acetate for multiple sclerosis.

By Tappenden P, Chilcott JB, Eggington S, Oakley J, McCabe C.

No. 28

Effectiveness and cost-effectiveness of imatinib for first-line treatment of chronic myeloid leukaemia in chronic phase: a systematic review and economic analysis.

By Dalziel K, Round A, Stein K, Garside R, Price A.

No. 29

VenUS I: a randomised controlled trial of two types of bandage for treating venous leg ulcers.

By Iglesias C, Nelson EA, Cullum NA, Torgerson DJ on behalf of the VenUS Team.

No. 30

Systematic review of the effectiveness and cost-effectiveness, and economic evaluation, of myocardial perfusion scintigraphy for the diagnosis and management of angina and myocardial infarction.

By Mowatt G, Vale L, Brazzelli M, Hernandez R, Murray A, Scott N, *et al.*

No. 31

A pilot study on the use of decision theory and value of information analysis as part of the NHS Health Technology Assessment programme.

By Claxton K, Ginnelly L, Sculpher M, Philips Z, Palmer S.

No. 32

The Social Support and Family Health Study: a randomised controlled trial and economic evaluation of two alternative forms of postnatal support for mothers living in disadvantaged inner-city areas.

By Wiggins M, Oakley A, Roberts I, Turner H, Rajan L, Austerberry H, *et al.*

No. 33

Psychosocial aspects of genetic screening of pregnant women and newborns: a systematic review.

By Green JM, Hewison J, Bekker HL, Bryant, Cuckle HS.

No. 34

Evaluation of abnormal uterine bleeding: comparison of three outpatient procedures within cohorts defined by age and menopausal status.

By Critchley HOD, Warner P, Lee AJ, Brechin S, Guise J, Graham B.

No. 35

Coronary artery stents: a rapid systematic review and economic evaluation.

By Hill R, Bagust A, Bakhai A, Dickson R, Dündar Y, Haycox A, *et al.*

No. 36

Review of guidelines for good practice in decision-analytic modelling in health technology assessment.

By Philips Z, Ginnelly L, Sculpher M, Claxton K, Golder S, Riemsma R, *et al.*

No. 37

Rituximab (MabThera[®]) for aggressive non-Hodgkin's lymphoma: systematic review and economic evaluation.

By Knight C, Hind D, Brewer N, Abbott V.

No. 38

Clinical effectiveness and cost-effectiveness of clopidogrel and modified-release dipyridamole in the secondary prevention of occlusive vascular events: a systematic review and economic evaluation.

By Jones L, Griffin S, Palmer S, Main C, Orton V, Sculpher M, *et al.*

No. 39

Pegylated interferon α -2a and -2b in combination with ribavirin in the treatment of chronic hepatitis C: a systematic review and economic evaluation.

By Shepherd J, Brodin H, Cave C, Waugh N, Price A, Gabbay J.

No. 40

Clopidogrel used in combination with aspirin compared with aspirin alone in the treatment of non-ST-segment-elevation acute coronary syndromes: a systematic review and economic evaluation.

By Main C, Palmer S, Griffin S, Jones L, Orton V, Sculpher M, *et al.*

No. 41

Provision, uptake and cost of cardiac rehabilitation programmes: improving services to under-represented groups.

By Beswick AD, Rees K, Griebusch I, Taylor FC, Burke M, West RR, *et al.*

No. 42

Involving South Asian patients in clinical trials.

By Hussain-Gambles M, Leese B, Atkin K, Brown J, Mason S, Tovey P.

No. 43

Clinical and cost-effectiveness of continuous subcutaneous insulin infusion for diabetes.

By Colquitt JL, Green C, Sidhu MK, Hartwell D, Waugh N.

No. 44

Identification and assessment of ongoing trials in health technology assessment reviews.

By Song FJ, Fry-Smith A, Davenport C, Bayliss S, Adi Y, Wilson JS, *et al.*

No. 45

Systematic review and economic evaluation of a long-acting insulin analogue, insulin glargine

By Warren E, Weatherley-Jones E, Chilcott J, Beverley C.

No. 46

Supplementation of a home-based exercise programme with a class-based programme for people with osteoarthritis of the knees: a randomised controlled trial and health economic analysis.

By McCarthy CJ, Mills PM, Pullen R, Richardson G, Hawkins N, Roberts CR, *et al.*

No. 47

Clinical and cost-effectiveness of once-daily versus more frequent use of same potency topical corticosteroids for atopic eczema: a systematic review and economic evaluation.

By Green C, Colquitt JL, Kirby J, Davidson P, Payne E.

No. 48

Acupuncture of chronic headache disorders in primary care: randomised controlled trial and economic analysis.

By Vickers AJ, Rees RW, Zollman CE, McCarney R, Smith CM, Ellis N, *et al.*

No. 49

Generalisability in economic evaluation studies in healthcare: a review and case studies.

By Sculpher MJ, Pang FS, Manca A, Drummond MF, Golder S, Urdahl H, *et al.*

No. 50

Virtual outreach: a randomised controlled trial and economic evaluation of joint teleconferenced medical consultations.

By Wallace P, Barber J, Clayton W, Currell R, Fleming K, Garner P, *et al.*

Volume 9, 2005

No. 1

Randomised controlled multiple treatment comparison to provide a cost-effectiveness rationale for the selection of antimicrobial therapy in acne.

By Ozolins M, Eady EA, Avery A, Cunliffe WJ, O'Neill C, Simpson NB, *et al.*

No. 2

Do the findings of case series studies vary significantly according to methodological characteristics?

By Dalziel K, Round A, Stein K, Garside R, Castelnovo E, Payne L.

No. 3

Improving the referral process for familial breast cancer genetic counselling: findings of three randomised controlled trials of two interventions.

By Wilson BJ, Torrance N, Mollison J, Wordsworth S, Gray JR, Haites NE, *et al.*

No. 4

Randomised evaluation of alternative electrosurgical modalities to treat bladder outflow obstruction in men with benign prostatic hyperplasia.

By Fowler C, McAllister W, Plail R, Karim O, Yang Q.

No. 5

A pragmatic randomised controlled trial of the cost-effectiveness of palliative therapies for patients with inoperable oesophageal cancer.

By Shenfine J, McNamee P, Steen N, Bond J, Griffin SM.

No. 6

Impact of computer-aided detection prompts on the sensitivity and specificity of screening mammography.

By Taylor P, Champness J, Given-Wilson R, Johnston K, Potts H.

No. 7

Issues in data monitoring and interim analysis of trials.

By Grant AM, Altman DG, Babiker AB, Campbell MK, Clemens FJ, Darbyshire JH, *et al.*

No. 8

Lay public's understanding of equipoise and randomisation in randomised controlled trials.

By Robinson EJ, Kerr CEP, Stevens AJ, Lilford RJ, Braunholtz DA, Edwards SJ, *et al.*

No. 9

Clinical and cost-effectiveness of electroconvulsive therapy for depressive illness, schizophrenia, catatonia and mania: systematic reviews and economic modelling studies.

By Greenhalgh J, Knight C, Hind D, Beverley C, Walters S.

No. 10

Measurement of health-related quality of life for people with dementia: development of a new instrument (DEMQOL) and an evaluation of current methodology.

By Smith SC, Lamping DL, Banerjee S, Harwood R, Foley B, Smith P, *et al.*

No. 11

Clinical effectiveness and cost-effectiveness of drotrecogin alfa (activated) (Xigris[®]) for the treatment of severe sepsis in adults: a systematic review and economic evaluation.

By Green C, Dinnes J, Takeda A, Shepherd J, Hartwell D, Cave C, *et al.*

No. 12

A methodological review of how heterogeneity has been examined in systematic reviews of diagnostic test accuracy.

By Dinnes J, Deeks J, Kirby J, Roderick P.

No. 13

Cervical screening programmes: can automation help? Evidence from systematic reviews, an economic analysis and a simulation modelling exercise applied to the UK.

By Willis BH, Barton P, Pearmain P, Bryan S, Hyde C.

No. 14

Laparoscopic surgery for inguinal hernia repair: systematic review of effectiveness and economic evaluation.

By McCormack K, Wake B, Perez J, Fraser C, Cook J, McIntosh E, *et al.*

No. 15

Clinical effectiveness, tolerability and cost-effectiveness of newer drugs for epilepsy in adults: a systematic review and economic evaluation.

By Wilby J, Kainth A, Hawkins N, Epstein D, McIntosh H, McDaid C, *et al.*

No. 16

A randomised controlled trial to compare the cost-effectiveness of tricyclic antidepressants, selective serotonin reuptake inhibitors and lofepramine.

By Peveler R, Kendrick T, Buxton M, Longworth L, Baldwin D, Moore M, *et al.*

No. 17

Clinical effectiveness and cost-effectiveness of immediate angioplasty for acute myocardial infarction: systematic review and economic evaluation.

By Hartwell D, Colquitt J, Loveman E, Clegg AJ, Brodin H, Waugh N, *et al.*

No. 18

A randomised controlled comparison of alternative strategies in stroke care.

By Kalra L, Evans A, Perez I, Knapp M, Swift C, Donaldson N.

No. 19

The investigation and analysis of critical incidents and adverse events in healthcare.

By Woloshynowych M, Rogers S, Taylor-Adams S, Vincent C.

No. 20

Potential use of routine databases in health technology assessment.

By Raftery J, Roderick P, Stevens A.

No. 21

Clinical and cost-effectiveness of newer immunosuppressive regimens in renal transplantation: a systematic review and modelling study.

By Woodroffe R, Yao GL, Meads C, Bayliss S, Ready A, Raftery J, *et al.*

No. 22

A systematic review and economic evaluation of alendronate, etidronate, risedronate, raloxifene and teriparatide for the prevention and treatment of postmenopausal osteoporosis.

By Stevenson M, Lloyd Jones M, De Nigris E, Brewer N, Davis S, Oakley J.

No. 23

A systematic review to examine the impact of psycho-educational interventions on health outcomes and costs in adults and children with difficult asthma.

By Smith JR, Mugford M, Holland R, Candy B, Noble MJ, Harrison BDW, *et al.*

No. 24

An evaluation of the costs, effectiveness and quality of renal replacement therapy provision in renal satellite units in England and Wales.

By Roderick P, Nicholson T, Armitage A, Mehta R, Mullee M, Gerard K, *et al.*

No. 25

Imatinib for the treatment of patients with unresectable and/or metastatic gastrointestinal stromal tumours: systematic review and economic evaluation.

By Wilson J, Connock M, Song F, Yao G, Fry-Smith A, Raftery J, *et al.*

No. 26

Indirect comparisons of competing interventions.

By Glenny AM, Altman DG, Song F, Sakarovitch C, Deeks JJ, D'Amico R, *et al.*

No. 27

Cost-effectiveness of alternative strategies for the initial medical management of non-ST elevation acute coronary syndrome: systematic review and decision-analytical modelling.

By Robinson M, Palmer S, Sculpher M, Philips Z, Ginnelly L, Bowens A, *et al.*

No. 28

Outcomes of electrically stimulated gracilis neosphincter surgery.

By Tillin T, Chambers M, Feldman R.

No. 29

The effectiveness and cost-effectiveness of pimecrolimus and tacrolimus for atopic eczema: a systematic review and economic evaluation.

By Garside R, Stein K, Castelnovo E, Pitt M, Ashcroft D, Dimmock P, *et al.*

No. 30

Systematic review on urine albumin testing for early detection of diabetic complications.

By Newman DJ, Mattock MB, Dawney ABS, Kerry S, McGuire A, Yaqoob M, *et al.*

No. 31

Randomised controlled trial of the cost-effectiveness of water-based therapy for lower limb osteoarthritis.

By Cochrane T, Davey RC, Matthes Edwards SM.

No. 32

Longer term clinical and economic benefits of offering acupuncture care to patients with chronic low back pain.

By Thomas KJ, MacPherson H, Ratcliffe J, Thorpe L, Brazier J, Campbell M, *et al.*

No. 33

Cost-effectiveness and safety of epidural steroids in the management of sciatica.

By Price C, Arden N, Cogan L, Rogers P.

No. 34

The British Rheumatoid Outcome Study Group (BROSG) randomised controlled trial to compare the effectiveness and cost-effectiveness of aggressive versus symptomatic therapy in established rheumatoid arthritis.

By Symmons D, Tricker K, Roberts C, Davies L, Dawes P, Scott DL.

No. 35

Conceptual framework and systematic review of the effects of participants' and professionals' preferences in randomised controlled trials.

By King M, Nazareth I, Lampe F, Bower P, Chandler M, Morou M, *et al.*

No. 36

The clinical and cost-effectiveness of implantable cardioverter defibrillators: a systematic review.

By Bryant J, Brodin H, Loveman E, Payne E, Clegg A.

No. 37

A trial of problem-solving by community mental health nurses for anxiety, depression and life difficulties among general practice patients. The CPN-GP study.

By Kendrick T, Simons L, Mynors-Wallis L, Gray A, Lathlean J, Pickering R, *et al.*

No. 38

The causes and effects of socio-demographic exclusions from clinical trials.

By Bartlett C, Doyal L, Ebrahim S, Davey P, Bachmann M, Egger M, *et al.*

No. 39

Is hydrotherapy cost-effective? A randomised controlled trial of combined hydrotherapy programmes compared with physiotherapy land techniques in children with juvenile idiopathic arthritis.

By Epps H, Ginnelly L, Utley M, Southwood T, Gallivan S, Sculpher M, *et al.*

No. 40

A randomised controlled trial and cost-effectiveness study of systematic screening (targeted and total population screening) versus routine practice for the detection of atrial fibrillation in people aged 65 and over. The SAFE study.

By Hobbs FDR, Fitzmaurice DA, Mant J, Murray E, Jowett S, Bryan S, *et al.*

No. 41

Displaced intracapsular hip fractures in fit, older people: a randomised comparison of reduction and fixation, bipolar hemiarthroplasty and total hip arthroplasty.

By Keating JF, Grant A, Masson M, Scott NW, Forbes JF.

No. 42

Long-term outcome of cognitive behaviour therapy clinical trials in central Scotland.

By Durham RC, Chambers JA, Power KG, Sharp DM, Macdonald RR, Major KA, *et al.*

No. 43

The effectiveness and cost-effectiveness of dual-chamber pacemakers compared with single-chamber pacemakers for bradycardia due to atrioventricular block or sick sinus syndrome: systematic review and economic evaluation.

By Castelnovo E, Stein K, Pitt M, Garside R, Payne E.

No. 44

Newborn screening for congenital heart defects: a systematic review and cost-effectiveness analysis.

By Knowles R, Griesch I, Dezateux C, Brown J, Bull C, Wren C.

No. 45

The clinical and cost-effectiveness of left ventricular assist devices for end-stage heart failure: a systematic review and economic evaluation.

By Clegg AJ, Scott DA, Loveman E, Colquitt J, Hutchinson J, Royle P, *et al.*

No. 46

The effectiveness of the Heidelberg Retina Tomograph and laser diagnostic glaucoma scanning system (GDx) in detecting and monitoring glaucoma.

By Kwartz AJ, Henson DB, Harper RA, Spencer AF, McLeod D.

No. 47

Clinical and cost-effectiveness of autologous chondrocyte implantation for cartilage defects in knee joints: systematic review and economic evaluation.

By Clar C, Cummins E, McIntyre L, Thomas S, Lamb J, Bain L, *et al.*

No. 48

Systematic review of effectiveness of different treatments for childhood retinoblastoma.

By McDaid C, Hartley S, Bagnall A-M, Ritchie G, Light K, Riemsma R.

No. 49

Towards evidence-based guidelines for the prevention of venous thromboembolism: systematic reviews of mechanical methods, oral anticoagulation, dextran and regional anaesthesia as thromboprophylaxis.

By Roderick P, Ferris G, Wilson K, Halls H, Jackson D, Collins R, *et al.*

No. 50

The effectiveness and cost-effectiveness of parent training/education programmes for the treatment of conduct disorder, including oppositional defiant disorder, in children.

By Dretzke J, Frew E, Davenport C, Barlow J, Stewart-Brown S, Sandercock J, *et al.*

Volume 10, 2006**No. 1**

The clinical and cost-effectiveness of donepezil, rivastigmine, galantamine and memantine for Alzheimer's disease.

By Loveman E, Green C, Kirby J, Takeda A, Picot J, Payne E, *et al.*

No. 2

FOOD: a multicentre randomised trial evaluating feeding policies in patients admitted to hospital with a recent stroke.

By Dennis M, Lewis S, Cranswick G, Forbes J.

No. 3

The clinical effectiveness and cost-effectiveness of computed tomography screening for lung cancer: systematic reviews.

By Black C, Bagust A, Boland A, Walker S, McLeod C, De Verteuil R, *et al.*

No. 4

A systematic review of the effectiveness and cost-effectiveness of neuroimaging assessments used to visualise the seizure focus in people with refractory epilepsy being considered for surgery.

By Whiting P, Gupta R, Burch J, Mujica Mota RE, Wright K, Marson A, *et al.*

No. 5

Comparison of conference abstracts and presentations with full-text articles in the health technology assessments of rapidly evolving technologies.

By Dundar Y, Dodd S, Dickson R, Walley T, Haycox A, Williamson PR.

No. 6

Systematic review and evaluation of methods of assessing urinary incontinence.

By Martin JL, Williams KS, Abrams KR, Turner DA, Sutton AJ, Chapple C, *et al.*

No. 7

The clinical effectiveness and cost-effectiveness of newer drugs for children with epilepsy. A systematic review.

By Connock M, Frew E, Evans B-W, Bryan S, Cummins C, Fry-Smith A, *et al.*

No. 8

Surveillance of Barrett's oesophagus: exploring the uncertainty through systematic review, expert workshop and economic modelling.

By Garside R, Pitt M, Somerville M, Stein K, Price A, Gilbert N.

No. 9

Topotecan, pegylated liposomal doxorubicin hydrochloride and paclitaxel for second-line or subsequent treatment of advanced ovarian cancer: a systematic review and economic evaluation.

By Main C, Bojke L, Griffin S, Norman G, Barbieri M, Mather L, *et al.*

No. 10

Evaluation of molecular techniques in prediction and diagnosis of cytomegalovirus disease in immunocompromised patients.

By Szczepura A, Westmoreland D, Vinogradova Y, Fox J, Clark M.

No. 11

Screening for thrombophilia in high-risk situations: systematic review and cost-effectiveness analysis. The Thrombosis: Risk and Economic Assessment of Thrombophilia Screening (TREATS) study.

By Wu O, Robertson L, Twaddle S, Lowe GDO, Clark P, Greaves M, *et al.*

No. 12

A series of systematic reviews to inform a decision analysis for sampling and treating infected diabetic foot ulcers.

By Nelson EA, O'Meara S, Craig D, Iglesias C, Golder S, Dalton J, *et al.*

No. 13

Randomised clinical trial, observational study and assessment of cost-effectiveness of the treatment of varicose veins (REACTIV trial).

By Michaels JA, Campbell WB, Brazier JE, MacIntyre JB, Palfreyman SJ, Ratcliffe J, *et al.*

No. 14

The cost-effectiveness of screening for oral cancer in primary care.

By Speight PM, Palmer S, Moles DR, Downer MC, Smith DH, Henriksson M *et al.*

No. 15

Measurement of the clinical and cost-effectiveness of non-invasive diagnostic testing strategies for deep vein thrombosis.

By Goodacre S, Sampson F, Stevenson M, Wailoo A, Sutton A, Thomas S, *et al.*

No. 16

Systematic review of the effectiveness and cost-effectiveness of HealOzone[®] for the treatment of occlusal pit/fissure caries and root caries.

By Brazzelli M, McKenzie L, Fielding S, Fraser C, Clarkson J, Kilonzo M, *et al.*

No. 17

Randomised controlled trials of conventional antipsychotic versus new atypical drugs, and new atypical drugs versus clozapine, in people with schizophrenia responding poorly to, or intolerant of, current drug treatment.

By Lewis SW, Davies L, Jones PB, Barnes TRE, Murray RM, Kerwin R, *et al.*

No. 18

Diagnostic tests and algorithms used in the investigation of haematuria: systematic reviews and economic evaluation.

By Rodgers M, Nixon J, Hempel S, Aho T, Kelly J, Neal D, *et al.*

No. 19

Cognitive behavioural therapy in addition to antispasmodic therapy for irritable bowel syndrome in primary care: randomised controlled trial.

By Kennedy TM, Chalder T, McCrone P, Darnley S, Knapp M, Jones RH, *et al.*

No. 20

A systematic review of the clinical effectiveness and cost-effectiveness of enzyme replacement therapies for Fabry's disease and mucopolysaccharidosis type 1.

By Connock M, Juarez-Garcia A, Frew E, Mans A, Dretzke J, Fry-Smith A, *et al.*

No. 21

Health benefits of antiviral therapy for mild chronic hepatitis C: randomised controlled trial and economic evaluation.

By Wright M, Grieve R, Roberts J, Main J, Thomas HC on behalf of the UK Mild Hepatitis C Trial Investigators.

No. 22

Pressure relieving support surfaces: a randomised evaluation.

By Nixon J, Nelson EA, Cranny G, Iglesias CP, Hawkins K, Cullum NA, *et al.*

No. 23

A systematic review and economic model of the effectiveness and cost-effectiveness of methylphenidate, dexamfetamine and atomoxetine for the treatment of attention deficit hyperactivity disorder in children and adolescents.

By King S, Griffin S, Hodges Z, Weatherly H, Asseburg C, Richardson G, *et al.*

No. 24

The clinical effectiveness and cost-effectiveness of enzyme replacement therapy for Gaucher's disease: a systematic review.

By Connock M, Burls A, Frew E, Fry-Smith A, Juarez-Garcia A, McCabe C, *et al.*

No. 25

Effectiveness and cost-effectiveness of salicylic acid and cryotherapy for cutaneous warts. An economic decision model.

By Thomas KS, Keogh-Brown MR, Chalmers JR, Fordham RJ, Holland RC, Armstrong SJ, *et al.*

No. 26

A systematic literature review of the effectiveness of non-pharmacological interventions to prevent wandering in dementia and evaluation of the ethical implications and acceptability of their use.

By Robinson L, Hutchings D, Corner L, Beyer F, Dickinson H, Vanoli A, *et al.*

No. 27

A review of the evidence on the effects and costs of implantable cardioverter defibrillator therapy in different patient groups, and modelling of cost-effectiveness and cost-utility for these groups in a UK context.

By Buxton M, Caine N, Chase D, Connelly D, Grace A, Jackson C, *et al.*

No. 28

Adefovir dipivoxil and pegylated interferon alfa-2a for the treatment of chronic hepatitis B: a systematic review and economic evaluation.

By Shepherd J, Jones J, Takeda A, Davidson P, Price A.

No. 29

An evaluation of the clinical and cost-effectiveness of pulmonary artery catheters in patient management in intensive care: a systematic review and a randomised controlled trial.

By Harvey S, Stevens K, Harrison D, Young D, Brampton W, McCabe C, *et al.*

No. 30

Accurate, practical and cost-effective assessment of carotid stenosis in the UK.

By Wardlaw JM, Chappell FM, Stevenson M, De Nigris E, Thomas S, Gillard J, *et al.*

No. 31

Etanercept and infliximab for the treatment of psoriatic arthritis: a systematic review and economic evaluation.

By Woolacott N, Bravo Vergel Y, Hawkins N, Kainth A, Khadjesari Z, Misso K, *et al.*

No. 32

The cost-effectiveness of testing for hepatitis C in former injecting drug users.

By Castelnuovo E, Thompson-Coon J, Pitt M, Cramp M, Siebert U, Price A, *et al.*

No. 33

Computerised cognitive behaviour therapy for depression and anxiety update: a systematic review and economic evaluation.

By Kaltenthaler E, Brazier J, De Nigris E, Tumor I, Ferriter M, Beverley C, *et al.*

No. 34

Cost-effectiveness of using prognostic information to select women with breast cancer for adjuvant systemic therapy.

By Williams C, Brunskill S, Altman D, Briggs A, Campbell H, Clarke M, *et al.*

No. 35

Psychological therapies including dialectical behaviour therapy for borderline personality disorder: a systematic review and preliminary economic evaluation.

By Brazier J, Tumor I, Holmes M, Ferriter M, Parry G, Dent-Brown K, *et al.*

No. 36

Clinical effectiveness and cost-effectiveness of tests for the diagnosis and investigation of urinary tract infection in children: a systematic review and economic model.

By Whiting P, Westwood M, Bojke L, Palmer S, Richardson G, Cooper J, *et al.*

No. 37

Cognitive behavioural therapy in chronic fatigue syndrome: a randomised controlled trial of an outpatient group programme.

By O'Dowd H, Gladwell P, Rogers CA, Hollinghurst S, Gregory A.

No. 38

A comparison of the cost-effectiveness of five strategies for the prevention of non-steroidal anti-inflammatory drug-induced gastrointestinal toxicity: a systematic review with economic modelling.

By Brown TJ, Hooper L, Elliott RA, Payne K, Webb R, Roberts C, *et al.*

No. 39

The effectiveness and cost-effectiveness of computed tomography screening for coronary artery disease: systematic review.

By Waugh N, Black C, Walker S, McIntyre L, Cummins E, Hillis G.

No. 40

What are the clinical outcome and cost-effectiveness of endoscopy undertaken by nurses when compared with doctors? A Multi-Institution Nurse Endoscopy Trial (MINuET).

By Williams J, Russell I, Durai D, Cheung WY, Farrin A, Bloor K, *et al.*

No. 41

The clinical and cost-effectiveness of oxaliplatin and capecitabine for the adjuvant treatment of colon cancer: systematic review and economic evaluation.

By Pandor A, Eggington S, Paisley S, Tappenden P, Sutcliffe P.

No. 42

A systematic review of the effectiveness of adalimumab, etanercept and infliximab for the treatment of rheumatoid arthritis in adults and an economic evaluation of their cost-effectiveness.

By Chen Y-F, Jobanputra P, Barton P, Jowett S, Bryan S, Clark W, *et al.*

No. 43

Telemedicine in dermatology: a randomised controlled trial.

By Bowns IR, Collins K, Walters SJ, McDonagh AJG.

No. 44

Cost-effectiveness of cell salvage and alternative methods of minimising perioperative allogeneic blood transfusion: a systematic review and economic model.

By Davies L, Brown TJ, Haynes S, Payne K, Elliott RA, McCollum C.

No. 45

Clinical effectiveness and cost-effectiveness of laparoscopic surgery for colorectal cancer: systematic reviews and economic evaluation.

By Murray A, Lourenco T, de Verteuil R, Hernandez R, Fraser C, McKinlay A, *et al.*

No. 46

Etanercept and efalizumab for the treatment of psoriasis: a systematic review.

By Woolacott N, Hawkins N, Mason A, Kainth A, Khadjesari Z, Bravo Vergel Y, *et al.*

No. 47

Systematic reviews of clinical decision tools for acute abdominal pain.

By Liu JLY, Wyatt JC, Deeks JJ, Clamp S, Keen J, Verde P, *et al.*

No. 48

Evaluation of the ventricular assist device programme in the UK.

By Sharples L, Buxton M, Caine N, Cafferty F, Demiris N, Dyer M, *et al.*

No. 49

A systematic review and economic model of the clinical and cost-effectiveness of immunosuppressive therapy for renal transplantation in children.

By Yao G, Albon E, Adi Y, Milford D, Bayliss S, Ready A, *et al.*

No. 50

Amniocentesis results: investigation of anxiety. The ARIA trial.

By Hewison J, Nixon J, Fountain J, Cocks K, Jones C, Mason G, *et al.*

Volume 11, 2007**No. 1**

Pemetrexed disodium for the treatment of malignant pleural mesothelioma: a systematic review and economic evaluation.

By Dundar Y, Bagust A, Dickson R, Dodd S, Green J, Haycox A, *et al.*

No. 2

A systematic review and economic model of the clinical effectiveness and cost-effectiveness of docetaxel in combination with prednisone or prednisolone for the treatment of hormone-refractory metastatic prostate cancer.

By Collins R, Fenwick E, Trowman R, Perard R, Norman G, Light K, *et al.*

No. 3

A systematic review of rapid diagnostic tests for the detection of tuberculosis infection.

By Dinnes J, Deeks J, Kunst H, Gibson A, Cummins E, Waugh N, *et al.*

No. 4

The clinical effectiveness and cost-effectiveness of strontium ranelate for the prevention of osteoporotic fragility fractures in postmenopausal women.

By Stevenson M, Davis S, Lloyd-Jones M, Beverley C.

No. 5

A systematic review of quantitative and qualitative research on the role and effectiveness of written information available to patients about individual medicines.

By Raynor DK, Blenkinsopp A, Knapp P, Grime J, Nicolson DJ, Pollock K, *et al.*

No. 6

Oral naltrexone as a treatment for relapse prevention in formerly opioid-dependent drug users: a systematic review and economic evaluation.

By Adi Y, Juarez-Garcia A, Wang D, Jowett S, Frew E, Day E, *et al.*

No. 7

Glucocorticoid-induced osteoporosis: a systematic review and cost-utility analysis.

By Kanis JA, Stevenson M, McCloskey EV, Davis S, Lloyd-Jones M.

No. 8

Epidemiological, social, diagnostic and economic evaluation of population screening for genital chlamydia infection.

By Low N, McCarthy A, Macleod J, Salisbury C, Campbell R, Roberts TE, *et al.*

No. 9

Methadone and buprenorphine for the management of opioid dependence: a systematic review and economic evaluation.

By Connock M, Juarez-Garcia A, Jowett S, Frew E, Liu Z, Taylor RJ, *et al.*

No. 10

Exercise Evaluation Randomised Trial (EXERT): a randomised trial comparing GP referral for leisure centre-based exercise, community-based walking and advice only.

By Isaacs AJ, Critchley JA, See Tai S, Buckingham K, Westley D, Harridge SDR, *et al.*

No. 11

Interferon alfa (pegylated and non-pegylated) and ribavirin for the treatment of mild chronic hepatitis C: a systematic review and economic evaluation.

By Shepherd J, Jones J, Hartwell D, Davidson P, Price A, Waugh N.

No. 12

Systematic review and economic evaluation of bevacizumab and cetuximab for the treatment of metastatic colorectal cancer.

By Tappenden P, Jones R, Paisley S, Carroll C.

No. 13

A systematic review and economic evaluation of epoetin alfa, epoetin beta and darbepoetin alfa in anaemia associated with cancer, especially that attributable to cancer treatment.

By Wilson J, Yao GL, Raftery J, Bohlius J, Brunskill S, Sandercock J, *et al.*

No. 14

A systematic review and economic evaluation of statins for the prevention of coronary events.

By Ward S, Lloyd Jones M, Pandor A, Holmes M, Ara R, Ryan A, *et al.*

No. 15

A systematic review of the effectiveness and cost-effectiveness of different models of community-based respite care for frail older people and their carers.

By Mason A, Weatherly H, Spilsbury K, Arksey H, Golder S, Adamson J, *et al.*

No. 16

Additional therapy for young children with spastic cerebral palsy: a randomised controlled trial.

By Weindling AM, Cunningham CC, Glenn SM, Edwards RT, Reeves DJ.

No. 17

Screening for type 2 diabetes: literature review and economic modelling.

By Waugh N, Scotland G, McNamee P, Gillett M, Brennan A, Goyder E, *et al.*

No. 18

The effectiveness and cost-effectiveness of cinacalcet for secondary hyperparathyroidism in end-stage renal disease patients on dialysis: a systematic review and economic evaluation.

By Garside R, Pitt M, Anderson R, Mealing S, Roome C, Snaith A, *et al.*

No. 19

The clinical effectiveness and cost-effectiveness of gemcitabine for metastatic breast cancer: a systematic review and economic evaluation.

By Takeda AL, Jones J, Loveman E, Tan SC, Clegg AJ.

No. 20

A systematic review of duplex ultrasound, magnetic resonance angiography and computed tomography angiography for the diagnosis and assessment of symptomatic, lower limb peripheral arterial disease.

By Collins R, Cranny G, Burch J, Aguiar-Ibáñez R, Craig D, Wright K, *et al.*

No. 21

The clinical effectiveness and cost-effectiveness of treatments for children with idiopathic steroid-resistant nephrotic syndrome: a systematic review.

By Colquitt JL, Kirby J, Green C, Cooper K, Trompeter RS.

No. 22

A systematic review of the routine monitoring of growth in children of primary school age to identify growth-related conditions.

By Fayter D, Nixon J, Hartley S, Rithalia A, Butler G, Rudolf M, *et al.*

No. 23

Systematic review of the effectiveness of preventing and treating *Staphylococcus aureus* carriage in reducing peritoneal catheter-related infections.

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Volume 12, 2008**No. 1**

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