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National Clinical Guideline developed by the National Collaborating Centre for Acute Care.

Faecal incontinence

The management of faecal incontinence in adults

Commissioned by the National Institute for Health and Clinical Excellence

Published by the National Collaborating Centre for Acute Care at The Royal College of Surgeons of England, 35-43 Lincoln's Inn Fields, London, WC2A 3PE

First published 2006

ISBN XXXXXXXXX

Foreword

Faecal incontinence, the involuntary loss of solid or liquid stool, has been a neglected health care problem, in the UK and around the world. In many instances it has been overshadowed by the more prevalent urinary incontinence, which itself has only recently gained widespread attention. Yet faecal incontinence is likely to affect over half a million adults in the UK and often it has very profound negative consequences for the patient. Fear of embarrassment, even at worst public humiliation, can impose major restrictions on the individual and the family. For this reason, the decision of NICE to address this hidden topic is most welcome.

Possibly past neglect of faecal incontinence has been because of the lack of a single professional healthcare group which takes a lead on this problem. Patients might be managed in primary care, or by colorectal surgeons, gastroenterologists, neurologists, care of the elderly specialists, or most often nobody. Continence nurses and physiotherapists have traditionally, with a few exceptions, focused more on urinary than faecal incontinence.

The task of producing a guideline on the management of faecal incontinence in adults has presented challenges, the greatest of which has been the almost complete absence of high quality evidence for most assessment and treatment methods. The guideline development group was therefore faced with a choice: recommending nothing in the absence of good evidence, or doing the best that we could on lesser quality evidence and expert opinion. We chose the latter as we felt that the needs of patients demanded that we at least provide a starting point. But we urge the reader to remember that little of what is contained in this guideline is based on incontrovertible evidence.

A second major challenge has been the absence of agreed and validated outcome measures for faecal incontinence. There is particularly an absence of measures based on patients' views of what is important in outcomes. For this reason, we have included a section on patients' views, from the very limited evidence that could be obtained. With a non life-threatening symptom such as faecal incontinence, where there is no objective gold standard for measuring symptoms, the patient's view must be paramount.

Some of our recommendations may seem conservative: such as avoiding costly unproven investigations and surgical interventions, at least in the absence of very specific indications. This is not because we believe that faecal incontinence should not be managed in the most vigorous manner, but rather that we wish to avoid potentially harmful interventions, pending the availability of better research.

The overall message of this guideline is simple: do not ignore the symptom of faecal incontinence and assume that nothing can be done. Clinical experience suggests that the majority of patients can be at least improved, and in many instances symptoms can be resolved. Success will usually depend upon identifying the often complex interaction of factors causing symptoms for each

individual, and some persistence in finding a combination of interventions that gives best control of those symptoms.

NICE guidelines are by their nature intended for the general situation, aiming to cover 80% of cases 80% of the time, rather than being totally all-inclusive of all possible eventualities. Guidelines deliberately suggest what should be done, rather than specifying service configurations and personnel to deliver care. We hope that this guideline will raise awareness, lead to structured systematic thinking about faecal incontinence and in time stimulate research that will improve quality of life for a substantial number of people.

Professor Christine Norton

Chair, Guideline Development Group

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Please note: the citation numbers in the chapters document refer to the bibliography at the end of the chapters document; the citation numbers in the appendices refer to the bibliography at the end of the appendices.

Appendices A–N are in a separate file for consultation

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Acknowledgements

The development of this guideline was greatly assisted by the following people:

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Rifna Aktar, Dr Gianluca Baio, Sophie Capo-Bianco, Enrico De Nigris, Kelly Dickinson, Saoussen Ftouh, Dr Jennifer Hill, Dr Jacqueline Rainsbury, Carlos Sharpin, Nishanthi Tallawila.

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Conflicts of interest

The Guideline Development Group members were asked to declare any possible conflicts of interest and none that could interfere with their work on the guideline were declared (see appendix N).

Stakeholder Involvement

The following stakeholders registered with NICE and were invited to comment on draft versions of these guidelines:

To be completed after consultation

1 Glossary

Absolute risk reduction (Risk difference)	The difference in the risk of an event between two groups (one subtracted from the other) in a comparative study.
Abstract	Summary of a study, which may be published alone or as an introduction to a full scientific paper.
Algorithm (in guidelines)	A flow chart of the clinical decision pathway described in the guideline, where decision points are represented with boxes, linked with arrows.
Allocation concealment	The process used to prevent advance knowledge of group assignment in a randomised controlled trial (RCT). The allocation process should be impervious to any influence by the individual making the allocation, by being administered by someone who is not responsible for recruiting participants.
Anal plug	Product intended to prevent faecal leakage from the anus.
Anal sphincter repair	Surgical repair of the anal sphincter.
Antegrade continence enema (ACE) operation	An operation to bring the appendix onto the abdominal wall to allow a catheter to be inserted into the colon (also known as Malone operation). Liquids and laxatives can be instilled to wash out the colon.
Applicability	The degree to which the results of an observation, study or review are likely to hold true in a particular clinical practice setting.
Arm (of a clinical study)	Sub-section of individuals within a study who receive one particular intervention, for example placebo arm.
Artificial bowel sphincter (ABS)	A cuff made of silicone that encircles the anus and contains liquid that is transferred between a reservoir and the cuff. This either opens or occludes the anal canal.

Association	Statistical relationship between two or more events, characteristics or other variables. The relationship may or may not be causal.
Audit	See ‘Clinical audit’.
Base case analysis	The results of an economic evaluation using the best point estimate for each model parameter. This contrasts with the term *sensitivity analysis*.
Baseline	The initial set of measurements at the beginning of a study (after run-in period where applicable), with which subsequent results are compared.
Baseline assessment	Baseline assessment includes structured assessment, clinician examination and patient reporting of symptoms.
Bias	Systematic (as opposed to random) deviation of the results of a study from the ‘true’ results that is caused by the way the study is designed or conducted.
Biofeedback	Use of equipment to amplify and display bodily functions that are normally subconscious or automatic, with the aim of improving that function.
Bioinjectible material	Biocompatible material injected into the body with the aim of improving function.
Blinding (masking)	Keeping the study participants, caregivers, researchers and outcome assessors unaware about the interventions to which the participants have been allocated in a study
Bristol Stool Scale	Rating of stool consistency on a 7 point scale from hard to liquid.
Carer (caregiver)	Someone other than a health professional who is involved in caring for a person with a medical condition.
Case-control study	Comparative observational study in which the investigator selects individuals who have experienced an event (for example, developed a disease) and others who have not (controls), and then collects data to

	determine previous exposure to a possible cause.
Case series	Report of a number of cases of a given disease, usually covering the course of the disease and the response to treatment. There is no comparison (control) group of patients.
Cleveland Clinic Incontinence Score	A scale from 0-20 where 0 = perfect continence and 20 = complete incontinence.
Clinical audit	A quality improvement process that seeks to improve patient care and outcomes through systematic review of care against explicit criteria and the implementation of change.
Clinical efficacy	The extent to which an intervention is active when studied under controlled research conditions.
Clinical effectiveness	The extent to which an intervention produces an overall health benefit in routine clinical practice.
Clinical impact	The effect that a guideline recommendation is likely to have on the treatment or treatment outcomes, of the target population.
Clinical question	In guideline development, this term refers to the questions about treatment and care that are formulated to guide the development of evidence-based recommendations.
Clinician	A healthcare professional providing direct patient care, for example doctor, nurse or physiotherapist.
Cochrane Library	A regularly updated electronic collection of evidence-based medicine databases, including the Cochrane Database of Systematic Reviews.
Cochrane Review	A systematic review of the evidence from randomised controlled trials relating to a particular health problem or healthcare intervention, produced by the Cochrane Collaboration. Available electronically as part of the

	Cochrane Library.
Cohort study	A retrospective or prospective follow-up study. Groups of individuals to be followed up are defined on the basis of presence or absence of exposure to a suspected risk factor or intervention. A cohort study can be comparative, in which case two or more groups are selected on the basis of differences in their exposure to the agent of interest.
Co-morbidity	Co-existence of more than one disease or an additional disease (other than that being studied or treated) in an individual.
Colostomy	Operation to divert bowel contents through the abdominal wall via a 'stoma'. Usually a bag is worn to collect faeces.
Comparability	Similarity of the groups in characteristics likely to affect the study results (such as health status or age).
Compliance	See 'Concordance'.
Concordance	The extent to which a person adheres to the health advice agreed with healthcare professionals. May also be referred to as ‘adherence’ or ‘compliance’.
Confidence interval (CI)	A range of values for an unknown population parameter with a stated ‘confidence’ (conventionally 95%) that it contains the true value. The interval is calculated from sample data, and generally straddles the sample estimate. The ‘confidence’ value means that if the method used to calculate the interval is repeated many times, then that proportion of intervals will actually contain the true value.
Confounding	In a study, confounding occurs when the effect of an intervention on an outcome is distorted as a result of an association between the population or intervention or outcome and another factor (the ‘confounding variable’) that can influence the outcome independently of the intervention under study.

Consensus methods	Techniques that aim to reach an agreement on a particular issue. Formal consensus methods include Delphi and nominal group techniques, and consensus development conferences. In the development of clinical guidelines, consensus methods may be used where there is a lack of strong research evidence on a particular topic. Expert consensus methods will aim to reach agreement between experts in a particular field.
Conservative management	Non-surgical treatment
Control group	A group of patients recruited into a study that receives no treatment, a treatment of known effect, or a placebo (dummy treatment) - in order to provide a comparison for a group receiving an experimental treatment, such as a new drug.
Controlled clinical trial (CCT)	A study testing a specific drug or other treatment involving two (or more) groups of patients with the same disease. One (the experimental group) receives the treatment that is being tested, and the other (the comparison or control group) receives an alternative treatment, a placebo (dummy treatment) or no treatment. The two groups are followed up to compare differences in outcomes to see how effective the experimental treatment was. A CCT where patients are randomly allocated to treatment and comparison groups is called a *randomised controlled trial*.
Cost-benefit analysis	A type of economic evaluation where both costs and benefits of healthcare treatment are measured in the same monetary units. If benefits exceed costs, the evaluation would recommend providing the treatment.
Cost-consequences analysis (CCA)	A type of economic evaluation where various health outcomes are reported in addition to cost for each intervention, but there is no overall measure of health gain.
Cost-effectiveness analysis (CEA)	An economic study design in which consequences of different interventions are measured using a single outcome, usually in ‘natural’ units (for example, life-years gained, deaths avoided, heart attacks avoided, cases detected). Alternative interventions are then

	compared in terms of cost per unit of effectiveness.
Cost-utility analysis (CUA)	A form of cost-effectiveness analysis in which the units of effectiveness are quality-adjusted life-years (QALYs).
Decision analysis or Decision model	A systematic way of reaching decisions, based on evidence from research. This evidence is translated into probabilities, and then into diagrams or decision trees which direct the clinician through a succession of possible scenarios, actions and outcomes. It can be used to estimate effectiveness or cost-effectiveness.
Defaecography	X-ray to examine the structure of the anorectum and its function during bowel emptying
Discounting	Costs and perhaps benefits incurred today have a higher value than costs and benefits occurring in the future. Discounting health benefits reflects individual preference for benefits to be experienced in the present rather than the future. Discounting costs reflects individual preference for costs to be experienced in the future rather than the present.
Dominance	An intervention is said to be dominated if there is an alternative intervention that is both less costly and more effective.
Dosage	The prescribed amount of a drug to be taken, including the size and timing of the doses.
Double blind study	A study in which neither the subject (patient) nor the observer (investigator/clinician) is aware of which treatment nor intervention the subject is receiving. The purpose of blinding is to protect against bias.
Double incontinence	Urinary and faecal incontinence.
Drop-out	A participant who withdraws from a clinical trial before the end.
Dynamic	Operation which transposes the gracilis muscle from the

graciloplasty (DGP)	leg and wraps it around the anus to form a new sphincter. An implanted electrical stimulator keeps the muscle contracted and thus the anus closed.
Economic evaluation	Comparative analysis of alternative health strategies (interventions or programmes) in terms of both their costs and consequences.
Effect (as in effect measure, treatment effect, estimate of effect, effect size)	The observed association between interventions and outcomes or a statistic to summarise the strength of the observed association.
Effectiveness	See ‘Clinical effectiveness’.
Efficacy	See ‘Clinical efficacy’.
Elective	Non-emergency procedure
Electrical stimulation	Use of electrical current to produce a contraction of a striated (voluntary) muscle.
Endoanal ultrasound	Ultrasound images of the anal sphincter taken using an intra-anal probe.
Endoscopy	Use of an endoscope to image the interior of the bowel.
Epidemiological study	The study of a disease within a population, defining its incidence and prevalence and examining the roles of external influences (for example, infection, diet) and interventions.
Evidence	Information on which a decision or guidance is based. Evidence is obtained from a range of sources including randomised controlled trials, observational studies, expert opinion (of clinical professionals and/or patients).
Evidence table	A table summarising the results of a collection of studies which, taken together, represent the evidence supporting a particular recommendation or series of

	recommendations in a guideline.
Exclusion criteria (literature review)	Explicit standards used to decide which studies should be excluded from consideration as potential sources of evidence.
Exclusion criteria (clinical study)	Criteria that define who is not eligible to participate in a clinical study.
Expert consensus	See ‘Consensus methods’.
Extended dominance	If Option A is both more clinically effective than Option B and has a lower cost per unit of effect, when both are compared with a do-nothing alternative then Option A is said to have extended dominance over Option B. Option A is therefore more efficient and should be preferred, other things remaining equal.
External anal sphincter (EAS)	Voluntary (striated muscle) portion of the anal sphincter.
Extrapolation	In data analysis, predicting the value of a parameter outside the range of observed values.
Faecal collector	Adhesive bag used to collect faeces.
Faecal impaction	The term used when there is large amount of hard faeces in the rectum.
Faecal loading	The term used to describe the presence of a large amount of faeces in the rectum with stool of any consistency.
Follow up	Observation over a period of time of an individual, group or initially defined population whose appropriate characteristics have been assessed in order to observe changes in health status or health-related variables.
Generalisability	The extent to which the results of a study based on measurement in a particular patient population and/or a

	specific context hold true for another population and/or in a different context. In this instance, this is the degree to which the guideline recommendation is applicable across both geographical and contextual settings. For instance, guidelines that suggest substituting one form of labour for another should acknowledge that these costs might vary across the country.
Gluteoplasty	Transposition of one or both gluteal muscles from the buttock to form a new anal sphincter. May additionally have an implanted electrical stimulator ('stimulated gluteoplasty').
Gold standard	See ‘Reference standard’.
Gracilis neosphincter	See 'Dynamic graciloplasty (DGP)'
Graciloplasty	See 'Dynamic graciloplasty (DGP)'
Harms	Adverse effects of an intervention.
Health economics	The study of the allocation of scarce resources among alternative healthcare treatments. Health economists are concerned with both increasing the average level of health in the population and improving the distribution of health.
Health-related quality of life	A combination of an individual’s physical, mental and social well-being; not merely the absence of disease.
Hypothesis	A supposition made as a starting point for further investigation.
Inclusion criteria (literature review)	Explicit criteria used to decide which studies should be considered as potential sources of evidence.
Incremental analysis	The analysis of additional costs and additional clinical outcomes with different interventions.
Incremental cost effectiveness	The difference in the mean costs in the population of interest divided by the differences in the mean outcomes

ratio (ICER)	in the population of interest.
Index	In epidemiology and related sciences, this word usually means a rating scale, for example, a set of numbers derived from a series of observations of specified variables. Examples include the various health status indices, and scoring systems for severity or stage of cancer.
Indication (specific)	The defined use of a technology as licensed by the Medicines and Healthcare products Regulatory Agency (MHRA).
Initial management	Initial management involves adjusting the patient's fluid intake, diet and medication separately and to ensure they complement each other.
Internal anal sphincter (IAS)	Involuntary (smooth muscle) portion of the anal sphincter.
Internal validity	The degree to which the results of a study are likely to approximate the 'truth' for the participants recruited in a study (that is, are the results free of bias?). It refers to the integrity of the design and is a prerequisite for applicability (external validity) of a study's findings. See 'External validity'.
Intervention	Healthcare action intended to benefit the patient, for example, drug treatment, surgical procedure, psychological therapy.
Intraoperative	Describes timing of anything that happens during a surgical procedure.
Length of stay	The total number of days a patient stays in hospital.
Levatorplasty	This involves plicating the muscles of the pelvic floor above the anal canal, between the rectum and the vagina (anterior levatorplasty) or posterior to the anal sphincter (post anal repair)

Malone operation	See 'Antegrade continent enema (ACE) operation'
Manometry	Measurement of anal sphincter pressures.
Medical devices	All products, except medicines, used in healthcare for the diagnosis, prevention, monitoring or treatment of illness or handicap.
Medicines and Healthcare Products Regulatory Agency (MHRA)	The Executive Agency of the Department of Health protecting and promoting public health and patient safety by ensuring that medicines, healthcare products and medical equipment meet appropriate standards of safety, quality, performance and effectiveness, and are used safely.
Meta-analysis	A statistical technique for combining (pooling) the results of a number of studies that address the same question and report on the same outcomes to produce a summary result. The aim is to derive more precise and clear information from a large data pool. It is generally more reliably likely to confirm or refute a hypothesis than the individual trials.
Narrative summary	Summary of findings given as a written description.
Neosphincter	A replacement for the sphincter when repair is not possible or has failed. See also 'Gracilis neosphincter' and ' Artificial bowel sphincter (ABS)'
Neuropathic faecal incontinence	FI secondary to neurological disease or injury
Neuroprosthesis	Implanted electrical stimulator to act in place of natural neurological impulses
Observational study	Retrospective or prospective study in which the investigator observes the natural course of events with or without control groups; for example, cohort studies and case–control studies.

Odds ratio	A measure of treatment effectiveness. The odds of an event happening in the treatment group, expressed as a proportion of the odds of it happening in the control group. The 'odds' is the ratio of events to non-events.
Outcome	Measure of the possible results that may stem from exposure to a preventive or therapeutic intervention. Outcome measures may be intermediate endpoints or they can be final endpoints. See ‘Intermediate outcome’.
P values	The probability that an observed difference could have occurred by chance, assuming that there is in fact no underlying difference between the means of the observations. If the probability is less than 1 in 20, the P value is less than 0.05; a result with a P value of less than 0.05 is conventionally considered to be ‘statistically significant’.
Peer review	A process where research is scrutinised by experts that have not been involved in the design or execution of the studies.
Pelvic floor muscles	Muscles extending unde the internal organs from the pubic bone at the front to the coccyx (tail bone) at the back.
Perioperative	The period from admission through surgery until discharge, encompassing pre-operative and post-operative periods.
Placebo	An inactive and physically identical medication or procedure used as a comparator in controlled clinical trials.
Placebo effect	A beneficial (or adverse) effect produced by a *placebo* and not due to any property of the *placebo* itself.
Plication	Surgical procedure for reducing the size of a hollow structure by taking folds or tucks in its walls
Post-anal repair	Plication of the pelvic floor muscles behind the anus

Postoperative	Pertaining to the period after patients leave the operating theatre, following surgery.
Preoperative	Pertaining to the period before surgery commences.
Primary care	Healthcare delivered to patients outside hospitals. Primary care covers a range of services provided by GPs, nurses and other healthcare professionals, dentists, pharmacists and opticians.
Prognosis	A probable course or outcome of a disease. Prognostic factors are patient or disease characteristics that influence the course. Good prognosis is associated with low rate of undesirable outcomes; poor prognosis is associated with a high rate of undesirable outcomes.
Prospective study	A study in which people are entered into the research and then followed up over a period of time with future events recorded as they happen. This contrasts with studies that are *retrospective*.
Puborectalis	The back portion of the pelvic floor muscles, around the rectum and anal canal
Qualitative research	Research concerned with subjective outcomes relating to social, emotional and experiential phenomena in health and social care.
Quality of life	See ‘Health-related quality of life’.
Quality-adjusted life-year (QALY)	An index of survival that is adjusted to account for the patient’s quality of life during this time. QALYs have the advantage of incorporating changes in both quantity (longevity/mortality) and quality (morbidity, psychological, functional, social and other factors) of life. Used to measure benefits in cost-utility analysis. The **QALYs gained** are the mean QALYs associated with one treatment minus the mean QALYs associated with an alternative treatment.
Quantitative research	Research that generates numerical data or data that can be converted into numbers, for example clinical trials or the national Census which counts people and

	households.
Quick Reference Guide	An abridged version of NICE guidance, which presents the key priorities for implementation and summarises the recommendations for the core clinical audience.
Randomisation	Allocation of participants in a research study to two or more alternative groups using a chance procedure, such as computer-generated random numbers. This approach is used in an attempt to ensure there is an even distribution of participants with different characteristics between groups and thus reduce sources of bias.
Randomised controlled trial (RCT)	A comparative study in which participants are randomly allocated to intervention and control groups and followed up to examine differences in outcomes between the groups.
Rectal prolapse	Descent of the rectum outside the body through the anal canal
Reference standard (or gold standard)	An agreed standard, for example for a test or treatment, against which other interventions can be compared.
Relative risk (RR)	The number of times more likely or less likely an event is to happen in one group compared with another (calculated as the risk of the event in group A/the risk of the event in group B).
Reliability/ repeatability	The degree of agreement exhibited when a measurement is repeated under identical conditions. Reliability refers to the degree to which the results obtained by a measurement procedure can be replicated.
Remit	The brief given by the Department of Health and Welsh Assembly Government at the beginning of the guideline development process. This defines core areas of care that the guideline needs to address.
Resource	The likely impact in terms of finance, workforce or other

implication	NHS resources.
Retrospective study	A retrospective study deals with the present/past and does not involve studying future events. This contrasts with studies that are *prospective*.
Review of the literature	An article that summarises the evidence contained in a number of different individual studies and draws conclusions about their findings. It may or may not be systematically researched and developed.
Sacral nerve stimulation (SNS)	This technique involves stimulating the sacral nerves, usually S3 or S4. Its main advantage is a trial period of temporary stimulation that only involves simple insertion of stimulating wires into the back. If this is successful, the patient can have an implantable stimulator to modulate sacral nerve function and improve continence.
Secca procedure	Radio frequency ablation of tissues with the aim of tightening.
Selection bias (also allocation bias)	A systematic bias in selecting participants for study groups, so that the groups have differences in prognosis and/or therapeutic sensitivities at baseline. Randomisation (with concealed allocation) of patients protects against this bias.
Selection criteria	Explicit standards used by guideline development groups to decide which studies should be included and excluded from consideration as potential sources of evidence.
Sensitivity (of a search)	The proportion of relevant studies identified by a search strategy expressed as a percentage of all relevant studies on a given topic. It describes the comprehensiveness of a search method (that is, its ability to identify all relevant studies on a given topic). Highly sensitive strategies tend to have low levels of specificity and vice versa.
Sensitivity analysis	A means of representing uncertainty in the results of economic evaluations. Uncertainty may arise from missing data, imprecise estimates or methodological controversy. Sensitivity analysis also allows for exploring

	the generalisability of results to other settings. The analysis is repeated using different assumptions to examine the effect on the results. **One-way** simple sensitivity analysis (univariate analysis): each parameter is varied individually in order to isolate the consequences of each parameter on the results of the study. **Multi-way** simple sensitivity analysis (scenario analysis): two or more parameters are varied at the same time and the overall effect on the results is evaluated. **Threshold** sensitivity analysis: the critical value of parameters above or below which the conclusions of the study will change are identified. **Probabilistic** sensitivity analysis: probability distributions are assigned to the uncertain parameters and are incorporated into evaluation models based on decision analysis.
Specialist assessment	Assessment by a health care professional with specialist training.
Specialised management	Management by a health care professional with specialised training.
Sphincter repair	See anal sphincter repair.
Stakeholder	Those with an interest in the use of a technology under appraisal or a guideline under development. Stakeholders include manufacturers, sponsors, healthcare professionals, and patient and carer groups.
Statistical power	The ability to demonstrate an association when one exists. Power is related to sample size; the larger the sample size, the greater the power and the lower the risk that a possible association could be missed.
Synthesis of evidence	A generic term to describe methods used for summarising (comparing and contrasting) evidence into a clinically meaningful conclusion in order to answer a defined clinical question. This can include systematic review (with or without meta-analysis), qualitative and

	narrative summaries.
Systematic review	Research that summarises the evidence on a clearly formulated question according to a pre-defined protocol using systematic and explicit methods to identify, select and appraise relevant studies, and to extract, collate and report their findings. It may or may not use statistical meta-analysis.
Time horizon	The time span used in the NICE appraisal which reflects the period over which the main differences between interventions in health effects and use of healthcare resources are expected to be experienced, and taking into account the limitations of supportive evidence.
Total pelvic floor repair	Surgical tightening of the pelvic floor in front of and behind the anus
Treatment allocation	Assigning a participant to a particular arm of the trial.
Treatment options	The choices of intervention available.
Ultrasonography	The use of sound waves to image the deep structures of the body.
Wexner Incontinence Score	See Cleveland clinic score

1

1 Abbreviations

ABS	Artificial bowel sphincter
ACE	Antegrade continence enema
BNF	British National Formulary
CCA	Cost-consequences analysis
CEA	Cost-effectiveness analysis
CI	Confidence interval
CUA	Cost-utility analysis
DGP	Dynamic graciloplasty
DH	Department of Health
EAS	External anal sphincter
EMG	Electromyography
ES	Electrical stimulation
FI	Faecal incontinence
GDG	Guideline Development Group
GP	General Practitioner
GRADE	Guidelines Recommendations Assessment Development Evaluation
GRP	Guideline Review Panel

HRQL	Health-related quality of life
HTA	Health technology assessment
IAS	Internal anal sphincter
ICER	Incremental cost-effectiveness ratio
INB	Incremental net benefit
LOS	Length of Stay
LY	Life-year
MRI	Magnetic resonance imaging
NCC-AC	National Collaborating Centre for Acute Care
NHS	National Health Service
NICE	National Institute for Health and Clinical Excellence
OR	Odds ratio
PICO	Framework incorporating patients, interventions, comparisons, outcomes
PNTML	Pudendal nerve terminal motor latency
PPIP	Patient and Public Involvement Programme
QALY	Quality-adjusted life year
RCT	Randomised controlled trial
RR	Relative risk

SNS	Sacral Nerve Stimulation
SR	Systematic review
vs	Versus

1

1 Introduction and methods

1.1 The need for guidelines on the management of faecal incontinence

Faecal incontinence (FI) is a sign or a symptom, not a diagnosis. As such the first task is to arrive at a diagnosis as to the cause/s for each individual. With a stigmatising condition, active case-finding will often be needed, probably best targeted at high risk groups.

Current epidemiological information shows that between 1 and 10% of adults are affected, depending upon the definition and frequency used[1,2]. It is likely that 0.5-1.0% of adults experience regular faecal incontinence which impacts on quality of life[2]. Little is known about the natural history of FI but for some groups (for example, women immediately after childbirth) there does seem to be some spontaneous resolution of symptoms. For understandable reasons, it has remained a largely hidden problem, with many patients feeling too embarrassed or ashamed to admit to symptoms to healthcare professionals, or even to family and friends.

There is no consensus on methods of classifying the symptoms and causes of faecal incontinence. The most common classifications include:

By symptom: for example, whether the patient experiences an urge before leakage (urge faecal incontinence) or has no sensation (passive soiling).

By character of the leakage: for example, solid, liquid, mucus or flatus ('anal incontinence' being the term most often used to include gas incontinence).

By patient group: for example, people with neurological conditions; frail older people; women with obstetric injuries.

By presumed primary underlying cause: for example, damage or weakness of the internal or external anal sphincter, faecal loading, neurological motor and/or sensory impairment, cognitive impairment, problems with toilet access, rectal capacity, gut motility or stool consistency.

There are many other possible causes and contributing factors such as diet and fluids, medication, and psychological state, amongst others. During its work, the guideline development group identified seven major patient groups (see section 1.8.3), while acknowledging that there are others.

For many people faecal incontinence is the result of a complex interplay of contributing factors, many of which can co-exist. Some may be relatively simple to reverse. For this reason, and because of the scale of the problem, we looked at recommending assessment and initial management in primary care for most patients in the first instance and onward referral if simple measures in the initial care do not have satisfactory results.

Prevention was beyond the scope of the current guideline, but we acknowledge that there is much work to be done on preventing faecal incontinence, notably in relation to obstetric-related anal sphincter injuries, in people with neurological diagnoses and in frail older people.

1.1.1 Patient views of the consequences of faecal incontinence

As part of the systematic review on patient's views, experiences and behaviour for this guideline we retrieved research on patient views of the consequences of faecal incontinence. The themes of this research are discussed below. The methods of this research are described in section 1.8.10.

Research into patient views of the consequences of FI focus mainly on the views of women with childbirth injuries and therefore may not be representative of the views of all incontinent patients and their carers.

Consequences of having FI encompassed, for patients and carers, both the emotional and physical and operated within both private and public spheres. A thematic analysis revealed the following recurring topics:

- **Psycho-emotional effects** (six studies[3-8])**:** including stress, distress, tearfulness, anxiety, exhaustion, fear of public humiliation, feeling dirty, poor body-image (related to stoma formation[6]), stated need to be in control of life outside of FI as means of compensation, desire to constrain sexual activity, anticipatory fear (which often increased the likelihood of an incontinent episode)[3], anger, humiliation, depression, isolation, secrecy, frustration and embarrassment

- **Physical symptoms** (three studies[3,6,9])**:** there was very little actually discussed about this topic, possibly due to a felt taboo, or embarrassment on the researchers' or patients' side at discussing it. In the four studies which did discuss physical symptoms, the main reported outcomes were to do with success or satisfaction with interventions. 71% (of the 38 with successful sphincter repair) reported improved outcomes[9], and the majority of patients undergoing stoma creation thought that it restricted their life a little or not at all (83%), although a minority intensely hated it[6]. In the only other study to touch on this topic, patients complained of soreness of skin and of pain in general[3].

- **Exercise** (two studies[3,7])**:** this was reported as reduced or stopped by many participants. Walking apparently precipitated incontinence for some and was avoided[3]. Difficulty in performing everyday tasks such as housework and chores was also reported[7].

- **Working** (2 studies[3,4])**:** most studies reported professional lives being restricted by FI symptoms, reporting fear of using toilets at work. There was also discussion of the difficulty of talking about the need for flexibility with working hours, especially with male colleagues. In one study, one woman

reported getting up as early as 4 am to empty her bowels before going to work, in order to feel better prepared[3].

- **Relationships**(four studies[3-5,7])**:** FI was reported to affect patients' relationships with their partners, families, carers and health professionals drastically. However, most felt that they had some support networks to call on, whether this was a partner, children, friends, family, hospitals or colleagues. Singles reported fearing starting new relationship sand those in long-term relationships said that they had concealed symptoms in the past from their partner[3],. However, most said that on disclosure of symptoms, they received warm understanding and support.

- **Self-image and appearance** (four studies[3,4,6,7])**:** most studies reported negative self-image to be associated with FI. FI also governed clothing choice for many, with some preferring trousers and some skirts, for reasons of cleanliness, ease of removal or comfort. Dark clothing was preferred too, and it was felt difficult generally to feel attractive and sexy, or to wear attractive clothing and underwear[3]. One study reported that women tended to concentrate on their face and hair in order to distract from or compensate for having to wear protective clothing[3].

- **Shopping** (two studies[3,7])**:** all patients in one study reported difficulties, such as avoiding supermarkets as there were not always public toilets. Communal changing rooms were also a problem, due to embarrassment about soiling or protective clothing, or even fear of having an episode[3]. Fear of flatus incontinence increased anxiety in public. Other findings suggested that sufferers preferred to stay in hotels rather than at friends' homes as it was less stressful and embarrassing

- **Social life** (Four studies[3,4,6,7])**:** most studies reported social lives being restricted by FI symptoms. Certain activities were avoided, such as going to the cinema or theatre. In general, social lives were planned around availability of toilets.

- **Travel** (two studies[3,4])**:** restricted, required careful planning, own car preferred, planned around known availability of public conveniences

- **Sex** (four studies[3,4,7,10])**:** sexual avoidance or aversion, lack of sexual desire (although interestingly this was not as common as might be expected). In one study[10] all participants said their sex lives had been hampered by FI, and nearly half (4/9 sexually active participants) said they had actually experienced incontinence during coitus, while the remainder (5/9) were worried about it. Of course, this finding may have been affected by the predominately older demography investigated by researchers.

- **Toilets** (four studies[3-5,8])**:** discussions within focus groups were found to centre on toilets without the prompting of the researchers. Toilets were a major topic of discussion in interviews too. Subtopics ranged from: availability and cleanliness of public toilets, lack of facilities, avoidance of supermarkets due to lack of facilities, preferences for cars as no toilets on some public transport, planning of social life around known availability of toilets, added

stress at work due to fear of using communal facilities }CHELVANAYAGAM2000, COLLINGS2004, WONG1995}. From carers' perspectives, problems ranged from difficulty for carers in getting relatives with dementia to use toilets appropriately, need for repeated clean-up operations, incontinence resulting in huge washing loads, to a perceived need to change the house structurally to accommodate changing toileting needs[5]. Inability to use toilet was used as a validation of the need for care, and was seen to impact hugely on the relationships between the patient and carer[5].

This literature demonstrates that FI impacts on virtually all aspects of life and can greatly diminish physical and mental health, and affect patients' personal, social and professional lives.

1.2 What is a guideline?

Our clinical guidelines are recommendations for the care of individuals in specific clinical conditions or circumstances within the NHS – from self-care though primary and secondary care to more specialised services. We base our clinical guidelines on the best available research evidence, with the aim of improving the quality of health care. We use predetermined and systematic methods to identify and evaluate the evidence relating to specific clinical questions.

Clinical guidelines can:

- provide recommendations for the treatment and care of people by health professionals
- be used to develop standards to assess the clinical practice of individual health professionals
- be used in the education and training of health professionals to help patients to make informed decisions
- improve communication between patient and health professional

While guidelines assist the practice of healthcare professionals, they do not replace their knowledge and skills.

We produce our guidelines using the following steps:

- Guideline topic is referred to NICE from the Department of Health
- Stakeholders register an interest in the guideline and are consulted throughout the development process.
- The scope is prepared by the National Collaborating Centre for Acute Care

- The National Collaborating Centre for Acute Care established a guideline development group
- A draft guideline is produced after the group assesses the available evidence and makes recommendations
- There is a consultation on the draft guideline.
- The final guideline is produced.

The National Collaborating Centre for Acute Care and NICE produce a number of versions of this guideline:

- the full guideline contains all the recommendations, plus details of the methods used and the underpinning evidence
- the NICE guideline presents the recommendations from the full version in a format suited to implementation by health professionals and NHS bodies
- the quick reference guide presents recommendations in a suitable format for health professionals
- 'Understanding NICE guidance' is written using suitable language for people without specialist medical knowledge.

This version is the full version. The other versions can be downloaded from our website at www.rcseng.ac.uk/surgical_research_units/nccac/ or are available from NICE www.NICE.org.uk.

1.3 The National Collaborating Centre for Acute Care

This guideline was commissioned by NICE and developed by the National Collaborating Centre for Acute Care. The centre is one of seven national collaborating centres funded by NICE and comprises a partnership between a variety of academic, professional and patient-based organisations. As a multidisciplinary centre we draw upon the expertise of the healthcare professions and academics and ensure the involvement of patients in our work. Further information on the centre and our partner organisations can be found at our website. (www.rcseng.ac.uk/surgical_research_units/nccac/)

1.4 Remit of the guideline

The following remit was received from the Department of Health and the Welsh Assembly Government as part of NICE's 10th wave programme of work:

To prepare a guideline for the NHS in England and Wales on the management of faecal incontinence.

1.5 What the guideline covers

The guideline covers adults (age 18 and older) presenting with faecal incontinence (defined as any involuntary loss of faeces that is a social or hygienic problem).

1.6 What the guideline does not cover

Patients under the age of 18 years.

1.7 Who developed the guideline

A multidisciplinary Guideline Development Group (GDG) comprising professional group members and consumer representatives of the main stakeholders developed this guideline (see section Guideline Development Group Membership and acknowledgements).

The National Institute for Health and Clinical Excellence funds the National Collaborating Centre for Acute Care (NCC-AC) and thus supported the development of this guideline. The GDG was convened by the NCC-AC and chaired by Professor Christine Norton in accordance with guidance from the National Institute for Health and Clinical Excellence (NICE).

The group met approximately every 6-8 weeks during the development of the guideline. At the start of the guideline development process all GDG members declared interests including consultancies, fee-paid work, share-holdings, fellowships and support from the healthcare industry. At all subsequent GDG meetings, members declared new conflicts of interest, which were also recorded (appendix N). Members are either required to withdraw completely or for part of the discussion if their declared interest makes it appropriate, however this was not deemed necessary for any group members on this guideline.

Staff from the NCC-AC provided methodological support and guidance for the development process. They undertook systematic searches, retrieval and appraisal of the evidence and drafted the guideline. The glossary to the guideline contains definitions of terms used by staff and the GDG.

1.8 Methodology

The guideline was commissioned by NICE and developed in accordance with the guideline development process outlined in 'The guidelines manual' updated in April 2006[11]. Development prior to this stage (for example, development of the scope, early reviewing) was carried out using the methodology outlined in the previous version of the manual (March 2005)[12].

1.8.1 Development of clinical questions

Clinical questions were developed to guide the literature searching process and to facilitate the development of recommendations by the guideline development group.

The scope (appendix A) was used to put an initial draft of clinical questions together. GDG members were also asked to submit five clinical questions which they considered to be a priority for the guideline. These were incorporated into the subsequent draft of clinical questions. The clinical questions were circulated and considered by the GDG a number of times before a final draft was reached (appendix B).

1.8.2 Types of intervention

The GDG considered the following interventions:

Diagnostic tools:

- Digital anal examination, clinical/continence assessment, functional assessment (to determine the type of intervention required to resolve problems such as going to the toilet, adjusting clothes), medical examination, physical examination, neurological examination.

- Records/scores: symptom scores, diaries, Quality of Life (QoL), questionnaires

- Anal manometry (anal resting and squeeze pressures, and rates of fatigue), rectal distension sensitivity, electro sensitivity testing, Pudendal Nerve Terminal Motor Latency (PNTML), electromyelography (EMG), rectal compliance

- Anal ultrasound, Magnetic resonance Imaging (MRI), defaecography, plain abdominal x-ray, endoscopy and barium enema, rigid sigmoidoscopy, CT colonography.

Management interventions

General:

- Educational interventions: provision of information to patients and, where appropriate, their carers, on clinical and practical aspects of their condition

Lifestyle changes:

- Exercise and work: physical exercise/mobility, weight loss, job type
- Smoking: smoking cessation
- Changing medication (side effects)
- Diet and fluid intake (dietary manipulation: increased or decreased fibre intake, prebiotics, probiotics and symbiotics, lactose, yogurt, sorbitol, fructose, caffeine and alcohol, and/or eating patterns), fluid intake, type of fluid, volume, timing.

Measures to assist Activities of Daily Living:

- Clothing adaptations
- Absorbent products, disposal facilities/arrangements
- Bags
- Plugs
- Adaptations to toilet facilities, increased privacy, care providers sensitive to needs and bowel habits, manageable clothing, accessibility, raised seat and foot blocks, hand rails, alternative commodes, chemical toilets.
- Odour control
- Skin care management

Bowel management and re-training programmes:

- Bowel habit: toileting schedules
- Resisting urgency
- Evacuation training: decreasing straining/treating constipation, modification of defaecation position, patient administered evacuation techniques, carer administered evacuation techniques.
- Behaviour modification: reward systems
- Rectal irrigation: retrograde irrigation (anal), colonic irrigation
- Digital or other stimulation
- Manual evacuation
- Abdominal massage

Drug treatment

- Anti-diarrhoeal agents

- Increasing anal canal pressure
- Planned bowel evacuation using laxatives, enemas and suppositories

Biofeedback and/or sphincter/pelvic floor exercises

- Biofeedback: EMG, manometry, ultrasound, sensitivity training
- Pelvic floor muscle training/anal sphincter exercises

Non-implanted electrical stimulation

- Perineal
- Perianal
- Intra-anal

Surgical procedures

- Anal sphincter repair
- Pelvic floor repair (includes levatorplasty and post-anal repair)
- Neosphincter
- Bioinjectables
- Secca procedure
- Stoma creation
- Antegrade irrigation (surgically or endoscopically constructed port)
- Sacral nerve stimulation

Any combination of the above

1.8.3 Types of populations

We searched for studies of patients aged 18 and over reporting faecal incontinence (defined as involuntary loss of liquid or solid stool). The GDG considered that the majority of patients with FI were likely to fall into one or more of the following groups:

- Structural ano-rectal abnormality (for example, sphincter trauma, sphincter degeneration, perianal fistula, rectal prolapse)
- Neurological disorders (for example, multiple sclerosis, spinal cord injury, spinal bifida, stroke, other)

- Constipation/faecal loading (for example, diet, medication, megarectum)
- Cognitive and/or behavioural dysfunction (for example, dementia, learning disabilities)
- Loose stools (for example, gastrointestinal problems such as inflammatory bowel disease (IBD), or the irritable bowel syndrome (IBS)
- Disability related (for example, patients who are frail, acutely unwell, or have chronic/acute disabilities)
- Idiopathic (for example, self caring adults with faecal incontinence and none of the above)

1.8.4 Types of outcomes

The primary outcome of interest was the frequency of episodes of faecal incontinence. This information was not always reported in the retrieved studies and a number of different non-validated continence scores were often used instead. The GDG considered the following list of outcomes to also be of value:

- Patient-related: incontinent episodes/diary/pad/drug use, bowel frequency, % continent bowel movements, patient and carer quality of life (QoL), anxiety, depression, patient rating of bowel control/change, missed work/avoidance of social occasions, rate of clothing changes, concordance, stool consistency (scale), improvement of activities of daily living, staff satisfaction, carer related outcomes, behavioural rating scales, self esteem, sexual activity.
- Qualitative data, including patients' experiences, opinions, attitudes, preferences and perceptions.
- Clinician related: clinician evaluation of result/continence score
- Biometric measures: anal pressures – rest/squeeze/fatigue rate, rectal compliance, surgical repair success on ultrasound or MRI, rectal sensitivity, EMG
- Process: length of stay/number of treatment episodes, missed treatment opportunities/futile treatment episodes
- Adverse events: wound/skin breakdown or infection, other complications, for example: operative septic complications; new evacuation difficulty; failure to cure FI; drug side effects (including bloating); soreness/discomfort; death
- Cost

1.8.5 Literature search for clinical effectiveness evidence

The aim of the literature search was to identify relevant evidence within the published literature, in order to answer the clinical questions identified. Searches of clinical databases were performed using generic and specific filters, relevant medical subject heading terms and free-text terms. Non-English studies and abstracts were not included. Each database was searched up to 2 October 2006. Papers identified after this date were not routinely considered. Search strategies can be found in appendix C. The following databases were included in the literature search to identify relevant journal articles:

- The Cochrane Library up to 2006 (Issue 3)
- Medline (Dialog Datastar) 1951-2006
- Embase (Dialog Datastar) 1974-2006
- Cinahl (Dialog Datastar) 1982-2006
- Allied & Complementary Medicine 1985-2006
- British Nursing Index 1994- 2006
- PsycINFO 1806-2006
- The Cochrane Library Issue 3, 2006 (including NHS EED)
- Health Economic and Evaluations Database (HEED)

Bibliographies of identified reports and guidelines were also checked to identify relevant literature. The Internet was searched to identify guidelines and reports. The following web sites were used to help identify these:

- Members of the Guidelines International Network's web sites (http://www.g-i-n.net)
- National Institute for Health and Clinical Excellence (NICE) (www.nice.org.uk)
- National electronic Library for Health (NeLH) (http://www.nelh.nhs.uk)
- Scottish Intercollegiate Guideline Network (SIGN) (www.sign.ac.uk)
- US National Guideline Clearing House (www.guidelines.gov)
- CMA Infobase (http://mdm.ca/cpgsnew/cpgs/)
- NIH Consensus Development Program (http://consensus.nih.gov)
- New Zealand Guidelines Group (http://www.nzgg.org.nz)

- Royal College of Surgeons of England (www.rcseng.ac.uk)
- Royal College of Physicians of London (http://www.rcplondon.ac.uk)
- The Joanna Briggs Institute (http://www.joannabriggs.edu.au)
- National Institute of Clinical Studies (http://www.nicsl.com.au)
- Royal College of Nursing (http://www.rcn.org.uk)
- Royal Australasian College of General Practitioners (http://www.racgp.org.au)

1.8.6 Hierarchy of clinical evidence

There are many different methods of ranking evidence of clinical effectiveness and there has been considerable debate about which system is best. We used the system for intervention studies developed by the Scottish Intercollegiate Guidelines Network (SIGN), shown in Table 1.

Table 1: Levels of evidence for intervention studies (reproduced with permission of the Scottish Intercollegiate Guidelines Network)

Level of evidence	Type of evidence
1++	High-quality meta-analyses, systematic reviews of RCTs, or RCTs with a very low risk of bias
1+	Well-conducted meta-analyses, systematic reviews of RCTs, or RCTs with a low risk of bias
1-	Meta-analyses, systematic reviews of RCTs, or RCTs with a high risk of bias
2++	High-quality systematic reviews of case–control or cohort studies High-quality case–control or cohort studies with a very low risk of confounding, bias, or chance and a high probability that the relationship is causal
2+	Well-conducted case–control or cohort studies with a low risk of confounding, bias, or chance and a moderate probability that the relationship is causal
2-	Case–control or cohort studies with a high risk of confounding bias, or chance and a significant risk that the relationship is not causal

3	Non-analytic studies (for example, case reports, case series)
4	Expert opinion

For each clinical question the highest level of evidence (randomised controlled trials and systematic reviews of RCTs) was initially sought.

Due to the paucity of data retrieved, non-randomised comparative trials (for example: before-after trials, cohort studies) were also considered for all clinical questions.

Due to the limitations of the evidence base on the clinical questions on assessment of FI, diagnostic studies were also retrieved to help inform the development of the recommendations in this area. The following system adapted from 'The Oxford Centre for Evidence-based Medicine Levels of Evidence' (2001) and the Centre for Reviews and Dissemination 'Report Number 4' (2001) was used to rank this evidence.

Table 2: levels of evidence for diagnostic studies

Levels of evidence	Type of evidence
Ia	Systematic review (with homogeneity)[a] of level-1 studies[b]
Ib	Level-1 studies[b]
II	Level-2 studies[c] Systematic reviews of level-2 studies
III	Level-3 studies[d] Systematic reviews of level-3 studies
IV	Consensus, expert committee reports or opinions and/or clinical experience without explicit critical appraisal; or based on physiology, bench research or 'first principles'

[a] Homogeneity means there are no or minor variations in the directions and degrees of results between individual studies that are included in the systematic review.

[b] Level-1 studies are studies:

- that use a blind comparison of the test with a validated reference standard (gold standard)
- in a sample of patients that reflects the population to whom the test would apply.

[c] Level-2 studies are studies that have only one of the following:

- narrow population (the sample does not reflect the population to whom the test would apply)
- use a poor reference standard (defined as that where the 'test' is included in the 'reference', or where the 'testing' affects the 'reference')
- the comparison between the test and reference standard is not blind
- case–control studies.

[d] Level-3 studies are studies that have at least two or three of the features listed for level-2 studies.

Due to the limitations of the evidence base retrieved for the clinical questions on surgery specifically case series were also retrieved for the surgical interventions considered (see section 6.4).

1.8.7 The literature reviewing methods for clinical effectiveness evidence

References retrieved by the systematic literature search were screened for appropriateness by title and abstract by an information scientist and a systematic reviewer. Selected studies were ordered and assessed in full by the NCC-AC team using agreed inclusion/exclusion criteria specific to the guideline topic, and using NICE methodology quality assessment checklists appropriate to the study design[11]. The guideline development group also suggested further references and these were assessed these in the same way. Approximately 10% of studies included in the guideline were appraised and underwent data extraction by two systematic reviewers.

1.8.8 Health economic methods

It is important to investigate whether health services are cost-effective (that is, value for money). If a particular treatment strategy were found to yield little health gain relative to the resources used, then it would be better to re-deploy resources to other activities that yield greater health gain.

To assess the cost-effectiveness of each recommendation, a comprehensive systematic review of the economic literature was conducted. It was not possible to conduct any formal cost-effectiveness models, since the evidence on effectiveness was very limited across the guideline. Unit costs associated with treatment were collected from standard NHS sources, the literature and from specific NHS Trusts and were discussed with the GDG immediately prior to formal consensus development (see appendix F).

The criteria applied for an intervention to be considered cost-effective were either:

a) The intervention dominated other relevant strategies (that is, it is both less costly in terms of resource use and more clinically effective compared with the other relevant alternative strategies);

or

b) The intervention cost less than £30,000 per quality-adjusted life-year (QALY) gained compared with the next best strategy (and compared with basic conservative management). We have used the upper end of NICE's cost-effectiveness range because the social stigma associated with faecal incontinence is unlikely to be fully captured in estimates of quality-adjusted life expectancy[13].

The economic evaluation of any strategy has to be in comparison with another strategy. Hence we refer to:

- incremental cost: the mean cost of one strategy minus the mean cost of a comparator study.

- QALYs gained: the mean QALYs associated one strategy minus the mean QALYs of a comparator study.

- incremental cost-effectiveness ratio: the incremental cost divided by the respective QALYs gained.

1.8.9 Literature review for health economics

We obtained published economic evidence from a systematic search of the following databases:

- Medline (Dialog Datastar) (1966-2006)

- Embase (Dialog Datastar) (1980-2006)
- Health Economic Evaluations Database (HEED)
- NHS Economic Evaluations Database (NHS EED)

For those clinical areas we reviewed, the information specialists used the same search strategy as for the clinical questions, using an economics filter in the place of a systematic review or randomised controlled trial filter. Each database was searched from its start date up to 2 October 2006. Papers identified after this date were not routinely considered. Search strategies can be found in appendix C.

Each search strategy was designed to find any applied study estimating the cost or cost-effectiveness of an included intervention. A health economist reviewed the abstracts. Relevant references in the bibliographies of reviewed papers were also identified and reviewed.

Given the diversity of economic studies, it was not possible to determine a general exclusion criterion based on study quality. Hence, all studies were included in the evidence tables and study quality and applicability are discussed in the review. Papers were only excluded from the evidence tables and review if:

- The study did not contain any original data on cost or cost-effectiveness (that is, it was a review or a clinical paper).
- The analysis was not incremental and was not described adequately to allow incremental analysis (so studies reporting only average cost-effectiveness ratios would have been excluded unless they provided data to allow the calculation of incremental cost-effectiveness ratios).

Included papers were reviewed by a health economist. In the evidence tables costs are reported as given in the paper. However, where costs were in another currency, the results were converted to pounds sterling using the relevant purchasing power parity for the study year.

We have included studies from all over the world in our review, however, we use overseas studies with caution since resource use and especially unit costs vary considerably. Particular caution is applied to studies with predominantly private health insurance (for example, USA or Switzerland) where unit costs may be much higher than in the UK and to developing countries where costs may be much lower.

Each study was categorised as one of the following: cost analysis, cost-effectiveness analysis, cost-utility analysis (that is, cost-effectiveness analysis with effectiveness measured in terms of QALYs), or cost-consequences analysis. We did not find any ‘cost-benefit analyses’ (studies that put a monetary value on health gain).

Models are analogous to systematic reviews as they are pooling evidence from a number of different studies and therefore if well-conducted they should

out-rank studies based on a single RCT. Statistical significance is not usually applicable to models and uncertainty is explored using sensitivity analysis instead. Hence the results reported in our economics literature review evidence tables and write-up may not necessarily imply statistical significance.

1.8.10 Literature review methods for evidence on patient views and preferences

A systematic review of patient views was carried out to identify qualitative studies of patients' experiences, perceptions, attitudes and opinions about methods of managing faecal incontinence. Comprehensive and exhaustive searches of the same databases mentioned in 1.8.5 were undertaken. Search strategies can be found in appendix C.

Stringent inclusion criteria were applied to the retrieved studies. Studies had to pass all criteria to be included in the review:

- Faecal incontinence

Faecal incontinence (defined as any involuntary loss of faeces that caused a social or hygienic problem) had to be the main topic of investigative research.

- Patient views research

Studies had to primarily access people's views on any of the following: their ideas about, and experiences of, faecal incontinence, interventions targeted at FI; influences on patient decision-making about management options; and their ideas about what could be done to facilitate better care

- Patient group

Patients had to be investigated primarily on the basis of their incontinence, and were not cancer patients, or being treated for rectal prolapse.

- Publication date

Studies were excluded if they were published before 1990.

Included studies were then quality assessed. High quality studies were defined as those which solicited views without pre-defining the terms of discussion. We agreed that studies of patients' views should not reflect researchers' a priori assumptions about a topic, but instead access people's views in a non-biased way. In practice, this translates largely to study methodology; open-ended questionnaires, focus groups or interviews tend to be employed by researchers in high-quality studies. Lower quality studies – those which used pre-defined scales to measure quality of life or other subjective outcomes or closed questionnaires - were included to give a broader view of the literature.

1.8.11 Evidence submitted by stakeholders

Stakeholders were invited to submit potential evidence of relevance to the guideline. References received were cross-checked with evidence identified through the systematic literature search. Stakeholder-submitted references were assessed using the same criteria for inclusion as studies retrieved in the literature search.

1.8.12 Consensus development methods

Due to the poor quality of evidence for most of the clinical questions the guideline development group agreed to use a consensus development exercise to utilise the GDG's expertise in drafting recommendations on the assessment and management of faecal incontinence.

We adopted a modified Nominal Group Technique approach for the consensus development exercise. The scope of the guideline was divided into three areas; assessment, conservative management and surgery. For each area, the GDG were presented with available evidence tables (see appendices D and E), economic data (see appendix F) and narrative summaries of the clinical and economic evidence reviewed. Recommendations were drafted on basis of the evidence wherever it was available.

A subgroup comprising selected GDG members and nominated expert advisors was convened for each of the three areas. These subgroups met between GDG meetings to consider the drafted recommendations and to develop a care pathway algorithm. The subgroup proposed additional recommendations based on their expert opinion. These recommendations were circulated to the GDG. The GDG was asked to independently feed back their comments on these recommendations to the NCC before their next meeting. This feedback was collated and circulated to the GDG prior to the meeting so that GDG members could consider their own feedback in relation to other group members. An independent facilitator from the NCC facilitated a structured discussion considering each recommendation and the feedback on that recommendation at the GDG meeting. The structured discussion focused on how each recommendation could be improved. Feedback from the discussion was recorded on prepared forms and summarised by the facilitator before moving onto the next recommendation. A draft of recommendations incorporating the feedback from the facilitated discussion was circulated after each consensus development exercise.

To encourage the GDG to reach a consensus that was underpinned by the principles of cost-effectiveness, the guideline health economist presented unit cost data and discussed the implications with the Group. This was carried out both at the subgroup meetings where recommendations were proposed and at the GDG meetings where the recommendations were formally agreed.

The expert advisors involved in the consensus development process were also given an opportunity to comment on the complete list of recommendations before the first draft of the guideline was submitted for stakeholder consultation (see section 1.8.16).

1.8.13 Grading of recommendations

Following a public consultation in April 2006 NICE is no longer publishing grades alongside recommendations contained within its guidance.

1.8.14 Research recommendations

When areas were identified for which good evidence was lacking, the guideline development group considered making recommendations for future research. Decisions about inclusion were based on factors such as the importance to patients or the population, national priorities, and the potential impact on the NHS and future NICE guidance. The list of research recommendations proposed for this guideline can be found in section 1.9.3.

1.8.15 Prioritisation of recommendations for implementation

To assist users of the guideline in deciding the order in which to implement the recommendations, the guideline development group identified 10 key priorities for implementation. The decision was made after discussion and voting by the GDG. They selected recommendations that would:

- Have a high impact on patient outcomes, including mortality and morbidity
- Have a high impact on reducing variation in health care
- Lead to a more efficient use of NHS resources
- Mean that patients reach critical points in the care pathways more quickly.

The key priorities for implementation proposed for this guideline can be found in section 1.9.1.

1.8.16 Validation of the guideline

As mentioned in section 1.8.12 the expert advisors were sent an early draft of the recommendations for comments, as were a small number of other healthcare professionals nominated by the GDG. These comments were

considered by the GDG and incorporated as appropriate for the draft of the recommendations submitted for stakeholder consultation.

Registered stakeholders will be given the opportunity to comment on the first draft of the guideline, which is posted on the NICE website. A Guideline Review Panel will also review the guideline and check that stakeholders' comments are addressed before the final guideline is issued in June 2007.

1.8.17 Related NICE guidance

Urinary incontinence: the management of urinary incontinence in women. NICE Clinical Guideline No. 40 (2006). Available from www.nice.org.uk/CG40

Artificial anal sphincter. NICE Interventional Procedure Guidance No. IPG066 (2004). Available from www.nice.org.uk/IPG066

Sacral nerve stimulation for faecal incontinence. NICE Interventional Procedure Guidance No. IPG099 (2004) Available from www.nice.org.uk/IPG099

Stimulated graciloplasty for faecal incontinence. NICE Interventional Procedure Guidance No. IPG159 (2006) Available from www.nice.org.uk/IPG159

Circular stapled haemorrhoidectomy. NICE Interventional Procedure Guidance No. IPG034 (2003) Available from www.nice.org.uk/IPG034

Percutaneous endoscopic colostomy. NICE Interventional Procedure Guidance No. IPG161 (2006) Available from www.nice.org.uk/IPG161

NICE is developing the following guidance (details available from www.nice.org.uk):

Irritable bowel syndrome in adults: diagnosis and management of irritable bowel syndrome in primary care. NICE Clinical Guideline. (Publication expected February 2008)

Injectable bulking agents for faecal incontinence. NICE Interventional Procedure Guidance. (Publication expected Winter/Spring 2007).

1.8.18 Updating the guideline

NICE clinical guidelines are updated as needed so that recommendations take into account important new information. We check for new evidence two and four years after publication, to decide whether all or part of the guideline should be updated. If important new evidence is published at other times, we may decide to do a more rapid update of specific recommendations.

1.9 Summary of the recommendations

1.9.1 Key priorities for implementation

People who report or are reported to have faecal incontinence should have their care managed by healthcare professionals with the relevant skills, training and experience and who work within an integrated continence service (see 'Good practice in continence services' National Service Framework for Older People(www.dh.gov.uk)).

Faecal incontinence is a socially stigmatising condition. Healthcare professionals should actively yet sensitively enquire about symptoms in the following high-risk groups:

- frail older people
- patients with loose stools or diarrhoea from any cause
- women following childbirth
- patients with neurological/spinal cord injury or disease
- patients with severe cognitive impairment
- patients with urinary incontinence
- patients with pelvic organ prolapse and/or rectal prolapse
- patients after colonic resection or anal surgery
- patients who have undergone pelvic radiotherapy
- patients with perianal soreness, itching or pain
- people with learning disabilities.

When assessing faecal incontinence healthcare professionals should:

- be aware that faecal incontinence is a symptom, often with multiple contributory factors for an individual patient
- avoid making simplistic assumptions that causation is related to a single primary diagnosis ('diagnostic overshadowing').

Healthcare professionals should carry out and record a focused baseline assessment for patients with faecal incontinence to identify the contributory factors. This should comprise:

- relevant medical history (see appendix I)
- general examination
- anorectal examination (see appendix I)
- cognitive assessment, if appropriate.

Patients with the following conditions should have these addressed with condition-specific interventions before progressing to initial management of faecal incontinence:

- faecal loading
- treatable causes of diarrhoea
- warning signs for lower gastrointestinal cancer (see NICE clinical guideline on referral for suspected cancer (www.nice.org.uk/CG027)
- rectal prolapse or third degree haemorrhoids
- acute anal sphincter injury
- acute disc prolapse.

Initial management should address bowel habit, aiming for ideal stool consistency and satisfactory bowel emptying at a predictable time.

Healthcare professionals should provide the following to symptomatic patients who either do not wish to continue with active treatment or who have intractable faecal incontinence:

- advice relating to the preservation of dignity and where possible independence
- psychological and emotional support, possibly including referral to counsellors or therapists if it seems likely that patients' attitude towards their condition and their ability to manage and cope with faecal incontinence could improve with professional assistance
- at least 6-monthly review of symptoms

- discussion of any other management options (including specialist referral)
- contact details for relevant support groups
- advice on continence products and information about product choice, availability and use
- advice on skin care
- how to talk to friends and family
- strategies such as planning routes around public conveniences if patients have to travel.

Patients who continue to have episodes of faecal incontinence after initial management, should be referred to a specialist continence service for consideration of specialised management options which may include:

- pelvic floor re-education programmes
- bowel retraining
- specialist dietary assessment and management
- biofeedback
- electrical stimulation
- rectal irrigation.

These treatments may not be appropriate for patients who are unable to understand and/or comply with instruction. For example, pelvic floor re-education programmes may not be appropriate for those with neurological or spinal disease/injury resulting in faecal incontinence due to complete loss of voluntary control.

All patients considering or being considered for surgery should be referred to a specialist surgeon to discuss:

- the surgical and non-surgical options appropriate for each patient
- the potential benefits and limitations of each option, with particular attention to long-term results
- realistic expectations of the effectiveness of any surgical procedures under consideration.

Healthcare professionals should consider a proactive approach to bowel management for the following groups of patients:

- patients with neurological or spinal disease/injury resulting in faecal incontinence due to complete loss of voluntary control
- patients with limited mobility
- people with faecal loading or constipation
- hospitalised patients who are acutely unwell and develop acute faecal loading and associated incontinence
- patients with acquired brain injury
- patients with cognitive or behavioural issues
- people with learning disabilities.

1.9.2 The complete list of clinical practice recommendations

1.9.2.1 Good practice in managing faecal incontinence

People who report or are reported to have faecal incontinence should have their care managed by healthcare professionals with the relevant skills, training and experience and who work within an integrated continence service (see 'Good practice in continence services' National Service Framework for Older People (www.dh.gov.uk)).

Faecal incontinence is a socially stigmatising condition. Healthcare professionals should actively yet sensitively enquire about symptoms in the following high-risk groups:

- frail older people
- patients with loose stools or diarrhoea from any cause
- women following childbirth
- patients with neurological/spinal cord injury or disease
- patients with severe cognitive impairment
- patients with urinary incontinence
- patients with pelvic organ prolapse and/or rectal prolapse

- patients after colonic resection or anal surgery
- patients who have undergone pelvic radiotherapy
- patients with perianal soreness, itching or pain
- people with learning disabilities.

Coordinated public health campaigns to raise public awareness of the causes, prevalence, symptoms and resources to treat faecal incontinence should be carried out in order to:

- aid mutual support between people with faecal incontinence
- decrease the taboo surrounding faecal incontinence.

All staff working with people with faecal incontinence should be aware of both the physical and emotional impact this symptom can have upon patients.

Healthcare professionals should ensure that people with faecal incontinence:

- are kept fully informed and have access to appropriate sources of information in formats and languages that are suited to an individual's requirements
- are offered access to or made aware of appropriate support groups (which may be alerting patients to likelihood of family and friends having similar experiences, community groups, or more formal organisations). Consideration should be given to cognition, gender, physical needs, culture and stage of life of the individual
- have the opportunity to discuss assessment, management options and relevant physical, emotional, psychological and social issues. Patients' views, experiences, attitudes and opinions about these issues should be actively sought.

When assessing faecal incontinence healthcare professionals should:

- be aware that faecal incontinence is a symptom, often with multiple contributory factors for an individual patient
- avoid making simplistic assumptions that causation is related to a single primary diagnosis ('diagnostic overshadowing').

1.9.2.2 Baseline assessment

Healthcare professionals should ensure that people who report or are reported to have faecal incontinence:

- receive a focused baseline assessment before any treatment is considered
- receive all appropriate initial management before any specialised treatment.

Healthcare professionals should carry out and record a focused baseline assessment for patients with faecal incontinence to identify the contributory factors. This should comprise:

- relevant medical history (see appendix I)
- general examination
- anorectal examination (see appendix I)
- cognitive assessment, if appropriate.

Patients with the following conditions should have these addressed with condition-specific interventions before progressing to initial management of faecal incontinence:

- faecal loading
- treatable causes of diarrhoea
- warning signs for lower gastrointestinal cancer (see NICE clinical guideline on referral for suspected cancer (www.nice.org.uk/CG027))
- rectal prolapse or third degree haemorrhoids
- acute anal sphincter injury
- acute disc prolapse.

1.9.2.3 Initial management

Healthcare professionals should inform patients that a combination of initial management interventions is likely to be needed to address faecal

incontinence. The specific management intervention(s) offered to patients should be based on the findings from baseline assessment, tailored to individual circumstances and adjusted to personal response.

Bowel habit

Initial management should address bowel habit, aiming for ideal stool consistency and satisfactory bowel emptying at a predictable time.

A bowel habit intervention should contain the following elements:

- encouraging bowel emptying after meals (to utilise the gastro-colic response)
- ensuring toilet facilities are private, comfortable and can be used in safety with sufficient time allowed (see ‘Essence of care’ (www.dh.gov.uk) and 'Behind closed doors: using the toilet in private' (www.bgs.org.uk))
- teaching patients to adopt a sitting or squatting position where possible while emptying the bowel
- teaching patients techniques to empty the bowel without straining.

Diet and fluid intake

Healthcare professionals should recommend a diet that promotes an ideal stool consistency and predictable bowel emptying. When addressing food and fluid intake healthcare professionals should:

- take into account existing therapeutic diets
- ensure that overall nutrient intake is balanced
- consider a food and fluid diary to help form a baseline
- advise patients to modify one food at a time if attempting to identify potentially contributory factors (see appendices K and L)
- encourage patients with hard stool and/or clinical dehydration to aim for at least 1.5 litres intake of fluid per day. Urinary output should be measured where intake is in doubt
- consider the opportunity to screen patients for malnutrition, or risk of malnutrition (see related NICE guideline on nutrition support (www.nice.org.uk/CG032)).

Toilet access

When addressing toilet access in any home or healthcare setting:

- locations of toilets should be made clear
- equipment to help people to gain access to a toilet should be provided
- advice should be given to patients on easily removable clothing to reduce time needed for access
- if patient is dependent on others for accessing the toilet, help should be readily available
- privacy and dignity should be maintained at all times
- if appropriate, patients should be referred to healthcare professionals for assessment of home/mobility.

Medication

When reviewing medications, healthcare professionals should consider alternatives to drugs that may be contributing to faecal incontinence (see appendix J).

Anti-diarrhoeal medication should be offered to patients with loose stools and associated faecal incontinence once other causes for loose stools (such as excessive laxative use and dietary factors) have been excluded. Anti-diarrhoeal medication should be prescribed in accordance with the summary of products characteristics.

Loperamide is the anti-diarrhoeal drug of first choice and can be used long-term in doses from 0.5 mg to 16 mg per day or as required. Patients who are unable to tolerate loperamide should be offered codeine phosphate, or co-phenotrope (Lomotil ®)[1].

Loperamide should not be offered to patients with:

- hard or infrequent stools
- acute diarrhoea without a diagnosed cause

[1] Check the Summary of Products Characteristics (SPC) for current licensed indications. Informed consent is needed when using outside the licensed indications. This should be discussed and documented in the notes.

- an acute flare-up of ulcerative colitis.

When loperamide is used it should be:

- introduced at a very low dose and the dose should be escalated, as tolerated by the patient until the desired stool consistency has been achieved
- taken as required by the patient with faecal incontinence
- advised that patients can adjust the dose and/or frequency up or down in response to stool consistency and lifestyle.

If a finer modification of dose is required loperamide syrup should be considered.

Coping strategies for symptomatic patients

During assessment and initial management patients should be offered advice on coping strategies including:

- continence products and information about product choice, availability and use
- skin care
- where to get emotional and psychological support. In some cases counselling or psychological therapy to foster acceptance and positive attitudes
- how to talk to friends and family
- strategies such as planning routes around public conveniences if patients have to travel.

Patients should be offered:

- disposable body-worn pads and disposable bed pads if needed
- pads in quantities appropriate to the individual's continence needs. Arbitrary ceilings are inappropriate

- anal plugs for patients who can tolerate them
- a choice of pad styles and designs
- skin care advice; both skin cleansing and protection
- advice on odour control and laundry needs.

The use of reusable absorbent products in the management of faecal incontinence is not generally recommended.

Review of treatment

After each intervention healthcare professionals should ask patients if faecal incontinence has improved. Patients continuing to experience symptoms should be:

- involved in discussions about further treatment options (including effectiveness and adverse effects) or alternative coping strategies
- asked if they wish to try further treatments.

Long-term management

Healthcare professionals should provide the following to symptomatic patients who either do not wish to continue with active treatment or who have intractable faecal incontinence:

- advice relating to the preservation of dignity and where possible independence
- psychological and emotional support, possibly including referral to counsellors or therapists if it seems likely that patients' attitude towards their condition and their ability to manage and cope with faecal incontinence could improve with professional assistance
- at least 6-monthly review of symptoms
- discussion of any other management options (including specialist referral)
- contact details for relevant support groups
- advice on continence products and information about product choice, availability and use

- advice on skin care
- how to talk to friends and family
- strategies such as planning routes around public conveniences if patients have to travel.

1.9.2.4 Specialised management

Patients who continue to have episodes of faecal incontinence after initial management, should be referred to a specialist continence service for consideration of specialised management options which may include:

- pelvic floor re-education programmes
- bowel retraining
- specialist dietary assessment and management
- biofeedback
- electrical stimulation
- rectal irrigation.

These treatments may not be appropriate for patients who are unable to understand and/or comply with instruction. For example, pelvic floor re-education programmes may not be appropriate for those with neurological or spinal disease/injury resulting in faecal incontinence due to complete loss of voluntary control.

Healthcare professionals should consider if patients with neurological or spinal disease/injury (for example spinal cord injury, spina bifida, stroke, multiple sclerosis) resulting in faecal incontinence, who have some residual motor function and are still symptomatic after baseline assessment and initial management, could benefit from specialised management.

A programme of pelvic floor re-education should be agreed with the patient. The progress of patients having pelvic floor exercises should be monitored by digital reassessment by an appropriately trained healthcare professional who is supervising the treatment. There should be a review of patients' symptoms on completion of the programme and other treatment options considered if appropriate.

1.9.2.5 Specialist assessment

Healthcare professionals should refer patients with continuing faecal incontinence after specialised conservative management for consideration for:

- anorectal physiology studies
- endoanal ultrasound. If not available, consider MRI, endovaginal ultrasound and perineal ultrasound
- other tests, possibly including proctography.

1.9.2.6 Surgery

All patients considering or being considered for surgery should be referred to a specialist surgeon to discuss:

- the surgical and non-surgical options appropriate for each patient
- the potential benefits and limitations of each option, with particular attention to long-term results
- realistic expectations of the effectiveness of any surgical procedures under consideration.

Patients with a full length external anal sphincter defect (with or without an associated internal anal sphincter defect) and faecal incontinence which restricts quality of life should be considered for sphincter repair for defects that are 90º or greater. Patients should be given a realistic expectation of what this operation can achieve and possible adverse events, both in the short and long term.

Patients with internal sphincter defects, pudendal nerve neuropathy, multiple defects, external sphincter atrophy, loose stools or irritable bowel syndrome should be informed that these factors are likely to decrease the effectiveness of anal sphincter repair.

Patients undergoing a sphincter repair to manage their faecal incontinence should not routinely receive a temporary defunctioning stoma.

Patients undergoing anal sphincter repair should not receive constipating agents in the post-operative period. Feeding should resume as required by the patient.

A trial of temporary sacral nerve stimulation should be considered for patients with faecal incontinence where sphincter surgery is deemed inappropriate. These may be patients with intact anal sphincters, or those with sphincter disruption. In those with a defect contraindications to direct repair may include atrophy, denervation, a small defect, absence of voluntary contraction, fragmentation of the sphincter or a poor quality muscle (see NICE interventional procedure guidance on sacral nerve stimulation (www.nice.org.uk/IPG099)). All patients should be informed of the potential benefits and limitations of this procedure and should undergo a trial stimulation period of at least 2 weeks to determine if they are likely to benefit. Patients being considered for sacral nerve stimulation should be assessed and managed at a specialist centre with experience of performing this procedure.

If a trial of sacral nerve stimulation is unsuccessful patients can be considered for a neosphincter. The two options to be considered are a dynamic graciloplasty or an artificial bowel sphincter (see NICE interventional procedure guidance on stimulated graciloplasty (www.nice.org.uk/IPG159)). Patients should be informed of the potential benefits and limitations of both procedures. Patients being considered for either procedure should be assessed and managed at a specialist centre with experience of performing this procedure.

Patients with an implanted sacral nerve stimulation device, dynamic graciloplasty or an artificial bowel sphincter should receive training and ongoing support at a specialist centre. Patients offered this procedure should be informed that they may experience evacuatory disorders and/or serious infection which may necessitate removal of the device. These patients should be monitored, have regular reviews and be given a point of contact.

Antegrade irrigation via appendicostomy, neo-appendicostomy or continent colonic conduit may be considered in selected patients with constipation and colonic motility disorders associated with faecal incontinence.

A stoma should be considered for patients with faecal incontinence that severely restricts lifestyle only once all appropriate non-surgical and surgical options, including those at specialist centres, have been considered. Patients should be informed of the potential benefits, risks and long-term effects of this

procedure. Patients assessed as a possible candidate for a stoma should be referred to a stoma care service.

1.9.2.7 Specific groups

When assessing faecal incontinence healthcare professionals should:

- be aware that faecal incontinence is a symptom, often with multiple contributory factors for an individual patient
- avoid making simplistic assumptions that causation is related to a single primary diagnosis ('diagnostic overshadowing').

Healthcare professionals should consider a proactive approach to bowel management for the following groups of patients:

- patients with neurological or spinal disease/injury resulting in faecal incontinence due to complete loss of voluntary control
- patients with limited mobility
- people with faecal loading or constipation
- hospitalised patients who are acutely unwell and develop acute faecal loading and associated incontinence
- patients with acquired brain injury
- patients with cognitive or behavioural issues
- people with learning disabilities.

Patients with faecal loading

Patients in whom acute severe faecal loading is identified as contributing to faecal incontinence should initially be offered a rectally administered treatment to satisfactorily clear the bowel. This will often require treatments to be repeated daily for a few days. The interventions should be offered in the following order, depending on tolerance and if satisfactory bowel clearance is achieved:

- glycerine suppositories
- bisacodyl suppositories

- micro enemas
- phosphate enemas.

If these interventions are not appropriate and/or fail to satisfactorily clear the bowel and bowel obstruction has been excluded as possible cause, a potent oral laxative should be offered. Patients should be informed that oral laxatives may cause griping abdominal pain, loose stools and prolonged bowel activity. Toilet access should be ensured.

Healthcare professionals involved in the management of faecal incontinence associated with chronic ongoing faecal loading/impaction should aim to reduce the chance of recurrence by recommending a combination of initial management options tailored to the individual patient (see recommendation 1.9.2.3). If this fails, consider use of orally administered laxatives to promote bowel emptying. Rectally administered preparations should be used if use of oral laxatives produces faecal incontinence episodes and there is a need to produce planned bowel evacuations.

Patients with limited mobility

Patients with limited mobility who continue to have episodes of faecal incontinence after initial management should be offered a regimen which will produce a planned, predicted bowel action when carers are present. This may be achieved by a combination of oral or rectal laxatives and/or constipating agents. This regimen should also consider:

- toilet access (see recommendations in 1.9.2.3).
- appropriate disposable products (see recommendations in 1.9.2.3)
- that the stool needs to be in the rectum at the time of the planned bowel action.

Patients using enteral tube feeding and reporting faecal incontinence

Healthcare professionals should ensure that patients reporting faecal incontinence who are receiving enteral tube feeding have their type and timing of feed modified on an individual basis to establish the most effective way to manage faecal incontinence.

Patients with severe cognitive impairment

Patients with confirmed severe cognitive impairment should be assessed using a behavioural and functional analysis to determine the nature of, and reason for the behavioural presentation of faecal incontinence. Following assessment, patients should be offered cause-specific interventions founded on structured goal planning that aim to resolve as well as manage faecal incontinence.

Patients with neurological or spinal disease/injury

Patients with neurological or spinal disease/injury resulting in faecal incontinence due to complete loss of voluntary control who continue to have episodes of faecal incontinence after initial management should be offered a bowel management programme which aims to achieve a predictable routine and avoid faecal incontinence and severe constipation. Management should involve progressing through the following steps until satisfactory bowel habit is established:

- ascertaining patient preferences
- ascertaining pre-morbid bowel habit, if possible
- maximising patient's understanding of normal bowel function and how it has been altered
- modifying diet and/or administration of rectal evacuants and/or oral laxatives, adjusted to individual response, to attempt to establish a predictable pattern of bowel evacuation
- consideration of digital anorectal stimulation for patients with a spinal cord injury and those with other neurogenic bowel disorders
- consideration of manual/digital removal of faeces, particularly for patients with a lower spinal injury if there is a hard plug of faeces in the rectum, presence of faecal impaction, incomplete defaecation, an inability to defaecate and/or all other bowel emptying techniques have failed to achieve bowel emptying and continence in a reasonable time.

Healthcare professionals should consider the following management options for a patient unable to achieve reliable bowel continence after a neurological bowel management programme:

- coping and long term management strategies for symptomatic patients (see recommendations in 1.9.2.3)
- rectal irrigation if feasible
- a stoma or other surgical options if faecal incontinence or time taken for bowel emptying imposes major limits on lifestyle.

Other specific groups

Healthcare professionals should consider a faecal collection bag for patients in intensive care settings and patients receiving palliative care who report or are reported with faecal incontinence and associated loose stools who are not undergoing active treatment.

1.9.3 Recommendations for research

The GDG identified the following priority areas for research:

The value of pelvic floor exercises in preventing and treating obstetric-related faecal incontinence.

Development of a valid and reliable tool to measure patient-rated outcomes including symptom severity and quality of life for people with faecal incontinence.

Would a self-care educational programme for patients and carers improve patient outcomes (symptom severity and quality of life)?

Does a bowel management programme for older people in care homes improve faecal incontinence, constipation and patients' and carer's perceptions of quality of care?

What is the prognostic value of physiologic assessment for defining outcome of surgery for treatment of faecal incontinence?

2 Good practice in managing faecal incontinence

2.1 Introduction

Faecal incontinence (FI) is a stigmatising condition, affecting men and women of all ages. People with FI commonly experience fear and embarrassment. It can have a distressing impact and restriction on quality of life; in some cases people with symptoms will limit their lives in order to maintain easy access to a toilet in case of an incontinence episode. Treatment of FI should aim not only towards enabling the patient to live with dignity at home, but also to participate in social, leisure, and cultural activities, education, training or work.

This chapter will outline the importance of good practice when managing FI by looking at general principles of patient-cantered care, specific issues associated with managing FI, educational needs and finally patients' views about the management methods available.

2.2 General principles of patient-centred care

Treatment and care should take account of patients' needs and preferences. People with faecal incontinence should have the opportunity to make informed decisions about their care and treatment, in partnership with their healthcare professionals. It should be recognised that people who have had FI for a long time may become experts in the management of their symptoms, if not the condition as a whole. Where it is believed that patients may lack the capacity to make decisions, healthcare professionals should follow the Department of Health guidelines – 'Reference guide to consent for examination or treatment' (2001) (available from www.dh.gov.uk). From April 2007 healthcare professionals will need to follow a code of practice accompanying the Mental Capacity Act (summary available from www.dca.gov.uk/menincap/bill-summary.htm).

Treatment and care and the information patients are given about it should be culturally appropriate. Information should be accessible to people with additional needs such as physical, sensory, mental or learning disabilities. Specialist techniques and tools should be employed to ensure that people with communication difficulties have the opportunity to receive information. It should be offered in a wide range of languages and formats (including face-to-face, telephone-based, web-based, electronic, printed and audiotapes). Specific strategies need to be put in place to meet the information and advice needs of hard-to-reach groups and those who do not currently access information[14]. Advice on the production of patient information by health professionals is available from www.nhsidentity.nhs.uk. Information by itself is not always enough: people should be offered one-to-one support in understanding and interpreting information and what it means for them as an individual.

Normally carers and relatives should have the opportunity to be involved in decisions about the patient's care and treatment, unless the patient specifically excludes them. Patients must be asked if they want carers and relatives to be involved due to the sensitive nature of the condition and the stigma attached. Carers and relatives should also be given the information and support they need. In some cultures disclosure of FI could lead to the patient being ostracised.

2.3 Systematic review of research into patient views on experiences and behaviour

People with FI often experience social stigmatisation and exclusion, and frequently suffer from stress, anxiety and depression. Many will try to hide their condition, particularly if there are associated cultural /religious issues. All these factors mean that there are frequently delays in people seeking help. People are often too embarrassed to talk to their healthcare provider, or may not know that there are treatment options available for this condition. Patients and carers often develop their own strategies to deal with the condition.

We conducted a systematic review of research on patient' views to answer questions about appropriateness, feasibility and acceptability of current medical care, and also to describe patients' experiences, attitudes and perceptions about living with faecal incontinence.

2.3.1 Studies considered for this review

We considered surveys, focus groups and both individual and group interviews for this review. Further details of the methods for this systematic review can be found in section 1.8.10.

2.3.2 Summary of evidence

Eight studies accessed the views of patients, while one study accessed those of carers (evidence table 1, appendix D). In total 728 patients were questioned. The majority were female patients who had already sought professional help. The age range was 51–90 years. Most studies were conducted in the UK, but one each was identified from Australia and the United Arab Emirates. The higher-quality studies tended to examine views in the context of everyday life.

The research is highly biased towards older female patients, and this publication bias is necessarily represented in the systematic review. It is a limitation of this review, which nevertheless offers a unique insight into patients' lives and values, which in turn allows appropriate recommendations to be developed.

This section will summarise the evidence on perceptions of causes of FI and coping strategies identified by thematic analysis of the qualitative research found in the systematic review of patients' views.

Perceptions of causes of FI

Causes identified within studies by patients and carers included:

- Childbirth

- Menopause
- Old age
- Paralysis
- Neurological disorders.

It was not always clear, however, that these causes were identified through entirely open-ended questions, which may have biased results. A frequent finding was the iteration that FI was all part of getting old; that it was to be expected and dealt with. This stoicism may be linked to a lack of information about the prevalence of FI and consequent awareness of support structures and treatment and management options.

Coping strategies

Our review also identified a remarkably wide range of coping strategies despite the small size and self-selected population of some studies. The views expressed are mainly from women. Some of the strategies used may impact on overall physical and mental well being, and could be described as having a negative effect on overall health. This makes a comprehensive description of patient behaviour and attitudes essential if effective strategies to assist patients are to be developed.

Coping strategies were classified into four main categories, with sub-topics arranged in no particular order within the boxes:

A. Attitudes

Taking control of one's own emotional responses to FI, managing individual mental states of mind and attitudes appeared to be a common strategy in coping with FI. By constructing an identity around or deciding on a particular response to incontinence, patients and carers are able to find a frame of mind which allows them to exert some control over their condition. The attitude held by the patient, whether positive or negative, may have a knock-on effect on their relationships with health professionals, carers and family.

Figure 1: Attitudes

Attitudes and opinions adopted
Fighting against it
Putting up with it
Learning to accept it
Humour
Denial
Considering dealing with continence as an ordinary component of family care.
Development of assertive and negotiation skills
Use of positive attitudes
Development of optimistic outlook on FI and life to facilitate coping.

B. Physical control – behavioural change

Most patients and carers stated that behavioural change was enforced upon them by their faecal incontinence. However, some of these strategies appeared to be detrimental to patients' mental and/or physical health, and to their social, professional and personal lives.

Figure 2: Physical control

Behavioural strategies adopted
Privacy in bathroom
Restricting activity
Knowing location of toilets when out and/or planning travel around them
Moving to new home or a new job
Working
Carrying a change of clothes
Careful regulation of food input and output to enable planning of professional, social and private life
Fasting, or avoiding certain food, e.g. fruit and vegetables
Restricted travel
Self-treatment – pads, washing etc but also local or traditional remedies
Waiting for FI to resolve by itself (also given as a reason for not seeking medical help)
Curtailed exercise as often found to precipitate FI
Obsessional washing

C. Support

Patients and carers repeatedly indicated how alone and embarrassed they felt. Social support networks were correspondingly narrow or non-existent. Most patients said that they had concealed symptoms, but on disclosure received support. It is possible that overcoming the taboo and shame associated with FI would allow patients to communicate more effectively and ask for support – which in most cases is willingly given, and allows FI patients to cope more effectively with their condition.

Those identified by patients and carers included:

Figure 3: Support

Support networks

Counselling
Calling on friends and family for support
Support group members and other people with FI
Colleagues
Religion
Books, magazines, internet
Community service providers, health professionals

D. Medical help

An interesting finding was that very few medical interventions were identified by patients and carers as potential coping strategies. Of the three mentioned below, one was from a study which specifically looked at the impact of stoma creation on patient experience.

Figure 4: Medical care

Medical interventions used

Biofeedback
Medication
Stoma

More general points raised about medical care by patients and carers included:

- reasons for **not seeking help** include embarrassment, not wanting male doctor to know, having insensitive, rude or apathetic health professionals to deal with, not knowing where to go for information.

- **Perception of health professionals as not understanding** what it's like to have FI, being ignorant about management techniques and the whole condition. There was a general lack of confidence about health professional's knowledge and a consequent loss of trust.

- All participants in one study stated they did not know where to go for **advice or information about continence products**, that it was hard to find, and inconsistent, that they were unaware of public support networks, and also that professional assessment and advice about management was available[15]. Suggestions for improvement made by patients included: provision of detailed product information (working capacity, instructions etc), also provision of general information about incontinence in simple language, with better marketing and distribution of information sources in general.

- Participants reported **anger at doctors** who were perceived to have misdiagnosed, misinformed or performed treatment (especially surgery) badly. Male doctors in particular were perceived by women as not understanding clearly the consequences of FI, or more generally of childbirth, and of not taking sufficient care with subsequent treatment such as suturing of tears.

2.3.3 Conclusions

In conclusion, the papers identified did not appear to be representative of the known demographic spread affected by faecal incontinence, and therefore these are potentially biased findings. However, some clear themes arose from the data, about patients' and carers' experiences and values, which have been synthesised with relevant quantitative data to form recommendations throughout the guideline.

Two major themes addressed here include the attitudes adopted by patients and carers to deal with their incontinence, and the behavioural strategies adopted. Both of these may be amenable to change if appropriate interventions are developed, and have led to recommendations on appropriate support and care for patients with FI (section 2.6.1, 2.6.2 and 2.6.3).

2.4 Systematic review on patient views of interventions to manage faecal incontinence

A systematic review was conducted to identify qualitative studies of patients' experiences, perceptions, attitudes and opinions about methods of managing faecal incontinence. Stringent inclusion and quality assessment criteria were applied to the 88 studies identified. Only studies which described a piece of research *primarily* accessing people's views were considered for inclusion.

In general, the higher-quality studies examined views in the context of everyday life, whereas the low-quality studies tended to look at views in a pre- and post-operative context. This is because the qualitative research was used in these cases to estimate effectiveness of an intervention, rather than accessing views of patients without pre-defining the terms of discussion.

2.4.1 Summary of evidence on patient views research on specific interventions

In summary:

- No high-quality studies addressing assessment of faecal incontinence were found.
- One high-quality study addressing conservative management of faecal incontinence was identified[15].
- Three high-quality studies soliciting views about surgery were identified[6,9,10], one each about permanent sacral nerve stimulation (SNS)[10], anterior anal sphincter repair[9], and colostomy[6].

These studies are discussed in more detail within the relevant chapter for the intervention(s) under consideration.

2.4.2 Conclusions from systematic review of patient' views

This guideline aims to deliver advice on the diagnosis and management of faecal incontinence, including patient teaching and information, life-style changes, conservative management, bowel management, biofeedback, electrical stimulation, surgery and complementary therapies. As this systematic review has demonstrated, qualitative research has only been carried out in some of these areas. Whilst some conclusions may be drawn about the effect of various interventions on patient experience and quality of life, further high quality qualitative research is needed.

2.5 Do any educational interventions improve outcome for patients with faecal incontinence?

It is difficult to assess the effectiveness of any one or combination of educational interventions due to many interacting variables, for example disability or cultural background. Patients can obtain information from a wide variety of sources. It is important to remember that patients or their carers may overemphasise the positive aspects of any educational intervention encountered because they feel vulnerable and many fear rejection if they give negative responses.

2.5.1 Studies considered for this review

Randomised and non-randomised comparative study designs were considered if they compared the effect of one educational intervention vs no educational intervention or a difference in educational intervention.

2.5.2 Clinical evidence

No studies were retrieved for this clinical question.

2.5.3 Cost-effectiveness evidence

No studies were retrieved for this clinical question.

2.5.4 Conclusions

As no clinical or cost effective evidence was retrieved for this clinical question the GDG used consensus development methods to propose recommendations (see section 2.6.2).

2.6 Recommendations

2.6.1 Active case finding

Faecal incontinence is a socially stigmatising condition. Healthcare professionals should actively yet sensitively enquire about symptoms in the following high-risk groups:

- **frail older people**
- **patients with loose stools or diarrhoea from any cause**
- **women following childbirth**
- **patients with neurological/spinal cord injury or disease**
- **patients with severe cognitive impairment**
- **patients with urinary incontinence**
- **patients with pelvic organ prolapse and/or rectal prolapse**
- **patients after colonic resection or anal surgery**
- **patients who have undergone pelvic radiotherapy**
- **patients with perianal soreness, itching or pain**
- **people with learning disabilities.**

Rationale: These high risk groups were identified through expert opinion as our literature search for this guideline did not include epidemiological evidence. However, in a review of patients' views, evidence indicated that few patients had experienced active enquiry about faecal incontinence or about progression of the condition if it were already known that the patient was incontinent (see section 2.3.2). Where healthcare professionals actively identify individuals with FI, interventions and appropriate management packages can be implemented.

2.6.2 Patient support

All staff working with people with faecal incontinence should be aware of both the physical and emotional impact that this symptom can have upon patients.

Rationale: As the literature review on patients views revealed, people with FI can feel alienated, misunderstood and hence defensive towards healthcare

professionals (section 2.3.2). This may hamper good communication and consequent delivery of care. The GDG wanted to emphasis the importance of communication skills and patient support for healthcare professionals providing treatment and care for people with FI.

Coordinated public health campaigns to raise public awareness of the causes, prevalence, symptoms and resources to treat faecal incontinence should be carried out in order to:

- **aid mutual support between people with faecal incontinence**
- **decrease the taboo surrounding faecal incontinence.**

Rationale: Although no specific effectiveness evidence on educational interventions was retrieved for this guideline, the GDG wanted to address the taboo surrounding faecal incontinence after considering the evidence in section 2.3.2. This taboo may act as a barrier to help-seeking, both from formal and informal support networks. Good information provision may directly improve patient well being by reducing uncertainty, relieving stress and contributing to empowerment. It may also change the pattern of service use in those whose faecal incontinence requires long term management.

Healthcare professionals should ensure that people with faecal incontinence:

- **are kept fully informed and have access to appropriate sources of information in formats and languages that are suited to an individual's requirements**
- **are offered access to or made aware of appropriate support groups (which may be alerting patients to likelihood of family and friends having similar experiences, community groups, or more formal organisations). Consideration should be given to cognition, gender, physical needs, culture and stage of life of the individual**
- **have the opportunity to discuss assessment, management options and relevant physical, emotional, psychological and social issues. Patients' views, experiences, attitudes and opinions about these issues should be actively sought.**

Rationale: As mentioned above, no specific evidence on the effectiveness of educational interventions was retrieved however the GDG wanted to recommend this level of support and information for patients after considering the evidence discussed in section 2.3.2. Public and patient education is needed regarding all aspects of faecal incontinence: prevalence, causes, diagnostic investigations and the range of management, treatments and care

available. More specific education may be delivered at each stage of the care pathway including information about what a test or investigation involves. Any information provided to patients should be in the appropriate format to meet the needs of the individual including the offer of support in understanding and interpretation. Additional help with education may be provided by other patients and carers, on a one to one basis through condition-specific or general support groups, self care programmes, or specialised internet chat rooms.

Information should be given regarding the nature of the assessment, test or investigation and the efforts that will be taken to overcome any embarrassment or cultural issues; also information detailing local NHS and social care resources, and patient and carer organisations.

2.6.3 Diagnostic overshadowing

When assessing faecal incontinence healthcare professionals should:

- **be aware that faecal incontinence is a symptom, often with multiple contributory factors for an individual patient**
- **avoid making simplistic assumptions that causation is related to a single primary diagnosis ('diagnostic overshadowing').**

Rationale: No specific evidence to support this recommendation was retrieved however, the GDG wanted to draw attention to the risk of assuming that all FI symptoms are secondary to a primary diagnosis, and therefore irreversible. The Disability Equality Duty[16] requires health professionals to take disability and consequent diagnostic overshadowing into account. This is important for this guideline as many causes of FI may be unrelated to a primary diagnosis. See chapter 7 for recommendations on high-risk groups.

2.6.4 Organisation of care

People who report or are reported to have faecal incontinence should have their care managed by healthcare professionals with the relevant skills, training and experience and who work within an integrated continence service (see 'Good practice in continence services', National Service Framework for Older People (www.dh.gov.uk)).

Rationale: No clinical questions were drafted on service organisation as it was considered outside the remit of the guideline. Therefore no literature searches were conducted to retrieve evidence on the effectiveness of service organisational interventions. However, as access to healthcare for people with

faecal incontinence can be haphazard and uncoordinated the GDG decided to explicitly support the recommendations made in the National Service Framework for Older People regarding the organisation of care for patients with FI. An integrated continence service should ensure planned referral pathways between primary care, continence service specialists, and colorectal, gastroenterology or other specialist care, as relevant to each patient.

2.7 Recommendations for research

The GDG identified the following two areas for research:

Would a self-care educational programme for patients and carers improve patient outcomes (symptom severity and quality of life)?

Why this is important:

Qualitative evidence suggests that mutual support groups improve patient quality of life. Moreover, there is evidence to suggest that information about management and treatment options are scarce, and that the taboo surrounding faecal incontinence hinders help-seeking behaviour. A self–care group programme to provide an integrated education and support programme covering topics such as support networks, coping strategies, identifying and provision of suitable products and treatments (including assessment and surgery options) may aid practical care and offer increased support, improving both physical and psychological outcomes.

In the study design patients with faecal incontinence and their carers in the community receiving standard care would be compared (at regular intervals) with a similar group exposed to the self-care programme. Assessed outcomes could include patient-rated outcomes (including symptom severity and quality of life).

The programme should be designed using qualitative research, patient input and advice from healthcare professionals. This programme should be piloted and refined after a process evaluation, incorporating views of health-care professionals, qualitative research and patients as well as effectiveness data. Regular refinement of the components would allow tailoring of the programme to the individual needs of the group. Evidence suggests that patients should benefit from mutual support and improved access to health care options, as well as better awareness of available management and treatment options, allowing (patients to be involved in) tailoring of individual care plans. It would provide community-based healthcare, involving healthcare professionals including continence specialist clinicians, clinical psychologists and integrate with social care. This type of patient/carer self-care programme may reduce the demand on secondary care. The views of those attending may shape future health/social care by reducing the number of admissions to residential care due to faecal incontinence.

Development of a valid and reliable tool to measure patient-rated outcomes including symptom severity and quality of life for people with faecal incontinence.

Why this is important:

Research into and treatment of faecal incontinence is hampered by the lack of a valid and reliable tool which has been refined through iterative piloting and

consultation stages. Such a tool would allow standardisation of outcome measures with which to compare results of interventions, allowing effectiveness of interventions to be genuinely compared, and accurately assessed.

Qualitative review for this guideline has highlighted paucity of information on patients' views and the crudeness of current evaluation of symptoms and outcomes. By involving users, healthcare providers and qualitative researchers in the design of a tool, the most relevant outcomes (to all groups) would be measured, including symptom severity and quality of life. Each group would bring different perspectives to the tool which would ensure that all relevant topics are covered and that the tool is useful to all groups.

3 Baseline assessment and initial management of faecal incontinence

Faecal incontinence is a distressing disorder, which may occur at any age; it affects both males and females. There are many causes and it is important to assess patients carefully to determine the optimal management pathway. This guidance has been divided into ‘baseline’ and ‘specialist’ assessment and ‘initial’ and ‘specialised’ management. The aim of this chapter is to provide an initial baseline strategy that will be effective for the many patients in primary and secondary care who might not need to progress onto the specialist assessment and specialised management options.

3.1 Baseline assessment introduction

Once patients have presented with a history of faecal incontinence, the majority never undergo formal functional and structural assessment of anorectal function. Such testing is likely only to be accessible through referral to a specialist. For many patients, a thorough basic assessment will provide enough information for the clinician to recommend an initial management strategy without recourse to more formal testing.

For the purposes of this guideline, we defined baseline assessment to include structured assessment, clinician examination and patient reporting of symptoms.

We undertook literature searches to retrieve RCTs, non-randomised controlled trials, cohort studies and before-after studies which measured the effect of performing an assessment vs not performing an assessment on patient outcomes. As only a small number of studies which met our inclusion criteria were retrieved for this section, we searched for assessment studies with an appropriate ‘gold standard’ to help inform the clinical questions.

3.2 What does a structured assessment add to the assessment of patients with faecal incontinence?

A step-by-step assessment should include a detailed history of the presenting complaint and physical examination. It should focus any further investigations, and therefore has the potential to avoid unnecessary procedures.

3.2.1 Studies considered for this review

A structured assessment was defined as an assessment protocol for patients reporting faecal incontinence which was designed to assess the contributing factors of FI and/or plan and manage their care.

3.2.2 Clinical evidence

We did not retrieve any appropriate studies.

3.2.3 Cost-effectiveness evidence

We did not retrieve any appropriate studies.

3.2.4 Conclusions

As no clinical or cost-effective evidence was retrieved for this clinical question the GDG used consensus development methods to propose a recommendation (see section 3.14).

3.3 What does clinician examination add to the assessment of the patient with faecal incontinence?

A physical examination is an important part of the assessment and is key to the management of faecal incontinence. It complements the history given by the patient, assists in excluding organic disease which might be the underlying cause of the symptoms and directs any subsequent investigations according to specific indications.

3.3.1 Studies considered for this review

Clinician examination was considered to cover visual and digital anorectal examination; abdominal and general assessment; neurological examination, clinical assessment and clinician evaluated symptom assessment.

3.3.2 Clinical evidence

We retrieved two diagnostic studies[17,18] that reported the diagnostic accuracy of clinical assessment (which usually encompassed history, general examination and anorectal examination) (evidence table 2, appendix D). Keating et al[17] used a combination of imaging and functional tests (referred to as 'special investigations') as a gold standard, while histology was used as the reference standard in Sultan et al[18].

Keating et al[17] report the sensitivity and specificity of clinical assessment for outcomes in patients referred to a specialist centre for assessment of faecal incontinence (N=50). Outcomes measured were structural damage to the sphincter and presence of associated causes of faecal incontinence (for example, rectal prolapse, haemorrhoids/local anal causes and rectocele). The outcomes sensitivities for clinical assessment ranged from 64–100% and the specificities ranged from 94–100% compared to 'special investigations'. Sultan et al[18] reports that both the sensitivity (56%) and specificity (33%) of detection of external sphincter defects by clinical assessment is poor in patients selected for surgical repair (N=12).

Both studies were focused on whether clinical examination could predict structural sphincter integrity. This only has relevance in the specialist setting where surgery is contemplated, which will seldom be the first option for management in the newly presenting patient. Therefore, the significance only becomes relevant at the specialist stage of investigations. The findings reported by Keating et al[17] suggest that inspection is as good as imaging at detecting vaginal or rectal prolapse. The results of both studies however should be interpreted with caution. As the study reported by Keating et al[17] took place in a specialist referral centre, it is not clear that the results can be replicated in a non-specialist setting. In addition, both studies are small and in

the case of Sultan et al[18], was undertaken in a highly selected group of patients.

Please note: studies reporting the diagnostic accuracy of digital examination vs manometry are reported in section 5.4.3.

3.3.3 Cost-effectiveness evidence

We did not retrieve any appropriate studies.

3.3.4 Conclusions

In addition to the two studies reported here, studies discussed in section 5.5.3 suggest that a significant proportion of patients who only receive clinical assessment may be inadvertently referred for the wrong surgical treatment. This suggests that in patients with faecal incontinence who are referred to specialist centres, clinical assessment alone cannot be relied upon to inform decisions on surgical options. However, in the initial management phase, clinical assessment is probably sufficient to determine which patients should be fast-tracked for specialist referral and which can proceed with initial management strategies. Recommendations on baseline assessment can be found in section 3.14.

3.4 What does patient-reporting add to the assessment of the patient with faecal incontinence?

A patient-centred approach is desirable, and quantification of the severity of symptoms experienced by patients is also valuable as an outcome measure of treatment. Despite being a subjective measure, the patient's perception of faecal incontinence is central to the management of this condition, which aims to improve the overall quality of a patient's life.

3.4.1 Studies considered for this review

Patient reporting was defined as any type of record or score which was completed by the patient (for example, symptom scores, diaries, questionnaires).

3.4.2 Clinical evidence

We did not retrieve any appropriate studies.

3.4.3 Cost-effectiveness evidence

We did not retrieve any appropriate studies.

3.4.4 Conclusions

As no clinical or cost-effective evidence was retrieved for this clinical question the GDG used expert opinion and consensus development methods to propose recommendations for baseline assessment. These can be found in section 3.14.

3.5 Research on patient views of assessment

A systematic review of patients' views about assessment and conservative management was undertaken. No high-quality studies were retrieved about baseline assessment.

3.6 Initial management introduction

Initial management will involve attempting to reverse or remedy factors identified as contributing to FI in the baseline assessment. Most are simple, low cost interventions which have a low potential to do harm. This may include addressing the patient's fluid intake, diet and medication, giving medication and addressing bowel habit and toilet access. Many patients will benefit from a combination of these measures. Products for containment and skin care advice should also be available for initial management purposes.

We undertook literature searches to retrieve RCTs, non-randomised controlled trials, cohort studies and before-after studies which compared the effect of one conservative intervention with another conservative intervention on patient outcomes.

3.7 What is the effectiveness of modifying diet or fluid intake in managing faecal incontinence?

3.7.1 Introduction

Some foods and drinks have components that are likely to alter bowel habit or stool consistency. The aim of dietary and fluid intervention is to promote a regimen that helps maintain an appropriate stool consistency and timing of defaecation. Many patients report clinically that the timing of food intake is important and eating triggers the gastro-colic response and a consequent call to stool. Many alter their diet or restrict intake in an effort to limit FI[19].

Some foods (for example, prunes, figs and rhubarb) contain naturally occurring laxative compounds. Artificial sweeteners such as sorbitol and other non-absorbable sugars also have laxative properties. There is a growing interest in the possible value of probiotics ('good bowel bacteria') and prebiotics (the foodstuffs that allow these bacteria to multiply in the bowel): these are currently classified as foods (rather than drugs) in the UK.

Many older and/or disabled patients have FI as a result of faecal impaction of hard stool with overflow leakage. Fibre in food or as supplements is often recommended, but must be used with great caution in individuals who have impaction or limited mobility and could, in theory, worsen symptoms.

This section reviews the evidence for any systematic change in content or timing for diet or fluids in managing FI.

3.7.2 Studies considered for this review

We considered RCTs, non-randomised controlled trials, cohort studies and before-after studies. We considered fibre supplements or restriction, probiotics, prebiotics, synbiotics, sorbitol, fructose, modification of eating patterns, any combination of dietary interventions and comparison of the effect of one method of modifying food or fluid intake with another method.

3.7.3 Clinical evidence

One randomised study[20] involving 39 adult volunteers with faecal incontinence and loose stool (13 in each of the three arms), evaluated the effects of a fibre supplement containing psyllium (metamucil), gum arabic or a placebo (0.25g of pectin/day) for 31 days (evidence table 3, appendix D). The dose reported for psyllium and gum arabic was 25g/day but they also report that the dose was progressively increased over the first 6 days of supplementation to

decrease the risk of flatus and worsening faecal incontinence (but the study does not mention what this progressive increase was). The fibre or placebo was mixed in 360 ml of half strength fruit juice and divided into two servings to be ingested at the morning and evening meal. The baseline period was eight days prior to the intervention. The intervention lasted 31 days and follow-up was until the end of the intervention. Three subjects from the psyllium group, two from gum arabic and three from the placebo group took and maintained some type of anti-diarrhoeal medications (atropine chloride, loperamide hydrochloride, bismuth subsalicylate or kaolin pectin) during both periods. The proportion of stools that were incontinent in the groups ingesting fibre supplements during the intervention period was less than half that of the placebo group (psyllium group: 0.17 ± 0.07; gum arabic group: 0.18 ± 0.07; placebo group: 0.50 ± 0.05; p= 0.002). However, this probably overstates the significance since the sample size was too small for the chosen statistical method (ANOVA). Outcomes for stool frequency, weight of stools, fibre fermentation and tolerance and in vitro fibre fermentation did not show significant differences between groups.

One randomised cross-over trial was identified[21] (evidence table 5, appendix D). This study comprised of 47 adult patients referred to an outpatient service with chronic faecal incontinence. The patients were randomised to loperamide, dietary advice for a low residue diet and placebo supplement or to loperamide, dietary advice for a balanced diet with a fibre supplement. Each intervention was assessed for six weeks and then crossed over to the other intervention. The results of this study [21] found that there was no significant difference between loperamide with a fibre supplement compared with loperamide with a low residue diet and a placebo supplement for faecal incontinence scores.

No appropriate evidence was found comparing different fluid intakes.

3.7.4 Cost-effectiveness evidence

No cost-effectiveness evidence was found.

3.7.5 Conclusions

One small RCT suggests that dietary supplementation with psyllium or gum arabic appeared to decrease the percentage of incontinent stools in people with faecal incontinence related to loose stools. Another larger RCT[21] found no difference between patients receiving loperamide with a low residue diet or with a fibre supplement. However, marked variability was found between individual patient results indicating that an individual assessment of fibre content could be beneficial for patients treated with loperamide. The recommendations on diet and fluid intake can be found in section 3.15.2.

3.8 What is the effectiveness of modifying drug administration in managing FI?

3.8.1 Introduction

Anti-diarrhoeal Medication

Patients will typically receive medication to treat faecal incontinence (FI) at one of two extremes of the clinical pathway – either as a first step in primary care or as part of a deliberate plan of management by a specialist. In either context it may represent the sole treatment option, or be an adjuvant part of another therapy. Anti-diarrhoeal medication is suitable for empirical use in primary care and for specialist use. In fact, in the former situation, it could be argued that failure to respond to these medications should be the precursor to specialist referral and functional assessment.

One advantage of the use of loperamide in particular (but also co-phenotrope) is that the drug(s) can be used as both regular treatment, but also on an as-required basis. The drugs are usually used as single agents for routine treatment of faecal incontinence.

Sphincter modifying drugs

A novel development is the use of medication to alter the performance of the anal sphincter mechanism, primarily targeted at raising sphincter pressures. These drugs remain developmental at present and none has reached the general drug tariff.

Drugs to promote bowel emptying

Some patients have faecal incontinence secondary to faecal loading or constipation. Laxatives or rectal evacuants may be used to promote complete rectal emptying.

Side effects of other medications

Many different drugs, usually prescribed for unrelated conditions, have possible side-effects on gut motility or stool consistency. For example, some diabetic oral therapies achieve effect by inducing diarrhoea, which in theory could compromise continence. Iron supplements and non-steroidal anti-inflammatory drugs may cause loose stool in some patients. Many analgesics have constipating side-effects. Changing medications or modifying the regimen may alter episodes of FI in these patients.

Fibre studies

Changes in fibre intake may be achieved by changing diet or use of fibre supplements.

3.8.2 Studies considered for this review

We considered RCTs, non-randomised controlled trials, cohort studies and before-after studies which compared the effectiveness of one drug with placebo, no drugs or another drug.

Two studies[20,21] were retrieved reporting the use of fibre at managing FI. These studies are discussed in section 3.7.3.

One study[22] was retrieved that used a combination of anti- diarrhoeal medication and laxatives or enemas in a nursing home environment. This study is discussed in section 7.1.3.

3.8.3 Clinical evidence for anti-diarrhoeal/constipating agents

Three randomised crossover studies met our inclusion criteria[23-25] (evidence table 4, appendix D). Read et al investigated the effectiveness of 6 mg of loperamide twice per day in 26 adults with persistent diarrhoea for more than 3 months, who complained of episodes of FI and severe urgency sufficient to limit their life style[23]. There were a variety of causes of incontinence with irritable bowel syndrome in 11 of the 26 being the most common. This study showed a significant reduction in the episodes of incontinence and urgency during the use of loperamide, but with an increase in the number of adverse events[23].

Sun et al investigated the effectiveness of 4 mg of loperamide oxide twice per day in 11 adults with chronic diarrhoea and faecal incontinence[24]. Any participant with a volume of diarrhoea greater than 500 ml per day was excluded from this study. The cause of FI was irritable bowel syndrome in nine of the participants and as a consequence of surgery in the other two participants. This study used a patient rated visual analogue score for measuring diarrhoea and FI[24]. There was a significant reduction in the score for diarrhoea and urgency during use of loperamide oxide but no significant difference in the score for FI or abdominal pain.

Hallgren et al[25] compared the effectiveness of loperamide hydrochloride with a placebo in a randomised crossover study of 28 participants with FI who had had ileo-anal pouch formation for ulcerative colitis. The covering stoma had been closed between 6 and 72 months previously. Twenty-four of the 30 participants had been using loperamide before entry into the study. The study showed that the use of loperamide several months after ileo-anal pouch formation improved anal resting pressure but not maximal squeeze pressure. The study also showed that the incidence of soiling at night was significantly less in the loperamide group compared to the placebo (p=0.007). There was no significant difference in soiling or leakage during the day.

3.8.4 Cost-effectiveness evidence for anti-diarrhoeal agents

No cost-effectiveness evidence was found.

3.8.5 Conclusions

There is a lack of evidence of good quality data on the effectiveness of anti-diarrhoeal agents on faecal incontinence. Loperamide may help improve a patient's faecal incontinence but with some minor side effects. Recommendations on initial management can be found in section 3.14.

3.8.6 Clinical evidence for drugs enhancing sphincter tone

Three randomised crossover studies were identified (evidence table 4, appendix D). The first two studies investigated a 10% gel of phenylephrine. In one study[26] the 12 participants had had an ileoanal pouch constructed for ulcerative colitis between 1 and 13 years previously. The episodes of faecal incontinence had been present for a similar amount of time.

In the other study[27] the 36 participants had passive FI and a structurally intact sphincter. The episodes of FI had been present for a mean of 5 years. In both studies, patients who were using loperamide before the study were permitted to continue using it during the trial as it had not controlled the episodes of FI. The order of interventions was randomised; they were given one intervention for 4 weeks after which there was a 1 week washout period before the next intervention. There were no side effects from phenylephrine reported for one study[26]. The other study reported mild dermatitis in three of the 36 participants when receiving the phenylephrine gel and no dermatitis when receiving the placebo[27]. The difference was not significant and no other side effects were reported. One study[27] showed no significant difference between phenylephrine and placebo in the change of incontinence score, percentage improvement in symptom scores or maximum anal resting pressure in patients with 'idiopathic' FI. The study[26] in patients with FI and an ileoanal pouch showed significantly more participants with a complete cessation of FI when receiving the phenylephrine gel (four compared to none) and more participants perceiving the gel to be better, but the difference was not significant. Incontinence and symptom scores were only reported for the first treatment period because the authors felt the washout period between interventions was not sufficient. The maximum anal resting pressure was significantly higher in the phenylephrine group. This medication is not licensed for this in the UK.

Kusunoki et al[28] conducted a randomised cross over study with a total of 17 adult patients with ulcerative colitis (n=8) or adenomatosis coli (n=9) which had been previously treated with surgical construction of an ileoanal pouch. Patients were randomised to sodium valproate 400 mg four times a day for 7 days or placebo for 7 days. The results of the study (follow up 17 days)

showed that more people achieved full continence, less frequent defaecation, and less perianal skin problems with sodium valproate; however the significance was not reported. This medication is not licensed for FI in the UK.

3.8.7 Cost-effectiveness evidence for drugs enhancing sphincter tone

No cost-effectiveness evidence was found.

3.8.8 Conclusions on drugs enhancing sphincter tone

Phenylephrine gel showed no impact on incontinence scores and resting anal pressure in faecally incontinent patients (not related to irritable bowel syndrome) with a structurally intact sphincter. However, the evidence available was only from one study of 36 participants. Phenylephrine gel may relieve incontinence in faecally incontinent patients who had previously had an ileoanal pouch and had tried loperamide without success. Recommendations on modifying drug administration can be found in section 3.15.4.

3.8.9 Clinical evidence for side effects of other drugs

No clinical evidence was retrieved.

3.9 What is the effectiveness of any combination of dietary, fluid or drug administration in managing FI?

3.9.1 Introduction

In clinical practice, dietary, fluid and drug regimens may all be modified at the same time or in combination.

3.9.2 Studies considered for this review

We considered RCTs, non-randomised controlled trials, cohort studies and before-after studies for inclusion which compared one combination of modifying food, liquid and drug administration with a different combination of modifying food, liquid and drug administration or no intervention.

3.9.3 Clinical evidence

No clinical evidence was retrieved.

3.9.4 Cost-effectiveness evidence

We did not retrieve any appropriate studies.

3.9.5 Conclusions

As no clinical or cost-effective evidence was retrieved for this clinical question the GDG used consensus development methods to propose a recommendation (section 3.15).

3.10 What are the most effective products (absorbent products, containment and plugs) to manage faecal incontinence?

3.10.1 Introduction

People experiencing faecal incontinence often need to wear a product (absorbent product or plug) for containment. This may be before consulting a health professional to assess their symptoms. Frequently a product will be worn 'just in case' an episode of FI is experienced. Once the problem has been assessed it is likely that management other than products for containment will be initiated. In addition, products will often still be worn to boost self-confidence or when the FI is not amenable to treatment.

Disposable, absorbent products are more suitable and preferable to washable products. Soiling of clothing and loss of solid stool can usually be contained within underwear and pads, but it is difficult to contain profuse diarrhoea or hide unpleasant odours. This should usually be preventable by planning better bowel management programmes.

There are many different treatments for FI but not all patients can be cured and some are left to manage intractable FI. Devices such as anal plugs or faecal collectors have limited use, and are generally only acceptable to certain populations. Although anal plugs are not tolerated by all patients, they may be helpful in preventing FI in selected groups, such as patients with neurological impairment who have less anal sensation. Both the anal plug and faecal collectors may possibly be of help in palliative care; the collector in situations where a patient has acute profuse diarrhoea (for example in intensive care situations).

3.10.2 Studies considered for this review

We considered randomised controlled trials, randomised crossover studies or systematic reviews of randomised controlled trials and/or randomised crossover studies, non-randomised controlled trials, before and after studies and cohort studies which compared: the effectiveness of absorbent products or anal plugs with no intervention; one type of absorbent product with another; or one type of anal plug with another. The review for this clinical question included studies of incontinent patients even if the proportion with faecal incontinence was less than 50% or unknown.

3.10.3 Clinical evidence

Four randomised studies evaluating absorbent products were identified: two investigated doubly incontinent patients[29,30], one investigated people with urinary, faecal or double incontinence[31] and the last did not specify the type of incontinence[32] (evidence table 5, appendix D). No studies in just faecally incontinent participants were identified. Two of the studies compared disposable with reusable absorbent products [29,32], one compared diapers with underpads in hospitalised patients[31] and one compared absorbent pads with undersheets in bedridden older patients[30].

Disposable vs reusable body worn products

One study showed that participants using the disposable products (n=34) had significantly better skin assessment scores and significantly more participants with an improvement in skin condition than those using reusable (n=34) products[29]. The reusable products were worn during the day but taken off at night. However, the mean number of episodes per day of urinary incontinence (6.7) was higher than the mean number of episodes per day of faecal incontinence (1.2). This could mean that disposable pads have an effect in patients with urinary incontinence but it is difficult to assess whether they have an effect in FI. The other study showed no difference in skin condition[32]. There was no indication as to the type of incontinence these participants had.

Bodyworn products vs underpads/bedsheets

A single RCT[31] of 166 adult incontinent patients at an acute hospital compared five different absorbent products. The randomised comparison was between diapers and underpads. However, there were also cross-over period comparisons within each randomised arm between polymer and non-polymer products. And in one centre cloth underpads were used instead of disposable for the entire study period. Skin integrity scores were reported by assessing five skin areas for redness, integrity and patient symptoms. Points assigned in each in a ranked order where 0 represented no alteration or symptoms. Mean skin integrity scores were significantly different between the five arms for redness ($p=0.0001$) and integrity ($p=0.003$), with the polymer diaper having the best outcome. Mean skin integrity scores for patient symptoms were not significantly different between the groups. There was no significant difference in skin integrity scores when comparing diapers with underpads.

Only 29% of the participants were routinely doubly incontinent and it is not clear how many of the new onset patients would have had FI, UI or both. The difference between the episodes of faecal and urinary incontinence was not recorded and no results were provided for the FI sub-group. Therefore it is difficult to draw any conclusions as to the effect of these products on participants with FI.

Absorbent bed pads vs cotton bedsheets

One randomised cross-over study[30] compared three interventions: absorbent bed pads, absorbent bed pads impregnated with an antimicrobial agent and

heavy cotton bed pads (N=32). Participants using the unimpregnated absorbent bed pads had significantly fewer incidences of wet skin than the group using the bed pads. They also had significantly fewer incidences of dry skin and more incidences of damp skin than the heavy cotton bed pads group; however, this was believed to be as a result of perspiration. These outcomes were heavily influenced by the urinary incontinence.

Anal plugs

One Cochrane review was identified with four studies[33] (evidence table 5, appendix D). Two studies[34,35] were in children and were therefore out of scope of the guideline. The two other studies included adults. One study looked at both children and adults. Some data was available for adults alone but due to recruitment problems the target of 2:1 randomisation between groups was not achieved, with three times as many adults in the intervention arm. The other had a high dropout rate and incomplete data. Both studies were excluded from our review.

3.10.4 Cost-effectiveness evidence

The approach taken was the same as for the review of clinical evidence – because of the lack of relevant studies; we included studies of incontinent patients even if the proportion with faecal incontinence was less than 50% or unknown. We found three economics studies that evaluated incontinence containment products (evidence table 8, appendix D).

One study[36] was based on a matched-pair RCT of 68 elderly care home residents with urinary and/or faecal incontinence comparing disposable with re-usable bodyworns. They found the cost of disposables to be lower (product and laundry costs), although not significantly so (£1.90 vs £2.30 per day). There was an improvement in skin quality in the disposable arm compared with deterioration in the reusable arm. This suggests that disposable dominates reusable, although the proportion of patients with FI was not reported.

A second RCT[37] of 166 adult incontinent patients at an acute hospital compared five different absorbent products. The randomised comparison was between diapers and underpads. However, there were also cross-over period comparisons within each randomised arm between polymer and non-polymer products; and in one centre, cloth underpads were used instead of disposable for the entire study period. There were not significant differences between the randomized arms. They found polymer underpads dominated nonpolymer underpads; that is, the former had similar skin scores and a lower cost (products, staff time and laundry) (£2.40 vs £3.20 per clean-up episode). Polymer diapers were more effective than nonpolymer diapers but at an increased cost (£3.10 vs £2.80). It is difficult to assess whether the health gain justifies the increased cost since health outcomes were not measured in terms

of QALYs. A limitation of this study is that it does not clearly report the proportion of patients with *faecal* incontinence.

A Cochrane review[38] conducted in the UK developed an economic evaluation from a systematic review of RCTs, which included the two studies just mentioned and four others. They made the general conclusion that disposable products were more effective but more costly than nondisposable products, however, disposable bodyworns had the lowest cost for strategies other than nondisposable underpads. Patients had significantly fewer skin complaints for disposable bodyworns compared to nondisposable bodyworns and had a lower cost. This suggests that disposable bodyworns dominate nondisposable bodyworns, although disposal costs were not measured. There was not enough evidence to compare bodyworns with underpads.

The two RCTs were conducted in a US setting where care pathways and prices are often very different to those in the UK NHS, although the UK Cochrane review reached similar conclusions using UK prices.

3.10.5 Conclusions

No evidence was found to determine whether absorbent products were effective in containing faecal incontinence. Some evidence exists for participants with both faecal and urinary incontinence but the results appear to be biased by the urinary incontinence. No good quality randomised evidence of the effectiveness of anal plugs in adults was found.

Cost-effectiveness: It is difficult to assess whether the health gain from disposable products is high enough to justify the extra cost. One study suggested that disposable bodyworns could be cost-saving compared with nondisposable bodyworns.

Recommendations on products can be found in section 3.15.5.

3.11 What are the most effective skin care products to manage faecal incontinence?

3.11.1 Introduction

The majority of people with faecal incontinence (FI) do not experience regular sore skin around the anus. However, certain patients seem to be prone to this, for example those with general frailty, immobility, poor health, continuous passive soiling or profuse diarrhoea. Patients with double incontinence may experience sore skin as urine and faeces can interact, resulting in a moist environment in the anal area. Other contributing factors include skin conditions, diabetes mellitus and patients who have had their colon removed, so that the stool which leaks is ileal contents.

In such circumstances, if no products are used on the patient's skin there may be redness, soreness and even skin breakdown which can contribute to the development of a pressure sore. Keeping the skin clean and dry is important in maintaining skin integrity. In residential settings, staff adherence to skin care protocols is essential to maintain patients' skin integrity.

3.11.2 Studies considered for this review

RCTs, non-randomised controlled trials, cohort studies and before-after studies which compared: the effectiveness of skin care products with no intervention or one type of skin care product with another were retrieved for this review. The populations included were adults with faecal incontinence. This included people with double incontinence (that is, with urinary and faecal incontinence).

3.11.3 Clinical evidence

Two randomised controlled trials were identified[39,40] (evidence table 7, appendix D). Both were in long term elderly hospital or nursing home patients. A foam cleanser was compared to water in one study where participants (N=93) were predominantly doubly incontinent[40]. Two creams (Sudocrem and zinc oxide) were compared in the other study[39]. Although the type of incontinence was not reported the 67 participants appear to have had some faecal incontinence.

Using a foam cleanser compared to soap and water resulted in significantly more participants retaining healthy skin and significantly fewer participants with a deterioration in skin condition after two weeks of intervention[40]. Using Sudocrem resulted in a significant reduction in skin redness after 1 week and 2 weeks of treatment when compared to a zinc oxide cream.

3.11.4 Cost-effectiveness evidence

The approach taken was the same as for the review of clinical evidence – because of the lack of relevant studies, we included studies of incontinent patients even if the proportion with faecal incontinence was less than 50% or unknown. We found three economics studies that evaluated incontinence cleansing products (evidence table 8, appendix D).

A study of 12 elderly care home residents with FI[41] found that a no-rinse incontinence cleanser reduced carer time and costs (by £15 per patient per week) compared with soap and water. The study was based on a subgroup of patients from a cohort study, but its design and sample size were not clearly stated. Health outcomes were not reported for the FI subgroup that was the subject of the costing analysis.

The second study[42] involved a case series of 19 elderly care home residents with FI. They found that a combined cleanser and barrier cream dominated separate cleanser and barrier cream; the former significantly reduced erythema and pain. Carer time was also reduced and subsequently so were costs by £85 per patient per year. The before and after study design is clearly open to bias and this was compounded by the absence of statistical analysis for carer time or cost.

A third study[43] evaluated 271 elderly care home residents with urinary and/or faecal incontinence in four cohorts undergoing different skin care interventions. Cost of product and staff time was substantially lower for a barrier film than for either of two brands of ointment (£1.10-£2.70 vs £6.00-£6.10 per week). There was no significant difference in incontinence dermatitis (3.0%-3.9% vs 2.6%) but the incidence was low and therefore the study was too small to detect a difference. Thrice weekly use of the film was, not surprisingly, less costly than once daily (£1.10 vs £2.70).

All three studies were in a US setting where care pathways and prices are often very different to those in the UK NHS.

3.11.5 Conclusions

Foam cleanser was better than soap and water in preventing skin deterioration in doubly incontinent elderly hospital or nursing home residents. Sudocrem improved skin condition over two weeks compared to a zinc oxide cream in incontinent elderly hospital patients. However, the study gave no indication what proportion of the participants had faecal incontinence.

Cost-effectiveness: Three poor quality studies indicated:

a. Non-rinse incontinence cleanser was cost-effective

b. Combined cleanser and barrier was cost-effective compared with separate products

c. A barrier film was cost-effective compared with ointments.

Recommendations on skin care can be found in section 3.15.5.

3.12 What is the best practice goal setting (including involving patients) for satisfactory treatment of faecal incontinence?

3.12.1 Introduction

For patients whose symptoms do not improve after a course of treatment, or if patients' symptoms had reached a plateau of improvement, it can be difficult to decide when and whether to stop treatment or to change to another modality or combination of modalities and whether to refer on or to request further investigations.

3.12.2 Studies considered for this review

Studies considered for this clinical question evaluated the best practice goals for satisfactory treatment of faecal incontinence.

3.12.3 Clinical evidence

We did not retrieve any appropriate studies.

3.12.4 Cost-effectiveness evidence

We did not retrieve any appropriate studies.

3.12.5 Conclusions

As no appropriate evidence was retrieved for this clinical question, the GDG used expert opinion and a consensus development exercise to develop recommendations on initial management (see section 3.15.6).

3.13 Research on patient views of initial management

A systematic review of patients' views about initial management was undertaken. One good quality study about management was found[15] (evidence table 6, appendix D).

This Australian study conducted a series of focus groups and interviews with 82 consumers and carers from culturally and linguistically diverse groups from rural/metropolitan/remote areas. All participants raised similar issues about managing FI and in particular, continence products. These issues can be summarised as follows:

- participants found it difficult to know where to seek information. Sources identified by participants included: continence product packaging, books, magazines, internet, social networks such as social clubs or church groups, health professionals and state-funded subsidy schemes

- participants highlighted the importance of receiving care from healthcare professionals who are able to respond to patients' feelings of vulnerability and embarrassment with sensitivity.

- participants stated they had a lack of faith in health professionals' knowledge and advice, and ability to empathise with the condition

- participants stated they had difficulty in identifying products. Often they were unaware that professional assessment and advice for management existed, or they received inconsistent advice. Patients' choices were limited by cost, availability, quality, comfort and design when choosing products.

Suggestions for improvement included detailed product information, such as reliable estimates of working capacities of continence products, and instructions for use. General information about incontinence in simple language and better marketing and distribution of information sources in general were also identified as a potential improvements.

3.14 Recommendations on baseline assessment

Healthcare professionals should ensure that people who report or are reported to have faecal incontinence:

- **receive a focused baseline assessment before any treatment is considered**
- **receive all appropriate initial management before any specialised treatment.**

Rationale: No specific evidence evaluating the effectiveness of different protocols of assessment and management was retrieved. However, after considering the evidence for the other clinical questions on assessment and management of faecal incontinence, consulting with expert advisors and participating in a consensus development exercise the GDG decided to recommend a step-wise approach to the management of patients with FI. Most people with FI will present in Primary Care, and many problems can be addressed here without immediate onward referral. We do not have specific evidence on cost-effectiveness but logically the employment in the initial stages of simple, safe and relatively cheap interventions in the community will be more cost-effective than more specialised assessment and treatment.

Healthcare professionals should carry out and record a focused baseline assessment for patients with faecal incontinence to identify the contributory factors. This should comprise:

- **relevant medical history (see appendix I)**
- **general examination**
- **anorectal examination (see appendix I)**
- **cognitive assessment, if appropriate.**

Rationale: After considering the retrieved evidence in section 3.3.2 and 3.14, consulting with expert advisors and participating in a consensus development exercise, the GDG decided to recommend a focused baseline assessment for all patients reporting faecal incontinence largely based on their expert opinion. The specific components of the baseline assessment listed above and in Appendices I, J, K and L can provide valuable information in formulating not only the causes of faecal incontinence, but also the impact on the patient such as coping strategies and ability to function on a daily basis. The findings from

the baseline assessment will also help to plan an appropriate management strategy.

Patients with the following conditions should have these addressed with condition-specific interventions before progressing to initial management of faecal incontinence:

- **faecal loading**
- **treatable causes of diarrhoea**
- **warning signs for lower gastrointestinal cancer (see NICE clinical guideline on referral for suspected cancer (www.nice.org.uk/CG027))**
- **rectal prolapse or third degree haemorrhoids**
- **acute anal sphincter injury**
- **acute disc prolapse.**

Rationale: Although no specific evidence was retrieved on evaluating the effectiveness of addressing underlying causes of FI, after considering the evidence for assessment and management of faecal incontinence (discussed chapters 3-5), consulting with expert advisors and participating in a consensus development exercise, the GDG decided to recommend that patients with the conditions listed above should be offered condition-specific interventions before being offered initial management options to treat faecal incontinence. These conditions will either prevent successful resolution of FI, or warrant further investigation in their own right.

3.15 Recommendations on initial management

Healthcare professionals should inform patients that a combination of initial management interventions is likely to be needed to address faecal incontinence. The specific management intervention(s) offered to patients should be based on the findings from baseline assessment, tailored to individual circumstances and adjusted to personal response.

Rationale: No specific evidence on combinations of management interventions was retrieved. After considering the evidence for all the clinical questions in section 3.6, consulting with expert advisors and participating in a consensus development exercise the GDG decided that because the symptom of FI often has multiple contributing factors, this will often mean several interventions are appropriate for each patient. The specific combination will depend on the findings of the assessment. It is not

appropriate to refer most patients for more specialised assessment until these basic factors have been addressed.

3.15.1 Bowel habit

Initial management should address bowel habit, aiming for ideal stool consistency and satisfactory bowel emptying at a predictable time.

A bowel habit intervention should contain the following elements:

- **encouraging bowel emptying after meals (to utilise the gastro-colic response)**
- **ensuring toilet facilities are private, comfortable and can be used in safety with sufficient time allowed (see 'Essence of care' www.dh.gov.uk and 'Behind closed doors: using the toilet in private' www.bgs.org.uk)**
- **teaching patients to adopt a sitting or squatting position where possible while emptying the bowel**
- **teaching patients techniques to empty the bowel without straining.**

Rationale: No evidence evaluating the effectiveness of interventions to address bowel habit was retrieved. After consulting with expert advisors and participating in a consensus development exercise the GDG decided to recommend the aims and principles of bowel habit interventions. If complete rectal emptying at a predictable time can be achieved many patients will thereby avoid episodes of FI. Evidence on patient views in section 2.3 in chapter 2 was also considered by the GDG who also wanted to draw attention to ensuring that patients are treated with dignity at all times.

3.15.2 Diet and fluid intake

Healthcare professionals should recommend a diet that promotes an ideal stool consistency and predictable bowel emptying. When addressing food and fluid intake healthcare professionals should:

- **take into account existing therapeutic diets**
- **ensure that overall nutrient intake is balanced**
- **consider a food and fluid diary to help form a baseline**

- **advise patients to modify one food at a time if attempting to identify potentially contributory factors (see appendices K and L)**
- **encourage patients with hard stool and/or clinical dehydration to aim for at least 1.5 litres intake of fluid per day. Urinary output should be measured where intake is in doubt**
- **consider the opportunity to screen patients for malnutrition, or risk of malnutrition (see NICE clinical guideline on nutrition support (www.nice.org.uk/CG032)).**

Rationale: After considering the evidence in section 3.7.3, consulting with expert advisors and participating in a consensus development exercise, the GDG decided to recommend a diet which promotes ideal stool consistency and bowel emptying, as food and fluids may affect faecal consistency and amount the effect of different foods will vary between individuals. These recommendations offer a framework on which to make appropriate adaptations to meet the individual person's needs. Other than fibre no specific evidence was retrieved defining the components of this diet. However, the GDG wanted to highlight the importance of ensuring that any existing therapeutic diets should be taken into account and that the overall nutrient intake should be balanced when advising patients and/or carers. Biochemical deficiency is common in older people particularly those in residential care[44]. In order that the effects of this diet be optimised, a food and fluid diary should be considered to establish a baseline and patients should be encouraged to modify one food at a time in order to establish contributory factors. Although there was no evidence on the effectiveness of specific amounts of fluid to be consumed for patients with hard stool and/or clinical dehydration, the GDG considered that 1.5 litres was an appropriate amount for these patients to aim for. Finally, the GDG wanted to draw specific attention to the risk of malnutrition which may be confounded by some dietary changes.

3.15.3 Toilet access

When addressing toilet access in any home or healthcare setting:

- **locations of toilets should be made clear**
- **equipment to help people to gain access to a toilet should be provided**
- **advice should be given to patients on easily removable clothing to reduce time needed for access**
- **if patient is dependent on others for accessing the toilet, help should be readily available**

- **privacy and dignity should be maintained at all times**
- **if appropriate, patients should be referred to healthcare professionals for assessment of home/mobility.**

Rationale: No evidence evaluating the effectiveness of interventions to address toilet access was retrieved. After consulting with expert advisors and participating in a consensus development exercise the GDG decided to recommend some simple, good practice points for patients with limited mobility. Difficulty with toilet access can make the difference between urgency and urge FI. People with limited mobility and/or disabilities can find it difficult to reach the toilet, transfer, adjust clothing, or sit stably and in comfort for long enough to achieve complete bowel emptying.

3.15.4 Medication

When reviewing medications, healthcare professionals should consider alternatives to drugs that may be contributing to faecal incontinence (see appendix J).

Anti-diarrhoeal medication should be offered to patients with loose stools and associated faecal incontinence once other causes for loose stools (such as excessive laxative use and dietary factors) have been excluded. Anti-diarrhoeal medication should be prescribed in accordance with the Summary of Products Characteristics.

Loperamide is the anti-diarrhoeal drug of first choice and can be used long-term in doses from 0.5 mg to 16 mg per day or as required. Patients who are unable to tolerate loperamide should be offered codeine phosphate, or co-phenotrope (Lomotil ®)[2].

Loperamide should not be offered to patients with:

- **hard or infrequent stools**
- **acute diarrhoea without a diagnosed cause**
- **an acute flare-up of ulcerative colitis.**

[2] Check the Summary of Products Characteristics (SPC) for current licensed indications. Informed consent is needed when using outside the licensed indications. This should be discussed and documented in the notes.

When loperamide is used it should be:

- **introduced at a very low dose and the dose should be escalated, as tolerated by the patient until the desired stool consistency has been achieved**
- **taken as required by the patient with faecal incontinence**
- **advised that patients can adjust the dose and/or frequency up or down in response to stool consistency and lifestyle.**

If a finer modification of dose is required loperamide syrup should be considered.

Rationale: After considering the evidence retrieved for section 3.8, consulting with expert advisors and participating in a consensus development exercise, the GDG decided to develop recommendations which both consider modifying drugs contributing to faecal incontinence and offering anti-diarrhoeals which are the drugs of first choice in treating faecal incontinence. Once other causes of loose stools have been excluded, anti-diarrhoeal should be offered. We do not have specific evidence on cost-effectiveness of anti-diarrhoeal drugs but the relatively low daily cost of drugs such as loperamide would suggest that for patients that find the drugs effective, they are highly cost-effective. Alternatives are available for people unable to tolerate this drug. The GDG used their expert opinion to recommend several good practice points for the administration of loperamide, relating to contraindications, long term use and modification of dose. While there was no specific evidence on modifying drugs which are contributing to FI, the GDG decided that if possible, alternative medications should be prescribed.

3.15.5 Coping strategies for symptomatic patients

During assessment and initial management patients should be offered advice on coping strategies including:

- **continence products and information about product choice, availability and use**
- **skin care**
- **where to get emotional and psychological support. In some cases counselling or psychological therapy to foster acceptance and positive attitudes**

- **how to talk to friends and family**
- **strategies such as planning routes around public conveniences if patients have to travel.**

Patients should be offered:

- **disposable body-worn pads and disposable bed pads if needed**
- **pads in quantities appropriate to the individual's continence needs. Arbitrary ceilings are inappropriate**
- **anal plugs for patients who can tolerate them**
- **a choice of pad styles and designs**
- **skin care advice; both skin cleansing and protection**
- **advice on odour control and laundry needs.**

The use of reusable absorbent products in the management of faecal incontinence is not generally recommended.

Rationale: After considering the evidence retrieved on patient views in section 2.3 in chapter 2 and 3.10 and 3.13 in this chapter, consulting with expert advisors and participating in a consensus development exercise, the GDG decided to recommend that patients with FI should be offered a number of coping strategies during the baseline assessment and initial management stage of the patient pathway. Uncontrolled FI can be depressing, demoralising and detrimental to social activities. Some interventions may take time to be effective. Sources of information on practical coping are few. Therefore, it is important for healthcare professionals to enable coping while patients undergo initial management. Anecdotal evidence would suggest that access to continence products can allow patients to lead active lives with substantial improvement in quality of life. The supply of such products is therefore likely to be cost-effective. However, if poor-fitting products are provided or products are provided in inadequate numbers, or products have to be regularly laundered then activity and quality of life are likely to be significantly diminished.

3.15.6 Review of treatment

After each intervention healthcare professionals should ask patients if faecal incontinence has improved. Patients continuing to experience symptoms should be:

- **involved in discussions about further treatment options (including effectiveness and adverse effects) or alternative coping strategies**
- **asked if they wish to try further treatments.**

Rationale: Evidence retrieved on patient views in section 2.3 in chapter 2 and 3.10, 3.11 and 3.13 in this chapter was considered by the GDG. After consulting with expert advisors and participating in a consensus development exercise the GDG decided to recommend that the wishes of patients should be checked at each stage of the care pathway. Not all patients want automatically to progress through a hierarchy of assessment and treatment. Some are happy with reassurance that there is no serious pathology underlying symptoms.

3.15.7 Long-term management

Healthcare professionals should provide the following to symptomatic patients who either do not wish to continue with active treatment or who have intractable faecal incontinence:

- **advice relating to the preservation of dignity and where possible independence**
- **psychological and emotional support, possibly including referral to counsellors or therapists if it seems likely that patients' attitude towards their condition and their ability to manage and cope with faecal incontinence could improve with professional assistance**
- **at least 6-monthly review of symptoms**
- **discussion of any other management options (including specialist referral)**
- **contact details for relevant support groups**
- **advice on continence products and information about product choice, availability and use**
- **advice on skin care**
- **how to talk to friends and family**

- **strategies such as planning routes around public conveniences if patients have to travel.**

Rationale: Evidence retrieved on patient views in section 2.3 in chapter 2 and 3.10, 3.11 and 3.13 in this chapter was considered by the GDG. After consulting with expert advisors and participating in a consensus development exercise the GDG decided to recommend specific support for patients who do not wish to continue with active treatment or have intractable FI. Since FI may not always be cured, the emphasis is on symptom control and follow-up which needs to be continued long-term. Themes arising from the research on patient views in section 2.3 in chapter 2 also suggested that specific advice on how to manage FI in everyday life would be beneficial.

4 Specialised management of faecal incontinence

For some patients, baseline assessment and initial management of faecal incontinence is not appropriate, or produces little or no benefit. In these cases, specialised assessment and management can both identify the cause of symptoms and indicate further treatment options.

If patients are not appropriate for initial conservative management or if symptoms have not adequately resolved as a result of initial conservative management, a number of specialised conservative management options can be considered. These include pelvic floor exercises, biofeedback and electrical stimulation and rectal irrigation.

We undertook literature searches to retrieve RCTs, non-randomised controlled trials, cohort studies and before-after studies which compared the effect of one specialised conservative intervention with another conservative intervention on patient outcomes, no intervention or a placebo.

4.1 What is the effectiveness of pelvic floor/anal sphincter exercises versus all other conservative therapies?

4.1.1 Introduction

In clinical practice pelvic floor muscle/anal sphincter exercises are often suggested for patients with FI. These might be self-directed, taught via verbal and/or written instructions from a health professional, or taught during a vaginal or anal digital examination. In some centres biofeedback equipment is used to facilitate patient teaching and monitor progress. The rationale is to enhance sphincter strength, endurance and speed of response by a programme of systematic exercises, usually over a period of several months. This could in theory enable the patient to better resist the urge to defaecate by use of the external anal sphincter and the puborectalis muscle of the pelvic floor. Better muscle function could also augment resting tone in the anus, thus improving episodes of passive faecal soiling (although the smooth muscle internal anal sphincter, which is mostly responsible for resting anal tone, is not amenable to exercising).

Exercises are often used in combination with other interventions (for example, diet, drugs, toileting and evacuation training). This question addresses the specific contribution of exercises vs other interventions.

4.1.2 Studies considered for this review

RCTs, non-randomised controlled trials, cohort studies and before-after studies which compared pelvic floor/sphincter exercises vs any other conservative therapy were considered for inclusion.

4.1.3 Clinical evidence

We identified four RCTs reported in five papers[45-49] that met our inclusion criteria for this clinical question (see evidence table 9, appendix D).

Pelvic floor exercises vs no exercises

Two studies (reported in 3 papers) compared pelvic floor exercises with no exercises[45,46,48]. Glazener et al[45,46] reported the results of a study 747 post-natal women with urinary incontinence, 111 of which had faecal incontinence at baseline (57/371 and 54/376 in the intervention and control groups respectively). The specific comparison under consideration was education on pelvic floor exercises administered vs standard post-natal management which included a brief description of pelvic floor exercises. Both interventions occurred 3 months post-delivery. The study had 9 month and 6 year follow-up periods.

Norton et al[48] reported results from 171 patients referred to a specialist colorectal hospital with episodes of faecal incontinence. These patients were allocated to one of four interventions:

a) general faecal incontinence advice

b) advice + pelvic floor exercises with feedback from digital examination

c) advice + pelvic floor exercises with computer assisted biofeedback

d) advice + pelvic floor exercises with computer assisted biofeedback + use of a home biofeedback device.

This section will consider the results of arm a vs arms b, c and d (no exercises, versus exercises with or without biofeedback). Further comparisons from this trial are reported in sections 4.2.3 and 4.3.3.

Both studies concluded that pelvic floor exercises yielded no greater benefit than standard care. Glazener et al[45,46] reported that although significant differences for faecal incontinence were found at 1 year (intervention group: 4% FI vs control group: 11%) these results were not sustained at 6 year follow up (control: 12% vs intervention: 13%) (95% CI -6.4% to 5.1%). Norton et al[48] concluded that there was no difference between the groups on any of the faecal incontinence outcomes recorded at 12 months follow-up.

Pelvic floor exercises vs biofeedback

Three studies[47-49] compared pelvic floor exercise with biofeedback. Solomon et al[49] assessed the effectiveness of the following interventions in patients with mild to moderate faecal incontinence with at least mild pudendal neuropathy on a single fibre, four quadrant sampling of external sphincter with electromyography and no anatomic defect in the external sphincter:

a) pelvic floor exercises with feedback from digital examination

b) pelvic floor exercises with biofeedback using transanal ultrasound

c) pelvic floor exercises with biofeedback using anal manometry

This study randomised 120 patients to one of three interventions above which was then administered over 4 months. The results of arm a vs b and a vs c are reported in this section, the results of arm b vs arm c are reported in sections 4.2.3 and 4.3.3.

Ilnyckyj et al[47] examined the effectiveness of education and pelvic floor exercises (n=11) against education, pelvic floor exercises plus biofeedback (n=7) over 2 months. This study was conducted in females with regular and frequent “idiopathic” faecal incontinence. These participants were recruited through poster and newspaper advertisement.

None of the studies reported any significant differences between the arms.

4.1.4 Cost-effectiveness evidence

No economic evidence was found for this question.

4.1.5 Conclusions

We did not retrieve any evidence to show that pelvic floor exercises are more effective than standard care or other conservative therapies, nor that biofeedback enhances the effect of exercises alone.

The GDG used expert opinion and consensus development methods to propose recommendations on specialised management. These can be found in section 4.5.

4.2 What is the effectiveness of biofeedback vs all other conservative therapies?

4.2.1 Introduction

The following modalities of biofeedback for FI are described in the literature:

Rectal sensitivity training: a rectal balloon is gradually distended with air or water and the patient is asked to report first sensation of rectal filling. Once this threshold volume is determined, repeated re-inflations of the balloon are performed, the objective being to teach the patient to perceive the distension at progressively lower volumes. The rationale is that some patients are found to have high threshold volumes and if the patient can detect stool arriving earlier, there is more possibility to either find a toilet or use an anal squeeze, or both. Conversely, the same technique has also been used in those with urgency and a hypersensitive rectum to teach the patient to tolerate progressively larger volumes.

Strength training: biofeedback techniques have been used to demonstrate anal sphincter pressures or activity to the patient, thereby enabling teaching of anal sphincter exercises and giving feedback on performance and progress. This can be achieved by using EMG skin electrodes, a manometric pressure probe, intra-anal EMG, or anal ultrasound. The patient is encouraged, by seeing or hearing the signal, to enhance squeeze strength and endurance. There is no consensus on an optimum exercise regimen for use at home between sessions, nor on the number of squeezes, the frequency of exercises or treatment duration, with different authors describing very different programmes.

Co-ordination training: some authors have described a three-balloon system for biofeedback for FI. One distension balloon is situated in the rectum; the second and third smaller pressure-recording balloons are situated in the upper and lower anal canal. Rectal distension triggers the recto-anal inhibitory reflex. This momentary anal relaxation is a point of vulnerability for people with FI and incontinence can occur at this time. By distending the rectal balloon and showing the patient this consequent pressure drop, the aim is to teach the patient to counteract this by a voluntary anal squeeze, hard enough and for long enough for resting pressure to return to its baseline level.

The three methods described above are not mutually exclusive, and many protocols combine two or three elements together. At present access to biofeedback is relatively limited in England and Wales and some patients have to travel long distances to access such a service. Some options may only be available via certain professionals (for example, not all continence nurses or physiotherapists have biofeedback or electrical stimulation equipment at present) and referral to a specialist centre or physiotherapist may be needed. Certain patient groups, for whom other conservative therapies are ineffective, may respond better to biofeedback. Also we need to know if there is any rational basis for allocating patients to a trial of

conservative therapy, immediate referral for biofeedback, or discounting both and opting for surgery.

4.2.2 Studies considered for this review

RCTs, non-randomised controlled trials, cohort studies and before-after studies which compared biofeedback vs any other conservative therapy were considered for inclusion.

4.2.3 Clinical evidence

We identified three RCTs[47-49] that met the inclusion criteria for this clinical question (evidence table 10, appendix D). The details of all three studies are also discussed in section 4.1.3.

Biofeedback vs no biofeedback (standard care)

We retrieved one study which compared two methods of biofeedback with standard care[48].

- Arm c: advice + pelvic floor exercises with computer assisted biofeedback vs arm a: general faecal incontinence advice

- Arm d: advice + pelvic floor exercises with computer assisted biofeedback + use of a home biofeedback device vs arm a: general faecal incontinence advice

Norton et al[48] concluded that there was no difference between the groups on any of the faecal incontinence outcomes recorded at 12 months follow-up.

Biofeedback vs pelvic floor exercises

We retrieved three studies which compared biofeedback and pelvic floor exercises[47-49]. No study found a significant difference. The details and results of the relevant comparisons in these studies are discussed in section 4.1.3 (see evidence table 10, appendix D).

4.2.4 Cost-effectiveness evidence

No economic evidence was found for this question.

4.2.5 Conclusions

We did not retrieve any evidence to show that biofeedback is more effective than standard care, exercises alone, or other conservative therapies.

The recommendations on specialised management are in section 4.5.

4.3 Which modality of biofeedback is most effective at managing faecal incontinence?

4.3.1 Introduction

Once the decision to use biofeedback has been made, there is a choice of modalities, which may be used singly or in combination. In practice, choice is often pragmatic, determined by availability of equipment. This review aims to identify which modalities are most effective.

4.3.2 Studies considered for this review

RCTs, non-randomised controlled trials, cohort studies and before-after studies which compared two or more different methods of biofeedback were considered for inclusion.

4.3.3 Clinical evidence

We identified five RCTs[48-52] which met the inclusion criteria for this clinical question (two studies[50,51] were reported in a systematic review[53] (evidence table 11, appendix D). Studies that compared the same method of biofeedback using different treatment protocols were retrieved, in addition to studies which compared different methods of biofeedback. One non-randomised controlled trial was identified[54].

Comparison of the same method of biofeedback using different treatment protocols

Three studies[48,50,52] randomised patients to receive the same type of biofeedback but compared different treatment protocols. One non-randomised controlled trial[54] compared treatment protocols, one based on face-to-face follow up and the other on telephone follow up (both groups had initial face to face assessment). Miner et al[50] examined sensory retraining using a rectal balloon in the first phase of the study. Twenty-five patients with predominantly idiopathic faecal incontinence were randomised to receive active retraining or sham retraining with no instruction on how to improve performance and were followed up after 4 weeks.

In Heyman et al[52], 40 patients with faecal incontinence who were identified as non-surgical candidates were randomised to receive one of the four treatment protocols:

1) Biofeedback display of EMG activity of pelvic floor muscles, education as to pelvic floor physiology and operant conditioning techniques to retrain this function

2) EMG biofeedback training plus balloon-distension sensory training plus pelvic floor exercises

3) EMG biofeedback training plus home trainer EMG biofeedback for the home practice portion of the training programme

4) EMG biofeedback training plus home trainer EMG biofeedback for the home practice portion of the training programme plus balloon distension sensory training.

The study described in Norton et al 2003[48], previously discussed in sections 4.1.3 and 4.2.3, compared arm c: advice + pelvic floor exercises with computer-assisted biofeedback and arm d: advice + pelvic floor exercises with computer-assisted biofeedback + use of a home biofeedback device. There was no difference between these two groups. Heyman reported a significant difference in percentage reduction in mean number of days per week with incontinent episodes (p= 0.001, 0.004, 0.001, 0.023 across groups 1-4 respectively)[52]. Miner et al[50] reported a significant difference in incontinent episodes per week (weighted mean difference: -1.40; 95%CI: -1.51 to -1.29), people achieving full continence (OR: 0.11; 95%CI: 0.01 to 0.90) and improving continence status (OR: 0.17; 95%CI: 0.03 to 0.83), all favouring the active sensory training. A number of other outcomes were reported, although none reached statistical significance.

The study by Byrne et al[54] compared incontinence outcomes between groups offered different management techniques. Patients were allocated into groups according to their ease of access to the clinic for face-to-face assessment; if there were difficulties in attending (if for example patients lived in a rural area) then the individual was allocated to the telephone intervention.

- Group one: Initial face-to-face assessment and treatment with transanal manometry and ultrasound biofeedback, followed by three treatments conducted via telephone and a final face-to-face session.

- Group two: Standard treatment involved five face-to-face treatment sessions with manometry and ultrasound biofeedback.

Both groups demonstrated significant improvements in incontinence scores pre- to post-intervention. However, there were no significant differences between the groups.

Comparison of different methods of biofeedback

We retrieved two studies[49,51] which randomised patients to receive different methods of biofeedback. Fynes et al[51] included in a systematic review[53] compared vaginal pelvic floor manometric pressure biofeedback conducted by a continence nurse vs weekly sessions of anal EMG biofeedback plus anal electrical stimulation by a physiotherapist in 40 female patients with impaired faecal continence after obstetric anal sphincter injury. Solomon et al[49] which is also discussed in section 4.1.3 and 4.2.3, compared anal ultrasound biofeedback with anal manometry.

In the study reported by Fynes et al there was a statistically significant difference in the proportion of patients to become asymptomatic or to improve in their incontinence status in favour of the anal EMG plus electrical stimulation group (respectively, OR 4.54 95% CI 1.30-15.83 in favour of electrical stimulation group; OR 12.38 95% CI 2.67-57.46 in favour of electrical stimulation group)[51]. However, due to the addition of electrical stimulation to the second arm, it is not clear if this treatment effect is due to the method of biofeedback or to electrical stimulation. In the study by Solomon et al there were no significant differences in outcomes between the treatment groups and the authors concluded that transanal ultrasound offered no benefit over anal manometric biofeedback[49].

4.3.4 Cost-effectiveness evidence

No studies of cost-effectiveness were identified.

4.3.5 Conclusions

In conclusion, one small study showed that active sensory training is more effective than sham training for patients with “idiopathic” faecal incontinence[50]. Two studies reported that the addition of a home training kit did not improve outcomes in patients with the former study also concluding that the addition of balloon distension sensitivity training did not improve outcomes[48,52].

In studies which compared different methods of biofeedback, one study concluded that EMG plus electrical stimulation produced better outcome than vaginal pelvic floor manometric pressure biofeedback[51]. A second study concluded that transanal ultrasound biofeedback offered no statistically significant benefit over anal manometry biofeedback[49].

The GDG used expert opinion and consensus development methods to propose recommendations on specialised management. These can be found in section 4.5.

4.4 What is the effectiveness of electrical stimulation to manage faecal incontinence?

4.4.1 Introduction

The stated purpose of neuromuscular electrical stimulation is to re-educate the anal sphincter and other muscles of the pelvic floor to contract. The treatments aim to progress towards graduated active exercises, in order to improve pelvic floor muscle strength and endurance and to regain function. Electrical stimulation is carried out using a specific anal probe, at frequencies capable of producing a tetanic muscle contraction, using a comfortable intensity and with an appropriate duty cycle. When possible, the patient works with the stimulating current (that is, performs a voluntary contraction at the same time). The treatment time is typically 5-30 minutes in duration, although there are no generally agreed published protocols. Electrical stimulation is an invasive and potentially uncomfortable procedure. It requires specialist equipment and training and it is not currently available at all centres.

Patients are often considered as suitable for electrical stimulation if, on examination, they either have no active anal sphincter contraction, or a weak or poorly sustained contraction. This would be identified at initial assessment following digital/manometric/electromyographic (EMG) evaluation of the sphincter. Alternatively, stimulation may be used to augment the effectiveness of anal sphincter/pelvic floor exercises.

4.4.2 Studies considered for this review

RCTs, non-randomised controlled trials, cohort studies and before-after studies which compared the effectiveness of electrical stimulation with either no electrical stimulation or any other conservative therapy in adult patients with faecal incontinence were considered.

4.4.3 Clinical evidence

Four RCTs[51,55-57] met the inclusion criteria for this clinical question (evidence table 12, appendix D.

Electrical stimulation vs no electrical stimulation

One RCT[57] looked at the effectiveness of electrical stimulation vs no electrical stimulation. Norton et al[57] recruited 90 adult patients who had been referred to a tertiary referral hospital. 47 patients received active anal stimulation at 35 Hz and 43 patients received 'sham' stimulation at 1 Hz. The follow-up period was 8 weeks. The authors reported that on an intention-to-treat analysis, that there was no difference between the two groups on any of the outcome measures.

Electrical stimulation + biofeedback vs biofeedback alone

Two studies compared electrical stimulation as an adjunct to biofeedback compared to biofeedback alone. The details, results and limitations of the study by Fynes et al[51] are reported in section 4.3.3. The second study[55] randomised 60 female patients with faecal incontinence episodes after obstetric injury at 12 weeks after delivery. Patients received either intra-anal EMG biofeedback alone or intra-anal EMG biofeedback augmented with electrical stimulation of the anal sphincter once a week for 12 weeks. Both groups also carried out pelvic floor exercises between treatments. However, this study only reports within-group comparisons. Between-group comparisons cannot be made using the data provided in the paper.

Electrical stimulation vs surgery

One study[56] randomised a total of 59 patients with disabling faecal incontinence to either levatorplasty surgery (n=31) or anal plug electrostimulation of the pelvic floor (n=28). At 24 months follow-up the only outcome which reached significance was improvement in physical and social handicap (p = 0.001 and 0.006 respectively), in favour of the levatorplasty group. At 3 months there was a significantly greater improvement in continence in favour of the levatorplasty group (p = 0.032), although this was not sustained at 24 months. No significant differences were therefore found between groups.

4.4.4 Cost-effectiveness evidence

No appropriate studies were retrieved.

4.4.5 Conclusions

The evidence was inconclusive in this area. Therefore, the GDG used expert opinion and consensus development methods to propose recommendations on specialised management. These can be found in section 4.5.

4.5 Recommendations

Patients who continue to have episodes of faecal incontinence after initial management, should be referred to a specialist continence service for consideration of specialised management options which may include:

- **pelvic floor re-education programmes**
- **bowel retraining**
- **specialist dietary assessment and management**
- **biofeedback**
- **electrical stimulation**
- **rectal irrigation**

These treatments may not be appropriate for patients who are unable to understand and/or comply with instruction. For example, pelvic floor re-education programmes may not be appropriate for those with neurological or spinal disease/injury resulting in faecal incontinence due to complete loss of voluntary control.

Rationale: After reviewing the evidence from sections 4.1, 4.2, 4.3 and 4.4 consulting with expert advisors and participating in a consensus development exercise, the GDG consequently decided to develop recommendations on the specialised management options available. As faecal incontinence can be due to a variety of factors, this specialised package of care can be tailored to the needs of the individual. We do not have specific evidence for the cost-effectiveness of these services. However, we know interventions, such as pelvic floor exercise are safer and cheaper than surgery and therefore are likely to be cost-effective compared with referral for surgery. On the other hand, they are likely to be more costly than initial management and therefore are only likely to be cost-effective in patients for whom initial management has not been fully effective.

Initial assessment and management of faecal incontinence will usually be available in the primary care setting. However, a specialist continence service will be staffed by healthcare professionals who have undertaken further study and training to acquire the skills needed for more comprehensive assessment. These healthcare professionals will have access to specialised equipment for their assessment and treatment.

Healthcare professionals should consider if patients with neurological or spinal disease/injury (for example spinal cord injury, spina bifida, stroke, multiple sclerosis) resulting in faecal incontinence, who have some residual motor function and are still symptomatic after baseline

assessment and initial management, could benefit from specialised management.

Rationale: No specific evidence on this patient group was retrieved. However, the GDG felt it was important that patients with neurological disease and/or injury with faecal incontinence with partial loss of sensory and motor function are considered for options listed above. It is important that these individuals should have the opportunity for specialist assessment and treatment and that diagnostic overshadowing does not prevent those with partial loss of control from appropriate care. Patients should also be re-assessed when appropriate, if they suffer from conditions that can show symptomatic improvement over time, such as stroke.

A programme of pelvic floor re-education should be agreed with the patient. The progress of patients having pelvic floor exercises should be monitored by digital reassessment by an appropriately trained healthcare professional who is supervising the treatment. There should be a review of patients' symptoms on completion of the programme and other treatment options considered if appropriate.

Rationale: No evidence of increased effectiveness of pelvic floor exercises compared with other management options was found (see section 4.1). After consulting with expert advisors and participating in a consensus development exercise, the GDG decided to develop recommend pelvic floor re-education. It is important to determine a plan of treatment at the outset, where the patient and the health professional have identified achievable targets. As the purpose of pelvic floor re-education is to improve the strength and endurance of the muscles, digital examination of the anal sphincter complex allows the monitoring of any changes.

4.6 Recommendation for research

The GDG identified the following priority area for research:

The value of pelvic floor exercises in preventing and treating obstetric-related faecal incontinence.

Why this is important:

Obstetric related faecal incontinence is a distressing symptom which may occur early after childbirth. Obstetric injury is also the major cause of incontinence in older women, so reducing risk would have important benefits for both young and old patients. Obstetric risk factors relate not just to sphincter disruption, but also to pelvic floor damage, and there is reason to suggest that improving pelvic and sphincter strength prior to potential injury may be beneficial. Equally, early intervention post-partum may help reduce the well recognised risks of delayed faecal incontinence in women.

Pregnant women and those who have given birth within the last 6 months (possibly excluding third and fourth degree tears) would usefully be randomised to one of 3 groups:

- standardised pelvic floor exercises
- generic advice and no specific pelvic floor intervention in second and third term pregnancy
- generic advice and no specific pelvic floor intervention in women post-partum

All groups could be stratified according to presence of symptoms. Within the post-partum group, patients could be stratified to those with and without known risk factors for faecal incontinence. This would allow comparisons to be drawn between treatment groups and also across strata of symptoms and risk factors. Outcome measurement would include symptoms, quality of life, carer outcomes, physiology, imaging data and health costs with intention of detailed economic modelling. Measurements should be taken at short term (6 months) and longer term (3 years) to allow comparison with baseline and between standard vs complete assessment limbs.

There is no standardisation of what pelvic floor exercises should comprise. There is also no evidence base of whether treatment prior to potential injury (i.e. labour) serves a protective role. This study will require the interaction of obstetric, colorectal and physiotherapy services across primary and secondary care.

5 Specialist assessment

Specialised testing may include the measurement of the pressures generated by the anal sphincter and rectum, testing anorectal sensation (functional assessment) and imaging (structural assessment). Other tests can help to categorise causes of incontinence. In patients with suspected anal sphincter disruption or neurological diseases, these additional tests may have a particular role in defining treatment options. The tests may also be useful in deciding treatments for neurologically intact patients. Endoscopic investigations are important if there is a suspicion that underlying bowel conditions may be the cause of symptoms.

5.1 What does functional testing add to the assessment of patients with faecal incontinence?

5.1.1 Introduction

In patients with a clinical history, symptoms or a test result that suggests a congenital or acquired structural change to the anal sphincter, there may be a need to assess if there is any change or abnormality in the resting or squeeze pressure of the anal sphincter complex.

5.1.2 Studies considered for this review

We undertook literature searches to retrieve RCTs, non-randomised controlled trials, cohort studies and before-after studies which measured the effect of performing a diagnostic test versus not performing a diagnostic test on patient outcomes. As a small number of appropriate studies were retrieved, we also searched for diagnostic studies with an appropriate 'gold standard' to help inform the clinical questions.

Functional testing for the purposes of this guideline included rectal compliance, anal manometry, rectal distension sensitivity, pudendal nerve terminal motor latency (PNTML), anal EMG and electro sensitivity testing.

5.1.3 Clinical evidence

We retrieved one study for this clinical question[18] (see evidence table 13, appendix D). Sultan et al reported the diagnostic accuracy of manometry and concentric needle electromyography to detect external sphincter defects against gold standard histology. The study was conducted in a small number of consecutive patients (N=12) selected for sphincter repair (the prevalence of external sphincter defects in this study was 75%).

The authors reported that manometry had both a sensitivity and specificity of 67% in the reported group of patients. Concentric needle electromyography was reported to have a high sensitivity (89%) but a low specificity (33%). The results of this study should be interpreted with some caution as the sample of patients was very small and had already been selected for surgery. In addition, two out of 12 patients could not tolerate multiple needle insertions so suspected defects were not confirmed. The authors also chose a definition of abnormal sphincter pressure (below 40mmH_2O) which may not be widely used in clinical practice.

On the basis of this study, neither manometry nor EMG appears to be sensitive or specific enough to diagnose anal sphincter defects with confidence. This may mean that patients undergo unnecessary sphincter

repair or are not offered surgery where it might be beneficial. It is also not clear what role these diagnostic tests may have in a group of patients not selected for surgery.

5.1.4 Cost-effectiveness evidence

We did not retrieve any appropriate studies.

5.1.5 Conclusions

As the only study retrieved for this question was small and in a very specific group of patients, there is no conclusive evidence on the role of functional testing in the assessment of patients with faecal incontinence.

The GDG used expert opinion and consensus development methods to propose recommendations on specialised management. These can be found in section 5.6.

5.2 What do imaging tests add to the assessment of patients with faecal incontinence?

5.2.1 Introduction

Structural assessment of the anal sphincter complex in patients with faecal incontinence may be important in defining the cause of symptoms and in planning treatment. Imaging assessment may help identify patients who have a disrupted sphincter and may also identify patients whose symptoms are contributed to by sphincter degeneration.

It is currently difficult to know how to select suitable patients for anal sphincter repair. Sphincter defects may involve either the internal or the external anal sphincter in isolation, or both. Such localisation of the injury is only really possible using imaging techniques, particularly in those with iatrogenic trauma (for example, perianal fistula surgery, haemorrhoidectomy, or lateral sphincterotomy for anal fissure). However, surgical findings may be at odds with results from imaging, which casts doubt on any currently available diagnostic tool for true anal sphincter defects.

Constipation, rectal evacuation difficulties or rectal prolapse may each contribute to faecal incontinence in some patients. Imaging may help to define these problems.

5.2.2 Studies considered for this review

RCTs, non-randomised controlled trials, cohort studies and before-after studies which compared pelvic floor/sphincter exercises vs any other conservative therapy were considered for inclusion.

Imaging techniques included for the purposes of this clinical question comprised anal, vaginal or perineal ultrasound, magnetic resonance imaging (MRI), defaecography, computed tomography (CT), colonography, plain abdominal x-ray and barium enema.

5.2.3 Clinical evidence

Eleven studies which evaluated the diagnostic accuracy of imaging techniques were retrieved[18,58,59,59,60,60-65] (evidence table 14, appendix D). There was some difficulty in synthesising the evidence for this review. The imaging techniques were compared to different gold standards, and also different outcomes were investigated across different papers. Additionally, definitions of outcomes (for example, scarring/thinning/defect) were not always defined well, therefore some measure of interpretation was required.

MRI

We retrieved three studies[58-60] on the diagnostic accuracy of MRI against histological gold standard or 'surgeons judgment'. Three[58-60]studies evaluated the role of endoanal MRI and three[58-60] studies looked at endovaginal MRI. The studies were carried out in predominately female populations with faecal incontinence due to obstetric trauma (evidence table 14, appendix D).

In two studies[58,60], the diagnostic accuracy across all the outcomes reported was high, sensitivity ranged from 67-100% while specificity ranged from 72-100%. One study[59] however, reported a low specificity of MRI at determining the condition of the external anal sphincter (14.3%) and internal anal sphincter (42.6%).

Some of the outcomes reported in these studies are compared to the surgeon's opinion, as opposed to an objective reference standard. In addition, all the studies were small (between 19 and 22 patients) conducted in patients who had already been selected for surgery. Therefore the results of the studies should be interpreted and generalised with caution. In addition to this general issue, in the study by Pinta et al[59] the endocoil used was not designed primarily for this work; a prostate coil was used in the vagina. This is not equivalent to an endoanal coil being used endoanally. The study by Briel et al[58] is also undermined by the assumption that all included patients with 'post-obstetric incontinence' had a tear, although it is unclear how this was confirmed.

Ultrasonography

We retrieved eight studies[18,59-65] which evaluated the diagnostic accuracy of ultrasonography against surgical findings, histology, or a different type of ultrasonography (evidence table 14, appendix D). Seven studies[18,59-64] used trans- or endoanal ultrasound while the study by Meyenberger utilised endoscopic ultrasound. One study compared transvaginal with transanal endosonography[65]. The predominant cause of incontinence in all studies was trauma, usually obstetric.

The sensitivities and specificities reported relate to the condition of the anal sphincter. The majority of studies reported both sensitivity and specificity to be above 80% (range 0–100% and 14.2–100% respectively), including those studies which used histology rather than surgical findings as the gold standard.

Additional limitations of the studies reviewed include small patient numbers (all had <50 patients) and that the patients had already been selected for surgery. In addition, Meyenberger et al[62] used an out-dated ultrasound technique with low resolution methodology. Although the results of this study are sensitive and specific, this particular ultrasound technique has not been reproduced. In addition, this study used the surgeon's estimate as the gold standard. The study by Pinta et al[59] which compares endovaginal MRI with endoanal ultrasound involves many inappropriate comparisons; different modalities and different anatomy. Finally, Frudinger et al[65] did not differentiate

the analysed results between incontinent and continent patients, thus invalidating their sensitivity and specificity data for this review.

5.2.4 Cost-effectiveness evidence

We did not retrieve any appropriate studies.

5.2.5 Conclusions

The studies retrieved for this clinical question document the relative paucity of evidence comparing imaging to a surgical gold standard. Such lack of evidence is understandable given the highly invasive nature of sphincter surgery.

The evidence-base discussed above suggests that EMG has no advantage in the era of endoanal ultrasound[18] although the limitation of this evidence makes this conclusion uncertain. In addition, as no study reported findings of imaging assessment techniques to long-term (or even short term) patient outcomes (for example, symptom relief) it is not clear what effect this would have on the management of patients.

The GDG used expert opinion and consensus development methods to propose recommendations on specialised management. These can be found in section 5.6.

5.3 What does endoscopy add to the assessment of patients with faecal incontinence?

5.3.1 Introduction

Inspection of the rectal and colonic mucosa may be important in excluding colorectal causes of incontinence (such as cancer, colorectal polyps, inflammatory bowel disease). If present, these conditions would need primary treatment before the faecal incontinence is addressed.

5.3.2 Studies considered for this review

RCTs, non-randomised controlled trials, cohort studies and before-after studies which compared pelvic floor/sphincter exercises vs any other conservative therapy were considered for inclusion.

For the purposes of this guideline, endoscopy included rigid sigmoidoscopy, flexible sigmoidoscopy and colonoscopy.

5.3.3 Clinical evidence

We did not retrieve any appropriate studies for this clinical question.

5.3.4 Cost-effectiveness evidence

We did not retrieve any appropriate studies.

5.3.5 Conclusions

As no clinical or cost-effective evidence was retrieved for this clinical question the GDG used expert opinion and consensus development methods to propose recommendations. These can be found in section 5.6.

5.4 Are any investigation techniques better than others?

5.4.1 Introduction

When assessing the patient with faecal incontinence, there are several ways of collecting the same information. There may be clinical, cost or patient related reasons as to why one test is preferable to another. For instance there are several different methods of assessing if there is any change or abnormality in the resting or squeeze pressure of the anal sphincter complex. Anal manometry is an invasive and potentially uncomfortable procedure. It requires specialist equipment and training and is not currently available at all centres. Digital examination also requires training, but can be used in most clinical situations.

5.4.2 Studies considered for this review

We undertook a literature review to retrieve studies which compared different investigation techniques to assess patients with faecal incontinence. Digital examination, manometry, surgical assessment, anal and vaginal ultrasound, external sphincter electromyography and defaecating proctography were all included.

5.4.3 Clinical evidence

The results from this section are summarised in evidence table 15, appendix D.

Digital examination vs manometry

We retrieved three studies[66-68] reported the diagnostic accuracy of digital examination alone on different outcomes relating to sphincter function. The gold standard used in all the studies was anal manometry. The specific patient groups in which these studies were conducted was not always clear; Hill et al[68] recruited patients with idiopathic faecal incontinence, while the study reported by Buch et al[66] reported results from patients with faecal incontinence at least monthly.

Across all the studies, the sensitivity of digital examination on all of the outcomes reported tended to be greater (range 73-96%) than the specificity (range 11-57%), apart from one outcome, gaping anus, reported in Hill et al[68] which has a high sensitivity (73%) and specificity (81%).

In one of these studies[66] it was unclear if the outcomes were calculated using the results from patients with FI (n=106), or if they were combined with results from healthy controls (n=44) and patients with constipation (n=41) who were also recruited into the study. In addition, 37% of patients within the group reported in Eckardt et al[67] were constipated.

Clinical assessment vs 'special investigations'

We found one study[17] which reported the sensitivity and specificity of clinical assessment in patients referred to a specialist centre for assessment of faecal incontinence (N=50) (see evidence table 16). The authors compared clinical assessment to ‘special investigations’ (anal ultrasound, anal manometry, external sphincter electromyography and defaecating proctography).

The outcomes reported, which include structural damage to the sphincter and presence of associated causes of faecal incontinence (for example, rectal prolapse, haemorrhoids/local anal causes), generally had high sensitivities (64-100%) and specificities (94-100%) for clinical assessment when compared to 'special investigations'.

The primary focus of this study was whether clinical examination could predict structural sphincter integrity. However this is only relevant when surgery is being considered. As surgery is seldom the first option for management in the newly presenting patient, this only becomes relevant at the specialist stage of investigations. Other outcomes reported in Keating et al[17] suggest that inspection is as good as imaging at detecting vaginal or rectal prolapse.

These results should be interpreted with some caution, as the study is both small and took place in a specialist referral centre. It is not clear that the results can be replicated in a non-specialist setting. It was also unclear if clinical assessment referred to history, general examination and anorectal examination or anorectal examination alone.

Transvaginal ultrasound vs transanal ultrasound

We found one small study[65] which compared the diagnostic accuracy of transvaginal ultrasound vs transanal ultrasound as gold standard. Participants were consecutive female patients reporting FI with a history of forceps delivery (as reported in section 4.3) Transvaginal ultrasound was reported to have a high specificity (88-96%) and low sensitivity (44-48%) for both internal and external sphincter defect outcomes (n=36). However, not all patients were faecally incontinent (n=36/48) and results were not divided up to give results among this group. Therefore the findings do not reflect sensitivity or specificity in incontinent patients.

5.4.4 Cost-effectiveness evidence

We did not retrieve any appropriate studies.

5.4.5 Conclusions

Despite some limitations in the studies retrieved there is some evidence that digital examination is not as accurate as anal manometry at detecting sphincter function. However, high sensitivities and specificities were reported,

although no study attempted to relate findings to patient selection for treatment options or outcomes of therapy. One study concluded that transanal ultrasound was more reliable than transvaginal ultrasonography at detecting sphincter defects. Therefore while vaginal ultrasound may be more readily available, particularly in obstetric settings, it appears not to be a good predictor of anal sphincter disruption.

The GDG used expert opinion and consensus development methods to propose recommendations on specialised management. These can be found in section 5.6.

5.5 Which combinations of tests effectively select patients for specific treatment strategies?

5.5.1 Introduction

There are many different tests available for investigating patients with FI. As there is no one 'gold standard' test, they are often performed in combination. The clinical assessment is then considered in the light of findings to decide on management options. The impression is that various tests are available in different investigation units, and often the combination is currently based more on historical custom or availability of equipment in that centre, rather than a rational combination selected for the individual patient. It is often unclear how to select the best combination of tests for an individual patient.

It would be helpful to know whether the results of any tests predict the outcome of a specific treatment (for example, drugs, surgery, biofeedback) or avoid futile treatment for any patient group. Are some tests of more relevance than others for specific patients? Does any combination of tests change clinical decision-making? Are some combinations redundant? What is the relative cost-effectiveness of performing tests?

5.5.2 Studies considered for this review

We undertook a literature search to retrieve studies which compared a combination of tests to a single test or a combination of tests to a different combination of tests.

5.5.3 Clinical evidence

Our literature search found two studies which compared clinical assessment with specialist tests in a before-after study design (see evidence table 16, appendix D). Keating et al[17] (N=50) and Liberman et al[69] (N=95) reported management plans based on the findings from clinical assessment alone before undertaking a number of specialist tests. The information from the specialised tests together with the clinical assessment informed a second management plan for each patient. Both sets of authors report the number of differences between the management plans based on clinical assessment alone and those based on clinical and specialised assessment.

The results of these studies report that between 10-30% of patients would have received either unnecessary surgery or would not have received appropriate surgery. However, in the absence of strong evidence for surgical efficacy in the long term (see Chapter 6) the latter group is uncertain to have benefited.

These results should be interpreted with caution; both studies were conducted in specialist referral centres (the findings may not be able to be extrapolated to a general community setting). In addition, it is not clear what impact the findings would have had on patient outcomes, such a quality of life or episodes of faecal incontinence, after treatment. The meaningfulness of the concept of 'correct diagnosis' as a result of gold standard tests should also be considered, especially as no gold standard is universally accepted and especially when many patients have faecal incontinence as a result of multifactorial problems.

5.5.4 Cost-effectiveness evidence

We did not retrieve any appropriate studies.

5.5.5 Conclusions

There is some limited evidence that clinical assessment alone cannot be relied upon to provide sufficient information for a management plan for patients referred to specialist centres for assessment and to be considered for sphincter repair.

The GDG used expert opinion and consensus development methods to propose recommendations on specialised management. These can be found in section 5.6.

5.6 Recommendations on specialist assessment

Healthcare professionals should refer patients with continuing faecal incontinence after specialised conservative management for consideration for:

- **anorectal physiology studies**
- **endoanal ultrasound. If not available, consider MRI, endovaginal ultrasound and perineal ultrasound**
- **other tests, possibly including proctography.**

Rationale: After reviewing the evidence from sections 5.1, 5.2, 5.3.1, 5.4 and 5.5 consulting with expert advisors and participating in a consensus development exercise, the GDG decided to develop recommendations which advise use of physiological, imaging and other tests as means of assessment. Manometric results are known to reflect patient symptoms (for example, low resting pressure correlates with passive soiling; low squeeze pressure with urge symptoms). However, there are no accepted standards for performing these tests and no 'normal ranges' agreed or validated. Digital examination is a poor predictor of manometric findings[18]. However, the clinical relevance of this, in terms of suggesting management options or predicting outcomes is unknown. Indeed, several studies have suggested that clinical outcomes are independent of changes in manometric pressures, casting doubt on the relevance of figures obtained.

Endoanal ultrasound requires a dedicated anal probe, and as such necessitates initial financial investment. However, day-to-day running costs for ultrasound are very low (the probe is reusable and there is no requirement for additional radiographic support). In some centres, endoanal sonography is performed by trained specialist nurses, rather than medically qualified personnel.

MRI is an expensive and scarce resource. While some MRI manufacturers provide a reusable dedicated endocoil, others produce disposable coils with resource implications. The per-patient cost of MRI is greater than that of ultrasound, and in general access to MRI imaging in the UK is less than ultrasound. MRI appears to be accurate, but ultrasound, where it is available, is likely to be sufficiently accurate and more cost-effective. In experienced hands, imaging findings correlate well with findings at operation. It should however be recognised that such examinations are specialised and performed by few UK radiologists. In those with experience, however a perineal or transvaginal approach is a reasonable alternative to endoanal ultrasound.

One area in which endocoil MRI is currently superior to ultrasound is in the diagnosis of external sphincter atrophy, although new 3D techniques may improve the accuracy of ultrasound. MRI has been validated against histology for external sphincter atrophy[58] but not for a tear (the latter being the more

recognised form of defect to date). Furthermore external sphincter atrophy has been shown to adversely influence outcome in patients undergoing surgical repair[70].

Perineal and endovaginal ultrasound show reasonable accuracy and importantly do not require a specialised anal probe. They can both be performed using standard probes available on most diagnostic ultrasound machines in the UK.

Although data on the cost effectiveness and impact of imaging investigation on patient management outcome is lacking, this can be said for many diagnostic test routinely performed in day-to-day clinical practice. The GDG developed the above recommendations using expertise and participating in a consensus-building exercise.

5.7 Recommendation for research

The GDG identified the following priority area for research:

What is the prognostic value of physiologic assessment for defining outcome of surgery for treatment of faecal incontinence?

Why this is important:

It is currently hard to predict which patients will benefit from surgical treatment for faecal incontinence. Developing an improved selection procedure would cut down on unnecessary procedures, cutting costs and improving patient care pathways.

By comparing standard physiology and structural assessment (anorectal physiology, pudendal nerve latencies, endoanal ultrasound) with full physiological and structural assessment (including anorectal physiology, pudendal nerve latencies, anorectal reflexes, rectal compliance dynamometry, endoanal ultrasound and MRI) in patients referred for specialist assessment in whom surgery is contemplated, a better correlative description of the relationship between symptoms and physiology or structure may be drawn. This in turn would allow a better selection procedure to be developed. By following patients through surgery and over a long-term follow-up period, the prognostic value of certain physiological/structural abnormalities in defining outcome from surgery would be evaluated. An additional point of investigation would be the long-term outcome of certain surgical procedures, particularly sacral nerve stimulation and evacuation dysfunction surgery. The decision to operate will be based on the individual indications for the procedure.

Using physiological and structural assessment outcomes at short and long-term, a comparison between the standard vs complete assessment limbs may be carried out. Additional outcomes could include a quality of life scale to gain the patient perspective, and health costs to allow detailed economic modelling. This research question would be best answered by a multi-centre study based on a network of NHS secondary care sites.

6 Surgical management of faecal incontinence

Surgery may be appropriate for some patients who have had an unsatisfactory response to conservative management. However it is essential that patients receive specialist assessment to check their suitability for surgery. It is vital that those undergoing surgery have realistic expectations and are aware of potential complications.

There are a number of surgical options for faecal incontinence, these include:

Sphincter Repair - the external anal sphincter can be repaired or simply tightened to try and improve control. The former applies to direct injuries such as those sustained obstetrically or following surgery. An anterior sphincter defect may be repaired some time after the injury. This operation is carried out through a small anterior incision. The divided ends of the external anal sphincter are identified and either approximated or more commonly overlapped. Also known as 'sphincteroplasty' or 'direct sphincter repair'.

Levatorplasty - an alternative approach in patients with no definable sphincter defect is to tighten or to plicate the external anal sphincter (EAS) and pelvic floor muscles (levatorplasty). This involves bringing together the muscles of the pelvic floor above the anal canal. This may be carried out anterior to the anal sphincter or posteriorly. The objective is to lengthen the anal canal and augment an anal sphincter repair if performed at the same time. A post-anal repair is carried out between the internal and external anal sphincters posteriorly and plicates the levator ani muscles, the puborectalis and the external sphincter.

Neosphincter - other operations have been developed to replace the sphincter when repair is not possible or has failed. These include the dynamic graciloplasty (DGP), a gluteoplasty and artificial bowel sphincter (ABS). In the first, the muscle is taken from the thigh and encircled around the anus. A nerve stimulator is inserted to make the muscle contract tonically. The gluteoplasty transposes one or both gluteus muscle from the buttock and uses them to encircle the anal canal. This can be combined with an electrical stimulator (stimulated gluteoplasty).The ABS is a cuff made of silicone that encircles the anus and contains liquid that is transferred between a reservoir and the cuff. This either opens or closes the anal canal.

Internal anal sphincter repair - attempts have been described to repair a disrupted internal anal sphincter in conjunction with external anal sphincter repair (described above), or as an isolated procedure. Other attempts to treat internal sphincter disruption or weakness have been tried by augmenting bulk into the anal canal using an island advancement flap anoplasty or by injecting biocompatible materials into the IAS to increase its bulk. The application of thermal injury to the anus to effect scarring and improve anal closure is another method that has been reported. The Secca procedure is an example.

Sacral nerve stimulation (SNS) - a recent innovation is sacral nerve stimulation. This technique involves stimulating the sacral nerves S3 or S4. Its

main advantage is that a trial period of temporary stimulation only involves simple insertion of stimulating wires into the back is possible. If this is successful, the patient can have an implantable stimulator to modulate sacral nerve function and improve continence.

Irrigation ports - irrigation can be performed through the anus or if unsuccessful, surgically constructed, lavage systems can be considered. One option is to bring the appendix onto the abdominal wall to allow catheters to be inserted into the colon (ACE or Malone operation). Liquids and laxatives can be instilled to wash out the colon. Another more complicated approach is to create a 'T' junction with the transverse colon to bring out a loop with a continent valve onto the abdominal wall. Percutaneous endoscopic colostomy (PEC) places an artificial irrigation tube into the colon, usually in the descending (left) colon. The patient then washes out the colon when appropriate. The major problem with PEC is that the device is foreign to the body and sepsis requiring removal is common.

Stoma - a stoma (usually a colostomy) may be considered for severe uncontrolled FI.

6.1 Is surgery effective and does it last compared with no surgery (conservative treatment)?

6.1.1 Introduction

For patients with faecal incontinence refractory to medical treatment, surgery may be an option. As surgical intervention is invasive and carries the risk of complications, it is important to assess the efficacy of surgery, incidence of adverse events and whether results of the operation are sustained over time.

6.1.2 Studies considered for this review

Randomised and non-randomised comparative study designs were considered for inclusion if they compared any surgical intervention for faecal incontinence with no surgery or conservative treatment. Long-term results of surgery were considered important to ascertain whether successful outcomes were maintained.

6.1.3 Clinical evidence

Five studies[56,71-74] met the inclusion criteria for this clinical question (evidence table 19, appendix D). Two studies were RCTs[56,71], two studies were cross-over trials[73,74] (one of which was randomised[73]) and one study was a non-randomised controlled trial[72].

Levatorplasty or post-anal repair vs anal plug electrostimulation

One study[56] with a total of 59 patients with disabling faecal incontinence randomised patients to surgery (anterior levatorplasty for women and post-anal repair for men) (n=31) or anal plug electrostimulation of the pelvic floor (n=28). There was a significant improvement in physical and social handicap at 3, 12 and 24 months follow-up in the surgery group. Although there was a statistically significant number of patients who reported an improvement in incontinence at 3 months in the levatorplasty group, this significance was lost at 12 and 24 months follow-up. None of the other clinical outcomes reported (less use of pads, deferring time, loose and solid stool) reached statistical significance. One case of wound infection was reported in the surgery group and one patient in the electrical stimulation group reported a ‘burning sensation in the vagina’. This study suggests only short-term benefit from surgery to tighten the anal canal and pelvic floor.

Artificial bowel sphincter vs supportive care

O'Brien et al[71] reported the results of 14 adults with severe faecal incontinence who were randomised to placement of an artificial bowel sphincter (Acticon neosphincter) (n=7) or supportive care (n=7). At 6 months follow-up there was a significant difference between groups in the Cleveland Clinic Incontinence Score favouring the artificial bowel sphincter group (p=0.002) and in the American medical systems (AMS) quality of life score (p=0.04) favouring the artificial bowel sphincter group. Three perioperative complications were reported in the surgical group.

Sacral nerve stimulation: stimulators 'on' vs 'off'.

Vaizey et al[74] and Leroi et al[73] both report results from cross-over studies during which all patients were implanted with a sacral nerve stimulator. All patients had their stimulators turned 'on' or 'off' for an initial phase of the trial which was immediately followed by a second phase during which the stimulator was turned to the opposite setting. They both had a highly selective study population as only patients that responded positively to the initial trial phase were included. Although the study by Vaizey et al[74] only recruited two patients, there was a large magnitude of treatment effect; the median episodes of incontinence (over the two weeks test period) of solid or liquid stool decreased from baseline to when stimulation was turned 'on' (12 vs. 1 respectively). Leroi et al[73] was a larger trial conducted in 27 patients. In this trial the treatment effect was not so large. The median frequency of FI episodes per week was 0.8 (range 0-11) during the 'on' phase compared to 1.9 (range 0-11) during the 'off' phase of the trial (p=<0.05).

In the Leroi et al study, even though the median frequency of FI episodes and the Cleveland Clinic Incontinence Score were both significantly reduced when the active 'on' period was compared to the 'off'' period; this difference was small compared with the reduction observed between the on period and the baseline period. One explanation could be that there is a substantial placebo response associated with SNS, in which case the results of SNS case series should be treated with scepticism. However, there was a significant increase in sphincter pressures in the treated group and interestingly, this increase was maintained during the 'off' period of the trial. The results of both these studies[73,74] could be due to 'contamination': during the off period patients were still benefiting from having the device switched on in the previous period and therefore the treatment effect is diluted. The suggestion is that SNS has a beneficial effect on nerve function that is prolonged for some time after stimulation has ceased.

Dynamic graciloplasty vs no surgery

Tillen et al[72] conducted a non-randomised controlled trial reported within an HTA report with a total of 88 patients. A group of 48 patients with stomas or refractory FI who underwent DGP were compared with a group of 40 patients not offered surgery (standard care). At 24 months there was a significantly greater change in the mean Cleveland Clinic Incontinence Score (p=0.001), depression scale (p=0.05) and lifestyle scale (p<0.0001) in favour of the surgery group however, this group also reported high numbers of evacuation difficulties/pain (n=33), infections (n=31) and circulatory problems (n=23).

6.1.4 Cost-effectiveness evidence

We found four economic studies that compared surgery for faecal incontinence with conservative management. Three were evaluating different types of surgery for patients with severe intractable FI and one evaluated implantation of a neuroprosthesis for patients with spinal cord injury (evidence table 34, appendix D).

A Dutch study evaluated a case series of 43 patients undergoing DGP for severe intractable FI[75]. They measured the costs and quality of life before and after surgery. Before surgery patients were being conservatively managed with 'diapers, enemas, tissues, and diets'. Costs and quality of life were observed up to 12 months post-surgery and were projected 29 years into the future. They found that DGP improved quality of life (by various measures) but was more costly (£19,800 vs £7,600) than conservative management. It is difficult to say whether DGP is cost-effective compared with conservative management because health outcomes were not measured in QALYs and were based on before-after comparisons.

A detailed model was developed for an NHS HTA report[72] using a case series of 91 patients undergoing DGP and costs from NHS hospitals. Costs and quality of life were observed up to 48 months post-surgery and were projected 21 years into the future. The changes over 12 months in the EQ-5D – the quality of life instrument used to calculate QALYs – (+4% vs +1%) were not statistically significant, although other measures of quality of life were significant. In their base case analysis the authors found that DGP cost £40,000 per QALY gained compared with conservative management ('incontinence pads, prescriptions, some inpatient and outpatient care and community health services'), which is above our threshold of £30,000 per QALY gained. However, when they used costs from other specialist NHS centres (rather than the Royal London Hospital where the case series was based), the ratio fell to £29,000 per QALY gained. The results of the model are highly contingent on the assumptions used to project the results in to the future, such as the constant failure rate for DGP and the rate of conversion to stoma for patients who are conservatively managed. In patients with a shorter life expectancy than the base case (25 years), DGP will be less cost-effective, because there is less time to offset the surgical costs with longer term cost savings.

Both of the above studies[72,75] additionally compared stoma formation (and aftercare) with conservative management. In both cases, stoma formation was considerably more costly than conservative management (£2,100 vs £400 per year[72]). Neither study presented evidence on the health gain associated with stoma formation, although each suggested that the improvement in quality of life was minimal.

The third study[76], a simple model based on two cohorts (n=49), compared both sacral nerve stimulation and anal sphincter repair with conservative management for patients with incapacitating FI due to a variety of causes.

Surgery was more costly than conservative management, although there was no statistical analysis and no estimate of health gain.

The fourth study[77] presented a case series of 17 patients with supra-sacral spinal cord injury in the USA. They found that neuro-prosthesis was cost saving after 5 years compared with conventional care. In addition to the small sample size and poor study design, the usefulness of this study is limited because:

a. It was not subjected to statistical or sensitivity analysis, and

b. Care pathways and costs are likely to be different in this US setting compared with the NHS. Moreover these results are only applicable to patients with major spinal injury and are therefore not applicable to the majority of patients with incapacitating FI.

6.1.5 Conclusions

The results of the Osterberg et al[56] study show that levatorplasty yielded better early results than anal plug electrostimulation of the pelvic floor, but this effect was lost by 1 year follow up. One comparative study was in favour of the artificial bowel sphincter over supportive care [71]. The Tillin et al[72] study showed that patients having DGP had a significant improvement in continence scores compared with the group without surgery.

DGP is borderline cost-effective compared with conservative management for patients with severe intractable FI and a reasonably long life expectancy. Stoma formation with aftercare and other forms of surgery are costly compared with conservative management but there is no evidence regarding their cost-effectiveness.

The recommendations on surgical management are in section 6.7.

6.2 Are any surgical interventions more effective than others?

6.2.1 Introduction

Several different surgical approaches may be possible for an individual patient. It is useful to compare, therefore, not only how effective surgery is for faecal incontinence, but how well each type of surgery performs in a given scenario compared with a different surgical intervention. For example, patients with anal sphincter disruption could be eligible for overlapping or end-to-end sphincter repair or sacral nerve stimulation (SNS). Injection of bulking agents is also a possible management option in these patients. Patients with weak but intact sphincters could have a post anal repair, pelvic floor plication (levatorplasty), a total pelvic floor repair, bulking agents, or SNS. Secondary procedures for failed primary interventions include repeat sphincter repair, artificial bowel sphincter, dynamic graciloplasty and sacral nerve stimulation.

6.2.2 Studies considered for this review

Randomised and non-randomised comparative study designs were considered for inclusion if they compared one surgical intervention for faecal incontinence with another surgical intervention in adult patients with faecal incontinence.

6.2.3 Clinical evidence

Four RCTs[78-81] and two non-randomised controlled trials[82,83] met the inclusion criteria for this clinical question (evidence table 20, appendix D). One of the non-randomised controlled trials was a matched control trial [82] while the second was a non-randomised controlled trial[83].

Post-anal repair vs levatorplasty vs total pelvic floor repair

One study[79] with a total of 36 female participants with faecal incontinence related to pundendal neuropathy and a history of obstetric trauma randomised participants to post-anal repair (n=12), anterior levatorplasty (n=12) or total pelvic floor repair (n=12) groups. This study with a follow-up period of 24 months reported that quality of continence, frequency of continence per month, continence score after total pelvic floor repair was significantly better than for post-anal repair and anterior levatorplasty.

Post-anal repair vs total pelvic floor repair

A study by van Tets et al[80] randomised 20 female patients to either post-anal repair (n=11) or total pelvic floor repair (n=9) groups. No significant differences were found between clinical, manometric and radiologic outcomes between the groups at the follow-up at 42 months.

Total pelvic floor repair vs total pelvic floor repair with plication

In a study by Deen et al[78] 33 female patients with FI related to pudendal neuropathy, patients were randomised to total pelvic floor repair (n=18) or total pelvic floor repair and plication of the internal anal sphincter (n=15). There was no significant difference in continence scores. There was a significant difference in maximum resting pressures in favour of total pelvic floor repair compared to total pelvic floor repair with plication.

Total pelvic floor repair vs gluteoplasty

The final RCT[81] reported results from 24 women with post-obstetric faecal incontinence who were randomised into total pelvic floor repair (n=12) or gluteoplasty groups (n=12). At a median follow-up of 10 months no significant differences were found in continence scores, manometry or adverse effects between the two groups.

Dynamic graciloplasty: one step vs two step

Rongen et al[82] conducted a matched control study to compare the effectiveness of one vs. two step dynamic graciloplasty for 26 patients with faecal incontinence. The one step procedure involved the muscle wrap and the implant of the electrodes and implanted pulse generator (IPG) in one operation. The two-step procedure received the implant in a separate operation 6 weeks after the muscle transposition. Although there was a difference between the faecal incontinence, morbidity and quality of life outcomes, there were not significant. The results of the trial suggest that a one-step procedure is feasible and will avoid the extra admission and secondary procedure of a two step approach.

Sphincter repair: perineal approach vs posterior fourchette approach

A non-randomised controlled trial[83] reported results at a mean of 22 months for 50 women with sphincter injuries who underwent anterior overlap sphincter repair. The first 32 underwent surgery by the perineal approach and the subsequent patients by the posterior vaginal fourchette approach. Both groups had significantly improved continence scores after surgery, but these postoperative scores were not significantly different between the groups. There was significantly more wound complications from perineal compared to the posterior fourchette approach.

6.2.4 Cost-effectiveness evidence

We found four economic studies that compared different types of surgery for faecal incontinence (evidence table 34, appendix D).

The first study[84] was a case series of 75 patients with severe FI undergoing surgery. The authors found that total pelvic floor repair improved continence and reduced costs compared with post-anal repair (£2,200 vs £2,700). There were a number of limitations; not least there was no statistical analysis and the follow-up periods differed between the groups.

A Dutch study compared a case series of 43 patients undergoing dynamic graciloplasty (DGP) with seven patients undergoing stoma formation. This study was described in 6.1.4. The authors found that DGP was cost-saving compared with stoma formation (£19,800 vs £44,700). This study has been criticised for inflating the cost of stoma care[72,85], which was based on only seven patients.

A detailed model was developed for an NHS HTA report[72] and has also been described in 6.1.4 above. They found that DGP was dominant (cost saving and quality of life improving) compared with stoma formation for patients being conservatively managed at the outset. For patients already receiving stoma care at the outset, the conversion to DGP was not cost saving but it was cost-effective (between £5,000 and £15,000 per QALY gained). As noted in 6.1.4, in patients with a life expectancy less than that assumed in the model (25 years), DGP will be less cost-effective, because there is less time to offset the surgical costs with longer term cost savings.

The fourth study[76], a simple model described above (6.1.4). Sacral nerve stimulation was substantially more costly than sphincter repair (£14,800 vs £3,600) but, using data from the Dutch study above, substantially less costly than DGP (£21,000) or stoma formation (£22,000), although statistical analysis was not conducted.

6.2.5 Conclusions

Although Oya et al[79] showed that total pelvic floor repair is more effective in improving faecal incontinence than post-anal repair or anterior levatorplasty, it is currently rarely performed in clinical practice.

Deen et al[86] found that total pelvic floor repair significantly improved the continence scores compared to levatorplasty and post-anal repair. However, van Tets et al[80] found no significant difference between total pelvic floor repair and post-anal repair. Another study[78] found no significant difference between total pelvic floor repair with and without placation of the internal anal sphincter. Yoshioka et al[81] found no significant differences between total pelvic floor repair and gluteus transposition.

The non randomised controlled trial[83] found that sphincter repair by the perineal approach had significantly more wound complications than the posterior fourchette approach.

Dynamic graciloplasty is cost-effective compared with stoma care, except in patients with a short life expectancy. The trial by Rongen et al[82] suggests that

a one-step procedure should be standard practice as opposed to a two-step procedure.

The recommendations on surgical management are in section 6.7.

6.3 Do any interventions, pre or post surgery, affect the outcome of surgery for FI?

6.3.1 Introduction

This review was conducted to evaluate if any pre or post operative conservative interventions would optimise the outcomes of surgery. Interventions pre/post surgery may alter stool consistency, optimise muscle function or promote optimal healing. Examples of interventions are medications, exercises, bowel retraining, biofeedback, diet, bowel management in the pre or post-operative period or a covering stoma.

6.3.2 Studies considered for this review

Randomised and non-randomised comparative study designs which compared the effectiveness of an additional conservative therapy (pre or post surgery) or surgical adjuncts compared with surgery alone at managing faecal incontinence. Studies conducted in adult patients with faecal incontinence were selected.

6.3.3 Clinical evidence

Three studies[87],[88],[89] met the inclusion criteria for this clinical question (evidence table 21, appendix D).

Sphincter repair vs sphincter repair and biofeedback

One study[87] with a total of 31 female participants with an external anal sphincter defect and faecal incontinence for at least 12 months randomised patients to either sphincter surgery (sphincter repair and levatorplasty) (n=17) or sphincter surgery plus biofeedback which commenced three months post surgery (n=14). This study with a follow-up period of 9 months reports comparisons between groups at 3 and 12 months which are not statistically significantly different in any of the functional or physiological variables.

Sphincter repair and medical bowel confinement vs sphincter repair plus regular diet

One study[88] reported results in 32 adult patients with faecal incontinence undergoing anal sphincter repair. Patients were randomised to receive either sphincter repair plus medical bowel confinement (n=17) which consisted of a clear liquid diet and loperamide and codeine phosphate until the third post-operative day or to receive sphincter repair plus regular diet beginning the day of the surgery (n=15). There was no statistical difference in the mean change of continence score from pre to postoperatively between the two groups. There was a significant difference between the groups in the first post-op bowel movement 3.9 mean days in the medical bowel confinement group vs. 2.8 in the regular diet group (p=0.05). The authors reported no significant difference in complications between the groups but the sample was too small for detecting such differences.

Sphincter repair with defunctioning stoma vs sphincter repair without a stoma

One study [89] randomised 27 patients with faecal incontinence requiring sphincter repair to additional defunctioning stoma (n=13) or no stoma (n=14). There was no significant difference between groups in any of the outcomes measured, for example, the Cleveland Clinic Incontinence Score, complications, and hospital stay at a mean follow-up period of 34 months.

6.3.4 Cost-effectiveness evidence

We found one relevant economic study for this question (evidence table 34, appendix D).

This study[88] mentioned in the clinical review above, was based on an RCT of 54 patients undergoing surgery for intractable FI. It evaluated immediate post-surgical feeding with normal diet versus post-surgical bowel confinement. They found no significant difference in either hospital charges (£8,000 vs £6,800) or complications but the sample was small for detecting such differences.

6.3.5 Conclusions

In the Nessim et al study[88] there was no significant differences between the sphincter repair plus medical bowel confinement group and sphincter repair plus regular diet groups.

Evidence from the Davis et al study[87] does not suggest that surgery plus post-operative biofeedback is more effective at managing faecal incontinence as compared with surgery alone. Results from the Hasegawa et al study[89] do not show any significant differences between having a defunctioning stoma and not having a stoma during sphincter repair.

The recommendations on surgical management are in section 6.7.

6.4 Systematic review of case series

6.4.1 Introduction

We undertook a systematic review of surgical case series for the treatment of faecal incontinence for the following reasons:

- a small number of RCTs and non-randomised comparative trials were retrieved for the clinical questions on surgery
- many of retrieved comparative studies were conducted in small patient groups
- most of the retrieved comparative studies investigated the effectiveness of surgical interventions which are rarely performed
- most of the retrieved comparative studies did not provide long-term results.

Case series, by definition, do not have a control group and therefore have to be interpreted with caution since observed outcomes could be attributable (partly or wholly) to a placebo response or to a regression to the mean effect, as well as to a real treatment response. The GDG considered this evidence with these issues in mind.

6.4.2 Inclusion criteria and methods

Due to the limitations of case series discussed above, the following inclusion criteria was agreed:

- reported results on sphincter repair, repeat sphincter repair, antegrade irrigation, levatorplasty, post-anal repair, total pelvic floor repair, bioinjectibles/sphincter bulking agents, island advancement flap anoplasty, sacral nerve stimulation, dynamic graciloplasty, gluteoplasty, artificial bowel sphincter +/- any conservative intervention
- reported results from at least ten truly consecutive patients with faecal incontinence
- had at least 12 months follow-up
- were published after 1990.

In addition to standard data extraction, patients were categorised as ‘cured’, ‘improved’ or ‘not improved’ and proportions calculated. ‘Cured’ was defined as attainment of complete continence to solid, liquid and gas. ‘Improved’ was defined as an improvement of symptoms. In studies which did not distinguish

between proportion of patients that were 'cured' and 'improved', the category 'improvement of symptoms' may include patients that were 'cured'. The category 'Not improved' included patients whose symptoms remained the same or worsened following surgery. These categories were also divided into two groups depending on whether the outcomes were reported by clinicians or patients. The GDG acknowledged that clinician-reported outcomes and patient-reported outcomes after surgery may differ; therefore both types of outcomes were recorded, and considered separately. When studies reported incontinence scores from patient's feedback this was considered to be a patient-reported outcome. However, if scores were determined from patient's case notes this was considered to be a clinician-reported outcome. Weighted mean percentages of 'cured', 'improved' or 'not improved' faecal incontinence were calculated to the nearest per cent for each surgical intervention using the number of patients in the study at time of follow-up. Frequently studies did not report outcomes amenable to all the categories used. Therefore weighted means often do not total 100% for each study. Some studies did not report outcomes amenable to any of these categories. Percentages of complications were also recorded.

6.4.3 Sphincter Repair

29 case series[9,70,90-116] with a total of 1379 subjects met the inclusion criteria (evidence table 22, appendix D).

The weighted mean percentages calculated from the clinician-reported outcomes are as follows; 40% of patients' reported no faecal incontinence symptoms ('cured'), 47% of patients symptoms were 'improved' and 13% of patients symptoms were 'not improved'.

The weighted mean percentages calculated from the patient-reported outcomes are as follows; 29% of patients reported being 'cured', 52% 'improved' and 36% had 'not improved' after surgery.

Wound complications were reported in 20% of patients, 2% of patients had bleeding complications and 12% had unknown or other complications from the surgery (summary results table 1, appendix E).

6.4.4 Repeat sphincter repair

Two studies[117,118] with a total of 46 patients met our inclusion criteria for repeat sphincter repair (evidence table 23, appendix D).

The weighted mean percentages calculated from the patient-reported outcomes are as follows; 64% of patients reported that their faecal incontinence symptoms had 'improved' after surgery while 36% reported 'no improvement'.

No complications from surgery were reported but in one study[117,118] two patients underwent further surgery for faecal incontinence (summary results table 2, appendix E).

6.4.5 Levatorplasty

Two studies[105,119] reported results from 76 patients undergoing levatorplasty, both describing anterior levatorplasty (evidence table 25, appendix D). One of these studies retrieved[119] combined anterior levatorplasty with external anal sphincter plication.

When the results from these studies were combined, 21% of patients reported a 'cured' outcome, 63% reported 'improved' symptoms while 6% of patients were reported by their clinicians not to have improved.

Six per cent of patients had wound infections. No other complications were reported (summary results table 3, appendix E).

6.4.6 Total pelvic floor repair

Only one study[120] assessed the affects of total pelvic floor repair surgery (evidence table 26, appendix D). Of the 57 patients available at follow-up, clinicians reported 70% had improved while 30% had not improved. Complications were not reported (summary results table 5, appendix E).

6.4.7 Post-anal repair

Six studies[121-126] with a total of 128 patients at follow-up reported results after post-anal repair surgery (evidence table 24, appendix D).

Combined clinician-reported outcomes resulted in 35% of patients being 'cured' and 65% 'improved'. Fourteen per cent of patient-reported they had been cured following surgery, 45% improved and 43% not improved.

Five per cent of patients had wound infections and a further 3% had other complications (summary results table 4, appendix E).

6.4.8 Dynamic Graciloplasty

Nine studies[127-134 135] reported results for patients undergoing dynamic graciloplasty (evidence table 28, appendix D) with a total of 559 patients.

Clinicians reported that 33% of the patients were ‘cured’ following surgery, 56% had ‘improved' while 45%’ not improved’. The patient-reported outcomes are as follows: 29% of patients reported that they were ‘cured’, 73% felt they were ‘improved’ while 15% reported that they had ‘not improved’ following the dynamic graciloplasty. Major wound complications were reported in 37%, minor wound complications in 22% and device/stimulation problems in 40% of patients (summary results table 9, appendix E).

6.4.9 Gluteoplasty

One study[127] reported results for dynamic gluteoplasty in 11 patients who were followed-up for 24 months (evidence table 29, appendix D). Forty-five per cent of patients reported that they had ‘improved’ episodes of faecal incontinence after surgery while 55% of patients had ‘not improved’.

Major wounds complications were reported in 36% of the patients, 18% had minor wound complications and 45% had problems with their device or stimulation problems (summary results table 10, appendix E).

6.4.10 Artificial bowel sphincter

13 case series[136-148 149] were found in which 390 patients underwent implantation of an artificial bowel sphincter (evidence table 30, appendix D). Of the four studies which reported changes in continence outcomes, clinicians reported that 80% of patients had ‘improved’. One study reported that 75% of patients reported having ‘improved’ symptoms. However, it should be noted that in the remaining nine studies continence outcomes were not reported.

There was a high complication rate for this procedure; nineteen per cent of patients had complications associated with wound infection, while 47% had other complications (summary results table 11, appendix E).

6.4.11 Island advancement flap anoplasty

One study[150] reported a case series of 15 patients who had undergone island advancement flap anoplasty to repair the internal sphincter (evidence table 33, appendix D).

No results were reported that indicated the proportion of patients cured, improved or not improved. Twenty per cent of patients had a wound infection following surgery (summary results table 7, appendix E).

6.4.12 Bioinjectibles/sphincter bulking agents

One study[151] reported on 15 patients undergoing injection of a bulking agent (Durasphere) to manage faecal incontinence (Evidence Table 32, Appendix D). No continence data appropriate for the weighted mean proportions was reported. Thirty-three per cent of patients had unspecified complications (summary results table 6, appendix E).

6.4.13 Radio frequency energy (secca procedure)

One study[152] reported on ten patients that underwent the SECCA procedure of radio-frequency energy (evidence table 31, appendix D). No continence or complication data appropriate for the weighted mean proportions was reported.

6.4.14 Sacral Nerve Stimulation

Six studies[10,153-158] were identified for sacral nerve stimulation surgery (evidence table 27, appendix D). Ninety four patients were assessed by a clinician for changes in faecal incontinence symptoms after surgery. Eighty nine per cent of patients had ‘improved’. No results were reported for ‘cured’ patients or patients who had not improved following surgery. Five per cent of patients suffered wound infection, with 15% of patients undergoing other complications (summary results table 8, appendix E).

6.5 Conclusions from surgical case series

The selection process for a particular operation can be difficult. The initial surgical management will depend on the severity of the clinical symptoms and the anatomy of the sphincter as depicted by anal ultrasonography or MRI.

There is no evidence for the direct repair of the internal anal sphincter. Other options may include injections of collagen or biospheres (see section 6.4.12), the Secca procedure (see section 6.4.13) or island flap anoplasty (see section 6.4.11). None of these procedures have been subjected to long-term follow-up and should be considered experimental for the present.

There are a large number of case series of anal sphincter repair involving a total of 1379 patients. Synthesis of this evidence suggests that physician reported outcomes are better than patient-reported outcomes and that there is a deterioration of symptoms over time.

A very small number of case series were found on all other procedures with almost no long term follow-up. Neosphincters are associated with high reported complication rates.

Cost-effectiveness of sacral nerve stimulation

We have not found published economic evidence concerning sacral nerve stimulation (SNS). However, we cautiously conclude that SNS is cost-effective on the basis of the case series evidence, as follows. It has been shown that dynamic graciloplasty (DGP) is borderline cost-effective (section 6.1.4). The case series evidence shows that SNS has a higher effectiveness rate and has fewer complications compared with DGP. Furthermore anecdotal evidence suggests that compared with DGP, SNS is associated with a shorter length of stay – most patients can undergo day surgery - and the costs of the SNS procedure are lower. From a small sample of Trusts we have found the procedural cost of SNS (permanent device) was between £6,500 and £10,500 compared with the £12,000 to £22,000 for DGP reported in the NHS HTA report[72]. Therefore, it would seem that SNS is likely to be more cost-effective than DGP, assuming that the patient cohorts are broadly similar in the severity of their FI and also assuming that the longer term effectiveness, currently unknown, would also favour SNS.

6.6 Research on patient views

A systematic review of patient views about surgery was undertaken. Three relevant studies were retrieved (evidence table 1, appendix D).

One study[10] investigated the effect of SNS on patients' sex lives. Of the 16 participants, nine were sexually active, all of whom said their sexual activity had been hampered by faecal incontinence. Seven of these nine reported an improvement in their sexual lives after SNS, with greater improvement for younger patients.

The second study investigated perception of success after anal sphincter repair for obstetric trauma[9]. Patients rated incontinence outcomes before and after the operation. 71% of patients with a successful outcome reported improvement in overall bowel control. These patients were also asked to rate their perceived change in incontinence symptoms. This showed a decrease in time with 85% (median score) of patients perceiving an improvement at 15 months compared to 50% at 77 months. No patient was fully continent. The results suggested that postoperative scores were affected by patients' perception of success. For instance, patients who had unsuccessful operations tended to rate preoperative incontinence outcomes higher than patients with successful operations did. This demonstrates the difficulty in using subjective assessment to evaluate interventions.

The third study investigated the views of 69 patients who had previously undergone colostomy operation (median 59 months previously). A majority thought that a stoma restricted their life 'a little' or 'not at all' (83%). Satisfaction with the stoma was 9/10 (median score), although a minority hated it. Five patients described life as being 'a nightmare', or 'hating themselves'. However, 84% of patients claimed they would 'probably' or 'definitely' have the stoma again. When asked to comment on how much change having a stoma made to quality of life, the median rating (from -5 to 5) was +4.5. However, this patient group was a self-selected sample and may not be representative.

6.7 Recommendations

All patients considering or being considered for surgery should be referred to a specialist surgeon to discuss:

- **the surgical and non-surgical options appropriate for each patient**
- **the potential benefits and limitations of each option, with particular attention to long-term results**
- **realistic expectations of the effectiveness of any surgical procedures under consideration.**

Rationale: Although no specific evidence was retrieved for this recommendation the GDG considered that it is important to have a logical plan of action for the management of faecal incontinence and to provide adequate information on the options.

Patients with a full length external anal sphincter defect (with or without an associated internal anal sphincter defect) and faecal incontinence which restricts quality of life should be considered for sphincter repair for defects that are 90º or greater. Patients should be given a realistic expectation of what this operation can achieve and possible adverse events, both in the short and long term.

Rationale: Evidence retrieved in section 6.4.3 was considered by the GDG. After consulting with expert advisors and participating in a consensus development exercise the GDG made the above recommendation.

Identification of which symptoms trouble the patient and what can be achieved by repair is essential. Thus continence to flatus can rarely be restored once lost and dietary modification with medication may be more helpful. Urgency is incapacitating but may not be improved by repair. In the main it is incontinence to solid stools that is helped by repair. On the other hand, passive soiling due to loss of internal sphincter function is rarely helped by surgery.

Patients need to understand that the results tend to deteriorate with time so this is an important consideration.

A patient with early onset incontinence after an obstetric or other injury to the external anal sphincter or with a combined IAS defect should be considered for repair. In later onset incontinence, where the defect may have been present for some time, caution should be exercised since the defect may not necessarily be the only cause of incontinence as it might have been expected to cause symptoms earlier if that were the case. It seems reasonable only to

repair larger defects as smaller defects would be expected to have less influence on overall continence.

Patients with internal sphincter defects, pudendal nerve neuropathy, multiple defects, external sphincter atrophy, loose stools or irritable bowel syndrome should be informed that these factors are likely to decrease the effectiveness of anal sphincter repair.

Rationale: No specific evidence was retrieved examining conditions that would lead to anal sphincter repair being less effective. After consulting with expert advisors and participating in a consensus development exercise the GDG recommended that patients should be informed that the effectiveness of anal sphincter repair decreases with the factors described above.

Expert opinion suggests that most surgeons have found that it is impossible to successfully repair the internal anal sphincter successfully. If passive soiling is the main complaint and an IAS defect is present, then patients need to understand that a successful outcome is probably not to be expected.

Attempts have been made to identify tests predictive of the results of sphincter repair. Measurement of pudendal neuropathy has shown poor correlation with outcome of sphincter repair. Nerve injury results in muscular atrophy. MRI may identify atrophy and anal ultrasound also provides some qualitative assessment of external anal sphincter muscle thickness.

Irritable bowel syndrome (IBS) and diarrhoea/loose stools are more difficult to control and the outcome of repair is less predictable in patients with diarrhoea.

Patients undergoing a sphincter repair to manage their faecal incontinence should not routinely receive a temporary defunctioning stoma.

Rationale: Evidence retrieved in section 6.3.3 was considered by the GDG. After consulting with expert advisors and participating in a consensus development exercise the GDG recommended that a temporary defunctioning stoma should not be used for routine practice during sphincter repair surgery. Certain clinical situations may make a stoma advisable and this is up to individual surgeons to consider.

Patients undergoing anal sphincter repair should not receive constipating agents in the post-operative period. Feeding should resume as required by the patient.

Rationale: After considering the evidence retrieved in section 6.3.3, consulting with expert advisors and participating in a consensus development exercise the GDG recommended that patients undergoing anal sphincter

repair should not receive constipating agents in the post-operative period. The randomised trial[88] retrieved did not shown any benefit from this policy. Indeed passage of a constipated stool days after the repair may be traumatic to the sphincter repair and may prolong hospital stay.

A trial of temporary sacral nerve stimulation should be considered for patients with faecal incontinence where sphincter surgery is deemed inappropriate. These may be patients with intact anal sphincters, or those with sphincter disruption. In those with a defect contraindications to direct repair may include atrophy, denervation, a small defect, absence of voluntary contraction, fragmentation of the sphincter or a poor quality muscle (see NICE interventional procedure guidance on sacral nerve stimulation (www.nice.org.uk/IPG099)). All patients should be informed of the potential benefits and limitations of this procedure and should undergo a trial stimulation period of at least 2 weeks to determine if they are likely to benefit. Patients being considered for sacral nerve stimulation should be assessed and managed at a specialist centre with experience of performing this procedure.

Rationale: Evidence retrieved in section 6.4 was considered by the GDG. After consulting with expert advisors and participating in a consensus development exercise the GDG recommended that SNS should be considered for patients with faecal incontinence where sphincter surgery is not appropriate. The simplicity of a trial of SNS makes it an attractive first option (section 6.4.14). A successful trial can be followed by a permanent implant. For those failing an implant, the other options can be considered. Recent data have suggested that SNS is successful in approximately 60% of patients tested[73]. The great advantage of temporary stimulation is it allows a trial before permanent implantation. This avoids the potential morbidity associated with implantation of a stimulator, and avoids unnecessary expenditure.

There are few long-term studies on SNS and as yet little information on which groups are more likely to do well.

The mode of action of SNS is not clearly understood. The crossover study carried out by Leroi and colleagues[73] found that a minority of patients selected the 'Off' mode, which appeared to be effective.

If the longer term clinical outcomes (currently not known) turn out to be as positive as the early results, then SNS will be cost-effective in patients with severe life-limiting FI who have not responded to conservative management. Furthermore, it is likely to be cost-saving compared with stoma formation.

Antegrade irrigation via appendicostomy, neo-appendicostomy or continent colonic conduit may be considered in selected patients with constipation and colonic motility disorders associated with faecal incontinence.

Rationale: Although no evidence was retrieved for this recommendation, the GDG made the above recommendation after consulting with expert advisors and participating in a consensus development exercise. Evacuatory disorders and colonic motility problems frequently co-exist with faecal incontinence. These are a challenge to the clinician. On the basis that an empty rectum is likely to leave the patient continent, these approaches have great appeal. However, they are not simple and as in any area of surgery case selection is the key. An appendicostomy is the simplest option but if the appendix has been removed then options using an ileal conduit with one end intussuscepted into the ascending colon are available. An alternative is the continent colonic conduit. These are all quite complex procedures and not effective in all patients.

If a trial of sacral nerve stimulation is unsuccessful patients can be considered for a neosphincter. The two options to be considered are a dynamic graciloplasty or an artificial bowel sphincter (see NICE interventional procedure guidance on stimulated graciloplasty (www.nice.org.uk/IPG159)). Patients should be informed of the potential benefits and limitations of both procedures. Patients being considered for either procedure should be assessed and managed at a specialist centre with experience of performing this procedure.

Rationale: Evidence retrieved in sections 6.1.3, 6.2.3, 6.4.8 and 6.4.10 was considered by the GDG. After consulting with expert advisors and participating in a consensus development exercise the GDG made the above recommendation. Device problems are common and revisional surgery is often required. Patients needs to be highly motivated and prepared to accept the prospects of failure and revisional surgery. The choice between ABS and dynamic graciloplasty will depend on local expertise.

Dynamic graciloplasty is likely to be borderline cost-effective in patients with severe life-limiting FI who have not responded to conservative management. Furthermore, it is likely to be cost-saving compared with stoma formation.

Patients with an implanted sacral nerve stimulation device, dynamic graciloplasty or an artificial bowel sphincter should receive training and ongoing support at a specialist centre. Patients offered this procedure should be informed that they may experience evacuatory disorders and/or serious infection which may necessitate removal of the device. These patients should be monitored, have regular reviews and be given a point of contact.

Rationale: Evidence retrieved in section 6.1.3, 6.2.3, 6.4.8, 6.4.10 and 6.4.14 was considered by the GDG. After consulting with expert advisors and participating in a consensus development exercise the GDG recommended that following SNS, DGP or ABS patients should receive training, support and regular reviews. Evacuation disorders are very frequently made worse after

implantation of an ABS or gracilis neosphincter. Thus it is important to select patients who appear to achieve satisfactory rectal emptying.

A stoma should be considered for patients with faecal incontinence that severely restricts lifestyle only once all appropriate non-surgical and surgical options, including those at specialist centres, have been considered. Patients should be informed of the potential benefits, risks and long-term effects of this procedure. Patients assessed as a possible candidate for a stoma should be referred to a stoma care service.

Rationale: Although no evidence was retrieved for this recommendation, the GDG made the above recommendation after consulting with expert advisors and participating in a consensus development exercise. The GDG felt that it is important to counsel patients that a stoma is not necessarily a simple procedure that will cure all their problems. As with any operation, there may be a price to pay in terms of the outcome. Many develop defunctioned proctitis that in severe cases may necessitate rectal excision. Patients are frequently left with incontinence of mucus and troublesome mucus plugs. A substantial proportion develop stoma related hernias and many require repair.

7 Specific patient groups with faecal incontinence

There may be specific considerations for some groups of patients reporting or who are reported with faecal incontinence. It is important that assumptions are not made regarding the underlying aetiology of patients' faecal incontinence, which is why all patients should initially receive a baseline assessment and be considered for initial management options. If faecal incontinence persists however, special management options should be considered for these groups.

7.1 What procedures are effective in patients or residents in care homes with faecal incontinence related to faecal loading, impaction or constipation?

7.1.1 Introduction

Faecal loading is the term used to describe the presence of a large amount of faeces in the rectum with stool of any consistency. The term faecal impaction is used when there is large amount of hard faeces in the rectum. The colon may also be loaded with faeces in some patients.

Softer consistency stool is more likely to leak than hard stool and is more difficult to contain when it does leak. Some patients with faecal incontinence may have a previous history of constipation, but this is not always the case as it might occur for the first time in the setting of an acute illness.

Many patients and care home residents are incontinent of faeces as a result of faecal loading of the rectum. There may be a problem with faecal incontinence when they enter the care home or it may develop during the course of their care. Physical and cognitive disabilities often co-exist in these residents. Faecal loading is the predominant feature contributing to faecal incontinence in those who have FI.

The management of the problem can be divided into the initial clearance of the faecal loading, followed by planning a bowel management programme in the longer term to prevent recurrence.

7.1.2 Studies considered for the review

Studies were considered for this review which had compared one intervention to manage faecal incontinence related to faecal loading, impaction or constipation to another intervention or no intervention.

7.1.3 Clinical evidence

Two randomised controlled trials were identified that met the inclusion criteria[22,159] (evidence table 18, appendix D).

Intervention vs no intervention

Tobin et al[22] randomised faecally incontinent patients in residential care homes to receive a treatment protocol (n=52) or standard care (n=30). The treatment protocol varied depending on whether the incontinence was “idiopathic” (n=25) or secondary to faecal impaction (n=27). Patients with faecal impaction were treated with lactulose and weekly enemas, while patients with idiopathic FI were treated with codeine phosphate and enemas

twice a week. There was a significant reduction in incontinence in the group with the treatment protocol. Twenty-seven of the 45 patients (60%) randomised to the treatment protocol were no longer incontinent compared to nine of the 28 (32%) patients that were not treated (p=0.047). When only patients with full concordance in the treatment group were considered (n=30) there were 26/30 patients no longer incontinent (87%) (p=0.001).

Laxative + suppository + enema vs laxative alone

In one study[159] elderly residents in long term care were randomised to receive a single osmotic laxative (lactulose) plus daily glycerine suppository and a tap-water enema once per week for 8 weeks or the laxative alone. All trial participants had faecal incontinence with impaired rectal emptying.

Chassagne et al found there was a high dropout rate for the trial as only 123 of the 206 participants (60%) completed 5 weeks of the trial, and 101 participants (49%) completed the full 8 weeks of the trial. A similar number of participants in each group had dropped out by week 5. Most of the dropouts were due to participants being lost to follow up. At week 5 there was no significant difference in the episodes of loss of faeces, soiled clothing or soiled laundry.

7.1.4 Cost-effectiveness evidence

No economic evidence was found.

7.1.5 Conclusions

There was a significant reduction in incontinence in residential care home patients that were given a treatment protocol (patients with faecal impaction were given lactulose and enemas and if the incontinence was idiopathic they received codenine phosphate and enemas) compared to patients that were left untreated.

One study found no additional benefit from giving a glycerine suppository and tap water enema to patients with impaired faecal incontinence and rectal emptying that are already using an oral laxative.

The recommendations can be found in section 7.7.1.

7.2 What procedures are effective in patients with limited mobility and faecal incontinence?

7.2.1 Introduction

Faecal incontinence is a common occurrence in patients with limited mobility. Continence is challenged in this group of patients as they are often dependent upon others to assist them onto a toilet or commode. This may be a transient feature of an acute illness, but in many people the limitations of mobility will be permanent and may be associated with other disabilities which include bowel dysfunction. The environment in which they are living may pose additional difficulties.

Mobility physiotherapy, exercise or interventions to improve mobility may help in both the short term and longer term.

7.2.2 Studies considered for this review

Studies were considered where participants were adults with faecal incontinence and had limited mobility. Interventions considered for inclusion were any mobility interventions, for example, mobility physiotherapy vs any other conservative treatment, with the aim to improve mobility.

7.2.3 Clinical evidence

One RCT[160,161] of 190 incontinent long stay nursing home residents, examined an intervention of exercise, toilet prompting and incontinence care (evidence table 17, appendix D). 73/92 and 74/98 patients from the intervention group and the control group respectively were available for assessment at the end of the 32 weeks study period. The study does not differentiate between urinary or faecal incontinent patients but the baseline incidence rate suggests that faecal incontinence was quite highly prevalent; on average there would be five faecal incontinence events per patient per fortnight. The intervention was provided by carers every 2 hours from 8.00 am to 4.00 pm for 5 days a week for a period of 32 weeks. Residents were encouraged to walk or, if nonambulatory, to wheel their chairs and to repeat sit–to-stands using a minimum level of human assistance. During one care episode per day each resident was given upper body resistance training (arm curls or arm raises) usually while in bed. Before and after each care episode, residents were offered fluids. Usual care was provided to the control group.

The intervention significantly decreased the frequency of faecal incontinence (based on five checks per day) and significantly increased the appropriate faecal toileting ratio (number of times a resident used a toilet or toilet substitute divided by the total number of rectal evacuations).

7.2.4 Cost-effectiveness evidence

Two studies assessed the economic consequences of toilet prompting for care home residents who are frail or have limited mobility (evidence table 8, appendix D).

One cost-consequences analysis[162] compared 2-hourly prompts with the aid of a pneumatic lift, with standard care. The study made before and after comparisons in a case series of 10 severely mobility-impaired female nursing home residents in the USA. Patients were followed up for an average of 68 days and the control period was paradoxically the early stage of the intervention. The cost of the intervention was more than offset by treatment cost savings (£9.44/day vs £17.80/day) due to reduction in bed sores (20% vs 80%) and urinary tract infections (0% vs 60%). They claimed a statistically significant improvement in faecal continence (92% vs 95%) however, 'faecal continence' was not clearly defined and it seems implausible that this difference could be significant in such a small sample. There were other severe limitations to this study. In particular the lack of a control group has great potential for bias and reporting was often unclear.

In a second study[161], also a cost-consequences analysis, an intervention of 2-hourly prompts plus an exercise programme was compared to standard care. The evaluation was based on an RCT of 190 incontinent residents in long stay beds at four nursing homes (see 'clinical evidence' in section 1.2.3). They evaluated potential cost savings from the intervention by measuring the incidence of 31 acute conditions (including: skin irritation, pressure ulceration, respiratory infection, urinary infection, constipation, faceal impaction, pain, injury, depression, weight loss, angina, stroke, hyperglycaemia, etc). The overall incidence, for all 31 conditions, was reduced by 10% but this was not statistically significant and therefore costs were not significantly reduced (£2.20/day vs £3.40/day). They did not cost the intervention itself but they note that staff time was considerable (21 minutes per patient per prompt). In our own crude analysis, we estimate that there was a cost of £88 per FI episode averted (unit costs table 5, appendix F). This cost would be offset in part by savings due to less staff time involved with cleaning and reduced laundry costs.

7.2.5 Conclusions

One RCT showed that prompting and exercise significantly reduced faecal incontinence frequency. There was an increased cost associated with this intervention due to the intensive involvement of staff. Without quality of life data, it is difficult to assess whether this intervention is or is not cost-effective. The GDG therefore decided by expert opinion and consensus development to make recommendations for this clinical question. The recommendations can be found in section 7.7.2.

7.3 In patients who report faecal incontinence who are using enteral nutritional support, what is the effect of lactose free nutritional intervention vs nutritional intervention containing lactose on patient related outcomes?

7.3.1 Introduction

Faecal incontinence (FI) can be exacerbated by diarrhoea. There is a high incidence of diarrhoea and faecal incontinence in critically ill patients. FI also occurs frequently in those with long term conditions receiving enteral tube feeds and in frail elderly patients on enteral sip feeding supplementation. The cause of FI in these cases is likely to be due either to faecal loading/impaction or true diarrhoea. In all groups lack of fibre and/or lactose intolerance may play a role. An enteral feed with fibre may alter bowel transit time and also have a prebiotic effect in the colon. Most manufacturers now produce a range of tube and sip feeds with at least one with fibre (or a mixture of sources of fibre) as well as lactose free feeds.

Faecal incontinence may be reduced or prevented by changing the type of enteral feed or mode of administration. Reducing the incidence of faecal incontinence in patients on enteral nutritional support improves patient's dignity and comfort. A patient on supplementary sip feeding is more likely to be concordant if there is a reduced incidence of diarrhoea. The burden/work load on nurses and carers is likely to be less. Reducing the incidence of FI/diarrhoea in the frail older people may reduce the incidence of falls caused by rushing to the toilet.

7.3.2 Studies considered for this review

Studies were considered where participants were adults with faecal incontinence and using enteral tube or sip feeding. Comparisons of interest included lactose containing feed vs a lactose free feed, feed via continuous drip vs a bolus feeding and a feed with fibre vs a standard enteral feed.

7.3.3 Clinical evidence

We did not retrieve any appropriate studies.

7.3.4 Cost-effectiveness evidence

We did not retrieve any appropriate studies.

7.3.5 Conclusions

As no appropriate evidence was retrieved for this clinical question, the GDG used a consensus development exercise and expert opinion to develop recommendations (section 7.7.3).

7.4 In patients who report faecal incontinence using antibiotics, what is the effect of probiotics vs no probiotics on patient related outcomes?

7.4.1 Introduction

Antibiotic therapy can disturb flora and may precipitate diarrhoea. Probiotics may modulate this effect.

7.4.2 Studies considered for this review

Studies considered for this clinical question evaluated the effectiveness of a probiotic compared to no intervention in adult patients reporting or who are reported with faecal incontinence.

7.4.3 Clinical evidence

We did not retrieve any appropriate studies.

7.4.4 Cost-effectiveness evidence

We did not retrieve any appropriate studies.

7.4.5 Conclusions

We did not retrieve any evidence for this clinical question. No recommendation is made in relation to this clinical question.

7.5 Patients with severe cognitive impairment

Continence is a behaviour that is learnt during early childhood but is lost in many people with severe cognitive impairment. Minor memory difficulty in early Alzheimer's disease or other conditions would be unlikely to contribute to loss of continence but faecal incontinence is very common in people with advanced disease.

The cognitive impairment in these patients will interact with other contributory factors to lead to incontinence episodes or inappropriate defaecation or other behavioural abnormalities to which frontal lobe dysfunction will feature prominently. The behavioural changes will include indifference, lack of insight, and social disinhibition which may lead to passive or active soiling.

Passive soiling refers to episodes when there loss of awareness the presence of faeces in the rectum and its subsequent leakage. This would also apply to patients who passively leak faeces due to loss of consciousness due to the effects of illness, for example coma or to a lesser extent with sedating medications.

Active soiling refers to 'incontinence' episodes that occur as a consequence of an abnormal behaviour. Examples of these include the use of inappropriate receptacle, for example: laundry basket; parcelling, that is, wrapping and concealing; or smearing.

The specialised assessment of a patient with severe cognitive dysfunction might include a search for the following: neuropsychological dysfunction which includes loss of goal-directed ability, disorientation, aphasia, agnosia, unilateral visual inattention, apraxia, frontal lobe apathy, dysexecutive syndrome; clinical depression; psychological motivation (for example: apathy, fear, embarrassment, curiosity, self-determination); manipulation; attention-seeking and spite; and over-dependency (for example, the consequence of de-skilling that evolves as a result of institutionalisation).

The assessment is likely to also include observations and functional analysis and lead to specific interventions founded on structured goal planning that might aim to resolve as well as manage faecal incontinence.

People with severe and profound learning disabilities may have had faecal incontinence from childhood and be labelled as having encopresis. Others may experience faecal incontinence for the first time in adulthood. It is also possible that neurological conditions affecting the bowel will co-exist. It is essential that these patients follow the same initial care pathway as other patients with faecal incontinence. Achieving equal outcomes for people with learning disabilities often means making adjustments. It is important that someone with a learning disability understands what they have to do with their treatment. Information should be provided in 'Easy Read' /or pictures if appropriate. Specialist learning disability providers should support people with learning disabilities in accessing treatment for faecal incontinence in primary, secondary and tertiary care.

No RCTs or non-randomised comparative trials which evaluated the clinical and cost-effectiveness of interventions to manage faecal incontinence in patients with severe cognitive impairment were retrieved. Expert opinion and consensus development was used to develop recommendations for this patient group as they have specific considerations outlined below. The recommendations can be found in section 7.7.4.

7.6 Patients with neurological or spinal disease/injury

These patients differ from non-neurologically impaired patients since the changes in bowel motility, anal sphincter control and manual dexterity contribute to the frequent grossly impaired ability to control bowel function. Faecal incontinence is more prevalent in neurologically impaired patients than in age and gender-matched controls, and management of their condition is often radically different due to the different contributing causes of the symptom[163,164].

No RCTs or non-randomised comparative trials which evaluated the clinical and cost-effectiveness of interventions specifically to manage faecal incontinence in patients with neurological or spinal disease/injury were retrieved. Expert opinion and consensus development was used to develop recommendations for this specific patient group in section 7.7.5.

7.7 Recommendations

When assessing faecal incontinence healthcare professionals should:

- **be aware that faecal incontinence is a symptom, often with multiple contributory factors for an individual patient**
- **avoid making simplistic assumptions that causation is related to a single primary diagnosis ('diagnostic overshadowing').**

Rationale: No specific evidence to support this recommendation was retrieved however, the GDG wanted to draw attention to the risk of assuming that all FI symptoms are secondary to a primary diagnosis, and therefore irreversible. The Disability Equality Duty[16] requires health professionals to take disability and consequent diagnostic overshadowing into account. This is important for this guideline as many causes of FI may be unrelated to a primary diagnosis.

Healthcare professionals should consider a proactive approach to bowel management for the following groups of patients:

- **patients with neurological or spinal disease/injury resulting in faecal incontinence due to complete loss of voluntary control**
- **patients with limited mobility**
- **people with faecal loading or constipation**
- **hospitalised patients who are acutely unwell and develop acute faecal loading and associated incontinence**
- **patients with acquired brain injury**
- **patients with cognitive or behavioural issues**
- **people with learning disabilities.**

Rationale: After consulting with expert advisors and participating in a consensus development exercise the GDG decided to recommend a proactive approach to bowel management should be considered for the above specific groups, as many patients in these groups will not be able to maintain continence without active planning of bowel care. A balance must be achieved between constipation and FI.

7.7.1 Patients with faecal loading contributing to faecal incontinence

Patients in whom acute severe faecal loading is identified as contributing to faecal incontinence should initially be offered a rectally administered treatment to satisfactorily clear the bowel. This will often require treatments to be repeated daily for a few days. The interventions should be offered in the following order, depending on tolerance and if satisfactory bowel clearance is achieved;

- **glycerine suppositories**
- **bisacodyl suppositories**
- **micro enemas**
- **phosphate enemas.**

If these interventions are not appropriate and/or fail to satisfactorily clear the bowel and bowel obstruction has been excluded as possible cause, a potent oral laxative should be offered. Patients should be informed that oral laxatives may cause griping abdominal pain, loose stools and prolonged bowel activity. Toilet access should be ensured.

Healthcare professionals involved in the management of faecal incontinence associated with chronic ongoing faecal loading/impaction should aim to reduce the chance of recurrence by recommending a combination of initial management options tailored to the individual patient (see recommendation in section 3.15). If this fails, consider use of orally administered laxatives to promote bowel emptying. Rectally administered preparations should be used if use of oral laxatives produces faecal incontinence episodes and there is a need to produce planned bowel evacuations.

Rationale: After considering the evidence in section 0, consulting with expert advisors and participating in a consensus development exercise, the GDG decided to recommend that patients with acute severe faecal loading contributing to FI should be offered a rectally administered treatment to clear the bowel. These recommendations formed a step-wise approach to the initial assessment and treatment of this specific group of patients. This is the most common cause of FI in frail older and dependent people. While the exact mechanism is poorly understood, if the bowel can be effectively cleared continence is likely to be restored. There is a high risk of recurrent loading, and so ongoing management plans are needed.

7.7.2 Patients with limited mobility and faecal incontinence

Patients with limited mobility who continue to have episodes of faecal incontinence after initial management should be offered a regimen which will produce a planned, predicted bowel action when carers are present. This may be achieved by a combination oral or rectal laxatives and/or constipating agents. This regimen should also consider:

- **toilet access (see recommendations in 3.15.3)**
- **appropriate disposable products (see recommendations in 3.15.5)**
- **that the stool needs to be in the rectum at the time of the planned bowel action.**

Rationale: After considering the evidence in section 7.2, consulting with expert advisors and participating in a consensus development exercise, the GDG decided to highlight these simple common sense measures for people with limited mobility.

7.7.3 Patients using enteral tube feeding and reporting faecal incontinence

Healthcare professionals should ensure that patients reporting faecal incontinence who are receiving enteral tube feeding have their type and timing of feed modified on an individual basis to establish the most effective way to manage faecal incontinence.

Rationale: No specific evidence evaluating the effectiveness of lactose or lactose-free nutritional intervention for patients who are using enteral nutritional support was retrieved. After consulting with expert advisors and participating in a consensus development exercise the GDG decided that as tube feeding can lead to diarrhoea in some patients that the feed content should be modified to each individuals needs.

7.7.4 Patients with severe cognitive impairment contributing to faecal incontinence

Patients with confirmed severe cognitive impairment should be assessed using a behavioural and functional analysis to determine the nature of, and reason for the behavioural presentation of faecal incontinence. Following assessment, patients should be offered cause-specific interventions founded on structured goal planning that aim to resolve as well as manage faecal incontinence.

Rationale: No specific evidence for this patient group was retrieved. The GDG participated in a consensus development exercise and based this recommendation on expert opinion.

A behavioural analysis should be conducted through observation or discussion to establish the relationship between the environment and faecal incontinence. This will determine the approximate times, location and context of faecal incontinence (antecedents), and reaction by self and others to faecal incontinence (consequences).

A functional analysis should be conducted as the causes of faecal incontinence in moderate/severe cognitive impairment are often multifactorial. A functional analysis builds on the empirical rigour of a behavioural analysis to identify the function of faecal incontinence.

Classification of common causes of faecal incontinence assists a functional analysis; neurologically disinhibited rectum, neuropsychological dysfunction (for example, loss of goal-directed ability, disorientation, aphasia, agnosia, unilateral visual inattention, apraxia, frontal lobe apathy, dysexecutive syndrome), clinical depression, psychological motivation (for example, apathy, fear, embarrassment, curiosity, self-determination), manipulation, attention-seeking and spite, and over-dependency (for example, the consequence of de-skilling that evolves as a result of institutionalisation).

After conducting a robust observation and functional analysis healthcare professionals should offer patients with confirmed severe cognitive impairment related FI cause-specific interventions founded on structured goal planning that aim to resolve as well as manage FI.

Multimodal intervention should be considered as a preventative methodology for patients in care homes. The clinical protocol constitutes a global response to the known causes of FI. It endeavours to avoid, compensate for or accommodate the reasons for faecal incontinence in cases of moderate-severe cognitive impairment.

7.7.5 Patients with neurological or spinal disease/injury resulting in faecal incontinence

Patients with neurological or spinal disease/injury resulting in faecal incontinence due to complete loss of voluntary control who continue to have episodes of faecal incontinence after initial management should be offered a bowel management programme which aims to achieve a predictable routine and avoid faecal incontinence and severe constipation. Management should involve progressing through the following steps until satisfactory bowel habit is established:

- **ascertaining patient preferences**

- **ascertaining pre-morbid bowel habit, if possible**
- **maximising patient's understanding of normal bowel function and how it has been altered**
- **modifying diet and/or administration of rectal evacuants and/or oral laxatives, adjusted to individual response, to attempt to establish a predictable pattern of bowel evacuation**
- **consideration of digital anorectal stimulation for patients with a spinal cord injury and those with other neurogenic bowel disorders**
- **consideration of manual/digital removal of faeces, particularly for patients with a lower spinal injury if there is a hard plug of faeces in the rectum, presence of faecal impaction, incomplete defaecation, an inability to defaecate and/or all other bowel emptying techniques have failed to achieve bowel empting and continence in a reasonable time.**

Healthcare professionals should consider the following management options for a patient unable to achieve reliable bowel continence after a neurological bowel management programme:

- **coping and long term management strategies for symptomatic patients (see recommendations in 3.15.5 and 3.15.6)**
- **rectal irrigation if feasible**
- **a stoma or other surgical options if faecal incontinence or time taken for bowel emptying imposes major limits on lifestyle.**

Rationale: No specific evidence was retrieved that considered the effectiveness of management of FI in patients with neurological or spinal disease/injury. However, after consulting with expert advisors and participating in a consensus development exercise the GDG decided to recommend that this group follow a progression of management steps to establish a satisfactory bowel habit. In addition, the GDG recommended that those patients that could not achieve this should consider other alternatives such as coping strategies. Patients with neurological or spinal disease/injury, there is delay in colonic transit and in-coordination of rectal and anal sphincter function[164,165]. The management of the former may result in worsening faecal incontinence due to the latter, and management must take in to account patient and carer preference and what is practically available to the patient. Multi-modal assessment and intervention is required to deal with the burden of faecal incontinence in these patients.

7.7.6 Recommendations on other specific groups

Healthcare professionals should consider a faecal collection bag for patients in intensive care settings and patients receiving palliative care who report or are reported with faecal incontinence and associated loose stools who are not undergoing active treatment.

Rationale: No specific evidence evaluating the effectiveness of a faecal collection bag for patients in intensive care or receiving palliative care was retrieved. After consulting with expert advisors and participating in a consensus development exercise the GDG decided to recommend the use of a faecal collection bag in these specific groups as severe uncontrolled diarrhoea is a threat to skin integrity and a major nursing care problem.

7.8 Recommendation for research

The GDG identified the following priority area for research:

Does a bowel management programme for older people in care homes improve faecal incontinence, constipation and patients' and carer's perceptions of quality of care?

Why this is important:

Over 50% of older people in care homes suffer from bowel related problems. This is the cause of much anxiety and discomfort for patients, as well as adding to the carer burden. Moreover, with the UK's ageing population, this problem will only increase with time. Little research has been done on effective bowel care in this population, and care is expensive (laxatives, pads and carer time) all contributing to the overall cost.

A management program for this population may provide a way to improve quality of patient and carer lives, and improve overall healthcare.

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