### **Committee 16**

# Conservative and Pharmacological Management of Faecal Incontinence in Adults

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# Conservative and Pharmacological Management of Faecal Incontinence in Adults

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#### I. INTRODUCTION

At present there is no accepted international consensus on terminology for faecal and anal incontinence. A working definition of anal Incontinence (AI) was adopted at the last consultation [1] as:

"Anal incontinence is the involuntary loss of flatus, liquid or solid stool that is a social or hygienic problem".

It is proposed by this committee that the consultation adopt this definition, with the additional definition of "faecal incontinence" (FI) as:

"Faecal incontinence is the involuntary loss of liquid or solid stool that is a social or hygienic problem".

The committee did not recommend that it is essential to choose one or other term to use exclusively, but rather recommends that either AI or FI can be used depending on context, as long as the definition is made clear. As the majority of intervention studies have focused on FI rather than AI as an outcome measure, FI is covered in this chapter, except where AI is specified.

This chapter covers conservative management of FI in adults. There is a specific section on issues of particular relevance to frail older adults (section 9). Covered elsewhere in the volume are surgical management of FI (Committee 17), and people with neurological disease or injury (Committee 10). Risk factors and prevention are covered for all groups. Some techniques developed and evaluated in these specific groups may have applications to an adult population, but most have not yet been evaluated. There is at present a very limited evidence base of high quality trials in FI and it remains challenging to provide strong evidence for most interventions. However, expert consensus in this committee and the world literature is unanimous in recommending conservative interventions, singly or in combination, for the majority of patients with FI as first-line management.

It was noted that outcome measures for FI and AI remain in the development stage and there is no consensus on the best measure to use in treatment trials (see Committee 5); this impacts evaluation of study findings because different criteria for successful outcome have been employed.

Conservative management is defined as any nonoperative intervention designed to improve FI incontinence or prevent deterioration. No studies were found exploring how to select patients for operative versus conservative or drug management, and only one study [2] compared these approaches in comparable patient groups, and one study investigated the adjunctive benefits of conservative with surgical management [3], so patient selection remains empirical. The committee recommends a trial of conservative and drug management in the vast majority of patients before considering surgical options because these conservative options are comparatively inexpensive and involve no significant morbidity (see Figure 1). Exceptions would be patients with acute traumatic anal sphincter rupture or an endosonographically confirmed major defect in the external anal sphincter in the presence of gross FI: these patients would be referred for surgical evaluation as first line treatment.

## II. PREVALENCE OF FI AND RISK FACTORS

#### 1. SEARCH

For the previous ICI report [4], the literature review covered the period 1966 to 2003, and 11 population based studies were identified. Since then new population-based studies have been published ( **Table 1**), and additional population based surveys have been identified that were missed in our earlier review. We have updated Table 1 to include all studies published through February, 2008, which met the

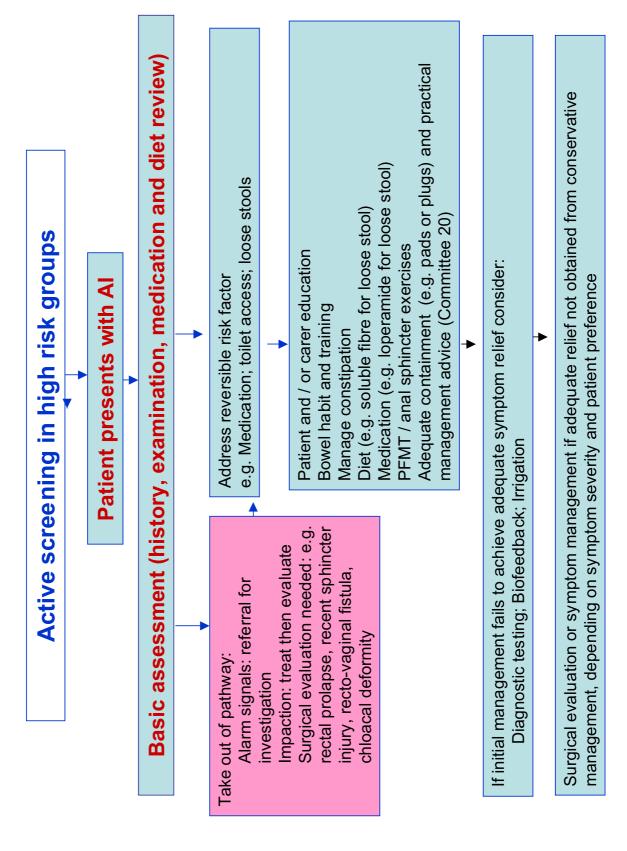


Table 1. Population Based Surveys

Source	Design	Risk Factors	Results
Thomas et al (1984)	Postal survey to all patients in 12 GP practices in London. Patient in nursing homes were included. FI was defined as involuntary leakage of feces at least twice in previous mo.89% response rate.	Age Sex Self-reported FI Confirmed by physi- chian interview.	Strong association. No association. 2,10% 0,40%
Kok et al (1992)	Postal survey of women aged 60+ in Amstelveen, Netherlands. 719 (68.5%) participated. Risk factors for FI not assessed (only for UI). FI defined as occasional involuntary loss of feces.	Age Overall prevalence	Significant association. 16,90%
Nelson et al (1995)	Random digit dialing telephone survey in 6,959 community dwelling adults, all ages. Fl definition includes flatus.	Age Female sex Physical limitations Poor general health	Adjusted OR=1.01 (CI, 1.01-1.02) OR=1.51 (CI, 1.10-2.11) OR=1.82 (CI, 1.20-2.74) OR=1.64 (CI, 1.48-1.91) Overall prevalence 2.2%
Nakanishi et al (1997)	Interviews in home of 1,405 men & women >65 yrs. Fl was ascertained by asking, "Do you soil yourself."	Age Female sex Physical disability Stroke Dementia	Significant association No association Significant association Significant association Significant association Prevalence 8.7% men, 6.6% women
Roberts et al (1999)	Postal questionnaire in age-stratified population sample of 778 men and 762 women aged >50 yrs. FI definition did not include uncontrolled flatus.	Urinary incontinence Age	> half of FI men and women had urinary incontinence Significant for men but not women Prevalence 17.0% for men and 24.6% for women
Verhagen et al (2001)	Postal survey of everyone aged 60+ in 7 general practices in Nijmegen, Netherlands. Supplemented by interview by family MD. n=3345 (86.1%) participated. FI was defined as loss of feces with social and hygenic consequences.	Age Sex Overall prevalence	Significant for men and women No association. 6%

Table 1. Population Based Surveys (Continued)

Source	Design	Risk Factors	Results
Bytzer et al (2001)	Postal survey of 8657 randomly selected Australian adults (60% response rate), including 423 w/ self-reported DM. FI was defined as involuntary loss of stool.	Diabetes mellitus	FI "Sometimes": 12.8% for DM, 3.8% for controls (p<.001). FI "Often": 2.6% vs. 0.8%, OR=2.74 (CI, 1.40-5.37).
Perry et al (2002)	Postal survey in 15,904 randomly selected community dwelling adults aged >40 years. FI definition not include flatus but required frequency of "several times a month."	Age Sex	Significant association No difference Overall prevalence 3.0% age >40
Kalantar et al (2002)	Postal survey of 477 randomly selected community dwelling Australian adults, all ages. FI definition excluded flatus and acute diarrhea.	Age Female sex Perianal injury/surgery Loose BMs Stool urgency Poor general health Straining, hard stools	Significant association No difference Significant association Significant association Significant association No association Prevalence 2% solid, 9% liquid
Walter et al (2002)	Postal survey of 2000 randomly selected Swedish community dwelling adults aged 31-76. Distinguished flatus and soiling underwear from loss of solid or liquid. Threshold was at least monthly.	Age Female sex Loose stools	Significant association in women Significant association for solid or liquid stool. Men reported more soiling of underwear. Significant association Overall prevalence not given
Edwards, Jones (2001)	Interviews in home of 2,818 men and women >65 yrs. Fl defined by the question,"Do you have any difficulty in controlling your bowels?"	Age Female sex Anxiety & depression Physical disability Urinary incontinence	Significant association Significant association Significant association Significant association Significant association Overall prevalence 3% age >65
Chen et al (2003)	Door-to-door survey of 1,253 Taiwanese women representative of the population. FI definition included flatus.	POP Parity >1 Prior GYN surgery Hypertension Overactive bladder	OR=3.2 (Cl, 1.1-8.9) OR=3.4 (Cl, 1.2-9.5) OR=1.8 (Cl, 1.1-2.9) OR=2.4 (Cl, 1.2-4.9) OR=3.2 (Cl, 1.6-6.7) Prevalence 2.8% Fl, 8.6% flatus

Table 1. Population Based Surveys (Continued)

Source	Design	Risk Factors	Results
MacLennan et al (2000)	Interviews in homes of 3,010 men & women >15 yrs. Distinguished incontinence for flatus from incontinence for stool.	Age Female sex Parity >1 Sphincter repair Vaginal vs. C-section Vaginal vs. Instrumental	Significant association OR=1.7 (CI, 1.3-2.2) for flatus; OR=1.6 (CI, 1.0-2.5) for stool Significant association No association No association No association Prevalence 2.3% for FI & 6.8% for flatus in men; 3.5% for FI & 10.9% for flatus in women
Fornell et al (2004)	Postal survey of 1000 randomly selected 40 year-old and 1000 randomly selected 60 year-old Swedist women. Fl defined as leakage >1/month; Ul defined as leakage weekly or more often. Reported flatal incontinence separately from stool incontinence.	3rd or 4th degree tear Parity Vacuum extraction Urinary Incontinence Pelvic Heaviness Obesity	OR=9.1 (CI, 3.0-27.3) for solid stool No significant association No significant association OR=5.9 (CI, 2.4-14.6) for solid stool OR=3.3 (CI, 1.6-7.0) for solid stool OR=2.5 (1.4-4.2) for liquid FI Prevalence 8.9% FI, 11.4% flatus
Stenzelius et al (2004)	Postal survey of 8500 men and women 75+ years. About 15% in "special accommodations". 52.5% response rate. "Have you had problems controlling stools in the last 3 months?" (Flatus was excluded.)	Diarrhea Urinary Sx other than UI Memory problems Difficulty talking Stomach pain Female gender Overall prevalence	OR=6.77 (4.20-10.90) FI, 7.72 (5.80-10.29) DI; OR=2.29 (1.69-3.12) DI; OR=2.26 (1.48-3.46) DI; OR=2.13 (1.56-2.93) DI; OR=1.86 (1.15-3.01) FI; OR=0.70 (0.53-0.93) DI 16.9% FI, 14.5% DI
Teunissen et al (2004)	Postal survey of population-based sample in the Netherlands. Subjects were aged 60+. Excluded were institutionalized people, dementia, too ill to participate, and those with a catheter. Response rate 88% (5748). FI defined as "involuntary loss of solid, liquid or mucus feces" at least 2/month.	Age Sex FI overall prevalence	No effect No effect 9% (includes 3% with double incontinence).

Table 1. Population Based Surveys (Continued)

Source	Design	Risk Factors	Results
Goode et al (2005)	1000 Medicare beneficiaries aged 65+ in 3	Diarrhea	OR=4.55 (2.03-10.20) in women OR=6.08 (2.20-16.16) in men
	Sex and race stratified. Response rate not listed. FI excluded flatus.	Hysterectomy Poor health status	OR=1.93 (1.06-3.54) OR=1.88 (1.01-3.50) in women, OR=2.18 (1.13-4.20) in wenn
		UI TIA or stroke	OR=2.65 (1.34-5.25) in mon. OR=3.11 (1.30-7.41) in men. OP=2.29 (1.04.5.02) in mon.
		Swollen feet & legs Overall prevalence	OR=3.49 (1.80-6.76) in men. 4 6% in women 5.8% in men
Quander et al (2005)	In-person interviews with 6,099 Chicago residents aged 65+. Response rate 78.8%. Institutionalized people were eligible. "Have you ever lost control of your bowels when you didn't want to?"	Age Race Income and education Diabetes mellitus Stroke Psychotropic meds Overall prevalence	Strong association.  No significant difference.  Lower SES strongly associated.  OR=1.7 (1.4-2.1) adjusted.  OR=2.8 (2.2-3.5) adjusted.  All significant associations 9,60%
Melville et al (2005)	Postal survey of 6000 women aged 30-90 enrolled in an HMO. Response rate 64%. FI meant loss of liquid or solid stool at least monthly.	Age Major depression UI Medical comorbidity Overall prevalence	OR=2.11 (1.47-3.03) for age 50-60 vs. age 30-49. 2.73 (1.67-4.51) 2.32 (1.70-3.15) 2.58 (1.66-4.01) (high vs. low) 7,20%

Table 1. Population Based Surveys (Continued)

Source	Design	Risk Factors	Results
Bharucha et al (2006)	2,109 randomly selected females aged 40-69 years from Kaiser HMO. Fl defined as any leakage of stool in last 12 months.	BMI (per 5 units) COPD IBS Colectomy UI Overall prevalence	OR=1.2 (1.1-1.3) OR=1.9 (1.3-2.9) OR=2.4 (1.7-3.4) OR=1.9 (1.1-3.1) OR=2.1 (1.7-2.6) 24% at least once; 3.4% monthly
	2,800 adult women responded to postal survey sent to age stratified random sample of adult women in Olmstead County, MN. Response rate 53%. Index question: "In the past 12 months have you experienced accidental leakage of liquid or solid stool?"	Age (per decade) Urgency Diarrhea IBS Anal injury (not obst) Anal fistula Cholecystectomy Obstet injury Overall prevalence	OR=1.3 (1.2-1.4) OR=5.1 (3.7-7.1) OR=2.4 (1.6-3.6) OR=1.9 (1.3-2.7) OR=2.4 (1.3-4.5) 2.5 (1.2-5.2) 1.4 (1.02-1.9) Not significant 12.1% (11.0-13.1)
Damon et al (2006)	Postal survey of 706 adults in France (30% response rate). Al was defined as >5 of 20 on the Wexner scale.	Age (increase limited to age 80+) Female sex Difficult defecation Incomplete evacuation Overall prevalence	Significant association Significant association Significant association Significant association 7.5% (5.0-10.7%) of women and 2.4% (1.1-4.7%) of men.
Whitehead et al (2008)	CATI assisted interviews with representative sample of 2229 females and 2079 males in U.S. aged 29+. Fl assessed by validated interview version of FISI. Fl defined as any involuntary loss of mucus, liquid, or solid stool in last mo.	Age Sex Ethnicity Marital status Education Family income Prevalence in females	Significant association No significant association Lower rate in Hispanics. No significant association No significant association No significant association 8.8% (7.1-10.4%) 7.7% (6.0-9.4%)

following criteria: [1] Sample is representative of the general population (not a convenience sample or sample recruited from a medical clinic or other setting in which there is a probable selection bias) [2]. At least 500 subjects provided data.

In 2006, Pretlove and colleagues [5] published a systematic review and meta-analysis of 29 studies of Al published prior to September 2004. However, many of the studies included in their analysis were drawn from medical or surgical clinics or were convenience samples. In 2007, the Center for Disease Control commissioned the University of Minnesota to prepare a systematic review of the prevalence and risk factors associated with FI for the State of the Science Conference on the Prevention of Fecal and Urinary Incontinence [6]. Their inclusion criteria differed from ours. The studies identified in both of these publications were reviewed for this report.

#### 2. REVIEW OF EVIDENCE

Prevalence estimates for faecal or anal incontinence vary widely, from 2.2% to 25%. This variability is related to the following differences among studies: a.) Case definition – some studies focus on Al and include subjects with accidental loss of flatus as well as solid stool [7;8], while other studies report the prevalence of FI, defined as the loss of solid or liquid stool or mucus. A few studies have also defined a category of soiling of underwear only and suggest that this occurs frequently [9;10]. In this review, the case definitions used by authors are listed in the literature tables. In the text, FI refers to the loss of solid or liquid stool or mucus, and when studies are referenced that used other definitions such as AI or soiling, these are specified. b.) Age range - FI is strongly associated with aging (Table 1), and studies that limit their subject selection to older individuals yield higher prevalence estimates [11]. Few studies have adjusted their estimates to the demographics of the population c.) Inclusion of subjects from skilled nursing facilities - Most studies of community prevalence exclude the institutionalized population where prevalence is known to be higher than in the community [12;13], while other studies include a representative mixture of community dwelling and institutionalized subjects [14].

The National Health and Nutrition Examination Survey (NHANES) in the United States (US) provides the a.) best estimate of FI prevalence to date because it surveyed both sexes, all major races represented in the US, and the full range of adult ages, and the authors extrapolated an age-adjusted prevalence estimate for the US; and b.) it provided separate estimates for different types (e.g., solid, liquid, mucus, and flatus) and frequencies of stool loss [15;16]. However, institutionalized individuals and those too ill to travel to examination sites were excluded.

Prevalence estimates. The age-adjusted prevalence of FI (defined as accidental loss of solid, liquid, or mucus incontinence in the month preceding the interview) in the non-institutionalized population of the United States is 8.9% of women and 7.7% of men [16]. When the data are broken down by type of incontinence, liquid incontinence is 2-3 times more common than solid stool incontinence, and incontinence for flatus is 2-3 times more common than the combination of liquid and solid [7;17-19]. In the NHANES study, liquid stool incontinence was reported by 6.2%, solid stool incontinence by 1.6%, and incontinence for mucus by 3.1%; 26% of subjects with any FI reported two or more types of FI consistency. Accidental loss of flatus, which was not included in the definition of FI in the NHANES study. was reported to have occurred at least once in the past month by 46% of men and 51% of women surveyed by NHANES. Table 1 gives prevalence estimates for several countries, but differences in survey methodology make it difficult to interpret observed differences between countries. There are no published data on the incidence (i.e., rate of new onset) of FI or Al in non-institutionalized populations.

Under-reporting of FI. In population based surveys, when people with FI or AI are asked whether they have discussed this problem with their health care providers, only a third have done so: the reported proportion are 36% in the United States [8], 32.6% in France [20], 40.8% in Sweden [21], 27% in Australia [19], and a third in The Netherlands [22]. This is found even in acute care hospitals [23] and nursing homes [24]. In a 1986 study of UK nursing home residents, only 4% of patients with long-standing FI had been referred to their general practitioner for further assessment of this problem [25]. A 1982 study of US nursing home patients found that only 15% of those with incontinence had a physician mention of it in the nursing home records [26]. A possible reason for the failure to recognize and report FI in acute care hospitals and nursing homes is the belief of many health care providers that FI is a normal part of aging: a UK nursing home survey found that the trained staff cited advanced age as the main cause of incontinence [27].

## a) Patient characteristics associated with increased risk of FI

#### 1. Age

Most surveys that include young as well as older adults find age to be strongly associated with FI (Table 1). This age-related increase in prevalence of FI is likely attributable to age-related declines in general health, muscle strength, mobility, and cognitive functioning, and the increased prevalence of other diseases that may contribute to FI (see below).

#### 2. Admission to an Acute Care Hospital

Admission to an acute care hospital is frequently

associated with a new onset or exacerbation of FI. A British survey of 627 hospitalised patients aged 65 and over (FI defined as at least one episode weekly) found a prevalence of 14% (28), and this is significantly higher than the community prevalence of FI. An Australian survey of 247 consecutive admissions to an acute care hospital (all ages) found that 22% self-reported FI [29]. Bliss et al. [30] reported that FI was present in 33% of hospitalized patients.

Risk factors for the development of FI subsequent to hospital admission include the following: having loose/liquid stool consistency (RR=11.1; 95% CI=2.2-56.7), greater severity of illness (5.7, 2.6-12.3) and older age (1.1, 1.02-1.1) as independent risk factors in a multivariate analysis [30]. A UK descriptive study found contributing factors to FI in acute hospital inpatients aged 65+ to be faecal loading (57%), functional disability (83%), loose stools (67%), and cognitive impairment (43%) [31]. When compared with 3 other settings (home, care homes and rehabilitation wards), acute hospital inpatients with FI were significantly more likely to have faecal loading, functional disability, and loose stools. Patients with loose stools and less comorbidity were more likely to have resolution of FI after 3 months follow-up.

#### 3. RESIDENCE IN A SKILLED NURSING FACILITY (Table 2)

FI in nursing homes is often discussed separately from FI in community dwelling individuals because a.) risk factors differ and may include a significant iatrogenic contribution, and b.) treatment/management strategies differ. In nursing homes the prevalence of FI ranges from 43% [12] to 54% [32], which is approximately 5 times the rate seen in community dwelling individuals. The incidence (onset rate) of FI in nursing homes was reported to be 20% [32] in France and 27% [33] in the U.S. An estimated 97% of nursing home residents with FI also have UI [13], which is significantly higher than is reported for community dwelling individuals of comparable age; this suggests a different spectrum of aetiologies.

There is a wide variation in the reported prevalence of FI among nursing homes in the UK, ranging from 17% to 95% between individual nursing homes [25;28;34]. As the case-mix within British nursing homes is likely to be comparable, the variations may well be more reflective of different standards of care, rather than of different patient characteristics. A recent nation-wide UK audit of FI in older people found that patients admitted to care homes with pre-existing FI tended to simply be placed on a containment management plan rather than being assessed for causes and possible treatment, and this was despite having good access to continence specialist care [35].

The strongest univariate associations with FI in longterm care studies are physical dependency and impaired mobility, particularly where help is needed to transfer from bed to chair [28;34]. However, faecal loading is also believed to be a significant and treatable cause of FI in this population: A UK study found faecal loading in 70% of residents with FI [31], which suggests that treatable overflow FI is being overlooked in this setting.

#### 4. SEX

Among 15 population-based studies that surveyed both men and women (Table 1), six surveys [8;9;17;36-38] found a significantly higher prevalence in women, eight [10;19;39-43] found no difference, and one study that was limited to people 75 years of age and older found a higher rate in men [11]. Thus, sex is a weak predictor of who will develop FI. However, young women are vulnerable to a unique set of risk factors associated with childbirth (see below). In older people men and women are found to have equal prevalence and men may predominate in advanced old age.

#### 5. RACE

In population based studies, race has not been found to be significantly associated with FI or AI [23;42;44]. However, there is evidence that obstetrical tears are more common in Hispanic, Filipino, and Chinese women compared to Caucasian women [45;46]. In addition to sphincter lacerations, there appears to be a higher incidence of post-partum FI in Asian women compared to Caucasians (OR=3.2) [47] and a lower incidence of post-partum FI in African Americans compared to Caucasian Americans [48;49]. These results may be confounded by a tendency to different parity rates in different groups and possibly by differing birthing practices.

#### 6. OBESITY

Having a body mass index (BMI) >30, which defines obesity, was associated with an increased risk of FI for women in two studies [18;48]. However, other surveys failed to find a significant association [50;51].

#### 7. Poor general health

In population-based surveys, poor general health is an independent predictor of FI [8;19;24;42]. FI is associated with increased mortality both in community dwelling older subjects [40] and in nursing home patients [32].

#### 8. Physical limitations

Three population-based surveys assessed physical limitations and found them to be risk factors for FI [8;37;40]. In nursing home patients, mobility impairment is consistently found to be a predictor of FI [12; 32;33;52;53].

#### 9. PHYSICAL EXERCISE

Endurance running is associated with diarrhoea and FI in over 10% of individuals [54]. Regular exercise did not predict prevalent FI or incident FI at a five and

Table 2. Nursing Home Surveys	urveys		
Source	Design	Risk Factors	Results
Borrie et al (1992)	Surveyed 457 residents of a single long- term care hospital in Ontario, Canada Also estimated costs attributable to Ul and FI combined. Defined FI as involuntary loss of feces that is a social or hygenic problem.	Dementia Mobility impairment Diagnosis & meds Overall prevalence Annual cost/patient	Significant association Significant association Significant association 46% \$9771 (1992 Canadian \$)
Johanson et al (1997)	All 388 residents of 5 nursing homes, both skilled & unskilled. Questionnaire was completed by patient if possible, otherwise by investigator or nursing staff. FI defined as any involuntary leakage or soiling.	Diarrhea Wheelchair dependent Dementia Male sex Age <65 yrs Daily exercise (-)	OR=8.0 (CI, 3.0-21.0) OR=2.7 (CI, 1.7-4.0) OR=4.3 (CI, 2.8-6.8) OR=2.5 (CI, 1.5-4.1) OR=2.6 (CI, 1.0-6.5) OR=0.5 (CI, 0.3-0.7) OR=0.2 (CI, 0.1-0.7)
Nelson et al (1998)	HCFA minimum data set for Wisconsin skilled nursing facilities for 1992 & 1993. Did not specify whether gas incontinence was included in report.	Urinary incontinence Tube feeding Loss of ADLs Diarrhea Truncal restraints Pressure ulcers Dementia Impaired vision Fecal impaction Constipation Stroke Male sex Overall prevalence	OR=12.6 (CI, 11.5-13.7) OR=7.6 (CI, 5.6-10.4) OR=6.0 (CI, 4.7-7.7) OR=3.3 (CI, 2.7-4.2) OR=3.2 (CI, 4.7-7.7) OR=2.6 (CI, 2.2-3.0) OR=1.5 (CI, 1.4-1.7) OR=1.5 (CI, 1.4-1.7) OR=1.5 (CI, 1.2-1.0) OR=1.4 (CI, 1.3-1.6) OR=1.3 (CI, 1.2-1.5) OR=1.3 (CI, 1.1-2.1) OR=1.3 (CI, 1.1-1.3) 43% in 1991; 51% in 1993
Chassagne et al (1999)	Incidence of new-onset FI in 1,186 residents of nursing homes or long-term care facilities. 234 (20%) developed FI within 296 days. Risk of long-lasting FI reported. France. FI was defined as involuntary loss of feces.	Hx urinary incontinence Decreased mobility Hx dementia MMSE score <15 Associated mortality Overall FI prevalence	OR=2.9 (CI, 1.8-2.6) OR=1.8 (CI, 1.1-3.0) OR=2.1 (CI, 1.2-3.5) OR=2.5 (CI, 1.4-4.4) 16% vs. 6.7% (p<.001) 54,40% 20,00%

Table 2. Nursing Home Surveys (Continued)

Source	Design	Risk Factors	Results
Gabrel (2000)	Incidence of FI in National Nursing Home Survey of 1997. Definition of FI not listed. Includes data on 1.465 million residents. Risk factors and cross tabs with other variables not provided in this report. U.S.	Double incontinence FI only Overall FI prevalence	44,20% 1,30% 45,50%
Nelson, Furner (2005)	Used MDS data from all Wisconsin Nursing Homes for 1992 and 1993 to estimate FI incidence and identify risk factors. FI defined as solid or liquid stool loss.	Trunk restraints Dementia Race (non-Caucasian) Loss of ADLs Incidence	OR=2.9 (2.0-4.3) for DI OR=1.8 (1.4-2.2) for DI OR=2.0 (1.2-3.4) Significant associations 27,10%

ten year follow-up in a large sample (N=8,949) of community-living elderly in Canada [55]. There are no studies on prevention of runner's diarrhoea and FI, although presumably avoiding the activity is an option.

#### 10. URINARY INCONTINENCE AND PELVIC ORGAN PROLAPSE

In community-based surveys, FI is strongly associated with urinary incontinence [18;38] and overactive bladder [7] in both men and women. Among nursing home patients, the association between urinary incontinence and FI is even stronger [12;13;32]. Pelvic organ prolapse is also significantly associated with FI [7;18]. Urinary incontinence and pelvic organ prolapse are unlikely to be causally related to FI but may serve as marker variables to identify patients who are at risk for the development of FI.

Some patient characteristics found to be associated with FI or AI in epidemiological surveys suggest pathophysiological mechanisms that may cause incontinence, and the modification of these risk factors might reduce the risk of developing FI or AI; examples are diarrhoea, obesity, mobility impairment, and endurance running. For other variables found to be associated with FI or AI, no plausible pathophysiological mechanism is known, and the association may be due to a cause which is common to both incontinence and the other condition. Examples are urinary incontinence, age, and poor general health. This last group of variables are unlikely to enable primary prevention of FI or AI but may be useful as marker variables, i.e. useful for identifying patients at risk for the development of FI so that they can be targeted for screening and early treatment.

#### b) Gastrointestinal symptoms and disorders

#### 1. DIARRHOEA

Diarrhoea or loose stools is consistently found to be a risk factor for FI both in community surveys [9;11;14;19;23;24;42] and nursing homes [12;53]. This is consistent with reports that FI is more prevalent in patients with irritable bowel syndrome [56], patients with illnesses that produce diarrhoea [30;57;58], and in people who run long distances for exercise [59]. Whenever the frequency of FI is reported separately for solid, liquid, and gas, liquid incontinence is found to be more frequent than solid stool incontinence, and gas is found to be the most common type of incontinence [17;24;60;61].

Potentially preventable causes of diarrhoea include drugs, dietary supplements, and some foods. Drugs known to cause diarrhoea as a side-effect include antibiotics, especially the erythromycin analogs; tegaserod, the 5HT4 agonist used to treat constipation-predominant irritable bowel syndrome; the serotonin reuptake inhibitor class of antidepressants; digoxin; and laxatives. Chronic laxative dependence or abuse may cause frequent diarrhoea. Food supplements that

have been reported to cause diarrhoea include lactose (in lactase deficient individuals); fructose, sorbitol, aspartame, and other artificial sweeteners that are poorly absorbed; and fat substitutes such as olestra. Some natural foods such as prunes and figs may also cause diarrhoea. The research literature has not established that these foods, food additives, and drugs cause FI, but it has established a link to diarrhoea.

#### 2. URGENCY TO DEFECATE

Bharucha and colleagues [14] reported that the symptom of urgency (having to rush to the toilet) is a strong risk factor for FI which is independent of diarrhoea and constipation. This is supported by an independent survey in Australia [19] and a survey of elderly health maintenance organization patients in the U.S [24].

#### 3. CONSTIPATION

Constipation was found to be a significant positive risk factor for FI in one nursing home survey [12], but in another study, hard stools appeared to be protective [53]. A UK survey of nursing home residents with FI found that faecal loading was present in 70% of individuals [31]. Constipation is considered to be the most common aetiology for FI in children (often referred to in the paediatric literature as encopresis when there is no recognized structural anomaly to explain the incontinence) [62;63]. The mechanism that is presumed to explain constipation-related FI is overflow: a mass of hard stool in the rectum or sigmoid blunts sensitivity for perceiving the movement of new stool into the area and also reflexly dilates the internal anal sphincter allowing liquid stool to seep out [62].

#### 4. IRRITABLE BOWEL SYNDROME

Three population based [48;64;65] and several studies of clinic samples have shown an excess incidence of FI in patients with IBS with estimates of odds ratios ranging from 2 to 8. When research criteria are used to diagnose IBS in population based samples [64;65], the proportion of IBS patients with FI is 12.0% to 22.7%. However, Varma et al [48] estimated that 44.6% of patients with a self-reported diagnosis of IBS had FI.

#### 5. INFLAMMATORY BOWEL DISEASE

FI is more common in patients with inflammatory bowel disease, although the precise prevalence has not been the focus of study and is not known. Estimates range from 22% [66] to 41% [48]. Two mechanisms are recognized for this association: both ulcerative colitis and Crohn's disease are associated with diarrhoea, which is a risk factor for FI. Crohn's disease is also associated with the development of anal fistulae that may drain liquid stool to the skin surface and abscesses that may create anatomical defects in the anal sphincters.

#### 6. HAEMORRHOIDS

A significant number of patients with prolapsing haemorrhoids (Grade 3 and 4) experience faecal soiling, although this has not been the specific focus of any study. Johansson and colleagues [67] reported that 21% of 507 patients treated for haemorrhoids listed hygiene or soiling as an indication for seeking treatment. Following treatment with the Milligan-Morgan procedure, 24% of patients who had not listed soiling or hygiene as an indication for surgery developed new onset FI. Bliss and colleagues [24], in a survey of 1,352 subjects older than 65 years who were attending health maintenance organization clinics, found that self-reports of haemorrhoids predicted the frequency and severity of FI.

#### 7. IMPERFORATE ANUS

High anal atresia is associated with FI 85% of the time and low anal atresia about 57% of the time [68]. The surgical correction of high anal atresia involves identifying the striated external anal sphincter and pulling the healthy portion of the bowel down through this sphincter to create an anus; contributing causes of incontinence are absence of an internal anal sphincter (passive barrier to soiling), weak contraction of the external anal sphincter, and decreased compliance of the neorectum [69-72]. The outcome of surgical repair is improving with improved surgical techniques and the use of the Malone antegrade colonic enema technique, but 10-30% of these patients remain totally incontinent for faeces [73].

## c) Obstetric and other injuries to the pelvic floor

Obstetric injuries are the most thoroughly investigated category of risk factors for FI or AI. **Table 3** shows studies that were enriched by recruitment from obstetrical hospitals or urogynaecology clinics and that included at least 500 subjects. The table shows that studies which assessed the impact of obstetrical injury soon after childbirth found strong associations to FI while studies that assessed the impact of obstetrical injury retrospectively in middle aged and older women found weaker associations or no associations [18;74-76].

#### 1. Parity

Most surveys investigating parity find it to be a risk factor for FI. The first vaginal delivery carries the greatest risk of new onset FI [77], and each subsequent delivery adds to that risk [7;17;74;75]. A French study [78] found a higher prevalence of AI in women who delivered at home compared to those who delivered in the hospital.

#### 2. SPHINCTER LACERATION

A prospective cohort study demonstrated that primiparous women with a 3rd or 4th degree sphincter

Source	Design	Risk Factors	Results
MacArthur et al (1997)	Home interview by midwife about 10 months after delivery in 906 women. Assessed new onset FI for solids or liquids.	Vacuum extraction Forceps delivery C-section (elective)	Significant association Significant association Trend favoring protective effect
Zetterstrom (1999)	For dependent measure of sphincter tears, hospital records of 845 women evaluated. FI was assessed by postal questionnaire at 0, 5, & 9 months postpartum, but data on relative risk were not presented. Reported incontinence of flatus separately from stool.	First delivery Gesta age >294 days Fundal pressure Midline episiotomy Increasing fetal wt	OR=9.8 (CI, 3.6-26.2) OR=2.5 (CI, 1.0-6.2) OR=4.6 (CI, 2.3-7.9) OR=5.5 (CI, 1.4-18.7) OR=1.3 (CI, 1.1-1.6)
MacArthur et al (2001)	Postal questionnaires sent to all women delivered during 1 year at 3 hosptials: one in Scotland, one in England, and one in New Zealand. Questionnaires completed 3 mos post-partum. N=7879 (71% response). Reported incontinence for flatus and stool separately.	Forceps delivery C-section Age >35 yrs Asian origin Vacuum extraction Episiotomy Body mass index	OR=1.94 (CI, 1.30-2.89) OR=0.58 (CI, 0.35-0.97) OR=1.75 (CI, 1.04-2.94) OR=3.21 (CI, 2.04-5.05) No association No association No association
Faltin et al (2001)	Questionnaire study in 666 women from general outpatient clinic, 298 from antenatal clinic, 264 from urogynecology, and 984 from a population sample. FI definition was solid, liquid, or flatus at least monthly.	Parity Anal sphincter tear Baby over 4 Kg Operative delivery	OR=3.1 (CI, 1.6-6.0) OR=4.4 (CI, 2.0-9.1) No association Univariate but not multivariate association
Wagenius et al (2003)	Postal survey comparing 186 with sphincter laceration to 348 matched controls (82% response rate) approx 4 years after delivery. Obstetric data taken from medical record. Definition of AI included loss of flatus.	Flatus >1/wk Liquid FI Solid FI Dyspareunia	OR=2.71 (1.78-4.15) OR=3.29 (1.93-5.60) OR=1.91 (0.71-5.17) OR=2.67 (1.44-4.92)
Roman et al (2004)	525 consecutive vaginal deliveries were interviewed 6 wks post-partum. France. Definition of FI unknown.	Forceps delivery Unassisted delivery at home Fetal head >93 mm Maternal age >30 yrs	OR=10.8 (2.82-41.3) OR=50.0 (3.09-802) OR=4.56 (1.46-14.1) OR=4.60 (1.11-19.1)

Table 3. Obstetric Samples (Continued)

Source	Design	Risk Factors	Results
Casey et al (2005)	Interviews completed prior to delivery and again 6 months later at return for advice on contraceptives. 3601 women (93% response rate; 88% Hispanic) competed both surveys. Definition: "Do you have problems controlling you 'gas' or bowel movement until you get to the bathroom? For example, do you stain your panties?"	Oxytocin augment 2nd stage >2 hrs Episiotomy 3rd or 4th degree tear Forceps delivery Cesarean delivery Fetal weight >4000 g.	OR-1.9 (1.2-3.0) univariate only No association OR=1.7 (1.1-2.6) univariate only No association No association No association 2.4 (1.3-4.4) adjusted 2,30%
McKinnie et al (2005)	Survey of 1004 urogynecology clinic patients from 6 sites. Average age 43 years. Al was defined as uncontrollable loss of stool or gas that was bothersome.	Any vaginal delivery vs. nuliparous Maternal age BMI Overall prevalence	OR=2.41 (1.30-4.49) OR=1.05 (1.03-1.07) univariate only No significant association 13,10%
Faltin et al (2006)	Postal survey 18 years after delivery in 259 women with sphincter tear vs 281 matched controls without sphincter injury. AI defined as Wexner score of 4 or greater (0-20 scale).	Sphincter laceration	OR=1.68 (1.01-2.79)
Hatem et al (2006)	Postal survey of all primips delivering in Quebec hospitals during 6 mo period. Survey mailed at 6 mo postpartum. 1291 (52%) completed survey. Definition: "Have you ever lost control of your intestines, resulting in involuntary gas or fecal loss after childbirth?"	Age >35 at delivery 3rd or 4th degree tear 2nd stage of labor >1hr Baby >4 kg Forceps or vacuum Al prevalence	OR=1.79 (1.01-3.43) OR=4.30 (2.62-7.03) OR=1.89 (1.29-2.77) OR=1.99 (1.05-3.74) OR=2.16 (1.37-3.42) 20,60%
Borello-France et al (2006); Burgio et al (2007)	Prospective study comparing FI at 6 wks and 6 mo after delivery in 407 with 3rd or 4th degree sphincter lacerations, 390 without sphincter lacerations, and 124 delivered by cesarean section. FI defined as solid, liquid, or mucus leakage in prior month. Risk factors assessed at 6 mo.	Sphincter laceration White race Antenatal UI Severity of laceration Maternal age BMI (per 5 kg/m2)	OR=2.8 (1.8-4.3) at 6 wks; OR=1.9 (1.2-3.2) at 6 mo. OR=6.1 (1.3-29.4) in tear group OR=2.2 (1.1-4.3) OR=2.0 (1.0-4.0) OR=1.6 (1.2-2.1) OR=1.3 (1.0-1.7)

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ource	Design	Risk Factors	Results
uise et al (2007)	Postal survey sent to all 21,824 women delivering live infants in Oregon state in 6 mo period. 8,744 (40%) responded 3-6 mo after delivery. Fl was defined as loss of solid or liquid stool.	Maternal age >30 BMI >30 pre delivery Sphincter laceration Current smoker Forceps delivery Fetal weight >4 kg Cesarean delivery AI prevalence FI prevalence	OR=0.61 (0.43-0.86) OR=1.70 (1.37-2.11) OR=2.31 (1.61-3.32) OR=1.85 (1.46-2.35) OR=1.66 (1.10-2.50) No association No association 29,3% 13,60%
itel et al (2007)	2640 women (85% participation) from the Gazel longitudinal cohort maintained by the French National Institute for Health and Medical Research. Ages were 50-61 yrs. Surveyed both AI and FI.	BMI >25 Anal surgery Ul surgery Completed high school Household income Depression or stress All obstetric variables All prevalence FI prevalence	OR=1.5 (1.1-2.0) OR=1.7 (1.1-2.9) OR=3.5 (2.0-6.1) OR=1.5 (1.1-2.0) No significant association OR=2.1 (1.6-2.7) No significant association 38.5%; 28.6% flatus only 9,50%

laceration recognized at delivery have a substantially increased risk of FI even though sphincteroplasty is routinely performed when a sphincter laceration is detected [79]. Other studies [18;19;74;80-82] support this association, although two studies [14;80] did not.

#### 3. INSTRUMENTED DELIVERY

Forceps delivery was found to be a risk factor for sphincter laceration [83] and FI [47;78;81;82], although two studies did not find this association [14;80]. The evidence that vacuum extraction is a risk factor for FI is more equivocal; two studies reported a significant association [81;84], and one study showed that vacuum extraction increases the risk of sphincter tear [83]. However, other studies failed to find an association of FI with vacuum extraction [18;47]. The evidence for a protective effect of caesarean section is inconclusive.

#### 4. Episiotomy

Midline episiotomy, which was formerly advocated for the prevention of uncontrolled sphincter lacerations and associated FI, has been found to increase the risk of sphincter laceration [77;83]. The risk of AI was reported to be increased in two studies [80;85] and unchanged in a third study [47]. No studies have found episiotomy to be associated with a reduced risk of sphincter laceration or FI/AI.

#### 5. Large baby, prolonged second stage of labour

Two studies [77;83] showed a significant association between sphincter laceration and foetal weight greater than 4000 grams. Other studies showed an association between Al and foetal weight greater than 4000 grams [80;81] or foetal head diameter greater than 93 mm [78]. However, a fourth study did not confirm this association [82]. A prolonged second stage of labour was associated with a greater risk of Al in one study [81] but not in a second study [80].

#### 6. MATERNAL CHARACTERISTICS

Age of the mother at the time of vaginal delivery was positively correlated with the risk of FI or AI in 5 studies [47;75;78;79;81], but was reported to be protective in one study [82]. Maternal depression and stress were also reported to be associated with an increased risk of AI [76]. A French study also found AI to be more common in women who had a history of anal or UI surgery and in those who completed high school [76].

#### d) Sequelae of surgical procedures

#### 1. COLECTOMY AND ILEOANAL ANASTAMOSIS

Because ulcerative colitis and familial polyposis both convey a high risk of colon cancer, the colon is often removed prophylactically. While a number of variations in surgical technique have been described, the commonest procedure is to create a neorectum from loops of ileum sewn together to create a pouch and to connect this to the anal canal. A temporary ileostomy

is usually performed to give the pouch time to heal. Post-operatively, 25-35% of these patients have daytime FI [86-89] and 32-52% have nocturnal FI [86;86;87]. Fazio and colleagues [89] reported that the preoperative frequency of FI was as great in their series of patients as was post-operative FI. The mechanisms that lead to FI in this population include frequent bowel movements (8 or more per day), high pouch pressures that exceed anal canal pressures, and high amplitude contractions of the pouch [90]. Such pouch contractions are recorded in continent as well as incontinent patients with an ileal pouch because the pouch is constructed from innervated bowel; however, the contractions produce higher pouch pressures in the incontinent patients.

When it is possible to preserve the rectum, the ileum can be sutured directly to the rectum, substantially reducing the risk of FI [91]. When bowel resection is performed for the treatment of colon or rectal cancer, some or the entire colon may be preserved, and the remaining colon may be sutured directly to the anal canal or it may be used to create a pouch that is connected to the anal canal. This is associated with a lower incidence of FI (estimated at 18%) according to some authors [92;93], but others [94] reported a rate of 49% FI following colo-anal anastamosis.

One randomised controlled study has investigated the use of daily irrigation of a colonic J-pouch prior to ileostomy closure. Irrigation was not found to improve post-closure nocturnal continence or defaecation frequency [95].

#### 2. INTERNAL ANAL SPHINCTEROTOMY

Patients with chronic anal fissure or haemorrhoids may be offered internal anal sphincterotomy (slit in the internal anal sphincter for 50-60% of its length to reduce anal canal pressures). In a large series of 585 patients with a chronic anal fissure treated in this fashion at the Mayo Clinic, 45% developed FI at some point in their recovery. However, this tended to improve with time from surgery, and at follow-up an average of 72 months after surgery, 11% reported FI [96].

#### 3. RADICAL PROSTATECTOMY FOR PROSTATE CANCER

Published prevalence rates of FI following radical prostatectomy alone range from 9% [97] to 15% [98]. In the largest survey, Bishoff and colleagues [99] reported that prostatectomy by the retropubic approach was associated with FI in 17% of cases whereas prostatectomy by the perineal approach was associated with FI in 32% of cases; the loss of moderate to large amounts of stool was reported by 4% and 10% respectively. Rates of FI are higher when prostate cancer is treated by radiation therapy [47]. These differences may be confounded by differences in severity of disease before treatment, extent of resection, and dose of radiotherapy.

#### 4. HAEMORRHOIDECTOMY

A large series of 507 patients who received the Milligan-Morgan surgical treatment for haemorrhoids were followed up by postal questionnaire 2-11 years after surgery (average of 6 years). A total of 33% (139/507) reported AI including 72 who were incontinent of gas only, 56 who were incontinent to liquid faeces, and 11 who were incontinent to solid faeces [67]. Other reports of surgical treatment for haemorrhoids list a lower incidence of FI [100], but only cases with loss of liquid or solid stool are usually reported. In a community based survey of people over age 65, Bliss [24] found self-reported haemorrhoid surgery was significantly associated with FI.

#### e) Sequelae of radiotherapy for cancer

The prevalence of FI following external beam radiation therapy for prostate cancer ranges from 14% [97] to 21% [67]. One group estimated the prevalence at up to 46% for a mixed group most of whom had been treated with both surgery and radiotherapy [101]. Radiotherapy for cervical cancer is associated with FI in 25% of cases compared to 8% for cervical cancer patients treated exclusively by surgery [102]. The mechanism through which radiotherapy contributes to FI is believed to be a decrease in rectal compliance [103], leading to increases in symptoms of urgency and loose stools [67;102].

#### f) Neurological Diseases that predispose to FI

#### 1. COGNITIVE IMPAIRMENT

Dementia is a significant predictor of FI both in the community [40] and in nursing homes [12;32;53]. In some community studies, dementia was not found to be a significant predictor after controlling for other risk factors [40;40;55], possibly because patients with severe dementia associated with FI are frequently admitted to nursing homes [104].

In people with a developmental disorder, the prevalence of FI in those with mild learning disability is little different from that of the general population; however, rates for those with moderate and severe learning disability are higher than population norms and are similar to each other. The prevalence of FI is substantially higher in those with a profound learning disability [105]. Nevertheless, around half of those with a profound learning disability will acquire bowel control by adulthood.

#### 2. SPINAL CORD INJURY

Traumatic spinal cord lesions result in substantial or complete denervation of pelvic floor muscles and loss of voluntary control over the external anal sphincter. However, many of these patients avoid FI because they are constipated due to delayed whole gut transit and/or hyper-reflexia of the external anal sphincter. Occasional FI is reported by 33-66% [106-108] but

frequent FI (more than monthly) is limited to 11% [109] to 14% [108;110]. Approximately 70% require mechanical or manual assistance to initiate defecation [110]. In patients with congenital spinal cord lesions (spina bifida), anorectal dysfunction may be more common: 53% in one study [111] and 34% in another survey [112] report that they soil regularly. As with traumatic spinal cord lesions, the majority of patients with spina bifida are constipated, which reduces the frequency of FI that would otherwise occur in these patients because they have partial or complete disruption of the efferent innervation to the pelvic floor muscles [113].

#### 3. STROKE

Two large studies have assessed the incidence of FI following stroke. In the Copenhagen Stroke Study of 935 consecutive admissions for stroke [114], 34% were fully incontinent and 6% were partially incontinent on admission to the hospital; 6 months later, 5% were fully incontinent and 4% were partially incontinent. In a study of 1069 patients taken from the South London Stroke Register [115], 29.7% were faecally incontinent 7-10 days after stroke, 10.8% were still incontinent at 3 months, 10.9% at one year, and 15.0% at 3 years. These data suggest that FI is transient for the majority of patients affected, but the prevalence of FI remains elevated compared to population norms at one year and shows little further improvement. A study of 186 stroke patients in Spain showed a similar pattern: 56% had FI at admission, and 22% remained incontinent 6 months later. Risk factors for FI included age, severity of stroke, diabetes, and comorbidity of other diseases [114].

#### 4. TRAUMATIC BRAIN INJURY

An excellent study [116] of the prevalence of FI following traumatic brain injury was carried out in 1,013 patients consecutively enrolled in any of 17 acute rehabilitation facilities. Prevalence rates were 68% at admission, 12.4% at discharge, and 5.2% at one year follow-up. The risk of incontinence at each time point was significantly related to all measures of the severity of brain injury including Glasgow Coma Scores and length of stay. In addition, at discharge from the rehabilitation facility, FI was significantly associated with pelvic fracture, urinary tract infection, and patient age (older patients were more likely to be incontinent); at one-year follow-up, FI was significantly associated with urinary tract infection and patient age. Patients with FI were more likely to be discharged to an institution rather than to return to their homes.

#### 5. DIABETES MELLITUS

Bytzer and colleagues [117] carried out a large population-based postal survey in 8,657 adults including 423 with self-reported diabetes mellitus (DM). The response rate was 60%. When patients with DM were contrasted to the remainder of the

sample the frequency of FI occurring at least "sometimes" was 12.8% vs. 3.8% (p<.001) and the prevalence of FI occurring "often" was 2.6% vs. 0.8%. The odds ratio (after adjusting for confounders) was 2.74 (CI, 1.40-5.37). The prevalence of FI was shown to be related to self-reported degree of glycemic control. These results were confirmed by two other studies that recruited patients from a diabetes register [118] or a diabetes clinic [60]. The risk of FI among patients with DM is known to be related to weakness of anal canal resting and squeeze pressures and impaired sensation in the rectum [119;120], and these physiological defects are related to duration of DM and the presence of microcirculatory abnormalities and autonomic and peripheral neuropathies [120].

#### 6. MULTIPLE SCLEROSIS

FI is reported by 29-51% [121-123] of multiple sclerosis patients living in the community, and it is frequent in 5% [121] to 25% [123]. Among 14,000 nursing home residents with multiple sclerosis, FI was present in 58% and occurred more than twice a week in 7.5% [124]. Incontinence in this group is associated with weak strength of contraction of pelvic floor muscles, a low threshold for elicitation of the internal anal sphincter inhibitory reflex, and impaired sensation for rectal filling [125;126]. Approximately half of patients with multiple sclerosis are also constipated, but constipation seems to occur about equally often in multiple sclerosis patients with and without FI [123].

## 3. SUMMARY OF EVIDENCE ON RISK FACTORS FOR FI AND POTENTIAL FOR PREVENTION

- There is a high prevalence of FI in communitydwelling populations
- 2. High risk groups fall into four main categories and include:

#### 1. Patient characteristics

- · Increasing age
- Nursing Home residence
- · Gender: equivocal evidence
  - Younger: 6 studies women>men; 8 studies no difference
  - Older men>women (one study)
- · Race: no difference except obstetric injuries
- Obesity, poor general health and physical limitations, urinary incontinence & pelvic organ prolapse, endurance running are all associated with FI
- Neurological disease or injury (learning disability, dementia, spinal cord injury, multiple sclerosis, spina bifida, stroke, head injury, diabetes mellitus)

## 2. Patients with gastrointestinal symptoms and disorders

Diarrhoea or loose stools (community & NH)

- Drugs (antibiotics, SSRIs, laxatives, digoxin, orlistat), dietary supplements (lactose, fructose, artificial sugars, olestra) foods (prunes, figs)
- Urgency (independent of stool consistency)
- Constipation (? "overflow")
- Irritable bowel syndrome (IBS) (OR 2-8)
- Inflammatory bowel disease (IBD) (diarrhoea + perianal)
- · Haemorrhoids (before and after surgery)
- · Congenital anomaly (imperforate anus)

## 3. Obstetric factors (note the disparity population vs. selected clinic studies)

- Parity for AI (1st vaginal delivery, subsequent deliveries: clinic populations)
- Sphincter laceration for Al & Fl (7 studies found increased risk, 2 not)
- Instrumental delivery (forceps 5 studies found increased Al risk, 2 not; vacuum equivocal)
- Episiotomy: midline ? risk; mediolateral not protective
- · CS: inconclusive, tending to not protective
- · Large baby, prolonged 2nd stage: equivocal

#### 4. Sequelae of surgical procedures

- Colectomy & ileo-rectal anastomosis or pouch: diarrhoea + pressures: 18-49% FI
- Sphincterotomy: 11% FI in long term
- Haemorrhoidectomy: 33% AI
- Radical prostatectomy: 9-32% (retropubic vs. perineal)
- Pelvic radiotherapy 14-46% (diarrhoea + compliance)

## 4. RECOMMENDATIONS FOR PRACTICE ON PREVENTION

#### 1. Primary prevention:

- Public health measures to prevent diarrhoeal diseases (Grade B/C)
- Treat reversible causes of diarrhoea (C)
- Obstetric: no convincing evidence of role for preventive caesarean section; avoid midline episiotomy; restrictive episiotomy protocols (A)
- Discourage the use of internal anal sphincter division for treatment of anal fissure and haemorrhoids (A)

#### 2. Secondary prevention (Table 4):

Active case finding/screening in high risk groups
 (C)

- Proactive bowel management in high risk groups (eg neurological) (C)
- Optimise stool consistency in people with loose stools (all ages); hard stools (children and older pops) (B)
- Treat obesity? (D)
- Consider medication alternatives in patients with FI & medication-induced diarrhoea (C)
- Alert patients to risk of FI following colorectal surgery (C)

## Table 4. Targets for Secondary Prevention Through Early Recognition

#### Patient characteristics:

Dementia/cognitive impairment

Physical limitations/ impaired mobility

#### Diseases and disorders:

Urinary incontinence

Pelvic organ prolapse

Hemorrhoids, grade 3 and 4

Irritable bowel syndrome

Diarrhea

Constipation

Diabetes mellitus

CNS injury: stroke, head injury, Alzheimer's,

Spinal cord injury: traumatic cord injury, spina bifida

Multiple sclerosis

Congenital anorectal anomalies: imperforate anus

#### Surgical interventions:

Vaginal delivery with sphincter laceration

Instrumented vaginal delivery

Colectomy, with or without ileal reservoir

Internal anal sphincterotomy for anal fissure, hemorrhoids, Hirschprung's disease

Prostatectomy, especially by perineal approach

#### **Drugs and Diet**

Drugs that cause diarrhea as a side-effect

Foods that cause diarrhea: dairy products in lactase deficient individuals, some fruits

Food additives that cause diarrhea or gas: artificial sweetners

#### Radiological treatment of pelvic cancer

## 5. RECOMMENDATIONS FOR RESEARCH ON PREVENTION

- Longitudinal studies to map natural history, especially in women with obstetric risk factors
- Prevention studies in childbearing women and other high risk groups
- Colorectal surgery and radiotherapy techniques
- Bowel management strategies in high risk groups (e.g. neurological)
- · Understanding mechanisms of FI in men
- Frail Elderly: community prevention/ screening/ early treatment to prevent NH admission
- Measures to prevent/reduce FI in nursing homes (functional FI, staffing etc)

## III. EDUCATION & "LIFESTYLE" INTERVENTIONS

#### 1. BACKGROUND

Most patients do not know how the bowel works and what might improve bowel function. Many also have attitudes to defaecation that are influenced by stigma and taboos prevalent in their particular family and wider cultural group within a society [127].

Expert opinion supports the use of general health education, patient teaching about bowel function and advice on lifestyle modification [128;129], but the evidence base is small. Unlike urinary incontinence, few "lifestyle" associations have been identified with FI and little is known about whether interventions designed to reduce potential risk factors might improve FI. Diet and fluid intake are covered in Section 4.

#### 2. SEARCH

The following keywords were searched: "anal, anorectal, bowel, faecal, fecal, rectal, stool" and "continent\$ or incontinent\$," or "diarrhea, diarrhoea" and the relevant lifestyle or intervention term: exercise; irrigat\$ and rectal or rectum or anal or transanal; smoking, tobacco smoke pollution, tobacco use disorder, and tobacco\$ or cigarette\$ with use\$ or abuse\$ or smok\$; toileting and toilet\$; psycholog\$ or effect\$ with carer, caregiver, spouse, family, families or parent\$ and nursing or care. The following databases were searched: CINAHL 1982- March, 2008 MEDLINE 1955- March, 2008. The Cochrane library and a recent systematic review of the epidemiology and prevention of urinary and FI was also reviewed [6]. All seemingly relevant abstracts were reviewed then salient articles were retrieved and reviewed, and the reference lists searched for further studies.

## 3. REVIEW OF EVIDENCE ON THE EFFECT OF EDUCATION AND LIFESTYLE CHANGES ON FI

#### a) Weight reduction

Obesity is a well-documented risk factor for FI (Section 2 above). The only data available about the association of weight loss and FI reduction is in morbidly obese individuals undergoing weight reduction surgery and findings conflict. One preliminary report of surgical intervention [130], is published only in abstract form so far and is included because of limited studies available. In that study, bariatric surgery was not beneficial: 159 massively obese patients underwent either gastric bypass surgery or gastric banding and were asked approximately 2 years later to report retrospectively on their continence status before and after surgery. A higher than expected proportion of them reported FI prior to surgery (23% solid, 47% liquid FI), but FI was worse rather than better in more than half of these patients following surgery despite an average 48kg weight loss. It is possible that diarrhoea, a common consequence of bariatric surgery and which exacerbates FI, might account for this worsening of FI, but this was not noted in the preliminary report. In contrast, a second study [49] reported a significant decrease in the prevalence of FI of solid or liquid stool from 19.4% preoperatively to 8.6% at 12 months (p=.018; 95% CI= 2.1–19.4%) in women who underwent bariatric surgery for morbid obesity (mean (sd) body mass index (BMI) = 48.9 (7.2) kg/m<sup>2</sup>). In a single group cohort study (i.e., no control group), 93 women (aged 20-55 years) received a laparoscopic Roux-en-Y gastric bypass and reported data about FI by answering two questions before and after surgery. Any association between weight loss and FI reduction was not reported.

#### b) Physical exercise and work

One study in a nursing home population found that a structured daily exercise programme, combined with increased fluid intake and regular toileting opportunities, significantly improved FI and increased the percentage appropriate toilet use compared with controls [131;132]. However, lack of exercise is not an established risk factor for FI or AI (see Section 2 above).

#### c) Smoking

Nicotine is thought to slow upper gut motility and increase total transit time [133], but it seems that it can speed recto-sigmoid transit [134], and this stimulation of distal colonic motility may exacerbate a tendency to faecal urgency. This fits with many anecdotal reports that smoking a cigarette facilitates initiation of defaecation. Smoking is a known risk factor for urinary incontinence and genital prolapse (OR 2.9) [135],

presumably via chronic coughing. No association has been found between antenatal smoking and postnatal FI [136]. In a survey of 271 pairs of identical twin sisters, smoking was not significantly related to FI or flatus incontinence [137]. In a study of community-living elderly men and women, smoking was not predictive of prevalent or incident FI [55]. Smoking cessation is anecdotally reported to be useful for reducing urgency of defaecation, but no formal studies were identified.

#### c) Medication side-effects

Medication used specifically to treat FI is covered in section 6 below. A vast number of drugs have direct or indirect effects on the gastrointestinal system, tending to cause constipation, diarrhoea, or either in different people. A careful drug history (including all over the counter or "herbal" preparations) should be taken in each person with FI. It is beyond the scope of this chapter to review drug effects in detail, and prescribers should be aware of the possible unintended side-effect of FI. No studies were identified that evaluated the benefits of patient or provider education regarding the gastrointestinal side-effects of medications.

One single case report was found reporting that a combination of olestra in the diet and orlistat given to treat obesity led to symptoms of FI, which resolved when the olestra was stopped [138]. Patients reporting soiling while on treatment with orlistat for obesity have been found to have pre-existing impaired anorectal function, thus predisposing them to symptom development [139].

#### d) Toilet facilities

In individuals who have physical or mental impairments, an adverse physical or social environment may impair the ability to maintain continence. This is particularly relevant to those in institutional settings; use of physical or chemical restraints in institutions also limit or delay access to toilet facilities (see Committee 13). Adverse environmental factors include: (a) toilet facilities that are inaccessible or that lack privacy so that the person avoids using the toilet; (b) care providers who are insensitive to the individual's needs and bowel habit; (c) clothes which are difficult to manipulate in a hurry; and a variety of other factors which vary with abilities of the individual. The toilet itself may be too high, leaving the feet dangling and thus making abdominal straining difficult. The toilet may be too low, making sitting and rising difficult for those with immobile hips. A social environment in which care-givers are overworked and harassed may lead the patient to repeatedly ignore the call to stool, in the hope of finding a quieter time later. Commode use is reviewed in Chapter 20.

There are many adaptations that can be made to a toilet to facilitate access and stability in use [140]. Effective bowel evacuation is helped by sitting well-

supported, with feet slightly raised to enable appropriate use of abdominal effort if needed, and leaning forward slightly [141]. Horizontal grab rails assist pushing up from a seated position, while vertical ones can enable pulling up. A raised seat or foot blocks can adjust the height as needed. For lateral transfer from a wheelchair, both seats need to be at the same height. Where it proves impossible for a person to use the toilet, alternative commodes or chemical toilets are available with appropriate features for the individual's needs. No studies were found examining the effect of modifying the physical or social environment in treating FI.

#### e) Patient and care-giver education and attitudes

The strongest data on education and lifestyle comes from a single RCT. Patients were randomised to nurseled education and advice alone, or education with the addition of exercises and/or, biofeedback. The education and advice group showed reduced frequency of FI and was as effective as biofeedback or exercises [142]. Other support for the benefits of patient education comes from a study reported in abstract form [143] which showed that education and standard medical care, when provided systematically to a group of FI patients who had failed prior attempts at medical management, led to a successful outcome in 38%. Success in this trial was defined as a patient's report that they had experienced adequate relief of bowel symptoms.

An RCT of a combination nurse-led intervention for bowel problems in 146 stroke patients found that a single educational visit with a detailed information booklet improved bowel dysfunction up to 6 months later, and changed diet and fluid behaviour up to one year later compared to controls who received routine care. The intervention group were more likely to have sought professional help from their family practitioner for bowel problems, demonstrating a heightened awareness of the possibility of treatment [144]. However, there was no difference in the rates of FI between the intervention and control groups.

For people with dementia or other severe intellectual impairments, expert opinion holds that the attitude and management methods adopted by care providers is as important as bowel function in maintaining continence [144]. No controlled studies on this subject were found. However, one quasi-experimental study examined care-givers' knowledge and compliance before and after an educational intervention [145]. Forty home care-givers of people with dementia, over half of whom had some degree of FI, completed a study-specific questionnaire before and after receiving a videotape and information booklet entitled "a practical approach to maintaining bowel control in people with dementia". Ninety percent of the care-givers accessed the information and there was an improvement in post-intervention knowledge scores measured on a 55-point scale, with the mean score increasing from 23 pre-test to 32 post-test (p=<0.001). However, it is not known if this improved knowledge translates into improved care or reduced FI.

#### f) Complementary therapies

No hypnosis treatment study was found which included FI as an outcome variable. Psychotherapy does not appear to enhance the effectiveness of behavioural interventions for FI in children [146], but no studies were found in adults. Likewise, there have been no studies of the use of acupuncture, reflexology, homeopathy or any other complimentary approach reported in the literature.

## 4. SUMMARY OF EVIDENCE ON EDUCATION AND LIFESTYLE INTERVENTIONS IN FI

There is at present limited evidence for any lifestyle intervention for FI.

- Obesity: FI may improve after bariatric surgery (Level 3)
- · Smoking: not predictive; no studies
- Medication side effects may cause FI related to diarrhoea

## 5. RECOMMENDATIONS FOR PRACTICE ON EDUCATION AND LIFESTYLE

- Medication side effects: consider alternatives if causing diarrhoea (C)
- Toilet access for people with disabilities (C)
- Education
  - of patient (B/C)
  - of carer (C)
- · Complementary therapies: no evidence (D)

There is insufficient evidence to recommend or discourage most lifestyle modifications either for the prevention or treatment of FI. Based on the consensus of experts (Level 3 evidence) the committee recommends patient education about the causes of FI and a systematic effort to remove barriers to effective toileting as an intervention that is likely to be beneficial. This may be provided at relatively low cost and involves no significant risk to the patient.

## 6. RECOMMENDATIONS FOR RESEARCH ON EDUCATION AND LIFESTYLE

 Based on encouraging preliminary reports that patient education, combined with conservative medical management, can reduce the frequency of FI, we recommend further research. An RCT may not be possible due to the challenge of identifying a suitable control for expectancy and attention, but a study which demonstrates a sustained benefit from a limited educational intervention (provided to patients or caregivers),

- would provide useful guidance for clinical management.
- Further investigation of the benefits for FI of weight reduction, especially in moderately obese patients without bariatric surgery.
- Exercise programmes, when incorporated into a multi-component intervention, have produced promising preliminary results and should be tested further. Such trials should differentiate between constipation-associated FI and diarrhoeaassociated FI as exercise may be more beneficial to the former group.
- Evaluation of the incremental or additive value of different lifestyle interventions in the patient pathway.
- Research on the contribution of complementary therapies.

#### IV. DIET AND FLUID INTAKE

## 1. BACKGROUND: RATIONALE FOR DIETARY INTERVENTIONS

The basis for investigating diet modification as a strategy for managing FI comes from anecdotal reports of this practice by patients to clinicians and recent qualitative and survey research reports. Community-living adults and elderly individuals, especially women, report that they manipulate their diet and eating patterns as a strategy for managing their FI [30; 147;148]. Dietary manipulation is employed by the approximately 20% of patients with irritable bowel syndrome (IBS) who also have FI [129;149] and by the approximately 19% to 40% of patients with inflammatory bowel disease who have FI [56; 66;129;150-152].

Empirical observations of a suspected relationship between diet and changes in bowel pattern are not limited to FI but have been reported by individuals with constipation, those with IBS with constipation (IBS-C) and some healthy individuals, and together with physiological principles of gastrointestinal (GI) function, supported an investigation of the evidence and discussion of possible mechanisms.

#### 2. LITERATURE SEARCH

The following databases were searched for studies to include in this review of dietary interventions for FI management: CINAHL (1982 to March, 2008) and Medline (1966 to March 2008). The Cochrane library and a recent systematic review of the epidemiology and prevention of urinary and FI was also reviewed [6] (**Table 5**).

The following key words were linked with anal, anorectal, bowel, faecal, fecal, rectal, stool" and "continent\$ or incontinent\$," or "diarrhea, diarrhoea,

Table 5. Randomised trials of the effects of dietary interventions on faecal incontinence

1	IIII ANIII AIII AIII AIII AIII AIII AII	- Illumings	Citalians	
Je of	One of the following soluble fibre	· The rate of faecal inconlinence for the	- The inclusion and exclusion	· Delails of the
picmor y of psy	supplements mixed into iruit juices: 25 a of psyllium source per day, 25 a	groups ingesting psyllium or gum arabic were significantly lower than those taking	criteria were reported. Sample size was based on a	assignment and
gum ar	of a gum arabic source per day, or	the placebo.	power analysis.	allocation concealment
per day).		<ul> <li>The rate of stoots with loose and</li> </ul>	· The liming of supplement	
		unformed or liquid consistency for the	consumption and was defined. The	How power was
ased on h of the	<ul> <li>based on the percent of fibre in each of the sources, the total amount</li> </ul>	groups ingesting psyllium or gum arabic were significantly lower that those taking	interval for data collection during the baseline and intervention	explained.
lielary fil bestiling	of dielary libre administered was: 7.1	The placebo.	periods was equal.	. Small aroun eizae
bic per d	arabic per day, or 0.2 g of the pectin	· There was no significant difference in		reduce generalizability
placebo.		bascline diet intake among groups.	There were attempts to control	of findings.
		<ul> <li>The water-holding capacity of stool solids</li> </ul>	concomitant treatments, e.g., none	
e supp	days in addition to usual dict intake,	was highest for the group ingesting psyllium.	of the subjects was taking biofeedback training for polyic	
ermined ord for 8	determined by a prospective diet record for 8 days in each period.	· Flatus did not differ between the baseline	muscle exercises.	
		and fibre supplementation periods or	Lord bostoling research of property of	
		among fibre groups.	supplements were pre-mixed and	
articipant sal incon	<ul> <li>Participants prospectively reported</li> <li>faceal incontinence on a daily stool</li> </ul>	· There were no differences among the	the supplements was determined	
y for 8 de	diary for 8 days in cach period.	groups in slool frequency, well or dry mainty of sloot mainty of sloot mainty of sloot exists.	by self-report.	
		fibre content of stool, stool pH, or short chain fath acids		
ie proporti	The proportion of incontinent stools	•	· 95% of subjects completed the	
ng me oa plementa	ounng me baseline and libre supplementation periods was the		were reported.	
primary mcasurc.	surc.			
			Measures of stool characteristics     were made using standard	
condary	Secondary clinical measures		objective laboratory procedures.	
uded sloa	included stool consistency and frequency stool wet and dry weights			
percen	and percentage water content of			
J. The a	stool. The adverse event of flatulence			
s monilore	was monitored daily by self-report of			
participa	the participants on the stool diary.			
condary	· Secondary measures of the effects			
he fibres	of the fibres on the stools included			
waler-h	the water-holding capacity of stool			
stool pH, a	solids, total more content of stool, stool pH, and faccal short chain fatty			

Table 5. Randomised trials of the effects of dietary interventions on faecal incontinence

Limitations Given the cross-over design, period and sequence cflores were not reported design, period and sequence offects were not reported design, period and sequence offects were not reported prior to combining all a subjects on Treatments A or st of analysis.  B for analysis.  B for analysis.  B for analysis.  There was no theoretical or physiological rationale for main analysis.  There was no theoretical or physiological rationale for leakage of mucus or solid stools.  The total amount of fiber in leakage of mucus or solid stools.  The total amount of fiber in leakage of mucus or solid stools.  S each supplement source was not reported.  Participants mixed their own supplements.	
Strengths  There were two power calculations based on a five-point difference in the Focal Incontinence Severity Index, which was considered by the investigators to be clinically significant one for a test of paired data and one for tests of unpaired data in the event of high altrition at the cross-over point.  Subjects were randomly assigned to treatments using a computer-generated list in blocks of 10.  Independent pharmacists dispensed the treatments.  The interval for data collection during both treatments was the same.	the attrition were reported.
Findings  - 67% of treatment A fiber and 73% of treatment B fiber were taken as determined by weighing the container containing the fiber source at the end of each fiber phase.  - The mean difference in the FISI score between treatments was -0.8 (95% confidence interval = -4.9 to 3.3) and was not statistically significant.  - There were no adverse events, it was noted that some subjects reported having a dry mouth and thought the supplements had low palarability.	
Intervention and Outcomes  Treatment A: self-titrated dose of loperamide (starting at 2 mg twice por day), 1 rounded toaspoon of a food thickener containing maize starch, maltodextin, and locust bean gum twice per day, and a diet advice shect about a low-fibre residue dict.  Treatment B: same self-titrated dose of loperamide, one rounded leaspoon of psyllium hydrocolloid fibor in water twice per day, and a diet advice sheet about a high and low fiber residue diet.  Participants self-reported anal incontinence outcomes for the last 4 wocks of the six weeks of each fibor treatment using the patient weighted FISI. FISI score during each treatment period was the primary measure of anal incontinence specific included a lease incontinence specific included a lease in included a lease in included a lease in incontinence specific included a lease in incontinence.	measure of general health status.
Design and sample  - A double-blind, randomized, cross-over design  - 47 adults (91% female) whose primary problem was incontinence of mucus, liquid or formed stools completed the study.  - Sixty-three subjects started the study (treatment A = 31 and treatment B = 32), and torty-nine crossed-over to the second treatment (treatment A = 27 and treatment (treatment A = 27 and treatment B = 22).  - The causes of faccal incontinence if known were not reported for all subjects. Approximately 40% had a partial (30%) or complete defect of the external anal sphincter (11%); 21% had an incharal anal sphincter that incharal and sphincter that inchar	partial (11%) defect or was fragmented in two (3%).
Study Lauti et al. [206]	

signs and symptoms digestive or digestive disease: alcohol, alcoholism, alcoholic beverages, ethanol\$, drinking; beverages, fluid, fluid intake; liquid, water; coffee, caffeine, cola; diet, dietary therapy, diet\$, eat\$, intake\$, consum\$ and fat\$ or lipid\$; fibre/fiber, dietary fibre/fiber; lactose, dairy; prebiotic, probiotic, symbiotic; oligofructose, oligofructose, oligosaccharides, fructans, fructo\$, fos or fructooligosaccharide; sorbitol or glucitol\$ or isosorbide\$ or meglumine\$; spice, spicy, hot; yogurt, bifidibacteria, Bifidobacterium, Lactobacillius acidophilus, acidophil\$. All seemingly relevant abstracts were reviewed; then salient articles were retrieved and reviewed, and the reference lists of these articles searched for further studies.

#### a) Criteria for considering studies for this review

#### 1. Types of studies

Only studies in the English language were reviewed. Systematic reviews and meta-analyses of randomised controlled trials and full-length manuscripts reporting individual studies published in a peer-reviewed journal were considered. Individual studies or reports were required to have one of the following designs as defined in the ICUD review guidelines: randomised, controlled trial; prospective, non-randomised cohort; case-control; or recommendations from an expert consensus panel or Delphi process.

#### 2. Types of study participants

Studies that involved people who were 18 years or older, had FI, and received a dietary intervention were included. People who were tube-fed or had an intestinal ostomy of any sort were ineligible.

#### 3. Types of dietary interventions

A dietary intervention was defined as any type of food, supplement, dietary product, or fluid that is purposefully consumed or restricted, limited or avoided to manage FI. Studies were excluded if it was not possible to distinguish any direct effect of the dietary intervention from other interventions introduced simultaneously. For example, a study was excluded if it combined pelvic floor muscle training and a dietary intervention and compared it to another intervention such as drug therapy making it impossible to determine the effect of the dietary intervention alone.

#### 4. Types of outcome measures

FI was required to be a primary outcome measure of the studies. Studies which focused primarily on the outcomes of stool consistency or form, stool amount, volume or bulk, defecation frequency, diarrhoea, or constipation without including any measure of FI were excluded.

#### b) Method of review

The reviewer examined the list of citations and abstracts yielded from the electronic search strategy. Potentially relevant papers were retrieved in full text. The reviewer was not blind to the journal titles, authors' names or their institutional affiliations. The quality of

the studies was evaluated using the checklist accompanying the CONSORT statement available at http://www.consort-statement.org. The levels of evidence for therapeutic interventions developed by the 3<sup>rd</sup> ICI 2004 were adopted.

## 3. REVIEW OF EVIDENCE ON DIET AND FLUIDS IN FI

#### a) Diet Modification

Studies of diet modification primarily used qualitative research methods or surveys and provide background and rationale for examining the effects of diet. A survey about FI and self-care practices administered to community-living elderly people showed that many of the respondents changed their diet and skipped meals as a management strategy for FI. Changing diet was a significantly more common practice among women (35.4%) compared to men (12.5%) [147]. A qualitative interview of women with FI revealed that some avoided eating anything on days they were going to be away from home or restricted the amount eaten while out in public [148]. Many also restricted foods that they thought worsened FI (for example, fried or spicy foods or caffeinated beverages and chocolate), or foods that increased flatus (for example, cabbage, onions); a few purposely ate certain foods as a therapy to decrease FI (for example, yogurt).

Using a trial and error approach, women with FI often modified their diet based on recommendations for other gastrointestinal problems (e.g., lactose intolerance and IBS) that were available in the professional or lay literature [148]. The effectiveness of these diet modifications was unmeasured and variable. Concerns of diet manipulation are nutritional deficiencies and subsequent poor health. However, Bliss et al. [153] found few significant differences in the nutritional composition of usual diets of persons with FI compared to the usual diets of age and gender matched controls with normal bowel function. The group with FI had a greater intake of carbohydrates, manganese, and vitamin B1.

#### b) Fluid intake

FI is associated with constipation in nursing homes (see section 2). Approximately 30% of elderly residents in long-term care institutions have faecal impaction [32;154] and general clinical recommendations for FI management in these cases are for an adequate intake of fluid to prevent hard stool consistency and constipation. However, there are no empirical data to support the recommendation of increased fluids either for constipation or for FI, and there is no evidence that the diets of patients with FI or constipation are deficient in fluids.

## c) Dietary fibre, prebiotics, probiotics, and synbiotics

A prebiotic is a general term describing a food ingredient that is not digested in the human small intestine and thus stimulates the growth and/or activity

of one or more types of bacteria in the colon that have the potential to improve the health of the host. Because of its ability to stimulate growth of bacteria in the colon, dietary fibre can be considered a prebiotic. Fructooligosaccharides and galacto-oligosaccharides are popular prebiotics. A probiotic is a food supplement containing live non-pathogenic and non-toxic microbes that have the potential to affect the balance of colonic microbes or improve the host's health. Bifidobacteria and lactobaccilli are the most commonly used probiotics, and yogurt which has active microbial cultures can be considered a probiotic. A synbiotic refers to a product that combines a prebiotic and probiotic. Probiotics have been investigated for their ability to prevent or reduce diarrhoea associated with antibiotics, Clostridium difficile infection, ulcerative colitis, acute infant dehydration due to diarrhoea and in treating Heliobacter pylori infections [155;156]. However, there are no published data on the use of probiotics or synbiotics to treat FI.

Dietary fibre is the non-starch, polysaccharide component of plant cell walls and lignin that resists digestion by human intestinal enzymes. Dietary fibre supplementation has been shown in a randomized, placebo-controlled pilot study to reduce FI associated with loose stool (see Section e). Moreover, persons with normal bowel function who had diarrhoea induced by administration of phenolphthalein reported that they had fewer days with urgency to defaecate or fear of FI when they ingested the soluble fibre psyllium compared to wheat bran, calcium polycarbophil, or placebo in an unblinded manner [157]. On the other hand, there are reports that dietary fibre may exacerbate FI in some patients. It has been observed that some patients with FI benefit from moderating their intake of foods containing largely insoluble fibre, such as whole grain breads and cereals, nuts, beans, fruits and vegetables with skin, and sweet corn [158]. Moreover, one clinical letter reported that treating constipation in elderly immobile people with a supplement of insoluble fibre and bran, resulted in FI in half of them [159]. Thus, fibre supplements appear to benefit diarrhoea-associated but not constipationassociated FI. Additional, larger studies are needed to determine the indications and overall efficacy of dietary supplements for FI.

## d) Lactose, yogurt, sorbitol, fructose, caffeine, and alcohol

Certain dietary components such as lactose, sorbitol, fructose, caffeine, and alcohol may cause loose stools that can potentially aggravate FI. A deficiency of the intestinal enzyme, lactase, prevents hydrolysis of the disaccharide lactose and its absorption. The presence of lactose creates an osmotic shift of intestinal water into the small intestine and speeds transit. In the large intestine, fermentation of lactose by colonic bacteria may result in flatulence, distension, diarrhoea, and cramps. However, the majority of adults who have

lactase deficiency can tolerate a small amount of lactose in foods [160]. Yogurt is usually well tolerated by lactose maldigesting individuals because the lactose is partially digested by the beta-galactosidase of the bacteria used to ferment the yogurt. However, yogurt has not been found to aid the digestion or tolerance for additional lactose simultaneously consumed with it [161].

Due to its prevalence in approximately two-thirds of the world's population, hypolactasia is currently regarded as a normal physiological pattern rather than a disease [162]. The prevalence ranges from highs of nearly 100% in some Asian countries and 70% in Italy to lows of 2% in Scandinavia and 15% in U.S. Whites [163]. Malabsorption of fructose and sorbitol results in osmotic diarrhoea and adverse symptoms, similar to lactose. A diet reduced in fructose and sorbitol content is suggested for some patients with irritable bowel syndrome to reduce adverse GI symptoms [164].

Caffeine, of which coffee is a popular source, induces a desire to defecate [165-169]. Caffeine has also been observed to stimulate defaecation urgency in some patients with FI [158]. However, regular consumption of coffee was not associated with prevalent or incident FI in elderly men and women [55], and no studies were found on caffeine restriction to improve FI.

Chronic consumption of alcohol has been associated with accelerated gastric emptying and small bowel transit in animal studies whereas a single large dose has an inhibitory effect on these parameters [170-172].

Excessive alcohol consumption leads to injury of the duodenal and upper jejunal mucosa and inhibition of sodium and water absorption. There is an increased prevalence of bacterial overgrowth in the small intestine of alcoholics, which may contribute to loose stools, diarrhoea, incontinence, and other GI symptoms [173]. No studies were found in which alcohol restriction was reported to reduce FI.

## e) Review of RCT evidence on diet and fluid intake

Two studies were found that met the inclusion criteria for review [174;175]. The methods, strengths and limitations of the studies are presented in Table 5. In the Bliss study, subjects were community-living adults living in the United States with incontinence of loose or liquid stools. The intervention was supplementation with one of two soluble dietary fibres compared to placebo. This study provided level 1 evidence suggesting that dietary fibre can reduce the rate of FI in patients with loose stool [175].

In the second study, subjects were outpatients of a colorectal service in Australia who were incontinent of mucus, liquid, or solid stools. Two combination treatments consisting of an antimotility medication, a diet advice sheet and a fibre supplement or placebo were compared.

This study was not limited to patients with FI of loose or liquid stools (i.e., other types of FI were included), and the study showed no additional benefit of a dietary fibre supplement over use of the antimotility medication, loperamide, for reducing incontinence of flatus, mucus or solid or liquid stool [174]. Differences in the findings of these studies (Table 5) may be explained in part by differences in the interventions, level of control of threats to internal validity, and lack of some analysis data.

#### 4. SUMMARY OF EVIDENCE

Patients consider diet a factor affecting the severity of their FI and they use diet modification as a self-care strategy (level 3 evidence). Dietary fibre supplementation appears to be a safe and tolerable intervention. However, findings from two randomised trials about its effectiveness differ.

## 5. RECOMMENDATIONS FOR PRACTICE ON DIET AND FLUIDS

- Soluble dietary fibre is recommended for the management of FI associated with loose stool. This recommendation is made despite inconsistent results between two RCTs because the metho-dology for the positive study was significantly better than that of the other study. (Evidence level 1. Recommendation Grade B).
- Dietary fibre is not recommended as an adjuvant to antimotility medication for managing AI when stools are not loose or liquid. (Evidence level 2 Grade B).
- Patients should be asked about dietary restrictions and meal skipping.

## 6. RECOMMENDATIONS FOR RESEARCH ON DIET AND FLUIDS

Further studies on the effect of dietary fibre and other diet modifications on FI are encouraged to build a greater body of evidence. Because dietary fibres differ in their chemical composition and properties, future studies are recommended to determine the optimal type and amount of fibre to use for FI. Whether a dietary intervention can augment other behavioural interventions, such as pelvic floor muscle exercises or bowel training, needs further study.

- Role of fibre and fluid in constipation/impaction related FI
- Effect of diet and eating pattern as a management strategy for FI
- Role of caffeine restriction in the treatment of FI and AI

There are several recommendations for methodological rigour in future studies. Theory-based, adequately powered, controlled trials are sought. Studies should control for variability in an individual's baseline severity of incontinence and any adjuvant therapies. Monitoring adherence to the dietary intervention is recommended. A common set of outcome measures that includes tolerance to diet interventions is recommended. Reporting outcomes of FI in addition to those of AI (which incorporates flatus incontinence) is recommended.

## V. BOWEL MANAGEMENT AND RETRAINING PROGRAMMES

#### 1. BACKGROUND

Constipation is a well-established risk factor for FI in children and older people but has not been found to be a consistent risk factor for FI in young and middle aged adults. Frail older people are covered in section 9. The use of rectal medications and enemas is covered in section 6. This section is limited to studies in younger adults.

#### 2. SEARCH

The following keywords were searched: "anal, anorectal, bowel, faecal, fecal, rectal, stool" and "continent\$ or incontinent\$," or "diarrhea, diarrhoea" and the relevant lifestyle or intervention term: bowel\$ and train\$ or retrain\$; digital\$ and stimulat\$); crede or massage; enema; and suppositor\$. The following databases were searched: CINAHL 1982- March, 2008 MEDLINE 1955- March, 2008. The Cochrane library and a recent systematic review of the epidemiology and prevention of urinary and FI was also reviewed [6]. All seemingly relevant abstracts were reviewed, after which salient articles were retrieved and reviewed, and the reference lists searched for further studies.

## 3. REVIEW OF EVIDENCE ON BOWEL MANAGEMENT AND RETRAINING PROGRAMMES

#### a) Bowel habit

Expert opinion supports the importance of attempting to establish a regular, predictable pattern of bowel evacuation by patient teaching and adherence to a routine [128;176]. Because peristaltic contractions of the colon that are associated with defaecation increase in frequency following awakening from sleep and following meals [177;178], the period after breakfast is the best time for scheduled defaecation. However, no studies have evaluated the effectiveness of this in young and middle aged adults.

#### b) Resisting urgency

The sensation of a strong urge to defaecate is frequently associated with diarrhoea, and it is a recognized risk factor for FI in adults [179]. In contrast to urinary incontinence, particularly the overactive bladder syndrome (Committee 14) for which a body of knowledge has developed on the efficacy of bladder

training techniques (i.e., voiding at specific intervals rather than in response to urge and deferment techniques), the possibility of bowel retraining for resisting urgency to defaecate is relatively unexplored. Some biofeedback protocols focus on altering rectal sensory thresholds (see below).

One RCT compared patients who received education, including urgency resistance techniques [158] and dietary advice, to a group of patients who received the same training plus anal sphincter exercises with or without home or clinic biofeedback. There were no significant difference in outcomes [142]. However, this study did not assess the effectiveness of the behavioural training compared to an appropriate control group.

#### c) Evacuation training

A common factor in the genesis of pelvic floor problems may be chronic straining with perineal descent from constipation; this may lead to pelvic floor damage (direct or neurological) [180;181] and may be associated with pelvic organ prolapse or urinary or Fl. In one small study women who reported straining were more likely to develop urogynaecologic symptoms such as prolapse and stress urinary incontinence [182]. However, straining has not been shown to be a risk factor for Fl. No studies were identified examining the effect of treating constipation or decreasing straining on preventing or treating Fl in non-institutionalised adults.

Clinically, many patients with FI are taught evacuation techniques or are encouraged to use laxatives, enemas or suppositories in an attempt to ensure that the rectum remains empty most of the time, thus giving less chance of FI. This is known to improve continence in children and elderly patients (Section 9), but there is no evidence that it improves FI in young and middle-aged adults.

Committee 10 has reviewed the evidence for digital rectal stimulation and manual evacuation. The use of these techniques to assist complete evacuation in non-neurological populations has not been evaluated.

One RCT of a combination treatment package for FI included training on evacuation techniques and noted that patients reported improved ease of evacuation after treatment [142]. No separate data on FI were presented. No studies were found utilising specific evacuation training to treat FI in younger adults.

#### d) Behaviour modification

Toilet training with rewards, either alone or in combination with laxatives has been found helpful in children with FI [183]. It is not known if a similar approach might be applicable to adults with learning difficulties or frail older people in institutional settings, although a behavioural approach to such problems has been recommended based on expert opinion [184].

Adults with learning difficulties may respond to formal behaviour modification techniques, but only small case series are currently available as evidence [185]. Similarly there are no controlled studies of training in adults with non-retentive FI [186].

#### e) Rectal irrigation

Irrigation of the lower bowel has been used for many years to manage both FI and constipation. Surgical construction of a portal for antegrade irrigation is covered in Chapter 17. Various equipment has been used for retrograde irrigation, including a stoma irrigation cone held in place manually against the anus [187], a mechanical pump [188] and more recently purpose-designed anal irrigation equipment [189;190]. Use in FI secondary to spina bifida has been widespread [189].

One single RCT was found in the literature. Rectal irrigation with tap water was found in an RCT to improve bowel management, constipation and FI in patients with problematic bowel management following spinal cord injury [190]. This warrants further evaluation in other populations as uncontrolled case series report possible efficacy in FI without neurological injury [188;191]. Benefit may be maintained with continued use in up to 50% in the long term [192].

#### f) Combination therapies

It is recognised that in many people, the symptom of FI is the result of a complex combination of disordered anatomy and physiology, stool consistency and gut motility, emotional and psychological status and restricted access to toilet facilities, amongst other factors (see Committee 5). Hence in clinical practice most patients receive a combined approach addressing diet, medications, lifestyle, muscle function and bowel habit simultaneously, depending on the result of initial assessment [193;194]. However, with the exception of one study [142] the few wellconducted studies on the conservative management of FI in adults have usually focused on evaluating a single intervention such as biofeedback, often not specifying what other advice (that might confound the results) was given to patients.

Norton et al compared a combination of conservative measures, including patient teaching, advice on diet, medication titration, and bowel retraining, with the same measures combined with anal sphincter exercises and/or biofeedback [142]. No statistically significant differences were detected between the four groups on any of the outcome measures (including diary, symptom questionnaire, manometry, anxiety, depression and quality of life). Over 50% of those randomised (171 patients) reported improved continence. Of those completing the protocol, 74% felt that they remained improved at one year following the end of treatment. The authors of this study suggest that the most effective element may have been

education and therapist-patient interaction rather than specific interventions.

In children a combination of behavioural training techniques and laxative therapy is as effective alone as it is when combined with biofeedback (183). Anecdotally, laxatives may enhance the effect of behaviour modification alone.

#### 4. SUMMARY OF EVIDENCE

There is very limited evidence in this area. In particular there are:

- · No studies in adults with learning disabilities
- · No studies in frail elders or Nursing Home patients
- No studies in neurological patients
- One study in adults (combination intervention: [142]): retraining alone is possibly as effective as biofeedback
- One RCT of rectal irrigation in SCI has found benefit for FI, constipation, time spent & QoL [190] (Level of evidence 2)

## 5. RECOMMENDATIONS FOR PRACTICE ON BOWEL TRAINING

- · Attempt to establish a bowel routine (C)
- Urgency resistance training possibly useful for urgency (D: need for research)
- No evidence on behaviour modification methods
   (D: need for research)
- Digital stimulation and manual evacuation useful in neurological patients (C)
- Rectal irrigation is useful in SCI (B) and has potential in other patients with FI (D)

#### 6. RECOMMENDATIONS FOR RESEARCH

Research is needed in all areas.

Combination studies with urinary incontinence are recommended.

#### VI. DRUG TREATMENT OF FI

#### 1. GOALS

The goals of this section are to identify the drugs and other medical interventions that have been used to treat FI and to evaluate the evidence regarding their efficacy. The medical management of FI has focused exclusively on three mechanisms:

- Reduction of diarrhoea. Diarrhoea is consistently found to be a strong risk factor for FI (see Section 2 above).
- Increasing resting anal canal pressure. Low resting anal canal pressure is a risk factor for passive FI, and is commonly seen following some types of

- anorectal surgery (e.g. sphincterotomy, ileal pouch procedures, abdominoperineal pull-through for imperforate anus).
- Treatment or prevention of constipation. Constipation is frequently found to be a risk factor for FI, especially in children and the elderly (see Section 2 above).

#### 2. SEARCH METHODS

- The Medline database and the Cochrane reviews [183;195] were searched for studies in any language and any year through March 2008 which matched the following search terms:
- "Faecal incontinence" OR "anal incontinence" AND "drug" OR "medical management" OR "medical treatment."
- 3. "Faecal incontinence" OR "anal incontinence" AND "loperamide" OR "diphenoxylate."
- 4. "Faecal incontinence" OR "anal incontinence" AND "laxative" OR "polyethylene."
- 5. "Faecal incontinence" OR "anal incontinence" AND "phenylephrine gel."

Additional articles were identified by examining systematic reviews [195-197].

## 3. REVIEW OF EVIDENCE ON MEDICATION AND FI

## a) Treatment of diarrhoea-associated FI with antidiarrhoeal drugs.

#### 1. LOPERAMIDE AND DIPHENOXYLATE

The most extensively tested drug treatment for diarrhoea-associated FI is loperamide. We identified 6 studies in adult subjects [174;198-202] and 3 studies in children [203-205]. These studies all have methodological weaknesses including small sample sizes and use of crossover designs or they are case series. These studies generally support the efficacy of loperamide for decreasing diarrhoea-associated FI. Three of these studies are briefly summarized below:

Palmer and colleagues [198] compared loperamide (average of 4.6 mg per day) to codeine (average of 103 mg per day) and diphenoxylate (average of 12.5 mg per day) in 30 patients with diarrhoea, of whom 19 had FI prior to treatment. However, FI was not the primary outcome measure. Loperamide was superior to diphenoxylate and similar to codeine with respect to decreased stool frequency, improved stool consistency, and reduced side-effects. Although not statistically significant, there was a trend for less FI while taking loperamide compared to diphenoxylate. Harford and colleagues tested diphenoxylate against placebo in 15 patients with diarrhoea-associated FI and reported a tendency for decreased FI.

Fox and colleagues [202] tested different doses of loperamide against placebo in a double-blind crossover study of 10 obese subjects who were soiling as a result of taking orlistat for weight control. These 10 subjects were selected for study because they had previously been found to soil while taking orlistat. In this study, loperamide decreased soiling and FI and increased resting anal canal pressure.

Lauti's group [206] compared loperamide plus fibre supplementation to loperamide with a low fibre diet and placebo fibre supplement in the first adequately powered study. This was a double-blind crossover study with order of treatments counterbalanced. Results showed a significant improvement in continence relative to baseline in both groups, but the addition of fibre to loperamide did not increase benefit. This suggests that loperamide may be more effective than fibre supplementation alone for the treatment of diarrhoea-associated FI. An earlier study by Bliss and colleagues [175], which is reviewed in Section 4, showed that fibre supplementation with either psyllium or gum agar improved diarrhoea-associated FI more than placebo.

#### 2. OTHER ANTIDIARRHOEAL DRUGS

Santoro and colleagues [207] carried out an uncontrolled study of the tricyclic antidepressant, amitriptyline, given 20 mg at bedtime, in 18 patients with FI; diarrhoea was not required. Thirteen of 18 became continent and 3 reported improvement. The authors attributed the benefits to increased anal resting pressure and decreased numbers of "rectal motor complexes." This study suggests that amitriptyline and other tricyclic antidepressants are of possible benefit for treating FI. Sucralfate is a formulation of aluminium hydroxide used primarily for the treatment of duodenal ulcers; it has the property of coating the stomach lining. An early study suggested that sucralfate might reduce diarrhoea secondary to radiation proctitis in patients receiving radiotherapy for pelvic cancer [208]. However, subsequent large randomized controlled trials have shown no significant benefit for diarrhoea [209] and a worsening of FI [210] in this patient population.

Mechanism of action Three possible mechanisms of action have been identified in the these studies of the drug treatment of diarrhoea-related FI: Loperamide, diphenoxylate, and amitriptyline appear to work in part by decreasing bowel movement frequency through an effect on motility and absorption. Fibre supplements (reviewed in Section 4 above), on the other hand, work by binding more water into the stools. Resting anal canal pressures were reported to be increased in response to loperamide [199;200] and amitriptyline [207].

## b) Increasing anal canal pressure in patients with passive FI

A subgroup of patients with FI have passive

incontinence, defined as FI that is not preceded by a sensation of urgency to defecate and that occurs without awareness. This is believed to be related to decreased resting pressure in the anal canal due to an impaired internal anal sphincter and/or to decreased sensation for rectal distension. A specific aetiology for passive FI is the patient with a colectomy (usually for ulcerative colitis) with a surgically constructed ileal reservoir connected to the anal canal [87].

#### 1. PHENYLEPHRINE GEL

Phenylephrine gel, an alpha-1 adrenergic agonist, has been investigated for the treatment of passive FI in several studies [211;211-215]. In an initial study of 36 patients with intact sphincters, no significant benefit was seen [214]. Two subsequent studies [211;215] suggested a benefit of phenylephrine gel, but a recent randomized controlled trial in 35 patients with passive incontinence secondary to low anterior resection failed to show a benefit [213]. Thus, the clinical utility of phenylephrine gel (if any) may be limited to patients with passive incontinence associated with ileal pouches.

L-erythro methoxamine gel, an alpha-1 adrenoreceptor agonist similar to phenylephrine, has also been shown in two proof-of-concept studies to increase internal anal sphincter resting pressure [216;217], although no clinical trial data are available as yet.

#### 2. VALPROATE SODIUM

The gamma-amino butyric acid transaminase inhibitor, valproate sodium, also increases anal canal resting pressure. It was compared to placebo in a double-blind, randomised crossover study [218] in 17 patients with diarrhoea-related FI secondary to colectomy and ileoanal anastamosis. The drug decreased FI episodes and stool frequency relative to baseline and increased anal canal pressure, whereas placebo did not have these effects. In a second randomized controlled trial by the same investigators [219], 12 patients with ileal pouches were treated with valproate sodium or placebo. There was a significant improvement in anal canal pressures, pouch capacity, and continence. Therefore, valproate sodium is of possible benefit in this population.

#### c) Drug treatment of constipation-associated FI

Constipation-associated FI, sometimes referred to as "overflow incontinence", occurs more frequently at the two ends of the lifespan. The prevalence of FI in children is estimated to be 0.8% [220] to 3% [221] and in 35% [63] to 96% of cases, FI in children is associated with constipation. FI occurs in 46% [222] to 47% [12] of nursing home residents and is more common in those with constipation [223]. However, the proportion of faecally incontinent nursing home residents whose FI is attributable to constipation is not known. Constipation-associated FI is also common in patients with spinal cord injury, occurring in an estimated 33% [106].

Constipation-associated FI in nursing homes is often treated with the prescription of daily or frequent laxatives. However, we found only two RCTs which tested the effectiveness of laxatives for treating FI associated with constipation in adults. Ryan [224] randomised 87 new admissions to a single nursing home to receive either 15 ml daily of sorbitol for up to 15 days or routine care without the use of a laxative. Patients were enrolled whether or not they had constipation or FI. The outcome measures recorded by nurses were amount of nursing time required for the care of FI and amount of soiled linen. Patients treated with sorbitol were found to have significantly less soiled linen, and they tended to require less nursing time. Limitations of the study included (a) analysing the aggregate amount of soiled linen used by each group rather than the proportion of the subjects in each group who had FI; (b) failure to control for expectancy by providing a placebo treatment to members of the control group; and (c) failure to include all randomised subjects in the data analysis, i.e. failure to use an intention to treat analysis.

A second study [225] compared daily enemas to no treatment in 206 nursing home residents who had FI and documented constipation. This was an open label RCT. Results showed no difference between groups either for frequency of FI or for amount of soiled linen.

However, post hoc subgroup analysis showed that patients with complete rectal emptying by digital examination exhibited a significantly greater improvement than the group that continued to have a faecal impaction. Strengths of this study were the large sample size, randomisation, strict inclusion criteria, and assessment of whether the enema regimen in fact eliminated faecal impaction. A weakness was that the post hoc analysis of the physical examination data suggest that the trial is not interpretable since the daily enema regimen did not eliminate faecal impaction in most patients.

A double-blind RCT testing the effectiveness of the prokinetic (motility stimulant) drug cisapride in paediatric FI found no evidence for efficacy [226] and adverse events led the US Food and Drug Administration to restrict access to this drug. An alternative prokinetic drug, tegaserod, has been approved for the treatment of chronic constipation in adults, but has not been tested for its effectiveness in patients with constipation-associated FI.

Several trials [227;228], including one high quality RCT [229] have compared laxatives alone to the combination of laxatives plus biofeedback in children with constipation-associated FI. For this indication, biofeedback is designed to teach the patient to relax the pelvic floor muscles during attempts to defecate in order to overcome a tendency to paradoxically contract these muscles and to obstruct defecation. The RCT by van der Plas and colleagues [229] showed

that combined treatment was associated with a higher success rate at the end of training (39% vs. 19%), but by follow-up 12 months later, there were no differences between groups.

Other studies support these findings by showing either no difference between the laxative only group and a biofeedback group [227] or faster acquisition of continence in the biofeedback group but no long-term difference in success rate [228].

These trials suggest that laxatives alone are as effective as biofeedback for constipation-associated FI in children in the long term, but they were not designed to show that laxatives are superior to placebo or to no treatment.

## 4. SUMMARY OF EVIDENCE ON MEDICATION AND FI

- Loperamide is useful for diarrhoea-associated FI.
   There is some evidence that the loperamide may be superior to diphenoxylate (level 2 evidence).
- There is a possibility that medication may improve FI associated with faecal impaction in a nursing home population if impaction is resolved.

#### 5. DRUG TREATMENT OF FI: RECOMMENDATIONS FOR CLINICAL PRACTICE

- Treat FI with diarrhoea with anti-diarrhoeal medication (C): titrate the dose to individual response (C)
- We are unable to recommend sphincter modifying drugs (D)
- Use oral or rectal laxatives/evacuants to treat constipation-associated FI (C): no evidence on the most effective agent. Need to confirm impaction is resolved (C)
- For constipation-associated FI, there is level 2
   evidence suggesting that daily or more frequent
   oral laxative regimens may be effective for the
   treatment of constipation-associated FI in
   nursing home residents [224] and children [230],
   but there are conflicting data [225;231].

#### 6. DRUG TREATMENT OF FI: RECOMMENDATIONS FOR RESEARCH

- Additional, well-designed studies are needed to validate the common clinical practice of using laxatives to treat constipation-associated FI.
- There is a need for further research on preparations, doses and combination therapies for all types of FI and all patient subgroups.

#### VII. BIOFEEDBACK AND/OR ANAL SPHINCTER / PELVIC FLOOR MUSCLE TRAINING

#### 1. BACKGROUND

Biofeedback can be defined as the use of an instrument that delivers a concurrent measurement of selected biological responses to enable the individual to alter his/her physiological response in directions associated with improved function [232].

The earliest reported application of biofeedback to treat FI used a simple pressure device in the anal canal to reinforce external anal sphincter (EAS) contraction [233], a procedure somewhat analogous to the vaginal perineometer that was used by Kegel to treat stress urinary incontinence [234]. However, the seminal biofeedback procedure [235] for FI, which was followed in a series of studies, used a 3-balloon manometry probe to reinforce changes in 3 distinct physiological variables rather than just EAS contraction. The responses that were reinforced with this protocol included: (a) the perception of sensory cues associated with rectal distension and potential loss of stool; (b) a short-latency EAS contraction; and (c) inhibition of activity that would increase rectal pressure (i.e. contraction of the abdominus rectus and diaphragm). The overall goal of this protocol was to strengthen the presumed EAS reflex contraction that normally counteracts the internal anal sphincter inhibitory response to rectal distension. However, reinforcement for EAS contraction was contingent upon maintaining stable rectal pressure, because increases in rectal pressure during stool urgency can overcome relative sphincter closure pressure, and thus would be counterproductive to retention. Subsequently, the EAS response to rectal distension was determined to be a learned, rather than an involuntary response. As a result, the theoretical basis for the use of operant conditioning (biofeedback) in the treatment of bowel disorders was established [236].

There is no standardisation in the biofeedback literature for FI. Studies use different instrumentation, training procedures, adjunctive strategies, samples, outcome measures, and follow-up periods. Therefore, straightforward comparison of study outcomes and statistical analysis of multiple outcomes is difficult. Most biofeedback protocols can be placed into one of three general categories on the basis of the procedures used for training and include:

 Strength training, defined as the reinforcement of anal sphincter and/or pelvic floor muscle (PFM) contraction to improve EAS strength, speed or endurance without attention to sensation.

- Sensory training, defined as the reinforcement of heightened sensitivity to stepwise reductions in rectal distension volumes without emphasis on improvements in sphincter strength.
- 3) Coordination training, enhancing deliberate voluntary anal contraction in response to rectal filling and thus counteracting the effect of the recto-anal inhibitory reflex in lowering anal pressure, usually combined with the reinforcement of rectal sensitivity, a rapid EAS response in the absence of rectal pressure changes and also sustained EAS contraction to improve sphincter strength.

These approaches can be combined. Variations of these procedures include the reinforcement of tolerance to progressively larger volumes of rectal distension and control of urgency. Instrumentation used to measure and reinforce the changes in biological activity include pneumatic and perfusion manometry, surface electromyography (EMG) and transanal ultrasound. Some workers have suggested the use of a multivariable EMG protocol that mirrors the manometric protocol by substituting surface abdominal EMG electrodes for the rectal pressure balloon to measure extraneous abdominal muscle wall contraction that is associated with increases in rectal pressure. An EMG probe is placed within the anal canal or vagina to measure external anal sphincter or pelvic floor muscle activity.

Historically, the use of pelvic floor muscle training (PFMT) without biofeedback has seldom been used as a primary treatment for FI, unlike its application for UI where PFMT has been recommended as an intervention prior to the use of biofeedback. For FI, most exercise protocols have used PFMT secondarily to augment the biofeedback protocol.

#### 2. LITERATURE SEARCH

A search of Medline, Cinahl and Embase (1970-April 2008) was conducted using the search terms "biofeedback", "exercise therapy", "pelvic floor" and "fecal incontinence", limited to randomised controlled trails (RCTs) in adults. The search was supplemented by a crosscheck of citations in the identified papers and other systematic reviews.

A Cochrane review [237] of randomised or quasirandomised studies found 11 eligible studies that used biofeedback and/or PFMT to treat FI. Our current review found three additional studies [238-240]. A total of 14 studies were therefore identified by this search. One study was published in a very brief German abstract only, with no extractable data [239], and a further two were in abstract form only [240;241] and so were excluded, leaving 11 studies for the review (**Table 6**). In addition, a large number of uncontrolled studies were identified. These are only quoted where they serve to augment the evidence

Table 6. RCTs of biofeedback and/or exercises for FI in adults (Continued).

Author, year country	Population	Intervention	Control	Outcome	Comments
Davis 2004 UK [3]	38 females undergoing anal sphincter repair Mean age 60 (range 26-78)	Manometric BFB starting 3 months after surgery: 1 hour/week for 6 weeks (exercise and sensory training)  N = 14 completed	Usual care N = 17 completed	31 completed at 12 months after surgery. VAS for subjective outcome: NSD QoL: NSD Score: NSD	No ITT analysis. Scores, satisfaction and manometry improved in both groups compared to 3 months post-surgery. Paper focuses on before-after changes within groups and does not report detailed differences between groups
Fynes 1999 Ireland [249]	40 females with obstetric related FI. Mean age 32 years (range 18-48).	Weekly anal EMG BFB + electrical stimulation (20 Hz & 50 Hz) with physiotherapist ("augmented BFB").	Weekly vaginal manometric BFB with nurse specialist.	At end of 12 weeks treatment: Score: improved more in augmented group (p = <0.001)	No ITT analysis. Paper focuses on before-after changes within groups and does not report detailed differences between groups.
Heymen 2000 USA [248]	40 patients with FI not suitable for surgery. Mean age 74 years (range 36-88)	4 groups:  1. Anal clinic EMG  2. Anal clinic EMG + sensory balloon training  3. Anal clinic + home trainer EMG  4. Anal clinic EMG + sensory balloon training + home trainer	See 4 intervention groups	34 patients completed. Diary (days with FI episode): NSD	No ITT analysis. All groups significantly reduced incontinence frequency.
llnyckyj 2005 Canada [371]	23 females with regular and frequent FI. Mean age 59 years (range 26-75). Excluded IBS.	Education + manometric BFB n = 7 completed	Education + PFMT n = 11 completed	18 completed. Success = no FI in last week of study: BFB 6/7 (86%) PFMT 5/11 (45%) p = 0.2	No ITT analysis. Underpowered to detect a difference?
Latimer 1984 Canada [246]	8 subjects (4 children) range 8-72 years	4 phases: A: one month diary B: PFMT with balloon and verbal feedback C: rectal sensory training D: 3 balloon BFB	Varied order of phases		Complex design Underpowered to detect a difference
Mahony 2004 Ireland [243]	60 consecutive females with FI after obstetric injury in perineal clinic. (range 22-42 years)	Anal EMG BFB weekly for 12 weeks (26 completed)	Anal EMG BFB weekly for 12 weeks + 20 mins electrical stimulation at 35 Hz (28 completed)	54 completed. Score: NSD Manometry: NSD	No ITT analysis. Both groups improved equally. Most results reported by group beforeafter.

Table 6. RCTs of biofeedback and/or exercises for FI in adults (Continued).

Author, year country	Population	Intervention	Control	Outcome	Comments
Miner 1990 UK [245]	25 consecutive patients with FI. 8 men. Age range 17-76 years.	Rectal sensation training     Strength or coordination training     (crossed over)	Sham rectal sensation training     Coordination or strength training (crossed over)	End of active vs. sham: active reduced FI.	No ITT analysis. Complex cross-over design and small sample size. Both groups improved: + 24 month follow up: improvement maintained
Naimy 2007 Norway [238]	49 females after 3 <sup>rd</sup> or 4 <sup>th</sup> degree obstetric tear (referred or identified via survey). Mean age 36 (range 22-44)	BFB: EMG, anal probe, home exercises (fast, 10 second and endurance squeezes). 20 mins, twice daily at home for 8 weeks + 2 sessions with therapist	Electrical stimulation at 30-40 Hz, pulse width 200 µs, limit at 80mAmp, anal probe 20 mins, twice daily at home for 8 weeks + 2 sessions with therapist	40 completed. Score: NSD QoL: NSD Both groups subjectively improved,	No ITT analysis.  Compared median changes pre-post treatment between groups rather than direct comparison.  Both groups improved subjective perception of control, but no changes shown in other parameters. Mostly mild FI: limits potential to benefit?
Norton 2003 UK [142]	171 patients referred for BFB. Mean age 56 (range 26-85). 12 men.	4 groups, all up to 6 one hour sessions: 1. Education, advice + urge resistance 2. As g roup 1 + PFMT taught digitally 3. As group 2 + clinic manometric BFB 4. As group 3 + home EMG BFB	See 4 intervention groups	140 completed. Immediate + 12 months: Subjective: NSD Satisfaction: NSD Score: NSD QoL: NSD Manometry: NSD Anxiety & depression:NSD Diary: NSD	Performed ITT analysis. Global improvement across all groups.
Solomon 2003 Australia [252]	120 patients who had failed diet and medical management. Mean age 62 years 13 men.	5 monthly 30 minute sessions. 3 groups: 1. PFMT taught digitally 2. PFMT + anal ultrasound BFB 3. PFMT + manometric BFB	See groups	102 completed. End of treatment: Score: NSD QoL: NSD Manometry: NSD Subjective: NSD	No ITT analysis. All groups improved equally and significantly.
Whitehead 1985 USA [244]	18 older patients recruited from clinics or newspaper advert. Mean age 73 years (range 65-92). 3 men. 6 double incontinence.	4 weeks habit training + PFMT (50 squeezes per day for 10 seconds)	4 weeks habit training alone	End of treatment: No statistical analysis given of difference between groups	No ITT analysis. If still incontinent after 4 weeks, all received BFB.

Key: NSD = no statistically significant difference ITT = intention to treat analysis

from RCTs, for example on possible mechanisms of efficacy or sustainability of effect.

All RCTs that included at least one arm where patients were given instrumented biofeedback or instructions/ coaching in PFMT to treat FI in adults were eligible for inclusion.

#### 3. REVIEW OF THE EVIDENCE

The 11 studies included a total of 592 patients. The median sample size was 40 (range 8-171). Only one study mentions an intention to treat analysis [142]. three trials did not mention number of drop-outs. Of those that do mention drop-outs, a total of 18% of recruited subjects failed to complete.

The majority (90%) of patients in the 11 RCTs were female. Ages ranged from 8-92 (studies primarily of children were excluded). Aetiology and symptom severity was highly heterogeneous. However, some studies did select subjects according to specific problems such as obstetric injury [238;242;243] or older people [244] or following sphincter repair (3). All studies were from a single hospital centre. All but one [238) were from English-speaking countries. Methodological quality was variable, and in many cases unclear.

Two studies attempted a component analysis to determine whether rectal sensory training or EAS strength training was more effective in reducing FI. They concluded that the primary mechanism responsible for symptomatic improvement was increased rectal sensitivity [245;246]. However, both studies were small, underpowered, and involved a complex cross-over design which makes analysis difficult due to carry over effects [247]. Also limitations in the applied strength training procedures preclude valid comparisons of strength vs. sensory training methods in these studies.

Other studies have investigated the additional benefits of aspects of therapy. In a between-group design, one study [248] compared out-patient intra-anal EMG strength training to EMG plus sensory training using an intra-rectal balloon, EMG plus home biofeedback training, and EMG, sensory training plus home biofeedback. No added benefit was found when the more comprehensive protocols were used, but small group sizes make this study inconclusive.

One study using a between-group design of 4 different treatments, compared management and advice that included the use of diet advice, urge resistance training and anti-diarrhoeals to the same protocol plus: EAS exercise; EAS exercise and clinic biofeedback; or EAS exercise, biofeedback and the use of a home trainer [142]. There were no statistically significant differences between the four groups.

In addition to diet and bowel management, another adjunctive treatment that has been used with biofee-

dback is electrical stimulation [243;249]. The first of these studies found some benefit from the electrical stimulation (however the biofeedback methods and therapist were also different between groups). The second study found no difference with or without electrical stimulation.

Some studies have added home biofeedback equipment [142;248]. There was no evidence of additional benefit over clinic biofeedback.

Most studies report that patients are instructed in home exercises but many do not specify the precise instructions given to the patients. Some studies state that subjects were simply instructed to contract the EAS with any feeling of rectal distension at home, while others provided structured sphincter exercise programmes. Some have taught exercise with biofeedback or digitally, while others have not mentioned the method of teaching. There was no measure of compliance with exercises. A relationship between long-term improvement and continued exercise has not been established. In one uncontrolled study, [250] only 26% of the subjects reported that they continued to perform PFM exercise at 12 month followup even though all subjects who improved initially (71%) maintained the gains at follow-up. No controlled study has examined intensity of follow-up, although one case series suggests that telephone follow up can be as effective as face-to-face clinic visits [251].

One study [248] compared 4 different biofeedback protocols but did not have a non-biofeedback control group. Before patients were randomised to the different biofeedback protocols, they underwent medical and bowel management but the time period of initial intervention was unspecified. Although there was an overall 74% reduction in stool incontinence after biofeedback, no difference in effect was found between the different protocols. However, interpretation of effects was hampered by small group size.

Another study compared manometric biofeedback, anorectal ultrasound biofeedback and sphincter exercise taught with digital examination alone [252]. All groups showed modest improvements in bowel control with 70% of the subjects reporting at least some clinical improvement. Improvements in bowel control were associated with modest changes in anorectal measures. However, neither manometric or ultrasound biofeedback provided added benefit to digitally taught sphincter exercise on any of the nine outcomes measures.

Another RCT [142] used four groups to compare the effects of a behavioural treatment from a specialized nurse that included advice on bowel management, diet, urgency control and the use of anti-diarrhoeal medication, to the same behavioural management but with the addition of: sphincter exercises; exercises plus clinically administered biofeedback; or exercises, clinical biofeedback and home biofeedback. Each

group received a median of five (range 1-9), 45-90 minute treatment sessions. No difference was found between groups on ratings of bowel control or physiological measures. These findings suggest that biofeedback did not provide any additional benefit to behavioural and medical management. When outcomes were collapsed across all subjects, modest reductions in symptoms of 54% and 53% were reported to occur in the advice and biofeedback groups, respectively. Although manometric indices of sphincter function improved across all groups, an unexpected and unexplained numerical decrease in squeeze pressure was reported in one of the biofeedback groups, and minimal change was reported in the other biofeedback group. However, the outcome analysis was appropriately conducted on an intention to treat basis. In this study a 20% drop out rate was reported, which is consistent with other studies that have also reported drop out rate. But unlike Norton, most studies have reported outcomes only on subjects completing treatment rather than on an intention to treat basis. As result of the more stringent analysis, the Norton outcomes appear to be lower than many of the other reports.

While there was little difference between groups in the RCTs, it should be noted that on a before-after analysis, all studies showed at least some improvement in patient symptoms or other parameters. This is consistent with the majority of case series. There are over 70 uncontrolled studies of BFB and/or PFMT for FI. All but one [253] report benefit to patient symptoms and a variety of other outcome measures. Most studies report an overall response rate that combines improvement and cure rates. Reported improvement ranges from 0% [253] to 100% [254], with the majority being in the range of 50-80% [255;256].

### a) Long-term follow-up

There are few long term follow up studies. One RCT found little fall-off in efficacy at one year [142]. One uncontrolled study found that a majority of patients maintained, and in some cases exceeded, improvements reported immediately after treatment [247]. The long-term positive outcome in this study was attributed to the 83% home exercise compliance during the active treatment phase. An uncontrolled study reports that 63% of patients were continent at one year [257] and another study reported that most responders are still improved at 5 years [258].

### b) Mechanism of treatment benefits

Many studies have reported changes in physiological variables such as resting and squeeze pressures and changes in rectal sensory threshold volumes as an outcome of biofeedback training. A few studies also have reported changes in the duration of EAS contraction [142] with researchers concluding that the ability to sustain an EAS contraction is more

important than maximum squeeze pressure. Two uncontrolled studies found that it was the subjects who learned to extend the duration their sphincter contraction who developed continence [259;260] after biofeedback training. This notion was supported by a study that compared the EAS fatigue rates of healthy controls to patients with constipation, seepage and stool incontinence and found that the EAS fatigue rate in incontinent patients was significantly greater compared to healthy controls and those with seepage [261].

Several studies report that improved rectal sensation is most consistently linked to improvements in continence as a result of biofeedback training [245;246;262]. Conversely, changes in sphincter strength are not consistently found to be associated with reductions in incontinence [245;263-267] and in two studies, squeeze pressure was found to increase even in those patients that did not improve in bowel control [250;268]. These inconsistencies have lead to questions regarding the mechanism(s) presumed to be responsible for symptom reduction as a result of biofeedback treatment [269]. They may also call into question the use of such proxy measures of patient improvement, as symptoms are only loosely related to physiology test findings.

# c) Identifying people likely to benefit from biofeedback

There are no established criteria that might predict which patients would most likely benefit from biofeedback or exercise therapy. One case series found that in addition to a rectal sensory threshold of 50ml or less, a lower EAS and IAS response threshold and an urgency threshold less than 100ml were associated with better outcomes after biofeedback [250]. Another study noted that positive outcomes were associated with those patients 55 years and older and having normal defecation patterns, while poorer outcomes were associated with those younger than 55 and having abnormal evacuation patterns [270]. One study noted that the need for more than 3 biofeedback sessions and a poor early response to biofeedback predicted poor long-term improvement at follow-up [258].

Several reports noted that improvements were not associated with the presence or absence of anal sphincter defects found with ultrasound [142;261; 271;272], but one study found that less robust improvements were obtained in those having passive incontinence rather than urgency incontinence [271]. In the one study that found that no functional improvement was obtained with biofeedback, all subjects had severe pudendal nerve neuropathy and absent sensation for call to stool [253]. Another study found that patients with spinal cord lesions were least likely to respond to treatment [273]. On the other

hand, one study did find that subjects with pudendal neuropathy could improve bowel control with biofeedback but were less likely to show improvement in EAS strength [266]. However, the effects of bowel management strategies were not controlled. Currently, there is little evidence that shows a relationship between pre-treatment anorectal function as measured by manometry and biofeedback outcomes, with the exception of rectal sensitivity which, if found to be greater than 100ml before treatment, is associated with a poor response to biofeedback [273]. As a result, some studies have excluded patients who have a rectal sensory threshold greater than 100 ml.

Unsurprisingly, one case series has found that those who completed treatment were most likely to benefit [274]. The latter study also found that patients who were older, female and had more severe incontinence were most helped, but this may be compounded by the greater likelihood of these patients completing treatment. One further study found that older and less obese patients were most likely to benefit [142].

### d) Comparison of PFMT and BFB

Given that PFMT without BFB has been accepted as a valid treatment for UI, similar protocols may potentially improve FI as well. Two studies that have directly examined the effects of pelvic floor muscle training on FI report similar outcomes [142;252]. When PFMT was used in addition to a comprehensive behavioural management programme, no added benefit was obtained [142]. Both studies found PFMT alone to be as effective as BFB combined with PFMT.

In a RCT which recruited women with urinary incontinence three months postnatally, the intervention group reported less FI at 12 months follow-up [275], although the effect does not appear to last at six years [276]. However, in this study, the effect of PFMT was not studied separately from education and patients were not recruited with FI as their primary problem. Given the limited data available, there is an obvious need to investigate the effectiveness of PFMT alone on FI because there are no known risks associated with its application and its cost is low relative to biofeedback.

# 4. SUMMARY OF THE EVIDENCE: BIOFEEDBACK AND EXERCISES FOR FI

In general, the outcomes reported from uncontrolled biofeedback studies for FI have been favourable. However, most studies have been small and have a multitude of methodological flaws that include inadequate descriptions of subject characteristics and procedures, the use of heterogeneous samples, and limited follow-up data. Only a handful of the studies have made efforts to control for non-specific effects. In contrast to the mostly favourable outcomes reported in uncontrolled studies, randomised controlled trials have generally found no additional benefit when

biofeedback was added to either a comprehensive behavioural and medical management programme [142] or to digitally taught sphincter exercises. There are limitations in all studies to date.

We still lack precise knowledge of the mechanisms responsible for improvement when biofeedback or exercise is used to treat FI, and we do not yet understand the extent to which any specific biofeedback protocol alters parameters of anorectal function. The exception is rectal sensitivity, which is the single physiological parameter that has been reported to most consistently improve with biofeedback. However, not all subjects who show improvements in rectal sensitivity also develop continence. Thus, good rectal sensitivity can be considered a necessary but not suffficient requirement for reliable continence. In contrast to rectal sensation, EAS strength has not been shown to consistently improve with biofeedback even when protocols have been directed to improve EAS function. Herein lies an essential empirical question for the field that must be answered before we can determine whether biofeedback is a useful tool in the treatment of stool incontinence.

For, if changes in sphincter function are not observed when the stated goal of a biofeedback procedure is to improve sphincter strength, the validity of the protocol can be questioned and accordingly, conclusions based on the outcomes must be limited. Protocols then should be appropriately altered to achieve the stated goal of changing EAS function. As in the field of psychophysiology from which biofeedback has evolved, a test of biofeedback effectiveness for any disorder cannot be accepted as an adequate evaluation of the treatment without evidence that the targeted physiology has been changed to a valid criterion of function [277].

Accordingly, any biofeedback protocol for FI should first be shown to have altered some target aspect of anorectal or bowel physiology, before it is be tested as a treatment. Additionally, measurement of these functions has yet to be standardised and validated. Without validation of the biofeedback procedure itself, the analysis of group effects tends to be primarily a test of non-specific effects.

In summary, the primary problems in the biofeedback and pelvic floor muscle literature are:

- Biofeedback studies for FI have employed a variety of methodologies that range from rectal sensitivity training to sphincter strength training but without standardisation of methodology or outcome evaluation tools.
- Although uncontrolled studies using biofeedback for FI have reported mostly favourable outcomes, results from larger RCTs have mostly not demonstrated a benefit of biofeedback over

comprehensively administered behavioural and medical management or sphincter exercises alone.

- Only one study has found significant differences between groups [242]
- Rectal sensation may be more important than sphincter strength [245;250]
- Changes in sphincter strength are not necessarily linked to symptoms
- There are few established predictors of outcome of biofeedback or exercises (rectal sensation, IBS, age, weight, sphincter disruption; each have weak or contradictory evidence as predictors)
- PFMT may be as effective as BFB [142;252]; advice alone may be as effective as PFMT [142]
- · More than 50% of patients in all groups improve

#### 5. RECOMMENDATIONS FOR PRACTICE

Because recent RCTs have raised questions as to whether biofeedback provides a specific benefit relative to education and good clinical management despite a large body of uncontrolled studies supporting its efficacy, the consensus of the committee is that it is possibly effective but currently unproven. This reinforces the case for using maximal education, lifestyle and dietary interventions before PFMT or BFB, as recommended by recent national guidelines in the UK [278].

- PFM exercises are recommended as an early intervention in the treatment of FI as part of a conservative management bundle of interventions, based upon low cost and morbidity and some, although limited, evidence suggesting efficacy (C).
- The use of biofeedback as a treatment for FI is recommended after other behavioural and medical management has been tried if inadequate symptom relief obtained, given the numerous positive outcomes from uncontrolled trials, limitations in the current RCTs and low morbidity associated with its application. (C).

### 6. RECOMMENDATIONS FOR RESEARCH

There is a need to conduct further RCTs to determine whether specific biofeedback and pelvic floor muscle exercise protocols can alter the hypothesised target physiological parameters of ano-rectal function (muscle strength and/or sensation) with concomitant changes in bowel control.

- Clear description of modalities and evaluation of different elements of BFB
- · Adherence monitoring
- · Standardisation of outcome measures

- · Long term follow up
- Robust patient-focused outcome measures
- Understanding of physiological effect and relationship to symptom change
- Work on clinically meaningful improvement and distinguishing cure from improvement rates
- The exploration of possible synergies between urinary and faecal incontinence interventions and evaluations should be considered in study designs

# VIII. EXTERNAL ELECTRICAL STIMULATION FOR FI

# 1. BACKGROUND: THE PHYSIOLOGICAL BASIS FOR ELECTRICAL STIMULATION

Sacral nerve stimulation through surgically implanted electrodes and stimulators have been found to be effective for reducing the severity of FI in randomized controlled trials [279;280]. These studies, which are reviewed in detail by Committee 17, provide an impetus for identifying electrical stimulation protocols for the treatment of FI that are less invasive than other surgical approaches such as sphincteroplasty and injection of bulking agents. This section reviews the use of external (surface) electrical stimulation.

Anal electrical stimulation was first described for treatment of FI over 40 years ago, firstly as an implanted stimulator [281] and later as needle EMG stimulation [282]. As technology developed, more comfortable surface electrodes became available either as skin or intra-anal plug devices with a battery box. ES may be provided by a mains-powered machine or by a portable battery-powered stimulator. The advantage of a small device is that it is easier for the patient to use on a daily basis. Development of vaginal and anal electrodes make it possible for the patient to sit, stand or move during a training programme. There is at present no experimental evidence upon which to select optimum electrical stimulation parameters for different symptoms and clinical conditions.

An electric current of sufficient amplitude will excite nerve and muscle tissue in its field. In addition, the current will alter cell membrane potentials and therefore exert an influence on all living cells. The full extent of this influence is not known but studies have shown an increase in axonal budding following denervation and an increase in vascularisation and muscle bulk when the stimulating electrodes are placed in an area of striated muscles [283]. Also normalisation of the reflex activity of the bladder by using electrical stimulation (ES) has been reported [284]. In an animal model (dog) anal stimulation significantly increased anal sphincter pressure and rectal compliance without changing recto-anal inhibitory reflexes. Vaginal

stimulation also reduces rectal tone and increases anal pressure. Pressure increases are dosedependent.

Maintenance of continence requires volitional cortical control which is dependent upon the sensory feedback from the ano-rectum [285] and the ability to sense rectal distension and impending defecation and to relax or contract the striated muscles of the pelvic floor [286]. Reduced rectal sensitivity is common in patients with constipation and/or FI [287]. The motor control of the pelvic floor muscles is a learned voluntary response albeit often at a subconscious level [236;288].

Functional electrical stimulation activates both sensory and motor axons. The sensory axons send signals to the brain and it is thought may cause plastic changes in the representational area of a body part. The result of this is enlargement of the representation and improvement of awareness of the stimulated body part. This leads to better control of movements. In theory ES may therefore reinforce weak functional signals that come from the pelvic floor musculature during the treatment [289], although this remains to be demonstrated experimentally.

Stimulation parameters such as stimulation frequency, pulse width, on:off ratios, and current intensity are very important as it is possible to cause fatigue and other problems by using incorrect parameters, too long a treatment time or too high an intensity.

#### 2. SEARCH

The following databases were searched for controlled trials up to April 2008 using the terms "faecal/fecal incontinence" and "electrical stimulation": Scopus, Medline, Embase, Cinahl. The reference lists of relevant studies and the Cochrane review [290] were also considered.

### 3. RESULTS

Six controlled studies of ES in FI were found (**Table 7**).

The first controlled study in forty women with obstetric-related FI [249] randomised patients to anal biofeedback and pelvic floor exercises with adjunctive electrical stimulation, or vaginal biofeedback and pelvic floor exercises without electrical stimulation (carried out by a different therapist). Both groups improved symptomatically, with no difference in symptoms between the groups. The stimulation group also improved manometric pressures. However, electrical stimulation was not the only variable in the study, and there was no follow up beyond the 12-week study period. Another attempted controlled study in patients who had FI following repair of obstetric third degree tear, abandoned stimulation because it caused discomfort [291].

Mahony et al studied a group of 60 women with FI

secondary to obstetric trauma and compared 12 weeks of anal EMG biofeedback to anal electrical stimulation [243]. They found no difference between the groups in outcome at the end of the treatment period. Healy [292] found no difference in outcome between home electrical stimulation and clinic stimulation with or without biofeedback. Naimy likewise found no difference between patients given electrical stimulation plus home exercises and those given clinic biofeedback plus home exercises [238]. Norton reported no difference between stimulation at 35Hz and 1Hz, suggesting any effect may be sensory rather than motor [293]. Osterberg (2) compared stimulation with surgical levatorplasty and found few differences in outcome at 2 years. In all studies a significant proportion of patients reported improvement compared to pre-treatment, whatever treatment was given.

### 4. SUMMARY OF EVIDENCE ON ELECTRICAL STIMULATION FOR FI

A Cochrane review of trials of electrical stimulation for FI has concluded that "At present, there are insufficient data to allow reliable conclusions to be drawn on the effects of electrical stimulation in the management of FI. There is a suggestion that electrical stimulation may have a therapeutic effect, but this is not certain. Larger, more generalisable trials are needed " [294].

Because there is a lack of consistency in electrical stimulation protocols and also a failure to use physiological principles when employing electrical stimulation, direct comparisons between studies are impossible. There are many parameter and clinical applications that have not yet been investigated. We know little about which patients are likely to benefit from ES. Sensory awareness of the body schema and the possibility of improving this cortically by using ES may be important in motor re-learning for those patients with severe sensory lost, but this has not been investigated.

# 5. RECOMMENDATIONS FOR PRACTICE ON ELECTRICAL STIMULATION FOR FI

Based on currently available evidence it is not possible to recommended electrical stimulation for FI.

# 6. RECOMMENDATIONS FOR RESEARCH ON ELECTRICAL STIMULATION FOR FI

- Randomised controlled trials with adequate sample sizes are necessary to investigate all aspects of the effectiveness of ES in FI.
- The effect of electrical stimulation in changing consciousness of the pelvic floor is one of the interesting future areas for research.
- When planning future research basic knowledge of electrical stimulation parameters and their likely physiological effects is essential.

Table 7. RCTS of electrical stimulation for FI

	Population	Intervention	Comparison	Outcomes
Naimy et al [238] 2007 Norway	49 women with H after 3" degree lear. Mean age 36 (range 22-44).	Anal slimulation (Neuro Trac ETS + anuform probe). 30-40Hz, pulse width 200, furn up to tolcrance, max 80 mAmp. 3 seconds on/off. 2 sessions with therapist. 2 x 20 mins sessions daily all home for 8 weeks.	Biofeedback (Neuro Trac ETS + anuform probe) 2 sessions with therapist. 2 x 20 mins sessions daily at home for 8 weeks.	40 completed.  No difference or change in Wexner score, or quality of life.  No difference in subjective evaluation of effect: both groups subjectively improved
Healy [292] 2006 Ireland	58 women with F1. Moan age 55 (range 40-78). Excluded significant sphincter defects.	3 months of home stimulation using ETS 90 + Anuform probe. 1 hour daily. Frequency: preset programme 3,10,20,30 & 40 Hz. 4 seconds on/off. Intensity patient controlled.	Comparison 1: 3 months of hospital physiotherapy Irealment once weekly. Alternale electrical stimulation (10 & 40 Hz) + biofoodback for 15 minutes cach. Comparison 2: I wice weekly hospital electrical stimulation without biofeedback.	48 completed. No intention to treat analysis. No difference in squeeze pressure, Wexner score, quality of life between groups. Both groups significantly improved squeeze pressure. Wexner score and quality of life (some parameters) compared to pre-Irealment.
Norton [293] 2005 England	90 patients (9 male). Mcdian age 55 (range 30-77). Blinded to intervention group.	Daily home stimulation using Eloha 4 Danmeter + Anuform anal probe at 35Hz for 8 wocks, with no other intervention. 20 minutes for 3 wocks then 40 minutes for 5 weeks.  Ramped pulse, 5 sec on/off, 300ms pulse width.	"Sham" stimulation at 1Hz (n = 43) to same daily protocol.	70/90 completed. Intention to treat analysis. No difference between groups in subjective rating of outcome, frequency of FI, use of pads, satisfaction, effect on life or anal pressures. Both groups reported subjectively improved bowel control and frequency of FI.
Osterberg [2] 2004 Sweden	70 palients randomised. Age range 43-81. 7 men. Excluded sphinctor defect & rectal prolapse.	Anal plug slimulation using MS210 Medicon (n = 28 completed). 25Hz, 1.5 sec on, 3 sec off. 12 x 20 minute sessions over 4-5 weeks.	Surgical levalorplasty, anterior in women, posterior in men (n =31 completed).	Evaluation at 3, 12 & 24 months.  No difference in patient evaluation of improvement in Fl. use of pads or urgency at any lime point. Surgical group reported better quality of life on several parameters.  Both groups significantly improved conlinence, decreased pad use and lossoned social handicap at each time point compared to pre-treatment. There was no difference or change in physiological parameters.
Mahony [243] 2004 Ireland	60 women with H after obstetric injury. Mean age 35 (rango 23-39).	12 weeks anal EMG biofeedback + electrical slimulation (Incare PRS 9400)	12 weeks anal EMG biofeedback (Incare PRS 9400).	54 completed. No difference in numbers achieving full continence. Both groups improved.
Fynos [249] 1999 Ireland	40 women with Fl after obstetric trauma. Mean age 32 (range 18-48).	12 x weekly 30 minute session of physiotherapist delivered anal biofeedback (fast and slow squeezes) and electrical stimulation (Incare PRS 9300), 20Hz 10 minutes (ramped, 5 sec on, 8 sec off), then 50Hz (8 sec on, 30 off).	12 x wockly 30 minuto sossions of nurso delivered vaginal biofeedback (Peritron pressure probe).	Significant difference in favour of stimulation group in improvement or cure of FI.

# IX. FAECAL INCONTINENCE IN FRAIL OLDER PEOPLE

#### 1. BACKGROUND

FI in older people is a distressing and social isolating symptom and is associated with increased risk of morbidity [8;37], mortality [32;295], and dependency [8;295]. Frailty, defined by having multiple comorbid chronic illnesses and/or limitations to physical activity (see Section 2), is an independent risk factor for FI. Many older individuals with FI will not volunteer the problem to their general practitioner or nurse, and regrettably, health care providers do not routinely enquire about the symptom. This 'hidden problem' can therefore lead to a downward spiral of psychological distress, dependency, and poor health. The condition can especially take its toll on informal care providers of home-dwelling patients [296], with FI being a leading reason for requesting nursing home placement [297;298].

Even when older people are noted by health care professionals to have FI, the condition is often managed passively, especially in the long-term care setting where it is most prevalent. Current surveys show that the level of awareness regarding appropriate assessment and treatment options is limited among primary care physicians [299]. The importance of identifying treatable causes of FI in frail older people rather than just managing passively (e.g. pads provision without assessment) is strongly emphasised in national and international guidance [1;278;297], but audits show that adherence to such guidance is generally poor, with non-integrated services, and suboptimal delivery by professionals of even basic assessment and care [35;300].

This section covers specific issues for frail older people with FI. As this group frequently has co-existing urinary incontinence, it should be read in conjunction with Chapter 11. Healthy older people should be managed using the interventions covered previously in this chapter.

### 2. SEARCH

The PUBMED database was searched up to March 2008 using the following keywords :

- 1. 'anal, bowel, faecal, fecal' and 'incontinence'
- 2. constipation
- 3. 'urinary' and 'incontinence'
- 4. laxatives, enemas, suppositories
- 5. other relevant phrases such as 'comprehensive geriatric assessment' 'stroke'

Additional articles were identified by examining reference lists, and the Cochrane other recent systematic reviews.

### 3. SUMMARY OF EVIDENCE ON PREVALENCE AND RISK FACTORS FOR FI IN FRAIL OLDER PEOPLE

The prevalence and risk factors for FI are detailed in Section 2. Summarized below are key points that are specific to the frail elderly population. The level of evidence is given in brackets.

- FI affects 1 in 5 older people (aged 65+) living in the community, and half of those resident in care homes (Level of evidence 1)
- The prevalence of FI increases with age alone, particularly in the 8<sup>th</sup> decade and beyond (1)
- The prevalence of FI is higher in the acute hospital and nursing home setting than in the community (1), thus the group most affected is frail older people.
- The prevalence of FI in frail older men is equal to or greater than in women (2). This predominance of older men over women with FI is most striking among nursing home residents (2).
- The prevalence of FI varies dramatically between institutions in nursing home studies(2)
- FI usually coexists with urinary incontinence in frail older people (1)
- Aside from age, the following are primary risk factors for FI in older people (2):
  - Loose stool
  - Impaired mobility
  - Dementia
  - Neurological disease
  - Chronic medical conditions
  - Depression
- Loose stool is a primary cause of transient FI in older people (2)
- Faecal loading and constipation are clinically linked to FI, but there is little epidemiological work assessing this association (3)
- Physicians and nurses in primary care, acute hospital, and long-term health care settings do not have a high awareness of FI in older people (2)
- Within nursing homes, there is a low rate of referral by nursing staff of residents to primary care physicians or continence nurse specialists for further assessment of FI (2), and there is a tendency toward passive management (e.g. use of pads only without further evaluation) (2). Faecal loading is often present in older care home residents with FI (2)
- Older people may be reluctant to volunteer the symptoms of FI to their health care provider for social or cultural reasons, or due to a popular misperception that the condition is part of the ageing process and therefore 'nothing can be done about it' (2)
- FI is associated with reduced quality of life, and poor health perception (2)

# 4. RECOMMENDATIONS - IDENTIFYING FAECAL INCONTINENCE IN FRAIL OLDER PEOPLE

- Bowel continence status should be established by direct questioning and/or direct observation in:
  - all nursing and residential home residents
  - hospital inpatients aged 65 and over
  - people aged 80 and beyond living at home
  - older adults with impaired mobility
  - older adults with impaired cognition
  - older adults with neurological disease
  - older adults with chronic disease
- Primary care staff, hospital ward staff, and longterm care staff should routinely enquire about FI in frail older patients
- Enquiry about FI should be systematic and include stool consistency, severity of FI and impact on activities of daily living and quality of life
- Health care providers should be sensitive to cultural and social barriers discouraging patients from talking about the condition
- Frail older patients with restricted ability to access primary care such as nursing home residents, and those with mobility, chronic illness, or cognitive impairments, should be screened for FI through systematic case-finding methods
- Systematic outreach programmes which make it easier for frail older people and those who care for them to volunteer the problem to their primary care provider should be implemented
- There are significant geographic variations in provision of specialist expertise in bowel care (both medical and nursing) nationally and globally, which may affect case-finding in older people
- Further examination of underlying reasons for the variations in prevalence of FI between nursing homes (standards of care, patient case-mix, reporting) is needed
- Urinary and FI often coexist; continence care workers (e.g. nurse specialists) should be trained in identification and management of faecal as well as urinary incontinence in older people
- Key requirements to improving detection in the practice setting should be implemented:
  - (a) education of health care workers to embed both a sense of value in identifying FI, plus confidence that the condition can be treated
  - (b) protocols should be in place clarifying all details of screening enquiry (who will ask, how to ask, when to ask, and who to ask)
  - (c) patients and carers should have access to educational materials at the point of enquiry

### 5. THE AGEING LOWER BOWEL AND PATHO-PHYSIOLOGY IN OLDER ADULTS WITH FAECAL INCONTINENCE

Chapter 4 covers the pathophysiology of FI. This section considers factors specific to frail older people.

### a) Quality of data

The findings from physiological studies of the lower bowel in older adults tend to be variable due to a) a variety of different techniques used in measuring anorectal function, b) unclear definition of the normative range of manometric measures for older people, c) poor matching between cases and controls of clinical factors which may affect gut function (e.g. level of mobility), or inadequate clinical information and d) usually small subject numbers. Studies reviewed are cohort case-control to evaluate age-effect [301-304], young-old healthy subject comparisons [305;306], and age- and sex-matched case-control studies of continent versus incontinent patients [154;307;308].

#### b) Anorectal function in healthy older adults

Studies of age effect in healthy volunteers have shown a linear reduction with ageing in squeeze pressures (external anal sphincter tone) in women after the age of 70, and in men from the 9th decade onwards [301;302]. Age beyond 70 years was associated with reduction in basal pressures (internal anal sphincter tone) in both genders, but to a greater degree in women [301;302;306]. The internal sphincter thickness and diameter is significantly increased in older versus younger nulliparous women with, however, reduced functionality in this smooth muscle [309].

Rectal motility appears to be unaffected by healthy ageing [305], but an age-related increase in anorectal sensitivity thresholds, and reduced rectal compliance has been observed, starting at an earlier age in women than men [303].

# c) Anorectal function in older adults with faecal incontinence

One study demonstrated prolonged pudendal nerve terminal motor latency (>2.2ms) in 34% of women aged over 50 with FI, though no relationship was observed between pudendal neuropathy and basal or squeeze pressures [310]. Advancing age was however related to declining basal pressures. Another study similarly found an age-related increase in pudendal neuropathy in incontinent women, again unrelated to squeeze pressures [311]. Single fibre EMG in incontinent patients aged over 70 years showed increase in polyphasic potentials in the external anal sphincter muscles compared with continent subjects, indicating some local reinnervation of these muscles following neurogenic damage [308]. A study comparing anorectal function in young (mean age 42) and old (mean age 72) women with FI (patients with constipation and/or pelvic floor dysfunction excluded) showed that older women were more likely to have

bilateral pudendal neuropathy, but less likely to have a sphincter deficit of >90 degrees and thin perineal body [304], although the validity of this test is questionable (Committee 7). Anorectal physiology was similar aside from a trend toward lower resting tone in older women.

An examination of anorectal function in elderly medically frail incontinent patients and continent ageand sex-matched controls showed that individuals with FI had reduced internal anal sphincter pressures, and a lower threshold for expulsion of a rectal balloon (307). Patients with FI and dementia were more likely to exhibit multiple rectal contractions in response to rectal distension, though the role of these 'uninhibited' contractions in causing incontinence was unclear [307;312].

A similar matched case-control study showed that elderly patients with rectal impaction and soiling had impaired rectal sensation (needing a larger volume before feeling the presence of a rectal balloon and the desire to void), lower rectal pressures during rectal distension, and impaired anal and perianal sensation ('rectal dyschezia') [154]. Basal and squeeze pressures were however unimpaired in these patients, and the rectoanal inhibitory response was well-preserved. The authors concluded that overflow FI is primarily due to locally secreted mucus from around an irritative rectal faecal mass leaking out, despite well-preserved anal sphincter integrity.

# SUMMARY OF EVIDENCE ON FAECAL INCONTINENCE AND THE AGEING GUT

- Anorectal function in healthy older persons is characterised by a tendency towards an age-related reduction in internal anal sphincter tone (Level of evidence 2), and a more definite decline in external anal sphincter tone, especially in older women (2)
- An age-related decline in anorectal sensitivity in women has been observed (2), but rectal motility is well-preserved (2)
- Ageing alone however, appears to have little impact on anorectal function until later old age – from the 7th decade upwards in women and even later in men (2)
- Age-related internal anal sphincter dysfunction (reduced anal resting tone) is an important factor in FI in later old age (3)
- Pudendal neuropathy is an age-related phenomenon in women with FI (2), and a likely predisposing factor for FI (2) although the validity of this test is questioned.
- Stool impaction predisposing to overflow is related to rectal dyschezia in frail older adults, a condition characterised by reduced tone, increased compliance and impaired sensation (3)
- Overflow FI is due primarily to mucus secretion from around a rectal faecal bolus, rather than to impaired sphincter function (3)

# RECOMMENDATIONS - PATHOPHYSIOLOGY OF FI IN OLDER PEOPLE

- Overall, the physiological data suggests that FI should not be considered an inevitable consequence of ageing
- Older adults with FI should be evaluated for age-related reduction in internal and external sphincter function
- Older patients with FI require a digital examination to identify rectal stool impaction causing overflow
- Patients who are unaware of the presence of a large faecal bolus in the rectum may have rectal dyschezia, and should be considered at risk of recurrent impaction with overflow

#### 6. CLINICAL CAUSES OF FI IN OLDER PEOPLE

The evidence for this review is poor and the following section is based largely on case series and expert opinion rather than robust empirical data. The causes of FI in older people are often multifactorial. The aim of this section is to categorise the causes of FI in the frail older adult in a clinically meaningful way emphasising the identification of potentially reversible factors. Comprehensive geriatric assessment (assessing medical, functional and psychosocial factors in addition to the bowel) is key to identifying all contributing causes for FI in frail older people.

### **6.1 O**VERFLOW INCONTINENCE SECONDARY TO CONSTI-PATION AND STOOL IMPACTION

Constipation is the most important cause of FI in frail older people, as it is treatable, preventable, and frequently overlooked. In a UK hospital, faecal impaction was a primary diagnosis in 27% of acutely hospitalised geriatric patients admitted over the course of a year [154]. A more recent survey found that faecal loading was present in 57% of older acute hospital inpatients with FI (31). Care home studies show that 52-70% of care home residents have faecal loading underlying FI [25;31]. In a Finnish study, the prevalence of constipation (defined as self-reported difficult evacuation or infrequent bowel movements) was 57% in women and 64% in men living in residential homes, and 79% and 81% respectively in the nursing home setting [223]. The high prevalence of constipation in nursing homes is all the more striking in that 50-74% of long-term care residents use one or more daily laxative [34;223;313-315].

A prospective study in the US looked at baseline characteristics predictive of new-onset constipation in elderly nursing home patients using the Minimum Data Set instrument [316]. Constipation was defined as having two or fewer bowel movements per week or straining on more than 25% of occasions. Seven percent (n=1,291) developed constipation over a 3-month period. Independent predictors were white

race, poor consumption of fluids, pneumonia, Parkinson's disease, allergies, decreased mobility, arthritis, more than five medications, dementia, hypothyroidism and hypertension. The authors postulated that allergies, arthritis, and hypertension were associated primarily because of the constipating effect of drugs used to treat these conditions. Other epidemiological data regarding risk factors for constipation (and their supporting level of evidence) are summarised below.

# SUMMARY OF EVIDENCE ON PREVALENCE AND RISK FACTORS FOR CONSTIPATION IN OLDER PEOPLE

- The prevalence of both self-reported and symptomatic constipation are high in frail older people (Level of evidence 2)
- Women predominate over men in prevalence rates of self-reported constipation and related symptoms among older people, though this gender difference is less marked beyond the age of 80 (2)
- Nursing home residents have a higher prevalence than community-dwelling individuals of all constipation-related symptoms, including infrequent bowel movements, straining, and hard stool (2)
- Faecal loading is often present in older patients with FI in the acute hospital (3) or care home setting (2)
- Advancing age increases the risk for heavy laxative use and symptom-based constipation among nursing home patients (3)
- The prevalence of constipation in nursing homes is high despite heavy laxative usage (2) implying that a) laxative prescribing may be ineffective, and b) non-pharmacological approaches to treatment are under-utilised in this setting.
- Frail older people are at greater risk of faecal impaction and overflow FI and other complications of constipation (2)
- There are numerous potentially modifiable risk factors for symptomatic constipation in frail older people (2). These include:
  - Polypharmacy (2) [223;316-318]
  - Anticholinergic drugs (2) [319] [314]
  - Opiates (2)
  - Iron supplements (3) [320]
  - Calcium channel antagonists (3) [321]
  - Nonsteroidal anti-inflammatory drugs (2) [322;323]
  - Immobility (2) [223;319;324]
  - Institutionalisation (3) [223]
  - Parkinson's disease (2) [316;319;325]
  - Diabetes mellitus (2) [326;327]
  - Dehydration (2) [316] [328]
  - Diet deficient in fibre (3) [318] [329]
  - Dementia (2) [154;307;316]
  - Depression (3) [318;330]

#### **6.2 OTHER CLINICAL CAUSES**

#### a) Functional incontinence

Functional incontinence occurs in individuals who are unable to access the toilet in time due to impairments in mobility, dexterity, vision, intellect / awareness. These patients may even have normal lower gut function. Epidemiological studies in older people (see above) have repeatedly shown that poor mobility is a strong risk factor for FI after adjustment for other variables [8;32;40;53;296]. It is also a primary risk factor for constipation in older people [223;319;324]. While these studies particularly examined immobility as a risk factor, it is likely that problems of impaired sensation and dexterity are also contributory.

### b) Dementia-related incontinence

Some patients with advanced dementia lack cortical control of the defecation process, and so tend to void formed stool once or twice daily following mass peristaltic movements. One study identified dementia as the primary cause of FI in 46% of nursing home residents [25], and the condition has been identified as an independent risk factor in epidemiological studies [32;40;53]. These individuals are very commonly incontinent of urine also [40].

### c) Comorbidity-related incontinence

The following diseases may cause FI, and are more common in older people:

#### 1. STROKE

FI affects 30-56% of individuals acutely after stroke, 11% at 3 months, and 11-22% at 12 months [114;115]. Major FI is four and a half times more prevalent in stroke survivors than the non-stroke population [331]. FI may develop months after acute stroke and can be transient, consistent with constipation with overflow as one possible cause [115;332]. Epidemiological data suggest that FI is associated more with disability-related factors (particularly functional difficulties in using the toilet, and anticholinergic medications) than stroke-related factors (e.g. severity and lesion location) [115;331;333].

#### 2. DIABETES MELLITUS

Prospective data show that diabetes is a risk factor for the development of FI, especially in men [55]. FI may occur in people with diabetic neuropathy affecting the gut through the dual mechanisms of a) bacterial overgrowth resulting from severe prolongation of gut transit causing the characteristic nocturnal diarrhoea [326] and b) multifactorial anorectal dysfunction. Casecontrol studies show that diabetic patients with FI have reduced basal and squeeze pressures, spontaneous relaxation of the internal anal sphincter, reduced rectal compliance, and abnormal rectal sensation [327;334]. Diabetic anorectal dysfunction predisposing to FI can be further exacerbated by acute hyperglycaemia [335].

#### 3. SACRAL CORD DYSFUNCTION

The neuropathophysiology of rectal dyschezia [154] is compatible with diminished parasympathetic outflow from the sacral cord. Rectal dyschezia is characterised by impaired rectal sensation (needing a larger volume before feeling the presence of a rectal balloon and the urge to void), lower rectal pressures during rectal distension, and impaired anal and perianal sensation, and is clinically associated with recurrent rectal impactions and continuous faecal soiling [154]. Common conditions in older persons that could impair sacral cord function are ischaemia and spinal stenosis.

#### 4. ANORECTAL INCONTINENCE

Studies of older people with FI suggest that agerelated internal anal sphincter dysfunction is an important contributing factor [310;312], as it lowers the threshold for balloon (stimulated stool) expulsion [312]. A study of women with anorectal FI compared underlying causes in young (mean age 42) and old (mean age 72) patients - the younger women were more likely to have an anal sphincter defect only, while the aetiology was more multifactorial in the older group, including a significantly higher occurrence of haemorrhoidectomy, diabetes, rectal and vaginal prolapse and pudendal neuropathy [304]. Later-life FI is linked to childbearing via structural damage to the external anal sphincter, and pelvic musculature [336]. Uterovaginal prolapse and rectocoele have been shown to be a predominant independent risk factor for FI in women attending urogynaecology clinics [337;338]. Rectal prolapse is also a condition associated with FI which occurs more commonly in older adults [302].

### 5. LOOSE STOOLS

Loose stool increases the risk of incontinence in normally continent older adults by overwhelming a functional but age-compromised sphincter mechanism. Frail older individuals are particularly susceptible to bowel leakage in the context of loose stools [25;32]. Forty-four percent of cases of FI in a prospective nursing home study were related primarily to acute diarrhoea [32].

# POTENTIALLY REVERSIBLE CAUSES OF LOOSE STOOLS IN FRAIL OLDER ADULTS ARE:

#### i) Excessive use of laxatives

One-third of community-dwelling people aged 65 and over regularly take laxatives, far exceeding the prevalence of constipation in this population [339]. In the nursing home, laxative use (in particular 'Codanthramer' a Docusate-stimulant combination agent) has been linked to FI [34].

### ii) Drug side-effects e.g.

Proton-pump inhibitors, selective serotonin re-uptake inhibitors, magnesium-containing antacids, choline-sterase inhibitors.

#### iii) Lactose intolerance

An age- and ethnicity-related phenomenon - Goulding et al. found a lactose malabsorption rate of 15% in healthy women aged 40-59 years as compared with 50% in those aged 60-79 [340].

### iv) Antibiotic-related diarrhoea

Among hospitalised patients, age, female gender and nursing home residency significantly increases the risk for Clostridium difficile-associated diarrhoea associated with antibiotic use [341]. The diarrhoea also takes longer to resolve following treatment of C.Difficile in frailer older patients [341]. In a case-control study of hospitalised patients, Tal et al found FI to be a risk factor for recurrent C. Difficile (53% of patients studied), in addition to prolonged fever during initial infective episode, and H2-antagonist treatment [342].

#### v) Cancer

Loose stools should also be considered a possible indicator of colorectal cancer, and all patients with this symptom should be screened clinically for neoplastic and systemic illness. A study comparing underlying aetiologies in younger and older (age >70) men with FI found colon cancer to be significantly more common in the older group [343]. Where a change in bowel in habit is identified, colonoscopy or other imaging should be considered to rule out a colorectal cancer.

# SUMMARY OF EVIDENCE ON CAUSES OF FI IN FRAIL OLDER PEOPLE

- Overflow incontinence secondary to stool impaction is a primary cause of FI in frail older people (Level of evidence 2).
- There are multiple potentially modifiable causes of constipation in older people (2), which are likely also to be risk factors for overflow FI.
- Frail older people (particularly those with neurological disability) may be incontinent because they are unable to use the toilet for physical functional reasons (2).
- Dementia is an important cause of FI in frail older people (2).
- FI is a common complication following stroke (2), but factors other than stroke status itself are contributory causes for incontinence in stroke survivors (2).
- Older people with diabetes (particularly if associated with autonomic neuropathy) are at risk of FI secondary of anal sphincter dysfunction (2)
- Loose stools predispose older people to soiling (1), and have numerous potentially reversible causes. Loose stools may however be indicative of underlying colonic disease such as colorectal cancer or colitis (2).

### RECOMMENDATIONS - IDENTIFYING REVER-SIBLE CAUSES OF FI IN OLDER PEOPLE

- The following potentially modifiable risk factors for FI should be carefully identified in all cases:
- 1. Constipation causing impaction and overflow
- 2. Loose stool
- 3. Impaired mobility
- 4. Difficulty with using the toilet (acute or chronic)
- Delirium (as a reversible cause of cognitive impairment)
- 6. Anal sphincter weakness
- 7. Impaired vision and/or manual dexterity
- 8. Medications
- All older people with FI should be assessed for reversible causes, regardless of their institutionalisation status
- All frail older people with overflow FI should be assessed for potentially modifiable causes of constipation
- The symptom of loose stools should be elicited in all older people with any degree of FI, and underlying causes rigorously sought
- Evaluate nursing home administrative factors such as poor resident:staff ratios as a reversible cause of FI
- Colorectal carcinoma may present with the symptom of loose stools, and this diagnosis should be considered where a change in bowel habit, or other indicators (rectal bleeding, abdominal pain, weight loss, anaemia) are present.

# 7. ASSESSMENT AND DIAGNOSIS OF FI IN OLDER ADULTS

The algorithm (Figure 2) summarises the clinical evaluation and management of FI in this population. The emphasis is on a structured comprehensive clinical approach, which can be undertaken by doctor or nurse specialist. In most cases the clinical approach will provide sufficient diagnostic information on which to base a feasible management plan without resorting to more specialised tests and assessments. The clinical usefulness of anorectal function tests and defecography in assessing FI in older people is limited by a) lack of normative data from healthy elderly, b) few standardised test protocols, and c) poor association between detected abnormalities and symptoms [344-346].

There is however much room for improvement in this clinical area; current surveys indicate a lack of thoroughness by doctors and nurses in assessing FI in older people in all settings (community, acute

hospital, and nursing home), with failure to obtain an accurate symptom history or to perform rectal examinations [35;347]. A national UK audit of older patients with FI in primary care, acute hospital, and care home settings showed that only 50% of individuals within each setting had a history taken, and only 22-33% had a documented basic examination (history and rectal) [35]. Cause(s) for FI was documented in 27-49%, the 27% being in the acute hospital sector.

### a) Results of search

Self-report of bowel symptoms relating to FI have been shown to be reliable and reproducible in older cohorts, including those in long-term care [348-350]. A study of women aged 65 years and older who were hospitalised with fractured neck of femur showed that proxy responses (proxy nominated by patient) for questions concerning FI has also been shown to concord well with index responses given by the patients [351].

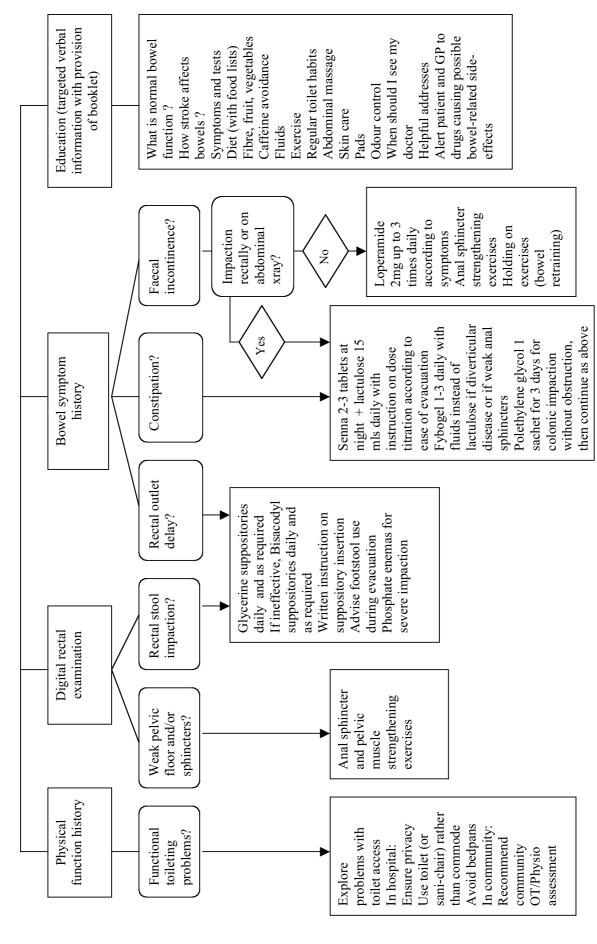
Documentation of the type of incontinence is diagnostically very important [297]. There is a strong association between loose stool and FI in older people. Urgency is more associated with diarrhoeal disease (e.g. infective). Constant passive leakage of loose stool or stool-stained mucus is characteristic of overflow around an impaction, while patients with anal sphincter dysfunction tend to leak small amounts of stool. A symptoms study in adults with FI showed that where external anal sphincter weakness predominates the patient often reported urgency prior to leaking (urge FI), while those with internal sphincter dysfunction tended to have passive leakage of stool (passive FI) [352]. Patients with dementia-related incontinence often pass complete bowel movements, especially after meals in response to the gastrocolic reflex.

Assessment of FI must include an assessment for constipation. Based on international consensus, constipation is defined according to self-report of a combination of at least two of the following symptoms: usually 2 or less bowel movements per week over at least 3 months, hard stool, straining on more than 25% of evacluations and, feeling of incomplete evacuation [322;353].

It is important to identify the constipation subtype of rectal outlet delay in older people, as it affects 21% of community-dwellers aged 65 and over [322], and may lead to rectal impaction and FI. It is defined as: feeling of anal blockage during evacuation and prolonged defaecation (more than 10 minutes) and/or need for manual evacuation. Constipated older people tend to suffer primarily from difficulties with rectal evacuation and symptoms of straining and hard stool rather than from reduction in stool frequency [354].

Objectively however, the clinical definition of constipation relies on evidence of excessive stool

Figure 2 : Multifactorial assessment and intervention protocol



retention in the rectum and/or colon. Such objective assessment is particularly important in frail older people who may:

- be unable to report bowel-related symptoms due to communication or cognitive difficulties
- have regular bowel movements despite having rectal or colonic stool impaction
- have impaired rectal sensation and rectal dyschezia and so be unaware of symptoms associated with a large faecal bolus in the rectum [154].
- have non-specific signs or symptoms (such as delirium, leucocytosis, anorexia, functional decline) in association with severe faecal impaction

Digital examination can reasonably assess anal sphincter tone in the clinical setting. Easy finger insertion with gaping of the anus on finger removal indicates poor internal sphincter tone, while reduced squeeze pressure around the finger when asking the patient to 'squeeze and pull up' suggests external sphincter weakness. Digital assessment of squeeze and basal tone has been shown to be as sensitive and specific as manometry in discriminating sphincter function between continent and incontinent patients aged over 50 [355].

A digital rectal examination is essential for identifying stool impaction, although an empty rectum does not exclude the diagnosis of constipation [324]. Incontinent patients without evidence of rectal stool impaction should ideally undergo a *plain* abdominal radiograph in order to a) establish or rule out the diagnosis of overflow, b) measure the extent and severity of faecal loading, c) evaluate the degree of bowel obstruction secondary to impaction, and d) rule out acute complications of impaction such as sigmoid volvulus and stercoral perforation [356;357].

Certain symptoms associated with FI (abdominal pain, rectal bleeding, recent change in bowel habit, weight loss, anaemia) should prompt further consideration of underlying neoplasm [358]. Colorectal cancer is associated with both constipation and use of laxatives, though this risk association is likely to be confounded by the influence of underlying habits [359]. Chronic constipation alone is generally not considered an appropriate indication for lower endoscopy [360]. However, as the prevalence of colorectal cancer increases with age, the index of suspicion should be higher in older adults [361]. It should be noted that bowel preparation for lower endsocopy or barium enema may itself cause FI. Furthermore, a prospective study of 649 patients showed that dementia and stroke were independent predictors of inadequate colonic preparation [362].

Evaluation of toilet access should be multidisciplinary, and include a broad functional assessment (e.g. Barthel Index), mobility test (e.g. 'up and go' test), visual acuity test (count fingers), upper limb dexterity

assessment (undoing buttons), and cognitive measure (e.g. Abbreviated Mental Test Score). An even more practical assessment is to watch someone transfer and manage clothing.

Appropriateness of the commode design for the individual concerned should be considered (e.g. trunk support, adaptability, mobility, foot support etc.) [35;363] (see Chapter 20). For community patients, the health care provider should be aware of the physical layout of the patient's home, and in particular bathroom details (location, distance from main living area, width of doorway for accommodating walking aids, presence of grab rails or raised toilet seat). Low lighting levels, high degree of clutter and hard to manage clothing may also be relevant.

FI is a primary independent risk factor for pressure sores in frail older people [296;364], so evaluation of skin integrity (with pressure ulcer risk assessment) is important. Pelvic examination is also relevant in view of the association between urogenital prolapse (particularly rectocoele) and FI in older women [337;338;365].

Bowel-specific quality of life scores have not specifically validated in the frail older population.

A UK RCT evaluated a multi-component assessment and treatment intervention for constipation and/or FI in frail older stroke patients, using an approach summarised in Figure 1 [144]. The assessment was undertaken in patients' homes, outpatient clinics and hospital wards by a non-specialist nurse who had received simple training in bowel care. The structured assessment showed that the majority of patients had more than one bowel problem. Forty-eight (66%) had constipation, 41 (56%) rectal outlet delay and 16 (22%) rectal impaction. Twenty-two (30%) reported FI, of whom 12 had constipation with overflow. Thirty (41%) had reduced internal sphincter tone, 40 (55%) weak external sphincter tone, and 27 (37%) excessive pelvic floor descent. Thirty-four (47%) had difficulties with toilet access.

# SUMMARY OF EVIDENCE ON ASSESSMENT OF FI IN FRAIL OLDER PEOPLE

- Evidence shows that current assessment of FI in frail older adults in routine healthcare settings is suboptimal (Level of evidence 2)
- Structured assessment of frail older people with bowel problems are likely to demonstrate multifactorial causes for FI and constipation (2)
- Structured nurse-led assessment is a feasible approach in various healthcare settings (2)
- Documentation of the type of incontinence and related bowel symptoms by self-report, proxy report or observation is feasible (2) and diagnostically important (2)

- Constipation can be characterised clinically according to standardised symptom-based definitions in patients able to give a history (2)
- Rectal examination can reveal faecal impaction in patients with overflow (2)
- Digital assessment of sphincter tone can effectively estimate anal sphincter function in assessment of adults with FI (3)
- Anorectal function tests and defecography show poor association between abnormal findings and symptoms in older people with FI (3)
- FI-related quality of life measures have not been specifically validated in frail older persons

### RECOMMENDATIONS ON ASSESSMENT OF FI IN FRAIL OLDER PEOPLE (ALL GRADE C)

- The emphasis in older people is on a structured clinical approach to identify multiple causes of FI, including cognitive and functional assessments.
   A standardised assessment of FI in frail older people is required to ensure proper identification of underlying causes. These assessments can feasibly be undertaken by nurses or doctors both in institutions, and in patients homes
- Physicians should prioritise assessment of FI of frail older people (especially in nursing homes). Nurses may be more aware of the problem, but should be specifically trained to look for underlying causes. A feasible practice-based approach is targeted training of non-specialist nurses providing routine care
- Hospital wards, primary care practices, and longterm care institutions internationally should have appropriate multidisciplinary protocols of casefinding and risk assessment
- Carers should be trained to routinely perform rectal examinations to evaluate stool retention
- A careful bowel symptom history (FI and constipation) and assessment of bowel pattern should form part of the assessment
- Digital assessment of sphincter tone should be performed in all older people with FI
- Ano-rectal physiology tests are not generally required in the frail elderly as they do not tend to alter the clinical examination conclusions or the management plan
- In the initial assessment of an older patient with FI, those without evidence of rectal stool impaction should undergo a plain abdominal radiograph to rule out higher impaction and other problems

- FI can be the presenting symptom of colorectal cancer and may require investigation by colonoscopy or barium enema. Bowel preparation should be carefully planned in frail older people to avoid causing acute diarrhoea, and/or inadequate clear-out
- Pelvic examination should form part of the assessment for FI, in particular to identify prolapse and rectocoele
- The impact of FI on patient and carer quality of life and usual activities should be qualitatively assessed, as well as patient attitude to their condition
- Evaluation of ability to access and use the toilet should be multidisciplinary

#### 8. TREATMENT OF FI IN OLDER ADULTS

### a) Quality of data

There are very few published trials of treatment of FI in older people, and no trials on prevention of FI. The studies reviewed had small numbers [25;144;244], problematic methodology (e.g. not applying intent-to-treat analysis, unclear reporting of drop-outs) [25;32;225], and were all non-blinded. Randomised controlled trials examining effective laxative treatment for constipation in older adults generally lack power, and are therefore unlikely to detect effects of treatment [366]. Issues of surgery, biofeedback, containment (pads and anal plugs) and skin care are covered elsewhere in the chapter.

# b) Treatment of faecal impaction and overflow FI in older people

(See also section VI.3.c). One trial evaluated a therapeutic intervention in 52 nursing home residents with FI, based on treatment recommendations to general practitioners [25]. Patients with rectal impaction and continuous faecal soiling were classed as having overflow and recommended treatment with enemas until no further response followed by lactulose complete resolution of incontinence was achieved in 94% of those in whom full treatment compliance could be obtained. Compliance with the recommended treatment was obtained in 67% of patients.

A French nursing home study of 206 frail elderly nursing home residents found that treatment of constipation was only effective in improving overflow FI (incontinence at least once weekly associated with impaired rectal emptying) when long-lasting and complete rectal emptying (monitored by weekly rectal examinations) was achieved using daily lactulose plus daily suppositories, plus weekly tap-water enemas. The number of FI episodes was reduced by 35% and staff workload (based on soiled laundry counts) fell by 42% in those with effective bowel clearance. However,

complete rectal emptying was only achieved in 40% of people receiving this regimen.

Over half of nursing home residents take laxatives at least once daily, prompting speculation that non-pharmacological approaches to optimise management of constipation may be under-utilised in this setting [34].

A 1997 a systematic review of laxative treatment in elderly persons found that the few published randomized controlled trials were potentially flawed due to small numbers and other methodologic concerns [366]. In the 10 years since that review, there has been little rigorous research specific to the older population. The following conclusions are drawn from the recent meta-analytical reviews [323;366] of efficacy of laxatives in treating chronic constipation in adults (it should be noted that none of these studies had relief of constipation-related FI as an outcome measure):

- Availability of published evidence is poor for many commonly used agents including senna, magnesium hydroxide, bisacodyl and stool softeners
- In trials conducted in older people, significant improvements in bowel movement frequency were observed with a stimulant laxative (cascara) (Level of evidence 3) and with lactulose (2), while psyllium (2) and lactulose (2) were individually reported to improve stool consistency and related symptoms in placebo-controlled trials
- Level (1) evidence supports the use of polyethylene glycol (PEG) in adults
- Level (2) evidence supports the use of lactulose and psyllium in adults
- None of the currently available trials include quality of life outcomes
- In trials conducted in older adults (>55 years) there is little evidence of differences in effectiveness between categories of laxatives
- A stepped approach to laxative treatment in older people is justified, starting with cheaper laxatives before proceeding to more expensive alternatives
- Note that none of these studies had relief of constipation-related FI as an outcome measure.

Polyethylene glycol (PEG) is a potent hyper-osmolar laxative. An RCT evaluating its use in treatment of faecal impaction (in combination with daily enemas) in elderly nursing home residents, showed greater efficacy than lactulose, without the dehydration or haemodynamic side-effects. Another RCT of adults (aged 17-88) with fecal loading on Xray or rectal examination, and bowels not open for 3-5 days showed that 1L (or 8 sachets) a day of PEG plus electrolytes (Movicol®) for 3 days resolved impaction in 89% of patients, with few adverse effects. The current

evidence base suggests that the role of PEG in older people is for acute disimpaction (ensuring that easy toilet access is guaranteed), and for regular use as a laxative only in high risk people whose constipation has proved resistant to milder and cheaper alternatives (e.g. senna).

Enemas and suppositories have a role in both acute disimpaction, and in preventing recurrent impactions in susceptible patients [25;225]. They induce evacuation as a response to colonic distension. Frail elderly patients with recurrent episodes of overflow FI despite regular laxative and suppository use can benefit from weekly enemas. Regular use of phosphate enemas should be avoided in patients with renal impairment as dangerous hyperphosphatemia may occur [367]. Tap water enemas are the safest type for regular use, although they take more nursing administration time than phosphate enemas, and are not available in certain countries. Soapsuds enemas should never be administered to older patients. Arachis oil retention enemas are particularly useful in loosening colonic impactions. In patients who have a firm and large rectal impaction, manual evacuation should be performed before inserting enemas or suppositories, using local anesthetic gel if needed to reduce discomfort.

The value of treating constipation in preventing FI in frail older people has not yet been reported.

### c) Treatment of dementia-related FI

Prompted toileting programmes significantly increased the number of continent bowel movements in an uncontrolled study of elderly nursing home residents in the US with dementia-related incontinence over a period of a few weeks, but no impact was seen on frequency of FI [368]. A further nursing home RCT showed that prompted toileting in frail residents significantly reduced the frequency of FI and increased the rate of appropriate toilet use in the intervention group, but did not overall impact the primary outcome measure of pressure ulcers [132].

A bowel programme in 25 nursing home residents with dementia-related FI consisting of daily codeine phosphate and twice weekly enemas achieved continence in 75% of those fully treated [25].

### d) Treatment of anorectal FI in older adults

Biofeedback treatment for FI in older people resulted in a 75% reduction in incontinent episodes short-term in one small study of a highly selected group of patients with no cognitive impairment, good motivation and intact anorectal sensation [244]. Pelvic floor retraining is effective treatment in older women with urinary incontinence [369], and there is no evidence to suggest that frail older people without significant cognitive problems are any less able to adhere to such programmes.

There is no data on the use of Loperamide in frail older people. Expert opinion suggests that it should be used only with extreme caution and monitoring for impaction in this patient group.

### e) Treatment of loose stools in frail older people

For prevention of C. Difficile in frail older hospital inpatients (and consequent loose stool with FI in those with weak sphincters), strict antibiotic policies and hand washing by all staff before and after contact with patients have been shown to reduce the risk of infectious disease. Preliminary trials suggest that use of probiotic yogurt drinks started simultaneously with antibiotic prescribing and continued for 2 weeks after course completion can reduce antibiotic-related diarrhoea and C.Difficile incidence.

# f) Multi-component treatment of FI in frail older people

While a multidimensional approach to FI treatment would clearly be indicated in view of the multifactorial causation in older people, there are few published studies of multicomponent interventions. A UK RCT in frail older stroke survivors with constipation and/or FI evaluated a one-off assessment leading to targeted patient/carer education with a booklet, and treatment recommendations to the routine health care provider [144]. At one year follow-up the intervention group (as compared with controls receiving usual care) were more likely to be altering their diet and fluid intake to control their bowels, and at 6 months had significantly more 'normal' defecations. This type of evaluation does not define any specific action that had a particular beneficial effect, but does test a multicomponent approach that non-specialist doctors and nurses could feasibly apply in various settings (see Figure 1).

A US study specifically looked at self-care practices among 242 home-dwelling older people with FI [147]. Most commonly used practices were dietary change, wearing pads, and limiting activity.

A UK study asked frail older patients with FI about privacy during defecation [370]. Adequate privacy was reported by only 23% of nursing home residents, and 50% of hospital inpatients. Lack of privacy, particularly in dependent older people in institutions, is a major care issue.

# SUMMARY OF EVIDENCE ON THE TREATMENT OF FI IN FRAIL OLDER PEOPLE

- Current evidence shows that stimulant laxatives, osmolar laxatives (PEG and lactulose), suppositories and enemas can be effective in treating faecal impaction in older people at risk of overflow (Level of evidence 2).
- Complete rectal clearance is required to reduce overflow FI (2), but may be hard to achieve in frail older patients (2). Weekly digital rectal examination is helpful in monitoring the effectiveness of a bowel clearance programme (2).

- Structured approaches to bowel care (including prompted toileting) can reduce the frequency of FI in the nursing home setting (2)
- Older people with FI may benefit from biofeedback and sphincter strengthening exercises if they are able to comply (3)
- Loperamide can reduce frequency of FI, particularly when associated with loose stool (once infection and other causes have been excluded) but should be used with caution (2)
- Changes in antibiotic prescribing and use of probiotics in antibiotic users can reduce the risk of C.Difficile and antibiotic related diarrhoea in older people (2)
- Multicomponent structured nurse-led assessment and intervention can improve bowel symptoms and alter bowel-related habits in older stroke patients (2)
- Self-care practices are prevalent in older people with FI, especially in those with more severe FI (3)
- Dependent older people with FI in care homes and hospital often lack privacy during defecation (3)

# RECOMMENDATIONS - TREATMENT OF FI IN FRAIL OLDER PEOPLE (ALL GRADE C)

- Patients identified as having constipation with overflow should have effective bowel clearance (using a combination of laxatives and enemas), and then maintenance therapy with stimulant or osmotic laxatives
- Regular digital rectal examinations should be performed to assess the effectiveness of a bowel clearance programme in frail older people with overflow
- Suppositories are useful in treating rectal outlet delay and preventing recurrent rectal impaction with regular use
- Loperamide is a useful treatment in anorectal FI, in the absence of constipation, but should be used with caution
- Causes of loose stool must be identified and treated. In the case of C. Difficile, appropriate preventive measures should be taken, particularly in frail older people who are at risk of recurrent infection
- All frail older people with FI should have structured multidisciplinary assessment and treatment of their bowel problem. Figure 1 summarises a structured approach that can be used in multiple heath care settings.

- Patient and carer education (using verbal and written materials) should be undertaken to promote self-efficacy and other coping mechanisms, and where appropriate selfmanagement (e.g. reducing risk of constipation and impaction through dietary and lifestyle measures, advice on how to take loperamide). Advice on skin care, odour control, and continence aids is also important.
- Privacy and dignity of care during defecation should be afforded to all older people in institutionalised settings. Particular attention should be paid to this in patients with FI, as privacy may be relatively overlooked in their care.
- Greater emphasis needs to be placed on systematic and effective management of FI in older people backed up by sound communications between all health care providers, especially in the nursing home and acute hospital setting.
- Education of health care providers with regards to heightening awareness of the problem plus methods of identification, assessment and management of FI in older people should be broad-ranging and include geriatricians, general practitioners, hospital physicians, hospital, community, general practice and long-term care nurses, and related disciplines (physiotherapists, occupational therapists, dieticians, pharmacists).
- Cyclical national audit with provider accountability, of current practice in managing FI in older people is needed to lay the ground-work for standardized care, and provide a culture of continuous quality improvement. Such audit tools should be developed using standardized consensus methodologies (35). Incentives to providers could be benchmarking their practice against national averages, opportunities to share successful practice change strategies, and professional validation linked to good practice.

# 8. AREAS FOR FURTHER RESEARCH ON FI IN FRAIL OLDER PEOPLE

- Trials of laxative and nonpharmacological treatment and prevention of faecal impaction and overflow are needed to optimise standards of prescribing and care.
- Multicomponent interventions to treat FI in frail older people should be evaluated in applied research projects to assess effective ways of delivering this type of intervention within routine health care settings.
- Multidisciplinary study assessing the feasibility and efficacy of a step-wise approach to the management of dementia-related FI in nursing home residents (prompted toileting in those with mild to

- moderate dementia, scheduled toileting plus suppositories next step, and a bowel programme of controlled evacuation in those with persistent incontinence) would provide useful evidence.
- The challenges of undertaking RCT's in frail older people are summarised in the chapter on urinary incontinence in frail elderly (Committee 11). In particular, it is important to balance feasibility and practicality versus high strength intervention, i.e. a team of specialist continence nurses in nursing homes are likely to have an impact, but at what cost, and what carry-over will there be when they are gone? Other methodologies (e.g. pre-post with multivariate case-mix adjustment) should also be considered.
- Evaluation of case-finding methods for FI in different settings including the fundamentals of staff education, screening protocols, patient's educational information would be very informative.
- Testing the feasibility of providing an integrative approach to assessment of FI in the frail older person, including a range of health and social care providers and different health care settings (acute, intermediate or sub-acute, long-term care, and community) would be relevant to national implementation of bowel care improvement programmes.
- Examination of the variability of FI rates between nursing homes within single nation states, (taking into consideration case-mix) will highlight problems areas both organizationally and clinically. Nursing home administrative factors such as resident:nurse staff ratios should be evaluated as a contributing factor to FI.
- Further epidemiological studies are required to document causes of FI in frail older people in different health care settings. Such studies should include evaluation of unmet need for patients and carers.
- Evaluation of aetiologies, and in particular the pathophysiological basis for high prevalence of FI in older men. Evaluation of potentially preventable causes of loose stools in institutionalized older people, and impact of their treatment on FI.
- Nurse-led initiatives are needed to develop care pathways for assessing of bowel problems in frail older people with a view to establishing integrated service delivery.
- Examine the research question, 'Do educational interventions by health care providers to informal carers of home-dwelling older people with FI reduce carer burden and improve quality of life for patient and carer?'

## X. CONCLUSIONS, RECOMMENDATIONS AND ALGORITHM

### 1. PREVENTION

### a) Primary prevention:

- Public health measures to prevent diarrhoeal diseases (Grade of recommendation B/C)
- Treat reversible causes of diarrhoea (C)
- Obstetric: no convincing evidence of role for preventive caesarean section; avoid midline episiotomy; restrictive rather than liberal episiotomy protocols (A)
- Discourage the use of internal anal sphincter division for treatment of anal fissure and haemorrhoids (A)

### b) Secondary prevention:

- Active case finding/screening in high risk groups
   (C)
- Proactive bowel management in high risk groups (eg neurological) (C)
- Optimise stool consistency in people with loose stools (all ages); hard stools (children and older populations) (B)
- Treat obesity? (D)
- Consider medication alternatives in patients with FI & medication-induced diarrhoea (C)
- Alert patients to risk of FI following colorectal surgery (C)

# c) Recommendations for research on prevention

- Longitudinal studies to map natural history, especially in women with obstetric risk factors
- Prevention studies in childbearing women and other high risk groups
- Colorectal surgery and radiotherapy techniques
- Bowel management strategies in high risk groups (e.g. neurological)
- · Understanding mechanisms of FI in men
- Frail: community prevention/screening/early treatment to prevent NH admission
- Measures to prevent/reduce FI in nursing homes (functional FI, staffing etc)

#### 2. EDUCATION AND LIFESTYLE

- Medication side effects: consider alternatives if causing diarrhoea (C)
- Toilet access for people with disabilities (C)

- Education
  - of patient (B/C)
  - of carer (C)
- Complementary therapies: no evidence (D)

There is insufficient evidence to recommend or discourage most lifestyle modifications either for the prevention or treatment of FI. Based on the consensus of experts (**Level 3 evidence**) the committee recommends patient education about the causes of FI and a systematic effort to remove barriers to effective toileting, are both interventions that are likely to be beneficial. They may be provided at relatively low cost and they involve no significant risk to the patient.

# Recommendations for research on education and lifestyle

- Based on encouraging preliminary reports that patient education, combined with conservative medical management, can reduce the frequency of FI, we recommend further research. An RCT may not be possible due to the challenge of identifying a suitable control for expectancy and attention. A study which demonstrates a sustained benefit from a limited educational intervention (provided to patients or caregivers), would provide useful guidance for clinical management.
- Further investigation of the benefits for FI of weight reduction, especially in moderately obese patients without bariatric surgery.
- Exercise programmes, when incorporated into a multi-component intervention, have produced promising preliminary results and should be tested further. Such trials should differentiate between constipation-associated FI and diarrhoea-associated FI as exercise may be more beneficial to the former group.
- Evaluation of the incremental or additive value of different lifestyle interventions in the patient pathway.

Research on the contribution of complementary therapies.

#### 3. DIET AND FLUIDS

- Soluble dietary fibre is recommended for the management of FI associated with loose stool. This recommendation is made despite inconsistent results between two RCTs because the methodology for the positive study was significantly better than that of the other study. (Evidence level 1. Recommendation Grade B).
- Dietary fibre is not recommended as an adjuvant to antimotility medication for managing AI when stools are not loose or liquid. (Evidence level 2 Grade B).
- Patients should be asked about dietary restrictions and meal skipping.

## Recommendations for research on diet and fluids

Further studies on the effect of dietary fibre and other diet modifications on FI are encouraged to build a greater body of evidence. Because dietary fibres differ in their chemical composition and properties, future studies are recommended to determine the optimal type and amount of fibre to use for FI. Whether a dietary intervention can augment other behavioural interventions, such as pelvic floor muscle exercises or bowel training, needs further study.

- Role of fibre and fluid in constipation/impaction related FI
- Effect of diet and eating pattern as a management strategy for FI
- Role of caffeine restriction in the treatment of FI and AI

There are several recommendations for methodological rigour in future studies. Theory-based, adequately powered, controlled trials are sought. Studies should control for variability in an individual's baseline severity of incontinence and any adjuvant therapies. Monitoring adherence to the dietary intervention is recommended. A common set of outcome measures that includes tolerance to diet interventions is recommended. Reporting outcomes of FI in addition to those of AI (which incorporates flatus incontinence) is recommended.

### 4. BOWEL TRAINING

- Attempt to establish a bowel routine (C)
- Urgency resistance training possibly useful for urgency (D: need for research)
- No evidence on behaviour modification methods (D: need for research)
- Digital stimulation and manual evacuation useful in neurological patients (C)
- Rectal irrigation is useful in SCI (B) and has potential in other patients with FI (D)

# Recommendations for research on bowel training

Research is needed in all areas.

Combination studies with urinary incontinence are recommended.

#### 5. DRUG TREATMENT OF FI

- Treat FI with diarrhoea with anti-diarrhoeal medication (C): titrate the dose to individual response (C)
- We are unable to recommend sphincter function modifying drugs (D)
- · Use oral or rectal laxatives/evacuants to treat

- constipation-associated FI (C): no evidence on the most effective agent. Need to confirm impaction is resolved (C)
- For constipation-associated FI, there is level 2
  evidence suggesting that daily or more frequent oral
  laxative regimens may be effective for the treatment
  of constipation-associated FI in nursing home
  residents and children, but there are conflicting
  data.

# Drug treatment of FI: recommendations for research

- Additional, well-designed studies are needed to validate the common clinical practice of using laxatives to treat constipation-associated FI.
- There is a need for further research on preparations, doses and combination therapies for all types of FI and all patient subgroups.

# 6. BIOFEEDBACK AND/OR ANAL SPHINCTER / PELVIC FLOOR MUSCLE TRAINING

Because recent RCTs have raised questions as to whether biofeedback provides a specific benefit relative to education and good clinical management despite a large body of uncontrolled studies supporting its efficacy, the consensus of the committee is that it is possibly effective but currently unproven. This reinforces the case for using maximal education, lifestyle and dietary interventions before PFMT or BFB, as recommended by recent national guidelines in the UK.

- PFM exercises are recommended as an early intervention in the treatment of FI as part of a conservative management bundle of interventions, based upon low cost and morbidity and weak evidence suggesting efficacy (C).
- The use of biofeedback as a treatment for FI is recommended after other behavioural and medical management has been tried if inadequate symptom relief is obtained, given the numerous positive outcomes from uncontrolled trials, limitations in the current RCTs and low morbidity associated with its application (C).

#### Recommendations for research

There is a need to conduct further RCTs to determine whether specific biofeedback and pelvic floor muscle exercise protocols can alter physiological parameters of ano-rectal function with concomitant changes in bowel control.

- Clear description of modalities and evaluation of different elements of BFB
- · Adherence monitoring
- Standardisation of outcome measures
- Long term follow up
- Robust patient-focused outcome measures

- Understanding of physiological effect and relationship to symptom change
- Work on clinically meaningful improvement and distinguishing cure from improvement rates
- The exploration of possible synergies between urinary and faecal incontinence interventions and evaluations should be considered in study designs

#### 7. ELECTRICAL STIMULATION FOR FI

Based on currently available evidence it is not possible to recommended electrical stimulation for FI.

# Recommendations for research on electrical stimulation for FI

- Randomised controlled trials with adequate sample sizes are necessary to investigate all aspects of the effectiveness of ES in FI.
- The effect of electrical stimulation in changing consciousness of the pelvic floor is one of the interesting future areas for research.
- When planning future research basic knowledge of electrical stimulation parameters and their likely physiological effects is essential.

#### 8. FI IN FRAIL OLDER PEOPLE

Bowel continence status should be established by direct questioning and/or direct observation in:

- all nursing and residential home residents
- · hospital inpatients aged 65 and over
- people aged 80 and beyond living at home
- · older adults with impaired mobility
- · older adults with impaired cognition
- · older adults with neurological disease
- · older adults with chronic disease

Appropriate investigation and active treatment is needed in all older adults with FI (see Chapter for details).

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