Status	SH organisation	Order no.	Document	Page No.	Line no.	Comments	Responses
SH	3M Health Care Limited	1	Full	General		The literature search strategy seems to be flawed and has omitted recent and important published evidence concerning skin care in the incontinent patient. This has led to inappropriate advice in the guideline regarding care of the skin of incontinent patients. 3M Health Care submitted several pieces of evidence to this project, one of which Zehrer et al was requested as a full paper and is reviewed in the draft Guideline. Advice was given by the reviewers not to submit data published in peer reviewed papers since these articles would be found in the literature search and where appropriate included in the Guideline. However two recent and strong publications were not included in the review of skin care of the incontinent patient. I have referenced these at the bottom of this comments document. It is evident from checking both the included and excluded clinical papers that the process of searching for the clinical evidence in skin care in the incontinent patient was flawed. The fundamental term "skin care" was not included as a search term. Critically only double and not "doubly" was included in the search terms which exacerbated the narrowness of the identification of papers in this area, many of which are written by authors whose	If papers contained faecal incontinence terms they would be picked up by the searches. Our inclusion criteria was that 50% of the study population at least had to present with faecal incontinence. Therefore studies primarily about skin care were excluded. Regarding 'doubly': thank you for pointing this out; we did omit this. We have now re-run searches to check what we missed; no relevant papers were found by adding the term 'doubly'.

Key: SH = stakeholder

Status	SH organisation	Order no.	Document	Page No.	Line no.	Comments	Responses
						background is in elderly skin care, dermatology and wound care/prevention.	
SH	3M Health Care Limited	2	Full	103	1 and 2	The section question asks "What are the most effective skin care products to manage faecal incontinence?" This is an inappropriate question since skin care has no activity in management of faecal incontinence per se. It can only ameliorate the symptoms caused by the caustic fluids that contact the perineal/sacral skin of the incontinent patient.	Thank you, the wording has now been amended.
SH	3M Health Care Limited	3	Full	103/104		The following studies should be included in the review References: 1. Bale S, Tebble N, Jones V, Price P. The impact of implementing a new skin care protocol in nursing homes. J Tissue Viability 14 (2) April 2004 44-50 2. Baatenburg de Jong H, Admiraal H. Comparing cost per use of 3M Cavilon No Sting Barrier Film with zinc oxide oil in incontinent patients. J Wound Care 2004 13 (9) 398-400 These articles are referenced in all the following comment sections	Bale et al, 2004 was wrongly excluded, thank you for bringing it to our attention. This study has been reviewed and is now included in the guideline. Baatenburg de Jong 2004 has been excluded because the group did not specifically have faecal incontinence, nor was the incidence of faecal incontinence reported.
SH	3M Health Care Limited	4	Full	103	24 to 36	An important before-after study1 including a total of 164 residents of 6 UK nursing homes is omitted from the review, "Clinical Evidence" relating to skin care in the incontinent patient. This study compared the condition of the perianal skin before and three months after adoption training of a	This was wrongly excluded, thank you for bringing it to our attention. This study has been reviewed and is now included in the guideline.

Key: SH = stakeholder

Status	SH organisation	Order no.	Document	Page No.	Line no.	Comments	Responses
						universal skin care protocol that utilised a durable barrier cream (intact skin) or a non sting barrier film (broken skin). 65% of residents included were doubly incontinent. The presence of grade 1 pressure ulcers was significantly reduced (p=0.042) and also the presence of incontinence dermatitis was significantly reduced (p=0.021) in the post intervention survey. We suggest adding the following text: "Adoption and training to a sacral skin care protocol including a durable barrier cream and a non sting barrier film, significantly reduced prevalence of grade 1 pressure ulcers and dermatitis due to incontinence in a UK nursing home population after 3 months intervention."	
SH	3M Health Care Limited	5	Full	103	24 to 36	An important RCT study is omitted from the review of Clinical Evidence relating to skin care in the incontinent patient. Baatenburg de Jong2 reported a randomised control trial where 40 incontinent residents of a large Dutch nursing home suffering moderate to severe redness and/or skin erosion were randomised to receive either Cavilon non sting film or a zinc oxide paste during a 14 day study. The skin was assessed for degree and area of erythema and degree and severity of skin erosion at the start and end. Total skin damage scores improved with both products but the patients treated with a non sting barrier film showed significantly better improvement	Baatenburg de Jong was excluded because the group did not specifically have faecal incontinence, nor was the incidence of faecal incontinence reported.

Key: SH = stakeholder

Status	SH organisation	Order no.	Document	Page No.	Line no.	Comments	Responses
						(p=0.04). We suggest adding the following text or similar: "Using a non sting barrier film led to significantly better skin improvement compared to a zinc oxide oil in a nursing home population"	
SH	3M Health Care Limited	6	Full	104	1 - 29	In 3.11.3 important evidence regarding the cost effectiveness of skin care in the incontinent patient was missed by the literature review2. Please consider adding this or similar text: "A study in a Netherlands nursing home environment measured cost effectiveness of Cavilon Non sting barrier film versus a zinc oxide paste. The mean costs of skin barrier products and disposable materials was 47% lower for the patients treated with Cavilon Non sting barrier film and also the costs for nursing time were 22% lower than for the zinc oxide paste. The costs per unit of skin improvement in the Cavilon non sting barrier film group were more than 30% lower than those residents treated with zinc oxide paste on a 12 point skin condition scale."	We have not included this study because the group did not have specifically faecal incontinence, nor was the incidence of faecal incontinence reported.
SH	3M Health Care Limited	7	Full	104	1 - 29	In 3.11.3 important evidence regarding the cost effectiveness of skin care in the incontinent patient was missed by the literature review. We suggest adding the following text or similar: "The cost effectiveness of a sacral skin care protocol in six UK nursing homes was	Thank you for submitting this paper. We have added a similar paragraph to the guideline text.

Key: SH = stakeholder

Status	SH organisation	Order no.	Document	Page No.	Line no.	Comments	Responses
						calculated compared to the residents' previous ad hoc methods for skin care1. The cost of both skin care products and staff time was reduced by the implementation of the sacral skin care protocol including Cavilon durable barrier cream or Cavilon non sting barrier film when compared to the usual skin care provided in the homes. The frequency of application of barrier products to the skin was reduced from an average of over 8 times a day to 2.5 times a day when using the skin care protocol with a concomitant reduction in staff costs."	
SH	3M Health Care Limited	8	Full	104	32 - 36	In 3.11.4 please add the following text or similar: "Skin protection with Cavilon No sting barrier film was more cost effective in improving the skin condition of incontinent patients but the study gave no indication what proportion of the participants had faecal incontinence. A skin care protocol including the use of Cavilon durable barrier cream or Cavilon no sting barrier film was effective in improving the skin condition of residents in a nursing home population where 65% of residents were doubly incontinent."	We have not included this evidence, since it does not pertain specifically to *faecally* incontinent patients.
SH	3M Health Care Limited	9	Full	104/105	37 - 2	In the 3.11.5 conclusions I suggest adding the following bullets or similar: Non sting barrier film was cost-effective compared with zinc oxide oil. A sacral skin care protocol including a	We have not reached the first conclusion, since we have not included the submitted evidence (see response above). With regard to the second conclusion, we did

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Status	SH organisation	Order no.	Document	Page No.	Line no.	Comments	Responses
						durable barrier cream and a non sting barrier film was more cost effective compared with previous products.	not feel that such a conclusion was worth emphasizing since the comparison group is so vague.
SH	3M Health Care Limited	10	NICE	General		We doubt the usefulness of health care professionals being advised to provide advice on skin care without any specific recommendations being made in the NICE guideline. The paper by Bale et al1 showed that basic education of carers (non-qualified staff) led to almost 100% compliance with the sacral skin care protocol in a nursing home environment.	The GDG have specifically recommended that patients should be offered skin-care advice that covers both cleansing and barrier products (1.3.1.12). Bale et al, 2004 was wrongly excluded, thank you for bringing it to our attention. This study has been reviewed and is now included in the guideline.
SH	Addenbrookes NHS Trust					This organisation was approached but did not respond.	
SH	Adults Strategy and Commissioning Unit					This organisation was approached but did not respond.	
SH	Airedale General Hospital - Acute Trust					This organisation was approached but did not respond.	
SH	Albyn Medical Ltd					This organisation was approached but did not respond.	
SH	American Medical Systems UK					This organisation was approached but did not respond.	
SH	Association for Continence Advice	1		3		good to see QOL mentioned, this is so important.	Thank you
SH	Association for Continence Advice	2		6-9		Key priorities. Good to see 'integrated continence services' has arisen again. This is systematically ignored by Trusts and should be embolden, as this is the single	Thank you

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Status	SH organisation	Order no.	Document	Page No.	Line no.	Comments	Responses
						beneficial aspect of the highest levels of clinical care.	
SH	Association for Continence Advice	3				6 monthly review' of symptoms. This is excellent news as it is stated in many other documents but singularly ignored	Thank you
SH	Association for Continence Advice	4				specialist continence services' are important as this allows SAP to continue and this is now seen as the way forward, contact assessment through to specialist assessment.	Thank you
SH	Association for Continence Advice	5				1.3.3.1 Would it be a good idea to include the Bristol Stool chart, stated as such and identified as an appendix to identify an 'ideal stool consistency.	The Bristol Stool Chart is not a validated tool. While this is a widely used tool, the GDG does not believe this is the only way to determine a problem with stool consistency.
SH	Association for Continence Advice	6		1.3.6.2		Patients should be offered … disposable bed pads… OK with body worn but the evidence suggests that bed pads (underpads) are not appropriate for general use and that body worn pads of the correct absorbency and shape are	The GDG disagree. Patients should be offered body worn pads in a choice of styles and designs. However, disposable bed pads should also be offered to patients if needed (to cope with leaking body worn pads for example in severe diarrhoea, and for bowel evacuation care for example in spinal cord injury).
SH	Association for Continence Advice	7		P66	2	Concern re use of phosphate enemas. Whils it is recognised that these are sometimes needed, all other treatments should be tried first. Should be used with extreme caution (Davies C Nursing Times Vol 100 (18)p32-35	We have suggested that other treatments are used before phosphate enemas. We did not find research evidence to back up the common assertion that they are dangerous. The reference you quote is not a research study demonstrating adverse events.
SH	Association for Continence Advice	8				Overall opinion Please make this guidance as strong as possible otherwise it will be consigned to the bin as	Thank you for this comment. We have to balance out the evidence available with the strength of the recommendations. Unfortunately, there is little quality evidence

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Status	SH organisation	Order no.	Document	Page No.	Line no.	Comments	Responses
						has happened with so much excellent guidance that relates to bladder or bowel dysfunction e.g. Good practice in continence services (DH 2000), NSF Older People (DH 2001) Essence of care (DH 2002), NSF Children's (DH 2004). I hope the N.I.C.E. guidance for urinary incontinence (N.I.C.E. 2006) will be equally well received by Trusts, however I fear that as it is not cancer or sexually orientated or caries an ethnicity or diversity tag it will receive poor notice within Trusts.	and we do not feel we can be too prescriptive.
SH	Association for Spina Bifida & Hydrocephalus (ASBAH)					This organisation was approached but did not respond.	
SH	Association of Chartered Physiotherapists in Women's Health	1	Full	74	38	Another main reason for not seeking help is fear of diagnosis, e.g. cancer, and fear that surgical intervention will be undertaken with possibility of a colostomy.	We agree that this is a possibility, but we did not find evidence of patients' views on this.
SH	Association of Chartered Physiotherapists in Women's Health	2	Full	78	14	Patients after radical pelvic surgery can also be at risk of poor bowel control	We did not find evidence on this. We were unable to provide exhaustive lists, but tried to highlight groups where epidemiological evidence points to high risk.
SH	Association of Chartered Physiotherapists in Women's Health	3	Full	94	27	Perhaps the effects of antibiotics should have been mentioned here, although they are mentioned later	The GDG do not agree and feel that antibiotics are adequately covered in Appendix D, Table 4.
SH	Association of	4	Full	107	14	The voluntary sector should also produce	Thank you for your comment. This is outside

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Status	SH organisation	Order no.	Document	Page No.	Line no.	Comments	Responses
	Chartered Physiotherapists in Women's Health					more literature on these problems e.g. MS Society, Help the Aged, etc. and focus more on some treatment options	the scope of this guideline.
SH	Association of Chartered Physiotherapists in Women's Health	5	Full	108	26	Baseline assessment should perhaps include a food/fluid diary, faecal diary and neurological assessment of reflexes and dermatomes	The GDG feel that this is adequately covered in baseline assessment (Table 1, Appendix D).
SH	Association of Chartered Physiotherapists in Women's Health	6	Full	110	17	Is this a good enough description?	The GDG have added more detail to this description.
SH	Association of Chartered Physiotherapists in Women's Health	7	Full	130	22	Words develop recommend do not make sense	Thank you, this has been amended.
SH	Association of Chartered Physiotherapists in Women's Health	8	Full	130	13	Not clear here: is the suggestion on pelvic floor re-education referring to neurological disease, etc? Also, should it recommend somewhere that exercises need to be done for at least 3 months and based on individual patient assessment? Biofeedback can be beneficial in those with poor muscle function and poor sensation and expert opinion suggests that patient motivation is improved.	Thank you, the GDG do not consider that the evidence warrants guidance of this level of detail.
SH	Association of Chartered Physiotherapists	9	Full	129	11	Rectal irrigation is mentioned several times in the document but there are no studies or references for its use as conservative	There was no evidence, and the recommendation was based on expert opinion.

Key: SH = stakeholder

Status	SH organisation	Order no.	Document	Page No.	Line no.	Comments	Responses
	in Women's Health					management.	
SH	Association of Child Psychotherapists					This organisation was approached but did not respond.	
SH	Association of Coloproctology of Great Britain and Ireland					This organisation was approached but did not respond.	
SH	Association of the British Pharmaceuticals Industry,(ABPI)					This organisation was approached but did not respond.	
SH	Barnet PCT					This organisation was approached but did not respond.	
SH	Barnsley Acute Trust					This organisation was approached but did not respond.	
SH	Barnsley PCT					This organisation was approached but did not respond.	
SH	Biosil Ltd	1	Full version	12	46-49	Glossary refers to Artificial Bowel sphincter – which is an abbreviation that also relates to the brand name of AMS Acticon Artificial Bowel Sphincter (ABS). Propose Glossary should also include reference to PAS Prosthetic Anal Sphincter - an inflatable, fluid filled silicone device that is implanted by trans-abdominal approach and is positioned at the junction of the upper anal canal / lower rectum. The sphincter cuff functions by reproducing the normal physiology of the ano-rectum by flattening and angulating the bowel without causing crenation.	The GDG have changed the wording to the generic term, artificial anal sphincter.

Key: SH = stakeholder

Status	SH organisation	Order no.	Document	Page No.	Line no.	Comments	Responses
SH	Biosil Ltd	2	Full version	29	4	Only reference to ABS Artificial bowel sphincter – see above. Request include reference to AAB – Artificial Anal Sphincter + PAS – Prosthetic Anal Sphincter	The GDG have changed the wording to the generic term, artificial anal sphincter.
SH	Biosil Ltd	3	Full version	51	11-12	1.8.17 Related NICE Guidance for Artificial Anal Sphincter refers to IPG066 which is specifically related to AMS Acticon ABS procedure and results. Request PAS is added to IP Guidance relating to Artificial Anal Sphincter implantation "by trans-abdominal approach". The current IPG066 reference is specific to a competitor device and is therefore misleading with regards PAS.	We have retrieved one study on PAS by Finlay 2004 {FINLAY2004}, which has now been reviewed and included.
SH	Biosil Ltd	4	Full version	64	19-26	1.9.2.6 Surgery indicates "if a trial of sacral nerve stimulation is unsuccessful, patients can be considered for a neosphincter. The two options to be considered are a dynamic graciloplasty or an Artificial bowel sphincter. Whilst there is reference to the IP Guidance for DGP, there is currently no reference to the PAS. The PAS is currently under review for addition into the IP Guidance programme – "Artificial Anal Sphincter implantation by trans-abdominal approach".	Thank you for your comment. We have added the IP Guidance for Artificial Anal Sphincter to this recommendation.
SH	Biosil Ltd	5	Full version	129	1-11	4.5 Recommendations. There is no reference to surgical intervention – e.g. artificial anal sphincter implantation within the 6 options listed. Is this correct ?	Yes this is correct. This recommendation is for specialised management options before surgery. The recommendations on surgical options come in chapter 7.
SH	Biosil Ltd	6	Full version	147	24-33	6 Surgical Management of FI. Reference to ABS is specific to AMS Acticon device and is misleading with regards the PAS. Request add reference to PAS - an	The GDG have changed the wording to the generic term, artificial anal sphincter.

Key: SH = stakeholder

Status	SH organisation	Order no.	Document	Page No.	Line no.	Comments	Responses
						inflatable, fluid filled silicone device that is implanted by trans-abdominal approach and is positioned at the junction of the upper anal canal / lower rectum. The sphincter cuff functions by reproducing the normal physiology of the ano-rectum by flattening and angulating the bowel without causing crenation.	
SH	Biosil Ltd	7	Full version	162	18-27	6.4.10 Artificial bowel sphincter. Reference to high complication rate for this procedure – relates specifically to AMS Acticon ABS device. Please amend to include reference to Pas device, refer to attached document indicating reported PAS wound infection complication rate 9.1% & typical complications 1:10 10% compared to 47% indicated on line 26.	The GDG have changed the wording to the generic term, artificial anal sphincter.
SH	Biosil Ltd	8	Full version	164	1-34	6.5 Conclusion from surgical case series. Introduction refers to (line 16) "Neosphincters are associated with high reported complication rates". Reference is specific to AMS Acticon ABS and is not relevant to comparative results related to PAS. Line 19 Cost-effectiveness of sacral nerve stimulation. Paragraph refers to SNS but no reference to cost-effectiveness of PAS. Please refer to attached document – Procedural cost of PAS implantation is £3,995.00 per device plus cost of surgery / post-surgery care etc. Therefore it is proposed that PAS is as, if not more, cost effective than SNS and is more cost	We have not included this report in our review, as it was not published before our cut-off of 2nd October 2006.

Key: SH = stakeholder

Status	SH organisation	Order no.	Document	Page No.	Line no.	Comments	Responses
						effective than DGP and colostomy.	
SH	Biosil Ltd	9	Full version	169	14-21	6.7 Recommendations. Reference to surgical option of Artificial Bowel Sphincter if SNS trial is unsuccessful is included, but there is only reference to DGP IP Guidance NOT Artificial anal sphincter implantation i.e. PAS – please refer to request for inclusion of PAS into IP Guidance programme relating to "Artificial Anal Sphincter implantation by trans-abdominal approach". In addition, it has been commented by numerous UK surgeons that the PAS could and should be equally considered as final stage treatment alongside SNS, rather than only if SNS fails. Numerous surgeons have indicated that there are known situations / circumstances where a patient will not respond to SNS trial and should therefore be immediately considered for PAS implantation.	The GDG have changed the wording to the generic term, artificial anal sphincter. On the basis of current evidence we believe that SNS and artificial sphincter are correctly sequenced.
SH	Boehringer Ingelheim Ltd					This organisation was approached but did not respond.	
SH	Bradford & Airedale Primary Care Trust					This organisation was approached but did not respond.	
SH	British Association for Counselling and Psychotherapy (BACP)					This organisation was approached but did not respond.	
SH	British Association of					This organisation was approached but did not respond.	

Key: SH = stakeholder

Status	SH organisation	Order no.	Document	Page No.	Line no.	Comments	Responses
	Paediatric Surgeons						
SH	British Association of Stroke Physicians					This organisation was approached but did not respond.	
SH	British Dietetic Association					This organisation was approached but did not respond.	
SH	British Geriatrics Society & Royal College of Physicians of London	1	Full version	General		The Guideline should ensure that it reflects the needs of older people as the prevalence is highest in this group, particularly the old and frail.	The GDG consider that this point is adequately addressed in the guideline. The GDG have highlighted 'frail older people' as a high risk group in recommendation 1.1.1.2. There is also a research recommendation (p188) specifically looking at bowel management programmes for older people in care homes.
SH	British Geriatrics Society & Royal College of Physicians of London	2	Full version	General		The role of surgery is perhaps given too much emphasis in the draft guideline but we are pleased to see that due consideration has been given to the main components of conservative management and the issue of dignity.	The GDG tried to keep a balance but there was a lot to consider within the guideline. Surgery is an important option and there were several procedures to review. We have now re-ordered sections to clearly identify surgery as an option only when all other avenues have failed to restore continence.
SH	British National Formulary (BNF)					This organisation was approached but did not respond.	
SH	British Psychological Society, The					This organisation was approached but did not respond.	
SH	British Society of Gastroenterology					This organisation was approached but did not respond.	
SH	British Society of Urogynaecologists					This organisation was approached but did not respond.	

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SH	Cambridgeshire Neurological Alliance					This organisation was approached but did not respond.	
SH	Central Surrey Health Ltd					This organisation was approached but did not respond.	
SH	Chartered Physiotherapists Promoting Continence (CPPC)	1	Full	general		Overall a very good & useful document	Thank you
SH	Chartered Physiotherapists Promoting Continence (CPPC)	2	Full	general		Disappointed that physiotherapy profession is not mentioned by name (other than in foreword) particularly in relation to specialist management & PF muscle exercises	The term healthcare professionals has been used to cover everyone involved in the management of faecal incontinence. We found no evidence on the relative merits of different professionals delivering care and service implementation/delivery is not generally included in NICE guidance unless it was specifically requested in the remit received from the Department of Health.
SH	Chartered Physiotherapists Promoting Continence (CPPC)	3	Full	general		Please could we use the term pelvic floor muscle exercises, rather than just pelvic floor exercises throughout the document.	Thank you, we will amend the document accordingly.
SH	Chartered Physiotherapists Promoting Continence (CPPC)	4	Full	121	21	No mention of patient specific exercise regimen. While accepting there is no consensus on an optimum exercise regimen etc., a patient specific regimen based on the findings of a digital assessment is advantageous.	Thank you, we will add this to the recommendations and text where relevant.
SH	Chartered Physiotherapists Promoting	5	Full	130	13	A patient specific exercise regimen should be provided based on the findings of the digital assessment, needs to be included at	Thank you, we will add this to the recommendations and text where relevant.

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Status	SH organisation	Order no.	Document	Page No.	Line no.	Comments	Responses
	Continence (CPPC)					this point.	
SH	Chartered Physiotherapists Promoting Continence (CPPC)	6	Full	144	27	Trained specialist nurses and physiotherapists needs to be included (some physiotherapists are being trained in this technique)	Thank you, we have amended this accordingly.
SH	Chartered Physiotherapists Promoting Continence (CPPC)	7	NICE	18	1.4.1.3	Biofeedback &/or muscle stimulation are not included in the wording of this section although included in algorithm 2. Do they need to be included in this section?	Thank you, we will amend the algorithm.
SH	Chartered Society of Physiotherapy					This organisation was approached but did not respond.	
SH	CISters					This organisation was approached but did not respond.	
SH	College of Occupational Therapists	1	NICE	40	11	Should the question be “is there a history of urinary incontinence” rather than “urinary continence”?	We agree. We have amended this accordingly in the NICE and full version appendices.
SH	College of Occupational Therapists	2	Full	Appe nd H p.285		Contact details for the ACA are incorrect. The address should be: c/o Fitwise Management Ltd. Drumcross Hall, Bathgate. West Lothian. EH48 4JT. Tel: 01506 811077 Fax: 01506 811477. Email and website details are correct	Thank you, this will be added.
SH	College of Occupational Therapists	3	Full	“ p 287		DLCC is now called ASSIST UK. Address is unchanged. Tel: 0870 770 2866 Fax: 0870 7702867. Web: www.assist-uk.org	Thank you, this will be amended.
SH	College of Occupational	4	Full	“ p.289		PromoCon’s name is slightly incorrect – should have an uppercase ‘C’ (as above) in	Thank you, this will be amended. The strap line has been changed to the wording

Key: SH = stakeholder

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	Therapists					the middle of it. The description of the service is incorrect – should read " impartial and independent advice on continence products and services"	requested by PromoCon.
SH	College of Occupational Therapists	5	Both	General		Very pleasing to see that the assessment of Quality of Life issues have been strongly promoted very well documented throughout all of the guidelines	Thank you
SH	College of Occupational Therapists	6	Both	General		Very pleasing the see that the importance of functional issues, assessment of mobility and activities of daily living are promoted though the guidelines. Very comprehensive details of areas to include as part of the assessment	Thank you
SH	College of Occupational Therapists	7	Full	39	8 – 18	Assessment of Activities of Daily living – great to see this included	Thank you
SH	College of Occupational Therapists	8	Full	114	7 - 8	Provision of pads – whilst this statement is to be applauded, it needs to be supported with the provision of the necessary financial backing to enable this to happen in reality. A pity the NICE guidelines are not mandatory in this aspect of care !	Thank you for your comment. We hope that all our recommendations are implemented locally. NICE will be producing implementation tools shortly after the guideline is published and these will include an interactive cost impact spreadsheet to assist Trusts in implementing the guideline.
SH	College of Occupational Therapists	9	Full	182	15 – 32	Groups of patients - many Occupational Therapists work with these groups of patients identified in the document so this may encourage OT's to take more of a proactive role in the assessment and promotion of continence rather than dismissing it as purely a nursing or medical issue	The GDG also hope this is the case and would consider OTs as integral to a well-structured "integrated continence service."
SH	Coloplast Limited	1	Full	Gene		We welcome the guidelines in this area and	Thank you

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				ral		feel they will contribute to a better outcome for patients who suffer from faecal incontinence.	
SH	Coloplast Limited	2	Full	General		Where rectal irrigation is written is it possible to change to trans anal irrigation? We feel this describes the procedure more fully, rather than rectal irrigation, which might indicate just irrigating the rectum.	Thank you, the GDG considers that rectal irrigation is more accurate.
SH	Coloplast Limited	3	Full	61	1	Could you remove 'for those who tolerate them' as this would be a clinical decision at the time and could be seen as negative?	Thank you, the GDG have decided to put this specified wording into brackets.
SH	Coloplast Limited	4	Full	62	15	We are pleased to see rectal irrigation as a bowel management option	Thank you for your comment.
SH	Coloplast Limited	5	Full	67	35	Can you remove 'if feasible' from the rectal irrigation statement, as this would be a clinical decision at the time and could be seen as negative	Thank you, the GDG have decided to amend the wording.
SH	Coloplast Limited	6	Full	76	17	We would suggest the study: Christensen, P et al (2006) A randomized, controlled trial of trans anal irrigation versus conservative bowel management in spinal cord-injured patients. Gastroenterology 131 (3). The figures for participants with faecal incontinence are increased when you include the figures for those who have indicated they experience faecal incontinence episodes once a month or more, even though their predominant symptom is constipation. The figures increase to 21 in the conservative group and 23 in the trans-anal irrigation group, giving a total of 44 out of the 87 included in	We have not been able to extract the data you mention from the paper and can only determine the number of patients in whom FI was dominant. Therefore we have excluded this as less than 50% of patients were faecally incontinent.

Key: SH = stakeholder

Status	SH organisation	Order no.	Document	Page No.	Line no.	Comments	Responses
						the study.	
SH	Coloplast Limited	7	Full	102	21	Would you consider this study: Bond, C et al (2007), Anal Plugs for the Management of Faecal Incontinence in Children and Adults; A Randomised Controlled Trial. Journal of Clinical Gastroenterology, Vol 41 (1) p 45-53	This study was identified and a draft obtained from the author. However, it was excluded as an uneven number of adults were randomised to each group "due to recruitment problems".
SH	Coloplast Limited	8	Full	114	9	Could you remove 'for those who tolerate them' as this could be seen as negative?	The GDG felt that this wording is appropriate but have agreed to put brackets around the words 'for those who can tolerate them'.
SH	Coloplast Limited	9	Full	130	3	We would put forward the study: Christensen, P et al (2006) A randomized, controlled trial of trans anal irrigation versus conservative bowel management in spinal cord-injured patients. Gastroenterology 131 (3). The figures for participants with faecal incontinence are increased when you include the figures for those who have indicated they experience faecal incontinence episodes once a month or more, even though their predominant symptom is constipation. The figures increase to 21 in the conservative group and 23 in the trans-anal irrigation group, giving a total of 44 out of the 87 included in the study.	We have not been able to extract the data you mention from the paper and can only determine the number of patients in whom FI was dominant. Therefore we have excluded this as less than 50% of patients were faecally incontinent.
SH	Coloplast Limited	10	Full	181	9 - 12	We would put forward the study: Christensen, P et al (2006) A randomized, controlled trial of trans anal irrigation versus conservative bowel management in spinal cord-injured patients. Gastroenterology 131 (3).	We have not been able to extract the data you mention from the paper and can only determine the number of patients in whom FI was dominant. Therefore we have excluded this as less than 50% of patients were faecally incontinent.

Key: SH = stakeholder

Status	SH organisation	Order no.	Document	Page No.	Line no.	Comments	Responses
						The figures for participants with faecal incontinence are increased when you include the figures for those who have indicated they experience faecal incontinence episodes once a month or more, even though their predominant symptom is constipation. The figures increase to 21 in the conservative group and 23 in the trans-anal irrigation group, giving a total of 44 out of the 87 included in the study.	
SH	Coloplast Limited	11	Full	186	22	Could you remove 'if feasible', as this could be seen as negative?	GDG removed 'if feasible' and replaced with 'if appropriate'
SH	Coloplast Limited	12	Full	186	22	Would you consider this option for consideration as part of the initial steps of bowel management, as the Christensen et al (2006) trial proves the effectiveness of anal irrigation when used with Spinal injured patients?	We have not been able to extract the data you mention from the paper and can only determine the number of patients in whom FI was dominant. Therefore we have excluded this as less than 50% of patients were faecally incontinent.
SH	Coloplast Limited	13	Full	186	26	We would put forward the study: Christensen, P et al (2006) A randomized, controlled trial of trans anal irrigation versus conservative bowel management in spinal cord-injured patients. Gastroenterology 131 (3). The figures for participants with faecal incontinence are increased when you include the figures for those who have indicated they experience faecal incontinence episodes once a month or more, even though their predominant symptom is constipation. The figures increase to 21 in the conservative group	We have not been able to extract the data you mention from the paper and can only determine the number of patients in whom FI was dominant. Therefore we have excluded this as less than 50% of patients were faecally incontinent.

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Status	SH organisation	Order no.	Document	Page No.	Line no.	Comments	Responses
						and 23 in the trans-anal irrigation group, giving a total of 44 out of the 87 included in the study.	
SH	Commission for Social Care Inspection					This organisation was approached but did not respond.	
SH	Connecting for Health					This organisation was approached but did not respond.	
SH	Continence Advisory Service					This organisation was approached but did not respond.	
SH	Continence Foundation	1	Both	General		The Continence Foundation welcomes the recommendation for a pathway which takes most patients through baseline assessment and initial management. However, this is clearer in the Algorithms and at no point in the text of either document is it suggested that the reader should refer to one of the algorithms. This should be rectified.	Thank you for your comment. The GDG have added a reference to the algorithm prior to the list of all the recommendations in the NICE and full version.
SH	Continence Foundation	2	NICE	11	1.1.1.2	The reference to "women following childbirth" as a high-risk group should be expanded to "women following childbirth and during pregnancy". Faecal incontinence may arise during the pregnancy and not only as a result of obstetric trauma.	The GDG found that there is no strong evidence that pregnancy itself is an independent high risk factor for FI. We would be interested to see evidence to the contrary.
SH	Continence Foundation	3	Full	61	18-20	The positioning of this recommendation about people with "intractable faecal incontinence" could be taken to imply that a conclusion about whether the condition is "intractable" can be made after baseline assessment and initial management only, without specialist investigation and care. This may have arisen out of the desire to	We agree and will amend accordingly and move long-term management recommendation to after specialist assessment.

Key: SH = stakeholder

Status	SH organisation	Order no.	Document	Page No.	Line no.	Comments	Responses
						avoid duplication by putting into one section the long-term management of two types of people: those who do not wish to continue treatment and those for whom there is no further treatment. A way needs to be found to re-write the recommendation on "long-term management" to ensure that the label "intractable faecal incontinence" is only applied after specialist involvement.	
SH	Continence Foundation	4	Either	General		Physiotherapists would prefer the term "pelvic floor muscle training" to be substituted for "pelvic floor exercises" wherever this occurs as part of a recommendation (as opposed to recording what is written in published articles). We note that the NICE Guideline on Urinary incontinence in women uses "pelvic floor muscle training" throughout its recommendations.	Thank you, we will amend the document accordingly.
SH	Continence Foundation	5	Full	131	27	The phrase "intention of" in the phrase "health costs with intention of detailed economic modelling", does not make sense. Should this be "attention to"? Note the same wording appears in the NICE version in 4.1.	We agree that this is grammatically incorrect. We have taken the clause out of this sentence and added a new sentence regarding economic analysis.
SH	Continence Foundation	6	Full	131	17	Since it is acknowledged at l.31 that there is "no standardisation of what pelvic floor exercises should comprise", it is not clear what programme would be offered in this proposed research to group one, who are to be given "standardised pelvic floor exercises". This needs to be clarified.	This has been changed to individualised PFM training, based on digital assessment.
SH	Continence	7	Full	186	12	"maximising patient's understanding" –	Thank you, this will be changed

Key: SH = stakeholder

Status	SH organisation	Order no.	Document	Page No.	Line no.	Comments	Responses
	Foundation					correct either to “the patient’s” or apostrophe after “patients”.	
SH	ConvaTec	1	Full	General		ConvaTec welcomes this guidance document and believes that it will contribute to the better management of patients with faecal incontinence.	Thank you
SH	ConvaTec	2	Full	General 37	1-4	ConvaTec notes the scope of the document, and agrees that as drafted, it is appropriate and covers all patients with faecal incontinence. However, the draft guidance appears, with few exceptions, to focus on patients with chronic faecal incontinence. ConvaTec suggests that this represents a missed opportunity. The guidance should be redrafted to include a section on the management of the acute stages of faecal incontinence. The justification for this comment is as follows: Patients with acute faecal incontinence and diarrhoea suffer increased morbidity which is preventable in many cases 1. The European Pressure Ulcer Advisory Panel has published a statement on pressure ulcer classification 2. This statement recognises a clear association between faecal incontinence and ‘moisture lesions’ . Effective management of such lesions starts with correction of the causative factors.	We believe that we have addressed this in our algorithm by requiring that patients with diarrhoea receive appropriate treatment before proceeding to initial management. To produce guidance on the management of acute diarrhoea or infection control was outside the scope of this document. We found no published studies that met our literature search criteria on the use of products to manage FI in the acute situation. We believe that our extensive section on patients’ views emphasises the dignity issue you raise.

Key: SH = stakeholder

Status	SH organisation	Order no.	Document	Page No.	Line no.	Comments	Responses
						The use of closed 'Faecal Management Systems' has been demonstrated to be safe, and effective in patients with liquid or semi-liquid faecal incontinence. The results of a pilot clinical study of one such system were reported in a poster in 2005 3. A second, larger study was presented at the American Critical Care Nursing meeting in 2006 and submitted for peer review to a journal in the USA 4 .This demonstrated that the collection of liquid stool in a closed system led to maintenance or improvement of perineal and buttock skin in 92% of patients. This demonstrates that there is a place for this new type of medical device in the clinical management of acute faecal incontinence associated with diarrhoea and the guidance should reflect this. Furthermore, the Department of Health has published its 'Standards for Better Health' to indicate the mandatory standards required of all hospitals and other healthcare organisations 5. Standards C4a and C21 are particularly relevant to the management of acute faecal incontinence, requiring Trusts to ensure that: C4a The risk of health care acquired infection to patients is reduced, with particular emphasis on high standards of hygiene and cleanliness,… C21 Health care services are provided in environments which promote effective care	With regards to the 2005 pilot study, unfortunately we are unable to consider evidence presented in posters. We are also unable to consider articles only published as abstracts.

Key: SH = stakeholder

Status	SH organisation	Order no.	Document	Page No.	Line no.	Comments	Responses
			Full	171		and optimise health outcomes by being well designed and well maintained with cleanliness levels in clinical and non clinical areas that meet the national specification for clean NHS premises. Closed Faecal Management Systems are designed to prevent the contamination of the clinical environment by infective agents such as Clostridium difficile. In addition, standard C13a highlights the importance of patient dignity: Staff treat patients, their relatives and carers with dignity and respect. Closed Faecal Management Systems have been demonstrated to prevent significant soiling of the bed by faecal material in over 80% of assessments, are well tolerated and in the majority of cases with acute episodes of diarrhoea can prevent the indignity of faecal incontinence. ConvaTec suggests that in light of the above, the draft guidance would be improved by expanding section 7, starting on page 171, to include a section on 'patients with acute episodic faecal incontinence including those with an infective aetiology'. This section should contain a clinical management protocol for patients with acute faecal incontinence,	

Key: SH = stakeholder

Status	SH organisation	Order no.	Document	Page No.	Line no.	Comments	Responses
						discuss the morbidity associated with the condition, and discuss clinical treatment options. These options should include Faecal Management Systems because these devices can reduce the morbidity experienced by patients with liquid faecal incontinence, maintain the dignity of these patients, and reduce the likelihood of microbiologically contaminated faecal material being released into the clinical environment. 1. Gray M 2004 Preventing and managing perineal dermatitis: a shared goal for wound and continence care. J Wound Ostomy Continence Nurs; 31: s2-9 2. Defloor T et al 2005 Statement of the European Pressure Ulcer Advisory Panel-Pressure Ulcer Classification JWOCN 302-306 3. Padmanabhan A, Stern M, Williams,J & Mangino, M. “Managing Diarrhea and Fecal Incontinence: Results of a Prospective Clinical Study in the ICU” 8th ECET Congress, Helsinki Finland 19-22 June 2005 4.Gallagher J, Wishin J “Managing Diarrhea and Fecal Incontinence: Results of a Prospective Clinical Study in the Intensive Care Unit” American Journal of Critical Care 2006 Vol 15 (3) 325-326.	

Key: SH = stakeholder

Status	SH organisation	Order no.	Document	Page No.	Line no.	Comments	Responses
						5. Standards for Better Health 2005 Department of Health	
SH	ConvaTec	3	Full	53	9-13	ConvaTec does not agree with the implication made by the current draft that the management of faecal incontinence starts after condition specific interventions have been made. Patient morbidity associated with faecal incontinence and diarrhoea, such as moisture lesions of skin in the perineal and buttock areas can be largely avoided if Faecal Management Systems are used in the acute stages (see previous comment reference 4).	GDG have amended this recommendation to include infective diarrhoea. Patients with acute diarrhoea are managed separately from the main patient pathway. We did not find published evidence for the efficacy of the products you mention.
SH	Conwy & Denbighshire Acute Trust					This organisation was approached but did not respond.	
SH	Curon Medical					This organisation was approached but did not respond.	
SH	Department of Health	1				The Department of Health has no comments to make on this draft guideline but considers that given the limited evidence available this is a very useful and important guidline.	Thank you
SH	Ferring Pharmaceuticals Limited	1	Full	General		We have no comments to make.	
SH	Fylde Primary Care Trust	1	Short version:	General		Referencing all accepted	Thank you
SH	Fylde Primary Care Trust	2		General		Contents list – great, comprehensive.	Thank you
SH	Fylde Primary Care Trust	3		Page 3		Introduction: good to see QOL mentioned, this is so important.	Thank you

Key: SH = stakeholder

Status	SH organisation	Order no.	Document	Page No.	Line no.	Comments	Responses
SH	Fylde Primary Care Trust	4		Page 4/5		Patient centred care. No problems or issues.	Thank you
SH	Fylde Primary Care Trust	5		Page 6/9		Key priorities. Good to see 'integrated continence services' has arisen again. This is systematically ignored by Trusts and should be embolden, as this is the single beneficial aspect of the highest levels of clinical care.	Thank you
SH	Fylde Primary Care Trust	6			Page 6/9 Cont.	Bullet point 'focused baseline assessment' is good, as this will deliver better for core care at contact assessment in accordance with SAP. I have concern about the over use of one word 'appropriate' this arises throughout the document and is open to interpretation. I would be happier if this one word could be removed altogether so leaving no ambiguity at all. This is not a criticism of the word just an attempt to remove all risks of misinterpretation. '6 monthly review' of symptoms. This is excellent news as it is stated in many other documents but singularly ignored. 'specialist continence services' are important as this allows SAP to continue and this is now seen as the way forward, contact assessment through to specialist assessment.	Thank you for your comments. With regard to the word appropriate, we were trying not to be too prescriptive but found it difficult to find better wording. There is almost no evidence on what "appropriate" is in the majority of instances. Healthcare professionals will still need to use their judgement not use something if it is not relevant.
SH	Fylde Primary Care Trust	7		Page s	1.1.1.1	Thank goodness, music to the ears, excellent news.	Thank you

Key: SH = stakeholder

Status	SH organisation	Order no.	Document	Page No.	Line no.	Comments	Responses
				10/32 Guidance			
SH	Fylde Primary Care Trust	8			1.1.1.2	It would be good hear to have a statement about the trigger question * Trigger question – should be asked at all initial contacts e.g. Does your bladder or bowel ever/sometimes cause you problems? A positive response = Yes, sometimes my bladder/ bowel does cause me problems. NB All Patients/ clients presenting themselves for help with continence problems have automatically given a positive response to the trigger question DH 2001 Essence of Care: Patient-focused benchmarking for health care professionals Department of Health. HMSO: London.	The GDG feel that this is adequately addressed in the current version. This question would be inappropriate as bladder is out of scope of this guideline and the wording 'bowel' is too vague.
SH	Fylde Primary Care Trust	9			1.3.3.1	Would it be a good idea to include the Bristol Stool chart, stated as such and identified as an appendix to identify an 'ideal stool consistency.	The Bristol Stool Chart is not a validated tool. While this is a widely used tool the GDG does not believe this is the only way to determine a problem with stool consistency.
SH	Fylde Primary Care Trust	10			1.3.6.2	Patients should be offered … disposable bed pads… OK with body worn but the evidence suggests that bed pads (underpads) are not appropriate for general	The GDG disagree. Patients should be offered body worn pads in a choice of styles and designs. However, disposable bed pads can be useful during the night when body

Key: SH = stakeholder

Status	SH organisation	Order no.	Document	Page No.	Line no.	Comments	Responses
						use and that body worn pads of the correct absorbency and shape are better than bed pads. Also bed pads have MHRA caution issued about their use for people to generally sit on as a result of a slip/trip.	worn pads may leak. They are also required for bowel evacuation care.
SH	Fylde Primary Care Trust	11			1.4.1.1	Would it be possible to add 'as part of the integrated continence service'? That is the specialist part is an integral part of the integrated service.	Thank you, the GDG have amended the wording accordingly.
SH	Fylde Primary Care Trust	12			1.4.1.3	appropriately trained and later in text. Can we look at stopping the use of that word appropriate?	We were trying not to be too prescriptive but found it difficult to find better wording. There is almost no evidence on what "appropriate" is in the majority of instances. Healthcare professionals will still need to use their judgement not use something if it is not relevant.
SH	Fylde Primary Care Trust	13			1.6.1.10	Should stoma care be part of the integrated continence service and as such a specialist part of the integrated team?	The GDG agree. However, this section of the guideline deals with treatment, not team membership.
SH	Fylde Primary Care Trust	14			4.1	Standardisation This would be better if it could be done as part of the integrated team as Physio's, O.T.'s etc. should all be included within that team so making the evidence base as quality biased as possible for contestability.	Thank you, the GDG do not consider that the evidence warrants guidance of this level of detail.
SH	Fylde Primary Care Trust	15			4.2	Para 1. Should the word 'iteractive' be 'interactive'?	Thank you, this will be changed.
SH	Fylde Primary Care Trust	16			4.3	Question. Would a self-care educational programme …. Patients insight into their clinical conditions in most cases will lead to better health outcomes due to realisation of the potential or otherwise of cure, therefore such programmes will work but are time	While we agree that education is important and have suggested this as part of initial management, we did not find evidence for the efficacy of such programmes. Hence it was not possible to have a strong recommendation on this. We have suggested research on this

Key: SH = stakeholder

Status	SH organisation	Order no.	Document	Page No.	Line no.	Comments	Responses
						intensive. They do work and we should stress the benefits and the essential nature of this.	topic.
SH	Fylde Primary Care Trust	17			Appendix C Algorithm 1. Algorithm 2. Footnotes	Looks fine. Looks fine. Looks fine	Thank you
SH	Fylde Primary Care Trust	18			Appendix D Table 1 Table 2 Table	Tables looks fine – consider the words 'as indicated' – perhaps should refer to a table of indications, also some references to (see table) but no table number - probably will have in final version. Excellent and will be useful As Table 2. As Table 2.	Thank you for your comment. The references to tables have table numbers.

Key: SH = stakeholder

Status	SH organisation	Order no.	Document	Page No.	Line no.	Comments	Responses
					3 Table 4.		
SH	Fylde Primary Care Trust	19				Overall opinion Please make this guidance as strong as possible otherwise it will be consigned to the bin as has happened with so much excellent guidance that relates to bladder or bowel dysfunction e.g. Good practice in continence services (DH 2000), NSF Older People (DH 2001) Essence of care (DH 2002), NSF Children's (DH 2004). I hope the N.I.C.E. guidance for urinary incontinence (N.I.C.E. 2006) will be equally well received by Trusts, however I fear that as it is not cancer, hearts or sexually orientated or caries an ethnicity or diversity tag it will receive poor notice within Trusts. This work and other such work could profoundly change the lot of those with bladder and/or bowel dysfunction and would not need to cost any significant sums but would require Trusts to radically review their provision. So many Trusts talk about their integrated continence services but in reality 'RCP national audit 2005 and 2006' it must be questioned what the word integrated means as it seems to mean something to one where it doesn't to others.	Thank you for this comment. We have to balance out the evidence available with the strength of the recommendations. Unfortunately, there is little quality evidence and we do not feel we can be too prescriptive.

Key: SH = stakeholder

Status	SH organisation	Order no.	Document	Page No.	Line no.	Comments	Responses
						Frank Booth. Head of Continence Services North Lancashire Primary Care Trust December 2006.	
SH	Hampshire Partnership NHS Trust					This organisation was approached but did not respond.	
SH	Health Commission Wales					This organisation was approached but did not respond.	
SH	Healthcare Commission					This organisation was approached but did not respond.	
SH	Heart of England NHS Foundation Trust	1	Nice	General		Comprehensive document. Would benefit from a para on parental training of childrens' defaecatory habits. Ie diet, going on demand not by clock etc	This is outside the scope of the guideline.
SH	Heart of England NHS Foundation Trust	2		General		Some surgical recommendations are quite precise and others vague. Ie colonic irrigation ante/retro grade	Thank you for this comment. We believe that this is appropriate based on the current published evidence.
SH	Heart of England NHS Foundation Trust	3			1.6.1.5	While I agree seems very specific	This recommendation came from an RCT, which suggested there may be adverse effects associated with using constipating agents after anal sphincter repair.
SH	Heart of England NHS Foundation Trust	4			1.6.1.9	Rather vague	The wording for this recommendation is as specific as the evidence allows.
SH	Heart of England	5		Gene		No mention of patients with short gut	The GDG consider this to be outside the

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Status	SH organisation	Order no.	Document	Page No.	Line no.	Comments	Responses
	NHS Foundation Trust			ral		syndrome, previous pouch surgery, ant resection syndrome.	scope of the guideline, except as related to the suggestions on management of loose stool.
SH	Heart of England NHS Foundation Trust	6				No mention of fistulae causing incontinence/seepage	This would be included with sphincter damage.
SH	Heart of England NHS Foundation Trust	7				Role of post anal repair if only to say a waste of time!	We do not understand what this comment refers to.
SH	Help the Hospices					This organisation was approached but did not respond.	
SH	Hertfordshire Partnership NHS Trust					This organisation was approached but did not respond.	
SH	IA (Ileostomy & Internal Pouch Support Group)					This organisation was approached but did not respond.	
SH	Incontact (Action on Incontience)	1		Gene ral		This guideline should facilitate an improvement in the care and management of people who have FI, especially if sensitive, routine questions are asked opportunistically in high risk groups. Prevention of diagnostic overshadowing should reduce the number of patients who are not offered treatment as it is assumed that their FI is simply due to a long term condition or disability which the patient should accept. One can hope that this taboo subject and current “Cinderella” area of NHS care receives adequate funding for public health campaigns and for implementation. People with faecal incontinence would appreciate more	Thank you, we agree with your comments and hope this is what happens with the guideline. With regards to more specific guidance, the GDG did not feel that the available evidence allowed us to be more prescriptive. We were wary of recommending interventions which are likely to be futile, or even may cause harm. Until further research becomes available many recommendations will remain general rather than detailed and specific.

Key: SH = stakeholder

Status	SH organisation	Order no.	Document	Page No.	Line no.	Comments	Responses
						specific guidance on coping strategies and surgical options. It is vital that those with FI have the option of referral to specialist centres for further treatment options if initial treatment fails to control symptoms.	
SH	Incontact (Action on Incontience)	2	NICE	6 10	11 16	It may be useful to add examples under patients with loose stools or diarrhoea from any cause including IBS, IBD	We agree and have amended this accordingly.
SH	Incontact (Action on Incontience)	3	 Full	52 55	14 26	ditto	We agree and have amended this accordingly.
SH	Incontact (Action on Incontience)	4	Full	41	5, 6	It would be helpful if this wording was used in NICE version above (pg 6 and 11)	We agree and have amended this accordingly.
SH	Incontact (Action on Incontience)	5	NICE Full Full Full NICE	8 &16 54 60 62 112 116 62, 115 17	6, 5 8,9 24 3,4 2 1 5 35 18	Coping Strategies- (these need mentioning to most patients many may currently avoid going out so need to be given the strategies to enable them to travel) strategies such as planning routes around public toilets (conveniences – old fashioned), add, carrying a card stating person has a medical condition and needs urgent use of a toilet, Disabled toilets including National Key Scheme, (and “Changing Places “for those who require a hoist or an adult sized changing table), taking an emergency pack (e.g. wipes, pads, disposal bags, pants) Need to add advice on entitlement to DWP benefits such as Disability Living Allowance/ Attendance Allowance. Support for carers?	We agree and ‘Toilet Access Cards’ and the ‘RADAR key’ have been added to recommendation 1.3.1.11 on Coping strategies. Advice on DWP benefits is outside the remit of this guideline.
SH	Incontact (Action on Incontience)	6	NICE Full	15 59	1 botto	Is there a reference for “Summary of Products”?	Thank you, this will be inserted.

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Status	SH organisation	Order no.	Document	Page No.	Line no.	Comments	Responses
				112	m 23		
SH	Incontact (Action on Incontience)	7	NICE Full NICE Full	16 60 112 16 104	8 2 10 13	More information is needed on type of body worn pads. E.g. use of all in one nappy style prevents use of toilet or urinal to pass urine and does not promote urinary continence. In patients who have some bladder control but need a larger pad for FI, the use of pull up pant style protection is appropriate. More information needed on skin care and use of barrier protection .- Full version states barrier films are cost effective	The GDG felt that this is sufficiently covered by recommendation offering 'choice of styles and designs'. We found very limited comparative evidence on skin care and do not feel more detail is warranted on the evidence, especially as most related to urinary or double rather than faecal incontinence.
SH	Incontact (Action on Incontience)	8	NICE Full Full Full	16 60 99 112	11 1 21-23 9	Anal Plugs – need to add in active users stool seepage round the expanded polymer portion may cause excoriation of external sphincter	The GDG feel that this is adequately covered by statement that they are for patients that can tolerate them. We did not find evidence on the problems you mention.
SH	Incontact (Action on Incontience)	9	NICE Full	18 63	Surgery general & SNS	Surgery –More guidance is needed on who may be suitable for the different procedures. SNS is now a common procedure for some types of FI including urge incontinence. Yet SNS comes across as having a very low priority – almost a "surgical after thought". Given the influence these guidelines can have, the net effect will be that a very useful technique may seldom be recommended as a result. Perhaps the various methods of surgery should be given parity? Unlike some other FI surgical procedures, it is reversible and this is a huge advantage from a patient's perspective if side effects develop. In the UI guidelines SNS is in pole	It is very clear that sphincter repair has significant limitations. In a patient with a 90 degree gap with good quality muscle on ultrasound scanning or MRI with no atrophy and a palpable voluntary contraction the sphincter repair is the ideal first operation. If there is an absent contraction or cough reflex, a small gap or no sphincter defect and or atrophy or poor quality muscle on the scans the PNE to assess for SNS should be the next step in patients being considered for surgery.

Key: SH = stakeholder

Status	SH organisation	Order no.	Document	Page No.	Line no.	Comments	Responses
			NICE Full	18 63	 11	position when it comes to surgical procedures and the evidence is not dissimilar in its strength: so why the disparity between UI and FI guidelines? 1,6.11- referred to a specialist colorectal surgeon	
SH	Incontact (Action on Incontience)	10	NICE	20		Stoma formation - No mention on use of Percutaneous endoscopic colostomy.	We did not find published case series to support this procedure. Additionally, there is a risk of sepsis.
SH	Incontact (Action on Incontience)	11	NICE Full	21 & 22 65 67	1.7.1 2 13 10	Resulting in FI - Patients with partial loss of voluntary control also need a proactive approach bowel management. Their symptoms may be equally severe –Miss out wording complete loss of voluntary control. Sign posting is needed to manual evacuation and digital stimulation.	1.7.1.2 patients with neurological or spinal disease only We agree and have amended the recommendation accordingly. The GDG has sign posted consideration of manual/digital evacuation as the last bullet point of recommendation 1.7.6.1.
SH	Incontact (Action on Incontience)	12	NICE	23		1.7.6.1 as above this needs to be altered to include partial as well as complete loss of voluntary control	The GDG have amended the recommendation appropriately.
SH	Incontact (Action on Incontience)	13	NICE	24		1.7.6.2. All management options including surgery must be fully explained to the patient. It is vital that stoma formation is not rushed into before less body disfiguring interventions have been tried. More detail is needed on rectal irrigation.	GDG have amended recommendation to place stoma after other surgical options. The GDG consider that the detail on rectal irrigation is appropriate. Current evidence does not allow a detailed patient selection to be recommended.
SH	Incontact (Action on Incontience)	14	NICE	24 99	 24	1.7.7.1 Faecal collection bags should also be considered for acutely ill patients with severe diarrhoea.	Management of acute diarrhoea is outside the remit of the Guideline Development Group.

Key: SH = stakeholder

Status	SH organisation	Order no.	Document	Page No.	Line no.	Comments	Responses
						Wording much better in full guidance - ? alter NICE version	The GDG had agreed to change wording to 'faecal collection devices' rather than collection bags.
SH	Incontact (Action on Incontience)	15	NICE Full-appendix	42 295		Artificial sweeteners – Aspartamine should be Aspartame, however there appears no reason to include it. It is not like fructose or sorbitol and there is no evidence of it causing loose stools. The EU Food Standard Agency states "Following ingestion, aspartame breaks down in the gut into its three constituent parts: aspartic acid, phenylalanine (both amino acids) and methanol. All of these substances occur normally in the body. Aspartame itself does not enter the bloodstream nor does it accumulate in the body. The three breakdown products from aspartame are also present naturally in other foods and are used by the body in the same way as those derived from common foods. Compared to common foods, the amounts of these components that we ingest from aspartame are small". Aspartame is added to a wide range of manufactured foods. As it is 200 times sweeter than sucrose (normal sugar) even the amount of methanol produced is tiny. It is present in a huge range of manufactured foods.	Thank you for your comment. We have removed Aspartamine from the 'artificial sweeteners' section in Table 2 Appendix B.
SH	Incontact (Action on Incontience)	16	Full version	18/19	Last/first	Evidence table and terms below need to be on one page, rather than split over two to improve comprehension	Thank you, the NCC think it is acceptable.
SH	Incontact (Action on Incontience)	17	Full	19/20	"	Incremental cost effectiveness , as above	Thank you, the NCC think it is acceptable.

Key: SH = stakeholder

Status	SH organisation	Order no.	Document	Page No.	Line no.	Comments	Responses
SH	Incontact (Action on Incontience)	18	Full	24/25	"	Quantitative Research, as above	Thank you, the NCC think it is acceptable.
SH	Incontact (Action on Incontience)	19	Full	25/26		Resource Implication, as above	Thank you, the NCC think it is acceptable.
SH	Incontact (Action on Incontience)	20	Full	33	14	It would be better to change "incontinent patients" to people with incontinence- not all consider themselves as patients.	Thank you, we have amended this.
SH	Incontact (Action on Incontience)	21	Full	34	8	Why weren't the views of the women in study 8 (Risk) included? – Most of these women continued to conceal their FI from their partners	Unfortunately, it is not clear which study you are referring to. We have checked study 8 on page 34 but we didn't find it to be relevant to your comment.
SH	Incontact (Action on Incontience)	22	Full	40	29	Spinal Bifida should be Spina Bifida	Thank you, we have amended this.
SH	Incontact (Action on Incontience)	23	Full	53 57 108	6 15 27	Need to add pelvic examination including vaginal examination in women	The GDG do not agree as there is no evidence to suggest that a vaginal examination helps in the diagnosis of faecal incontinence.
SH	Incontact (Action on Incontience)	24	NICE	7	5	As above	The GDG do not agree as there is no evidence to suggest that a vaginal examination helps in the diagnosis of faecal incontinence.
SH	Incontact (Action on Incontience)	25	Full NICE	54 8	25 21	It jumps from specialist management options to surgery without stating patients should be referred to specialist centre for further investigations to see if surgery is suitable. We realise that this is because this section is the key recommendations. It would help if an improved Algorithm was near by to show complete care pathway.	Key recommendations can only give the headline priorities. We hope that clinicians involved in the management of FI will at least read the full NICE version, and preferably the full NCCAC guideline to underpin their practice. The algorithm will be published as integral to the NICE guidance.
SH	Incontact (Action on Incontience)	26	Full	56	13	Add and relative carers	We have added 'and their carers'' to the recommendation.
SH	Incontact (Action	27	Full	57	27	Add Cauda equina syndrome	We will incorporate this accordingly.

Key: SH = stakeholder

Status	SH organisation	Order no.	Document	Page No.	Line no.	Comments	Responses
	on Incontience)		NICE	109 7	14 16		
SH	Incontact (Action on Incontience)	28	Full	58	9	After a meal rather than after meals, otherwise it suggests that one should open one's bowels after every meal.	We agree, and this has been changed to after a meal.
SH	Incontact (Action on Incontience)	29	Full Full NICE	67 186 24	36 23	Rewording needed. Too much emphasis placed on stoma. Possible surgical options include sacral nerve root stimulation, antegrade irrigation and lastly stoma. Many patients have been told that stoma is the only option. It is imperative that patients are given the same advice as on page 63 lines 10 -16	The GDG felt that the recommendation reflected the evidence available and the consensus of the group. A stoma is the last resort, as stated and implied by its position in the document after other options. We suspect that with SNS far fewer patients will need to consider this option in future, but this remains to be proven.
SH	Incontact (Action on Incontience)	30	NICE Full Full	23 68 179	 32-43	Other specific groups should include a small section on specific advice for those with learning disabilities. There is such a section tucked away on pg lines 32 -43 in Full guidelines.	This is now included as a new recommendation.
SH	Incontact (Action on Incontience)	31	Full appendix	288		Incontact's web address is www.incontact.org	Thank you, we have amended this.
SH	Incontact (Action on Incontience)	32	Full appendix NICE	296/297 35/36		Algorithm 2, arrow appears to be missing from first pink box to second pink box. Currently confusing.	This would side step the box offering specialised management options (box on right hand side), and would not have been inline with our recommendations.
SH	Incontact (Action on Incontience)	33	Both Full	 112	 9, 10	Urge incontinence needs mention and explanation in the NICE version. Sacral nerve stimulation interventional procedure guidance is aimed at this type of FI. Mention is made of it in the full guidance in relation to toilet access	Unfortunately, we are not allowed to put the evidence or rationale for recommendations in the NICE version and space for background information is severely limited. Consequently, this does not get mentioned.
SH	King's College					This organisation was approached but did	

Key: SH = stakeholder

Status	SH organisation	Order no.	Document	Page No.	Line no.	Comments	Responses
	Acute Trust					not respond.	
SH	L'Arche UK					This organisation was approached but did not respond.	
SH	Liverpool PCT					This organisation was approached but did not respond.	
SH	Maidstone and Tunbridge Wells NHS Trust					This organisation was approached but did not respond.	
SH	Medicines and Healthcare Products Regulatory Agency (MHRA)					This organisation was approached but did not respond.	
SH	Midlands Centre for Spinal Injuries					This organisation was approached but did not respond.	
SH	National Association for Colitis and Crohns Disease (NACC)	1	NICE version	General		We question why these guidelines do not acknowledge patients with Inflammatory Bowel Disease (IBD) as a group at 'high-risk' of faecal incontinence,	We have added IBD as an exemplar of people who are at high risk due to diarrhoea.
SH	National Association for Colitis and Crohns Disease (NACC)	2	NICE version	6 10	6 12	We support the recognition of faecal incontinence as a socially stigmatising condition, and guidance to healthcare professionals to actively yet sensitively enquire about symptoms in high risk groups. We are concerned that IBD patients are not specifically identified as a group to whom this should be applied.	The GDG agree that we need to be more explicit about the types of diarrhoea. We have added this example to 1.2.1.3 where it is a listed as a treatable cause of diarrhoea.
SH	National Association for Colitis and Crohns Disease	3	NICE version	6	20-25	We welcome the recognition of faecal incontinence as a symptom, often with multiple contributory factors, requiring the avoidance of simplistic assumptions related	We agree and have amended this accordingly.

Key: SH = stakeholder

Status	SH organisation	Order no.	Document	Page No.	Line no.	Comments	Responses
	(NACC)					to a single primary diagnosis. Failing to include IBD patients as a group at 'high-risk' could mitigate the effective implementation of the guideline in this group of patients.	
SH	National Association for Colitis and Crohns Disease (NACC)	4	NICE version	7 12	8-10 18	This guideline refers to patients with conditions for whom condition-specific interventions should be addressed before progressing to initial management of faecal incontinence. We suggest that this guideline also applies to IBD, which is not specifically included in this context.	We consider that this is covered under treatment of diarrhoea and have added IBD as an exemplar of this above.
SH	National Association for Colitis and Crohns Disease (NACC)	5	NICE version	8 21	28-30 10	This guideline names groups of patients for whom a proactive approach to bowel management should be considered. Again, we are concerned that IBD patients are not specifically referred to in this context.	We consider that this is adequately covered by making it clear that IBD needs appropriate treatment before joining the main treatment pathway for FI.
SH	National Association for Colitis and Crohns Disease (NACC)	6	NICE version	16	9	In determining the range of continence products that should be offered, we question whether there has been adequate product development for faecal incontinence and suggest that this may be an area that should be identified within these guidelines for further development.	We agree with your comments but can only make a few research recommendations. We hope that the general awareness that this guideline will stimulate might encourage companies to develop products for this market.
SH	National Patient Safety Agency					This organisation was approached but did not respond.	
SH	National Public Health Service - Wales					This organisation was approached but did not respond.	
SH	National Spinal Injuries Centre	1	Full version	54	28	A specialist surgeon is without doubt the appropriate person to discuss surgical options with the patient but perhaps not the non-surgical?	We agree. Thank you for your comment. We did not mean to imply that the surgeon was discussing anything except surgery, as evidenced by the placement of surgery within the guideline, when all else has been tried.

Key: SH = stakeholder

Status	SH organisation	Order no.	Document	Page No.	Line no.	Comments	Responses
SH	National Spinal Injuries Centre	2		55	16	Spinal cord injury units often provide sound bowel management and care for their in- and out-patients but would not be regarded as part of an integrated continence service	An integrated continence service should include liaison between primary, secondary and tertiary care. We were unable to list every potential element of the service to patients.
SH	National Spinal Injuries Centre	3		65	14	A pro active approach to bowel management is also required in individuals with incomplete spinal cord injury and hence possibly impairment of voluntary control as well as those with complete injury and hence total loss of voluntary control	The GDG agree and have amended the recommendation accordingly.
SH	National Spinal Injuries Centre	4		66	10-17	For individuals with neurogenic bowel function it may be more appropriate to use rectal preparations before or combined with oral preparations initially as use of oral preparations alone is likely to result in episodes of faecal incontinence	This recommendation refers to patients with chronic ongoing faecal loading/impaction. Please see appropriate recommendation on neurological or spinal disease/injury (page 67, line 8). This recommendation does not specify order of treatment and includes patient preferences.
SH	National Spinal Injuries Centre	5		67	26	I assume there will be a comma between 'lower spinal injury' and 'if there is a hard plug…'	Thank you, we have amended this.
SH	National Spinal Injuries Centre	6		67	29	Has any consideration been given to what might be regarded as a 'reasonable time'?!	The GDG have amended the recommendation to clarify this comment.
SH	National Spinal Injuries Centre	7		181	9	A recently published study (Treatment of fecal incontinence and constipation in patients with spinal cord injury - a prospective, randomized, controlled, multicentre trial of transanal irrigation vs. conservative bowel management. Christensen P, Bazzocchi G, Coggrave M, Abel R, Hultling C, Krogh K, Media S, Laurberg S. Gastroenterology. 2006 Sep;131(3):738-47) provides strong support for the use of transanal irrigation to reduce	We have not been able to extract the data you mention from the paper and can only determine the number of patients in whom FI was dominant. Therefore we have excluded this as less than 50% of patients were faecally incontinent.

Key: SH = stakeholder

Status	SH organisation	Order no.	Document	Page No.	Line no.	Comments	Responses
						FI in spinal cord injured individuals. While FI was the dominant system for just 9 and 8 participants in the intervention and control groups respectively, when individuals who reported episodes of FI more than monthly are included these figures increase to 23 and 21 respectively, a total of 44 of the 87 individuals who participated in the study. The St. Mark's FI score was significantly reduced in the intervention group (p=.015). Why is this study not referenced?	
SH	National Spinal Injuries Centre	8		185	35	As indicated above individuals who have partial loss of control due to incomplete spinal cord injury also benefit from the same range of interventions which help those with complete loss – perhaps the wording should say 'complete or partial loss of voluntary control'	The GDG agree and have amended the recommendation accordingly.
SH	National Spinal Injuries Centre	9	Nice Guideline	13	1.3.1.1	The second sentence of the paragraph should include personal preference also	Thank you for your comment. We have added personal preference to this recommendation.
SH	National Spinal Injuries Centre	10		14	Second bullet point	Should a note of caution re excess fluid intake be included	Thank you for your comment. We have amended recommendation 1.3.1.2 accordingly.
SH	National Spinal Injuries Centre	11		16	1.3.6.2	Patients should also be offered disposable gloves for self management	The GDG agree and will incorporate this into the recommendation.
SH	National Spinal Injuries Centre	12		22	1.7.3.1	Even where mobility is limited carers may not be required but it is still desirable to limit the need for toilet access due to excessive time/energy required for bowel car, transfers etc.	Thank you for your comment. We have amended this recommendation accordingly.
SH	National Youth					This organisation was approached but did	

Key: SH = stakeholder

Status	SH organisation	Order no.	Document	Page No.	Line no.	Comments	Responses
	Advocacy Service					not respond.	
SH	Newcastle PCT					This organisation was approached but did not respond.	
SH	Newcastle Upon Tyne Hospitals NHS Foundation Trust					This organisation was approached but did not respond.	
SH	NHS Health and Social Care Information Centre					This organisation was approached but did not respond.	
SH	NHS Quality Improvement Scotland					This organisation was approached but did not respond.	
SH	Norfolk Suffolk and Cambridgeshire Local Specialised Commissioning Group					This organisation was approached but did not respond.	
SH	Norgine Ltd	1	Full version	65,66 183	24-31, 1-17 1-39	The guidance recommends that patients with severe faecal loading be treated with rectally administered interventions offered in the following order: • Glycerine suppositories • Bisacodyl suppositories • Micro enemas • Phosphate enemas And the guidance goes on to say that if these interventions fail to satisfactorily clear	The GDG do not believe this is an illogical recommendation. Patients with impaction and faecal incontinence are frequently elderly and have weak sphincters. We feel it is likely that they could not tolerate the suggested eight sachets of movicol in one litre of liquid without causing significant incontinence. This is the key issue about dignity in this population. The rectal approach is supported by Tobin et al study {TOBIN1986} and we found no comparative studies of oral vs. rectal agents in FI. This guideline in focused on FI not

Key: SH = stakeholder

Status	SH organisation	Order no.	Document	Page No.	Line no.	Comments	Responses
						the bowel, a potent oral laxative should be used. This means that with this recommended stepwise approach, an individual patient will have been administered 4 sets of rectally administered interventions before an oral intervention is tried. This really is a highly illogical recommendation. Surely it is better as a general principle in medicine to try non-invasive treatments first and only resort to invasive treatments if non-invasive treatments are unsuccessful. Rectally administered medicines may cause distress to patients and a loss of dignity. It cannot be right to recommend rectal interventions as first line treatment, when a licensed, effective and safe oral treatment is available. Movicol® sachets are licensed in the UK for the treatment of faecal impaction in adults and the elderly. 8 sachets dissolved in 1 litre of water administered daily for up to 3 days are effective in resolving or substantially improving faecal impaction in around 90% of patients without the need for rectal interventions (Culbert et al. Clin Drug Invest 1998; 16(5): 355-360, Chen et al. Current Med Res Opinion 2005; 21(10); 1595-1602).	management of constipation.

Key: SH = stakeholder

Status	SH organisation	Order no.	Document	Page No.	Line no.	Comments	Responses
						For those patients who can drink an oral liquid, Movicol treatment should be recommended first line in patients with faecal impaction/faecal loading. Rectal interventions should only be recommended as second line treatment if the patient cannot tolerate the volume of solution (I litre/day) or if the treatment with Movicol is unsuccessful.	
SH	Norgine Ltd	2	Full version	66 183	5-6 16	In relation to the above, it is not clear what the guideline means by "potent oral laxatives" It is worth pointing out the no oral laxatives other than Movicol are licensed for the treatment of faecal impaction. NICE guidelines should not recommend unlicensed treatments where a licensed treatment for the same indication exists.	Thank you for your comment. Recommendation 1.6.2.2 on potent oral laxatives now contains the example Macrogols.
SH	Norgine Ltd	3	Full version	78	2	Active case finding of faecal incontinence is somewhat akin to shutting the stable door after the horse has bolted. Chronic	We agree, but the scope of this guideline did not include prevention of FI, therefore we were unable to review the literature on this

Key: SH = stakeholder

Status	SH organisation	Order no.	Document	Page No.	Line no.	Comments	Responses
						constipation and faecal impaction are major causes of faecal incontinence. 'High risk' patients as listed in section 2.6.1 should be asked about symptoms of chronic constipation so that this can be treated to prevent faecal incontinence developing in the first place. As chronic constipation is a preventable cause of faecal incontinence, it is a far more cost-effective use of healthcare resources to case-find and treat chronic constipation, than wait until the patient has developed faecal incontinence. Patients would also greatly benefit from this approach. In many cases patients who are happy living in residential accommodation are forced against their will to move to a nursing home simply because they have become incontinent of urine or faeces. Because this has such a major impact on the patient and their family, all that can be done should be done to prevent faecal incontinence occurring in the first place, rather than to wait for it to happen, and then try and treat it.	topic. We hope that we have covered this in a proactive approach to bowel management for frail older people and immobile people.
SH	North Eastern Derbyshire PCT					This organisation was approached but did not respond.	
SH	North Tees and					This organisation was approached but did	

Key: SH = stakeholder

Status	SH organisation	Order no.	Document	Page No.	Line no.	Comments	Responses
	Hartlepool Acute Trust					not respond.	
SH	North Tyneside Primary Care Trust					This organisation was approached but did not respond.	
SH	Northwest London Hospitals NHS Trust					This organisation was approached but did not respond.	
SH	Northwick Park and St Mark's Hospitals NHS Trust					This organisation was approached but did not respond.	
SH	Nutrition Society					This organisation was approached but did not respond.	
SH	Oldham Primary Care Trust					This organisation was approached but did not respond.	
SH	Oxfordshire & Buckinghamshire Mental Health Trust	1				It is very comprehensive and offers a range of assessments and interventions some of which, will be not fully relevant in a mental health setting and I would imagine that such a guideline will be of benefit in establishing an integrated continence service for our patients.	Thank you for this comment.
SH	Oxfordshire & Buckinghamshire Mental Health Trust	2				More specifically, I felt that point 1.7.5.1 which referred to those with cognitive and behavioural difficulties appeared to suggest that the faecal incontinence was as a result of the behavioural disturbance - I think it is really important to emphasise that people with cognitive impairments can also have physical impairments, which can contribute to the faecal incontinence	It is reflected in the guideline that all contributory factors are considered. That will include the physical as well as cognitive and behavioural factors. We have amended this recommendation to clarify this point.
SH	Oxfordshire &	3				I would like to see the guideline refer to the	Thank you for your comment. There was no

Key: SH = stakeholder

Status	SH organisation	Order no.	Document	Page No.	Line no.	Comments	Responses
	Buckinghamshire Mental Health Trust					complexities often involved in the assessment of people with cognitive impairment and the need to establish either a physical or psychological cause for the incontinence.	evidence retrieved on assessment and management of this group to provide more detail. Therefore, the GDG consider that this point is adequately covered in the medical history (Appendix D, Table 1 in NICE version, Appendix I in full version) and in the section on specific management of this group of patients.
SH	Pancreatic Cancer UK					This organisation was approached but did not respond.	
SH	Parkinson's Disease Society					This organisation was approached but did not respond.	
SH	Pembrokeshire and Derwen NHS Trust					This organisation was approached but did not respond.	
SH	PERIGON (formerly The NHS Modernisation Agency)					This organisation was approached but did not respond.	
SH	Peterborough & Stamford NHS Hospitals Trust					This organisation was approached but did not respond.	
SH	PromoCon (Disabled Living)	1	NICE	21	1.7.2.1.	Patients with faecal loading The recommendation that rectal administration should be first line treatment in disimpaction is not acceptable for many patients. Patients should be offered and given informed choice regarding both rectal and oral treatments were possible. Rectal administration can be costly in terms of nursing time	Patients with impaction and faecal incontinence are frequently elderly and have weak sphincters. We feel it is likely that they could not tolerate the suggested 8 sachets of movicol in one litre of liquid without causing significant incontinence. This is the key issue about dignity in this population. Patient and staff preference has not been formally assessed in any studies of impaction, and it should be re-emphasised that the scope of

Key: SH = stakeholder

Status	SH organisation	Order no.	Document	Page No.	Line no.	Comments	Responses
							the guideline is to deal with incontinence, not faecal impaction
SH	PromoCon (Disabled Living)	2	NICE	22	1.7.2.2	Re administration of oral laxatives causing gripping pain The use of Macrogols is less likely to cause gripping pain as its action is primarily on the stool (softening and bulking) rather than directly stimulating the bowel There is not enough detail re disimpaction. Explanation regarding the use of Macrogols or combining an initial softener then adding in a stimulant, for example, can reduce the risk of increased abdominal pain	Pain with laxatives is not purely related to whether the agent acts as a stimulant. Bulking agents in particular may cause pain, as can osmotic agents and even stool softeners – these are well described clinical observations. We also wish to reiterate that this is a feacal incontinence guideline, not one on faecal impaction.
SH	PromoCon (Disabled Living)	3	NICE	general		There is no mention of or suggestions where patients can get independent advice regarding the different types of products etc available	The contact details for PromoCon are listed in Appendix H in the full guideline.
SH	PromoCon (Disabled Living)	4	FULL	65	25	Patients with faecal loading The recommendation that rectal administration should be first line treatment in disimpaction is not acceptable for many patients. Patients should be offered and given informed choice regarding both rectal and oral treatments were possible. Rectal administration can be costly in terms of nursing time	Patients with impaction and faecal incontinence are frequently elderly and have weak sphincters. We feel it is likely that they could not tolerate the suggested 8 sachets of movicol in one litre of liquid without causing significant incontinence. This is the key issue about dignity in this population. Patient and staff preference has not been formally assessed in any studies of impaction, and it should be re-emphasised that the scope of the guideline is to deal with incontinence, not faecal impaction.
SH	PromoCon (Disabled Living)	5	FULL	66		Re administration of oral laxatives causing gripping pain The use of Macrogols is less likely to cause gripping pain as its action is	Pain with laxatives is not purely related to whether the agent acts as a stimulant. Bulking agents in particular may cause pain, as can

Key: SH = stakeholder

Status	SH organisation	Order no.	Document	Page No.	Line no.	Comments	Responses
						primarily on the stool (softening and bulking) rather than directly stimulating the bowel There is not enough detail re disimpaction. Explanation regarding the use of Macrogols or combining an initial softener then adding in a stimulant, for example, can reduce the risk of increased abdominal pain	osmotic agents and even stool softeners – these are well described clinical observations. We also wish to reiterate that this is a feacal incontinence guideline, not one on faecal impaction.
SH	PromoCon (Disabled Living)	6	Appendix to full	287		Disabled living information no longer correct needs to be amended to Assist UK Redbank House, St Chads Street, Manchester M8 8QA TEL: 08707702866 Fax: 08707702867 Minicom: 08707705813 Email: general.info@assist-uk.org Website: www.assist-uk.org	Thank you. We will amend accordingly.
SH	PromoCon (Disabled Living)	7		289		The strap line for PromoCon should read Promoting Continence and Product Awareness	Thank you. We will amend accordingly.
SH	Q-Med (UK) Ltd					This organisation was approached but did not respond.	
SH	Reckitt Benckiser Healthcare (UK) Ltd					This organisation was approached but did not respond.	
SH	Regional Public Health Group - London					This organisation was approached but did not respond.	
SH	Royal College of General	1	NICE			This is an important subject the document contains extensive recommendations for	We tried to get input from a GP by inviting the Royal College of General Practitioners Wales

Key: SH = stakeholder

Status	SH organisation	Order no.	Document	Page No.	Line no.	Comments	Responses
	Practitioners					primary care. It is noted that many of these are based, in the absence of research evidence, on the consensus opinion of a group of experts that appears not to have included a GP, community or practice nurse. Reasonable conclusions The full version is rather repetitive (same paragraphs appearing four times), but the NICE version is fine. Sad that no GP involved in the GDG since inevitably much of the detection and treatment of FI will be in the community.	and the Primary Care Society for Gastroenterology to nominate a member for the GDG, but they were unable to put forward anyone who could commit to the duration of the guideline's development.
SH	Royal College of General Practitioners	2	Full	4	5	Welcome this statement, since it puts patients first rather than trying to change professional work boundaries and income (via PBR/PBC).	Thank you for your comment.
SH	Royal College of General Practitioners	3		52	10	I wonder if a high risk group has been missed out. As a GP I am occasionally aware that patients smell, often it is when the patient pulls up the vest for chest auscultation (the vest sign). Sensitive questioning of this group could prove more rewarding than that of other groups.	The GDG did not agree that this is appropriate. It would be difficult to specify which group to ask and we hope this is adequately covered by stressing the need for active case-finding.
SH	Royal College of General Practitioners	4		34	7	3 mildly amusing typos below:	Thank you for your comment. We have amended this accordingly.
SH	Royal College of General	5		155	35	3 mildly amusing typos below:	We have amended this accordingly.

Key: SH = stakeholder

Status	SH organisation	Order no.	Document	Page No.	Line no.	Comments	Responses
	Practitioners						
SH	Royal College of General Practitioners	6		175	27	3 mildly amusing typos below:	We were unable to find any typos at the specified location.
SH	Royal College of General Practitioners	7				The recommendations are on the whole reasonable. The question of delivery is not satisfactorily addressed, and it raises questions of specialised training for persons with an identified lead responsibility in primary care, as well as awareness-raising among the wider primary care workforce.	NICE guidance does not generally address service delivery issues, except where specific research evidence is retrieved on effectiveness of different delivery models. We agree that increased training will be desirable to support implementation of this guideline and hope that your College will consider addressing this.
SH	Royal College of General Practitioners Wales					This organisation was approached but did not respond.	
SH	Royal College of Midwives	1	Full version	General		The RCM is pleased to offer comment on the faecal incontinence guidelines.	Thank you for your comment.
SH	Royal College of Midwives	2		3	12	A statement could be made to refer to the role of the midwife in prevention of faecal incontinence with education in the antenatal and postnatal periods as well as raising awareness of the condition following trauma sustained by a vaginal delivery.	The point you make is a good suggestion but this is beyond the scope of our guideline which was to cover the treatment of faecal incontinence rather than prevention. We did not find evidence on the role of the midwife in postnatal FI.
SH	Royal College of Midwives	3		118	37,38	No results were given for these studies	The results for this study are reported on p119 lines 12-18.
SH	Royal College of Midwives	4		129	23 - 28	There needs to be emphasis that education on the importance of pelvic floor exercises can be introduced antenatally and postnatally therefore impacting on sustained healthy living throughout life that may reduce the incidence of faecal incontinence. Midwives are in a unique position to deliver	Prevention of faecal incontinence is outside the remit of this guideline.

Key: SH = stakeholder

Status	SH organisation	Order no.	Document	Page No.	Line no.	Comments	Responses
						this education as part of their health promotion role.	
SH	Royal College of Midwives	5		129	23 - 28	Cost effectiveness in trauma caused by the condition as opposed to purely financial costs needs to be alluded to. Midwifery time in the education of mothers both antenatally and postnatally could be a factor in the cost benefits analysis as a preventative intervention.	We agree that the cost-effectiveness ought to consider trauma. However, the definition of cost-effectiveness used throughout this guideline incorporates quality of life as well as resource costs – we do not think it needs re-stating at this specific point. We agree that the use of pelvic floor exercise is an interesting research question but it is outside of the scope of this guideline.
SH	Royal College of Midwives	6		131	1 – 35	The College supports the recommendation for this research as we believe in a proactive line of management.	Thank you for your comment.
SH	Royal College of Midwives	7		131	1 – 35	How would compliance with performing the exercises be measured?	Patient compliance with any intervention is always difficult to measure and much has to be taken on trust. However, there are small portable biofeedback devices available for home use that have a “memory” function. Of course, the use of these would greatly increase the cost of any research study.
SH	Royal College of Midwives	8		131	1 – 35	How would you be assured in a research trial addressing the value of pelvic floor exercises that a group allocated no specific pelvic floor intervention would not investigate and perform pelvic floor exercises they have read about?	This is a challenge for any exercise intervention. However a study (Bump et al 1991){BUMP1991} has shown that the majority of patients are unable to perform correct PFM exercises on instruction alone. Moreover, in such a situation the patient would not be working on an individualised programme of exercises based on their PFM assessment.
SH	Royal College of Midwives	9		131	1 – 35	Will the trial be approved by an ethics committee?	Any research trial involving patients needs to get ethical approval.

Key: SH = stakeholder

Status	SH organisation	Order no.	Document	Page No.	Line no.	Comments	Responses
SH	Royal College of Midwives	10		General		There needs to be mention of the level of competency required by health professionals suturing 3rd and 4th degree tears (RCOG Guidelines).	This is an important point but prevention of faecal incontinence is beyond our remit for the guideline. As you state the RCOG guidelines are clear on this.
SH	Royal College of Midwives	11		General		Best practice should ensure that women who have sustained a 3rd or 4th degree tear should have a consultant appointment for their postnatal check.	This is an important point but prevention of faecal incontinence is beyond our remit for the guideline.
SH	Royal College of Midwives	12		General		Midwives build relationships with women and are therefore best placed (with training) to broach the subject of faecal incontinence therefore enabling early treatment to reduce morbidity of the symptoms.	This is an important point but prevention of faecal incontinence is beyond our remit for the guideline.
SH	Royal College of Nursing	1	General			With a membership of over 395,000 registered nurses, midwives, health visitors, nursing students, health care assistants and nurse cadets, the Royal College of Nursing (RCN) is the voice of nursing across the UK and the largest professional union of nursing staff in the world. The RCN promotes patient and nursing interests on a wide range of issues by working closely with Government, the UK parliaments and other national and European political institutions, trade unions, professional bodies and voluntary organisations. The RCN welcomes the opportunity to review this guideline.	Thank you for your comment.
SH	Royal College of Nursing	2	NICE	21	1.7.2.1.	Patients with faecal loading The recommendation that rectal administration should be first line treatment	Patients with impaction and faecal incontinence are frequently elderly and have weak sphincters. We feel it is likely that they

Key: SH = stakeholder

Status	SH organisation	Order no.	Document	Page No.	Line no.	Comments	Responses
						in disimpaction is not acceptable for many patients. Patients should be offered and given informed choice regarding both rectal and oral treatments where possible. Rectal administration can be costly in terms of nursing time.	could not tolerate the suggested 8 sachets of movicol in one litre of liquid without causing significant incontinence. This is the key issue about dignity in this population. Patient and staff preference has not been formally assessed in any studies of impaction, and it should be re-emphasised that the scope of the guideline is to deal with incontinence, not faecal impaction.
SH	Royal College of Nursing	3	NICE	22	1.7.2.2	Re administration of oral laxatives causing gripping pain The use of Macrogols is less likely to cause gripping pain as its action is primarily on the stool (softening and bulking) rather than directly stimulating the bowel. There is not enough detail re disimpaction. Explanation regarding the use of Macrogols or combining an initial softener then adding in a stimulant, for example, can reduce the risk of increased abdominal pain.	Pain with laxatives is not purely related to whether the agent acts as a stimulant. Bulking agents in particular may cause pain, as can osmotic agents and even stool softeners – these are well described clinical observations. We also wish to reiterate that this is a feacal incontinence guideline, not one on faecal impaction.
SH	Royal College of Nursing	4	NICE	general		There is no mention of or suggestions where patients can get independent advice regarding the different types of products etc available.	The contact details for PromoCon is listed in Appendix H in the full guideline.
SH	Royal College of Nursing	5	FULL	65	25	Patients with faecal loading As in NICE version - The recommendation that rectal administration should be first line treatment in disimpaction is not acceptable for many patients. Patients should be offered and given informed choice regarding both rectal and oral treatments were possible.	Patients with impaction and faecal incontinence are frequently elderly and have weak sphincters. We feel it is likely that they could not tolerate the suggested 8 sachets of movicol in one litre of liquid without causing significant incontinence. This is the key issue about dignity in this population. Patient and staff preference has not been formally

Key: SH = stakeholder

Status	SH organisation	Order no.	Document	Page No.	Line no.	Comments	Responses
						Rectal administration can be costly in terms of nursing time	assessed in any studies of impaction, and it should be re-emphasised that the scope of the guideline is to deal with incontinence, not faecal impaction.
SH	Royal College of Nursing	6	FULL	66		Re administration of oral laxatives causing gripping pain As in NICE version - The use of Macrogols is less likely to cause gripping pain as its action is primarily on the stool (softening and bulking) rather than directly stimulating the bowel. There is not enough detail re disimpaction. Explanation regarding the use of Macrogols or combining an initial softener then adding in a stimulant, for example, can reduce the risk of increased abdominal pain.	Pain with laxatives is not purely related to whether the agent acts as a stimulant. Bulking agents in particular may cause pain, as can osmotic agents and even stool softeners – these are well described clinical observations. We also wish to reiterate that this is a feacal incontinence guideline, not one on faecal impaction.
SH	Royal College of Nursing	7	Appendix to full	287		Disabled living information no longer correct needs to be amended to Assist UK Redbank House, St Chads Street, Manchester M8 8QA TEL: 08707702866 Fax: 08707702867 Minicom: 08707705813 Email: general.info@assist-uk.org Website: www.assist-uk.org	Thank you. We have amended accordingly.
SH	Royal College of Nursing	8		289		The strap line for PromoCon should read Promoting Continence and Product Awareness	Thank you. We have amended accordingly.
SH	Royal College of Paediatrics and Child Health					This organisation was approached but did not respond.	

Key: SH = stakeholder

Status	SH organisation	Order no.	Document	Page No.	Line no.	Comments	Responses
SH	Royal College of Physicians of Edinburgh					This organisation was approached but did not respond.	
SH	Royal College of Physicians of Edinburgh	1		General		All the documentation is extremely lengthy and this will adversely affect its impact. We would envisage the full version being largely used for reference purposes, which makes it particularly important that the NICE version is concise and focussed. Both documents contain much repetition, providing considerable scope for shortening of each.	The recommendations have to be same in all versions of the guideline. The GDG believe there is no unnecessary repetition and the recommendations are important as they stand.
SH	Royal College of Physicians of Edinburgh	2	NICE	General		1.1.1.2, 1.1.1.6 and all of Section 1.2 are repetitions.	These are not the same recommendations. 1.1.1.2 recommends what a healthcare profession should look out for, 1.1.1.6 recommends how the healthcare profession should approach/manage the patient.
SH	Royal College of Physicians of Edinburgh	3	NICE	15		This could be shortened as prose. Some would consider that Loperamide is best taken on a regular basis for fæcal incontinence.	The GDG do not agree that these recommendations should be shortened. They consider the amount of detail appropriate as some physicians may not be aware of appropriate use. There is no evidence that loperamide is best taken on a regular basis to make this recommendation.
SH	Royal College of Physicians of Edinburgh	4	NICE	17		Again, repetitions as are the first two paragraphs in Section 1.7.	The GDG do not agree and feel that this is an important point that needs to be covered in both sections.
SH	Royal College of Physicians of Edinburgh	5	NICE	26-30		The Section on Research recommendations would be usefully shortened to five statements. The rest reference to the full document rather than setting out the justifications in full in the shortened version.	The full details for each research recommendation is required to go into the NICE version by NICE.

Key: SH = stakeholder

Status	SH organisation	Order no.	Document	Page No.	Line no.	Comments	Responses
SH	Royal College of Physicians of Edinburgh	6	NICE	35 and 36		The algorithms are useful and to be commended. We can see no reference in the text to these useful algorithms.	Thank you for this. We have cross referenced them with the summary of recommendations.
SH	Royal College of Physicians of Edinburgh	7	NICE	Page 38		Further initial comment pointing out need to use a vocabulary, including slang, which that is clearly understood by the patient is recommended. This table also addresses neurological problems on page 40 and then asks about Parkinson's disease as a co-morbidity a few lines below.	NICE will be producing a patient version of this guideline where appropriate terminology for the patient will be used. We have removed Parkinson's Disease from algorithm as an example of comorbidity.
SH	Royal College of Physicians of Edinburgh	8	NICE	7		We feel that cognitive assessment is always appropriate including detailed questioning, even in people without obvious intellectual loss.	We take your point but do not wish to imply that everyone needs formal cognitive assessment. We consider 'general examination' would give clinicians a global idea of whether further cognitive assessment is needed. If there is no obvious cognitive loss, then it is highly unlikely that cognitive impairment will contribute to faecal incontinence. When cognitive impairment contributes to faecal incontinence the patient is likely to be severely impaired with an MMSE that is almost unrecordable as it is so low.
SH	Royal College of Physicians of Edinburgh	9	BOTH	General		Many of the issues in maintaining dignity for the person affected are general issues of good nursing care and good medical practice rather than being specific to fæcal incontinence; perhaps these general issues could be highlighted by cross-reference to	The GDG feel that this was unnecessary as these documents are not specific to faecal incontinence.

Key: SH = stakeholder

Status	SH organisation	Order no.	Document	Page No.	Line no.	Comments	Responses
						the relevant documentation used elsewhere rather than reiterated.	
SH	Royal College of Physicians of Edinburgh	10	BOTH	General		The question of follow-up and what is required at such visits should be addressed in more detail than just a statement about the frequency required. This would be particularly useful for general practitioners and primary care teams to provide the necessary continuum of treatment after Specialist intervention.	It is difficult to be prescriptive because what is offered at a follow up would be different for each patient.
SH	Royal College of Physicians of Edinburgh	11	FULL			Although we agree with its omission, it would be wise to specifically state that psychiatric disorders are not covered by this document. Whilst limited mobility is considered a specific mention of the increasing importance of marked obesity in limiting mobility should be included.	Although we do not specifically mention these patient groups they are covered by the guideline.
SH	Royal College of Physicians of Edinburgh	12	NICE	40		Medical review could usefully mention constipating drugs.	These drugs are included in the drug appendix.
SH	Royal College of Psychiatrists					This organisation was approached but did not respond.	
SH	Royal College of Radiologists					This organisation was approached but did not respond.	
SH	Royal National Hospital For Rheumatic Diseases					This organisation was approached but did not respond.	
SH	Royal Pharmaceutical					This organisation was approached but did not respond.	

Key: SH = stakeholder

Status	SH organisation	Order no.	Document	Page No.	Line no.	Comments	Responses
	Society of Great Britain						
SH	Salford PCT					This organisation was approached but did not respond.	
SH	Scottish Intercollegiate Guidelines Network (SIGN)					This organisation was approached but did not respond.	
SH	Sheffield Children's Hospital Trust					This organisation was approached but did not respond.	
SH	Sheffield PCT					This organisation was approached but did not respond.	
SH	Sheffield Teaching Acute Trust					This organisation was approached but did not respond.	
SH	Society and College of Radiographers					This organisation was approached but did not respond.	
SH	South East Sheffield Primary Care Trust					This organisation was approached but did not respond.	
SH	South Essex Partnership NHS Trust					This organisation was approached but did not respond.	
SH	Spinal Injuries Association	1	Full version	General on Section 7.7.5		From a Spinal Cord Injury (SCI) point of view we tend to use the term continence, not incontinence, as we strive to achieve this through good bowel regime. As a SCI person I do not see myself as faecal incontinent but I do acknowledge that I have a struggle to maintain a good bowel regime which keeps me continent. I also realise	Thank you for your comment. However, the scope of the guideline is faecal incontinence.

Key: SH = stakeholder

Status	SH organisation	Order no.	Document	Page No.	Line no.	Comments	Responses
						that I will throughout my life have to use a number of the methods described in item 7.7.5 (Patients with neurological or spinal disease/injury resulting in faecal incontinence).	
SH	Spinal Injuries Association	2	Full version	General on Section 7.7.5		SIA was glad to see an acknowledgement of the fact that management of faecal incontinence in people with neurological or spinal disease/injury is often radically different due to the different contributing causes of the symptom. This is a fact that is often overlooked by the medical profession when a SCI person is admitted to a non-specialist DGH. SIA would like to see recognition of the position taken by the NPSA and the RCN that Manual Evacuations and Digital Stimulation should be provided to a SCI person when it is part of an established bowel regime.	Thank you for your comment. It has been amended to include the NPSA web address (www.npsa.nhs.uk/advice).
SH	Spinal Injuries Association	3	Full version	General on Section 7.7.5		I gathered that the Guideline Development Group and expert opinion had been consulted regarding the recommendations the draft has put forward. It is a shame though that there had not been any studies actually involving SCI patients' faecal incontinence management, which I believe might have been more revealing.	We searched for all trials of patients with faecal incontinence, including patients with SCI and faecal incontinence. Unfortunately, no evidence was retrieved specifically on this group of patients and we had to rely on expert opinion and consensus development.
SH	Spinal Injuries Association	4	Full version	General on Section 7.7.5		I concur with the proposals which are really the standard practices for SCI bowel management (digital stimulation, manual evacuation, diet, laxatives) and reviews with SCI patients to discuss efficacy of interventions and alternative treatment	Thank you for your comments.

Key: SH = stakeholder

Status	SH organisation	Order no.	Document	Page No.	Line no.	Comments	Responses
						options such as surgical options if there is no improvement. It was good that long-term management strategies were touched upon and also the importance of providing coping strategies.	
SH	Spinal Injuries Association	5	Full version	General on Section 7.7.5		I would just like to see added the importance of information on the options open to SCI people and that life-style should be taken into consideration when decisions are being made about methods of managing their continence. Newly injured people with high lesions should not be given a colostomy just because they are easier for staff carrying out nursing and care, the long-term and psychological considerations of the SCI person need to be taken into account.	The GDG agree. The option for a stoma is at the final option on the list for recommendation 1.6.6.2 (full version p67 line 36). The guidance recommends this option only if faecal incontinence or time taken for bowel emptying imposes major limits on lifestyle.
SH	Staffordshire Moorlands PCT					This organisation was approached but did not respond.	
SH	Stockport PCT					This organisation was approached but did not respond.	
SH	Tameside and Glossop Acute Trust					This organisation was approached but did not respond.	
SH	The British Psychological Society					This organisation was approached but did not respond.	
SH	The Chartered Society of Physiotherapy	1				The CSP has no further comments to make on this guideline.	
SH	The David Lewis Centre					This organisation was approached but did not respond.	
SH	The IBS Network					This organisation was approached but did	

Key: SH = stakeholder

Status	SH organisation	Order no.	Document	Page No.	Line no.	Comments	Responses
						not respond.	
SH	The North West London Hospitals NHS Trust					This organisation was approached but did not respond.	
SH	The Robert Jones & Agnes Hunt Orthopaedic & District Hospital NHS Trust					This organisation was approached but did not respond.	
SH	The Royal College of Surgeons Edinburgh	1				This is an extremely detailed document and has been produced to an extremely high standard. The College would not take issue with any of the contents and believe NICE should be commended for looking at this hitherto neglected area.	Thank you for your comments.
SH	The Royal Society of Medicine					This organisation was approached but did not respond.	
SH	The Survivors Trust					This organisation was approached but did not respond.	
SH	Tissue Viability Nurses Association					This organisation was approached but did not respond.	
SH	UK Specialised Services Public Health Network					This organisation was approached but did not respond.	
SH	University College London Hospitals (UCLH) Acute Trust					This organisation was approached but did not respond.	
SH	University Hospitals	1	NICE	1.3.5.6		For the reasons outlined by the reviewers ie small dose control, loperamide should be	The GDG have incorporated that loperamide syrup should be used for doses under 2mg.

Key: SH = stakeholder

Status	SH organisation	Order no.	Document	Page No.	Line no.	Comments	Responses
	Birmingham NHS Trust					offered in syrup form as 1st choice. Many patients are sensitive and can be put off by a significant constipating effect. Occasional patients pass tablets un-dissolved	The GDG recommend (1.3.1.10) that is introduced at a very low dose, which can only be taken as a syrup when less than 2mg.
SH	University Hospitals Birmingham NHS Trust	2	NICE	1.6.1.2		Should read full thickness when referring to external sphincter defects	The GDG do not agree. We considered that gaps should be 90 degrees but do not believe the wording needs to be changed.
SH	University Hospitals Birmingham NHS Trust	3	NICE	1.7.6.2		Should include antegrade irrigation procedures for this group with spinal cord injury/ neuological disease	The GDG disagreed as antegrade irrigation is covered in the final bullet point for surgical options.
SH	University Hospitals Birmingham NHS Trust	4	NICE	4.2		Agree with reviewers comments – need for standardised symptomatic and QOL assessment tools. Such tools will need to be accessible to primary & secondary care. They must be electronic and internet based. They must have value to both researchers evaluating outcomes etc but also to the healthcare professional for symptom assessment and response	Thank you for this comment.
SH	University Hospitals Birmingham NHS Trust	5		General		No comment in document regarding traumatic sphincter injuries RTA, blast, gunshot, initial management, or incontinence resulting from such injuries. Little or no evidence base but should be managed in specialist center	This is included in acute sphincter rupture, which we considered should be managed acutely and separately from the main patient pathway. As you state, no evidence was found on management.
SH	University Hospitals Birmingham NHS Trust	6		General		Identification of high risk groups. A number of UK trusts have reported their results from specialist follow up clinics for women who have sustained a third or fourth degree obstetric injury. Appropriate follow up and support should be available for these	Thank you for your comment. We have added women with 3rd and 4th degree obstetric injury as a high risk group. We have changed the relevant sentence to 'women following childbirth (especially following third and fourth degree obstetric injury).

Key: SH = stakeholder

Status	SH organisation	Order no.	Document	Page No.	Line no.	Comments	Responses
						women	
SH	University Hospitals Birmingham NHS Trust	7		General		It is not clear to me from the guidelines whether or not PAR, TPFR levatoroplasty have a role and if so where do they fit in any treatment algorithm	The GDG do not recommend these types of surgery.
SH	University Hospitals Birmingham NHS Trust	8	Full	5.7		I would agree entirely with the reviewers conclusions on physiological testing and assessment. Until there are standardised techniques with established age related normal values comparisons between studies are meaningless and furthermore we will not know whether or not physiological testing has any value at all	Thank you for your comment.
SH	University Hospitals Birmingham NHS Trust	9		General		With regard to SNS. Sacral nerve modulation should be considered in those patients with combined faecal and urinary incontinence- it is the only single treatment that may affect this type of patient. SNS should be offered to patients with incontinence with intact sphincters repaired sphincters and can should be considered in patients with a sphincter defect of less than 33% particularly when other factors may be important such as neuropathy sphincter atrophy etc. SNS should be offered on the basis of a response to percutaneous nerve evaluation. PNE should be considered as a diagnostic tool. Successful PNE is highly predictive of therapy success.	Thank you for this comment, the GDG have amended the relevant sections accordingly.
SH	University Hospitals of Leicester	1	FULL	63	8	Uniquely, patient eligibility and response to SNS can be effectively tested prior to implant through preliminary percutaneous nerve evaluation (PNE). The high predictive	Thank you, the GDG agree and have amended the recommendations accordingly.

Key: SH = stakeholder

Status	SH organisation	Order no.	Document	Page No.	Line no.	Comments	Responses
						value of PNE allows for efficient patient selection and management of financial resources, and should be considered as a diagnostic tool for therapy success. PNE should therefore be offered once referred for specialist assessment after failing conservative treatment. This should be included at this position in the document.	
SH	University Hospitals of Leicester	2	FULL	63	17	There is a large volume of evidence on sacral nerve stimulation which has demonstrated that up to three-quarters of patients achieve continence or substantial improvements in symptoms with this therapy. Studies have also shown that SNS is effective in patients with intact or repaired anal sphincters as well as those with anal sphincter defects of less than 33% of the circumference. In addition it is the only intervention to effectively address dual incontinence (faecal and urinary). The demonstrated effectiveness across these indications together with the minimally invasive nature and safety of the therapy suggests that SNS should be considered as an alternative treatment option to other surgical interventions once specialized conservative treatments have failed (http://www.nice.org.uk/guidance/IPG99). This would be aligned with the position of SNS in the NICE guideline on the management of urinary incontinence (UI) in women in October 2006, which	The GDG do not agree. The conclusion that SNS should be first line treatment has no evidence to justify it to date. See points above on selection for sphincter repair.

Key: SH = stakeholder

Status	SH organisation	Order no.	Document	Page No.	Line no.	Comments	Responses
						recommends SNS for the treatment of UI in women who have not responded to conservative treatment based on the safety and effectiveness as evaluated by the Interventional Procedures Programme at NICE (http://www.nice.org.uk/guidance/IPG64). It is therefore recommended that SNS be placed at line 17 on this page.	
SH	University Hospitals of Leicester	3	FULL	64	5-6	This statement seems contrary to the evidence and could be potentially restrictive of patient choice. This should be removed.	The GDG do not agree. Post anal repair and total pelvic floor repair are not practiced. They are in the guidelines because there were randomised trials. The points made are valid and need to be discussed.
SH	University Hospitals of Leicester	4	FULL	64	7-17	The following adjustment to this section is put forward to reflect the available evidence: "Patients should be offered sacral nerve stimulation on the basis of their response to preliminary percutaneous nerve evaluation during specialist assessment. P*ercutaneous nerve evaluation is highly predictive of long term therapy success and should be considered as a diagnostic tool. Percutaneous nerve evaluation and consequent implant of the permanent neurostimulator are achieved with a minimally invasive procedure with a low risk of complications.*	PNE has now been mentioned in the recommendation. However, the GDG do not agree where you suggest is the appropriate place to put the recommendation, and have left it where it is. See chapter 7.

Key: SH = stakeholder

Status	SH organisation	Order no.	Document	Page No.	Line no.	Comments	Responses
						Sacral nerve stimulation is recommended for the treatment of faecal incontinence in patients who have failed specialised conservative treatments. It should be considered in patients with intact or repaired anal sphincters and those with an anal sphincter defect of less than 33% of the circumference. Patients being considered for sacral nerve stimulation should be assessed and managed at a specialist centre with experience of performing this procedure. Life-long follow-up is recommended." This could be inserted at page 63, line 17.	
SH	University Hospitals of Leicester	5	FULL	65	22	Insertion of "Dual Incontinent" patients as a specific group should be considered in this section.	The GDG considers that 'dual incontinent' patients are not a special group: questions about urinary symptoms need to be asked of faecally incontinent patients, and this may influence their management timing.
SH	University Hospitals of Leicester	6	FULL	68	7	Under a subheading of dual incontinence the following insertion is suggested: "Sacral nerve stimulation is recommended for patients with dual (faecal and urinary) incontinence as it is the only single treatment which is effective in this type of patient."	The GDG considers that 'dual incontinent' patients are not a special group: questions about urinary symptoms need to be asked of faecally incontinent patients, and this may influence their management timing. Urinary incontinence is outside the scope of this guideline.
SH	University Hospitals of Leicester	7	NICE	General		Please note all the changes proposed for the FULL guideline should be incorporated into the content of the shorter "NICE"	We agree. We will amend accordingly.

Key: SH = stakeholder

Status	SH organisation	Order no.	Document	Page No.	Line no.	Comments	Responses
						guideline to ensure consistency between both documents.	
SH	University of Hertfordshire					This organisation was approached but did not respond.	
SH	Uroplasty Ltd	1	Full version	P23 of 207	?	Percutaneous Tibial Nerve Stimulation (PTNS) This technique involves percutaneous electrical stimulation of the tibial nerve with a needle electrode inserted in the leg above the ankle and attached to a hand-held stimulator, thereby delivering retrograde access to the sacral nerve plexus. Periodic stimulation modulates sacral nerve function and improves faecal incontinence.	We have not included this as a clinical question and therefore have not reviewed the evidence for this.
SH	Uroplasty Ltd	2	Full version	P31 of 207	?	PTNS Percutaneous Tibial Nerve Stimulation	Thank you, this has been added to the abbreviations as suggested.
SH	Uroplasty Ltd	3	Full version	P41 of 207	14	Percutaneous Tibial Nerve Stimulation (PTNS) should be added as a minimally-invasive neuromodulation treatment with a non-implantable stimulator to modulate the sacral nerve plexus via the tibial nerve and improve continence. A publication by Shafik (Shafik A, Ahmed I, El-Sibai O, Mostafa RM. Percutaneous peripheral neuromodulation in the treatment of fecal incontinence. Eur Surg Res 2003; 35: 103-107) describes this treatment modality.	We have not included this study as this was not covered by one of the clinical questions.
SH	Uroplasty Ltd	4	Full version	General		Bioinjectible should be bioinjectable. (Reference NICE Interventional Procedure Guidance: overview of injectable bulking agents for faecal incontinence, prepared in	We have amended this accordingly.

Key: SH = stakeholder

Status	SH organisation	Order no.	Document	Page No.	Line no.	Comments	Responses
						May 2006).	
SH	Uroplasty Ltd	5	Full version	P151 of 207	General	Injection therapy with implantable bulking agents to augment the anal sphincter and increase anal pressure should be added as a minimally-invasive option for treating faecal incontinence (reference NICE Interventional Procedure Guidance: overview of injectable bulking agents for faecal incontinence, prepared in May 2006).	We do not recommend the use of this. The NICE interventional guidance published in February this year does not recommend its use.
SH	Uroplasty Ltd	6	Full version	P167 of 207	General	More studies are reported with more than 10 patients than only the Durasphere on bioinjectable sphincter bulking agents. - The published RCT of Tjandra and Rajendra with 82 patients should be added. It describes a study on injection of bulking agent biosilicone particles for treatment of faecal incontinence. (reference NICE Interventional Procedure Guidance: overview of injectable bulking agents for faecal incontinence, prepared in May 2006; Tjandra JJ, Lim JF, Hiscock R, Rajendra P. Injectable silicone biomaterial for fecal incontinence caused by internal anal sphincter dysfunction is effective. Dis Colon Rectum 2004; 47: 2138-2146).	This study was excluded as it did not have a relevant comparison for any of the guideline's clinical questions. It was also considered for the systematic review of case series but did not meet the inclusion criteria detailed on page 159 (less than 12 months follow-up).
SH	Uroplasty Ltd	7	Appendices full version	After 245 of 333	General	To be added to evidence table 32: - Tjandra et al 2004 (ref. NICE Interventional Procedure Guidance: overview of injectable bulking agents for faecal incontinence, prepared in May 2006; Tjandra JJ, Lim JF, Hiscock R, Rajendra P.	This study was excluded as it did not have a relevant comparison for any of the guideline's clinical questions. It was also considered for the systematic review of case series but did not meet the inclusion criteria detailed on page 159 (less than 12 months follow-up).

Key: SH = stakeholder

Status	SH organisation	Order no.	Document	Page No.	Line no.	Comments	Responses
						Injectable silicone biomaterial for fecal incontinence caused by internal anal sphincter dysfunction is effective Dis Colon Rectum. 2004; 47: 2138-2146) a RCT on injection of bulking agent biosilicone particles for treatment of faecal incontinence	
SH	Uroplasty Ltd	8	Appendices full version	265 of 333	General	To be added to summary results table 6: Bioinjectables / sphincter bulking agents Tjandra et al 2004, RCT on injection of bulking agent biosilicone particles for treatment of faecal incontinence (ref. NICE Interventional Procedure Guidance; overview of injectable bulking agents for faecal incontinence, prepared in May 2006; Tjandra JJ, Lim JF, Hiscock R, Rajendra P. Injectable silicone biomaterial for fecal incontinence caused by internal anal sphincter dysfunction is effective Dis Col Rect 2004; 47: 2138-2146).	The GDG disagree that this study should be included. It does not meet the agreed inclusion criteria for surgical case series (p159: lines 20-31). There was less than 12 months follow-up reported in the trial.
SH	Vygon (UK) Ltd					This organisation was approached but did not respond.	
SH	Welsh Assembly Government					This organisation was approached but did not respond.	
SH	Whipps Cross University Hospital NHS Trust					This organisation was approached but did not respond.	
SH	Wirral Hospital Acute Trust					This organisation was approached but did not respond.	

Key: SH = stakeholder