NICE National Institute for Health and Care Excellence

Appendix A: Stakeholder consultation comments table

2018 surveillance of faecal incontinence in adults: management (2007)

Consultation dates: 2 to 16 May 2018

Do you agree with the proposal to not to update the guideline?			
Stakeholder	**Overall response**	**Comments**	**NICE response**
THD (UK) Ltd	No	"A further study suggested that people with faecal incontinence whose symptoms improved were satisfied with their continence status after nurse-led care, **but those whose symptoms did not improve were dissatisfied**" (CG49 Surveillance Review Proposal) A recent review of FI activity (NHS Digital Hospital Episode Statistics 2017-18) showed **5,303** Primary Diagnosis of FI with a further **79,415** with FI as a secondary diagnosis. The trends between male and female and median ages were as you would expect. Following that, I had a look at the number of inpatient interventions by OPCS procedure code to try and get an idea on how many of these actually ended up with some kind of surgical intervention. I took the OPCS codes for all current surgical interventions/options	Thank you for your comment. The issue of poor implementation of the guideline was also raised by topic experts who advised us on the surveillance review. However, the issues in implementing the guideline do not appear to be due to problems with the current recommendations or changes in practice.

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

		(not diagnostic) as per in place IPG's from bulking agents through to artificial sphincter, I also looked at the coding for SNS for FI (NHS Digital Hospital Episode Statistics 2017-18) [See figure 1 below. NICE has moved and enlarged this figure to improve readability.] <table><tr><td>A701</td><td>Implantation of neurostimulator into peripheral nerve</td><td>301</td></tr></table> The high-lighted statement above, taken from the Surveillance proposal consultation document highlights the lack of solutions/treatments for those patients failing the conservative treatment pathway. With the only solutions appearing to be Sacral Nerve Stimulation (If the trust offers it), Stoma or stay on the conservative treatment of Plugs and Pads etc. Perhaps this is also indicative of a perceived disconnect between primary and secondary care pathways and highlights a lack of awareness from the primary care continence teams as to what is actually available to these patients. The majority of patients are managed by the primary care continence teams who are only able to offer limited options and also aren't always aware of the alternatives. Many of the current IPG's for FI procedures are no longer routinely offered or carried out. Leaving the surgical solutions extremely limited.	
3M UK PLC	No	This could be a missed opportunity to include the management of Incontinence Associated Dermatitis (IAD) in the guideline. Currently the only reference to skin care	Thank you for your comment. The guideline looked for evidence on skin care, recognising the need to keep the skin clean and dry and acknowledging that this can

		is in section 1.3.12 which recommends people with faecal incontinence should be offered: 'skin-care advice that covers both cleansing and barrier products'. Incontinence Associated Dermatitis (IAD) is skin damage associated with urine and/or faecal exposure and is a frequent problem in and out of hospital, which can be time consuming for nurses to treat, costly for facilities and the cause of patient morbidity. There is a wide variation in reported prevalence and incidence probably due to differences in diagnosis of IAD across care settings. The reported incidence of IAD ranges from 3.4% to 25% dependent on the setting with prevalence reports ranging from 5.6% to 50% (references available). IAD is often reported under the general term of Moisture Injuries of which expert opinion would suggest about 90% are most likely to be IAD of which 40% can be classified as severe. A more accurate estimation of incidence would clearly be useful, there is currently no ICD-10 coding but there is a new ICD-11 coding for 'irritant contact dermatitis due to incontinence' in place ready for future recording. As IAD decreases the skin's protective barrier it makes the area much more prone to infection. The most common infections involve Candida sp. and Staphylococcus aureus; with fungal infection due to IAD also being very common (Campbell, 2014). Additionally, the development of IAD is considered a likely risk factor for pressure ulcers (Beeckman 2014) which have been found to increase with the severity of IAD (Park KH 2014). IAD is associated with pain, discomfort, depression and poor quality of life (Peterson, 2006). Pain associated with	contribute to pressure ulcer development (see section 3.11 of the guideline, page 71). Only three small studies were identified, along with three small cost-effectiveness studies, which were considered to be 'too small and heterogeneous to reach any reliable conclusions'. The studies that you provided were assessed: Campbell et al. (2014) provides epidemiological data in incontinence-associated dermatitis from Australia. It does not inform management of the condition, so has no impact on current recommendations. Beekman et al. (2014) provides evidence of the association between incontinence-associated dermatitis and pressure ulcers. It does not inform management of the condition, so has no impact on current recommendations. Park (2014) provides evidence from a cohort study that silicone border foam dressings may be associated with lower rates of incontinence-associated dermatitis and pressure ulcers in people in intensive care units. However, it is unlikely that these results can be extrapolated to the wider population with faecal incontinence. No online record of the abstract by Peterson (2006) was identified No full publication of this work was identified. Therefore, it could not be considered. Junkin (2008) appears to be an article providing an overview and opinion of this issue. It does not provide evidence suitable for developing recommendations. Heidegger et al. (2016) is a small survey and observational study about diarrhoea in intensive care units. However, it provides no information on improving care in this area.

		IAD has a downstream impact on patient health and wellbeing leading to increased morbidity and decreased mobility, potentially increasing the patient's length of stay. (Junkin, 2008) Managing incontinence is time consuming and costly and patients that are experiencing moderate to severe IAD can only exacerbate this. Two large surveys of caregivers across Europe revealed that a patient with faecal incontinence requires approximately 4 hours of nursing time per day per patient or 17-20 minutes for 2 nurses over an average of 6 incontinent episodes per day (Heidegger, 2016) amounting to £621 per week for the nursing time alone. Although reliable data on the extra cost of treating IAD are lacking, estimates confirm that IAD will require extra care in the cleansing process and potentially extra time spent removing barriers (especially if pastes are used) due to the sensitivity. Development of IAD can have a significant impact on the patient experience and hopefully you will reconsider the proposal not to review the guideline. References cited: **Campbell** JL, Coyer FM, Osborne SR. Incontinence-associated dermatitis: a cross-sectional prevalence study in the Australian acute care hospital setting. Int Wound J 2014; doi:10.1111/iwj.12322 **Beekman**, D. *et al.* (2014) 'A systematic review and meta-analysis of incontinence-associated dermatitis, incontinence, and moisture as risk factors for pressure ulcer development', *Res Nus Health*.	Overall, we have not identified sufficient new evidence to justify and update of this section of the guideline, but will add the eligible studies to the body of evidence informing this surveillance.

		Park KH. The effect of a silicone border foam dressing for prevention of pressure ulcers and incontinence-associated dermatitis in intensive care unit patients. J WOCN 2014; 41(5): 424-29 **Peterson** KJ, Bliss DZ, Nelson C, Savik K. Practices of nurses and nursing assistants in preventing incontinence associated dermatitis in acutely/critically ill patients. Amer J of Crit Care. (Abstract) 2006; 15(3): 325. **Junkin** J, Selekof JL. Beyond "diaper rash": incontinence-associated dermatitis: does it have you seeing red? Nursing 2008;38(11 Suppl):56hn1-10.	
Bladder and Bowel UK	Yes	We would like to see reference being made to NICE MTG36. Peristeen Transanal Irrigation for Management of Bowel Dysfunction. With reference also to Section 1.7.10 Rectal Irrigation would not be confined only to those with neurological disease or injury	Thank you for your comment. The NICE medical technologies guidance on the Peristeen transanal irrigation system for managing bowel dysfunction (NICE MTG36) is linked with the guideline in the specialised management section of the NICE Pathway on faecal incontinence. Additionally, rectal irrigation is listed as a specialised management option in the guideline for people who continue to have episodes of faecal incontinence after initial management (recommendation 1.4.1). We therefore consider rectal irrigation to be adequately covered by existing NICE guidance.
Paediatric Continence Forum	No	We believe that the recommendations within recent NICE Guidance MTG36 mean that those suffering from faecal incontinence, including young adults, now have a treatment option which wasn't available to them previously due to the lack of evidence. Guideline CG49 should therefore be	Thank you for your comment. Please see the response above.

		updated to include reference to MTG36. We believe that this is complimentary to the fact that Clinical Commissioning Groups should commission services based upon NICE recommendations.	
Royal College of Nursing	Yes	We agree with the proposal not to update the guideline for the management of faecal incontinence in adults at this time. We would, however, urge NICE to encourage further research in this area.	Thank you for your comment. Several recommendations for research were made during guideline development (see section 1.9.3, page 51). No new evidence to answer these research recommendations was identified.
Cogentix Medical	No	The decision to not update the guideline is not in line with current practice and clinical evidence. We believe that the minimal invasive neuromodulation treatment of the tibial nerve for faecal incontinence (FI) should be added to the treatment algorithm. We argue that percutaneous tibial nerve stimulation (PTNS) should have a supported position in the NICE guideline for management of FI, or at least a sound open discussion should be held why to keep it out. Below arguments are listed to support this statement. A] PTNS is currently not placed in the management flow chart. It is named under the umbrella of the category "Specialised Care for Faecal Incontinence", and described here by the NICE IPG 395 as follows. The evidence on PTNS for FI raises no major safety concerns. There is evidence of efficacy in the short term in a limited number of patients. Therefore, this procedure should only be used with special arrangements for clinical governance, consent and audit or research. Since the publication of the IP in October 2010 more than 16 studies have been published. The fact that there is no objective assessment tool of faecal	Thank you for your comment. George et al. (2013), an RCT of posterior tibial nerve stimulation in 30 people, suggested benefit of percutaneous or transcutaneous posterior tibial nerve stimulation compared with sham. Hotouras et al (2012a), a cohort study of 100 people (including 88 women) suggested benefit after percutaneous tibial nerve stimulation compared with baseline. Hotouras et al. (2012b), a cohort study of 88 women, suggested benefit after percutaneous tibial nerve stimulation compared with baseline. This cohort appears to be a duplicate publication of data from the women included in the Hotouras et al (2012a) cohort. Allison (2011) had no data in the abstract, but appears to be a narrative review that may include a single-centre cohort analysis. Knowles et al. (2015), a cluster RCT of 227 people suggested insufficient benefit of percutaneous tibial nerve stimulation compared with sham. Horrocks et al. (2017), a post-hoc subgroup analysis of Knowles et al. (2015), suggested that people with obstructive defaecation may be less likely to respond to percutaneous tibial nerve stimulation.

		incontinence complicates the evaluation of clinical efficacy of the PTNS and could be one of the reasons of the difficulty to determine efficacy of treatment. This however should not be the reason to withhold a minimally invasive treatment that has proven to be effective with subjective assessments in many patients, and from patients' perspective is preferred above more invasive treatments. B] At least 16 clinical studies are published that justify a discussion on including PTNS in treatment algorithm, and to place of minimally invasive PTNS before more invasive treatments. When comparing PTNS to Sacral Neuromodulation (SNS) by using intention to treat analysis (including the pre-testing of SNS) efficacy numbers of both neuromodulation treatments are in the 13] George AT, Kalmar K, Sala S, Kopanakis K, Panarese A, Dudding TC, Hollingshead JR,Nicholls RJJ, Vaizey CJ. Randomized controlled trial of percutaneous versus transcutaneous posterior tibial nerve stimulation in faecal incontinence. Br J Surgery 2013; 100: 330-338 14] Hotouras A, Thaha MA, Allison ME, Currie,A, Scott SM, Chan CLH Percutaneous tibial nerve stimulation (PTNS) in females with faecal incontinence: the impact of sphincter morphology and rectal sensation on the clinical Outcome. Int J Colorectal Dis 2012; 27: 927-30 15] Hotouras A, Thaha MA, Boyle D, Allison ME, Currie,A, Knowles CH, Chan CLH Short-term outcome following percutaneous tibial nerve stimulation (PTNS) for faecal incontinence: a single-centre prospective study. Colorect Dis 2012; 14: 1101-5	Sanagapalli et al. (2018), a cohort study of 33 people with faecal incontinence and multiple sclerosis, suggested that percutaneous tibial nerve stimulation was effective compared with baseline. Ruiz-Tovar and Llavero C (2017), an RCT in 40 people with anal fissure, suggested benefit of percutaneous tibial nerve stimulation on healing compared with glyceryl trinitrate. This population is not directly relevant to the guideline on faecal incontinence. Overall, the evidence for percutaneous tibial nerve stimulation is mixed. These studies will be shared with the interventional procedures team. See reviewing and updating interventional procedures guidance in the interventional procedures programme manual for information on reviewing this type of guidance. NICE guidelines usually only include recommendations on interventions covered by interventional procedures guidance that are recommended with 'normal arrangements' for clinical governance, consent and audit. Any impact on the guideline will be considered if Percutaneous tibial nerve stimulation for faecal incontinence (NICE IPG395) is updated. We welcome further evidence to support the observed differences in effects for varying types of faecal incontinence. We also welcome evidence for tools to diagnose and categorise the type and severity of faecal incontinence. Ongoing studies that we identify, or receive notification about, will be assessed for the potential to impact on the guideline. We will track studies meeting this criterion and check for publication on a regular basis. If new evidence with an impact on recommendations is identified at any time, we may decide to update the guideline outside of the usual surveillance cycle.

		16] Allison M Percutaneous tibial nerve stimulation for patients with faecal incontinence. Nursing Standard 2011; 25 (24) :44-8. C] While the initial outcome of the Confident trial (1), showed no significant additional benefit of PTNS compared to sham for FI. Sub-analysis (2) confirmed that more factors are associated with the outcome of PTNS treatment. The most recent assessment shows a clinically and statistically significant improvement in FI symptoms compared to sham in patients without obstructive defaecation problems dysfunction. (1) Knowles et al. percutaneous tibial nerve stimulation versus sham electrical stimulation for the treatment of faecal incontinence in adults (CONFIDeNT): a double-blind, multicentre, pragmatic, parallel-group, randomised controlled trial. Lancet. 2015; 386:1640-8). (2) Horrocks et al. Factors associated with efficacy of percutaneous tibial nerve stimulation for fecal incontinence: a post-hoc analysis of data from a randomized trial. Clin Gastroenterol Hepatol. 2017;15:1915-21 D] also patient groups with other cause of FI, or pain have had successful PTNS; Patients with neurogenic disease (Multiples Sclerosis, Parkinson) suffering from FI; 1] Sanagapalli S, Neilan L,Tung LO, JY, Anandan L, Liwanag J, Raeburn A, Athanasakos E, Zarate-Lopez N, Emmanuel A. Efficacy of Percutaneous Posterior Tibial Nerve Stimulation for the Management of Fecal Incontinence in Multiple Sclerosis: A Pilot Study Neuromodulation 2018 [Epub 25Mar2018]. Patients with pain and anal fissures;	

		2] Ruiz-Tovar J, Llavero C. Percutaneous tibial nerve stimulation vs perianal application of glyceryl trinitrate ointment in the treatment of chronic anal fissures: A randomized clinical trial Dis Colon Rectum 2017; 60:81-6	
Renew Medical UK	No	Renew Medical respectfully request the inclusion of the Renew Insert where reference is made to the anal plug or Peristeen Anal Plug. At the time the guidelines were initially drawn up the Renew Insert was not available in the UK.	Thank you for your comment. The recommendations list anal plugs as an option for people who can tolerate them. However, neither the guideline nor the surveillance report specify any particular brand of anal plug, and clinicians may provide the most appropriate product for the patient.
Coloplast A/S	No	**Comment 1:** The current guideline CG49 does not take into account the recently published NICE Medical Technology Guidance 36 (MTG36): *Peristeen transanal Irrigation for managing bowel dysfunction* (https://www.nice.org.uk/guidance/mtg36) NICE MTG36 states clearly in its opening recommendation that "Peristeen can reduce the severity of constipation and incontinence, improve quality of life and promote dignity and independence." This newly published guidance (23/02/18) addresses the clinical and cost-effectiveness evidence to support the use of Peristeen transanal irrigation in all people with bowel dysfunction. We feel strongly that given the evidence detailed in MTG36, CG49 should be updated to reflect these findings and recommendations thereby offering a viable treatment option for people suffering from faecal incontinence. **Comment 2:** NICE CG49 , in Section 4: 'Specialised management of faecal incontinence', provides a bullet-point list of treatment possibilities. Among them is anal irrigation (also known as transanal irrigation, see comment 4 below on terminology). The same Section 4 goes on to review the existing clinical and cost-effectiveness evidence	Thank you for your comment. We consider the use of rectal irrigation systems to be adequately covered by current guidance. The NICE medical technologies guidance on the Peristeen transanal irrigation system for managing bowel dysfunction (NICE MTG36) is linked with the guideline in the specialised management section of the NICE Pathway on faecal incontinence. Additionally, rectal irrigation is listed as a specialised management option in the guideline for people who continue to have episodes of faecal incontinence after initial management (recommendation 1.4.1). Christensen et al. (2006), Christensen et al. (2009), Emmanuel et al. (2016) and Passananti et al. (2016) were considered during the development of MTG36. Therefore, they are not eligible for consideration again in surveillance. The guideline noted that the terms rectal irrigation and transanal irrigation are synonyms. The term 'transanal irrigation' may have

		available for this bullet-point list of therapies, but fails to address anal irrigation/transanal irrigation. We would like to point to the existence of more than a dozen of studies, including one RCT, on the Peristeen transanal irrigation device for the management of bowel dysfunction (including faecal incontinence) in multiple adult patient populations. We would like to point out the extensive evidence on transanal irrigation (specifically with the Peristeen device), including the RCT by Christensen et al A Randomized, Controlled Trial of Transanal Irrigation Versus Conservative Bowel Management in Spinal Cord–Injured Patients (GASTROENTEROLOGY 2006;131:738–747). Additionally, a long-term cost-effectiveness study based on an UK NHS cost model was published in 2016, resulting in an estimated cost-saving when comparing the use of Peristeen versus standard bowel care in patients with constipation and/or faecal incontinence of neurogenic origin. NICE, through MTG36, recognised that for all people with bowel dysfunction "is likely that Peristeen provides additional clinical benefits without costing more than standard bowel care". A full list of clinical and cost-effectiveness evidence for Peristeen transanal Irrigation for both the adult and the pediatric population can be found as part of the extensive literature review that NICE MTEP conducted for MTG36 . We believe that will be remiss of NICE not to update CG49 by omitting the evidence found in MTG36. **Comment 3**: CG49 addresses the management and needs of specific patient populations particularly prone to suffering faecal incontinence. In its section 6.6 (p.106), the current guideline addresses FI in patients with neurological or spinal disease/injury. In its current form, the guidance states: "No RCTs or non-randomised comparative trials which evaluated the clinical and cost-effectiveness of interventions specifically to manage faecal incontinence in	become more commonly used; however, it is unlikely that clinicians will be unduly confused by these differing terms.

		patients with neurological or spinal disease/injury were retrieved". As pointed out in the above comment, , the clinical evidence from the RCT by Christensen et al is a well-designed multi-centre RCT which includes UK patient population consisting exclusively of adults with spinal cord injury. It is our opinion that this study clearly meets the criteria to be considered in Section 6.6 of NICE CG49. There are as well other UK-based non-randomised studies on patients with neurologic conditions, such as the one published by Passananti et al in Neurogastroenterol Motil 2016 (doi: 10.1111/nmo.12833) on a series of patients with multiple sclerosis and bowel dysfunction (of which 33% had faecal incontinence as predominant symptom) using Peristeen transanal irrigation over a follow-up that averaged over 3 years. Here, the mean weekly frequency of episodes of faecal incontinence fell significantly ($p < 0.005$) from 4.8 (range 1–21) at baseline to 0.9 (range 0–7) at follow-up. Additionally, two cost-effectiveness studies have been published based on the use of Peristeen transanal Irrigation in patients with neurogenic bowel dysfunction. The first one, by Christensen et al (2009) called *Cost-effectiveness of transanal irrigation versus conservative bowel management for spinal cord injury patients* was published in Spinal Cord (2009) 47, 138–143. The second one, based on a larger patient population and with data and outcomes corresponding to a UK NHS setting, was published in 2016 by Emmanuel A et al. in PLOS ONE with the title *Long-Term Cost-Effectiveness of Transanal Irrigation in Patients with Neurogenic Bowel Dysfunction* (available on Open Access from PLOS ONE | DOI:10.1371/journal.pone.0159394). The later, based on 227 UK adult patients with neurologic conditions such as spinal cord injury, multiple sclerosis and cauda equina, predicted cost-savings for the NHS when comparing Peristeen transanal irrigation with failing	

		standard bowel care over a lifetime of a patient. This same study pointed out to a reduction in faecal incontinence episodes which was superior in the patients using Peristeen. **Comment 4**: The current guideline uses the term “Anal irrigation” throughout. We believe that this should be replaced with the term “Transanal irrigation” or its abbreviation “TAI” for describing this procedure, as these are commonly used in clinical literature.	

Do you know of a suitable resource for information on toilet access cards? **Please see 'Footnote 10' in section 'Editorial amendments' in the consultation document for further information**			
Stakeholder	**Overall response**	**Comments**	**NICE response**
THD (UK) Ltd	No response	Other than the ones already mentioned in the footnote, no	Thank you for your comment.
3M UK PLC	No	No comment provided	Thank you for your response.
Bladder and Bowel UK	Yes	Available from Bladder and Bowel UK (other organisations also offer Just cant wait cards)	Thank you for your comment. We will consider this as a possible source for amending the cross-reference in footnote 10.
Paediatric Continence Forum	No	No comments provided	Thank you for your response.
Royal College of Nursing	No	No comments provided	Thank you for your response.
Cogentix Medical	No response provided	No comments provided	Thank you for your response.
Renew Medical UK	No	No comments provided	Thank you for your response.
Coloplast A/S	No	No comments provided	Thank you for your response.

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Do you know of a suitable resource for information on Radar keys? **Please see 'Footnote 11' in section 'Editorial amendments' in the consultation document for further information**			
Stakeholder	**Overall response**	**Comments**	**NICE response**
THD (UK) Ltd	No response	No, however a quick google provides a range of options to obtain one	Thank you for your comment. We will consider this when deciding on possible sources for amending the cross-reference in footnote 11.
3M UK PLC	No	No comment provided	Thank you for your response.
Bladder and Bowel UK	No response provided	Online mobility retailers, other charitable and other organisations offer / sell these and they are available by a number of online sellers. sometimes provided with some prescription delivery services	Thank you for your comment. We will consider this as a possible source for amending the cross-reference in footnote 11.
Paediatric Continence Forum	No	No comments provided	Thank you for your response.
Royal College of Nursing	No	No comments provided	Thank you for your response.
Cogentix Medical	No	No comments provided	Thank you for your response.
Renew Medical UK	No	No comments provided	Thank you for your response.
Coloplast A/S	No	No comments provided	Thank you for your response.

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Do you have any comments on areas excluded from the scope of the guideline?			
Stakeholder	**Overall response**	**Comments**	**NICE response**
THD (UK) Ltd	No	No comments provided	Thank you for your response.
3M UK PLC	No	No comments provided	Thank you for your response.
Bladder and Bowel UK	No	No comments provided	Thank you for your response.
Paediatric Continence Forum	No	No comments provided	Thank you for your response.
Royal College of Nursing	No	No comments provided	Thank you for your response.
Cogentix Medical	No response provided	No comments provided	Thank you for your response.
Renew Medical UK	No	No comments provided	Thank you for your response.
Coloplast A/S	Yes	**Comment 5**: We would like to bring to your attention how women suffering from obstetric (post vaginal delivery) faecal incontinence have very specific needs as a result of their injuries. In some cases their faecal incontinence is permanent and it is worthwhile noting how many of these individuals are young, productive but unable to contribute to society because of their condition. As a result of low	Thank you for your comment. The guideline recommends (recommendation 1.2.3) that people with the obstetric trauma should have condition-specific interventions before healthcare professionals progress to initial management of faecal incontinence.

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		awareness within themselves and among healthcare professionals, some are not even offered the range treatment options to alleviate their symptoms. Similarly, their care has to be provided by a multidisciplinary team of pelvic floor specialists including gynaecologists, colorectal surgeons and physiotherapists. For this reason, we suggest that a separate CG is developed for the care and management of faecal incontinence as a result of 3rd and 4th degree anal tearing in childbirth. As there are ongoing studies being done with the NHS, NICE can link up with these organisations on the production of a CG. Comment 6: On the penultimate paragraph in the Surveillance proposal consultation document about medication for diarrhoea, we would like to point out that in the current guideline, patients with diarrhoea from any cause are considered a high-risk group. In NHS England's guidance document Conditions for which over the counter items should not routinely be prescribed in primary care: A consultation on guidance for CCGs https://www.england.nhs.uk/medicines/conditions-for-which-over-the-counter-items-should-not-routinely-be-prescribed/, it was decided that diarrhoea is a condition that is suited to self-care and therefore medication will not be prescribed by the NHS. With regards to the impact of this policy move to CG49, there needs to be consideration in instances when a patient self-medicates, does not receive any support and finds that his condition worsens which may lead to surgical intervention. This is especially true in vulnerable patients who may not have the skills to articulate the distress they feel. It is important for CG49 to note that in these rare cases, patients should continue to be monitored by health services and offered other treatment options should there be no improvement in their condition.	We welcome any new evidence on interventions that have a particular role in faecal incontinence as a result of obstetric trauma. However, we have not identified any evidence indicating that the management of people with faecal incontinence due to obstetric injury differs from that due to other causes. Therefore, a separate guideline in this area is not justified. In addition, NICE guidelines are commissioned by the Department of Health and Social Care, and the department would need to give NICE due instruction to develop a new guideline. We welcome any new evidence on interventions that have a particular role in faecal incontinence as a result of obstetric trauma. Ongoing studies that we identify, or receive notification about, will be assessed for the potential to impact on the guideline. We will track studies meeting this criterion and check for publication on a regular basis. If new evidence with an impact on recommendations is identified at any time, we may decide to update the guideline outside of the usual surveillance cycle. The guidance on conditions for which over the counter items should not routinely be prescribed in primary care applies to acute diarrhoea only. Although the guideline does not specify that diarrhoea or loose stools from any cause are considered a chronic condition, we do not expect that clinicians would be confused by the differing needs of patients with acute versus chronic diarrhoea. Therefore, we see no reason that people with diarrhoea and faecal incontinence would not receive appropriate treatment within the NHS.

Do you have any comments on equalities issues?			
Stakeholder	**Overall response**	**Comments**	**NICE response**
THD (UK) Ltd	No	No comments provided	Thank you for your response.
3M UK PLC	No	No comment provided	Thank you for your response.
Bladder and Bowel UK	No	No comments provided	Thank you for your response.
Paediatric Continence Forum	No	No comments provided	Thank you for your response.
Royal College of Nursing	No	No comments provided	Thank you for your response.
Cogentix Medical	No response provided	No comments provided	Thank you for your response.
Renew Medical UK	No	No comments provided	Thank you for your response.
Coloplast A/S	Yes	Comment 7: Due to the taboo, stigma and shame associated with having faecal incontinence, many with the condition face some form of discrimination in society and the workplace. The protected characteristics found in the Equality Act 2010, in particular, those pertaining to age, disability and pregnancy/maternity, mean that due consideration must therefore be given to people suffering from chronic constipation and acute faecal incontinence	The guideline on faecal incontinence aims to improve the physical and mental health and quality of life of people with this condition. The Equalities Act 2010 has guidance on matters to be taken into account in determining questions relating to the definition of disability. It notes that difficulty carrying out activities associated with toileting, or caused by frequent minor incontinence would be reasonably regarded as having a substantial adverse effect on normal day-to-day activities.

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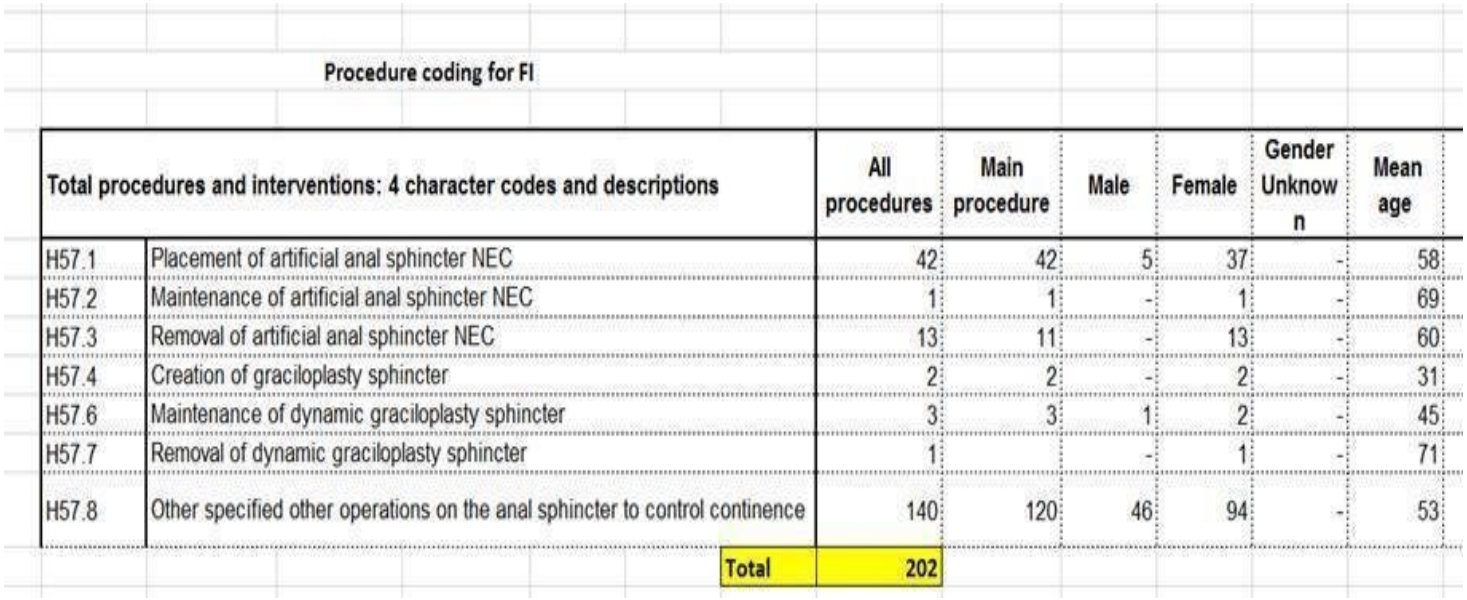
		who fall within these three categories. It is our expressed view that these individuals must have the same access to timely, safe and high quality care (including access to mental health support to deal with their symptoms) as would any citizen. Additionally, specific patient populations affected by faecal incontinence due to neurologic conditions (such as spinal cord injury, multiple sclerosis and others) often suffer an underlying disability as direct consequence of their condition, and are therefore at risk of double discrimination (disability + faecal incontinence). This highlights the need for specific guidelines and pathways to address bowel dysfunction in these patients.	Therefore, we consider that many people with faecal incontinence will already be protected by the Equality Act 2010. The guideline has recommendations aimed at specific groups, and we have found no evidence to inform new recommendations.

Figure 1 Procedures and interventions for faecal incontinence

(©NHS Digital 2018)



Procedure coding for FI

Total procedures and interventions: 4 character codes and descriptions		All procedures	Main procedure	Male	Female	Gender Unknown	Mean age
H57.1	Placement of artificial anal sphincter NEC	42	42	5	37	-	58
H57.2	Maintenance of artificial anal sphincter NEC	1	1	-	1	-	69
H57.3	Removal of artificial anal sphincter NEC	13	11	-	13	-	60
H57.4	Creation of graciloplasty sphincter	2	2	-	2	-	31
H57.6	Maintenance of dynamic graciloplasty sphincter	3	3	1	2	-	45
H57.7	Removal of dynamic graciloplasty sphincter	1		-	1	-	71
H57.8	Other specified other operations on the anal sphincter to control continence	140	120	46	94	-	53
	Total	202					

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