

National Institute for Health and Care Excellence

8-year surveillance (2017) – [Constipation in children and young people](#) (2010) NICE guideline CG99

Appendix B: stakeholder consultation comments table

Consultation dates: 11 to 26 April 2017

Do you agree with the proposal not to update the guideline?			
Stakeholder	Overall response	Comments	NICE response
Action for Sick Children Scotland	Yes	No comments	Thank you.
Western Health and Social Care Trust	No	No comments	Thank you.
Coeliac UK	Yes	The recommendation 1.3.2 to test for coeliac disease is in line with the NICE guideline for recognition, assessment and management of coeliac disease (NG20) which recommends that serological testing for coeliac disease is offered to people with persistent unexplained abdominal or gastrointestinal symptoms.	Thank you for your comment and for highlighting that CG99 recommendations are in line with the NICE guideline for recognition, assessment and management of coeliac disease (NG20).
Blackpool Teaching Trust	No	Evidence around the use of probiotics needs to be considered. Lactulose should be discontinued.	<p>Thank you for your comment regarding the use of probiotics. We considered new evidence on the use of probiotics for the management of idiopathic constipation in this surveillance review. We found that the evidence was limited by conflicting reports from small trials with short follow-up periods. Furthermore, during guideline development the topic experts felt it was not possible to recommend specific probiotics due to a lack of consistent evidence. Further research is needed before considering probiotics for inclusion in the guideline.</p> <p>Thank you for your comment regarding the use of lactulose. The guideline currently advises adding lactulose only if stools are hard and also after a stimulant laxative has been substituted (if PEG is not tolerated by the child). Recommendations on the use of lactulose</p>

			therefore provide alternative strategies if first-line treatment is unsuccessful. We identified new evidence which questioned the effectiveness of lactulose when used alone, however as our guidance does not recommend treatment with lactulose alone it was deemed unlikely to impact the guideline.
Bladder and Bowel UK	No	<p>It would appear that transanal irrigation was not considered when evidence was assessed for review of the guideline (National Institute for Health and Care Excellence Surveillance Programme, Surveillance proposal consultation document pg 2, assessing the evidence: https://www.nice.org.uk/guidance/CG99/documents/surveillance-review-proposal)</p> <p>Transanal irrigation is increasingly used as an option for intractable functional constipation with soiling in children. However, some areas are now considering withdrawing this option from care. Having it included in the NICE guidance would mean that this effective option remains available nationally for those children for whom other treatments have not been fully effective and prior to considering ACE.</p> <p>There is an increasing body of evidence for the effectiveness of this treatment.</p> <p>If successful transanal irrigation negates the need for ACE, avoiding risks from anaesthetic, post-op infection, stenosis of the catheterisable channel, surgical reversal, scarring and of hospital admission for the surgical procedure. All of these can be more traumatic for a child and their family as well as being more expensive for the NHS.</p>	<p>Thank you for your comment relating to trans-anal irrigation.</p> <p>A small amount of evidence on trans-anal irrigation was identified in the literature search however these studies were not originally included as they did not meet our inclusion criteria on study type. These have now been added to Appendix A: Summary of evidence from surveillance.</p> <p>It is noted that this is an area of research that shows promising results for the treatment of constipation in this population, however the findings are considered too preliminary at this point to have an impact on guidance. Until the safety and efficacy of trans-anal irrigation is confirmed in this population by consistent reports from a reliable evidence base, it is unlikely that the guideline will be impacted. In the meantime NICE are currently developing medical technologies guidance on 'The Peristeen anal irrigation system to manage bowel dysfunction' and we will review this area again at the next surveillance point.</p>
British Academy of Childhood Disability	Yes	No comment	Thank you.
Royal College of Paediatrics and Child Health	No answer	<p>Our reviewers advised that the newly generated evidence should be incorporated to the guideline.</p> <p>They felt that the document is well written and the proposal is timely. The commentators suggested that it would be useful if NICE audited how well previous guidelines have been used and influenced patient care. Their concern is in primary care and the long winded nature of them that makes them poorly accessible to GPs. The reviewer advised that in their opinion, RCPCH recognises well the problem of</p>	<p>Thank you for your comment. NICE do not carry out their own audits on how well previous guidelines have been used and influenced patient care. However, we do have a designated Adoption and Impact Team which produces tools and signposts to other support that can help organisations put guideline recommendations into practice. There is also an Implementation Support Team which works with external organisations on selected priority areas, which depend on the interests</p>

		managing childhood conditions in primary care and lack of input from paediatricians compared to Europe. They have suggested that NICE could re-consider any issues identified in regards to the previous guidelines and release 1-2 page long summaries suitable for GPs that can be easily accessed and used.	of our partner organisations and resources. Also, implementation consultants from the Field Team work with local organisations to promote the guideline. We have passed on your comment to this team for further consideration.
Royal College of Nursing	Yes	No comment	Thank you.
Paediatric Continence Forum (PCF)	No	<p>The PCF believes that an emerging body of evidence on the use of transanal irrigation (TAI) for children and young people with constipation provides reason to update this guideline. TAI can be used as an alternative to ACE, avoiding the need for the more intensive and expensive treatment that ACE offers. As the guideline does not refer to TAI, this provides reason to update it.</p> <p>Although published after NICE's original literature review, Mosiello G et al (2017), Consensus review of best practice of transanal irrigation in children JPGN 64, 3, 343-52 draws together much of this evidence and concludes that TAI offers an alternative treatment for bowel dysfunction which has not responded to traditional treatments, albeit with some uncertainty on the use of TAI in children.</p> <p>In the discussion of the ACE procedure there is no reference to the influence of the anatomical site of the ACE stoma or tube (i.e. caecum versus distal colon), nor technique (i.e. open versus endoscopic placement. Rawat DJ et a. Percutaneous endoscopic colostomy of the left colon: a new technique in the management of intractable constipation in children. Gastrointest Endosc 2004; 60: 39-43. Blackburn SC et.al. The first 5-year follow-up of distal antegrade continence enema stoma</p>	<p>Thank you for your comment and for highlighting references on trans-anal irrigation and the ACE procedure. It is noted that this is an area of research that shows promising results for the treatment of constipation in this population, however the findings are considered too preliminary at this point to have an impact on guidance. Until the safety and efficacy of trans-anal irrigation is confirmed in this population by consistent reports from a reliable evidence base, it is unlikely that the guideline will be impacted. In the meantime NICE are currently developing medical technologies guidance on 'The Peristeen anal irrigation system to manage bowel dysfunction' and we will review this area again at the next surveillance point.</p> <p>The study by Mosiello et al., 2017 was identified through the literature search. However, this study was excluded because it did not meet the inclusion criteria for study type because it is a consensus review. In this review and in the original protocol of the guideline, this study type was not considered.</p> <p>The study by Rawat et al., 2004 was not identified through the surveillance review because it was published outside of the literature search cut-off dates and was available for consideration when the guideline was developed.</p>
Leicestershire Partnership NHS Trust	No	No comment	Thank you.
ERIC, the Children's Bowel and Bladder Charity	No	The current Guideline makes no mention of Trans-anal Irrigation (TAI) – also known as Rectal washout or Bowel washout. The current advice is to go straight from conservative measures to an ACE (Antegrade Continence Enema). This is a surgical intervention	<p>Thank you for your comment and for highlighting the reference on trans-anal irrigation.</p> <p>It is noted that trans-anal irrigation is an area of research that shows promising results for the treatment of constipation in this population</p>

		<p>and therefore both invasive and costly, and should be regarded as a last resort for the vast majority of patients.</p> <p>When the Guideline was published in 2010 TAI was already being used, but the selection of equipment available was small, and little evidence had then been published. ERIC believes that the Guideline should be updated to reflect the range of equipment now in regular use, and the papers which have been written in the intervening years.</p> <p>Clinicians on the ERIC Professional Advisory Committee believe that all children should be offered a range of options, but using a step-by-step approach, continuing to explore until the child's symptoms are optimally managed but with the least invasive, most cost effective method.</p> <p>ERIC believes that note should be taken of the recent publication Mosiello G et al (2017), Consensus review of best practice of transanal irrigation in children JPGN 64, 3, 343-52, which suggests that TAI offers an alternative treatment for bowel dysfunction which has not responded to traditional treatments.</p>	<p>and 'Appendix A: Summary of evidence from surveillance' has been amended to reflect this. However after carefully considering the new evidence, we decided that the findings are too preliminary at this point to have an impact on guidance. Many of the studies are limited by small sample sizes and lack of comparator groups. Until the safety and efficacy of trans-anal irrigation is confirmed in this population by consistent reports from a reliable evidence base, it is unlikely that the guideline will be impacted.</p> <p>In the meantime NICE are currently developing medical technologies guidance on 'The Peristeen anal irrigation system to manage bowel dysfunction' and we will review this area again at the next surveillance point.</p> <p>The study by Mosiello et al., 2017 was identified through the literature search. However, this study was excluded because it did not meet the inclusion criteria for study type because it is a consensus review. In this review and in the original protocol of the guideline, this review type was not considered.</p>
<p>NHS England Clinical reference Group Specialised Paediatric Medicine</p>	<p>Yes</p>	<p>It was stated in the review of 2014 that further evidence was required before the use of rectal irrigation treatment should be included in this guideline.</p> <p>There have been additional reports of trans anal irrigation since 2014 that could be considered. The guideline may not necessarily justify a revision until further research is published on the indications, long-term benefits and potential harm of this treatment in children with idiopathic constipation. The indications for treatment would need defining, for example, in which patients it should be considered (such as before an ACE procedure), and if it should be prescribed by a specialist only.</p> <p>1. The first study below was available in February 2017. It may have been published after February 2 when your review was completed.</p> <p>Reading the abstract, I cannot determine if the included population had taken an optimum amount of medicine for an appropriate time</p>	<p>Thank you for your comment and for highlighting references on trans-anal irrigation.</p> <p>It is noted that trans-anal irrigation is an area of research that shows promising results for the treatment of constipation in this population and 'Appendix A: Summary of evidence from surveillance' has been amended to reflect this. However after carefully considering the new evidence, we decided that the findings are too preliminary at this point to have an impact on guidance. Many of the studies are limited by small sample sizes and lack of comparator groups. Until the safety and efficacy of trans-anal irrigation is confirmed in this population by consistent reports from a reliable evidence base, it is unlikely that the guideline will be impacted.</p> <p>In the meantime NICE are currently developing medical technologies guidance on 'The Peristeen anal irrigation system to manage bowel</p>

	<p>with adequate support but information on indications for treatment in this group may be available in the full paper.</p> <p><u>J Pediatr Gastroenterol Nutr.</u> 2017 Feb; 64 (2): 225-229. doi: 10.1097/MPG.0000000000001236.</p> <p>Trans anal Irrigation in the Treatment of Children With Intractable Functional Constipation.</p> <p><u>Koppen IJ1, Kuizenga-Wessel S, Voogt HW, Voskeuil ME, Benninga MA.</u></p> <p>OBJECTIVES: The aim of the study was to assess the treatment efficacy of trans anal irrigation and parental satisfaction in children with intractable functional constipation (FC) treated with Peristeen.</p> <p>METHODS: Cross-sectional survey study among parents of children (age 0-18 years) treated with Peristeen for FC (based on the Rome III criteria). Anonymous questionnaires were sent out to parents via mail, these consisted of 25 self-developed, multiple-choice questions regarding the use of Peristeen, current gastrointestinal symptoms, adverse effects of Peristeen, concomitant medication use, and parental satisfaction.</p> <p>RESULTS: Out of 91 invited families, 67 (74%) returned the questionnaire. In total, 84% of patients experienced fecal incontinence prior to treatment. Out of all children who still used Peristeen at the time of survey (n=49), fecal incontinence had resolved completely in 41%, 12% experienced occasional episodes of fecal incontinence (<1 episode per week) and the remaining 47% still experienced episodes of fecal incontinence regularly (≥1 time per week). A total of 28 children (42%) experienced pain during rectal irrigation, especially during insertion of the catheter, inflating the balloon, or during irrigation. Overall, 86% of the parents were satisfied with the result of trans anal irrigation and 67% reported that they would continue using trans anal irrigation for the treatment of their child's symptoms.</p> <p>CONCLUSIONS: Trans anal irrigation may be effective in the treatment of children with FC and renders a high parental satisfaction. Future prospective studies, preferably RCTs, are necessary to further evaluate this treatment option.</p> <p>2. The second study below considers treatment for children with resistant constipation and was published after your review date and so I presume it would not be considered in the assessment?</p> <p><u>Eur J Pediatr.</u> 2017 Apr 12. doi: 10.1007/s00431-017-2902-3. [Epub</p>	<p>dysfunction' and we will review this area again at the next surveillance point.</p> <p>The study by Koppen et al., 2017 was identified in the literature search for the surveillance however it was excluded because it did not meet the inclusion criteria for study type. We have since considered this study and added a summary of the findings to 'Appendix A: Summary of evidence from surveillance'. Results from this paper indicate that although parental satisfaction with this procedure was high, a large proportion of the children who were treated still experienced episodes of fecal incontinence as well as pain during the procedure. These results were derived from a cross-sectional survey and authors did not report any formal statistical comparisons. Due to the uncertainty of these findings, this study was not considered to have an impact on the guideline.</p> <p>The study by Jørgensen et al., 2017 was not identified through the surveillance review because it was published after the literature search cut-off date. This is a retrospective study that aimed to evaluate the feasibility and efficacy of trans-anal irrigation in the treatment of functional faecal impaction in 63 children with a mean age of 9.2. Results of this study indicated that a large proportion of children (73%) achieved complete remission of incontinence episodes. The authors did not report any formal statistical results on the effectiveness of the procedure and it is unclear whether there were any adverse effects. The study had no comparator group. Due to the preliminary nature of these findings, this study was not considered to have an impact on the guideline.</p> <p>The study by Ng et al., 2015 was identified in the literature search. However, this study was excluded because it did not meet the inclusion criteria for study type because it is an observational study. We have since considered this study and added a summary of the findings to 'Appendix A: Summary of evidence from surveillance'. The study examined the response rates and quality of life outcomes for 42 patients aged under 17 years who commenced trans-anal irrigation for constipation. This was a retrospective database study where 62% of the patients had idiopathic constipation. Results indicated that quality of life scores were significantly improved after trans-anal irrigation.</p>
--	--	--

		<p>ahead of print] Trans anal irrigation is effective in functional fecal incontinence. <u>Jørgensen CS1, Kamperis K2, Modin L3, Rittig CS2, Rittig S2.</u></p> <p>Functional fecal incontinence (FFI) is divided into cases related to functional constipation (FC) and cases without concomitant constipation termed functional non-retentive fecal incontinence (FNRFI). Trans anal irrigation (TAI) is widely used in children with neurogenic fecal incontinence but is less studied in children with functional defecation disorders. The aim was to evaluate the feasibility and efficacy of TAI in the treatment of FFI. A retrospective study in 72 children (mean age 9.2 ± 2.2 years, 47 males) with treatment-resistant FFI was performed. All children accepted treatment and 35% (n = 25) were titrated to daily sessions. Of the 63 children who fulfilled the Rome III criteria of constipation, 46 (73%) showed full response with complete remission of incontinence episodes. Eleven (17%) showed partial response (≥50% reduction). Of nine children with FNRFI, four (44%) showed full response whereas two (22%) showed partial response. We found no significant difference in the reduction of incontinence episodes between the children with FC (87%) and children with FNRFI (68%) (p = 0.11).</p> <p>CONCLUSION: TAI is an effective, well tolerated, and safe choice in children with FC. No clinical parameters seemed to predict response to treatment. The number of children with FNRFI was low, but TAI seemed effective in this group of children. What is Known: • Functional fecal incontinence (FFI) is a frequent, chronic condition with significant impact on children's quality of life. • Transanal irrigation (TAI) is used in children with neurogenic bowel dysfunction but less studied in children with functional defecation disorders. What is New: • TAI seems an effective, well-tolerated, and safe choice in children with FFI due to functional constipation. • Albeit the number of children with functional non-retentive fecal incontinence was low in our study, TAI seems effective also in this group of children.</p> <p>3. The study below from 2015 includes children with various underlying diagnoses: idiopathic constipation (62%), anorectal malformation (26%), Hirschsprung disease (5%), spina bifida (5%) and gastroschisis (2%). The full paper may separate outcomes from the different groups so that interpretation of results in idiopathic constipation may be possible.</p>	<p>Response rates suggested that a larger proportion of patients adopted the treatment (compared to those who stopped within 1 month after commencement). Out of those who adopted the treatment, a larger proportion were classed as responders (defined as totally continent or occasional soiling). The method of analysis is unclear however and significance is not stated for these differences. The results of this study were considered too preliminary to impact the guideline and the population was only partially relevant as just 62% of the participants had idiopathic constipation.</p> <p>Taken together, although the studies highlighted were considered to show some promising results, the potential for the studies to impact guidance is limited. Small sample sizes, lack of comparator groups, weak study designs and imprecise populations make the results too preliminary to have an impact on guidance at this point. However, we have decided to withdraw our proposal to place this guideline on the static list, enabling us to actively monitor this area going forward.</p>
--	--	--	--

		<p>Pediatr Surg Int. 2015 Aug;31(8):729-34. doi: 10.1007/s00383-015-3735-7. Epub 2015 Jul 11.</p> <p>Transanal irrigation for intractable faecal incontinence and constipation: outcomes, quality of life and predicting non-adopters.</p> <p><u>Ng J1, Ford K, Dalton S, McDowell S, Charlesworth P, Cleeve S.</u></p> <p>PURPOSE: Intractable faecal incontinence (FI) and constipation is a challenging condition to manage in children. Transanal irrigation (TAI) is a non-operative treatment option. This study presents our experience with TAI with the aim of finding predictive factors of non-compliance.</p> <p>METHODS: This is an outcome and quality of life (QoL) study of a prospectively maintained database of patients < 17 years old commenced on TAI for intractable FI/constipation between 2008 and 2014. Outcome measures were: (1) compliance-classified as non-adopter (use of TAI stopped within 1 month after commencement) or adopter; (2) functional outcome-classified as responder (totally continent or occasional soiling) or non-responder; (3) Rintala score; and (4) QoL score (PedsQL™ 4.0 Generic Core Scale). Analysis to determine predictive factors was also performed.</p> <p>RESULTS: 42 patients were started on TAI [74% male, median age of commencement was 7 (3-16) years]. Underlying diagnoses were: idiopathic constipation (62%), anorectal malformation (26%), Hirschsprung disease (5%), spina bifida (5%) and gastroschisis (2%). Median follow-up period was 14 (3-78) months. 24% were non-adopters. 84% of the adopters responded to treatment. Rintala scores (mean ± SD) pre- and post-TAI were 6.7 ± 3.5 and 11.2 ± 4.8, respectively (P < 0.001). QoL scores pre- and post-TAI were 55.6 ± 24.1 and 65.5 ± 23.7, respectively (P < 0.001). Median age at which TAI was commenced in the non-adopter and adopter group were 6 (IQR 4.5-8.25) and 8 (IQR 7-12), respectively (P = 0.008).</p> <p>CONCLUSION: TAI is a safe and effective treatment for intractable constipation/FI in children. If tolerated, it can significantly improve quality of life. Age and underlying diagnosis are important factors when recommending TAI to children with intractable FI/constipation</p>	
--	--	---	--

Do you agree with the proposal to put the guideline on the static list?

Stakeholder	Overall response	Comments	NICE response
-------------	------------------	----------	---------------

Action for Sick Children Scotland	Yes	No comments	Thank you.
Western Health and Social Care Trust	No	No comments	Thank you. After considering all stakeholder responses, we have decided not to place this guideline on the static list.
Leeds Children's Hospital	No	No comments	Thank you. After considering all stakeholder responses, we have decided not to place this guideline on the static list.
Coeliac UK	Yes	No comments	Thank you.
Blackpool Teaching Trust	No answer	No comment	Thank you.
Bladder and Bowel UK	No	There is an increasing body of evidence for TAI in functional constipation. This evidence does not appear to have been evaluated by NICE	Thank you for your comment. Please see our above response to you regarding the evidence on trans-anal irrigation. We recognise that there is an increasing body of evidence around the use of trans-anal irrigation for the treatment of constipation in children and young people. We have therefore withdrawn our proposal to place the guideline onto the static list and will review this area at the next surveillance point.
British Academy of Childhood Disability	Yes	No comments	Thank you.
Royal College of Paediatrics and Child Health	No answer	No comment	Thank you.
Royal College of Nursing	Yes	No comment	Thank you.
Paediatric Continence Forum (PCF)	No	Constipation is a widespread and easily preventable issue among children, with new evidence and treatment options consistently emerging. The PCF therefore believes it would not be advisable to place this guideline on the static list and remove the possibility of reviewing it for five years, which would be to the disadvantage of a substantial number of children and young people across the UK.	Thank you for your comment. We have taken stakeholders' comments into account and we recognise that there is an increasing body of evidence around the use of trans-anal irrigation for the treatment of constipation in children and young people. We have therefore withdrawn our proposal to place the guideline onto the static list and will review this area at the next surveillance point.

Leicestershire Partnership NHS Trust	No	<p>7 years since the publishing of the last guidelines (evidence update in 2014) so some content to be reviewed/ updated such as first line treatment re medication and referring to current BNFC and not BNFC 2009 as cited in document.</p> <p>Consideration of emerging evidence eg use of prescription probiotics and Milk of Magnesia</p>	<p>Thank you for your response on whether you agree with the proposal to put the guideline on the static list. After considering all stakeholder responses, we have decided not to put this guideline on the static list.</p> <p>Thank you for your comments on the recommendations around medication and the BNFC. As part of this surveillance review, we examined the guidance taken from the BNFC and are not aware of any discrepancies in this information. Further advice was also sought from members of the previous guideline committee group and colleagues within NICE who were able to confirm this. However, we plan to make some minor editorial corrections to ensure statements on medical availability and manufacturer information is accurate and up-to-date.</p> <p>Thank you for your comment on the emerging evidence around probiotics and milk of magnesia. We did consider evidence on probiotics in this surveillance review. We found that the evidence was limited by conflicting reports from small trials with short follow-up periods. Furthermore, during guideline development the topic experts felt it was not possible to recommend specific probiotics due to a lack of consistent evidence. It was decided that further research is needed before considering probiotics for inclusion in the guideline.</p> <p>Regarding the use of milk of magnesia, the new evidence identified in the literature search indicated that it was not as effective as polyethylene glycol in the treatment of constipation, which is what the guideline currently recommends. Please see 'Appendix A: Summary of evidence from surveillance' for full details.</p>
ERIC, the Children's Bowel and Bladder Charity	No	<p>Constipation is highly prevalent in the UK, and if not effectively treated can cause a significant negative impact on a child or young person's life. ERIC believes that all children and young people (CYP) should be offered the most up-to-date assessment and treatment of this debilitating condition.</p> <p>Care of CYP with constipation improved dramatically after CG99 was published in 2010. Being able to refer to the Nice Guideline means both parents and professionals can commend best practice, and effect change.</p>	<p>Thank you for your comment. We have taken stakeholders' comments into account and we recognise that there is an increasing body of evidence around the use of trans-anal irrigation for the treatment of constipation in children and young people. We have therefore withdrawn our proposal to place the guideline onto the static list and will review this area at the next surveillance point.</p>

		It is vital that the Guideline is reviewed regularly, and is not placed on the static list, so new evidence can be incorporated in a timely manner.	
NHS England Clinical reference Group Specialised Paediatric Medicine	No	Further evidence may be available in the short term that may merit a review.	Thank you for your response. After considering all stakeholder responses, we have decided not to put this guideline on the static list.

Do you have any comments on areas excluded from the scope of the guideline?

Stakeholder	Overall response	Comments	NICE response
Action for Sick Children Scotland	Yes	Children and young people whose constipation is secondary to other health problems but still equally significant to their health and wellbeing and often overlooked when they are attending specialist services for specific organ related review.	<p>Thank you for your comment. The final scope of the guideline states that newborns, infants and children who have constipation with a known cause will not be covered.</p> <p>The principles of assessment and management covered in the guideline can apply to children whose constipation may be secondary to other health problems (such as underlying, congenital, genetic, metabolic, endocrine or neurological disorders). Individual clinicians may choose to extrapolate the guidance in CG99 to children and young people whose constipation is secondary to other health problems, but they should be aware that this involves extrapolation from, not direct application of, CG99.</p>
Western Health and Social Care Trust	Yes	The use of bowel irrigation systems for the management of chronic constipation needs to be reviewed. There is new evidence available that suggests that this is an effective management of constipation in all children and not just those with neurological disorders. It should be trialled before a child would be considered for ACE procedure.	<p>Thank you for your comment on the use of bowel irrigation systems. It is noted that this is an area of research that shows promising results for the treatment of constipation in this population, however the findings are considered too preliminary at this point to have an impact on guidance. Until the safety and efficacy of trans-anal irrigation is confirmed in this population by consistent reports from a reliable evidence base, it is unlikely that the guideline will be impacted. In the meantime NICE are currently developing medical technologies guidance on 'The Peristeen anal irrigation system to manage bowel dysfunction' and we will review this area again at the next surveillance point.</p>

Leeds Children's Hospital	No answer	No comments	Thank you.
Coeliac UK	No	No comment	Thank you.
Topic expert June Rogers	No	No comment	Thank you.
Blackpool Teaching Trust	Yes	There is no mention of bowel irrigation, only ACE. We need to retain bowel irrigation.	<p>Thank you for your comment on the use of bowel irrigation systems. It is noted that trans-anal irrigation is an area of research that shows promising results for the treatment of constipation in this population and 'Appendix A: Summary of evidence from surveillance' has been amended to reflect this. However after carefully considering the new evidence, we decided that the findings are too preliminary at this point to have an impact on guidance. Many of the studies are limited by small sample sizes and lack of comparator groups. Until the safety and efficacy of trans-anal irrigation is confirmed in this population by consistent reports from a reliable evidence base, it is unlikely that the guideline will be impacted.</p> <p>In the meantime NICE are currently developing medical technologies guidance on 'The Peristeen anal irrigation system to manage bowel dysfunction' and we will review this area again at the next surveillance point.</p>
Bladder and Bowel UK	Yes	<p>Transanal irrigation is not currently included in NICE guidance as an option when other treatments have failed to elicit sustained improvement to symptoms. Rather, the guidance goes straight to ACE. As a surgical procedure ACE is not without possible risks and is traumatic for child and their family.</p> <p>There is evidence that the use of transanal irrigation in children may negate the need for ACE. There is an increasing body of evidence about the safety and efficacy for transanal irrigation, including in children with intractable idiopathic constipation.</p> <p>A particularly relevant publication is:</p> <ul style="list-style-type: none"> Mosiello G et al (2017) <i>Consensus review of best practice of transanal irrigation in children</i> JPGN 64, 3, 343-52 	<p>Thank you for your comment and for highlighting references on trans-anal irrigation. It is noted that trans-anal irrigation is an area of research that shows promising results for the treatment of constipation in this population and 'Appendix A: Summary of evidence from surveillance' has been amended to reflect this. However after carefully considering the new evidence, we decided that the findings are too preliminary at this point to have an impact on guidance. Many of the studies are limited by small sample sizes and lack of comparator groups. Until the safety and efficacy of trans-anal irrigation is confirmed in this population by consistent reports from a reliable evidence base, it is unlikely that the guideline will be impacted.</p>

		<p>Other relevant publications include:</p> <ul style="list-style-type: none"> • Christensen P (2016) <i>From misbelieve to proofs in transanal irrigation for functional bowel problems</i> P. Tech Coloproctol 20:609.doi:10.1007/s10151-016-1510-y (accessed online 26.3.17) • Ng J et al (2015) <i>Transanal irrigation for intractable faecal incontinence and constipation: outcomes, quality of life and predicting non-adopters</i> Paed Surg Int 31, 729-734 • Nasher O et al (2014) <i>Peristeen transanal irrigation system for paediatric faecal incontinence: a single centre experience</i> International Journal of Pediatrics http://dx.doi.org/10.1155/2014/954315 	<p>In the meantime NICE are currently developing medical technologies guidance on 'The Peristeen anal irrigation system to manage bowel dysfunction' and we will review this area again at the next surveillance point.</p> <p>The study by Mosiello et al., 2017 was identified through the literature search. However, this study was excluded because it did not meet the inclusion criteria for study type because it is a consensus review. In this review and in the original protocol of the guideline, this review type was not considered.</p> <p>The study by Christensen et al., 2016 was not identified through the literature search. However, as the paper is an editorial, this is not an evidence type that would meet the inclusion criteria for a surveillance review and therefore cannot be considered in this review.</p> <p>The study by Ng et al., 2015 was identified in the literature search. However, this study was excluded because it did not meet the inclusion criteria for study type because it is an observational study. We have since considered this study and added a summary of the findings to 'Appendix A: Summary of evidence from surveillance'. The study examined the response rates and quality of life outcomes for 42 patients aged under 17 years who commenced trans-anal irrigation for constipation. This was a retrospective database study where 62% of the patients had idiopathic constipation. Results indicated that quality of life scores were significantly improved after trans-anal irrigation. Response rates suggested that a larger proportion of patients adopted the treatment (compared to those who stopped within 1 month after commencement). Out of those who adopted the treatment, a larger proportion were classed as responders (defined as totally continent or occasional soiling). The method of analysis is unclear however and significance is not stated for these differences. The results of this study were considered too preliminary to impact the guideline and the population was only partially relevant as not all of the participants had idiopathic constipation.</p>
--	--	--	--

			<p>The study by Nasher et al.2014 was identified through the literature search and was considered during the previous consultation in 2014. The results reported in the abstract indicated that all patients had an improvement in their faecal continence score with some increase in quality of life scores. This was a small scale (n=13) retrospective study and, from an assessment of the abstract, there was no evidence that the included population had taken an optimum amount of medicine for an appropriate time with appropriate support before undertaking trans-anal irrigation treatment. As such, it would be pertinent to await further research on the long-term benefits and harms of this management option in children with idiopathic constipation before considering for inclusion in the guideline.</p> <p>In summary, some of the studies highlighted were considered to show promising results on the use of trans-anal irrigation in children and young people with constipation. However, the potential for the studies to impact guidance is limited by the preliminary nature of the findings and the lack of controlled trials in this area.</p>
British Academy of Childhood Disability	No	No comment	Thank you.
Royal College of Paediatrics and Child Health	No	No comment	Thank you.
Royal College of Nursing	No	No comment	Thank you.
Paediatric Continence Forum (PCF)	Yes	<p>As referenced above, the absence of TAI in the NICE guideline is something which we believe should be amended. The experience of the PCF's clinical supporters indicates that some CCGs are blacklisting TAI despite its benefits for many children. The inclusion of TAI in this guideline would give clinicians a stronger argument for its use. Publications considering the use of TAI include:</p> <ul style="list-style-type: none"> Christensen P (2016), <i>From misbelieve to proofs in transanal irrigation for functional bowel problems</i> P. Tech Coloproctol 20:609.doi:10.1007/s10151-016-1510-y 	<p>Thank you for your comment. Please see the response to your comment above regarding how we have since considered the evidence on the use of trans-anal irrigation (including the highlighted papers by Christensen et al., Ng et al., and Nasher et al.).</p> <p>Thank you for highlighting the consensus document. This is not an evidence type that meets our inclusion criteria and therefore we are unable to consider this study in the surveillance review.</p>

		<ul style="list-style-type: none"> • Ng J et al (2015), <i>Transanal irrigation for intractable faecal incontinence and constipation: outcomes, quality of life and predicting non-adopters</i> Paed Surg Int 31, 729-734 • Nasher O et al (2014), <i>Peristeen transanal irrigation system for paediatric faecal incontinence: a single centre experience</i> International Journal of Pediatrics <p>Additionally, a number of PCF member organisations were involved in the development of a consensus document on guidance for the provision of continence containment products to children and young people. Consideration of this document would be relevant to the section of the guideline focusing on the management of constipation in children and young people, which does not evaluate containment products.</p> <p>This consensus document is available at https://www.eric.org.uk/Handlers/Download.ashx?IDMF=d1ca5737-a1a8-4612-83af-19a8789e195f.</p>	
Leicestershire Partnership NHS Trust	Yes	<p>Further and more detailed evidence based information regarding the use of abdominal massage as a form of prevention and management of chronic idiopathic constipation</p> <p>Clarity/ specificity re titration of medication guidance. Current content reads “gradually reduce the dose over a period of months in response to stool consistency and frequency”.</p>	<p>Thank you for your comment on the use of abdominal massage. We did not find any evidence at any surveillance point on abdominal massage for the management of constipation in children and young people. Therefore this treatment is not included in our guidance.</p> <p>Thank you for your comment regarding details on the titration of medication. As this guideline covers the treatment of children and young people up to the age of 18, guidance on reducing the specific dosages was not appropriate given the wide range of outcomes possible. Recommended maintenance dosages are given in Table 4 and clinicians are expected to use their own judgement during regular follow-up visits to determine how best to reduce medications over time, as this is likely to vary between individual patients.</p>
ERIC, the Children’s Bowel and Bladder Charity	Yes	<p>As mentioned in point 1, ERIC feels that the exclusion of TAI from the Guideline is no longer appropriate. Various articles have been published since 2010: Christensen P (2016), From misbelieve to proofs in transanal irrigation for functional bowel problems P. Tech Coloproctol 20:609.doi:10.1007/s10151-016-1510-y Ng J et al (2015), Transanal irrigation for intractable faecal incontinence and constipation: outcomes, quality of life and predicting non-adopters Paed Surg Int 31, 729-734</p>	<p>Thank you for your comment. Please see the response to your comment above regarding how we have since considered the evidence on the use of trans-anal irrigation (including the highlighted papers by Christensen et al. and Nasher et al.).</p>

		Nasher O et al (2014), Peristeen transanal irrigation system for paediatric faecal incontinence: a single centre experience International Journal of Pediatrics ERIC is aware of funding for TAI being withdrawn in a number of areas across the UK. This is puzzling as use of TAI can reduce costs of oral laxatives, enemas/suppositories and containment products, as well as reducing the need for ongoing outpatient appointments for poorly managed constipation. Inclusion in the NICE Guideline would commend use of TAI and enable practitioners to promote its use via GP prescription.	
NHS England Clinical reference Group Specialised Paediatric Medicine	No	No comment	Thank you.

Do you have any comments on equalities issues?

Stakeholder	Overall response	Comments	NICE response
Action for Sick Children Scotland	Yes	<p>The recommendations for frequent review of the effect of treatment does not indicate who should review and this is the commonest reason in my experience for treatment failure. The necessary resources and linked services that can ensure the family is offered consistent knowledgeable advice and support must be prioritised if this guidance is to be effective. In particular the assessment of response to treatment, adjustment in dose of laxative and behavioural support for the child are essential components of clinical management. This must include family but also education and care staff where appropriate.</p> <p>There should also be mention of the additional needs of children with motor disabilities who may have more difficulty in using toilets or tolerating higher fibre diets and whose additional needs may make them vulnerable to constipation, inadequate fluid intake and mechanical difficulties in toileting.</p>	<p>Thank you for your comment. The guideline is aimed at healthcare professionals and the families and carers of children and young people with idiopathic constipation. Section 1.8 of the guideline makes detailed recommendations on the importance of providing tailored follow-up to children and their families and offering multiple forms of information and support. General recommendations on the safe and effective use of medicines can be found in the NICE guideline on medicines optimisation: the safe and effective use of medicines to enable the best possible outcomes (NG5, published 2015). NICE guideline NG5 contains detailed advice on medicines reconciliation and medication review which should complement CG99 recommendations.</p> <p>The guideline was developed to be relevant to all newborns, infants and children up to their 18th birthday who have idiopathic constipation. When exercising their judgement, professionals are expected to take this guideline fully into account, alongside the individual needs, preferences and values of their patients or service users. The application of the recommendations in this guideline is not mandatory and the guideline does not override the responsibility of healthcare</p>

			professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or their carer or guardian.
Western Health and Social Care Trust	No	No comment	Thank you.
Leeds Children's Hospital	No answer	No comments	Thank you.
Coeliac UK	No	No comment	Thank you.
Topic expert June Rogers	No	No comment	Thank you.
Blackpool Teaching Trust	Yes	More research is required for children with neurodevelopmental issues and constipation.	Thank you for your comment. It is not within the scope of the guideline to make a research recommendation on children with neurodevelopmental issues and constipation as this would be covered by other NICE guidance.
Bladder and Bowel UK	No	No comment	Thank you.
British Academy of Childhood Disability	No	No comment	Thank you.
Royal College of Paediatrics and Child Health	No	No comment	Thank you.
Royal College of Nursing	No	No comment	Thank you.
Paediatric Continence Forum (PCF)	No	No comment	Thank you.
Leicestershire Partnership NHS Trust	No	No comment	Thank you.
ERIC, the Children's Bowel and Bladder Charity	No	No comment	Thank you.

NHS England Clinical reference Group Specialised Paediatric Medicine	No	No comment	Thank you.
--	----	------------	------------