National institute for Health and Care Excellence

Medical technologies evaluation programme

MT315 – Peristeen anal irrigation system for managing bowel dysfunction

Consultation comments table

Final guidance MTAC date: November 17 2017

There were 43 consultation comments from 18 consultees (9 NHS professionals and 1 healthcare professional from the private sector, 3 manufacturer representatives, 3 healthcare industry representatives [from companies manufacturing comparator devices], 1 professional society and 1 patient organisation). The comments are reproduced in full and are arranged in the following groups – corrections, children, functional bowel disorder, user experience, other TAI devices, frequency of use, cost and adverse events.

#	Consultee number and group	Sec. no.	Comment	Response
Theme: corrections				
1	6. Manufacturer	4.11, Page 9, Line 11	Current text - The company has a staff of 20 nurses in the UK that provide training for patients and for continence specialists who prescribe Peristeen. Coloplast currently have we have 13 Peristeen Advisors (bowel specialist nurses) plus a nursing team of 45 that can be mobilised to support patients and provide training. Corrected text - The company has a staff of 13 bowel specialist nurses (Peristeen advisors) plus a nursing team of 45 in the UK that provide training for patients and for NHS bowel specialists who prescribe Peristeen.	Thank you for your comment. The committee decided to change section 4.11 to refer to a 'team of nurses' because the actual number will change over time.
2	12. NHS professional	4.11, Page 9	Rather than continence specialist who prescribes Peristeen, Peristeen is mostly prescribed/ started by a dedicated specialist Health Care Professional.	Thank you for your comment. Section 4.11 has been changed in response to this comment.
3	6. Manufacturer	4.12, Page 9, Line 17	Current text - The committee was advised that Peristeen is usually prescribed by specialist continence teams, but that there is a need for improved awareness of transanal irrigation in the NHS as a treatment option for bowel dysfunction. Peristeen does not have to be continually prescribed by a specialist continence team and once the patient is trained with Peristeen, the ongoing prescribing can be done in primary care where there is access to specialist services. We would suggest the following wording - The committee was advised that prescription of Peristeen is usually initiated by a dedicated bowel specialist who have received specific bowel care education and training in relation to transanal irrigation (TAI).	Thank you for your comment. Section 4.12 has been changed to reflect the arrangements described by the consultee.

			Ongoing prescribing can be done in primary care with access to specialist services. There is a need for improved awareness of transanal irrigation in the NHS as a treatment option for bowel dysfunction.	
4	2. NHS professional	4.12	refers to specialist continence teams and instead should say specialist teams as it may be taught by individuals who are not based in continence teams such as myself, physios etc	Thank you for your comment. Section 4.12 has been changed in response to this comment.
Theme: children				
5	15. Professional organisation	4.6-4.7 Page 8	1. This response has been drafted on behalf of the PCF, an independent national campaigning group, which was set up in 2003 to improve awareness amongst policymakers of the needs of children and young people with continence problems and to improve NHS services in this often-neglected area of child health. The PCF has formal representation from expert clinicians, the charities ERIC and Bladder and Bowel UK, as well as the Royal College of Nursing, the Royal College of Paediatrics and Child Health, the Community Practitioners' and Health Visitors' Association and the School and Public Health Nurses' Association. 2. The PCF also has five company members that support our work. One of these is Coloplast Ltd, the producer of the Peristeen anal irrigation system. The PCF would like to emphasise that while Coloplast has had sight of this response after its completion, it has not had any input into or opportunity to comment on the content prior to its submission. This response was produced by the PCF's clinical members who have experience of using Peristeen, with no involvement from our company members. 3. The PCF agrees with the document's assertion that evidence around the use and effectiveness of Peristeen in children is varied, but believes that this should not prevent transanal irrigation, whether with Peristeen or other irrigation systems from being used in children. The PCF made similar assertions in a previous response to the consultation on the proposal for ˜no update' to the NICE guideline on constipation in children and young people, submitted in April 2017. 4. Chronic idiopathic (functional) constipation can usually be successfully treated with appropriate laxatives, as per the NICE Guidance (CG99). However, a small number of children with idiopathic constipation continue to soil and CG99 recommends progression along a pathway to ACE procedure. Although a decision has been taken to have a further review on whether to include transanal irrigation when there is more evidence on its use, clinical experience confirms a role for irrigation in children who are not responding to treatment, prior to consideration of a surgical option (ACE procedure). 1. For children with constipation secondary to anorectal malformation, Hirschsprung's disease or neurogenic bowel, transanal irrigation is a long-established treatment, having been documented thirty years ago, as follows: Shandling B, Gilmour RF. 1987 The enema Continence catheter in spina bifida: successful bowel managementJournal of pediatric surgery. 22: 271-3. According	Thank you for your comment. The committee considered this comment carefully, alongside others about the use of Peristeen in children. It decided to change sections 1, 2 and 3 of the guidance to include children within the scope of the recommendation for technology adoption.

			to Google this work is cited in 144 related articles. The Shandling enema was the forerunner of Persiteen and other modern transanal irrigation systems. While its primary use was in children with spina bifida, particularly those with a negative anocutaneous reflex and therefore no anal sphincter tone, it was also useful for children with high congenital anorectal anomalies, resulting in an ineffective anal sphincter. 5. The experience of some of the PCF's clinical supporters is that some CCGs are blacklisting all transanal irrigation (including Peristeen) in spite of its benefits for adults and children with intractable faecal soiling. The inclusion of guidance on the use of Peristeen in children in these recommendations would highlight to clinicians that transanal irrigation should be an option available to children and young people with soiling secondary to constipation and/or congenital or acquired bowel dysfunction, as part of a pathway of bowel management. 6. To avoid bias the PCF believes that NICE should acknowledge the existence of other transanal irrigation systems and consider evidence for their use in children with faecal incontinence, for whom other treatments have been ineffective. Evidence not reviewed by NICE includes: Koppen I et al (2017) Transanal Irrigation in the Treatment of Children With Intractable Functional Constipation.Journal of pediatric gastroenterology and nutrition; Feb 2017; vol. 64 (no. 2); p. 225-229, and Jorgensen C et al (2017) Transanal irrigation is effective in functional fecal incontinence. European Journal of Pediatrics; Jun 2017; vol. 176 (no. 6); p. 731-736. 7. We believe that transanal irrigation should be considered prior to formation of a stoma (colostomy or ileostomy) or an ACE procedure as it negates the need for general anaesthetic and formation of a catheterisable channel, with the associated financial costs, potential problems including infection and stenosis, the need for surgical reversal and impact of altered body image. Children do not appear to have the same high drop-out rate shortly after starting as has been reported in adults. As transanal irrigation is commenced at a young age in many children with neurogenic bowel and is often only needed for a period of months in children with intractable functional constipation, it must represent significant cost savings as compared to surgical alternatives. 8. Point 4.6 of this consultation document highlights that children who had used Peristeen were able to maintain bowel control that allowed them to attend school. As well as the impact on education, soiling is associated with a great deal of social stigma, with children experiencing bullying and avoiding social situations. As the consultation document has recognized the benefits of Peristeen for some children in enabling them to go to school regularly and socialise with their peers, the PCF believes that this provides grounds for transanal irrigation to be utilised for children where other treatment methods have been unsuccessful, whilst further high-quality research is undertaken. Furthermore, the PCF would be	

			happy to contribute to a group for expert opinion and experience while that research is awaited.	
6	4. NHS professional	general	It seems little Paediatric Consultant consultation has been completed in this review, Peristeen is used a lot for children with Neuropathic conditions such as Spina Bifida, preventing ACE procedures and colostomies. However recently we have used it with children with Functional Chronic constipation, this has most definitely prevented children having to use Phosphate Enemas, and colostomies. it provides a better quality of life, reduces the need to wear pads or nappies. Children can be taught how to do themselves. if the use of Peristeen was to stop then many children would have to go through surgical procedures.	Thank you for your comment. Please refer to the response to comment 5.
7	13. NHS professional	general	1. Has all the relevant evidence been taken into account? We don't think that all relevant evidence has been taken into account, in particular for paediatric patients. Evidence that has been omitted in the assessment include: - Jessica Ng et al. Transanal irrigation for intractable faecal incontinence and constipation: outcomes, quality of life and predicting non-adopters. Pediatric Surgery international 2015 (DOI 10.1007/s00383-015-3735-7) - Costigan et al. Transanal irrigation in children: 3 years in practice of the peristeen system. Gastrointestinal Nursing Supplement 2014; 12 (2):7-11 - Etherson et al. Transanal irrigation for refractory chronic idiopathic constipation: patients perceive a safe and effective therapy. Gastroenterology Research and Practice 2014 (http://dx.doi.org/10.1155/2017/3826087) - Mosiello et al. Consensus review of best practice of transanal irrigation in children. JPGN 2017; 64: 343-352 - Marte et al. Transanal irrigation and intestinal transit time in children with myelomeningocele. Minerva Pediatric 2013; 65:1 - JÃ¸rgensen CS1 et al. Transanal irrigation is effective in functional fecal incontinence. Eur J Pediatr 2017; 176(6):731-736 Local experience: - Sanders and Bray. Examining professionals' and parents' views of using transanal irrigation with children: Understanding their experiences to develop a shared health resource for education and practice. Journal of Child Health Care 2013 (DOI: 10.1177/1367493512474866) - Bray and Sanders. An evidence-based review of the use of transanal irrigation in children and young people with neurogenic bowel. Spinal Cord 2013; 51: 88-93 - Sanders et al. Parents of children with neurogenic bowel dysfunction: their experiences of using transanal irrigation with their child. Child Care Health and Development 2013; 40: 863-869 - Governance process in place locally: http://www.alderhey.nhs.uk/wp-content/uploads/2013/04/Rectal_Irrigation_Toolkit.pdf	Thank you for your comment. Please also refer to the response to comment 5. During the development of the assessment report, the EAC identified the papers by Ng (2015), Etherson (2017), Marte (2013), Mosiello (2015), Sanders (2013a), Sanders (2013b) and Bray (2013) but excluded them from further consideration, mainly because they included multiple devices and did not allow results to be extracted for Peristeen. Costigan (2014) was not identified by the manufacturer or EAC, and was appropriate for inclusion. The EAC produced a summary of this paper for presentation at the final guidance meeting, however, no additional information was added to the guidance as this was not a pivotal study. Jørgensen (2017) was not identified, but would have been excluded as it did not include Peristeen. The local experience papers were identified but excluded. Sanders et al (2013) was in scope, but was excluded during the writing up phase, as no outcomes were appropriate for extraction to data summary tables. The paper reports semi-structured interviews with parents whose children use Peristeen.

			We agree that the quality of evidence in paediatric is poor. However, this is often the case for the majority of clinical studies in children due to the difficulty in getting a decent sample size for an RCT and the challenge in obtaining valid patient reported outcome measures from children. However, the additional evidence provided above has strongly reflected practice-based evidence to support the use of transanal irrigation in children. This has not been considered in the appraisal document.	
8	13. NHS professional	general	2. Are the summaries of clinical effectiveness and resource savings reasonable interpretations of the evidence? The summaries of clinical effectiveness and resource savings may be reasonable for adults, but doesn't apply for children. The cost of bowel management in children is higher compare to that of in adults. The actual savings that can be made from a tertiary paediatric centre is as below: Standard Bowel Care Annual cost per child: Medication Â£185, Anal plug Â£820 (Â£44.89 for 20 units), Incontinence pads Â£310 (Â£5.95 for 7 pads), Healthcare Professional Visits: - General Paediatric clinic (every 3 months) Â£215 (new), Â£136 (follow-ups) approx. Â£623 pa, - Gastro Paediatric clinic (every 3 " 6 months) Â£232 (new), Â£146 (follow-ups), approx. Â£524 pa, - Paediatric Dietitian (every 8 weeks) Â£136 (each appointment), approx. Â£816 pa - Specialist Continence Nurse in primary care (every 4 " 6 weeks) Average Â£19.44 an hour; approx. Â£233 pa, -Total cost of healthcare professional visits: Â£2196 per annum (on average), Carer time (2 to 3 hours daily), £10,950 (average Â£30 a day), Adverse events See below Treatment costs Cost per single episode (weighted average tariffs at Alder Hey), UTI admission Â£1,180, A&E admission for manual faecal evacuation (under general anaesthetics) Â£1,055, A&E admission for constipation / impaction needing oral treatments / enema Â£95 - Â£575 (ward admission), A&E admission for anal fissure as a result of unmanaged constipation Â£95 - Â£575 (ward admission), A&E admission for possible complex complication [admission and surgery stoma] Â£761, Pressure ulcer admission Â£1,021, Sacral Nerve stimulation Â£2,576 (+ any device costs), Antegrade continence enema surgery Â£1,239,	Thank you for your comment. Please also refer to the response to comment 5. The cost model submitted by the company only considered adults with neurogenic bowel dysfunction due to a spinal cord injury. The decision to limit to this population was made by the company and it was understood that the company judged that no suitable data were available to construct a similar model for a paediatric population. The costs provided by the consultee were helpful to the committee but were not sufficient to allow additional cost modelling in children.

			Ileostomy Â£14,700, Colostomy Â£5,300, Associated stoma care Â£11,055	
9	13. NHS professional	general	3. Are the provisional recommendations sound, and a suitable basis for guidance to the NHS? The provisional recommendations have excluded children. Based on our local experience and other published evidence provided, the indications should be extended from neurogenic bowel dysfunction to faecal incontinence and chronic constipation in children.	Thank you for your comment. Please refer to the response to comment 5.
10	13. NHS professional	general	4. Are there any equality issues that need special consideration and are not covered in the consultation document? The decision to exclude paediatric patients in the appraisal will influence the commissioners (CCGs) for not funding the device in children. We have nearly 10 years' experience in using transanal irrigation in paediatrics. Any negative statement from NICE will have a detrimental effect for our patients. Another aspect that NICE has not considered in children is around attendance at school (lost days due to social or physiological issues). This could be related to children refuse to go to school or schools are reluctant to have these children, as a result of inadequate funding for care provision and the extra cost for changing facilities. This can also limit access to the full curriculum which is discriminatory in line with the disabilities act. Carers/parents may lose employment opportunity as they may be the child's sole care provider. We feel that the appraisal should look into transanal irrigation system as a whole, including other products e.g. Qufora as well as IrypumpÂ® to allow options for patients. This will also avoid a single supplier in the market and create competition by allowing other products entering the market.	Thank you for your comment. Please refer to the response to comment 5. NICE medical technologies guidance evaluates a single medical technology based on the claimed advantages of introducing the specific technology compared with current management of the condition. The guidance recommendations are preceded by explanatory text which states that the specific recommendations in the medical technologies guidance on individual technologies are not intended to limit use of other relevant technologies which may offer similar advantages.
11	15. Professional organisation	general	The UK Paediatric Colorectal Group registered as stakeholders for this guidance and I have written a report summarising our experience of using Peristeen and suggestions for this review. This document has been submitted seperately to medtech@nice.org.uk	Thank you for your comment. This comment included a link to a document which is included in the appendix. Please see response to comment 5.
12	16. Professional organisation	general	Dear Medtech As registered stakeholder in the Peristeen anal irrigation system for managing bowel dysfunction NICE guidance consultation I would like to submit a report on behalf of the UK Paediatric Colorectal Group. I have made a brief statement of this intention on the comments section of the consultation page but need to submit our report in full to you. Please find the report attached. I would be very grateful for an acknowledgement of receipt. Many thanks	Thank you for your comment. This comment included a link to a document which is included in the appendix. Please see response to comment 5.
Theme: functional bowel disorder				
13	6. Manufacturer	4.5, Page 8, Line 11	Current text - The clinical experts explained that people with neurogenic bowel dysfunction are most likely to benefit from Peristeen, but that some people with other types of long-term bowel dysfunction and with limited treatment options may also find it effective. There are several studies that have demonstrated the	Thank you for your comment. The EAC noted that the assessment report includes details of the following papers that consider non-neurogenic patients. For adults:

			benefit of TAI (using Peristeen) in patients with functional bowel disorders (Grainger et al, 2017, submitted as AIC; Etherson et al, 2017). It may be of use to these patients to highlight in the guidance that they may also benefit from TAI. We would like to suggest the following wording - The clinical experts explained that people with neurogenic bowel dysfunction are most likely to benefit from Peristeen, but that some people with other long-term bowel dysfunction, such as functional constipation may also benefit from Peristeen. There is additional evidence for the use of Peristeen demonstrating plausible benefits for patients with functional bowel disorders.	Chan (2011), Grainger (2017), Rosen (2011), Whitehouse (2010) and for children: Corbett (2014), Koppen (2017), Marzheuser (2016), Midrio (2015), Pacilli (2014). Etherson (2017) was excluded as it reports results for several devices grouped together. The assessment report did not highlight which papers were for non-neurogenic bowel dysfunction. The committee decided to change sections 1, 2 and 3 of the guidance to include people with bowel dysfunction of any cause.
14	2. NHS professional	1.1, 4.5	patient selection refers to neurogenic Bowel but irrigation is used in particular very well with chronic constipation/ slow transit. Would always consider irrigation before surgical intervention such as a stoma.	Thank you for your comment. Please see response to comment 13.
15	1. NHS professional	2.3	Transanal irrigation reduces the need for other treatments in ALL functional bowel disorders not just neurogenic bowel. It also reduces the numbers of admissions through A&E which can result in an average of 3 day stay whilst the bowels are sorted out.	Thank you for your comment. Please see response to comment 13.
Theme: User experience				
16	1. NHS professional	Page 2	Some patients do have difficulties and find irrigation complicated. However, this can be said for any medical device, people learn at different rates and need different levels of support. The vast majority of our patients get on well and do not experience any problems at all.	Thank you for your comment. Section 4.12 has been reworded to describe the support required by people starting transanal irrigation.
17	1. NHS professional	4.5	Patient selection needs to take account of the patients engagement and motivation, as well as their ability both mentally and physically to use the system you are offering them.	Thank you for your comment. Section 4.12 has been reworded to describe the support required by people starting transanal irrigation.
18	1. NHS professional	4.12	Peristeen is started by a nurse, physio or physiologist within primary or secondary care. The most important thing is that they have been trained to train patients on the device they are showing them. It is also very important that they know who is to follow the patient up.	Thank you for your comment. Section 4.12 has been reworded and now refers to specialist healthcare professional and describes ongoing support for people using transanal irrigation.
19	2. NHS professional	4.13	suggests that irrigation will often take time to teach. In some cases this is true but more often then not it will only involve 1 face to face appointment and then the patient can be followed up by phone.	Thank you for your comment. Section 4.12 has been reworded to describe the support required by people starting transanal irrigation.
20	6. Manufacturer	4.13, Page 9, Line 22	Current text – The clinical and patient experts explained that Peristeen should be offered as part of a supportive bowel care programme. People using Peristeen should have training from a specialist continence nurse. The experts noted that it takes most people a few months to get used to Peristeen, and that throughout this time they need ongoing support from the specialist nurse. Even after someone is confident	Thank you for your comment. The committee discussed the support required by people starting transanal irrigation with the clinical and patient experts and amended the wording of section 4.12.

			with using Peristeen, they still need access to a professional support system (such as easily accessible contact details of a specialist nurse) to provide ad hoc advice as needed. As stated, Peristeen does have to be delivered within a supportive bowel care programme and that the Peristeen trainer needs to have completed specialised training in order to train the patient. In addition, Coloplast provides a telephone support service for patients who are new to Peristeen and this, in conjunction with the bowel specialist nurses within the NHS, can continue to support the patient with their use of Peristeen. We would suggest the following wording - The clinical and patient experts explained that Peristeen should be offered as part of a supportive bowel care programme and must include training from a dedicated specialist, who has received specific bowel care education and training in TAI. The experts noted that it is not uncommon for some patients to take a few months to get used to Peristeen, and that throughout this time they need ongoing support from a specialist nurse. This is provided by the company who have a dedicated telephone support for patients starting on Peristeen, in addition to a nursing team. Even after someone is confident with using Peristeen, they still need access to a professional support system (such as easily accessible contact details of a specialist nurse) to provide ad hoc advice as needed.	
21	6. Manufacturer	4.14, Page 10, Line 1	Current text - The patient experts commented that the support of dedicated specialists was essential to their being able to use Peristeen effectively. They added that they would have found a patient support group helpful. The committee noted clinical and patient expert advice that people using Peristeen initially need regular contact with a specialist continence nurse but over time, they may only require access to occasional and ad hoc advice. Coloplast provides customers with access to specialist Peristeen support nurses and a dedicated telephone support programme. Suggested changes to text " The patient experts commented that the support of dedicated specialists was essential to their being able to use Peristeen effectively. They added that they would have found a patient support group helpful. The committee noted clinical and patient expert advice that people using Peristeen initially need regular contact with a bowel specialist nurse but over time, they may only require access to occasional and ad hoc advice. The manufacturers have both a team of specialist nurses and also offer support through a dedicated telephone support programme for ad hoc advice.	Thank you for your comment. The committee decided to change section 4.12 and removed the last sentence of section 4.13 to clarify its consideration on patient support.
22	1. NHS professional	general	ALL patients should have initial training by a person who has been trained to use and demonstrate trans anal irrigation. This could be a specialist physiotherapist, physiologist or specialist nurse. It may also be within primary or secondary care. ALL patients should have a structured follow up and support plan in place. We phone our patients after a week then after a month and see them in clinic after	Thank you for your comment. Section 4.12 has been reworded to describe the support required by people starting transanal irrigation.

			3months, then 6 months then 1 year. They have our number to ring if there are any difficulties and we can bring them in sooner if needed.	
23	18. NHS professional	general	In St Helens and Knowsley NHS Trust have developed a pelvic floor team over the last eighteen months. The team consists of: - Colorectal consultants who have a specialist interest in patients with pelvic floor issues - Urology consultant - Gynaecologist - Urogynaecologist (From a neighbouring trust) - Care of the elderly consultant and - Rehab/head injury consultant - Urology continence nurse specialist, - Colorectal pelvic floor nurse specialist, - physiotherapist with a specialised interest in pelvic floor issues. We also have input from all continence teams in the surrounding areas. We all meet on a monthly basis to discuss patients who may need specialist input with complex needs. Majority of the patients we see are referrals from GPs with bowel and bladder issues. Within my role as colorectal pelvic floor nurse specialist I see patients with ongoing bowel problems which range from: - Neurogenic patients (MS Parkinson's) - previous bowel resections - sphincter damage (previous childbirth or surgical treatment) - chronic constipation - Faecal seepage. We follow a pathway for each patient which will include dietary and lifestyle advice review of medication and referring them for tests such as manometery proctagrams colonoscopies sigmoidoscopies, Transit studies. Irrigation is just one of the treatments we offer to our patients. Patients are seen by me, in my clinics each new patient is given an hour appointment to asses them and give them the information and education on the irrigation system they are going to use. The system is decided on by assessing each patient on their presenting problem and which system will suit their needs best in this trust we offer Aquaflush all systems, Qufora all systems, Peristeen, Braun and Novina both systems. They are given my contact details so they can contact me when needed they are then seen again in six weeks and will continue to have follow up appointments until we feel they are confident and stable enough to be discharged back to their GP.Within our trust we have had a really good response to TAI, patients reporting that they now have a better quality of life feel more confident and clean. There are some patients whom have been able to return to work as they can now manage their bowel problem in a more predictable way as many medications can be very unpredictable and have very varied side effects many have actually stopped using these medications. Patients have also reported that	Thank you for your comment. The guidance now refers to specialist healthcare professionals throughout the document. The amended recommendations now include people with non-neurogenic causes of bowel dysfunction. The availability of other transanal devices and importance of choice is noted in section 4.9. Section 4.12 has been reworded to better describe the support required by patients.

			they now do not need to use continence pads, Creams to help with sore ulcerated and excoriated perineal area; many have either stopped or reduced medications for depression and anxiety. It is felt that TAI is a safe manageable way to help patients manage their ongoing bowel issues. Many patients may be able to avoid or delay surgery for stomas, ileostomies and A.C.E procedures. All of these interventions do carry an ongoing cost implication to GPs and medicine management, due to hospital admissions and the cost that that entails. Also the costs of stoma bags, creams, pastes, mickey buttons, syringes and dressings. Since starting this new service I have seen patient's quality of life change immensely due to Trans anal irrigation. We have also been able to reduce emergency admissions with constipation and currently developing pathways to use irrigation to avoid A&E admissions. This project includes the community continence teams as well. We were due to take part in the capacity study but unfortunately due to the CCG withdrawing funding we have had to withdraw from the study this study was to provide evidence on the use of high verses low flow irrigation systems. We at Whiston feel that irrigation is a good tool that will avoid pts needing unnecessary surgical interventions in the form of a stoma and better quality of life. This also means that there might be cost saving but also to the society as the patients are able to return to work.	
Theme: other TAI devices				
24	2. NHS professional	4.1	why is NICE just consulting on 1 manufacture and their device, should they not be looking at rectal irrigation as a whole and the benefits it brings to patients i.e. Low volume rectal irrigation, large volume such as Peristeen and the Navina classic and then electric irrigation pumps such as the Navina Smart.	Thank you for your comment. In the development of medical technologies guidance the case for adoption of a single medical technology is evaluated based on the claimed advantages of introducing the specific technology made by the company at notification, compared with current management of the condition. It is not a multiple technology assessment and does not compare evidence for all similar or comparator technologies. The recommendations in the guidance are not meant to limit use of other relevant technologies which may offer similar advantages. These principles are described in further detail in the medical technologies evaluation programme methods guide, and in the block of text at the beginning of the medical technology guidance. In section 4.9 of the guidance the committee noted the existence of alternative technologies and the important of choice for this patient group and section 1.2 states that Peristeen may not be suitable for all patients.

25	3. Healthcare industry (other)	4.1	We would be pleased to supply information on the Qufora IrriSedo range including the positive cost comparisons.	Thank you for your comment. Please see response to comment 24.
26	3. Healthcare industry (other)	1.2	'Peristeen can be difficult to use' . This is why a choice is important for patients as some may find a different product easier.	Thank you for your comment. Please see response to comment 24.
27	3. Healthcare industry (other)	general	TAI/Rectal Irrigation is now used widely in the UK for functional and neurogenic bowel management. However, the principle of instilling water into the rectum and then evacuating it with the stool is a procedure that has been used for many thousands of years. The first drug tariff approved medical device for TAI was Peristeen in 2007. Hence, it was the product used for much of the initial research. However, since then more products (including more cost effective and water volume options) have been launched. This has enabled health care professionals to choose the correct product for their patients needs. Some patients do not require a catheter based system, so the cost can be lowered and it can be easier for the patient to use. Options now include low volume irrigation e.g. Qufora IrriSedo Mini and high volume using a cone rather than a catheter e.g. Qufora IrriSedo cone irrigation. Plus a way of irrigating on the bed - Qufora IrriSedo bed system. There are also options of electronic versions of a catheter and a cone irrigation system. Many thousands of patients with functional and neurogenic bowel have benefited in using the Qufora IrriSedo irrigation range in the UK, including children. The choice of product is imperative for the health care professional. Therefore, we feel this document would be better titled 'Trans-anal/rectal irrigation for managing bowel dysfunction'. This would include functional bowel management.	Thank you for your comment. Please see response to comment 24.
28	7. NHS professional	general	My main concern is the use of "Peristeen" to describe trans anal irrigation, there are many products on the market which help with bowel evacuation, Peristeen is only one and as we know one product does not suit all people. Sure the wording should be Trans anal irrigation product?	Thank you for your comment. Please see response to comment 24.
29	8. Private sector professional	general	As a Specialist Nurse who sees predominantly patients requiring transanal irrigation, I think this proposal is too narrow in it's scope. There are many different irrigation products available on the market and professionals and patients should have the freedom to choose a product based on individual needs and assessment. Peristeen is indeed a good product, but does not suit every patient's needs. It is not cost-effective for patients who require smaller volume irrigation, in comparison with other products on the market (eg Qufora mini or Aquaflush compact), or for patients who are able to use a cone based system. There are also electronic systems on the market that can demonstrate further cost savings (eg Bbraun Irypump S). Whilst I am employed by a commercial company, I must stress that the company I work for do not manufacture any irrigation products, so I have no commercial interest in this decision and my comments are purely professional and personal, but in advocacy for my patients. My concern is this recommendation will exclude practitioners from using the most appropriate and cost-effective system for their patients. In addition, patients who	Thank you for your comment. Please see response to comment 24.

			may have benefited from a transanal irrigation system may dismiss it as too complicated for them as they are not being shown some of the simpler systems to use. Potentially this will increase the referrals for surgical interventions such as SNS, ACE and stoma formation. Thank you for considering my comments.	
30	9. NHS professional	general	Regarding anal irrigation - Peristeen is not the best system for every person - people need to be assessed on an individual basis and whichever irrigation system is easiest for them to use, should be prescribed. Peristeen is quite complicated for some people compared to the Quofora systems and B Braun systems.	Thank you for your comment. Please see response to comment 24.
31	10. NHS professional	general	Thank you for this very useful and much needed document. However, I would recommend that the emphasis is on trans-anal irrigation per se, and not a particular product. Kind regards.	Thank you for your comment. Please see response to comment 24.
32	14. Healthcare industry (other)	general	Medical Technology Guidance: Peristeen anal irrigation system for managing bowel dysfunction. In response to the consultation on the above draft guidance, Wellspect HealthCare would like to highlight the following points in the consultation document and associated reports. The innovations claimed in the External Assessment Centre report (section 2.1) and points raised in the consultation document (sections 2.6 and 4.10) that other Transanal Irrigation devices are available: Peristeen is no longer the only transanal irrigation product featuring a rectal balloon catheter and a constant-flow pump which is not gravity-based. Wellspect HealthCare manufacture two such systems, Navina Smart and Navina Classic, which have been available on drug tariff since September 2016. Section 2.4 in the Assessment report overview: some people may require help from a nurse or carer, particularly if they have limited mobility in their hands. The Navina Smart system features an electronic pump and touch-sensitive control unit to ensure it can be used independently by more people with reduced hand function. Section 4.11 in the consultation document regarding Coloplast's commitment to increase company nursing staff should the uptake of Peristeen increase: Wellspect HealthCare provide comprehensive educational resources to support patients and continence specialists who prescribe Navina Systems, including a CPD-accredited e-learning app, nursing support and telephone follow up. The Navina Smart system can also utilise the Navina Smart app to facilitate accurate, patient-specific follow-up and promote compliance. Please note, the cost of the Peristeen system and consumable pack have increased from those shown in the consultation document (section 2.2) to Â£76.28 and Â£132.95 respectively. Wellspect HealthCare welcomes this guidance as a way for NICE to ensure the therapy of Transanal Irrigation is made available to all those who may benefit from it. If you require any additional information please do not hesitate to contact me.	Thank you for your comment. Please see response to comment 24.
33	3. Healthcare industry (other)	2.1	Peristeen has a constant flow pump which does not rely on gravity so that the user does not need to hang the bag up for the water to flow'. The Qufora IrriSedo cone, balloon and bed systems are also use a pump to get the water in but have	Thank you for your comment. Please see response to comment 24.

			the advantage of being able to use gravity if the user prefers or is not able to use a pump.	
34	17. Patient organisation	general	- Peristeen is not the only form of Trans Anal Irrigation (TAI) and to avoid bias and to ensure an appropriate response, NICE should consider other forms as well. There is now a wider choice of TAI devices for patients. - TAI can potentially offer benefit for some adults / children with chronic constipation and/or faecal incontinence in general and for those with a neurological disability. - It is acknowledged that TAI is not considered first line bowel management, however for those who have tried, found ineffective, or exhausted conservative bowel treatment and management options, trans anal irrigation should be a considered bowel management option for some individuals. This can potentially bring improved quality of life, independence and predictable bowel management for adults and children experiencing difficulties. - Transanal irrigation has been used for soiling associated with anorectal malformations since 1987: Shandling B, Gilmour RF. 1987 The enema Continence catheter in spina bifida: successful bowel management Journal of paediatric surgery. 22: 271-3 and according to Google it is cited by 144 related articles. - Aware that some areas of the country are not allowing/restricting the prescribing of TAI (affecting both adults and children) . This appears to be across all irrigation devices, not just Peristeen. - If TAI is not allowed or restricted to be prescribed, there is a reduced chance of good quality research. - Faecal incontinence has significant impact on psychological, physical and emotional well being and can impact on socialisation, employment and education. TAI has a place in a treatment pathway. - Impact of alternative surgical procedures on body image, infection risk, herniation, stoma bag leakage etc as well as cost of appliances for stomas, admission costs for GA etc. - Further evidence not considered by NICE includes: Koppen I et al (2017) Transanal Irrigation in the Treatment of Children With Intractable Functional Constipation.Journal of pediatric gastroenterology and nutrition; Feb 2017; vol. 64 (no. 2); p. 225-229, Jorgensen C et al (2017) Transanal irrigation is effective in functional fecal incontinence. European Journal of Pediatrics; Jun 2017; vol. 176 (no. 6); p. 731-736, Mosiello G et al (2017) Consensus review of best practice of transanal irrigation in children JPGN 64, 3, 343-52	Thank you for your comment. Please see response to comment 24 with regards to other transanal irrigation devices. The EAC reviewed the evidence referred to here and noted that the assessment report includes details of the following papers that consider non-neurogenic patients; for adults: Chan (2011), Grainger (2017), Rosen (2011), Whitehouse (2010) and for children: Corbett (2014), Koppen (2017), Marzheuser (2016), Midrio (2015), Pacilli (2014). The assessment report did not highlight which papers were for non-neurogenic bowel dysfunction. Koppen (2017) was identified and included in the assessment report Jørgensen (2017) was not identified, but would have been excluded as it does not include Peristeen. Mosiello (2015) was identified and excluded as it was not possible to extract information related solely to Peristeen. The committee decided not to change the guidance.
Theme: frequency of use				
35	12. NHS professional	4.16	I recommend this addition to the end of the paragraph: Some patients will need to use Irrigation daily others may need to use it less often that alterative days.	Thank you for your comment. The committee decided not to change section 4.16 because use every other day is the expected average.

36	12. NHS professional	2.1 page 2	Should be recommended to be used a maximum of once daily. Can be used on alternative days or even less.	Thank you for your comment. Section 2.1 is a brief description of the technology and reports the frequency in the company's instructions for use. .
37	1. NHS professional	2.1	Irrigation should initially be used every day to establish a good bowel routine. It can then be reduced and it is generally used every other day, although some patients can use it less frequently.	Thank you for your comment. Please see response to comment 36.
38	6. Manufacturer	4.17, Page 10, Line 27	Current text - The committee noted the EAC's sensitivity analysis which showed that Peristeen would become cost incurring if it were to be used more often than 4 times per week. The patient experts stated that although they normally use the device every other day, there are times when they need to irrigate their bowels more frequently (such as when travelling or after a change in diet). There is both scientific and real world evidence that demonstrates that every other day is optimal for Peristeen use. In 2003, a scintigraphic study (Christensen P et al. Scintigraphic assessment of retrograde colonic washout, 2003,) showed in both spinal cord-injured (SCI) patients and in functional patients with idiopathic fecal incontinence, irrigation with 500ml achieves a complete or almost complete emptying of the rectum, sigmoid and descending colon. In these SCI patients, Krogh et al (Krogh K et al (2000). Gastrointestinal and segmental colonic transit times in patients with acute and chronic spinal cord lesions) showed that the time it would take for new stools to transit from the beginning of the descending colon and through the rectosigmoid is typically 2 days. We believe that this supports that, for neurogenic patients, the average time for a new stool to reach the rectum again would be 48 hours, hence making irrigation every other day an effective way of preventing leakage of faeces and constipation of the descending parts of the colon. For patients with functional constipation, a recent study from 2017 in the UK by Etherson et al, (Etherson K, Yanniokou Y et al. Transanal Irrigation for Refractory Chronic Idiopathic Constipation: Patients Perceive a Safe and Effective Therapy) demonstrated with patient reported outcomes an average frequency of irrigation of 3.7 irrigations/week (3.7 +/- 0.2) in the 102 patients included. Coloplast would also like to submit their CHARTER dataset to support the frequency of use. The information below is the property of Coloplast A/S and must be kept in a confidential manner. No unpublished information contained herein may be disclosed without prior written approval by Coloplast A/S. Data is sourced from the orders database (orders placed between 01 Apr and 30 Sep 2016) of the Coloplast Charter Dispensing Appliance Contractor (DAC), UK's largest DAC dispensing to around [redacted] of Peristeen users, of all kinds of baseline conditions (neurogenic and functional disorders, adult and children). The analysis only included orders from those customers who had previously placed at least one order including Peristeen rectal catheters, up to 2 years prior to the 6-month period of analysis. This inclusion criteria aims at selecting only customers who were well-adhered to the therapy with Peristeen. A frequency of	Thank you for your comment. The EAC noted that the studies by Christensen (2003) and Krogh (2000) are not considering the use of Peristeen and that Etherson (2017) was excluded from the assessment report as it does not present results for Peristeen alone. The manufacturer submitted a brief summary of data extracted during the period 01 Apr and 30 Sep 2016 which was presented to the committee at the final guidance meeting. This reported confidential sales data, resulting in an average use of 3.71 catheters per user per week. The manufacturer reports that the analysis only included orders from those customers who had previously placed at least one order including Peristeen rectal catheters, up to 2 years prior to the 6-month period of analysis, in order to include only customers who were well-adhered to the therapy with Peristeen. This information agrees with other indications that the average use is approximately every other day, across all users. It does not give any insight into the patterns of use between different individuals, or groups of patients. The sensitivity analysis highlights the important role that the cost of consumables plays in the economic model. It is the average use across all patients that determines the total cost of providing Peristeen, and the sensitivity analysis is not intended to force individual users of Peristeen to comply with a particular regime that does not suit their needs.

			use of 3.71 catheters/costumer/week was estimated based on the total volume of sold catheters [redacted], the total number of unique costumer IDs [redacted] and the duration of the observation (182 days), assuming the use one rectal catheter per therapy, per user. The CHARTER document can be sent to the Committee if required. We would like to suggest the following wording - The committee noted the EAC's sensitivity analysis which showed that Peristeen would become cost incurring if it were to be used more often than 4 times per week. However, it should be noted that this would only be a very sporadic occurence for most patients. The patient experts stated that although they normally use the device every other day, there are times when they need to irrigate their bowels more frequently (such as when travelling or after a change in diet).	
Theme: cost				
39	1. NHS professional	2.6	Sacral Nerve Stimulation is not funded for patients in Wales	Thank you for your comment.
40	6. Manufacturer	1.3, Page 2, Line 14	Current Text " Peristeen provides additional clinical benefits without costing more than standard bowel care. Whilst Coloplast agree with the comment about the level of uncertainty, a more definitive statement could be made on the ability of Peristeen to be cost saving. In section 3.8 the EAC state that their revised model generates a cost saving of Â£3,175 per patient over 37 years. A key driver to the sensitivity of the model is the frequency of use; if used every day it may become cost-incurring but if used every other day or less, then Peristeen is cost-saving. There is both scientific and real world evidence to prove that the majority of patients use Peristeen every other day " please see additional comment for Section 4.17. We feel that this cost saving could be reflected in section 1.3. We would like to suggest the following wording - Peristeen provides additional clinical benefits and is considered to be at least cost-neutral and should be cost-saving in the majority of patients compared to standard bowel care.	Thank you for your comment. The committee decided not to change section 1.3 because no new evidence on the economic benefits was presented at consultation.
41	11. Manufacturer	1.3, Page 2, Line 14	The Document states that "Peristeen provides additional clinical benefits without costing more than standard bowel care." Section 3.8 states that the revised EAC model generates a cost saving of Â£3,175 per patient over 37 years. There appears to be sufficient evidence in the document that Peristeen is used every other day and would therefore be cost saving (rather than cost-neutral/cost incurring) in most people. Could this potential cost saving be reflected more strongly in section 1.3.	Thank you for your comment. Please see response to comment 40.
Theme: adverse events				
42	6. Manufacturer	3.5, Page 5, Line 23	Current text " It was a rare complication according to the global audit by Christensen et al. (2016). It may be useful to give the actual incidence rate for bowel perforations as calculated by Christensen et al (2016) to allow the reader to understand the scale of this serious adverse event. We would like to suggest	Thank you for your comment. The committee decided to include the calculated incidence rate from the paper in the text of section 3.5.

			the following wording “ It was a rare complication (2 per million irrigations) according to the global audit by Christensen et al. (2016).	
43	11. Manufacturer	3.5, Page 5, Line 23	The Document states that "It was a rare complication according to the global audit by Christensen et al. (2016)." The actual incidence of the rates of bowel perforation are calculated in the audit (2 per million procedures) and it might be helpful if this figure was actually given in the text rather than being described as rare.	Thank you for your comment please see response to comment 42.

"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."

Appendix – additional information submitted with comment 11/12

Peristeen anal irrigation system for managing bowel dysfunction – NICE draft guidance

Stakeholder consultation

Stakeholder report: UK Paediatric Colorectal Group

27th September 2017

Author: Mr Richard England, Consultant Paediatric Surgeon (Norwich) and Secretary of the UKPCG.

1) Who are we?

The UK Paediatric Colorectal Group (UKPCG) is affiliated to the British Association of Paediatric Surgeons. We are a subspecialty group consisting of paediatric general surgeons with an interest in paediatric colorectal surgery. We hold national meetings twice each year and collaborate on research, projects and resource sharing.

There are 21 centres in England and Wales each with usually 2 or more colorectal subspecialists. There are additional 4 centres in Scotland and Northern Ireland.

Paediatric Colorectal Surgery encompasses the surgical treatment of children (0-16 or 18 usually) who have congenital disorders of the colon, rectum and anus such as Hirschsprungs disease where there is disordered peristalsis of the lower colon and rectum and Anorectal Malformations which includes a spectrum of disorders where the anus needs to be reconstructed or moved within the sphincter complex.

In both these conditions the initial clinical situation is of bowel obstruction in the newborn. Reconstructive surgery, which can involve a temporary stoma, often occurs in the first year of life and following this children attempt to go through a normal toilet training phase. For various surgical or anatomical reasons constipation or soiling and incontinence can be major issues and toilet training can be delayed or impossible to accomplish.

We are also referred patients with severe functional constipation where gross distention of the rectum, faecaloma formation and overflow soiling are part of the clinical picture. Often the family, social and psychological issues that have developed while trying to manage this

situation prior to our input, play a huge role in the ongoing management. We therefore work closely where possible with paediatric gastroenterologists, psychologists, and constipation or continence nurse specialists.

2) Why are we interested in this NICE guidance?

As mentioned above we deal with children whose anorectum does not function normally through the presence of a congenital anomaly such as an Anorectal malformation, Hirschsprungs disease or severe functional disorders. Surgery cannot always ensure a completely normal bowel habit and many children need help to manage constipation or soiling. Constipation or incontinence due to Spina bifida may also present to us as would other spinal injuries or disorders in children. These are often managed in dedicated MDT clinics.

Our strategies in dealing with these problems is often to exclude a correctable anatomical problem – which might involve surgery and then work through the stepwise approach to bowel management.

This can involve oral medications – which often has already been tried and can be counterproductive in incontinence. Rectal medications - which can be more useful and we as a group are more likely to suggest this approach, as we understand it works at the site of the problem – and in troublesome cases, parents and children are more likely to be on board with this idea. However, the idea of a colonic or rectal washout is also more familiar to us as a specialist group as we use it regularly in the early treatment of Hirschsprungs disease. Post-operative long term problems are also amenable to washout therapy and 'bowel management' is a familiar term to us. The literature often recalls the development of the Shandling catheter1. We are also familiar with the construction of the Malone Antegrade Continence Enema (aka MACE or ACE). This is where a conduit into the caecum is constructed usually using the appendix, through which a catheter can be passed to instill a volume of fluid to washout the entire colon[2].

Our colleagues in the US who have been at the forefront of Anorectal Malformation surgery have encouraged the use of bowel washouts using a catheter to help patients with long term soiling stay clean[3].

The idea of emptying out the colon with a flush of water to ensure the colon is clean and empty -leaving the child clean for 24 hours or more is a strategy we need to offer many of our children.

Recently we have adopted the engineered Peristeen pump and other devices available as the preferred way of instilling fluid. This sea change in practice is almost complete across the country. This is not a new idea in our specialty but these devices are more effective and more user friendly than more traditional or surgical options.

3) Our response to the consultation.

I reported to the UKPCG that this consultation was taking place and asked members to send their comments to me along with if possible a summary of their experience with Peristeen. Only centres in England and Wales were asked to respond as any guidance would only be applicable in that region of the UK.

The table below summarises the responses received.

Centre	Experience	Comments	Comment on draft guidance
Brighton	9 cases, 2 failed due to compliance issues.	"A big fan" Careful selection required. Easy to use, quick, no soiling and improve QoL. Good support from Coloplast Rep.	Concentrates on adults.
Bristol	We use Peristeen a lot.		
Evelina -London	Not used frequently	Good nurse specialist who helps - some patients have stuck with it but often end up having an ACE	
Leicester	Over 40 children	Most doing very well with it. Most start using it on daily basis and some progress to alternate days but not all. Some are cured of the bowel dysfunction	The document concentrates on neurogenic cause of bowel dysfuction. Why doesn't it include ARM and Hirschsprungs as well as idiopathic constipation? Why is it only looking at Peristeen? There are lots of products on market and choice helps compliance. Some children don't like the balloon and prefer a cone based system.
Leeds	Numbers not available but experienced users of Peristeen	Good response in Spina bifida and Anorectal Malformations.	No comments.
Liverpool	Have registered separately as Stakeholders		

Manchester	Have registered separately as Stakeholders		
Norwich	5 patients currently using it although 1 patient had funding withdrawn by GP	Lives transformed - use of and dependence on laxatives has reduced and they have managed to establish cleanliness. Peristeen used as it comes with nurse support. Qufora only has telephone support but is sometimes useful to start with this system. Only used in functional disorders but patients with Hirschsprungs and ARM will be introduced to concept soon if funding available.	See authors comments below.
Oxford	Used in children with ARM and Hirschsprungs. Youngest 3 years old. Paediatric urology team use it in Spina Bifida	Works well. Experience published[5]	
Sheffield	Extensive experience. 111 patients on Transanal Irrigation between 2009-2016. 61% functional, 21% neuropathic and 11% ARM. 90% Peristeen.	Symptom resolution (clean) between 50-83%. 2 were ineffective and 16% were non-compliant or went onto have ACE. 19% with constipation and soiling were weaned off TAI. Safeguarding issues discovered in some with poor outcome.	Scope of guidance needs to be widened to where medical management (as per current NICE guidance) of constipation or incontinence has failed to control symptoms.
Southampton	Use Peristeen a lot and numbers of ACE procedures performed (in the centre that developed the technique![2]) have dropped dramatically. ACE still preferred in patients also having bladder Augmentation and mitroffanoff.	Experience published[4]. 24 cases published with 2 failures and significant improvement in QoL. Nurse specialists report that some patients like the Iri-pump and cone variations.	Most paediatric published data is fairly poor but often comes from an era when Peristeen was relatively new. Coloplast seem to have overcome early issues with balloon bursting and large catheters.

4) Comments on the draft guidance and consultation.

4.1 The scope of the guidance is not specified clearly. The title of the guidance suggests 'bowel dysfunction' in general but the wording of the document often refers to neurogenic

bowel disorders usually indicating Spina bifida or other spinal cord injuries. We use Peristeen for a wide range of congenital and acquired anorectal disorders.

4.2 The draft guidance and EAC report focuses mainly on adult practice. There is poor representation of paediatric practice which is disappointing. Achieving continence in childhood will enable them to transition to adulthood with established confidence about their cleanliness and enable them to enagage in work and other activities.

4.3 Why is transanal irrigation being considered for guidance? This method of establishing continence is well established in paediatric practice. It has a long history and established usefulness in medical and surgical care for children with congenital malformations and intractable constipation and incontinence.

4.4 We have already been made aware of CCG and GP funding decisions against transanal irrigation. Funding has been withdrawn for some patients where they have used Peristeen for sometime and managed to establish cleanliness. The mere fact a consultation and NICE guidance is taking place has led to decisions being put on hold pending publication. The UKPCG opinion is that Peristeen and Transanal irrigation in the management of paediatric bowel dysfunction is well established and should not be suddenly up for debate, affecting the lives of many children.

4.5 Why is Peristeen being targeted for a consultation? Peristeen is one of many available products on the market. Choice is important to many of our patients and nurse specialists report that some patients prefer one to another.

4.6 Peristeen is marketed alongside support from a Coloplast nurse representative which has been invaluable in many cases to help achieve compliance which is especially difficult in paediatric practice.

4.7 The EAC report and the draft guidance makes no mention of the ACE procedure. This is the surgical technique which should be compared with Transanal irrigation. The UK practice has shown a significant transition from providing the ACE procedure to using transanal irrigation. Even to the extent that the preference at the centre that developed the ACE procedure has also switched! A non-surgical option for achieving continence and cleanliness is usually preferable to a surgical option. The ACE procedure is accepted to have a relatively high complication rate and further operations to deal with these complications such as stomal stenosis are relatively common[5].

4.8 Cost effectiveness calculations are difficult to apply in these conditions. In paediatric practice establishing cleanliness has a significant effect on schooling, engagement in social activities and overall QoL. Some patients will need daily washouts, some will migrate to alternate day washouts. Some patients will wean from irrigations and their bowel dysfunction will recover. Those with congenital disorders may never recover and need continued irrigation even after transition into adult care. Those who have developed cleanliness early will be more socially integrated and able to join the workplace, thereby contributing to productivity and become tax payers.

4.9 Any negative decisions regarding the funding of Peristeen in the adult market is likely to have knock on effects with the paediatric population of users, however unintentional. This detrimental effect should be carefully considered when publishing guidance for adult users.

5) Conclusions.

The UKPCG members have considerable experience in the use of colonic irrigation in congenital and functional bowel disorders. The draft NICE guidance on Peristeen seems to be limited in its scope and has not adequately taken into account the needs of the paediatric population. The intention to have NICE guidance has created uncertainty and led to a trend towards seeing Transanal Irrigation as an optional therapy in terms of funding decisions.

The opinion of the UKPCG is that NICE needs to widen the scope of this review and should encourage the use of transanal irrigation therapies in general as a suitable alternative to surgical options in the paediatric population.

6) Acknowledgements

I would like to thank my surgical and specialist nurse practitioner colleagues who responded to the request for information on their experience of Transanal Irrigation.

7) References

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4) Corbett P, Denny A, Dick K et al. Peristeen integrated transanal irrigation system successfully treats faecal incontinence in children. J Pediatr Urol. 2014 10:219-222

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