NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Medical technology guidance

Assessment report overview

Peristeen anal irrigation system to manage bowel dysfunction

This assessment report overview has been prepared by the Medical Technologies Evaluation Programme team to highlight the significant findings of the External Assessment Centre (EAC) report. It includes **brief** descriptions of the key features of the evidence base and the cost analysis, any additional analysis carried out, and additional information, uncertainties and key issues the Committee may wish to discuss. It should be read along with the company submission of evidence and with the EAC assessment report. The overview forms part of the information received by the Medical Technologies Advisory Committee when it develops its recommendations on the technology.

Key issues for consideration by the Committee are described in section 6, following the brief summaries of the clinical and cost evidence.

This report contains information that has been supplied in confidence and will be redacted before publication. This information is highlighted in yellow. This overview also contains:

- Appendix A: Sources of evidence
- Appendix B: Comments from professional bodies
- Appendix C: Comments from patient organisations

1 The technology

Peristeen is a transanal irrigation system that is usually self-administered while sitting on a standard toilet, commode or shower chair. It comprises a rectal catheter with inflatable balloon, a manual control unit with pump, leg straps and a bag to hold water. Peristeen was designed with people with limited mobility in mind; the pump has large switches and the balloon catheter means that the irrigation tube does not need to be held in place. Peristeen is a constant-flow pump and is not gravity-based, meaning the user does not need to hang the bag up for the water to flow. Peristeen is intended for use by all people with bowel dysfunction including people with neurogenic bowel dysfunction. It is typically used every 2 days or so to empty the rectum and distal sigmoid colon and prevent unexpected bowel movements or to relieve and/or prevent constipation. Peristeen received a CE mark in May 2003 as a class 1 medical device for transanal irrigation.

2 Proposed use of the technology

2.1 Disease or condition

Peristeen is used for transanal irrigation, specifically for people with bowel dysfunction such as neurogenic bowel dysfunction.

Neurogenic bowel dysfunction can be caused by neurological conditions such as spinal cord injury (SCI), spina bifida, multiple sclerosis (MS), Parkinson's disease and other conditions associated with impairment or loss of sphincter control and bowel mobility disorders. Bowel dysfunction may also be caused by an injury (for example following childbirth), slow transit constipation (unrelated to childbirth), obstructed defaecation symptoms, metastatic spinal cord compression, and low anterior resection syndrome in people who have had treatment for rectal cancer (radiation to the pelvis and/or surgery).

2.2 Patient group

Peristeen is intended for people with bowel dysfunction such as neurogenic bowel dysfunction who choose anal irrigation as a treatment option.

Between 1% and 10% of adults are affected with faecal incontinence and it is estimated that 0.5–1.0% of adults experience regular faecal incontinence that affects their quality of life. Bowel dysfunction leading to faecal incontinence and constipation has a prevalence of around 70% in people with central neurological disease such as MS, spina bifida, Parkinson's disease, stroke, or SCI.

Approximately 100,000 people in the UK have MS and most are diagnosed between 20-40 years of age. Spina bifida affects around 1 in every 2,000 pregnancies; this varies by ethnicity and is slightly more common in girls than boys. Parkinson's disease affects around 65.6–125 per 100,000 people and is more common in elderly men.

2.3 Current management

Current treatment options for bowel dysfunction may include medication (oral drugs, suppositories and enemas), dietary advice and changes, physiotherapy and surgery. People with bowel dysfunction may also be offered training to help manage their symptoms at home, using biofeedback, bowel washouts and manual removal of faeces.

The NICE guideline on the management of faecal incontinence in adults states that healthcare professionals should explain to people with the condition that a combination of management interventions is likely to be needed. People with faecal incontinence should be offered advice on a range of coping strategies and treatment options and are encouraged to find the method that works best for them. If bowel continence cannot be achieved by conservative lifestyle changes such as diet changes or medication, long-term management strategies should be offered.

The guideline states that rectal irrigation may be suitable treatment option for such patients. A variety of systems, including Peristeen, are available which differ in design and use. These choices should be discussed by clinician and patient and a number of systems may be tried before a preferred device for anal irrigation is found.

Surgery, comprising the fashioning of a colostomy or ileostomy may be required or preferred by some patients. Other surgical interventions include sacral nerve stimulation, sphincter repair, artificial sphincter, ventral mesh rectopexy for rectal intussusception.

2.4 Proposed management with new technology

Peristeen should be offered to people who choose anal irrigation to manage faecal incontinence. The device is designed for self-administration but some people may require help from a nurse or carer, particularly if they have limited mobility in their hands.

The adoption team has produced a scoping report for this technology.

3 Company claimed benefits and the decision problem

These are described in the scope here (see Appendix D). The company did not propose any variations to the decision problem in its submission.

4 The evidence

4.1 Summary of evidence of clinical benefit

The company submitted 10 studies (Christensen et al. 2008, Christensen 2006, Del Popolo 2008, Grainger et al. 2017 (AIC), Hamonet-Torny 2013, Loftus 2012, Passananti 2016, Preziosi et al. 2012, Rosen 2011 and Midrio 2016); EAC agreed with the inclusion of these and include a further 14 (Chan et al. 2011, Kim et al. 2013, Nafees 2016, Whitehouse et al. 2010, Alenezi et al. 2014, Ausili et al. 2010, Choi et al. 2015, Corbett et al. 2013, Kelly et al. 2016, King 2016, Koppen et al. 2017, Lopez Pereira et al. 2010, Marzheuser et al. 2016, Nasher et al. 2014, Pacilli et al. 2013) studies. Another 2 studies and one global audit were included for information on adverse events. A total of 26 included studies and 1 global audit included in the AR.

The EAC included 13 adult studies and 11 in children plus 2 studies and 1 audit that were included to provide information on adverse events. One of these studies was a randomised controlled trial (RCT), the rest were observational. The rationale for this study selection decision is in section 3.5 of the assessment report (AR).

Table 1 Included studies

Studies included by both EAC and company	
9 adult studies included by both plus 1 study in children. 3 studies and 1 global audit were included for information on adverse events	
Publication	All studies were full papers, 1 was prepublication (academic-in-confidence, AIC). Global audit data are unpublished.
Study design	1 RCT (Christensen 2006), all other studies were observational plus global audit registry data
Adults: Christensen et al. 2008, Christensen et al. 2006, Del Popolo 2008, Grainger et al. 2017 (AIC), Hamonet-Torny 2013, Loftus 2012, Passananti 2016, Preziosi et al. 2012 and Rosen 2011 Children: Midrio 2016 AE only: Biering Sorensen et al. 2009, Faaborg 2009, Christensen et al. 2016 (audit)	
Additional studies not in submission but included by EAC	
4 adult studies included plus 10 studies done in children	
Publication	All studies were full papers
Study design	All studies were observational
Adults: Chan et al. 2011, Kim et al.2013, Nafees 2016, Whitehouse et al. 2010 Children: Alenezi et al. 2014, Ausili et al. 2010, Choi et al. 2015, Corbett et al. 2013, Kelly et al. 2016, King 2016, Koppen et al. 2017, Lopez Pereira et al. 2010, Marzheuser et al. 2016, Nasher et al. 2014, Pacilli et al. 2013	

Studies on adult populations

The clinical evidence focusses on 1 RCT (Christensen 2006, summarised in table #) which meets the decision problem for the primary population. This study compared Peristeen with supportive bowel care (defined as best supportive bowel care without using irrigation). The study included 87 patients with spinal cord injury and neurogenic bowel dysfunction from 5 European spinal cord injury centres, including the UK.

Overall, there was a significant improvement in Cleveland Clinic constipation scoring system (CCCS), St Mark's faecal incontinence grading system (FIGS) and neurogenic bowel dysfunction score (NBDS) for the Peristeen group

compared with standard care. Post-hoc sub-group analysis found no significant difference between Peristeen and standard care for patients who could walk, but a significant improvement in the Peristeen group for those who used a wheelchair or were confined to bed.

12 patients in the Peristeen arm and 2 standard care patients withdrew from the study. The large number of withdrawals from the study is consistent with the observational studies where patients withdraw at an early stage if they do not like the device or find it unhelpful. Blinding is not possible due to the nature of the device. The study is described as having been supported by the company.

All the other included adult studies are observational case series and do not have a comparator. One paper was unpublished. Nine of these case series are prospective and three are retrospective in design. Most studies are small, single centre studies. The patient populations vary in the observational studies; some are of a single condition such as multiple sclerosis, whereas other studies include patients with a variety of conditions. The observational studies are summarised in appendix B of the AR.

The observational studies report on inconsistent outcome measures, including some locally devised non-validated questionnaires. Outcomes are often subjective and may require the patient to recall answers, in some cases up to one year indicating a risk of recall bias. Several studies grouped results by those who have continued to use Peristeen, compared to those who have ceased or alternatively compare “responders” to “non-responders” (Hamonet-Torny, 2013). This is likely to lead to reporting bias in the results.

Studies done in children

The studies done in children were non-comparative, observational case series; 6 are prospective and 5 are retrospective in design. One consisted of qualitative interviews with parents and carers.

In some cases patient reported outcome measures (PROMs) that may not be adapted or validated for children have been used and it is not always clear if parents have completed questionnaires for children. Some studies reported patient and/or parent satisfaction.

The evidence from the paediatric studies of lower quality than the evidence for adults. This is partly due to the difficulty in obtaining valid PROM data from children. The patient populations studied include congenital conditions, such as spina bifida, whereas adult patients mainly have acquired conditions. A variety of outcomes are reported and there are differences in populations and patient ages making it difficult to compare the results of these studies. Some outcomes in the studies showed improvements for children using Peristeen. Similar trends in early discontinuation of Peristeen use were observed as in the adult studies. The paediatric studies are summarised in appendix B of the AR.

Adverse events

Bowel perforation is a potential serious adverse event linked to Peristeen use. It is a rare complication according to the global audit by Christensen et al., (2016). Other, less serious adverse events such as abdominal pain and nausea are more common.

Table 2 Summary of key study

Study and design	Christensen et al. (2006), RCT
Participants/ population	87 recruited – 62 men, 25 women, average age 49.1 years. All were 18 years or older, at least 3 months after SCI. 5 European SCI centres: UK, Sweden, Italy, Germany, Denmark.
Intervention & comparator	42 people randomised to treatment with Peristeen vs 45 to SBC Difference in mobility of people: wheelchair use was 29/42 in Peristeen group and 40/45 in control arm. Blinding was not possible.
Outcome measures and follow up	Primary outcomes: CCCS and FIGS Secondary outcomes: NBDS, modified ASCRS, numeric score on: bowel function, influence on daily activities and general satisfaction. Outcomes collected at week 0 and 10, plus weekly telephone interview.
Results	CCCS, FIGS and NBDS were significantly improved for Peristeen. Sub-group analysis found no significant difference for patients who could walk, but significant improvement for those who used wheelchairs or were confined to bed found that these ASCRS scores were significantly improved for Peristeen in domains of coping/behaviour but no significant difference for the lifestyle and depression/self-perception domains. The numeric scores were significantly improved for bowel function, general satisfaction and improvement in quality of life, but not for influence on daily activities
Withdrawals	14 (12 Peristeen, 2 SBC) withdrawals 73 completed, 5 lost to follow-up
Funding	Company funded
Comments	Large number of patients stopped using Peristeen before the end of the study. These were included in an ITT analysis using baseline data for missing data. Imbalance between groups for wheelchair use or confined to bed. Sub-group analysis not stated as planned.
Abbreviations used: ASCRS – American society of colon and rectal surgeons fecal incontinence score; RCT – randomised controlled trial; CCCS – Cleveland Clinic Constipation Score; FIGS – St Mark's Faecal Incontinence Grading Score; ITT – intention to treat; NBDS – Neurogenic Bowel Dysfunction Score; SBC – Standard bowel care	

4.2 Summary of economic evidence

The company submission identified 2 studies (Emmanuel et al. 2016 and Christensen 2009); the EAC excluded 1 of these (Christensen 2009) as it was from the societal perspective and not relevant to the decision problem.

Emmanuel et al. (2016) is a cost-effectiveness model based on an audit database from three UK hospitals that was set up in 2006. The company provided the EAC with an extract of audit data that was used for quality of life calculations and also gave information on length of use, and if patients had stopped using Peristeen. The audit data was not submitted by the company as part of the clinical evidence.

The EAC stated that the audit data seemed to be in an appropriate NHS setting, with suitable patient pathways and an appropriate, if heterogeneous, population (227 patients aged 17 to 70 years with neurogenic bowel disease (NBD) and a variety of neurological diagnoses).

The EAC stated that it did not have enough information to fully critique the audit or its suitability for the model. Questionnaires were collected annually, but it is not known at what time point data for resources were taken. Some patients stopped using Peristeen but there is no explanation of how this is treated in the data analysis.

De novo analysis

The company submission includes a cost-effectiveness analysis using utility data from a clinical audit. This shows an improvement in quality of life following treatment with Peristeen. The EAC re-ran this analysis with corrections and adjustments and found that Peristeen is less costly and more effective than SBC, and is thus classified as dominant. At a willingness to pay threshold of £30,000 Peristeen would be cost effective in 70.5% of cases. The remainder of this section focuses on the cost-consequence model provided by the company.

The model provided by the company was the same as that described in Emmanuel et al. (2016) with updated prices. The Markov model had a 6 month cycle and a whole life time horizon of 37 years corresponding to the life expectancy of a 30 year old male SCI patient (see figure 9.1 in the company submission). Discounting is 3.5% and an NHS and social care perspective is used.

Model parameters

The model submitted by the company assumed that the population was homogenous, that all people using Peristeen have had a SCI. The age of entry into the model and gender of the individual can be changed but this only varies the time horizon. The model assumes constant variables for transition probabilities and for people stopping using the device; there is no death state or underlying mortality in the model. In several instances, out of date information had been used e.g. for life expectancy data, cost of treating pressure ulcers and NHS reference costs for consumables.

The EAC made corrections and alterations to the economic model which reduced estimated cost saving due to Peristeen. The cost saving is largely due to reduced time for health care professional visits and carer time; reduced incidence of faecal incontinence requiring the use of incontinence pads; reduced incidence of urinary tract infection (UTI) and fewer hospitalisations. The changes made by the EAC are listed in the table below:

Table 3 EAC changes to economic model

EAC change to model	Impact on model/comments
For patients in the Peristeen arm, who return to SBC: cost of healthcare practitioner (HCP), consumables and SBC related adverse events included. Transition probabilities for surgery and stoma were also changed so that they are now the same as the SBC arm.	These corrected errors in the company model. Including the costs for HCP and SBC related adverse events lead to a large decrease in cost savings. Correcting the costs of consumables and transition probabilities also lead to a decrease in the cost savings.
Carer time for both arms is now calculated in minutes rather than hours.	Increase in cost saving as Peristeen requires less carer time.
Variable transition probabilities included to model reduction in Peristeen use in the first year.	The trend for a high initial drop off for people using Peristeen is supported by the clinical evidence. These changes lead to a decrease in cost saving.
Background mortality added in using data from Savic 2017	Increase in cost saving. Background mortality rates were added as this is usual for models with a long time horizon. Rates for people with SCI were used, although this would be different for different diagnoses, the impact is likely to be minimal as there was a small impact on the results.

Cost of pressure ulcer changed to £15,134.84 (Dealey et al. 2012, £14,108, inflated to 2017).	Decrease in cost saving. The source of this value was out of date (1993) and has been updated.
Cost of UTI changed to £52.57 (Bermingham et al. 2013), £49 inflated to 2017).	Decrease in cost saving. The company model costed UTI events at £166.77. This was judged to be too high and the source of the figure was unclear.

Costs and resource use

The costs in the model include device, training and consumable costs, HCP costs, sacral nerve stimulation/ sacral anterior root stimulator/ antegrade continence enema surgical costs (SNS/SARS/ACE), stoma costs and the cost of adverse events. In most cases these values are taken from NHS reference costs, NHS drug tariff and the British national formulary.

Annual costs for Peristeen and SBC are as shown in the table below:

Table 4 Annual costs of Peristeen and SBC

	Peristeen annual costs	**SBC annual costs**
System and catheter	£1,712.86	£0
Training	£217.00 one-off cost	£0
Medication	£315.94	£146.32
Anal plug and incontinence pads	£1,875.53	£2,483.57
HCP visits	£807.17	£1,046.12
Carer time	£843.80	£1,673.44
Adverse events	£2,054.63	£4,598.35
Total:	**£7,609.93 + initial training £217**	**£9,947.80**

The model assumes that Peristeen is used once every 2 days. The frequency of use of Peristeen is the main driver of costs as more frequent use increases the need for catheters. The frequency of faecal incontinence is the main driver of costs for the SBC arm as this is used to calculate the need for incontinence plugs and pads as well as medication such as bulking agents, stimulants and suppositories. The cost of treating pressure ulcers was also identified to be a major driver.

Procedure costs for SNS/SARS/ACE and stoma are included in the model. Annual cost for SNS/SARS/ACE and stoma disposables is lower than Peristeen following the initial SNS/SARS/ACE surgical procedures.

Results

The EAC corrected model shows that Peristeen has an incremental cost saving of -£3,175 over a 37 year time horizon.

Table 5 Company and EAC base-case results

	Company base case			EAC base case		
	Peristeen	*SBC*	*Diff**	*Peristeen*	*SBC*	*Diff**
P/SBC costs	55135**	29,788	25,347	41,443	24,580	16,863
HCP time	45,726	55,590	-9,864	21,334	25,418	-4,084
SNS/SARS/ ACE	6,924	6,820	104	4,480	4,637	-157
Stoma	13,806	25,917	-12,111	9,157	15,889	-6,732
AEs for P/ SBC	27,061	52,084	-25,023	12,081	28,395	-16,314
Subsequent AEs	299	521	-222	7,579	329	7,250
Total	**£148,951**	**£170,719**	**-£21,768**	**£96,073**	**£99,248**	**-£3,175**

All costs are in £ per patient over a 37 year time horizon
**Difference – negative values indicate a cost saving for Peristeen*
***This is the cost of Peristeen plus the cost of SBC for those who returned to this treatment option*

The key drivers of the costs (frequency of use of Peristeen, frequency of faecal incontinence and the cost of treating pressure ulcers) were investigated by the EAC in a one-way sensitivity analysis.

Table 6 Key drivers

	High	**Incremental cost (37 years)**	**Low**	**Incremental cost (37 years)**
Frequency of Peristeen use	Daily	£12,229	Every 3 days	-£8,115
Frequency of faecal incontinence in SBC	4.38 per week	-£4,607	2.63	-£1,743
Cost of pressure ulcers	£18,919	-£4,592	£11,351	-£1,757

The EAC also ran a probabilistic sensitivity analysis that varied the frequency of use, giving a mean incremental cost of using Peristeen of -£3,233, with 69.7% of cases being cost saving for Peristeen use.

The cost saving for Peristeen is largely due to reduced time for health care professional visits and carer time; reduced incidence of faecal incontinence

requiring the use of incontinence pads; reduced incidence of UTI and fewer hospitalisations.

5 Ongoing research

The company submitted 1 AIC pre-publication study (Grainger et al.) and stated that a post-market surveillance database is collecting information on adverse events.

The EAC found 2 more relevant ongoing studies due to complete in July 2016 and 2019 (see section 3.9 of the AR).

6 Issues for consideration by the committee

Clinical evidence

The clinical evidence shows that people who choose and continue to use Peristeen report improvements in outcomes and quality of life. Peristeen may help some people gain more independence with their bowel care and may help improve confidence if a reliable routine is established. The committee have been provided with patient expert testimony to aid understanding of this.

The clinical evidence shows that there is often an initial drop-off of Peristeen use. This is happens when people try Peristeen and quickly decide to stop using it because they dislike it or find it painful or ineffectual. Only a small number of discontinuations are likely to be due to adverse events. This highlights the need for good education and training on Peristeen for users, carers and NHS staff. The committee may wish to seek patient and clinical expert advice on the importance of allowing people to explore options for bowel management should be taken into consideration.

The clinical evidence for use of Peristeen in children is of lower quality than the evidence in adults. However, similar trends of improvements in outcomes for a self-selecting group of users is observed. The committee may wish to seek patient and clinical expert advice on the wider societal impact of caring for a child with faecal incontinence.

Cost evidence

On average, Peristeen is cost saving compared to SBC, these savings are expected to accumulate over the lifetime of a patient (£3,175 over a 37-year horizon). These savings are highly sensitive to the frequency of use of Peristeen due to the need for a new catheter each time it is used. This means that Peristeen may be cost incurring in some people (for example if it is used daily) but may also lead to higher cost savings if it is used less frequently.

Although Peristeen may lead to significant cost savings for some people, averaged across the entire faecal incontinence population, cost savings are modest. For information, the recommendations available to the committee include a scenario where there is sufficient certainty that the technology produces significantly greater clinical and/or healthcare system benefits compared with current management options for similar investment of resources (MTEP methods guide section 8.2.1).

Unusually for a medical technology guidance submission, the company provided a cost-effectiveness model using data from a NHS audit, which shows Peristeen to be dominant (cost-saving/more effective) or cost-effective compared with usual bowel care.

7 Authors

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NICE medical technologies evaluation programme

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Appendix A: Sources of evidence considered in the preparation of the overview

A Details of assessment report:

- (Dale M, Carolan-Rees G, Ray A, et al.) Peristeen anal irrigation system to manage bowel dysfunction, June 17

B Submissions from the following sponsors:

- Coloplast

C Related NICE guidance:

- Irritable bowel syndrome in adults: diagnosis and management (2015) NICE guideline 61
- Multiple sclerosis in adults: management (2014) NICE guideline 186
- Stroke rehabilitation in adults (2013) NICE guideline CG162
- Autism spectrum disorder in under 19s: recognition, referral and diagnosis (2011) NICE guideline CG128
- Constipation in children and young people: diagnosis and management (2010) NICE guideline CG99
- Rehabilitation after critical illness in adults (2009) NICE guideline CG83
- Metastatic spinal cord compression in adults: diagnosis and management (2008) NICE guideline CG75
- Faecal incontinence in adults: management (2007) NICE guideline CG49

D References

Alenezi H, Alhazmi H, Trbay M et al. (2013) Peristeen anal irrigation as a substitute for the MACE procedure in children who are in need of reconstructive bladder surgery. Journal of the Canadian Urological Association 8(1-2), E12-E15

Ausili E and Focarelli (2010) Transanal irrigation in myelomeningocele children: an alternative, safe and valid approach for neurogenic constipation. Spinal Cord 48(7), 560-5

Biering-Sorensen F, Bing J, Berggreen P et al. (2009) Rectum perforation during transanal irrigation: a case story. Spinal Cord 47(3), 266-7

Choi E, SW Han S, Shin S,Ji Y, Chon J and Im Y (2015) Long-term outcome of transanal irrigation for children with spina bifida Spinal Cord 53, 216–220

Christensen P (2006) A Randomized, Controlled Trial of Transanal Irrigation Versus Conservative Bowel Management in Spinal Cord-Injured Patients. Gastroenterology 131(3), 738-47

Christensen P (2009) Cost-effectiveness of transanal irrigation versus conservative bowel management for spinal cord injury patients. Spinal Cord 47(2), 138-43

Christensen P (2016) Global audit on bowel perforations related to transanal irrigation. Techniques in Coloproctology 20(2), 109-15

Christensen P, Bazzocchi G, Coggrave M et al. (2008) Outcome of transanal irrigation for bowel dysfunction in patients with spinal cord injury. Journal of Spinal Cord Medicine 31(5), 560-7

Corbett P, Denny A, Dick K et al. (2014) Peristeen integrated transanal irrigation system successfully treats faecal incontinence in children. Journal of pediatric urology 10(2), 219-22

Del Popolo G (2008) Treatment of neurogenic bowel dysfunction using transanal irrigation: a multicenter Italian study. Spinal Cord 46(7), 517-22

Emmanuel A (2015) Long-Term Cost-Effectiveness of Transanal Irrigation In Patients With Neurogenic Bowel Dysfunction Who Have Failed Standard Bowel Care. Value in Health 18(7), A360

Emmanuel A (2016) Long-term cost savings of transanal irrigation in patients with neurogenic bowel dysfunction: A medicare payer perspective. Value in Health Conference(var.pagings), A303

Emmanuel A, Kumar G, Christensen P et al. (2016) Long-Term Cost-Effectiveness of Transanal Irrigation in Patients with Neurogenic Bowel Dysfunction. PLoS ONE [Electronic Resource] 11(8), e0159394

Faaborg P M (2009) Long-term outcome and safety of transanal colonic irrigation for neurogenic bowel dysfunction. Spinal Cord 47(7), 545-9

Faaborg P M, Christensen P, Krassioukov A et al. (2014) Autonomic dysreflexia during bowel evacuation procedures and bladder filling in subjects with spinal cord injury. Spinal Cord 52(6), 494-8

Hamonet-Torny J (2013) Long-term transanal irrigation's continuation at home. Preliminary study. Annals of Physical & Rehabilitation Medicine 56(2), 134-42

Kim H R (2013) Application of transanal irrigation for patients with spinal cord injury in South Korea: a 6-month follow-up study. Spinal Cord 51(5), 389-94

Koppen I J N, Kuizenga-Wessel S, Voogt H W et al. (2017) Transanal Irrigation in the Treatment of Children With Intractable Functional Constipation. Journal of Pediatric Gastroenterology and Nutrition 64(2), 225-9

Loftus C (2012) Transanal irrigation in the management of neurogenic bowel dysfunction. Irish Medical Journal 105(7), 241-3

Lopez Pereira P, Salvador O P, Arcas J A et al. (2010) Transanal irrigation for the treatment of neuropathic bowel dysfunction. Journal of pediatric urology 6(2), 134-8

Marzheuser S, Karsten K and Rothe K (2016) Improvements in Incontinence with Self-Management in Patients with Anorectal Malformations. European Journal of Pediatric Surgery 26(2), 186-91

Midrio P (2016) Peristeen() transanal irrigation in paediatric patients with anorectal malformations and spinal cord lesions: a multicentre Italian study. Colorectal Disease 18(1), 86-93

Nafees B (2016) Managing neurogenic bowel dysfunction: what do patients prefer? A discrete choice experiment of patient preferences for transanal irrigation and standard bowel management. Patient preference & adherence 10, 195-204

Pacilli M, Pallot D, Andrews A et al. (2014) Use of Peristeen transanal colonic irrigation for bowel management in children: a single-center experience. Journal of Pediatric Surgery 49(2), 269-72

Passananti V (2016) Long-term efficacy and safety of transanal irrigation in multiple sclerosis. Neurogastroenterology & Motility 28(9), 1349-55

Preziosi G, Gosling J, Raeburn A et al. (2012) Transanal irrigation for bowel symptoms in patients with multiple sclerosis. Diseases of the Colon & Rectum 55(10), 1066-73

Rosen H (2011) Transanal irrigation improves quality of life in patients with low anterior resection syndrome. Colorectal Disease 13(10), e335-e338

Whitehouse P A, McWilliams D, Katt C et al. (2010) Peristeen rectal irrigation for functional bowel disorders: Which patients benefit? Gastrointestinal Nursing 8(2), 40-6

Appendix B: Comments from professional bodies

Expert advice was sought from experts who have been nominated or ratified by their Specialist Society, Royal College or Professional Body. The advice received is their individual opinion and does not represent the view of the society. Please see the collated expert advice table included in the pack for full details.

Dr Ian Beales
Consultant gastroenterologist, British society of gastroenterology

Ms Brigitte Collins
Lead nurse, royal college of nursing

Mr Simon Dunlop
Consultant gastroenterologist, British society of gastroenterology

Prof Anton Emmanuel
Consultant gastroenterologist, British society of gastroenterology

Mr Oliver Jones
Consultant colorectal surgeon, association of coloproctology of Great Britain and Ireland

Ms Karen Nugent
Consultant colorectal surgeon, association of coloproctology of Great Britain and Ireland

Prof Paul Skaife
General surgeon, association of coloproctology of Great Britain and Ireland

Appendix C: Comments from patient organisations

Advice and information was sought from patient and carer organisations. Please see the patient expert statements included in the pack for full details.

Appendix D: decision problem from scope

	Draft scope issued by NICE
Population	People with bowel dysfunction in any setting.
Intervention	Peristeen anal irrigation system
Comparator(s)	Conservative bowel management, which can include: • diet and bowel habit advice • medication (oral drugs, suppositories and enemas) • disposable pads and anal plugs • muscle training/bowel retraining • biofeedback and electrostimulation • digital stimulation and manual evacuation It should be noted that the type of treatment a person receives is highly dependent on their personal preference, ability and the carer support available to them. (see also 'Cost analysis' below)
Outcomes	The outcome measures to consider include: severity and frequency of incontinence and severity of constipation using appropriate scores (such as Cleveland clinic incontinence and constipation scores [also known as Wexner-incontinence and –constipation scores], St Mark's faecal incontinence score and neurogenic bowel dysfunction score) quality of life length and frequency of irrigation device-related adverse events frequency of urinary tract infection (UTI) incidence of stoma surgery and hospitalisations staff time including primary care and community care visits individual length of use/user satisfaction
Cost analysis	Comparator(s): Costs will be considered from an NHS and personal social services perspective. The time horizon for the cost analysis will be sufficiently long to reflect any differences in costs and consequences between the technologies being compared. Sensitivity analysis will be undertaken to address uncertainties in the model parameters, which will include carer costs, patient/carer training costs and costs of treating UTI.
Subgroups to be considered	neurological bowel dysfunction complications for example Parkinson's disease, stroke, multiple sclerosis, spina bifida and spinal cord injury bowel dysfunction caused by injury e.g. following childbirth slow transit constipation (unrelated to childbirth) obstructed defaecation symptoms metastatic spinal cord compression

	low anterior resection syndrome in people who have had treatment for rectal cancer	
Special considerations, including those related to equality	Faecal incontinence is a socially stigmatising condition, and if not managed properly can cause huge distress and can cause people to withdraw from society. People with faecal incontinence may require a carer, particularly if they have an underlying condition that affects their mobility. If bowel management is poor, carers may spend a lot of time cleaning and washing clothing. Some people may go without treatment or help if they are too embarrassed to speak to healthcare professionals or family and friends. Constipation causes pain and straining. If these symptoms cannot be resolved, constipation can lead to faecal impaction, bleeding, prolapse and bowel incontinence. If standard treatment fails, colostomy or ileostomy may be required. Constipation can also predispose to UTI since a full rectum may press on the bladder neck leading to incomplete emptying of the bladder and urinary retention.	
Special considerations, specifically related to equality issues	Peristeen is not suitable for children under 3 years of age, for use during the first 3 months following anal or colorectal surgery or for people with the following conditions: anal or colorectal stenosis, colorectal cancer, acute inflammatory bowel disease, acute diverticulitis and ischaemic colitis. Peristeen is not suitable for people with bowel routines that must take place on a bed.	
	Are there any people with a protected characteristic for whom this device has a particularly disadvantageous impact or for whom this device will have a disproportionate impact on daily living, compared with people without that protected characteristics?	No
	Are there any changes that need to be considered in the scope to eliminate unlawful discrimination and to promote equality?	No
	Is there anything specific that needs to be done now to ensure MTAC will have relevant information to consider equality issues when developing guidance?	No