

Peristeen transanal irrigation system for managing bowel dysfunction

Medical technologies guidance

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Your responsibility

This guidance represents the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, healthcare professionals are expected to take this guidance fully into account. However, the guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

Commissioners and/or providers have a responsibility to implement the guidance, in their local context, in light of their duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity, and foster good relations. Nothing in this guidance should be interpreted in a way that would be inconsistent with compliance with those duties.

Commissioners and providers have a responsibility to promote an environmentally sustainable health and care system and should assess and reduce the environmental impact of implementing NICE recommendations wherever possible.

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1 Recommendations

- 1.1 The case for adopting Peristeen for transanal irrigation in people with bowel dysfunction is supported by the evidence. Peristeen can reduce the severity of constipation and incontinence, improve quality of life and promote dignity and independence.
- 1.2 Peristeen may not be suitable for all people with bowel dysfunction. It may take several weeks before a person is comfortable with using Peristeen, and some people may choose to stop using it. Peristeen is therefore most effective when it is offered with specialist training for users, carers and NHS staff, and structured patient support.
- 1.3 Cost modelling for Peristeen is uncertain, but it is likely that Peristeen provides additional clinical benefits without costing more than standard bowel care.

2 The technology

Description of the technology

- 2.1 Peristeen (Coloplast) is a transanal irrigation system for managing bowel dysfunction. The company's instructions for use in this indication recommend that it should be used every other day to empty the rectum and distal sigmoid colon, in order to prevent uncontrolled bowel movements (faecal incontinence) or to relieve and prevent constipation. Peristeen is usually self-administered while sitting on a 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 uses 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. Peristeen needs a new catheter each time it is used.
- 2.2 The cost of Peristeen is £76.28 per system (comprising a Peristeen pump, 2 catheters, 2 straps and a water bag) and £132.95 per consumable pack of 15 catheters and replacement water bag (excluding VAT).
- 2.3 The claimed benefits of Peristeen in the case for adoption presented by the company are that it:
- improves symptoms and reduces the severity of chronic constipation
 - reduces the severity and frequency of faecal incontinence
 - improves quality of life for people with bowel dysfunction
 - reduces the incidence, frequency and costs associated with urinary tract infections
 - reduces the rate of stoma surgery
 - reduces the cost of treating neurogenic bowel dysfunction in people who have already had unsuccessful standard care
 - reduces the rate of hospitalisation in people with neurogenic bowel dysfunction.

Current management

- 2.4 Bowel dysfunction may be caused by a neurogenic disorder (such as spinal cord injury, spina bifida, multiple sclerosis or Parkinson's disease), or by a non-

neurogenic disorder (such as injury to the rectum or bowel, slow transit constipation or obstructed defaecation symptoms).

- 2.5 Current treatment options for bowel dysfunction include medication (oral drugs, suppositories and enemas), changes to diet, 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.
- 2.6 The NICE guideline on [managing faecal incontinence in adults](#) states that a combination of management strategies is likely to be needed. People with faecal incontinence should therefore be offered advice on a range of coping strategies and treatment options and are encouraged to find the methods that work best for them. There is currently no NICE guidance on managing bowel dysfunction in children.
- 2.7 If bowel continence cannot be achieved by medication, changes to diet and physiotherapy and long-term management strategies such as transanal irrigation should be considered. A number of different transanal irrigation systems, including Peristeen, are available. Clinicians and patients should discuss the options available and may try a number of devices before settling on a preferred system. Some patients may need or prefer surgery, most often a colostomy, ileostomy or a procedure to allow treatment with antegrade continence enemas (ACE procedure).

3 Evidence

Summary of clinical evidence

3.1 The evidence for Peristeen assessed by the external assessment centre (EAC) comprises 13 studies in adults and 11 studies in children, plus 2 studies and 1 audit that were included specifically to provide information on adverse events. Only 1 study was a randomised controlled trial (Christensen et al. 2006); all others were observational studies. For full details of the clinical evidence, see section 3 of the assessment report.

EAC's analysis of the clinical evidence

3.2 Christensen et al. (2006) was a randomised controlled trial in adults (n=87) that showed statistically significant improvements in bowel-related patient-reported outcomes for Peristeen compared with standard bowel care over 10 weeks' follow-up. The EAC considered this to be the best quality evidence to support the use of Peristeen.

3.3 The other 12 studies in adults were observational case series (9 prospective and 3 retrospective). The EAC acknowledged that these studies have a high risk of bias because they included a broad patient population (including people with neurogenic and non-neurogenic bowel dysfunction) and often used inconsistent and non-validated outcome measures and questionnaires. Furthermore, there were high initial drop-out rates in all studies. The EAC stated that despite these uncertainties, the evidence showed that adults who choose to continue using Peristeen report improved clinical outcomes.

3.4 All the studies in children were non-comparative, observational case series (6 observational and 5 retrospective). The studies were done in a very broad patient population with a wide range of ages, types of bowel dysfunction and concurrent conditions. The studies showed improvements in some outcomes for children using Peristeen but the EAC considered the overall published evidence in children to be of low quality. Many of the patient-reported outcomes in the studies were not adapted or validated specifically for use in children, and it was often unclear if the questionnaires had been completed by the child themselves or by a carer or guardian. The EAC and clinical experts commented that these limitations are to be expected, considering that Peristeen is used in a

community environment with patient or carer support, and is associated with subjective as well as objective clinical benefits that children may find difficult to describe themselves.

- 3.5 Bowel perforation is a serious adverse event that is potentially linked to the use of Peristeen. It was a rare complication (1 in 2 million irrigations) reported in the global audit by Christensen et al. (2016). Other, less serious adverse events such as abdominal pain, rectal bleeding and nausea were more common. For full details of the adverse events, see section 3.7 of the assessment report.

Summary of economic evidence

- 3.6 The cost model submitted by the company includes only adults with neurogenic bowel dysfunction as a result of a spinal cord injury. It is based on the economic methodology used in Emmanuel et al. (2016), a paper that describes a cost-effectiveness model based on an audit database from 3 UK hospitals that was set up in 2006. It is a Markov model with a 6-month cycle and 37-year time horizon, and assumes that patients entering the model are the same in terms of spinal injury and constant transition probabilities. It also assumes that Peristeen is used every other day (as recommended by the company), and that the comparator is standard bowel care. For full details of the economic evidence see section 3 of the assessment report.

EAC's analysis of the economic evidence

- 3.7 The company did not include the audit data (on which the model was based) as part of its clinical evidence submission, and these data are not published elsewhere. However, the company provided the EAC with an extract from the data that was used for quality-of-life calculations and also provided information on length of use, and whether patients had stopped using Peristeen. The EAC considered that the audit data seemed to be taken from 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 and different neurological diagnoses). However, the EAC concluded that it had not seen enough information to fully critique the audit data or its suitability for the model.

- 3.8 The company's base-case results showed that using Peristeen could lead to cost savings of £21,768 per patient over 37 years. However, the EAC identified limitations in the company's base case. It made a number of changes and corrections to the model, including:
- incorporating the costs of standard care for people who stop using Peristeen within the Peristeen arm
 - adjusting transition probabilities
 - changing the costs of pressure ulcers and urinary tract infections
 - adding background mortality.

These changes decreased the cost savings associated with Peristeen to £2,867 per patient over the same period. For full details of these changes, see section 4.5 of the assessment report.

- 3.9 The main factors affecting these cost savings are the number of catheters used (driven by frequency of use), carer time to help with irrigation, frequency of faecal incontinence and hospitalisations (particularly for pressure ulcers).

Additional evidence submitted during consultation

- 3.10 During consultation, a healthcare professional submitted a retrospective service review that described the use of transanal irrigation and ACE procedures to treat bowel dysfunction in children (n=111) at 1 UK centre in the UK between 2007 and 2016. The review included children with a wide range of neurological and non-neurological bowel dysfunctions between 2007 and 2016. Children in the study were offered 1 of 3 devices: Peristeen (which 90% of children had) or either of 2 cone-based systems. Although 18 of the 111 children discontinued transanal irrigation during the study, 75 (68%) had restored continence or symptom resolution. The review also noted that 13 of the 68 children with constipation and soiling (19%) had been weaned off transanal irrigation and discharged from the centre. The review reported highly positive comments from parents and carers, who stated that transanal irrigation had significantly improved their child's quality of life. The EAC noted that this study would have been excluded from the literature search, because it included results from 3 devices.

4 Committee discussion

Clinical effectiveness

- 4.1 Christensen et al. (2006) and the observational studies reported significant improvements in patient-reported outcome measures. The committee noted some uncertainty in the quality of this evidence including because Peristeen is self-administered, so there are limitations with patient-reported outcome measures.
- 4.2 The clinical and patient experts explained that for people with bowel dysfunction, even small improvements in these patient-reported outcome measures can translate into significant quality-of-life benefits and could mean the difference between adequate bowel control and incontinence. The committee concluded that the evidence with which it had been presented may underestimate the quality-of-life benefits of Peristeen.
- 4.3 The patient experts emphasised that using Peristeen has vastly improved their lives, allowing them a degree of functional independence (such as going on holiday and maintaining a permanent job) that was not possible with the standard bowel care they had previously received. The committee also heard from the clinical experts that using Peristeen may lead to improved attendance and participation in school and social life for some children with bowel dysfunction.

Drop-out rates in the trials

- 4.4 The committee discussed the high initial drop-out rates in the clinical trials, and was advised by the experts that this accurately reflected their own clinical practice experience. People who try Peristeen are likely to know within the first 1 or 2 months if it is going to be suitable for them. The patient experts explained that it takes up to 2 months to become confident with using Peristeen and that people wishing to use Peristeen must be motivated and determined to succeed with the technology.

Peristeen's use in children

- 4.5 The committee noted that the evidence for Peristeen in children is less robust than in adults. However, it recognised that clinical studies are difficult in children with a wide range of underlying conditions, particularly because of challenges with communicating patient-reported outcome measures. One clinical expert had experience of using Peristeen in teenagers with megarectum. This group used the device on average once a week and were able to maintain bowel control that allowed them to attend school. Several comments were received during consultation about the successful use of Peristeen in children at centres across the NHS, including a report from the UK Paediatric Colorectal Group of the British Association of Paediatric Surgeons.
- 4.6 The committee acknowledged that Peristeen is successfully used in children in the NHS and that there is anecdotal evidence describing its long-term use. The committee noted observations that the drop-out rate for children using Peristeen was not as high as for adults. The expert advisers considered that this is likely to be because of ongoing encouragement and support from parents and carers for children using Peristeen. Despite limitations in the published evidence, the committee concluded that Peristeen may offer significant benefits for children with bowel dysfunction. The committee was aware that the economic modelling only considered adults, but it judged that using Peristeen in children is unlikely to cost any more than standard bowel care.

Comparators

- 4.7 The patient experts explained that, before trying Peristeen, their symptoms were severe enough for them to have considered more invasive treatments such as colostomy.
- 4.8 The clinical experts stated that stoma surgery may represent an improvement in quality of life for some people with bowel dysfunction who are severely disabled by their symptoms and find a colostomy easier to manage. ACE procedures may also be offered to patients and are often an option in children. The experts advised, however, that stoma surgery is associated with a risk of subsequent hernias and the need for revision surgery.

NHS and system impact considerations

- 4.9 The committee was aware that there are other transanal irrigation devices available in the NHS. It considered that clinicians should discuss the different options with the patient to help identify the device which is most appropriate.
- 4.10 The clinical and patient experts explained that the high initial drop-out rates associated with using Peristeen may be reduced by ensuring good quality training and support for both patients and staff. The company has a team of nurses in the UK that provide training for patients and for bowel care specialists, with additional non-clinical resources including a patient support phone programme.
- 4.11 The committee was advised that Peristeen is usually first prescribed by specialist bowel care teams with ongoing prescription in primary care. It considered that there is a need for improved awareness of transanal irrigation in the NHS as a treatment option for bowel dysfunction.
- 4.12 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 healthcare professional. The committee heard that most people will have 1 face-to-face appointment to learn how to use Peristeen, and then have further follow-up support in the community (usually over the phone). The experts noted that it takes most people a few months to get used to Peristeen. Even once someone is confident with using the device, they still need access to a professional support system (such as easily accessible contact details of a specialist nurse) to provide advice as needed.
- 4.13 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.

Cost modelling

- 4.14 The committee accepted the external assessment centre's (EAC) suggested changes to the company's model, and concluded that its results were more plausible than the company's base case. The EAC's updated model showed that using Peristeen could result in cost savings of £2,867 per patient over 37 years.

These savings mainly come from fewer healthcare professional visits and less carer time, reduced incidence of faecal incontinence needing incontinence pads, reduced incidence of urinary tract infections and fewer hospitalisations.

- 4.15 The committee considered that there was considerable uncertainty in the cost modelling for Peristeen. The audit data used in the model was not available for scrutiny and a number of assumptions used in the model were not sourced. Although the EAC was unable to source more robust assumptions, it identified that the hospitalisation rates for pressure ulcers and urinary tract infections were higher than expected so included these in its changes to the model.
- 4.16 The committee discussed the frequency of administration because the cost of each catheter is an important factor influencing the overall cost of treatment. The instructions for use recommend that it should be used every other day after an initial few weeks of using it every day. The clinical experts confirmed that this was the average frequency of use for most people with neurogenic bowel dysfunction using Peristeen.
- 4.17 The committee noted the EAC's sensitivity analysis which showed that Peristeen would become cost incurring if it were used more 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 more frequently (such as when travelling or after a change in diet).
- 4.18 The committee considered that Peristeen can provide important clinical benefits in most people with bowel dysfunction, including improving quality of life and promoting independence. It acknowledged that it may take several weeks before a person is comfortable with using Peristeen, so the device is most effective when offered with specialist training and structured patient support. The committee concluded that although the cost modelling is uncertain, it is likely that using Peristeen in people with bowel dysfunction does not cost any more than standard care.

5 Committee members and NICE project team

Committee members

This topic was considered by the [medical technology advisory committee](#) which is a standing advisory committee of NICE.

Committee members are asked to declare any interests in the technology to be appraised. If it is considered there is a conflict of interest, the member is excluded from participating further in that evaluation.

The [minutes](#) of each committee meeting, which include the names of the members who attended and their declarations of interests, are posted on the NICE website.

NICE project team

Each medical technologies guidance topic is assigned to a team consisting of 1 or more health technology analysts (who act as technical leads for the topic) and a technical adviser or senior technical analyst.

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Accreditation

