# NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

## Medical technology consultation document

# Peristeen anal irrigation system for managing bowel dysfunction

The National Institute for Health and Care Excellence (NICE) is producing guidance on using Peristeen for management of bowel dysfunction in the NHS in England. The medical technologies advisory committee has considered the evidence submitted and the views of expert advisers.

This document has been prepared for public consultation. It summarises the evidence and views that have been considered, and sets out the draft recommendations made by the committee. NICE invites comments from the public. This document should be read along with the evidence base (see Sources of evidence considered by the committee).

The advisory committee is interested in receiving comments on the following:

- Has all of the relevant evidence been taken into account?
- Are the summaries of clinical effectiveness and resource savings reasonable interpretations of the evidence?
- Are the provisional recommendations sound, and a suitable basis for guidance to the NHS?
- Are there any equality issues that need special consideration and are not covered in the medical technology consultation document?

**Note that this document is not NICE's final guidance on Peristeen for management of bowel dysfunction. The recommendations in section 1 may change after consultation.** After consultation the committee will meet again to consider the evidence, this document and comments from public consultation. After considering these comments, the committee will prepare its final recommendations which will be the basis for NICE's guidance on the use of the technology in the NHS in England.

For further details, see the Medical technologies evaluation programme process guide and Medical technologies evaluation programme methods guide.

Key dates:

- Closing time and date for comments: 17:00 on 27th September 2017
- Second medical technologies advisory committee meeting: 17th November 2017

NICE medical technologies guidance addresses specific technologies notified to NICE by companies. The 'case for adoption' is based on the claimed advantages of introducing the specific technology compared with current management of the condition. This case is reviewed against the evidence submitted and expert advice. If the case for adopting the technology is supported, then the technology has been found to offer advantages to patients and the NHS. The specific recommendations on individual technologies are not intended to limit use of other relevant technologies which may offer similar advantages.

# 1 Draft recommendations

1.1 The case for adopting Peristeen for managing neurogenic bowel dysfunction in adults is supported by the evidence. Peristeen can reduce the severity of constipation and incontinence, improve bowel-related quality of life and promote dignity and independence.

1.2 Peristeen may not be suitable for all people with neurogenic bowel dysfunction. Peristeen can be difficult to use: it may take several weeks before a person is comfortable using it themselves, 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 associated with significant uncertainties but it is likely that, overall, 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. It is recommended by the company to 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 as stated in the company's submission is £74.78 per system (comprising Peristeen pump, 2 catheters, 2 straps and a water bag) and £130.00 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 (UTI)
- 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 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.

2.5 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.

2.6 If bowel continence cannot be achieved by medication, changes to diet and physiotherapy, and long-term management strategies such as rectal irrigation should be considered. A number of different rectal 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 or ileostomy or sacral nerve stimulation.

# 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; n=87 adults); all others were observational studies. For full details of the clinical evidence please see section 3 of the assessment report.

## *Key points from the 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 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). They showed improvements in some outcomes for children using Peristeen but the EAC considered the evidence to be very poor quality. The patient-reported outcomes measured in the studies were not adapted or validated for use in children, and it was often unclear if questionnaires were completed by the patient themselves or by a carer or guardian.

3.5 Bowel perforation is a potentially serious adverse event linked to the use of Peristeen. It was a rare complication according to 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 please see section 3.7 of the assessment report.

## *Summary of economic evidence*

3.6 The model submitted by the company was based on that used in Emmanuel et al. (2016; a paper that describes a cost-effectiveness

model which used 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, and that the comparator is standard bowel care. For full details of the economic evidence please 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 it is not otherwise published. However, the company did provide 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, it concluded that it did not have enough information to fully critique the audit data or its suitability for the model.

3.8 The company base-case results showed that use of Peristeen could lead to cost savings of £21,768 over a 30-year time horizon. The EAC made a number of changes and corrections to the model which decreased the cost savings associated with the use of Peristeen to £3,175 per patient over 37 years.

3.9 The changes made to the model by the EAC included:

- included treatment costs for people who stop using Peristeen to the Peristeen arm

- adjusted transition probabilities in the model
- costs of pressure ulcers and UTIs changed
- addition of background mortality and increased time horizon.

For full details of these changes please see section 4.5 of the assessment report.

3.10 The main factor affecting costs for Peristeen is the number of catheters used (driven directly by frequency of use); the main factors affecting costs for standard care are frequency of faecal incontinence and the cost of treating pressure ulcers.

# 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 clinical evidence due to the self-administration of the device and the limitations of the patient-reported outcome measures.

4.2 The clinical and patient experts explained that for people with neurogenic 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 quality-of-life benefits of Peristeen may be underestimated in the evidence.

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.

## *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 was true of 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.

## *Patient selection*

4.5 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.

## *Peristeen's use in children*

4.6 The committee noted that the evidence for Peristeen in children is less robust than that in adults. 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.

4.7 The committee concluded that there were plausible benefits for the use of Peristeen in children but there was currently very limited data on which base patient selection.

## *Comparators*

4.8 The patient experts explained that before trying Peristeen, their symptoms were severe enough for them to have considered more invasive treatments such as nasogastric feeding tubes or colostomy.

4.9 The clinical experts stated that stoma surgery may represent an improvement in quality of life for some people with neurogenic bowel dysfunction who are severely disabled by their symptoms and find a colostomy easier to manage. The experts also advised, however, that stoma surgery is associated with a risk of subsequent hernias and the need for revision surgery.

## *NHS and system impact considerations*

4.10 The committee was made aware that there are other anal irrigation devices available in the NHS.

4.11 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 staff of 20 nurses in the UK that provide training for patients and for continence specialists who prescribe Peristeen. The company has committed to increasing these staff numbers should the uptake of Peristeen increase.

4.12 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.

4.13 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 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.

4.14 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.

## *Cost savings*

4.15 The committee considered the EAC's corrected cost model to be more robust than the cost model submitted by the company. The EAC model showed that using Peristeen could result in cost savings of £3,175 per patient over 37 years. These savings were accounted for by reduced healthcare professional visits and carer time, reduced incidence of faecal incontinence needing incontinence pads, reduced incidence of urinary tract infections and fewer hospitalisations. Despite the significant uncertainties with the data used to inform the model (section 3.9), the committee considered that for most people using Peristeen, the improved clinical outcomes would be at least cost neutral compared with standard bowel care.

4.16 The main factor influencing the cost of Peristeen is the need for a new catheter each time it is used. The device's 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 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).

4.18 The committee concluded that using Peristeen is likely to provide important clinical benefits without incurring additional costs in most adult patients with neurogenic bowel dysfunction.

Peter Groves
Chair, medical technologies advisory committee
August 2017

# 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.

**Kimberley Carter**

Technical analyst

**Bernice Dillon**

Technical adviser

**Jae Long**

Project manager