



Adoption support resource – insights from the NHS

Implementation support

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1 Introduction

This adoption report was written to support the original NICE guidance evaluating Peristeen. The original Peristeen system was discontinued at the end of 2021. From January 2022, only Peristeen Plus is available to the NHS.

Peristeen Plus has minor functional changes. These include new connections, a new dial design, more intuitive symbols on the control unit, and a temperature indicator on the water bag. Peristeen Plus can also be used with either a balloon catheter or a cone catheter. This guidance review focuses on Peristeen Plus with the balloon catheter only.

These product changes did not alter any of the adoption considerations covered in this report. So, it remains valid and relevant to Peristeen Plus.

This resource provides practical information and advice on the <u>NICE medical technologies</u> guidance on Peristeen transanal irrigation system for managing bowel dysfunction.

NICE's adoption team worked with contributors in NHS organisations who use transanal irrigation systems, including Peristeen.

The information presented in this resource is intended to support the NHS in adopting, evaluating the impact of adopting, or further researching this technology. It is complementary to the medical technologies guidance and was not considered by the medical technologies advisory committee when developing its recommendations.

Peristeen (Coloplast) is a transanal irrigation system for managing bowel dysfunction. Further detail is described in the <u>guidance</u>.

The benefits of using Peristeen, as reported by the NHS staff involved in producing this resource, include:

 Offering an additional treatment option for people with bowel dysfunction when conservative treatment has failed or is not suitable or when surgery is unlikely to improve symptoms.

- Providing a less invasive option and reducing the need for surgery.
- Improving people's quality of life, dignity and independence.
- Reducing pain relief (including opioids) people take to help relieve symptoms and may reduce the need for bowel medicines (such as laxatives).
- Facilitating transfer of people's care from surgeons' caseloads to a service led by a specialist clinician.
- Reducing healthcare use (scheduled and unscheduled) including hospitalisations.

2 NICE recommendations

The NICE medical technologies guidance on Peristeen Plus transanal irrigation system for managing bowel dysfunction recommends the following:

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 (recommendation 1.1).

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 (recommendation 1.2).

<u>Cost modelling</u> for Peristeen is uncertain, but it is likely that Peristeen provides additional clinical benefits without costing more than standard bowel care (recommendation 1.3).

The specific recommendations on individual technologies are not intended to limit use of other relevant technologies which may offer similar advantages.

3 Current practice

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). Current treatment options include medication, changes to diet, physiotherapy and surgery. People 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 managing faecal incontinence in adults states that a combination of management strategies 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 methods that work best for them. There is currently no NICE guidance on managing bowel dysfunction in children.

If bowel management cannot be achieved by conservative management, strategies such as transanal irrigation should be considered. A number of different transanal irrigation systems are available, including Peristeen. Clinicians and people with bowel dysfunction should discuss the options available and may try a number of devices before deciding on a preferred system. Some people may need surgery, most often a colostomy, ileostomy or a procedure to allow treatment with anterograde continence enemas (ACE procedure).

4 Tips for adopting the Peristeen transanal irrigation system

NHS contributors to this resource considered the following to be important:

- Representation from relevant <u>members of the multidisciplinary team</u> on the implementation group.
- Finding out if Peristeen is <u>already in use</u> in other teams locally to identify learning or collaboration opportunities.
- Adopting Peristeen as part of an <u>integrated care pathway</u> between specialists and primary care, including agreement about who takes responsibility for long-term ongoing support, monitoring and prescribing.
- <u>Formalising funding</u> through the integrated care pathways to allow coordinated funding and provision of transanal irrigation services.
- Approved training for staff in assessing, starting and supporting the use of Peristeen.
- Support for patients and carers from suitably trained healthcare professionals.

5 How to implement NICE's guidance on Peristeen

To implement this technology into routine practice, contributors to the resource suggest the following steps.

Project management

This technology can be best adopted using a project management approach. NICE has produced the <u>into practice guide</u>, which sets out the most common steps taken when putting evidence-based guidance into practice.

Implementation team

The first step is to form a local project team who will work together to implement the technology and manage any changes in practice.

Individual NHS organisations will determine the membership of this team and how long the project will last. Consider the following membership of the team so that the guidance is implemented in an effective and sustainable way:

- Clinical champion: they could be a senior clinician with an interest in continence, and should have the relevant knowledge and understanding to be able to drive the project, answer any clinical queries and champion the project at a senior level. This could be a colorectal consultant, specialist nurse or physiotherapist.
- Project manager: they could be someone in a clinical or managerial role who will be responsible for the day-to-day running of the project, coordinating the project team and ensuring the project is running as planned.
- Management sponsor: they will be able to help assess the financial viability of the project, ensure the business case is produced and help to show the cost savings achieved.

- Healthcare professionals with expertise in managing continence, which may include:
 - colorectal consultant
 - relevant surgeons
 - gastroenterologist
 - urology consultant
 - specialist nurse
 - urogynaecologist
 - gynaecologist
 - physiotherapist
 - gastrointestinal physiologist
 - care of the elderly consultant
 - rehabilitation/head injury consultant
 - cognitive behaviour therapist
 - play specialist
 - GP
 - representatives from local area prescribing committee and continence clinics.
- Data analyst: they will be able to help set up systems to collect and analyse <u>local data</u> to ensure the pathway is being appropriately followed and resulting in expected outcomes.

Assessment of readiness

The project team may wish to consider the following questions when preparing to adopt this technology:

• Is Peristeen already being used in the organisation by another team? Can we learn from this or collaborate?

- What is our current service and care pathway for people with bowel dysfunction?
- What changes need to be made to best integrate the technology into the care pathway?
 - Do we have a dedicated clinic such as a specialist pelvic floor service or dedicated healthy bowel clinic we can use?
 - Do we need specific irrigation clinics?
 - How can we offer supervised trials of Peristeen in an appropriate environment?
 - Once the person is stable using Peristeen, who will provide longer-term support and review?
- Which people is the technology most suitable for, considering selection criteria and contraindications?
- Should we adopt it within a single standalone clinic or engage with other local healthcare organisations and commissioners as part of a region-wide adoption plan?
- Will a pilot period be helpful?
 - Is any new documentation needed? For example: protocols, flow charts, referral forms, consent forms and proformas to support adherence to the care pathway.
- How will a pilot be funded and how will the long-term financial support for the service be provided?
- How will project performance measures at a local level be identified and implemented?
- Are there any obvious challenges and how can these be overcome?

Care pathway mapping

Individual organisations need to consider the point at which to implement the guidance, and any changes to the current pathway that may be needed. Firstly, identify current practice. This should be what usually happens and not what ideally would happen.

Once current practice has been established, asking the questions in <u>assessment of readiness</u> will help in understanding where the technology will fit in the care pathway and what changes to the pathway are needed.

Integrated care pathway

Peristeen is one of a suite of transanal irrigation systems used in practice. It is most successfully adopted when integrated into care pathways that have been agreed across a locality and by the <u>multidisciplinary team (specialists and primary care)</u>. Peristeen is commonly started by specialist continence services, which may be secondary care outpatient or community based. Use of <u>documentation</u> helps to raise awareness of the pathway and where Peristeen fits, and supports a standardised approach for use across all healthcare professionals. The <u>Centre for Nursing Innovation's Rectal irrigation clinical toolkit</u> can be used to support the paediatric care pathway and the <u>Greater Manchester Trans-Anal Irrigation Pathway</u> could be used to support the adult care pathway.

People who would benefit from Peristeen will commonly be referred from other hospital and community teams. It will be important to agree and document who has responsibility for what aspects of patient care. For example, to manage demand, a service offering Peristeen may only be responsible for starting treatment, with the referrer being responsible for all other aspects of care.

Once a person has been <u>assessed as suitable</u> for transanal irrigation, and Peristeen selected as the most suitable system for that individual, contributors to this resource recommend offering an induction session with a specialist clinician. Ideally, during this session the person will have chance to <u>use the device under supervision</u>. This may need more than 1 appointment.

Children will need desensitisation to Peristeen; contributors recommend at least 2 appointments to achieve this, allowing the child to play with the device and become familiar with it.

To support long-term sustained use, regular follow-up is important. The timing should be agreed as part of the integrated care pathway; contributors explained that follow-up ranged from every 2 weeks until stable or at 1, 4, 6 and 12 weeks by phone or in clinic. At these follow-up appointments, a healthcare professional with appropriate knowledge and skills can check patient experience, the correct use (including volume and frequency) of the device and its <u>effectiveness</u>, any current medication and the overall effect on quality of life. Ideally this would be the same person gathering consistent information to allow reliable assessment. Any changes to therapy should be given for at least 2 weeks to take effect before being changed. Some contributors suggested that if the person is stable at 12 weeks, they can be discharged back to the referrer; if not, a re-evaluation may be

needed and reviews will continue every 3 months.

Once a person is stable the integrated care pathway must detail who has responsibility for ongoing support, regular reviews and the continued prescribing of the device and consumables. This ensures that Peristeen continues to be the most appropriate option for the person, thereby supporting sustained use and potentially reducing re-referrals to specialist continence services. This should be delivered by healthcare professionals with the appropriate knowledge and skills.

Patient selection

Peristeen is not suitable for all people needing bowel dysfunction management and appropriate patient selection is important for successful treatment and effective use of resources. Input from members of the multidisciplinary team can be used to assess a person's suitability for transanal irrigation and in partnership with the person to choose which device is most appropriate. Patient selection is informed by a combination of factors including:

- Any relevant contraindications.
- Tests such as transit marker studies, defecating proctograms and anorectal physiology studies may be helpful to identify conditions for which Peristeen is recommended.
- Assessing the person's symptom history for suitability for Peristeen. Contributors report using Peristeen for:
 - long-term bowel dysfunction (over 6 months) with symptoms such as incomplete bowel emptying, slow-transit constipation, neurogenic bowel dysfunction, faecal incontinence and obstructive defaecation syndrome
 - in children with urological conditions associated with bowel incontinence, anorectal malformations, Hirschsprung's disease and chronic constipation.
- Assessing whether previous interventions and less invasive conservative treatments such as toilet training, laxatives, dietary modifications, physiotherapy, lifestyle changes have failed or do not work. Use of laxatives with Peristeen should be discussed and agreed on a case-by-case basis.

 Assessing the person's (and if appropriate carer's) individual needs, physical and cognitive abilities to use the devices and their motivation and determination to succeed with this type of treatment.

Use <u>local documentation</u> including proformas to ensure that the agreed process is followed for selecting and training patients.

Patient training, information and support

Having noted the considerable dropout rate when people were using Peristeen in clinical studies, the medical technologies advisory committee recommended that it is most effective when offered with specialist training and structured patient support. Contributors said support should be tailored and that people need information, training, support and encouragement both before and while using Peristeen to promote long-term use. Contributors suggested the following considerations:

- Setting realistic expectations about how long it can take to establish an effective routine (this can reduce frustration and encourages people to keep using the device).
- Identifying the most suitable environment for people to first use Peristeen while supervised. This allows for a practical demonstration and an opportunity to solve any initial problems. Contributors noted that settings include a person's own home, a care setting or clinic (for example a disabled toilet, within the clinic). Note that some people may not wish to travel straight after trialling this for the first time.
- Explaining the side effects that people should be aware of.
- Providing both hands-on training and written information (diagrams and pictures).
- Involving a play specialist when using transanal irrigation in children.
- Giving people the name of a dedicated healthcare professional who they can contact
 if they have questions or problems to ensure they feel supported (this may be a
 qualified nurse, physiotherapist or physiologist).

Healthcare professional education and training

The success of Peristeen depends on the expertise, skills and competence of healthcare professionals responsible for selecting people and providing initial and ongoing support.

Training needs will depend on current knowledge, skills and role in relation to Peristeen. For example, staff who start treatment with Peristeen (such as nurses and physiotherapists with a special interest in continence) may work in a different service to those responsible for the long-term support and monitoring of people who are stable.

Those responsible for training people in using Peristeen should be signed off as trained and competent following an approved course. Training should cover anatomy and physiology, colorectal surgery, gastrointestinal disorders and a specific focus on transanal irrigation.

The manufacturer of Peristeen provides tailored training and refresher sessions as needed from their registered nurse advisors, who will also support joint patient visits if required.

Business case

The <u>NICE guidance</u> states that the cost modelling for Peristeen is uncertain, but it is likely that it provides additional clinical benefits without costing more than standard bowel care. The <u>NICE resource impact statement</u> states that any additional costs as a result of implementing Peristeen are likely to be offset by a reduction in adverse events.

Producing a business case should be a priority for the implementation team. Local arrangements for developing and approving business plans will vary, and each organisation is likely to have its own process in place. Submitting the business case to the local area prescribing committees will be particularly important if seeking agreements with primary care to support the long-term prescribing and monitoring of people who are stable.

Commissioning and prescribing

If there are no formal agreements about who takes responsibility for the ongoing prescribing of Peristeen once the person is stable, there is a risk that funding may not be available.

A number of approaches could be used to support a formalised funding agreement that allows coordinated funding and provision of transanal irrigation services:

- Having an agreement with an area prescribing committee that Peristeen can be
 prescribed in primary care. This is likely to be following submissions of business cases
 and information to support adoption from specialist services.
- Including Peristeen on a local formulary. Transanal irrigation systems, including
 Peristeen, are on the NHS Electronic Drug Tariff (Part IXA Appliances). This means
 that Peristeen can be prescribed by any primary care prescriber and supplied by
 community pharmacy. However, including devices on the local formulary supports a
 consistent approach and gives reassurance that it has specialists' approval.
- Having a local agreement (for example, as a shared care agreement) that GPs will be responsible for prescribing Peristeen for a person in whom it has been established. This approach will be supported through regular communication with GPs about the potential benefits and:
 - training days for primary care staff
 - supporting people to engage with their GP
 - writing individualised letters to the person's GP detailing the training and information the person has received about Peristeen, improvements in symptoms to date, the average quantities that the person will need monthly and contact details for advice if the person needs help.
- <u>Commissioning a continence prescribing service</u> which takes responsibility for the
 ongoing prescribing of continence products, including transanal irrigation systems, for
 all patients within an agreed area. Examples include: <u>Nottinghamshire Healthcare NHS</u>
 Foundation Trust and Rotherham NHS Foundation Trust.
- The clinical commissioning group commissions the specialist service that has initiated transanal irrigation to provide long-term support and prescribing rather than the person being referred to primary care.

Ensure that plans are in place to maintain the cost-effective use of transanal irrigation systems once established in practice. This could include reminders for clinical staff to ensure the correct type and quantity (taking into account the person's routine) are prescribed and developing a system to flag up people who are using the products too frequently so that they can be followed up.

Measuring success

It is important to record a baseline assessment and take measurements during and after implementation to show the cost and clinical benefits of adopting Peristeen.

Contributors to this resource suggested that before implementation, the team should plan who will be responsible for collating and managing this data.

Individual patient-level data

Aims to show demonstrable improvement in symptoms. This informs the care plan review process and can support a person's case for long-term funding. Patient-level data should be collected before and after starting Peristeen (at regular review points) using visual analogue scores (using the same validated measure across the locality supports a consistent approach). Qualitative data should also be collected from patients about how Peristeen affects their quality of life.

Service-level data

Includes:

- number of people offered Peristeen and number who accepted
- number of people still using Peristeen at set points over time, starting at 12 weeks
- changes in costs of a person's medicines for managing the condition before and after starting Peristeen
- how often irrigation needs to be done and volume of irrigation solution used
- rates of surgery for stoma and anterograde continence enema (ACE) procedures before and after adopting Peristeen.

If a service offers more than 1 transanal irrigation system, collecting this data for all systems is likely to be beneficial.

Developing local documentation

The following are examples of tools developed by NHS services using Peristeen, which can

be used for developing local documentation. They have been shared by contributors; they were not produced for or commissioned by NICE.

Care pathways

- <u>Functional bowel dysfunction care pathway: a real-world example</u> (Aintree University Hospital NHS Foundation Trust)
- <u>GP letter TAI initiation: a real-world example</u> (Manchester University NHS Foundation Trust)
- <u>Patient passport: a real-world example</u> (St Helens and Knowsley Teaching Hospitals NHS Trust)

Patient assessment and selection

 <u>Developing an adult Peristeen assessment tool: a real-world example</u> (Manchester University NHS Foundation Trust)

6 Shared learning examples

The following shared learning examples show how NHS organisations have implemented this NICE medical technologies guidance:

- Manchester University NHS Foundation Trust
- Aintree University Hospital NHS Foundation Trust
- St Helens and Knowsley Teaching Hospitals NHS Trust

7 Acknowledgements

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One contributor is a member of the Coloplast Continence Advisory Board and another contributor has provided ad hoc training and chaired a meeting for healthcare professionals on behalf of Coloplast.

8 About this resource

This resource accompanies <u>NICE medical technologies guidance on Peristeen Plus</u> transanal irrigation system for managing bowel dysfunction. It is an implementation tool that summarises the experiences reported by NHS contributors who have adopted this technology and shared the learning that took place.

It is the responsibility of local commissioners and providers to implement the guidance at a local level, being mindful of their duty to advance equality of opportunity and foster good relations. This document should be interpreted in a way that is consistent with this.

More information about the adoption team.

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