Peristeen anal irrigation system for managing bowel dysfunction – NICE draft guidance

Stakeholder consultation

Stakeholder report: UK Paediatric Colorectal Group

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1) Who are we?

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

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

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

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

We are also referred patients with severe functional constipation where gross distention of the rectum, faecaloma formation and overflow soiling are part of the clinical picture. Often the family, social and psychological issues that have developed while trying to manage this situation prior to our input, play a huge role in the ongoing management. We therefore work closely where possible with paediatric gastroenterologists, psychologists, and constipation or continence nurse specialists.

2) Why are we interested in this NICE guidance?

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

Our strategies in dealing with these problems is often to exclude a correctable anatomical problem – which might involve surgery and then work through the stepwise approach to bowel management. This can involve oral medications – which often has already been tried and can be counterproductive in incontinence. Rectal medications - which can be more useful and we as a group are more likely to suggest this approach, as we understand it works at the site of the problem – and in troublesome cases, parents and children are more likely to be on board with this idea. However, the idea of a colonic or rectal washout is also more familiar to us as a specialist group as we use it regularly in the early treatment of Hirschsprungs disease. Post-operative long term problems are also amenable to washout therapy and ‘bowel management’ is a familiar term to us. The literature often recalls the development of the Shandling catheter\(^1\). We are also familiar with the construction of the Malone Antegrade Continence Enema (aka MACE or ACE). This is where a conduit into the caecum is constructed usually using the appendix, through which a catheter can be passed to instill a volume of fluid to washout the entire colon\(^2\).

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

The idea of emptying out the colon with a flush of water to ensure the colon is clean and empty -leaving the child clean for 24 hours or more is a strategy we need to offer many of our children. Recently we have adopted the engineered Peristeen pump and other devices available as the preferred way of instilling fluid. This sea change in practice is almost complete across the country. This is not a new idea in our specialty but these devices are more effective and more user friendly than more traditional or surgical options.

3) Our response to the consultation.

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

The table below summarises the responses received.

<table>
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<tr>
<th>Centre</th>
<th>Experience</th>
<th>Comments</th>
<th>Comment on draft guidance</th>
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<tbody>
<tr>
<td>Brighton</td>
<td>9 cases, 2 failed due to compliance issues. Hirschsprungs, ARM and intractable constipation. “A big fan” Careful selection required. Easy to use, quick, no soiling and improve QoL. Good support from Coloplast</td>
<td></td>
<td>Concentrates on adults.</td>
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<td>Rep.</td>
<td>Bristol</td>
<td>We use Peristeen a lot.</td>
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<tr>
<td>Evelina - London</td>
<td>Not used frequently</td>
<td>Good nurse specialist who helps - some patients have stuck with it but often end up having an ACE</td>
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<tr>
<td>Leicester</td>
<td>Over 40 children</td>
<td>Most doing very well with it. Most start using it on daily basis and some progress to alternate days but not all. Some are cured of the bowel dysfunction. The document concentrates on neurogenic cause of bowel dysfuction. Why doesn’t it include ARM and Hirschsprungs as well as idiopathic constipation? Why is it only looking at Peristeen? There are lots of products on market and choice helps compliance. Some children don’t like the balloon and prefer a cone based system.</td>
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<tr>
<td>Leeds</td>
<td>Numbers not available but experienced users of Peristeen</td>
<td>Good response in Spina bifida and Anorectal Malformations. No comments.</td>
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<tr>
<td>Liverpool</td>
<td>Have registered separately as Stakeholders</td>
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<tr>
<td>Manchester</td>
<td>Have registered separately as Stakeholders</td>
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<tr>
<td>Norwich</td>
<td>5 patients currently using it although 1 patient had funding withdrawn by GP</td>
<td>Lives transformed - use of and dependence on laxatives has reduced and they have managed to establish cleanliness. Peristeen used as it comes with nurse support. Qufora only has telephone support but is sometimes useful to start with this. See authors comments below.</td>
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<td>Location</td>
<td>Details</td>
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<tr>
<td>Sheffield</td>
<td>Extensive experience. 111 patients on Transanal Irrigation between 2009-2016. 61% functional, 21% neuropathic and 11% ARM. 90% Peristeen. Symptom resolution (clean) between 50-83%. 2 were ineffective and 16% were non-compliant or went onto have ACE. 19% with constipation and soiling were weaned off TAI. Safeguarding issues discovered in some with poor outcome. Scope of guidance needs to be widened to where medical management (as per current NICE guidance) of constipation or incontinence has failed to control symptoms.</td>
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<tr>
<td>Southampton</td>
<td>Use Peristeen a lot and numbers of ACE procedures performed (in the centre that developed the technique!) have dropped dramatically. ACE still preferred in patients also having bladder Augmentation and mitroffanoff. Experience published. 24 cases published with 2 failures and significant improvement in QoL. Nurse specialists report that some patients like the Iri-pump and cone variations. Most paediatric published data is fairly poor but often comes from an era when Peristeen was relatively new. Coloplast seem to have overcome early issues with balloon bursting and large catheters.</td>
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4) Comments on the draft guidance and consultation.

4.1 The scope of the guidance is not specified clearly. The title of the guidance suggests ‘bowel dysfunction’ in general but the wording of the document often refers to neurogenic bowel disorders usually indicating Spina bifida or other spinal cord injuries. We use Peristeen for a wide range of congenital and acquired anorectal disorders.

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

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

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

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

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

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

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

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

5) Conclusions.

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

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

6) Acknowledgements

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

7) References