POSITION STATEMENT: Trans-Anal Irrigation Systems- Amber 0 colour classification.

Trans-anal Irrigation Systems are recommended for use within the Lancashire Health Economy for the treatment of **Neurogenic Bowel Dysfunction and Non-Neurogenic Bowel Dysfunction including; chronic constipation and chronic faecal incontinence.**

Treatment should be initiated and stabilised by specialist service providers for a period of 3 months. Prescribing responsibilities may then be transferred to primary care **after the initial 3 month period** only where there has been a demonstrable improvement in validated measures of bowel function such as the Cleveland Clinic constipation scoring system, St Mark's faecal incontinence score or neurogenic bowel dysfunction score.

The Choice of product should be made by an appropriately trained specialist, in conjunction with the patient. Where possible the least invasive device, which meets the patients' needs should be used in preference.

It is recognised that there are differences in the levels of service provision across Lancashire and that use of TAI in non-neurogenic bowel dysfunction may result in a significant increase of use. Existing primary care services cannot be expected to provide support for this. Therefore, TAI is only supported by the LMMG in the context of an agreed commissioning pathway. Specialist services are expected to retain responsibility for on-going patient follow-up and review (until such time that treatment is stopped).

Supporting Safety Information

Risk of using the devices inappropriately.
A Medical Device Alert (MDA) was issued by the MHRA in February 2014 in relation to the peristeen® device.[1] As a consequence, the manufacturer has updated the instructions, contra-indications, precautions and warning sections. More detailed instructions for patient examination before starting transanal irrigation were also added. **All devices require specialist initiation by an appropriately trained healthcare professional.** Where an individual device is used contrary to the manufacturers current recommendations, the company will not accept any liability for any injury or loss.

The Risk of bowel perforation.
There are three mechanisms of bowel perforation; impaling trauma following catheter insertion, over inflation of the balloon or exaggerated hydrostatic pressure during water instillation. Evidence suggests that the perforation rate is most likely to occur in the 1st few months of treatment, i.e. the risk is not cumulative.[2&3]
Historically the risk has been estimated to be between 1 in 50,000-100,000.[2] But more recently a 2015 publication based on audit data from 2005-2013 quantified the risk as 6 perforations per million procedures.[3]

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Contraindications.
A Consensus review of best practice in transanal irrigation in adults, outlined the following contraindications to irrigation:

Absolute Contraindications[2]

- Anal or rectal stenosis
- Active inflammatory bowel disease
- Acute diverticulitis
- Colorectal cancer
- Within 3 months of rectal surgery
- Within 4 weeks after endoscopic polypectomy
- Ischaemic colitis

Relative Contraindications[2]

- Severe Diverticulitis: Diffuse disease, dense sigmoid disease, previous diverticulitis or diverticular abscess
- Long term steroid medication
- Radiotherapy to the pelvis
- Prior rectal surgery
- Faecal impaction
- Painful anal conditions
- Current or planned pregnancy, bleeding diathesis or anticoagulant therapy (not including aspirin or clopidogrel)
- Severe autonomic dysreflexia

It is also important to consider patient factors such as ability to self-administer and acceptability of using an invasive device. The following should be taken into consideration, history of sexual abuse, patient vulnerability, capacity to consent and risk of self-harm. **The patients home environment should be risk assessed prior to initiation where possible.**

A Digital rectal examination prior to first irrigation is essential to assess faecal impaction, anal sphincter function and co-ordination. Faecal impaction should be treated prior to starting treatment. If the patient has had previous anal or colorectal or pelvic surgery an endoscopy or comparable examination should be performed to exclude co-morbidity.

Patient/carer understanding of adjunctive management strategies. Continued compliance with adjunctive management strategies, e.g. diet, fluid intake co-prescribed laxatives is usually required as directed by the specialist, there is a risk of deterioration if patients/carers inappropriately stop alternative management strategies. It is important that realistic expectations are set with the patient.

Product Choice

The Choice of product should be made by an appropriately trained specialist, in conjunction with the patient. The product which the patient finds easier to use should be ordinarily be chosen, with consideration of cost and invasiveness where a number of devices are suitable.

- There are 4 categories of irrigation devices. Low volume 'mini' devices, cone devices, catheter/balloon devices and bed systems. Although the majority of published evidence in support of trans-anal irrigation relates specifically to the peristeen® device, or to trans-anal irrigation (device not specified). It is the view of local expert advisors that the benefits achieved from irrigation using one type of device are applicable to the other devices. That is the treatment outcomes relate to the bowel being irrigated (not to the particular device). This view is supported by local patient outcomes data.
- The choice of device used, is dependent on a number of patients factors including their anatomy, dexterity, ability to use the device and volume of irrigation required. Where possible the least invasive device, which meets the patients' needs should be used in preference.
- The 'bed' device is considered to have a theoretical increased risk of bowel perforation compared to the other devices due to the wide diameter and rigidity of the rectal device. Organisations should ensure that appropriate risk assessments are undertaken prior to use of this system. Consideration should be given to incorporating additional restrictions on use for example, only under the direct supervision of a registered healthcare professional with appropriate training or two members of staff required.

- Because the licensing process for medical devices differs considerably from that of medicines, product specific evidence of clinical effectiveness and safety is often lacking. The LMMG have carried out a detailed review of information provided from the device manufactures and local expert advisors. Based on this, the following devices are considered appropriate for use within the Lancashire Health Economy, (when used in accordance with the manufacturers instructions); Peristeen® Quofora® range, IryPump®.
  The LMMG have not made a recommendation regarding the use of Aquaflush® because the manufacturer did not respond to requests for product information and the clinical team did not consider this product to have any specific advantages over alternative irrigation systems.
- Organisations should be mindful that any modifications to the system could potentially result in changes to the products safety or effectiveness. Where the manufacturer updates their product, organisations should ensure that there is a process in place which ensures that the new or modified device is assessed for safety and functionality.

References

1. MHRA. Medical Device Alert. Ref:MDA/2014/007. 2014 Accessed via: https://www.oxfordshire.gov.uk/cms/sites/default/files/folders/documents/business/providers/MDA-2014-007final.pdf
2. Emmanuel et al. Consensus review of best practice transanal irrigation in adults. Spinal Cord 51, 732-738. 2013.
3. Christensen et al 2015. Global audit on bowel perforations related to transanal irrigation

Please access this guidance via the LMMG website to ensure that the correct version is in use.

Version Control

Version Number	Date	Amendments Made	Author
Version 1.0	April 2016	Approved	Susan McKernan
Version 1.1	May 2016	Recommendation re; non-neurogenic bowel updated	Susan McKernan

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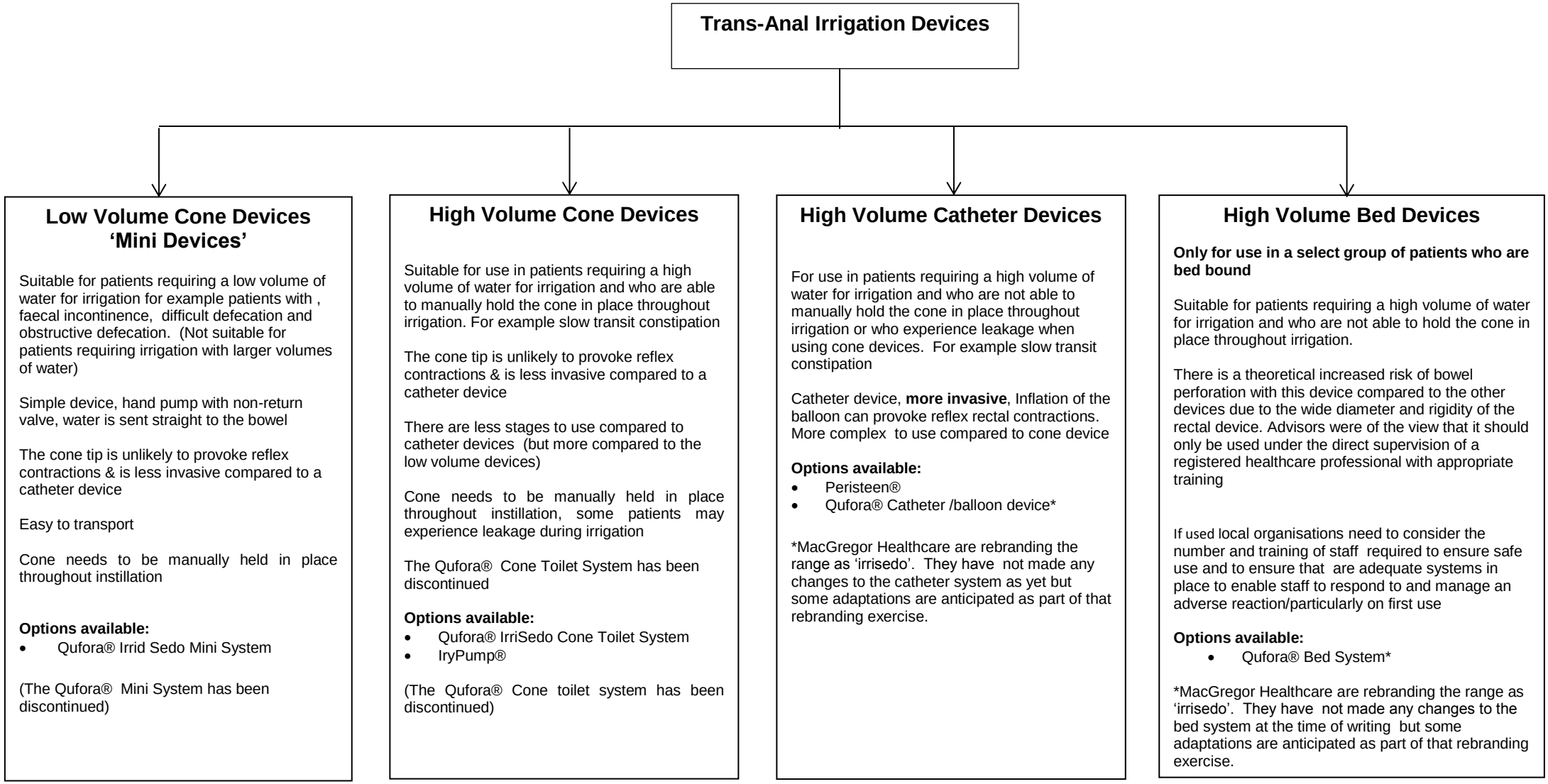
Figure 1. Overview of Device Types and Place in Therapy (Produced by MLCSU Following Specialist Discussions)



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From left to right
As a broad generalisation, there is increasing cost, complexity of use and risk of adverse events