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An tÚdarás Um Fhaisnéis
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Protocol for a rapid HTA on the use of vesicostomy buttons in children

Publication date: 16 April 2026

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The Health Information and Quality Authority (HIQA) is an independent statutory body established to promote safety and quality in the provision of health and social care services for the benefit of the health and welfare of the public.

Reporting to the Minister for Health and engaging with relevant government Ministers and departments, HIQA has responsibility for the following:

- **Setting standards for health and social care services** — Developing person-centred standards and guidance, based on evidence and international best practice, for health and social care services in Ireland.
- **Regulating social care services** — The Chief Inspector of Social Services within HIQA is responsible for registering and inspecting residential services for older people and people with a disability, and children’s special care units.
- **Regulating health services** — Regulating medical exposure to ionising radiation.
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- **Health technology assessment** — Evaluating the clinical and cost effectiveness of health programmes, policies, medicines, medical equipment, diagnostic and surgical techniques, health promotion and protection activities, and providing advice to enable the best use of resources and the best outcomes for people who use our health service.
- **Health information** — Advising on the efficient and secure collection and sharing of health information, setting standards, evaluating information resources and publishing information on the delivery and performance of Ireland’s health and social care services.
- **National Care Experience Programme** — Carrying out national service-user experience surveys across a range of health and social care services, with the Department of Health and the HSE.

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1 Introduction

1.1 Background

Problems with storing urine and emptying the bladder can arise in children with particular health conditions. These include neurogenic bladder (where the nerves which control the urinary bladder and sphincter are damaged, for example due to spina bifida), posterior urethral valves (a congenital condition where tissue blocks the male urethra), prune belly syndrome (a rare condition which causes abnormalities in the urinary tract), and postoperative or temporary urinary retention (inability to fully empty the bladder).⁽¹⁻³⁾ Management options for urine storage and bladder emptying problems vary, depending on factors such as the severity of the condition, patient or caregiver's preferences and whether an option is feasible and safe due to an individual patient's anatomy.⁽⁴⁾

The main goals of bladder emptying are to:

- maintain low bladder pressure to prevent damage to the upper urinary tract
- minimise infections of the urinary tract
- prevent pain and discomfort
- manage urine leakage.⁽⁵⁾

The use of a vesicostomy button was proposed over 20 years ago, in 1996 as an alternative surgical management strategy for some children with urine storage and bladder emptying problems.⁽⁶⁾ A vesicostomy is a surgically-created opening (known as a stoma) in the bladder. The vesicostomy button consists of a silicone device which uses a retained feeding tube (a soft tube usually placed in the stomach to allow for feeding), known as a gastrostomy button. The tube component of the vesicostomy button is placed into the vesicostomy to allow intermittent emptying of the bladder, without the need for a traditional catheter and catheter bag.^(7, 8)

Initial scoping of the literature indicated that there are at least two devices currently being used in this way: the 'MiniONE[®]' (Applied Medical Technologies)⁽⁹⁾ and the 'MIC-KEY[®]' (Avanos Medical).⁽¹⁰⁾ Both of these devices are made from medical-grade silicone and are CE marked for the purposes of gastrostomy feeding (feeding through a surgical opening from the abdominal wall directly into the stomach), but not for urine storage and bladder emptying. CE marking is a declaration by a manufacturer that a product meets all of the relevant European Union requirements, for example, health, safety and environmental requirements. However, the use of these devices in urine storage and bladder drainage is outside the manufacturers' intended purpose and instructions for use at present.⁽¹¹⁻¹³⁾

Following a request from the Minister for Health, HIQA agreed to undertake a rapid Health Technology Assessment (HTA) of the use of vesicostomy buttons in children. This rapid HTA aims to identify and summarise the international evidence on the safety, effectiveness, and outcomes associated with the 'off-label' use of gastrostomy buttons as vesicostomy buttons in children. 'Off-label', in this context, refers to the use of medical devices outside the manufacturer's intended purpose or instructions for use.

1.2 Aims and objectives

The aim of this rapid HTA is to evaluate the use of vesicostomy buttons in children to facilitate urine storage and bladder emptying.

The objectives for this rapid HTA are to:

- describe common clinical indications for the use of vesicostomy buttons in children.
- provide a description of the technology (vesicostomy buttons) to include a brief overview of the role of medical devices used for a clinical indication outside of their instructions for use, engagement with the relevant manufacturers and distributors and, where available, a brief overview of the guidance for the use of vesicostomy buttons internationally.
- describe the clinical effectiveness and safety of vesicostomy buttons, including, where available, a comparison with the potential benefits and harms associated with the alternative management options (for example, traditional suprapubic catheters).
- provide advice to the Minister for Health, based on the evidence identified in this assessment.

2 Establishment of the Expert Advisory Group

An appropriately represented Expert Advisory Group (EAG) has been convened as a source of expertise to inform interpretation of the evidence and development of the advice to the Minister for Health. This group comprises nominees from a range of stakeholder organisations, including patient representatives, healthcare providers and managers, as well as clinical and methodological experts. The terms of reference of the Expert Advisory Group (EAG) are to:

- Contribute to the provision of high-quality research and considered advice by HIQA to the Minister for Health.
- Contribute to the work of the group by providing expert guidance, as appropriate.

- Be prepared to provide expert advice on relevant issues, outside of group meetings as requested.
- Provide advice to HIQA regarding the scope of the report.
- Support the Evaluation Team during the process by providing expert opinion and access to pertinent data, as appropriate.
- Review the draft report from the Evaluation Team and recommend amendments, as appropriate.
- Contribute to HIQA's development of its approach to evidence synthesis by participating in an evaluation of the process on the conclusion of the project.
- Notify the project lead if a nominee can no longer participate or contribute to the process as non-participation may require alternative EAG membership to be sought.

3 Description of the technology

A description of the use of gastrostomy buttons and their associated attachments in the context of urine storage and bladder emptying will be provided. This will include a brief overview of the role of medical devices used for a clinical indication outside of their instructions for use, a high-level overview of the characteristics of the different forms of the available vesicostomy buttons, and a description of the methods used to insert them.

A brief overview of guidance for the use of vesicostomy buttons internationally will be provided. This section will be informed by a search of grey literature sources including the International Network of Agencies for Health Technology Assessment, Guidelines International Network, Guideline Central, and the Turning Research Into Practice (TRIP) database. The full list of grey literature sources is provided in the [Appendix](#).

4 Epidemiology and burden of disease

A brief overview of the common clinical indications for the use of vesicostomy buttons in children will be provided. This section will be informed by a review of national and international literature.

5 Clinical effectiveness and safety

5.1 Review question

This rapid HTA will consider the following question:

- What is the clinical effectiveness and safety of the use of vesicostomy buttons in children?

5.2 Search strategy

Electronic searches will be conducted in MEDLINE (EBSCOhost), Embase (Elsevier), and CINAHL (EBSCOhost) and Web of Science. The search strategy for the MEDLINE (EBSCOhost) search is outlined in the [Appendix](#). In addition, a search will be conducted using the Cochrane Controlled Register of Trials (CENTRAL) via the Cochrane Library, clinicaltrials.gov and ICTRP to identify ongoing and completed clinical trials and research studies. A search of the *Journal of Pediatric Urology*, *Urology* and the *Journal of Urology* will also be undertaken.

A grey literature search will also be performed, including a search of the International Network of Agencies for Health Technology Assessment, Guidelines International Network, Guideline Central, UpToDate.com and the Turning Research Into Practice (TRIP) database. Up to the first 50 results for each search on each website will be reviewed.

Reference lists from the included records will be searched for potentially relevant citations. Forward-citation searching of included studies will be undertaken using the citationchaser package <https://estech.shinyapps.io/citationchaser/>. No language or date restrictions will be applied to the eligibility criteria or the search strategy. Where documents are considered for inclusion in the evidence summary, they will be translated via DeepL translation software.⁽¹⁴⁾ Complete documentation of all search strategies for this project can be found on the Zenodo open repository: <https://doi.org/10.5281/zenodo.18875842>.

5.3 Eligibility criteria

The review question was formulated in line with the Population, Intervention, Comparator, Outcome, Study Type (PICOS) framework, as presented in [Table 1](#).

Table 1: Population, intervention, comparator, outcomes, study type (PICOS)

Population	Newborns or children who need urinary drainage due to poor urine storage or bladder emptying.
Intervention	Bladder drainage using a gastrostomy button, also known as a vesicostomy or cystostomy button.
Comparator	Any or none.
Outcome	Any clinical effectiveness, safety or humanistic outcomes. Examples include:

	<ul style="list-style-type: none"> ▪ clinical effectiveness: proportion of patients with adequate voiding, adequate urine storage, rate of UTI, and rate of lithiasis. ▪ safety: complication rate, incontinence rate, reversal rate. ▪ humanistic: acceptability, quality of life, satisfaction.
Study type	<p>Included:</p> <ul style="list-style-type: none"> ▪ HTAs, systematic reviews, clinical guidelines, narrative reviews, RCTs, non-randomised controlled trials, cohort studies, case-control studies, cross-sectional studies, case series, case reports. <p>Excluded:</p> <ul style="list-style-type: none"> ▪ Editorials, correspondence, opinion pieces.
Languages	Only articles for which an adequate English translation can be obtained will be included.

Key: HTA – health technology assessment; RCT - randomised controlled trial; UTI – Urinary tract infection

5.4 Selection of eligible records

All citations identified from the collective search strategy will be exported to EndNote for reference management. Duplicates will be identified and removed before uploading to Covidence for screening. Using Covidence, two reviewers will independently review the titles and abstracts of the remaining citations to identify those for full-text review. The full texts will be obtained and independently evaluated by two reviewers applying the defined inclusion and exclusion criteria. Where disagreements occur, discussions will be held to reach consensus and where necessary, a third reviewer will be involved. Records excluded during the full-text review stage will be documented alongside the reasoning for their exclusion.

5.5 Data extraction and management

Data will be extracted by one reviewer using a pre-piloted standardised data extraction template in Microsoft Excel (as outlined in the [Appendix](#)) and checked by a second reviewer. Where disagreements occur, discussions will be held to reach consensus and where necessary, a third reviewer will be involved. The data extraction form will be piloted before use and refined as necessary.

5.6 Quality appraisal

Two reviewers will independently assess the methodological quality or risk of bias of included studies or systematic reviews, using standardised critical appraisal tools, with any disagreements resolved through discussion. Any major disagreements may lead to the involvement of a third reviewer. As different study designs warrant different tools to assess methodological quality and or risk of bias, [Table 2](#) outlines

the different critical appraisal tools that may be used. All tools will be piloted first on a small number of included studies, and modifications made if needed, before standardising for the remaining studies.

Table 2: Critical appraisal tools

Study design	Critical appraisal tool
Systematic reviews or HTA	ROBIS
RCTs	RoB 2
Cohort studies and case-control studies	ROBINS-I
Clinical guidelines	AGREE II
Case studies, case reports and case series	JBI checklist for case series JBI checklist for case reports

Key: AGREE - Appraisal of Guidelines for Research & Evaluation; HTA health technology assessment; RCT – randomised controlled trial; RoB 2 – risk of bias tool for randomized trials; ROBIS – risk of bias in systematic reviews

5.7 Data synthesis

A preferred reporting items for systematic reviews and meta-analyses⁽¹⁵⁾ (PRISMA) flow chart of the identified documents will be presented and a summary of the evidence for the clinical effectiveness and safety of vesicostomy buttons will be compiled. The study design and baseline characteristics for all included studies will be presented, followed by the outcome results. As it is expected that the main data to be extracted for this rapid HTA will be descriptive in nature, a narrative synthesis of included records will be produced.

6 Dissemination

The evidence gathered, as outlined above, will be synthesised in a draft report and shared with the EAG for their review. The finalised report will be published on the HIQA website and submitted to the Minister for Health as advice.

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Appendix

Table 1: Grey literature search strategy

Organisation type	Link to URL
Guideline Central	https://www.guidelinecentral.com/
Guidelines International Network international guideline library and registry of guidelines	https://g-i-n.net/international-guidelines-library
International HTA database	https://database.inahta.org/
MAGIC Evidence Ecosystem Foundation	https://app.magicapp.org/#/guidelines
Trip Database	https://www.tripdatabase.com/
UpToDate	https://www.uptodate.com/contents/search?search=guidelines

Table 2: MEDLINE Search strategy

#	Query	Limiters/Expanders	Last Run Via	Results
S4	S1 OR S2 OR S3	Expanders - Apply equivalent subjects Search modes - Proximity	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - MEDLINE Complete	65

S3	XB (("mic key" OR mic-key OR mini OR minione OR mini-one) N3 (gastronomy OR button*))	Expanders - Apply equivalent subjects Search modes - Proximity	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - MEDLINE Complete	47
S2	XB button* N1 gastrostomy AND XB (bladder OR urin*)	Expanders - Apply equivalent subjects Search modes - Proximity	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - MEDLINE Complete	8
S1	XB (button* N1 (vesicostomy OR cystostomy))	Expanders - Apply equivalent subjects Search modes - Proximity	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - MEDLINE Complete	17

Table 3: Data extraction template: summary of characteristics of included research studies

Author and Year (DOI number)	Study Design	Population, indications and inclusion criteria	Intervention (device name), details of surgery technique	Follow-up time	Outcome(s)
Study Title	Country			Time VB <i>in situ</i>	Clinical effectiveness
Study aim	Number of patients	Relevant previous procedures	Comparator or NA		Safety
Sponsor/Funding	Age of patients (Mean/median; range)				QoL or patient/carer satisfaction
	Sex				Authors conclusions

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(HIQA).**

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