External Assessment Group's Protocol

GID-HTE10049 Intermittent urethral catheters for long-term urinary management in adults: late-stage assessment

External Assessment Group: Newcastle EAG

Project lead(s): Kim Keltie, Lead Healthcare Scientist,
The Newcastle upon Tyne Hospitals NHS Foundation Trust (NuTH);
Emma Belilios, Project Co-ordinator and Business Manager, NuTH;
Rachel O'Leary, Clinical Scientist, NuTH;
Paula Leslie, Pre-registrant Clinical Scientist, NuTH;
Elliot Blacklock, EAG Administrator, NuTH;
Jabez Barnabas, Research Associate, Newcastle University
Sheila Wallace, Research Fellow, Newcastle University
Ryan Kenny, Research Associate, Newcastle University;
Nick Meader, Principal Research Associate, Newcastle University;
Nawaraj Bhattarai, Senior Research Associate (Health Economics), Newcastle University;
Giovany Orozco-Leal, Research Associate (Health Economics), Newcastle University
Luke Vale: Professor of Health Economics, London School of Hygiene and Tropical Medicine; NuTH;
Andrew Sims, EAG Director, NuTH

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Acknowledgements:

Daphne Colpman, Clinical Nurse Specialist, University College London Hospitals NHS Foundation Trust

Marcus Drake, Professor of Neurological Urology, University of Southampton

Ann Yates, Director of Continence Services, Cardiff and Vale University Health Board

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Abbreviations

Term	Definition
BNF	British National Formulary
CADTH	Canadian Agency for Drugs and Technologies in Health
CAUTI	Catheter-Associated Urinary Tract Infection
CNMA	Component Network Meta Analysis
EAG	External Assessment Group
HRQoL	Health-Related Quality of Life
ICA	Intervention Component Analysis
LSA	Late-Stage Assessment
NICE	National Institute for Health and Care Excellence
PROMs	Patient Reported Outcome Measures
PSS	Personal Social Services
PSSRU	Personal Social Services Research Unit
QALYs	Quality Adjusted Life Years
RCT	Randomised Controlled Trial
SCM	Specialist Committee Members
UTI	Urinary Tract Infection

1 Background and objectives

1.1 Introduction

The late-stage assessment (LSA) will explore the evidence base for intermittent urethral catheters used for intermittent catheterisation for long-term urinary management in adults. Newer intermittent urethral catheters may have additional, innovative features intended to overcome barriers to intermittent catheterisation, or to reduce the risk of catheter-associated urinary tract infection (CAUTI). This protocol outlines the steps the EAG will take to assess whether price variations between technologies are justified by these incremental differences and advancement in features, and which features of the intermittent catheters represent value for money for the NHS.

1.2 Decision problem

NICE, together with Clinical Experts, Patient Representatives, industry, academic experts, and other Stakeholders, developed a scope for the assessment of intermittent urethral catheters for long-term use. The decision problem arising from the NICE scope for this assessment is summarised in Table 1. The EAG have added comments to clarify their interpretation of each point of the decision problem and have sought advice from Clinical Experts as to the appropriateness of these interpretations where needed. The EAG will use the decision problem to assess eligibility of evidence for inclusion in the LSA report.

Table 1: Summary table of the decision problem

Item	Description	EAG Notes
Population	Adults (18 and over) with chronic incomplete bladder emptying using intermittent urethral catheters to perform catheterisation for bladder drainage.	In line with the title, the EAG will restrict analysis to long-term catheterisation, defined as greater than 28 days (NICE scope).
Subgroups	If the evidence allows, the following subgroups will be considered: • by gender • people needing life-long intermittent catheterisation • people with UTIs or being significantly vulnerable to UTIs (for example, people with renal transplant) • people with mobility or cognitive impairment • intermittent catheterisation done by carers or others rather than patients themselves	The EAG assume that 'people with UTIs' refers to people with recurrent UTIs, which is defined as a person having 2 or more UTIs in the last 6 months or 3 or more UTIs in the last 12 months, confirmed by urine culture (NG112, 2018). People being significantly vulnerable to UTIs may be interpreted in two ways, to include 1) those more likely to experience UTIs, and 2) those where the consequences of UTI are severe. One Clinical Expert identified that this may include people who are immunosuppressed, people with history of hospitalisation for kidney infection and sepsis, and people who have a structural abnormality of the urinary tract. From early scoping, the EAG identified evidence on intermittent catheterisation in people with spinal cord injuries, which is a complex and heterogeneous group. However, when asked, one Clinical Expert advised that this subgroup may overlap with others and may therefore not need to be considered separately. The same Clinical Expert also identified people with impaired dexterity, and people with an abnormal bladder outlet (for example, people with history of urethral strictures) as subgroups that may need to be considered separately. The EAG will summarise subgroups where data is available in the published literature.
Intervention	Intermittent urethral catheters that are single-use and sterile that: • have traditional lubrication (pre-lubricated or externally applied), hydrophilic coated, or enhanced lubrication or coating technology • have 2 to 4 drainage eyelets (drain holes or catheter eyes) • are available in a range of sizes and lengths • have Nelaton tip or other tip types • have catheter drainage funnels or connectors • clearly labelled sizes. Additional features, adaptions and potential innovations include, but not limited to: • Integrated drainage bag • Integrated handle or markings • Insertion sleeve or grip • Tip protector or introducer • Micro-hole zone technology • Enhanced lubrication or coating technology (such as multi-layer coating and hydrophilic integrated amphiphilic surfactant)	Features have been decided through a scoping exercise that included industry, Clinical Expert and Lay Experts. Only features associated with the manufacturer and device names available on part IXA of the drug tariff as of September 2024, which meet the basic technology requirements will be assessed. Clinical Experts and Patient Representatives will help to determine which additional features inform choice of catheter, through the user preference assessment by NICE. Information provided by the Companies will identify which products include which additional features. The EAG will not verify this information independently. Features of interest may evolve depending on information provided by the Companies participating in this assessment. The impact of the intervention features on key outcomes and cost-effectiveness will be assessed where evidence allows (see section 2.1.6). Where assessment is not possible because of lack of evidence or available evidence not being of suitable quality, this will be noted.

Item	Description	EAG Notes
	• Specially designed catheter case (such as hard case, compact design, telescopic catheter and resealable case) • Specially designed packaging (such as ring pull and flip top)	
Comparator	Intermittent urethral catheters, that are single-use and sterile, with traditional lubrication (pre-lubricated or externally applied) or hydrophilic coated and other basic requirements, but without any additional or innovative features.	The EAG will focus on comparative evidence which will enable the evaluation of the effectiveness of one or more innovative features to be assessed. The EAG will consider evidence comparing catheters with additional features, both with basic catheters, and with other catheters with additional features. For example, evidence comparing the intervention with externally lubricated catheters will be considered separately, as there is a significant difference in infection risk between pre-lubricated (no touch) catheters and externally lubricated catheters.
Healthcare Setting	Primary and community care	This is interpreted as patients or carers managing a catheter in a primary or community care setting, regardless of where the catheters were initially prescribed. For example, studies describing populations who were prescribed catheters at a hospital outpatient clinic, but their catheter care was managed in the community, will be considered. However, studies describing catheter care in hospital, or where catheterisation was done by hospital-based healthcare professionals (that is, not done by patients themselves or carers), will be excluded.
Outcomes	Outcome measures for consideration may include but are not limited to: Intermediate outcomes • successful drainage, for example, post residual volume • frequency of use per day Clinical outcomes • UTIs and recurrent UTIs - Catheter-associated UTIs • sepsis • urethral trauma, bleeding, haematuria, strictures and urethritis • bladder or kidney stones • other device related adverse events (for example, retained fragments) • hospitalisation Patient reported outcomes • adherence and compliance rate • comfort and ease of use • satisfaction • preference • health-related quality of life Costs and resource use • cost of the technology and supporting products	The EAG will consider all published evidence meeting the criteria described in the decision problem and will list all outcomes with published evidence. If a large volume of relevant evidence is identified, the EAG will liaise with Clinical Experts and Specialist Committee Members (SCMs), to prioritise outcomes, based on those likely to have the greatest effect, based on incidence rates, management costs, and impact on utilities. The EAG may also adopt methods from the Cochrane Handbook for prioritising outcomes (McKenzie et al. 2024). The Clinical Experts advised at the Scoping Workshop that CAUTI is an important clinical outcome. The EAG will use the definition of CAUTI from the NICE guideline on antimicrobial prescribing for CAUTI (NG113, 2018). Clinical Experts advised the EAG that there is no agreed threshold for post residual volume, because it varies by person, and depends on bladder capacity and symptoms. Evidence for this outcome may therefore be subjective. The EAG will consider aggregating complication outcomes (urethral trauma, bleeding, haematuria, strictures, urethritis, bladder or kidney stones, device related adverse events and hospitalisation) based on their severity and level of care needed to manage them. The

Item	Description	EAG Notes
	• costs of medicines • costs of other resource use including: - healthcare professional appointments or visits - costs associated with managing catheter- associated complications - hospital admissions - staff time: such as training people who perform self-catheterisation or carers to do intermittent catheterisation User views, experience, need and preference will be captured to understand the features of the technology that influence decision making when selecting which technology to use.	appropriateness of this, and any classifications used will be advised by Clinical Experts after the evidence base has been established. The EAG will only consider costs and resource use arising from the use of intermittent catheterisation for bladder drainage, and not from other care needs or conditions.
Economic analysis	A health economic model will be developed, where possible, comprising a cost-comparison or cost utility analysis. Costs will be considered from a UK NHS and Personal Social Services (PSS) perspective. Sensitivity and scenario analysis should be undertaken to address the relative effect of parameter or structural uncertainty on results. The time horizon should be long enough to reflect all important differences in costs or outcomes between the technologies being compared.	Economic evaluation will be dependent upon the clinical evidence identified. It is envisaged that the economic model will be evaluated over a lifetime horizon, however the exact time horizon will be informed by published clinical and economic evidence and Clinical Experts. The time horizon will be long enough to capture differences in frequency of UTI between arms, along with any other outcomes for which comparative evidence suggests a difference between basic catheters and catheters with additional features.

1.3 Objectives

The assessment will address the following research questions:

- What evidence is available to determine the clinical efficacy or effectiveness and cost effectiveness of additional and innovative features of intermittent urethral catheters, compared with standard intermittent catheters?
- Which additional and innovative features are associated with benefits for adults requiring intermittent urethral catheters for long-term urinary management, and are these commensurate with the price charged by manufacturers?

The assessment will include a systematic search for published evidence that enables evaluation of the efficacy or effectiveness of additional or innovative features of (above that of standard) intermittent urethral catheters. This will be supplemented by evidence provided by the Companies. Evidence that is relevant to the decision problem for this assessment (that is, represents the relevant population, interventions, outcomes, settings and is of suitable quality to inform clinical decisions) will be extracted and appraised by the EAG. The evidence will be tabulated to identify where there are meaningful gaps for the decision problem. The EAG will also develop an economic model to provide an initial assessment of the potential cost-effectiveness of innovative features of intermittent urethral catheters.

The findings of this assessment are intended to be used by adults using intermittent urethral catheters for long-term urinary management, healthcare professionals supporting them, and commissioners, to inform decisions about the procurement and selection of intermittent urethral catheters in practice.

2 Methods

2.1 Evidence Review

A review will be undertaken to identify evidence for the plausible clinical and cost effectiveness benefits of additional and innovative features of intermittent

urethral catheters, using methods in line with the NICE late-stage assessment interim methods and process statement.

From early scoping searches by the EAG, a relevant Cochrane review (Prieto et al. 2021) was identified, which included randomised controlled trials (RCTs), of parallel or crossover design, comparing at least two different catheterisation techniques, strategies or catheter designs published up to 12 April 2021. This systematic review included a total of 23 trials (1,339 randomised participants, including children and adults using intermittent urethral catheterisation for bladder emptying). However, setting varied across included studies (hospital, outpatient clinic, community care, nursing home), the length of follow-up ranged between 1 to 12 months, and there was considerable variation in the definition of UTI. It was noted that study design and reporting issues were significant, and that future studies should incorporate cost-effectiveness due to likely substantial differences associated with different catheterisation techniques, strategies and catheter designs. Of the studies included in Prieto et al. 2021, the EAG considered only 1 to be aligned with the NICE scope for this assessment (Chartier-Kastler et al. 2013), which compared SpeediCath Compact with a basic hydrophilic catheter. The other studies would be excluded for including children, being conducted in a hospital setting, comparing basic hydrophilic coated catheters (no additional features) with uncoated catheters, comparing clean and sterile techniques, comparing the same catheter in different lengths, and including reusable catheters.

Due to the broad aims of the above identified systematic review (Prieto et al. 2021), and to ensure no duplication of effort, the EAG will firstly conduct a systematic search for further relevant systematic reviews of controlled comparative studies, published after the search dates outlined in the Prieto et al. 2021 review (April 2021). Assuming no systematic reviews are found that are relevant to the decision problem, a wider systematic search will be carried out for primary clinical evidence.

The review methods, including the systematic literature search and evidence synthesis, will be conducted in a transparent manner, with the aim to produce a comprehensive overview of the key literature as relevant to the decision-making context. Early scoping searches and sifting of an initial sample of results by the EAG suggest there will be a large proportion of results irrelevant to the decision problem. To focus on evidence which is most relevant to the decision problem, the literature search will have a filter applied to include only controlled comparative studies which include relevant terms in the title or abstract. The EAG anticipates that most additional catheter features will have been introduced since 2010. Also, patient care is likely to have changed since then, such that older studies may have little relevance to the decision problem and are unlikely to be generalisable to current NHS care. However, to avoid missing potentially relevant studies, results will be sorted in date order and an appropriate date limit, as advised by Clinical Experts, will be applied at sifting. Studies will be prioritised for sifting, and if limited evidence is found, a second search may be done without restrictions on controlled comparative study design. Where no controlled comparative evidence is identified for key features, the EAG will consider the appropriateness and relevance of evidence from other study designs to answer the research questions. The EAG will consider use of digital tools to rank studies in order of relevance to minimise the chances of missing a relevant study within a broader literature search of studies with non-controlled comparative design. The EAG will prioritise key studies, based on the hierarchy of evidence or other classification method, and outcomes as guided by advice from Clinical Experts, where appropriate.

Systematic literature searches conducted by the EAG will be supplemented by information that was provided by the Companies. During scoping, NICE requested that the Companies supply key studies relating to the additional or innovative features of their intermittent urethral catheters, which will be considered and reviewed by the EAG. The EAG will consider including unpublished comparative studies provided by the Companies, provided they meet the decision problem and other eligibility criteria outlined within this

protocol. Any studies submitted by Companies which are excluded by the EAG will have reasons for exclusion documented in the EAG report.

2.1.1. Inclusion and exclusion criteria

The inclusion and exclusion criteria were informed by the NICE scope (Section 1.2), discussion with the NICE team, and feedback from Clinical Expert and Lay Experts advising this assessment given in the scoping workshop and in consultation with the EAG. The following modifications are considered:

- Because the aim of the evidence review is to identify the incremental benefit of intervention features, comparisons between catheters with and without at least 1 additional feature are pertinent. The EAG will prioritise controlled comparative evidence and will apply the hierarchy of evidence, or other suitable classification method, to prioritise evidence based on study design and relevance to the decision problem, and when considering generalisability will also prioritise evidence from UK settings and for outcomes deemed most important by Clinical Experts.
- As described previously, a time limit, based on Clinical Expert advice, may be applied to capture the most recent evidence, most relevant to the decision problem. The following evidence types will be excluded: animal only studies, narrative reviews, editorials, opinions, letters. The EAG will only consider conference abstracts and posters, where enough detail is provided to be sure it is in scope. Articles describing the management of intermittent catheterisation conducted fully in a secondary or tertiary care setting (managed by medically trained staff) will be excluded. For example, the EAG would include evidence where the study participants were recruited from a hospital outpatient clinic, but where their catheter care was managed outside of a hospital setting by the user or carer.

- Language limits will be applied (English only), and taking a pragmatic approach, articles with no innovative additional catheter feature identifiable in the title or abstract, will be excluded.

If evidence is limited, the EAG will consider relevant evidence that had been excluded for not meeting all aspects of the decision problem. For example, evidence in mixed populations, or conducted in a hospital setting. The EAG will consult with Clinical Experts to determine the generalisability of such evidence. In addition, as described above in section 2.1, if there is still no controlled comparative evidence identified for key features, the EAG will consider the appropriateness and relevance of evidence from other study designs.

2.1.2. Search Strategy

Separate searches will be carried out for clinical and cost-effectiveness evidence.

2.1.2.1 Search for clinical effectiveness studies

A search strategy will be developed by one of the EAG's information specialists in MEDLINE and then translated, adapted and run independently for each individual database. A set of terms related to intermittent urethral catheters will be combined with a relevant search filter designed to identify 1) relevant systematic reviews, and 2) relevant controlled comparative studies.

The following databases will be searched:

- MEDLINE ALL (on Ovid) (including In-Process and In-Data-Review & Other Non-Indexed Citations, Epub Ahead of Print, and Daily)
- Embase (on Ovid)
- Cochrane Library (Cochrane Central Register of Controlled Trials) (via Wiley) (only for controlled comparative studies)
- CINAHL (on EBSCOhost)

- International HTA Database (INAHTA)

Ongoing trials will be searched for (ClinicalTrials.gov, WHO ICTRP); studies conducted in a UK setting will be prioritised if there are more than 10 ongoing studies identified relevant to the decision problem.

Sample search strategies for systematic reviews and for controlled comparative studies, for MEDLINE on Ovid are presented in Appendix A1 and Appendix A2 respectively.

2.1.2.2 Search for economic evaluations and models

A search for economic evaluations and systematic reviews of economic evaluations will be conducted in NHS EED (covering publications up to the end of 2014 after which it ceased to be updated), using the set of intervention terms only. For publications from 01 January 2015 onwards, the EAG will search for systematic reviews of economic evaluations (and primary economic evidence if no secondary evidence is identified), in MEDLINE and EMBASE. If a relevant systematic review of economic evaluations is identified the search for primary economic evaluations will be updated from the date of search for that relevant systematic review. If no relevant systematic review is identified the search for primary economic evaluations will cover from 1 January 2015 onwards (to cover the years since NHS EED was last updated with economic evaluations). Sample search strategies for systematic reviews and primary economic evidence including economic models, for MEDLINE on Ovid are presented in Appendix A3.

Economic evaluations identified within the proposed literature searching will be considered for relevance to the decision problem. Targeted searches will be undertaken as needed for specific economic parameters if these are not available from the clinical or cost effectiveness evidence identified. The search would combine the set of intervention terms with a filter relevant for the missing parameter. This may include searches of IDEAS/RePEc, CEA Registry (via Tufts Medical Center), and the International HTA Database (INAHTA).

During scoping searches, the EAG identified that the same broad model structure was described in published economic evaluations in intermittent catheterisation. This was largely based on the economic model used in NICE Clinical Guideline on Healthcare-associated infections: prevention and control in primary and community care (NICE CG139, 2012). See section 3.1 for more details.

2.1.3. Study selection

Three levels of study selection will be conducted:

- Step 1: Titles and abstracts of records identified in literature searches will be screened against a subset of the inclusion criteria (population, intervention, comparator) by a single reviewer. Independent review of title and abstract screening will be conducted for a 10% sample by a second reviewer.
- Step 2: Full publications will be retrieved for records included at Step 1 and will be screened by a single reviewer to confirm setting and to determine the outcomes with results reported. All included studies will be checked by a second reviewer.
- Step 3: If the evidence base identified is large, publications included at Step 2 will be screened by a single reviewer and as part of the pragmatic approach to the evidence review, reporting of patient reported outcome measures (PROMs) and a subset of outcomes specified on the NICE scope will be prioritised for consideration. The EAG will consult with Clinical Experts to define prioritised outcomes which are considered strong determinants of the effectiveness of intermittent catheters with additional or innovative features.

The flow of studies through all three levels of screening will be recorded and displayed on a PRISMA diagram. Studies excluded after full paper review will have the reason for exclusion documented and tabulated within the EAG report.

2.1.4. Data extraction strategy

Data will be extracted from included studies reporting clinical outcomes into a bespoke table to enable descriptive statistics, including study design, setting, eligibility criteria, population characteristics, intervention characteristics (particularly, the additional or innovative features) and list of outcomes where results are reported. Data will be extracted from included studies reporting on economic outcomes into a bespoke table to enable descriptive statistics, including model design, setting, time horizon, intervention and comparator characteristics, and key findings.

2.1.5. Quality assessment strategy

Quality assessment will be in accordance with Section 3 of NICE's health technology evaluations manual. Independent, quality assurance of data extraction from clinical or economic evidence will be conducted for all included studies by a second reviewer. Key evidence will be critically appraised using a standardised tool specific to the research design. Economic evaluations will only be formally quality assessed if they compare innovative features of intermittent catheters in a UK setting. The EAG report will include a broad narrative description of the strengths, risk of bias and generalisability of findings to clinical practice in the NHS will be considered for studies included in the review. Quality of life studies identified will not be formally quality assessed as there is no suitable assessment tool currently, instead their quality will be considered informally as part of the consideration for selection of utility data to be included within the decision model. The judgements made in the critical assessment of included evidence will be presented in the EAG report and considered in the evidence landscape and gap map.

2.1.6. Methods of analysis and synthesis

Clinical evidence will be tabulated and narratively synthesised.

Intervention components analysis (ICA) will be considered to identify the innovative features of intermittent catheters and explore how these may explain differences in outcomes (Sutcliffe et al. 2015), and if appropriate, will be used to inform the economic analysis, which is described further in Section

3. ICA is an inductive approach to categorising and evaluating intervention components in an evidence base. Prior to the analysis, the EAG will develop a matrix of the additional or innovative features of intermittent catheters, as categorised in the NICE scope, and the hypothesised influence they have on clinical outcomes extracted in the evidence review. For example, integrated collection bag may be hypothesised to improve ease of use and portability, improving adherence. The EAG's starting matrix will be based on evidence in published studies (for example Chartier-Kastler et al. 2013 which was considered relevant to the decision problem as identified from the systematic review by Prieto et al. 2021) and input from Clinical Expert and Lay Experts advising this assessment. The matrix may be updated if new information is identified from studies included in the evidence review. This matrix will be used to organise coding of included studies. Template analysis-based coding will be used to identify the features of interventions for which evidence has been included in the evidence review. A reviewer will code intervention features as described in free-text descriptions of interventions using the EAG's starting template as a guide. New intervention features will be added to the template where required, and where very similar features are identified, these will be collapsed into one code. Where feasible and appropriate, the EAG will seek feedback on the codes from the Companies and Clinical Expert and Lay Experts advising this assessment. Outcomes for each comparison in the review will be presented alongside a description of the difference in intervention features between comparators.

Once the ICA is completed, the EAG will assess the feasibility and appropriateness of the results of this leading into component network meta-analyses (CNMA) (Welton et al. 2009; Freeman et al. 2018) to assess the effectiveness of intervention features, and interactions between them. If there are insufficient data to conduct CNMA, or CNMA is judged inappropriate, the EAG will conduct a narrative synthesis of the findings from the ICA instead. This will include the reporting of the plausible range in effect estimates available for each intervention feature. The identification of a plausible range will be based on the applicability and certainty of evidence sources included in the review for each feature. The narrative synthesis will also consider the

presence of patterns in the results, including variation in feature effectiveness across population subgroups.

For each feature, the EAG will draw upon all relevant comparisons to identify patterns in the outcomes included in the review, associated with the presence of that feature. Initially, this will result in an assessment of the features associated with positive outcomes, negative outcomes, or no change in outcomes. Where feasible, the EAG will also attempt to identify plausible effect sizes associated with each feature. Where comparisons include variation in more than one feature, we will draw upon the broader evidence base, including regression and mediation analyses reported in included studies and health-related quality of life (HRQoL) data reported in primary utility studies, to evaluate the plausible relationships between features and outcomes.

Methods and findings from included published economic evaluations will be summarised in a tabular format and synthesised in a narrative review. Economic evaluations carried out from the perspective of the UK NHS and Personal Social Services (PSS) perspective will be presented in greater detail.

Following review of the clinical and economic evidence, the EAG will describe key evidence gaps where appropriate.

3. Economic evaluation

3.1. Model update

Where data is available, the EAG will perform an economic evaluation of the additional or innovative features of intermittent catheters from the perspective of the UK NHS and PSS, consistent with the methods recommended in the NICE reference case (NICE HTE manual).

A targeted search, at the scoping stage of this project, identified economic models used in published economic evaluations (Baker et al. 2022; Bermingham et al. 2013; Clark et al. 2016; Health Quality Ontario, 2019) of

intermittent catheterisation. However, the economic model structures used in these economic evaluations have primarily been informed by the economic model used in the NICE Clinical Guideline on Healthcare-associated infections: prevention and control in primary and community care (NICE CG139, 2012). The EAG are not aware of any changes to the clinical pathway of UTI resulting from intermittent catheterisation that would require changes to the economic model structure. Therefore, the EAG will utilise the economic model structure used in NICE CG139 for this LSA.

The EAG will construct an executable economic model reflecting the general structure of CG139 using standard software (for example Microsoft Excel, R; NICE PMG34, 2017). The economic model will include additional functionality to incorporate the innovative features. The model will follow a state-transition structure, as outcomes for patients under long-term intermittent catheterisation can include repeated urinary tract infections as well as other acute catheter-related adverse events, as listed in the NICE scope (see Table 1) and described by published economic models considering intermittent catheterisation (Bermingham et al. 2013, NICE CG139, 2012). The parameters to be included in the model will be determined from previous economic evaluations identified from the systematic review (see above). The economic model will be parameterised with evidence identified by the EAG, information provided by Companies, and from Clinical Expert advice. Should there be gap in parameter information, assumptions will be made, and Clinical Experts will be consulted to ensure the appropriateness of the assumption and outcomes considered in the economic model. The EAG will use the highest quality evidence where available, prioritised according to the hierarchy of evidence described previously. The EAG will only consider costs and resource use arising from the use of intermittent catheterisation for bladder drainage, and not from other care needs or conditions. The unit costs of resources utilised will be taken from NHS reference costs, Personal Social Services Research Unit (PSSRU), British National Formulary (BNF), information provided by Companies and evidence identified from published economic evaluations (or from targeted literature searches if no suitable evidence identified). Health benefits will be quantified as quality adjusted life

years (QALYs) through the combination of utilities of health states considered in the economic model (including disutilities of any adverse events or complications, if appropriate) and time spent in each state. Utilities used in the economic model will be identified from published economic evaluations (or from targeted literature searches if no suitable utility weights are identified from published economic evaluations) and information provided by the Companies.

The EAG will clearly report all assumptions employed to build the model structure, along with all data inputs and their respective source.

It is envisaged that the economic model will be evaluated over the lifetime horizon, however the exact time horizon of the economic model will be informed by Clinical Experts and the evidence identified.

Consistent with the ICA approach applied to the clinical effectiveness evidence (Section 2.1.6), comparisons in the economic evaluation are expected to be conducted at the feature level rather than across multiple brands of catheters with the same features. The comparator intervention will be made to meet the basic technology criteria set in the NICE scope (that is absence of ‘innovative features’) and will endeavour to represent standard practice within the NHS, which will be further validated with Clinical Experts for this purpose.

The economic evaluation results will be presented as an incremental cost-effectiveness analysis in terms of incremental costs, incremental QALYs, and incremental cost-effectiveness ratio in line with NICE’s reference case and the final scope. Where appropriate, and if data allow, sensitivity analysis will be undertaken to explore uncertainty, which may include deterministic and probabilistic sensitivity analysis. Where probabilistic sensitivity analysis is undertaken, results will be presented using the cost-effectiveness plane and cost-effectiveness acceptability curves. Scenario analyses will be undertaken where considered appropriate and advised by Clinical Experts.

As part of the ICA (Section 2.1.6) a matrix outlining the proposed mechanism of action through which each additional catheter feature is expected to

influence the outcomes of interest will be developed and validated by Clinical Experts. This matrix will be used to aid understanding of the relationship between additional features and their expected impact on HRQoL and costs. If an ICA is not possible, this matrix will be informed by narrative synthesis and, where necessary, supplemented by clinical expert opinion. Following the hierarchy of evidence, features expected to provide efficiency gains or increase costs will be assessed through a cost-comparison analysis.

3.2. Validation

The internal validity of the economic model will be checked independently by health economists within the EAG and will be undertaken by varying model input parameters and assessing whether the model results are sensitive and logical. Each model parameter will be checked against its source to ensure that it has been incorporated within the economic model appropriately. The model structure, assumptions, clinical parameters, and results from the economic model will be shared with Clinical Experts to ensure clinical validity.

4. Handling information

4.1 Company information

Standard requests for information regarding their technologies will be sent by NICE to each Company; submissions received after 04 October 2024 will be considered by the EAG on a case-by-case basis. The EAG may seek clarifications from Companies regarding their technology throughout the assessment.

4.2 Confidential information

Any ‘commercial in confidence’ data provided and specified as such will be highlighted in blue and underlined in the EAG Report. Any ‘academic in confidence’ data provided will be highlighted in yellow and underlined in the EAG Report. Any ‘personally identifiable’ data provided will be highlighted in pink and underlined in the EAG Report. Any ‘confidential price agreements’ data provided will be highlighted in green and underlined in the EAG Report.

All confidential information, as identified above, will be redacted before publication on the NICE website.

5. Competing interests of authors

None.

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Appendices

Appendix A1: Search for systematic reviews of controlled comparative studies – MEDLINE on Ovid

Ovid MEDLINE(R) ALL <1946 to September 19, 2024> (date of search: 23 September 2024)

#	Searches	Results
1	exp urinary catheterization/ [exploding picks up Intermittent Urethral Catheterization/ too]	15,240
2	Urinary Catheters/	1,529
3	(catheter$ adj5 (urin$ or urethra$ or intermittent)).tw,kf.	18,213
4	in out catheter*.tw,kf.	10
5	(self adj5 catheter*).tw,kf.	2,252
6	(catheter$ adj5 (urological or transurethra$ or bladder)).tw,kf.	5,510
7	or/1-6	30,533
8	(systematic review or meta-analysis).pt.	362,402
9	meta-analysis/ or systematic review/ or systematic reviews as topic/ or meta-analysis as topic/ or "meta analysis (topic)"/ or "systematic review (topic)"/ or exp technology assessment, biomedical/ or network meta-analysis/	404,917
10	((systematic* adj3 (review* or overview*)) or (methodologic* adj3 (review* or overview*))).ti,ab,kf.	381,332
11	((quantitative adj3 (review* or overview* or synthes*)) or (research adj3 (integrati* or overview*))).ti,ab,kf.	18,191
12	((integrative adj3 (review* or overview*)) or (collaborative adj3 (review* or overview*)) or (pool* adj3 analy*)).ti,ab,kf.	43,943
13	(data synthes* or data extraction* or data abstraction*).ti,ab,kf.	47,229
14	(handsearch* or hand search*).ti,ab,kf.	11,756
15	(mantel haenszel or peto or der simonian or dersimonian or fixed effect* or latin square*).ti,ab,kf.	39,425
16	(met analy* or metanaly* or technology assessment* or HTA or HTAs or technology overview* or technology appraisal*).ti,ab,kf.	13,427
17	(meta regression* or metaregression*).ti,ab,kf.	17,122

#	Searches	Results
18	(meta-analy* or metaanaly* or systematic review* or biomedical technology assessment* or bio-medical technology assessment*).ti,ab,kf.	539,594
19	(medline or cochrane or pubmed or medlars or embase or cinahl).ti,ab,kf.	397,491
20	(cochrane or (health adj2 technology assessment) or evidence report).ti,ab,kf.	22,082
21	(comparative adj3 (efficacy or effectiveness)).ti,ab,kf.	19,676
22	(outcomes research or relative effectiveness).ti,ab,kf.	11,938
23	((indirect or indirect treatment or mixed-treatment or bayesian) adj3 comparison*).ti,ab,kf.	4,759
24	(multi* adj3 treatment adj3 comparison*).ti,ab,kf.	317
25	(mixed adj3 treatment adj3 (meta-analy* or metaanaly*)).ti,ab,kf.	182
26	umbrella review*.ti,ab,kf.	2,249
27	(multi* adj2 paramet* adj2 evidence adj2 synthesis).ti,ab,kf.	15
28	(multiparamet* adj2 evidence adj2 synthesis).ti,ab,kf.	19
29	(multi-paramet* adj2 evidence adj2 synthesis).ti,ab,kf.	13
30	or/8-29	781,173
31	7 and 30	816
32	(Randomized Controlled Trial or Controlled Clinical Trial or Pragmatic Clinical Trial or Clinical Study or Adaptive Clinical Trial or Equivalence Trial).pt.	720,730
33	(Clinical Trial or Clinical Trial, Phase I or Clinical Trial, Phase II or Clinical Trial, Phase III or Clinical Trial, Phase IV or Clinical Trial Protocol).pt.	621,579
34	Multicenter Study.pt.	354,801
35	Clinical Studies as Topic/	844
36	exp clinical trial/	1,004,874
37	multicenter study/	354,801
38	Random allocation/	107,590
39	Double-Blind Method/	180,504
40	single-blind method/	34,014
41	Placebos/	35,998
42	Control Groups/	2,132
43	cross-over studies/	57,522
44	Interrupted time series analysis/	2,197
45	(random* or sham or placebo*).tw,kf.	1,722,217
46	((singl* or doubl*) adj (blind* or dumm* or mask*)).tw,kf.	206,808
47	((tripl* or trebl*) adj (blind* or dumm* or mask*)).tw,kf.	1,920

#	Searches	Results
48	(control* adj3 (study or studies or trial* or group*)).tw,kf.	1,328,335
49	(clinical adj3 (study or studies or trial*)).tw,kf.	848,683
50	Interrupted time series.tw,kf.	6,806
51	(Nonrandom* or non random* or non-random* or quasi-random* or quasirandom*).tw,kf.	58,599
52	(phase adj6 (study or studies or trial*)).tw,kf.	198,173
53	((crossover or cross-over) adj3 (study or studies or trial*)).tw,kf.	55,118
54	((multicent* or multi-cent*) adj3 (study or studies or trial*)).tw,kf.	171,644
55	allocated.tw,kf.	91,222
56	((open label or open-label) adj5 (study or studies or trial*)).tw,kf.	49,202
57	((equivalence or superiority or non-inferiority or noninferiority) adj3 (study or studies or trial*)).tw,kf.	13,249
58	(pragmatic study or pragmatic studies).tw,kf.	672
59	((pragmatic or practical) adj3 trial*).tw,kf.	6,883
60	((quasiexperimental or quasi-experimental) adj3 (study or studies or trial*)).tw,kf.	14,379
61	trial.tw,kf.	840,895
62	or/32-61	3,919,515
63	31 and 62	404
64	exp animals/ not humans/	5,260,351
65	63 not 64	398
66	limit 65 to yr="2021 -Current"	124

The search filter used to identify systematic reviews (lines 8-30 inclusive) in MEDLINE is based on the CADTH multifile search filter for systematic reviews on Ovid: (SR / MA / HTA / ITC - MEDLINE, Embase, PsycInfo. In: CADTH Search Filters Database. Ottawa: CADTH; 2024: Accessed 2024-09-23. Line 17 of the original CADTH filter was removed as it was intended for use in PsycInfo only).

The search filter used to identify controlled comparative studies is that developed by CADTH (lines 32-61): All Clinical Trials - MEDLINE, Embase. In: CADTH Search Filters Database. Ottawa: CADTH; 2024: https://searchfilters.cadth.ca/link/117. Accessed 2024-09-17. The filter was

originally a multifile search which has been adapted for use in MEDLINE. Terms were added to the filter to find interrupted time series. This filter would not find studies using historical controls or single armed studies; it is not designed to identify observational studies.

Appendix A2: Search for controlled comparative studies - MEDLINE on Ovid

Ovid MEDLINE(R) ALL <1946 to September 16, 2024>

Date of search: 17 September 2024

#	Searches	Results
1	Intermittent Urethral Catheterization/	387
2	(catheter* adj3 intermittent).tw,kf.	4,250
3	in out catheter*.tw,kf.	10
4	(self adj3 catheter*).tw,kf.	1,984
5	or/1-4	5,047
6	(Randomized Controlled Trial or Controlled Clinical Trial or Pragmatic Clinical Trial or Clinical Study or Adaptive Clinical Trial or Equivalence Trial).pt.	720,185
7	(Clinical Trial or Clinical Trial, Phase I or Clinical Trial, Phase II or Clinical Trial, Phase III or Clinical Trial, Phase IV or Clinical Trial Protocol).pt.	621,418
8	Multicenter Study.pt.	354,329
9	Clinical Studies as Topic/	844
10	exp clinical trial/	1,004,276
11	multicenter study/	354,329
12	Random allocation/	107,576
13	Double-Blind Method/	180,391
14	single-blind method/	33,996
15	Placebos/	35,994
16	Control Groups/	2,132
17	cross-over studies/	57,490
18	Interrupted time series analysis/	2,191
19	(random* or sham or placebo*).tw,kf.	1,720,264
20	((singl* or doubl*) adj (blind* or dumm* or mask*)).tw,kf.	206,638
21	((tripl* or trebl*) adj (blind* or dumm* or mask*)).tw,kf.	1,914
22	(control* adj3 (study or studies or trial* or group*)).tw,kf.	1,326,887
23	(clinical adj3 (study or studies or trial*)).tw,kf.	847,706
24	Interrupted time series.tw,kf.	6,787
25	(Nonrandom* or non random* or non-random* or quasi-random* or quasirandom*).tw,kf.	58,534
26	(phase adj6 (study or studies or trial*)).tw,kf.	197,946

#	Searches	Results
27	((crossover or cross-over) adj3 (study or studies or trial*)).tw,kf.	55,078
28	((multicent* or multi-cent*) adj3 (study or studies or trial*)).tw,kf.	171,327
29	allocated.tw,kf.	91,110
30	((open label or open-label) adj5 (study or studies or trial*)).tw,kf.	49,104
31	((equivalence or superiority or non-inferiority or noninferiority) adj3 (study or studies or trial*)).tw,kf.	13,232
32	(pragmatic study or pragmatic studies).tw,kf.	671
33	((pragmatic or practical) adj3 trial*).tw,kf.	6,866
34	((quasiexperimental or quasi-experimental) adj3 (study or studies or trial*)).tw,kf.	14,344
35	trial.tw,kf.	839,818
36	or/6-35	3,915,718
37	exp animals/ not humans.sh.	5,259,243
38	36 not 37	3,486,406
39	5 and 38	955

The search filter used to identify controlled comparative studies is that developed by CADTH (lines 6-37): All Clinical Trials - MEDLINE, Embase. In: CADTH Search Filters Database. Ottawa: CADTH; 2024: https://searchfilters.cadth.ca/link/117. Accessed 2024-09-17. The filter was originally a multifile search which has been adapted for use in MEDLINE. Terms were added to the filter to find interrupted time series. This filter would not find studies using historical controls or single armed studies; it is not designed to identify observational studies. The set of terms related to intermittent catheters (lines 1-5) is narrowed to search for records reporting directly on intermittent catheters in order to make the size of the search more manageable. (Terms tested but not used were: exp urinary catheterization/; Urinary Catheters/; (catheter* adj5 (urin* or urethra* or intermittent)).tw,kf.; (catheter* adj5 (urological or transurethra* or bladder)).tw,kf.) This could mean that poorly reported studies may be missed.

Appendix A3: Search for economic evaluations

Search for systematic reviews of economic evaluations

Database(s): **Ovid MEDLINE(R) ALL** 1946 to September 26, 2024

Search Strategy:

#	Searches	Results
1	exp urinary catheterization/ [exploding picks up Intermittent Urethral Catheterization/ too]	15242
2	Urinary Catheters/	1528
3	(catheter* adj5 (urin* or urethra* or intermittent)).tw,kf.	18230
4	in out catheter*.tw,kf.	10
5	(self adj5 catheter*).tw,kf.	2253
6	(catheter* adj5 (urological or transurethra* or bladder)).tw,kf.	5512
7	1 or 2 or 3 or 4 or 5 or 6	30550
8	(systematic review or meta-analysis).pt.	363067
9	meta-analysis/ or systematic review/ or systematic reviews as topic/ or meta-analysis as topic/ or "meta analysis (topic)"/ or "systematic review (topic)"/ or exp technology assessment, biomedical/ or network meta-analysis/	405618
10	((systematic* adj3 (review* or overview*)) or (methodologic* adj3 (review* or overview*))).ti,ab,kf.	382228
11	((quantitative adj3 (review* or overview* or synthes*)) or (research adj3 (integrati* or overview*))).ti,ab,kf.	18222
12	((integrative adj3 (review* or overview*)) or (collaborative adj3 (review* or overview*)) or (pool* adj3 analy*)).ti,ab,kf.	43996
13	(data synthes* or data extraction* or data abstraction*).ti,ab,kf.	47334

14	(handsearch* or hand search*).ti,ab,kf.	11759
15	(mantel haenszel or peto or der simonian or dersimonian or fixed effect* or latin square*).ti,ab,kf.	39503
16	(met analy* or metanaly* or technology assessment* or HTA or HTAs or technology overview* or technology appraisal*).ti,ab,kf.	13433
17	(meta regression* or metaregression*).ti,ab,kf.	17154
18	(meta-analy* or metaanaly* or systematic review* or biomedical technology assessment* or bio-medical technology assessment*).mp,hw.	540675
19	(medline or cochrane or pubmed or medlars or embase or cinahl).ti,ab,hw.	398328
20	(cochrane or (health adj2 technology assessment) or evidence report).jw.	22093
21	(comparative adj3 (efficacy or effectiveness)).ti,ab,kf.	19709
22	(outcomes research or relative effectiveness).ti,ab,kf.	11966
23	((indirect or indirect treatment or mixed-treatment or bayesian) adj3 comparison*).ti,ab,kf.	4764
24	(multi* adj3 treatment adj3 comparison*).ti,ab,kf.	316
25	(mixed adj3 treatment adj3 (meta-analy* or metaanaly*)).ti,ab,kf.	182
26	umbrella review*.ti,ab,kf.	2256
27	(multi* adj2 paramet* adj2 evidence adj2 synthesis).ti,ab,kf.	15
28	(multiparamet* adj2 evidence adj2 synthesis).ti,ab,kf.	19
29	(multi-paramet* adj2 evidence adj2 synthesis).ti,ab,kf.	13
30	or/8-29	782609
31	Economics/	27539
32	exp "Costs and Cost Analysis"/	273366
33	Economics, Nursing/	4013
34	Economics, Medical/	9291

35	Economics, Pharmaceutical/	3148
36	exp Economics, Hospital/	25985
37	Economics, Dental/	1922
38	exp "Fees and Charges"/	31528
39	exp Budgets/	14258
40	budget*.ti,ab,kf.	38796
41	(economic* or cost or costs or costly or costing or price or prices or pricing or pharmacoeconomic* or pharmaco-economic* or expenditure or expenditures or expense or expenses or financial or finance or finances or financed).ti,kf.	302251
42	(economic* or cost or costs or costly or costing or price or prices or pricing or pharmacoeconomic* or pharmaco-economic* or expenditure or expenditures or expense or expenses or financial or finance or finances or financed).ab. /freq=2	418589
43	(cost* adj2 (effective* or utilit* or benefit* or minimi* or analy* or outcome or outcomes)).ab,kf.	232859
44	(value adj2 (money or monetary)).ti,ab,kf.	3297
45	exp models, economic/	16525
46	economic model*.ab,kf.	4563
47	markov chains/	16461
48	markov.ti,ab,kf.	31542
49	monte carlo method/	33319
50	monte carlo.ti,ab,kf.	64455
51	exp Decision Theory/	13855
52	(decision* adj2 (tree* or analy* or model*)).ti,ab,kf.	45151
53	or/31-52	969915
54	7 and 30 and 53	87

The search will be limited to 1 January 2015 onwards (the date at which the searches for NHS EED ceased to be updated).

The search filter used to identify systematic reviews (lines 8-30 inclusive) in MEDLINE is based on the CADTH multifile search filter for systematic reviews on Ovid: (SR / MA / HTA / ITC - MEDLINE, Embase, PsycInfo. In: CADTH Search Filters Database. Ottawa: CADTH; 2024: Accessed 2024-09-23. Line 17 of the original CADTH filter was removed as it was intended for use in PsycInfo only).

The search filter used to identify economic evaluations and models (lines 31-53) in MEDLINE is the CADTH search filter. Economic Evaluations & Models - MEDLINE. In: CADTH Search Filters Database. Ottawa: CADTH; 2024: https://searchfilters.cadth.ca/link/16. Accessed 2024-09-30.

Search for economic evaluations

Database(s): **Ovid MEDLINE(R) ALL** 1946 to September 26, 2024

Search Strategy:

#	Searches	Results
1	exp urinary catheterization/ [exploding picks up Intermittent Urethral Catheterization/ too]	15242
2	Urinary Catheters/	1528
3	(catheter* adj5 (urin* or urethra* or intermittent)).tw,kf.	18230
4	in out catheter*.tw,kf.	10
5	(self adj5 catheter*).tw,kf.	2253
6	(catheter* adj5 (urological or transurethra* or bladder)).tw,kf.	5512
7	1 or 2 or 3 or 4 or 5 or 6	30550
8	Economics/	27539
9	exp "Costs and Cost Analysis"/	273366
10	Economics, Nursing/	4013
11	Economics, Medical/	9291
12	Economics, Pharmaceutical/	3148

13	exp Economics, Hospital/	25985
14	Economics, Dental/	1922
15	exp "Fees and Charges"/	31528
16	exp Budgets/	14258
17	budget*.ti,ab,kf.	38796
18	(economic* or cost or costs or costly or costing or price or prices or pricing or pharmacoeconomic* or pharmaco-economic* or expenditure or expenditures or expense or expenses or financial or finance or finances or financed).ti,kf.	302251
19	(economic* or cost or costs or costly or costing or price or prices or pricing or pharmacoeconomic* or pharmaco-economic* or expenditure or expenditures or expense or expenses or financial or finance or finances or financed).ab. /freq=2	418589
20	(cost* adj2 (effective* or utilit* or benefit* or minimi* or analy* or outcome or outcomes)).ab,kf.	232859
21	(value adj2 (money or monetary)).ti,ab,kf.	3297
22	exp models, economic/	16525
23	economic model*.ab,kf.	4563
24	markov chains/	16461
25	markov.ti,ab,kf.	31542
26	monte carlo method/	33319
27	monte carlo.ti,ab,kf.	64455
28	exp Decision Theory/	13855
29	(decision* adj2 (tree* or analy* or model*)).ti,ab,kf.	45151
30	or/8-29	969915
31	7 and 30	884

The search will be limited to 1 January 2015 onwards (the date at which the searches for NHS EED ceased to be updated).

The search filter used to identify economic evaluations and models (lines 8-30) in MEDLINE is the CADTH search filter. Economic Evaluations & Models - MEDLINE. In: CADTH Search Filters Database. Ottawa: CADTH; 2024: https://searchfilters.cadth.ca/link/16. Accessed 2024-09-30.