Late-stage assessment

GID-HTE10051 Slide sheets for repositioning or moving a person: late-stage assessment

Final Protocol

Produced by: CEDAR (Centre for Healthcare Evaluation, Device Assessment, and Research)

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1 Decision problem

This late-stage assessment (LSA) aims to assess the clinical and economic benefits of innovations in slide sheets (used for moving or repositioning a person), as well as how product features impact outcomes and user preferences, and which technology features represent value for money.

Table 1 summarises the decision problem to be addressed in this assessment. Further detail on each element can be found in the published scope for the assessment.

Table 1. Summary table of the decision problem

Item	Description
Population(s)	Any person who is temporarily or permanently unable to move unassisted and has to be repositioned or moved, and the caregivers performing the handling task
Subgroups	If the evidence allows, the following subgroups may be considered: • People who need longer-term care • People who are particularly frail or with a poor skin integrity.
Intervention(s)	Flat, tubular, hybrid and in situ slide sheets that are available for purchase in the NHS
Comparators	Slide sheets without additional or innovative features. The comparator may differ between subgroups.
Healthcare setting	Hospital and community care settings
Outcomes eligible for inclusion (organised by outcome type)	Outcome measures for consideration may include, but are not limited to: Caregiver related outcomes: • Measures of musculoskeletal injury (e.g. rate or risk) and pain related to injury • Perceived risk and burden (e.g. using the Borg scale). Patient related outcomes: • Adverse events, such as skin tears and pressure damage • Patient reported outcomes, including health-related quality of life and comfort. Technology related outcomes: • Biomechanical measures of horizontal (pushing) and vertical (lifting) forces • Incidences when the technology does not function

	• Microclimate and breathability. Costs and resource use: • Cost of the technology and associated lifecycle costs • Cost of treating adverse events • Number of carers needed to perform a moving or repositioning task • Time for performing the moving or repositioning task. In addition, user preference and non-clinical outcome measures will be assessed as part of a user preference assessment.
Economic analysis	An appropriate health economic model will be developed, where possible. Costs will be considered from an NHS and Personal Social Services 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.

1.1 Objectives

The objective of this assessment is to identify and analyse evidence that will inform guidance on use of slide sheets in the NHS. The overall research question the assessment will aim to answer is:

- Is there any value added by incremental innovation in features of slide sheets that could justify variation in price to the NHS?

The following broad objectives are proposed to address the research question:

Clinical Effectiveness:

- Identify and assess relevant evidence, focusing on available features, rather than specific devices.
- Highlight any equalities issues not described in the scope.
- Briefly outline the limitations of all evidence identified.

Cost Effectiveness:

- Identify and assess relevant economic information.
- Identify and assess additional evidence to inform the economic modelling.
- Develop economic models to determine value for money of each feature where sufficient evidence is available.
- Report available model parameters and any key limitations.

2 Evidence review

An independent search for relevant clinical and economic evidence will be conducted by the EAG. Evidence relevant to the scope will be identified using a combination of databases of published evidence and evidence provided by device manufacturers. In line with NICE interim methods and processes for LSA in HealthTech, the evidence review will be conducted using rapid review methods.

2.1 Inclusion criteria

Table 2 outlines the inclusion and exclusion criteria for the evidence review.

Table 2: Inclusion and exclusion criteria

	Inclusion Criteria	Exclusion Criteria
Population	• Any person who is temporarily or permanently unable to move unassisted and has to be repositioned or moved, and the caregivers performing the handling task	
Intervention	• Any flat, tubular, hybrid or in-situ slide sheet	• Transfer sheet • One-way glide sheet • Air assist devices • Assistive technologies that do not consist of 2 layers of low-friction material that work together to reduce friction • Slide film

Comparators	• Slide sheets without additional or innovative features **OR** • Any/no comparator (single arm studies), where good quality evidence with a comparator as described above is not available	
Outcomes	• Only those included in scope	• Evidence will be excluded if no relevant outcomes are reported. If a subsection of outcomes are relevant to the scope, these alone will be reported
Study design	All study designs including: • Systematic reviews, meta-analyses, network meta-analyses • RCTs • Observational studies, including those reporting audit data • Abstracts, conference papers	• Narrative reviews
Limits	Human studies	Animal studies

2.2 Search strategy

Searches will be developed in Medline ALL (Ovid) by an experienced Information Specialist. Search terms will include free-text terms and controlled terms from databases (e.g. MeSH). A comprehensive search will be conducted and search terms will be structured around device terms as detailed in the inclusion criteria (Section 2.1). The search strategy will be peer-reviewed by a second Information Specialist. A draft search strategy is available in Appendix A. The search strategy will be translated to each database.

The following bibliographic databases will be searched:

- Medline ALL (Ovid)
- Embase (Ovid)
- AMED (Ovid)

- CINAHL (Ovid)
- Cochrane Database of Systematic Reviews (CDSR)
- Cochrane Central Register of Controlled Trials (CENTRAL)
- International HTA database (INAHTA)
- NHS Economic Evaluation Database (via CRD)
- Database of Abstracts of Reviews (DARE, via CRD)
- Web of Science
- Scopus.

The following clinical trials registries will be searched for ongoing trials:

- ClinicalTrials.gov
- International Clinical Trials Registry Platform (ICTRP).

Where possible, the EAG will identify additional studies from the information companies provide to NICE. To identify studies that have not been retrieved by the database searches, company websites will be searched for relevant publications.

Depending on the volume of evidence available from database searches, supplementary searches may be conducted. This may comprise of citation tracking of studies included in the evidence review, asking experts about known studies on the topic, identifying studies from the instructions for use documents, and searching stakeholder websites.

2.3 Study selection

Retrieved references will be imported into EndNote and deduplicated. EndNote will also be used to record reviewers' screening decisions. Titles and abstracts of identified studies will be screened by one reviewer and a minimum of 20% of excludes will be checked by a second reviewer against the pre-specified inclusion and exclusion criteria. Full-text articles of eligible studies will be obtained and screened by one reviewer with final inclusions and a random 20% of exclusions checked by a second reviewer. A list of studies excluded at the full text stage, with reasons for their exclusion, will be presented in an appendix in the report.

2.4 Data extraction strategy

Where available, the following data will be extracted from studies: study information (i.e., author, year), study design, intervention characteristics (i.e., slide sheet name, type, key features), comparator, participant characteristics (i.e., demographics, indication), patient outcomes relevant to the economic model, cost and resource data if relevant to a UK setting. Data will be extracted into a standardised table by a single reviewer and checked by a second reviewer.

2.5 Quality assessment strategy

Critical appraisal of key studies included in the clinical evidence review will be conducted using the JBI Critical Appraisal Tools as a guide, in accordance with NICE's health technology evaluations manual. Studies that compare slide sheets with and without additional or innovative features will be prioritised as key studies. A narrative summary of the key strengths and limitations of the evidence will be presented in the final report. This summary will highlight potential biases in individual studies for example, relevance to scope, potential confounding, and will discuss how these impact on the certainty of the results. The results of critical appraisal will also be presented in a table in the final report.

2.6 Methods of Synthesis

Clinical outcome data will be presented in a suitable tabular format, accompanied by brief narrative synthesis highlighting any evidence of differences in caregiver, patient, or technology related outcomes that can credibly be attributed to a feature of the slide sheet.

3 Economic analysis

The economic analysis will compare different features of the slide sheets, and will not compare individual products. The EAG will consider the use of regression analysis to investigate the correlation between features and product cost. The devices will be based on those currently available through NHS Supply Chain. This may be different from future NHS Supply Chain frameworks, and does not represent the entire UK market.

Initial scoping searches have indicated there will be limited evidence in this area. Where there is insufficient data to allow modelling of features, the EAG will summarise any relationship identified between the costs and features of the slide sheets, together with expert opinion on the impact of these features.

The economic analysis will be performed in line with the NICE reference case, where there is sufficient clinical evidence available. An NHS and Personal Social Services perspective will be used. Costs will be expressed in 2023 prices and where applicable, costs will be inflated using NHS Cost Inflation Index (NHSCII). If a time horizon of greater than one year is required, discounting of 3.5% will be applied.

Device costs will be based on prices from NHS Supply Chain using a weighted average by volume of sales for each feature group. Calculations will account for the need for 1 or 2 purchases per patient, as some are sold as a pair, or are tubular (requiring only a single purchase), and some are sold as single sheets.

Economic evidence will be identified from guidance and literature identified during the main search strategy and information submitted in Requests for Information (RFIs). Additional searches will be conducted to inform model parameters, as well as expert opinion as needed.

3.1 Model development

Single use, patient specific and washable slide sheets

Available evidence on outcomes will be examined to determine if clinical equivalence can be assumed across these features, and therefore a cost consequence approach used. If there is a lack of clinical evidence, then the EAG will consult clinical experts. The evaluation will consider purchase, storage, laundering and drying (for washable slide sheets) and expected number of uses in the device lifetime.

As this evaluation is not comparing individual devices, each arm of the model will be based on a weighted mean cost of the group of devices (NICE health technology evaluations: the manual). The time horizon will be based on the number of times a reusable device can plausibly be laundered.

Scenario analysis will consider different approaches to laundering, and threshold analysis for device lifetime and numbers of uses. Narrative description will be used to capture the different types of laundering that might be used, considerations for these, and the possible impact on device life and hence lifetime costs.

Removable or in-situ slide sheets

A decision tree model will be used to consider the changes in cost, resource use and outcomes for these two groups of devices. The patients included in the model will be a sub-group of the total population as this decision is unlikely to be relevant for out-patients, or patients who are admitted for a short time duration.

The EAG will search for utilities data on patient impact suitable to inform a cost-effectiveness model. If this is not available, we will consider options for expert elicitation or a cost consequences approach. Device costs will be based on a weighted mean cost of the group of devices as currently purchased through NHS Supply Chain. Additional cost inputs will be taken from literature, or through consultation with experts. The time horizon will be based on the expected service life of an in-situ slide sheet (approximately 1-2 years), and the expected duration of need for the person who is being moved.

Threshold analysis will be used to consider the impact of duration of use, and number of expected uses. Scenario analysis will be considered if there is sufficient information available e.g. for people at end of life and for people cared for in different settings.

The model will use an NHS and Personal Social Services perspective, however there may be an impact on costs or care activities incurred by patients, family members, friends or partners. Where this is the case the EAG will consider including an additional analysis that includes these costs (NICE health technology evaluations: the manual). Information emerging from user preference workshops may also be referenced in narrative form to consider any changes in the support needed from unpaid carers.

4 Handling information from the companies

All data submitted by the companies in RFIs by NICE or other stakeholders will be considered by the EAG if received by 21st October 2024. Data received after this date will not be considered. If the data included in the information provided meets the inclusion criteria for the review they will be extracted, and quality assessed in accordance with the procedures outlined in this protocol.

All correspondence between the EAG and companies will occur through NICE. The EAG may seek clarification or additional information from companies where necessary. Any 'commercial in confidence' data provided by the company, and specified as such, will be highlighted in blue and underlined in the report, economic model and correspondence log. Any 'academic in confidence' data provided by the company, and specified as such, will be highlighted in yellow and underlined in the report, economic model and correspondence log. If confidential information is included in the economic model, the EAG will provide a copy of the model with 'dummy variable values' for the confidential values (using non-confidential values).

5 Additional information sources

Clinical experts identified by NICE will be consulted by the EAG during the assessment process to provide clarification and guidance on interpreting evidence that has been identified as relevant to the assessment, where necessary. Where necessary the EAG may also consult additional experts with particular areas of expertise. Additionally, clinical experts may be asked to contribute opinions on key points of uncertainty that arise from the clinical evidence review and economic modelling. This may involve consideration of user preference work or discussions conducted by NICE.

6 Competing interests of authors

None

7 References

National Institute for Health and Care Excellence (NICE). (2023). NICE health technology evaluations: the manual. Available from: Overview | NICE health technology evaluations: the manual | Guidance | NICE. Last accessed 27th September 2024

Joanna Briggs Institute (JBI). JBI Critical Appraisal Tools. (n.d.). Available from: JBI Critical Appraisal Tools Last accessed 27th September 2024

National Institute for Health and Care Excellence (NICE). (2024a). Slide sheets for repositioning or moving a person on or from a bed: Late Stage Assessment. [GID-HTE10051] Final scope. Available from: https://www.nice.org.uk/guidance/indevelopment/gid-hte10051/documents. Last accessed 27th September 2024

Appendix A: Draft search strategy

Ovid MEDLINE(R) ALL <1946 to September 26, 2024>

1 ((slide or sliding or glide or gliding or "low friction") adj2 (sheet* or bedsheet* or "bed sheet*" or bedding)).tw. 76

2 (("manual handl*" or "patient handl*") adj3 (sheet* or bedsheet* or "bed sheet*" or bedding)).tw. 2

3 ("assistive technolog*" and reposition*).tw. 2

4 "Bedding and Linens"/ and (slide or sliding or glide or gliding or "low friction").tw. 21

5 "Moving and Lifting Patients"/ 727

6 (sheet* or bedsheet* or "bed sheet*" or bedding).tw. 96618

7 5 and 6 26

8 (or/1-4) or 7 102

9 exp animals/ not humans.sh. 5262597

10 8 not 9 99

11 limit 10 to english language 97