YHEC

York Health Economics Consortium

NICE

Bed Frames for Adults in Acute Settings (GID- HTE10050): Late-Stage Assessment

Final Protocol

26/09/2024

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Table of Contents

Abbreviations

CDSR	Cochrane Database of Systematic Reviews
CEAC	Cost-effectiveness acceptability curve
EAG	External Assessment Group
HTA	Health Technology Assessment
ICER	Incremental cost effectiveness ratio
ICU	Intensive care unit
ISPOR	The International Society for Pharmacoeconomics and Outcomes Research
LSA	Late-stage assessment
NHB	Net health benefit
NHS	National Health Service
NICE	National Institute for Health and Care Excellence
NMB	Net monetary benefit
PICO	Population, Intervention, Comparison, and Outcome
QALY	Quality-adjusted life year
RFI	Request for information
YHEC	York Health Economics Consortium

1 Background

Acute adult bedframes have been identified by NICE for late-stage assessment (LSA). As described in the NICE scope, the aim of this LSA is to assess whether price variations in acute adult bedframes are justified by differences in outcomes, and therefore, determine if different acute adult bedframes are value for money. This document was prepared in response to the NICE Scope and presents the methods that the external assessment group (EAG) commissioned by NICE will undertake to produce the LSA.

1.1 Research Questions

This LSA aims to identify and assess evidence for the clinical and cost effectiveness of acute adult bed frames for people with an acute admission to NHS hospitals, and people associated with their care. The evaluation will cover bedframes which have additional innovative features, but also meet basic technology requirements, to determine whether price variations are justified. The outcome(s) of the assessment will support NHS procurement and commissioning decisions. To do this, the LSA will address the following research questions:

- How do innovative features of acute care bed frames impact clinical, user preference, safety outcomes in adults receiving care in acute settings?
    - How do innovative features impact people with an acute mental health hospital admission?
    - How do innovative features impact people who are frail?
    - How do innovative features impact people with a learning disability or cognitive impairment?
- Do differences between bedframes (and their associated innovative features) bring additional benefits and are these worth the cost?
- What is the economic evidence for acute adult bedframes for adults receiving care in acute settings?

In accordance with Section 4.8 of the NICE interim methods and process statement for LSA [1], we will undertake a rapid evidence review, taking a pragmatic approach. A systematic search for relevant published evidence will be conducted, and any relevant evidence supplied by manufacturers as part of NICE's request for company information will be incorporated into the evidence base. Retrieved evidence will be screened according to the eligibility criteria (Section 2.1). The EAG's scoping searches suggest the evidence base to meet this decision problem is small. If an insufficient number of relevant studies is found, we will consider widening eligibility settings to include intensive care units (ICU). In the event that a large evidence base is identified, relevant evidence will be prioritised. Both approaches are discussed in Section 2.4.

Relevant data will be extracted from the eligible documents and synthesised, with relevant clinical and health-related quality of life (HRQoL) data informing the parameters of an Excel-based economic model.

At the time of protocol preparation, the likelihood of using registry data was discussed. It is unlikely that there will be any available registry data on bedframes to inform this evaluation. If any real-world registry data is identified, either by stakeholders or NICE, we will consider if it can feasibly be incorporated into the economic model.

The findings of this LSA will inform clinical and procurement decisions by establishing whether there are differences in outcomes between acute adult bedframes used within the NHS, and whether their costs justify these differences.

2 Evidence Review

The eligibility criteria for including studies in the evidence review are summarised in Table 2.1 and reflect the decision problem as set out in the NICE scope.

2.1 Eligibility Criteria

Table 2.1: Summary of the review eligibility criteria

	Inclusion Criteria	Exclusion Criteria
Population	Adult patients (≥18 years and older) admitted to acute care settings and people associated with their care. The following subgroups are of interest: ▪ Adults with a mental health condition ▪ People who are frail ▪ People with a learning disability or cognitive impairment	▪ Studies in children (<18) ▪ Studies in patients with atypical anatomy (e.g. short stature requiring a paediatric bed) ▪ Studies in bariatric or maternity patients using acute care beds ▪ Studies in healthy people using acute care beds
Setting	Any secondary care setting described as giving acute care, including: ▪ Acute medical units/wards ▪ Acute care hospitals ▪ Acute care facilities ▪ Surgical wards ▪ Other specialist medical wards Studies that are not in settings specifically described as acute, but appearing to meet setting criteria, will be included if they evaluate acute bed frames	Studies taking place in the following settings (unless evaluating acute, non-highly specialised, bed frames): ▪ ICU ▪ Critical care ▪ Maternity wards ▪ Community healthcare ▪ Mental health wards
Intervention	Acute adult bed frames available to purchase in the NHS that meet the basic technology requirements and also have at least one additional innovative feature, as listed in the NICE scope	▪ Non-adult acute bed frames ▪ Acute care bed frames that do not have any additional innovative features ▪ Highly specialised bed frames, not commonly used in the acute care setting[1] ▪ Bariatric beds ▪ Maternity beds ▪ Characteristics of bed frames i.e. not actual features but characteristics resulting from the use of those features[2] ▪ Beds designed for use in children
Comparators	▪ Acute adult bed frames that are considered as standard care ▪ Acute adult bed frames with one or more innovative features that are different to the intervention bed ▪ No comparator	▪ Non-adult acute bed frames ▪ Highly specialised bed frames
Outcomes	All outcomes listed in the NICE final scope.[3]	▪ Studies not reporting outcomes relevant to the NICE final scope
Study design	For clinical effectiveness and safety data: ▪ RCTs ▪ Non-randomised comparative studies, including: • Non-randomised comparative trials • Cohort studies • Case-control studies	▪ Reviews, both systematic and non-systematic Any retrieved relevant systematic reviews published in the last 5 years will have their included studies lists checked to identify any relevant

	Inclusion Criteria	Exclusion Criteria
	▪ Single arm studies, including case series For the economic review: ▪ Cost-effectiveness analyses (including cost-utility analyses) ▪ Cost-benefit analyses ▪ Cost-consequence analyses ▪ Cost-comparison analyses ▪ HTA reports investigating the cost-effectiveness of treatments For costs and resource use data, eligible studies will be any of the above.	studies that may have been missed in the searches
Limits	▪ Studies in English language only ▪ Unpublished studies/reports submitted by companies	▪ Studies not in the English language ▪ News items, opinion pieces and editorials ▪ Preprints ▪ Abstracts and conference posters[4]

Abbreviations: HTA, health technology assessment; ICU, intensive care unit; NHS, National Health Service; RCT, randomised controlled trial.

[1]Studies in highly specialised beds evaluating a non-specialised feature will be excluded unless the outcome assessed can be solely attributed to the non-specialised feature.
[2]Studies of the associations between bed frame characteristics (but not specific features) and outcome will be excluded since they do not meet eligibility criteria. For example, studies of the association between accidental activation of controls with injury would be excluded as they do not evaluate a specific innovative bed frame feature (the feature would be functionality to prevent inadvertent activation of controls). However, since these types of studies may be useful for modelling purposes, those evaluating characteristics associated with innovative features, will be tagged during study selection.
[3]We note that proof of concept studies reporting 'Technical outcomes' are likely to be conducted in populations and settings that do not meet the decision problem. These would therefore be excluded with the current eligibility criteria. However, should the EAG identify an insufficient number of studies, we may expand the eligibility criteria for the population and setting to include these studies, as described in Section **Error! Bookmark not defined.Error! Reference source not found.** below.
[4]Although excluded, we will retrieve and set aside conference abstracts. In the event that insufficient evidence is obtained, and there is potentially time for additional study identification, we will screen conference abstracts for inclusion.

2.2 Identifying Relevant Studies

A single set of searches will be conducted to identify evidence on clinical, safety and economic outcomes.

Reflecting the NICE interim methods and process statement for LSA, search methods (including strategy design, selection of search resources and approach to strategy translation) will incorporate some pragmatic elements, as appropriate to the LSA timeline and resource context. Searches will be conducted systematically (the searches will be conducted in a methodical pre-planned way, will be appropriately transparent and reproducible, and will be designed to be appropriately robust for the project context).

2.2.1 Search strategy

A MEDLINE (OvidSP) search strategy designed to identify studies reporting on features of bed frame design in acute hospital settings is presented in Appendix B. The search strategy is not

restricted by outcome or study design and is therefore appropriate for identifying evidence on clinical, safety and economic outcomes.

The strategy comprises four concepts:

- Bed purchasing / leasing (search lines 2 to 4).
- Bed design / specific bed features (search lines 5 to 53).
- Inpatient / hospital setting (search lines 54 to 66).
- Product names (search lines 69 to 82).

The concepts are combined as follows: bed purchasing / leasing OR (bed design / specific bed features AND inpatient / hospital setting) OR product names.

Generic terms for bed design are additionally searched in the title and not combined further with terms for any other concept (search line 1). This mitigates the possibility of missing potentially eligible records that are highly relevant.

The strategy was devised using a combination of subject indexing terms and free text search terms in the Title, Abstract and Keyword Heading Word fields. The search terms were identified through discussion within the research team, scanning background literature and browsing database thesauri.

Database records may refer to specific features of bed frames. The search terms for bed design / features include terms for generic and specific bed features. These are adapted from the NHS Supply Chain framework for beds. These terms have, in some cases, been intentionally restricted in order to achieve manageable screening numbers that suit the project timelines and resources.

The terms for inpatients and hospital settings is not a comprehensive selection of terms but aims to balance sensitivity and specificity in order to retrieve manageable record numbers that suit the project timelines and resources. We note that, since the literature searches were not designed to retrieve studies outside of an acute care setting, any evidence will be summarised with caveats regarding the potential for having missed other studies of bed frames within these broader settings.

The product names in the strategy reflect those listed in the scope. Product names that are words in common usage have been combined with terms for beds.

The strategy excludes animal studies from MEDLINE using a standard algorithm (search line 84). The strategy also excludes some ineligible publication types which are unlikely to yield relevant study reports (editorials, news items and case reports) and records with the phrase 'case report' in the title (search line 85).

Reflecting the eligibility criteria, the strategy is restricted to studies published in English language (search line 88). The final Ovid MEDLINE strategy will be peer-reviewed before execution by a second Information Specialist. Peer review will consider the appropriateness of the strategy for the review scope and eligibility criteria, inclusion of key search terms, errors in spelling, syntax and line combinations, and application of exclusions.

2.2.2 Resources to be searched

We will conduct the literature search in the databases shown in Table 2.2.

Table 2.2: Proposed databases and information sources

Resource	Interface / URL
Databases	
MEDLINE(R) ALL	OvidSP
Embase	OvidSP
Cochrane Database of Systematic Reviews (CDSR)	Cochrane Library/Wiley
Cochrane Central Register of Controlled Trials (CENTRAL)	Cochrane Library/Wiley
Reference list checking	n/a
Company Submission Evidence	n/a

Reflecting the eligibility criteria, records indexed in Embase as preprints will be excluded from the Embase search results. Records indexed as conference abstracts in Embase will be downloaded at the time of the search. These records will be screened if there is sufficient time (see Section 2.4).

We will also check included studies lists of any retrieved relevant systematic reviews published in the last 5 years for any eligible studies that may have been missed by the database searches.

For details of how we will use company submission evidence to identify eligible evidence, see Section 5.

2.2.3 Running the search strategies and downloading results

We will conduct searches using each database or resource listed in the protocol, translating the agreed Ovid MEDLINE strategy appropriately. Translation includes consideration of differences in database interfaces and functionality, in addition to variation in indexing languages and thesauri. The approach taken to strategy translation may incorporate some pragmatic elements, as appropriate to LSA timelines and resources. The final translated database strategies will be peer-reviewed by a second Information Specialist. Peer review will consider the appropriateness of the translation for the database being searched, errors in syntax and line combinations, and application of exclusions.

We will document all search strategies and search results and we will provide this in the final report to meet standard requirements for clear formal reporting of the search process. The report of search methods will be informed by the PRISMA-S (Preferred Reporting Items for Systematic reviews and Meta-Analyses literature search extension) checklist [2] and the PRISMA 2020 statement [3, 4].

Where possible, we will download the results of searches in a tagged format and load them into bibliographic management software (EndNote) [5]. The results will be deduplicated using several algorithms and the deduplicated references held in a duplicates EndNote database for checking if required. Results from resources which do not allow export in a format compatible

with EndNote will be saved in Word or Excel documents as appropriate and manually deduplicated.

2.3 Study Selection

Record assessment will be undertaken using pragmatic methods in line with the NICE interim methods and process statement for LSA [6].

A single researcher will assess the search results for relevance to the review and will remove the obviously irrelevant records such as those about ineligible diseases or in children. Where identified, studies in ineligible indications will be grouped for later use in case of a paucity of evidence.

A single reviewer will assess the titles and abstracts of remaining records for relevance against the eligibility criteria, with the first 10% completed in duplicate by an independent second reviewer to ensure consistency.

We will obtain the full text of potentially relevant studies. A single reviewer will assess the full text documents for relevance against the eligibility criteria, with the first 10% completed in duplicate by an independent second reviewer to ensure consistency.

We will record the number of records included and removed at each selection stage in the PRISMA flow diagram. We will list studies excluded after assessment of the full document in an excluded studies table, with the reasons for exclusion.

We will obtain electronic or paper copies of potentially relevant full documents meeting the evidence review's eligibility criteria.

Where results for one study are reported in more than one paper, all related papers will be identified and grouped together to ensure that participants in individual trials are only included once.

2.4 Study Prioritisation

Based on examination of initial scoping searches, the EAG does not anticipate identifying a large number of studies. If we do identify a large number, then we will prioritise studies for inclusion based on the most relevant evidence. We will prioritise:

- Studies reporting comparative evidence, and using the most relevant comparators.
- Studies conducted in the UK.
- Studies reporting clinical outcomes over those reporting proof of concept outcomes.

Deprioritised studies will be listed in an appendix for information, but will not be extracted.

If few eligible studies are identified, we will consider adding broadly relevant evidence identified by the searches but excluded at full text for not meeting all PICO criteria. This would include:

- For all outcomes, studies conducted in ICUs that evaluate non-specialised acute care beds. Following review of the literature and in agreement with NICE, we may also include any

additional settings where acute care beds have been used (for example, accident and emergency).

- For ‘technical outcomes’ derived from proof-of-concept studies, studies conducted in any setting and population would be included.
- Conference abstracts: In the event that insufficient evidence is obtained, and there is potentially time for additional study identification, we will screen conference abstracts retrieved from the existing searches for eligibility.

For all of these adaptions, only studies meeting the intervention and comparator criteria and reporting eligible outcomes would be included.

2.5 Data Extraction

One researcher will extract data from the included studies and a second researcher will check a random 20% sample of the extracted data. We will extract data into standardised data tables, with pilot extraction conducted on four studies before progressing to full data extraction.

2.5.1 Clinical effects and safety

Data extraction will be targeted. Key patient and study details will be extracted, including bibliographic details, details of study design, and key patient and/or caregiver characteristics (including age, gender, clinical condition (where reported), and healthcare setting). Details of the intervention and comparator assessed will be extracted.

For each outcome extracted, the timepoint of measurement will also be extracted, along with the authors’ description of the outcome.

2.5.2 Economic evaluations

Data extraction will be high-level and will include methods of analysis, model structure, (including health states, time horizon, cycle length, treatment arms and treatment sequencing), main model sources used, model summary outputs including total QALYs, total costs and incremental outcomes if relevant to a UK setting, key scenario analyses, and any major study limitations.

2.6 Quality Assessment Strategy

One reviewer will assess the risk of bias of the eligible studies using a validated tool specific to the study’s design. A second reviewer will check all formal risk of bias assessments. Formal risk of bias assessment will not be performed for any studies included with broader eligibility criteria (see Section 2.4). However, we will include a discussion of any concerns regarding study reliability due to study designs used, and consequently how any risk of bias might have affected key outcomes. The report will also discuss the transferability of results across clinical practice in the NHS.

We will summarise the results of formal risk of bias assessments in a table and provide a detailed assessment in an Appendix to the main report.

For economic evaluations, we will assess the structure of all relevant models to identify those that could be used to inform the modelling approach for this LSA. If we identify multiple models as appropriate, researchers will perform a formal quality assessment of those models using the CHEERs checklist [7]. We will not perform formal quality assessment of other relevant models.

2.7 Methods of Analysis/Synthesis

2.7.1 Clinical effects and safety

Studies will be summarised in tables providing data on their methods and results. We will provide a narrative summary exploring the quality of the studies, the relationship between studies and patterns that have been discerned in the data.

Should study methods and characteristics be considered similar enough to produce clinically meaningful pooling, we will meta-analyse effect estimates of included studies. We will provide an overall assessment of the strength of the research evidence in relation to the research question.

2.7.2 Economic evaluations

The methods and results of economic evaluations will be summarised in tables accompanied by a short narrative summary. Utility, cost and resource use outcome data will be passed directly to the EAG modelling team conducting the economic model.

2.8 Protocol Amendments

Any essential protocol amendments or clarifications will be recorded in Appendix C. Changes will be made to the text of the protocol and flagged with [PA#].

3 Economic Modelling Methods

3.1 Draft Decision Problem

We will develop an economic model to evaluate bedframes for adults with acute admission to NHS hospitals in the UK which have additional innovative features, but also meet basic technology requirements. We will consider the intervention in adults admitted to acute care settings.

The model will be developed in line with NICE process' and methods [8]. The draft decision problem is presented in the table below.

Table 3.1: Key decision elements

Population	Users of acute adult bed frames, which includes adults admitted to acute care settings and caregivers providing care for these patients.
Subgroups	If the evidence allows, the following subgroups will be considered: ▪ People with an acute mental health hospital admission ▪ People who are frail ▪ People with a learning disability or cognitive impairment.
Healthcare setting	Secondary care setting.
Intervention	Acute adult bed frames available to purchase in the NHS that meet the basic product requirements and safety standards and also have additional innovative features.
Comparator(s)	An acute adult bed frames that meets basic product requirements and safety standards.
Time horizon	To be confirmed, based on available clinical evidence. The time horizon will be long enough to reflect all important differences in costs or outcomes between the technologies being compared. It is important to note there is very limited evidence on previous economic evaluations of bedframes. It is anticipated that a short-term time horizon will be most appropriate to model bed frame complications.
Measuring and valuing health effects	Health effects (e.g. pain and HRQoL) should be expressed in QALYs. The EQ-5D-3L is the preferred measure of health-related quality of life in adults.
Equity considerations	An additional QALY has the same weight regardless of the other characteristics of the individuals receiving the health benefit. This aligns with the NICE health technology evaluations manual. Section 6.2.19 which states that *'medical technologies evaluated through the medical technologies evaluation programme, the concept of a quantitative QALY weight is not applicable'.*
Evidence on resource use and costs	Costs should relate to NHS and social services perspective. Consequences from the bedframe within the acute secondary care setting are likely to relate to secondary care costs. If evidence is available then the impact outside of secondary care, such as primary care, should be reflected in the analysis.
Discounting	The same annual rate for both costs and health effects (currently 3.5%).
Model outcomes	Probabilistic and deterministic total and incremental costs; quality adjusted life years (QALYs), and life years if feasible. Depending on the time horizon, available evidence and expected benefit, QALYs may not be appropriate to be captured in the economic analysis. In this case, a cost-comparison model should be conducted. If it is appropriate to capture QALYs, a probabilistic and deterministic incremental cost effectiveness ratio (ICER); net monetary benefit (NMB); net health benefit (NHB) should be captured. Fully incremental analysis should also be considered, if QALYs are appropriate. Additional outcomes of interest to be confirmed in order of importance.

Abbreviations: HRQoL, health related quality of life; ICER, incremental cost effectiveness ratio; NHS, National Health Service; NHB, net health benefit; NICE, National Institute for Health and Care Excellence; NMB, net monetary benefit; QALYs, quality adjusted life years.

The model will be built using Microsoft Excel because this is a format that can be easily accessed by all users of the model.

3.2 Intervention and Comparators

The economic analysis will answer the research question by comparing acute adult bed frames which are available to purchase in the NHS, or taking a feature-based approach across bedframes. However, it is anticipated that there will not be sufficient evidence to model the impact of features individually. Therefore, it is likely bed frames will be compared with their additional feature(s) highlighted. The intervention of interest comprises bed frames that meet the basic technology requirements and have one or more additional innovative features. The bed frames included in the analysis and the list of additional innovative features of interest will be informed by clinical experts and user groups and agreed with NICE. The number of additional features included and potential combination of those features within a bed frame will be evidence dependent.

The comparator in the economic analysis will be an acute adult bed frame that meets basic product requirements and safety standards. The level of detail available in studies on bed frame features may be minimal, therefore, assumptions may need to be made on which bed frames meet the basic requirements.

3.3 Model Structure

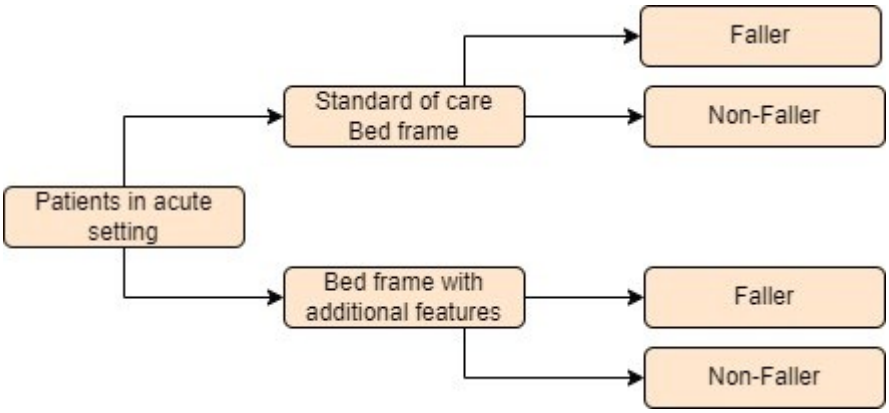
Prior to the model being built, we will undertake a development period whereby available data from the evidence review will be evaluated along with any existing economic evaluations to determine an appropriate model structure. At the end of the scoping phase, we will meet with clinical experts to discuss the final structure of the model to be developed.

The modelling aspects presented here are based on the final NICE scope and a targeted literature review. The model structure may be changed following the scoping phase based on review of the evidence, any changes will be discussed with the NICE project team.

The model structure will capture key clinical outcomes impacted by bed frames. We propose a cohort-based modelling approach using separate decision tree structures for different clinical outcomes. Figure 1, is an example decision tree modelling patient falls. Patient falls is likely to be a key clinical outcome, based on an early review of the evidence. Example outcomes which may be modelled, dependent on evidence availability include:

- Patient falls
- Patient pressure ulcers
- Musculoskeletal injuries in caregiver
- Patient or user entrapment in bed

Figure 1: Falls decision tree



The clinical outcomes captured in the model will be guided by the studies identified in the evidence review, Section 2.5. The associated costs and QALYs from clinical outcomes will be modelled. In addition, the economic evaluation will incorporate any efficiencies in staff time as a result of innovative features and the resultant cost.

It is anticipated that there may be insufficient data to model all bed frames available on the NHS with additional features. Published evidence will be used to inform the economic model, including real-world evidence. Assumptions may be necessary to model the different interventions, these assumptions will be discussed with clinical experts for validation.

3.4 Model Inputs

Populating a model involves a synthesis of data from multiple sources. All model inputs will be clearly referenced for clarity.

The clinical (for example, bed frame effectiveness at reducing falls) and HRQoL model parameters will be populated where possible using data from studies such as clinical trials identified during the evidence review (see Section 2.5.2). This data will be supplemented with targeted searches if necessary.

The model will adopt a health service and personal social service cost perspective. Therefore, the main costs are expected to include:

- Acquisition costs of the bed frames
- Maintenance costs
- Staff time
- Healthcare costs associated with clinical outcomes e.g. patient falls

Published evidence and all potentially relevant studies identified in the economic review will be assessed for use in the model.

Unit costs to be applied to the resources in each model will be compiled from the latest publicly available sources. Anticipated sources are the NHS Reference Costs for secondary care costs, the Unit Costs of Health and Social Care which provides costs for health and social care resources and the NHS Supply chain for costing the bed frames.

QALYs will be included if appropriate, if there is no available evidence of bed frame features having an impact on clinical outcomes and resultant QALY impact then a cost-comparison approach will be undertaken rather than cost-utility approach.

3.5 Model Outcomes

Probabilistic analysis will be presented as the reference case results of the economic model as per the NICE processes and methods handbook [8]. The key outcome from the probabilistic analysis will be the net health/monetary benefit (NHB/NMB) and incremental cost-effectiveness ratio (ICER), presented as an incremental cost per quality adjusted life year (QALY) gained, if a cost-utility approach is taken. This result will be compared against the pre-established NICE cost-effectiveness threshold of £20,000 per QALY gained in a fully incremental analysis to establish which agents are the most efficient use of health care resources. If a cost-utility analysis is not feasible, due to available evidence, QALYs, ICER, NHB and NMB will not be considered in the analysis

In the probabilistic analysis, input parameters are represented as distributions around the point estimate. Each distribution will be summarised using specific data outputs (such as mean and standard deviation for a normal distribution). A set of input parameter values will be drawn by random sampling from an appropriate distribution and the model is ‘run’ to generate outputs (cost and health outcomes). This is repeated many times (typically 1,000 to 10,000 with the exact number of iterations selected based upon a test for stability of results within the model), resulting in a distribution of outputs that can be graphed on the cost-effectiveness plane and inform conclusions. The probability of the bed frame being cost-effective will also be reported for a range of cost-effectiveness thresholds in a cost-effectiveness acceptability curve (CEAC), if a cost-utility analysis is feasible.

Sensitivity analysis will quantify the level of confidence in the output of the analysis, in relation to uncertainty in the totality of model inputs.

The model will also include a deterministic summary of results, a deterministic sensitivity analysis and a deterministic scenario analysis. In deterministic sensitivity analysis key input parameter values are varied within a pre-specified range and the results are analysed to determine to what extent the change has an impact on the output values. A ‘tornado’ diagram will be produced with the sensitivity analysis results. The ranges used in the deterministic sensitivity analysis will be, wherever possible, derived from published evidence.

3.6 Quality Assurance

Once the model is completed, it will be subjected to our internal quality assurance procedure, which includes a technical validation and cross validation. The model will be validated by a member of staff completely independent of the project.

The technical validation will focus on checking the formulae to ensure that they are correct and appropriately applied. We will use a standard checklist as a starting point for validation of the model. Any issues or errors noted in the reviews will be documented and will be addressed in the final version of the models. We will also provide the ‘model review checklist’, which is used for the pressure testing of models. In addition to the use of a checklist a cell-by-cell check of the models will be conducted. This will involve error checking each calculation within the model to ensure that there are no functional errors.

Cross validation involves providing a comparison between the results of the models developed for this analysis and any other published models with a similar decision problem that are identified in the evidence review. This type of validation can increase confidence in the results generated by the model. The validation of the analysis will follow the good practice guide as set out by the ISPOR Modelling Task Force [9]. In addition, all outputs are quality assured and signed off by a senior member of the modelling team.

4 Additional Information Sources

We will consult with clinical experts identified by NICE during the assessment process to provide clarification and guidance on interpreting and prioritising evidence that has been identified as relevant to the assessment, where necessary. Clinical experts may also be asked to contribute opinions on key points of uncertainty that arise from the clinical evidence review and the economic modelling.

5 Handling Information

We will consider any data or evidence supplied by the companies or stakeholders involved. If the data meet the inclusion criteria for the review, they will be considered. It may not be possible to include data received later than 26th September 2024.

Company RFI evidence will be screened against the eligibility criteria outlined in Section 2 and prioritised, data extracted, and quality assessed alongside the identified published literature. Evidence that is supplementary to a study found in the literature searches will be considered as part of the quality assessment for that study.

Any ‘commercial in confidence’ data provided and specified as such will be highlighted in blue and underlined in the assessment report. Any ‘academic in confidence’ data provided will be highlighted in yellow and underlined in the assessment report. Any ’depersonalised data’ (DPD) in the assessment report document will be underlined and highlighted in pink.

If confidential information is included in any economic models produced, then a version using dummy data or publicly available data in place of confidential data will be provided.

In cases when no RFI has been submitted by a company, only publicly available information will be used.

6 Authors

A list of authors from YHEC involved in this LSA are provided below:

- Hayden Holmes, Associate Director
- Lavinia Ferrante di Ruffano, Project Director
- Robert Malcolm, Senior Research Consultant
- Mary Chappell, Senior Research Consultant
- Laura Kelly, Senior Research Consultant
- Chris Bartlett, Senior Research Consultant
- Luc Curtis-Gretton, Research Consultant
- Paul Miller, Information Specialist
- Alice Sanderson, Research Consultant
- Daniela Afonso, Research Consultant
- Maisie Green, Research Assistant
- Katie Reddish, Research Assistant

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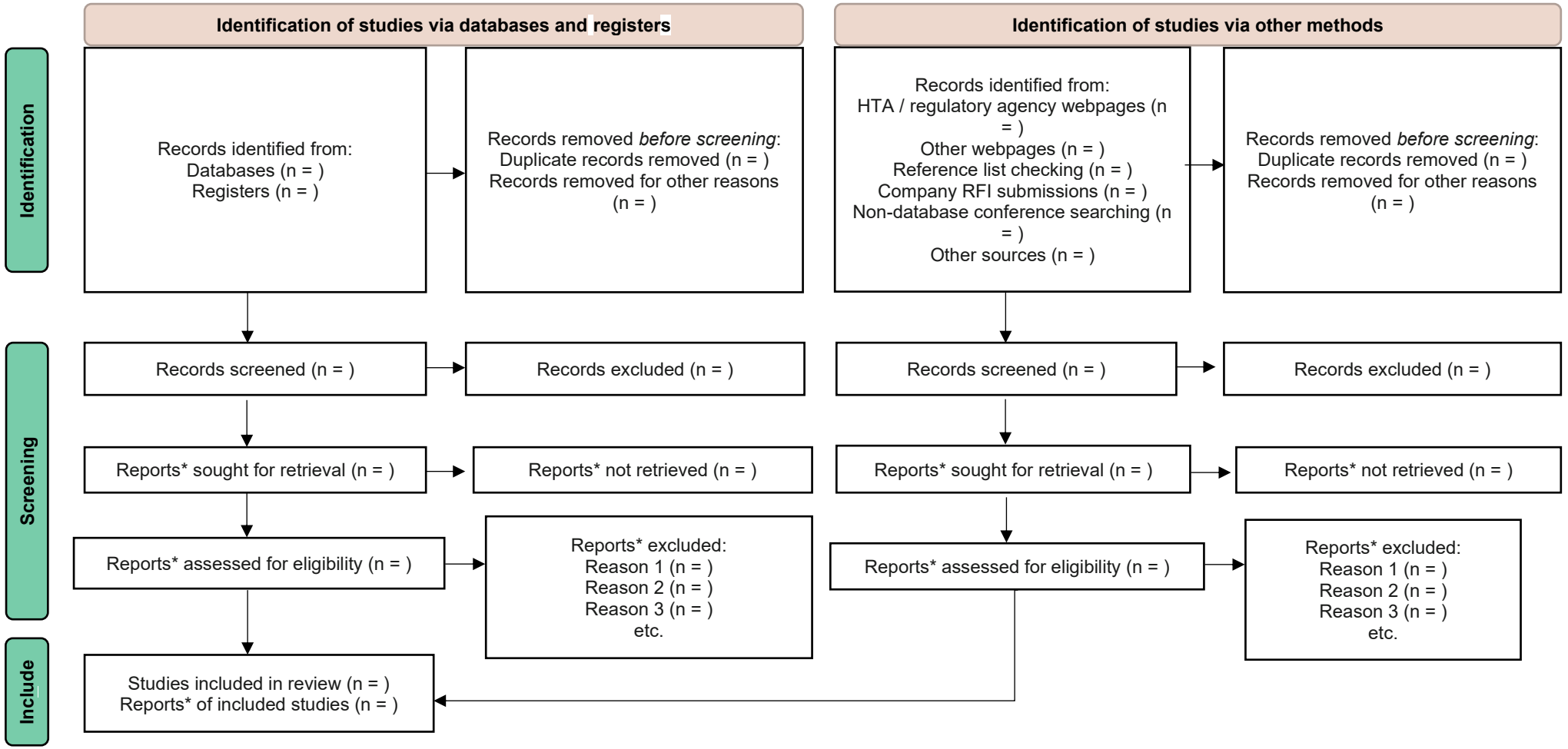
Appendix A – PRISMA Record Selection Process

Figure A.1: PRISMA flow diagram of record selection process [10]



* "Note that a "report" could be a journal article, preprint, conference abstract, study register entry, clinical study report, dissertation, unpublished manuscript, government report or any other document providing relevant information": https://www.bmj.com/content/372/bmj.n71.

Adapted from: Page MJ, McKenzie JE, Bossuyt PM, Boutron I, Hoffmann TC, Mulrow CD, et al. The PRISMA 2020 statement: an updated guideline for reporting systematic reviews. BMJ 2021;372:n71. doi: 10.1136/bmj.n71. For more information, visit: http://www.prisma-statement.org/

Appendix B – Medline Search Strategy

Figure B.1: Search strategy for Ovid MEDLINE® ALL

1	((bed or beds) adj6 (design or designs or feature or features or innovat*)).ti. 187
2	beds/ and (exp purchasing, hospital/ or leasing, property/ or hospitals/) 242
3	((bed or beds) adj3 (tender* or procur* or purchas* or contract* or lease* or leasing or hire* or hiring or rent*)).ti,ab,kf. 172
4	or/2-3 406
5	beds/ and (equipment design/ or equipment safety/) 570
6	beds/ and patient positioning/ 110
7	beds/ and (frame or frames).ti,ab,kf. 45
8	((bed or beds) adj3 (frame or frames)).ti,ab,kf. 67
9	bedframe*.ti,ab,kf. 7
10	((bed or beds) adj1 (design or designs or feature or features or innovat*)).ab,kf. 75
11	((bed or beds) adj3 (access* or egress* or exit or awareness monitor*)).ti,ab,kf. 328
12	((bed or beds) adj3 safe*).ti,ab,kf. 199
13	((bed or beds) adj3 (profile or profiles or profiling)).ti,ab,kf. 121
14	((bed or beds) adj3 (ultralow or low or high or height or heights or width* or length or lengths)).ti,ab,kf. 2616
15	((bed or beds) adj1 (novel* or new*)).ti,ab,kf. 152
16	((bed or beds) adj3 (castor or castors or caster or casters or wheel or wheels or brake or brakes)).ti,ab,kf. 35
17	((bed or beds) adj3 (rail or rails or siderail* or grabrail* or bedrail*)).ti,ab,kf. 198
18	((bed or beds) adj3 (CPR or chest compression* or resus*)).ti,ab,kf. 74
19	((bed or beds) adj3 flatten*).ti,ab,kf. 13
20	((bed or beds) adj3 (adjust* or adapt* or variable)).ti,ab,kf. 457
21	((bed or beds) adj3 (back rest* or backrest* or back support*)).ti,ab,kf. 20
22	((bed or beds) adj3 (plug* or socket* or cable*)).ti,ab,kf. 29
23	((bed or beds) adj3 (power* or battery or batteries)).ti,ab,kf. 114
24	((bed or beds) adj3 (weight* limit* or patient* weight* or load or loads or loadbearing)).ti,ab,kf. 124
25	((bed or beds) adj3 (clean* or disinfect* or hygien*)).ti,ab,kf. 290
26	((bed or beds) adj3 (decontaminat* or hydrogen or peroxide or wash* or UV or ultraviolet or ultra-violet or steam*)).ti,ab,kf. 193
27	((bed or beds) adj3 (water proof* or waterproof* or water resist* or water repel* or splash* or IPX 4 or IPX4)).ti,ab,kf. 4
28	((bed or beds) adj3 (maintenance or maintain* or repair*)).ti,ab,kf. 361
29	((bed or beds) adj3 (compatible or compatibility)).ti,ab,kf. 20
30	((bed or beds) adj3 (assembly or assemble* or construct* or build*)).ti,ab,kf. 259
31	((bed or beds) adj3 (decommission* or dispos* or waste or WEEE or recycl* or re cycl* or sustainable or sustainability)).ti,ab,kf. 180
32	((bed or beds) adj3 (electric* or electronic* or auto or automat*)).ti,ab,kf. 268
33	((bed or beds) and (cardiac chair* or chair position*)).ti,ab,kf. 14
34	((bed or beds) adj3 (trendelenburg or incline* or inclining or recline or reclining or tilt* or angle* or self-level* or selflevel* or elevat*)).ti,ab,kf. 997
35	((bed or beds) adj3 (position* or reposition* or turn or rotate or rotation or CLRT)).ti,ab,kf. 980
36	((bed or beds) adj3 (migrat* or move or moving or movement or mobility)).ti,ab,kf. 1813
37	((bed or beds) adj3 (extend* or extension*)).ti,ab,kf. 248
38	((bed or beds) adj3 (steer* or lock* or motor* or drive)).ti,ab,kf. 84
39	((bed or beds) adj3 (head board* or headboard* or foot board* or footboard* or feet board* or feetboard*)).ti,ab,kf. 11
40	((bed or beds) adj3 (control panel* or controls or dashboard*)).ti,ab,kf. 136
41	((bed or beds) adj3 (hand held or handheld or handset* or hand set*)).ti,ab,kf. 7
42	((bed or beds) adj3 (light* or scales or indicator*)).ti,ab,kf. 231
43	((bed or beds) adj3 (connectivity or wifi or wi-fi or wlan or wireless)).ti,ab,kf. 24
44	((bed or beds) adj3 (buffer or buffers)).ti,ab,kf. 12

45	((bed or beds) adj3 (attach* or accessor* or pole or poles or drip or drips or rack or racks or catheter or catheters or hoist? or pump?)).ti,ab,kf. 194
46	((bed or beds) adj3 contour*).ti,ab,kf. 37
47	((bed or beds) adj3 (storage* or slide away or slideaway)).ti,ab,kf. 26
48	((bed or beds) adj3 (xray* or x-ray*)).ti,ab,kf. 39
49	((bed or beds) adj3 (cutout* or cut out* or sensor* or alarm or alarms or alert or alerts or shutdown* or shut down*)).ti,ab,kf. 305
50	((bed or beds) adj3 (trap* or entrap*)).ti,ab,kf. 116
51	or/5-50 11100
52	inpatients/ 31611
53	hospitals/ 105853
54	hospital units/ 10519
55	inpatient*.ti,ab,kf. 151589
56	(hospital* adj3 bed*).ti,ab,kf. 13241
57	(acute adj3 (bed or beds or hospital or hospitals or ward or wards or unit or units or facility or facilities)).ti,ab,kf. 34979
58	(surg* adj3 (bed or beds or ward or wards)).ti,ab,kf. 7797
59	(general* adj3 (ward or wards)).ti,ab,kf. 5793
60	(acute adj5 setting*).ti,ab,kf. 20676
61	((short stay or short stays or fast track* or fasttrack*) adj3 (ward or wards or unit or units)).ti,ab,kf. 626
62	(medical adj3 (admission* or plan* or assessment*) adj3 unit*).ti,ab,kf. 592
63	(acute care or acute medical or acute surgical or acute admission*).ti,ab,kf. 37184
64	or/52-63 346451
65	51 and 64 1363
66	1 or 4 or 651891
67	OOK SNOW*.ti,ab,kf,ot. 0
68	(enterprise E5000* or enterprise E8000* or enterprise E9000*).ti,ab,kf,ot. 0
69	(citadel* adj10 (bed or beds)).ti,ab,kf,ot. 0
70	((centuris* or hillrom* or hill rom* or hillenbrand* or welch allyn* or avantguard* or total care sport* or versacare* or centrella* or advanta or advantar or advantatm or progressa*) adj10 (bed or beds)).ti,ab,kf,ot. 14
71	deprimo*.ti,ab,kf,ot. 5
72	((delta 4* or lago or lagor or lagotm) adj10 (bed or beds)).ti,ab,kf,ot. 1
73	innov8*.ti,ab,kf,ot. 2
74	interlude v3*.ti,ab,kf,ot. 0
75	((eleganza* or essenza* or image 3* or multicare*) adj10 (bed or beds)).ti,ab,kf,ot. 1
76	((solo* or solo luxe*) adj10 (bed or beds)).ti,ab,kf,ot. 9
77	OSKA florence*.ti,ab,kf,ot. 0
78	(SV2 electric hospital bed* or ProCuity*).ti,ab,kf,ot. 0
79	(IMO matrix E30* or IMO matrix U24*).ti,ab,kf,ot. 0
80	or/67-79 32
81	66 or 80 1920
82	exp animals/ not humans/ 5260079
83	(news or editorial or case reports).pt. or case report.ti. 3415203
84	or/82-83 8609056
85	81 not 84 1803
86	limit 85 to english language 1629

Key to Ovid symbols and commands:

*	Unlimited right-hand truncation symbol
*N	Limited right-hand truncation - restricts the number of characters following the word to N
?	Wildcard symbol
ti,ab,kf,ot.	Searches are restricted to the Title (ti), Abstract (ab), Keyword Heading Word (kf), and Original Title (ot) fields
adjN	Retrieves records that contain terms (in any order) within a specified number (N) of words of each other

/	Searches are restricted to the Subject Heading field
exp	The subject heading is exploded
pt.	Search is restricted to the publication type field
or/5-50	Combines sets 5 to 50 using OR

Saved in Ovid as: temp - MTAC312 - medline - final protocol v4

Appendix C – Protocol Amendments

The following protocol amendments (PA) were made subsequent to agreement of the draft protocol. The final protocol was agreed by email on --

Date of amendment	Protocol Section	PA number	Description of change

PA: Protocol Amendment