TECHNICAL SUPPORT DOCUMENT 27: PRIORITISING STUDIES AND OUTCOMES FOR NICE HEALTHTECH LITERATURE REVIEWS

REPORT BY THE DECISION SUPPORT UNIT

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ABOUT THE DECISION SUPPORT UNIT

The Decision Support Unit (DSU) External Assessment Centre is based at the University of Sheffield with members at York, Bristol, Leicester and the London School of Hygiene and Tropical Medicine. The DSU is commissioned by The National Institute for Health and Care Excellence (NICE) to provide a research and training resource to support the Institute's Centre for Health Technology Evaluation Programmes. Please see our website for further information www.nicedsu.org.uk.

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NICE describes the methods it follows when carrying out health technology evaluations in its process and methods manual. This provides an overview of the key principles and methods of health technology assessment and appraisal for use in NICE appraisals. The manual does not provide detailed advice on how to implement and apply the methods it describes. The DSU series of Technical Support Documents (TSDs) is intended to complement the manual by providing detailed information on how to implement specific methods.

The TSDs provide a review of the current state of the art in selected topic areas. They make recommendations on the implementation of methods and reporting standards where it is appropriate to do so. They aim to provide assistance to all those involved in submitting or critiquing evidence as part of NICE technology evaluations, whether companies, assessment groups or any other stakeholder type.

We recognise that there are areas of uncertainty, controversy and rapid development. It is our intention that such areas are indicated in the TSDs. All TSDs are extensively peer reviewed prior to publication (the names of peer reviewers appear in the acknowledgements for each document). Nevertheless, the responsibility for each TSD lies with the authors and we welcome any constructive feedback on the content or suggestions for further guides. The TSDs will be amended and updated whenever appropriate. Where minor updates or corrections are required, the TSD will retain its numbering with a note to indicate the date and content change of the last update. More substantial updates will be contained in new TSDs that entirely replace existing TSDs.

Please be aware that whilst the DSU is funded by NICE, these documents do not constitute formal NICE guidance or policy.

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ABSTRACT

Background: The National Institute for Health and Care Excellence (NICE) HealthTech programme requires production of literature reviews of clinical effectiveness and safety. The volume and type of available evidence can vary widely between reviews, and time to undertake reviews is limited.

Aim: To outline possible approaches to prioritising studies in NICE HealthTech reviews, to further narrow or widen inclusion beyond the original review Scope, when the number of studies for review in the time available is likely to be higher or lower than anticipated.

Methods: A three-stage process was conducted, including 1) a review of rapid review methods literature to develop a framework of approaches to prioritising studies; 2) a summary of prioritisation approaches used within a sample of NICE assessments; and 3) consultation with review authors and NICE committee members to understand key issues around study prioritisation and to develop a final framework.

Results: Key processes informing prioritisation of evidence included stakeholder consultation and scoping of the literature, ideally during protocol development, and optionally as an iterative process during the review itself to further refine criteria. Eligibility criteria may be narrowed if the evidence base is large, or widened if insufficient evidence is identified. Studies may be prioritised via criteria including population, intervention, comparators, outcomes, study design, publication type, setting or date, and the needs of the economic evaluation. How criteria interact may also need to be considered (e.g. prioritising randomised controlled trials [RCTs] based on study design, but also including observational data for specific outcomes or settings).

Conclusions: The prioritisation of some studies over others to further narrow or widen inclusion beyond the original review Scope has both advantages and disadvantages, but can be a way of ensuring reviews focus on the evidence of highest rigour and relevance, whilst being deliverable within time constraints.

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ABBREVIATIONS AND DEFINITIONS

DG	Diagnostic Guidance
EAG	External Assessment Group
EVA	Early Value Assessments
HealthTech	Health Technology
IP	Interventional Procedures
LSA	Late Stage Assessments
NICE	The National Institute for Health and Care Excellence
PICO	Population, Intervention, Comparators and Outcomes
RCT	Randomised Controlled Trials
RWE	Real-World Evidence
TSD	Technical Support Document
WHO	World Health Organization

1. BACKGROUND

1.1. Background to NICE HealthTech programme

The National Institute for Health and Care Excellence (NICE) Health Technology (HealthTech) programme combines the former NICE Diagnostics Assessment Programme, Interventional Procedures (IP) Programme and Medical Technologies Evaluation Programme. The HealthTech programme does not cover drug evaluations. HealthTech assessments require the production of literature reviews to collate the evidence from relevant studies on a specific topic.

Reviews conducted to inform HealthTech guidance are generally produced by external assessment groups (EAGs). Meanwhile, literature reviews for the NICE IP programme are typically done in-house by NICE technical review teams.

1.2. Process and timing of specifying the review question and eligibility criteria

Most systematic reviews begin with the development of an initial brief or scope, including a review question and set of broad inclusion criteria, often specifying the relevant Population, Intervention, Comparators and Outcomes (PICO) for the review. This process is generally led by the review commissioners, with input from topic experts and sometimes from the review team. Within the NICE process, this generally equates to the development of the NICE Scope. The Scope outlines the review question and broad inclusion criteria (often in PICO format or similar) and is developed by NICE together with clinical/topic experts and key stakeholders.

The next stage is generally for the review team (i.e. the EAG) to develop and agree a review protocol. The protocol should be consistent with the review question (i.e. NICE Scope) but often defines the PICO in greater detail, as well as specifying the study types to be included (i.e. PICOS for the review). Development of the review protocol usually entails additional scoping of the evidence base, which may lead to further refinement of the eligibility criteria to ensure that the review will answer the relevant question whilst being deliverable in the time available. Refinement of the inclusion criteria may also occur during the review process itself, for example if the volume or type of evidence identified differs from that expected based on protocol development.

This later refinement of eligibility criteria may be particularly necessary when the number of eligible studies is larger or smaller than anticipated, and either will be insufficient to address the review question, or will not be feasible to review in the time available. Within the NICE process, the number of includable studies may be particularly large when multiple technologies are included in an assessment; or in late stage assessments (LSAs) (1) where technologies are already in widespread use in the NHS and may have accrued a large number of studies over time; or where the technology has multiple uses within a disease area or

treatment pathway or can be used across multiple disease areas (described as 'multi-indication health technologies' in a recent NICE HTA Innovation Laboratory Report (2)). Conversely, some reviews may identify insufficient relevant literature to address the original review question; this may occur for example in NICE Early Value Assessments (EVAs).

1.3. Examples of prioritising particular types of evidence

Time is limited, so EAGs may need to make decisions about which studies to prioritise for inclusion if the evidence base is large, whilst aiming to minimise potential bias in study inclusion. The approaches used to prioritise studies can vary between EAGs, and choices about what evidence is included in assessment reports, and presented to committee, can be strongly contested by companies and stakeholders. For example, assessment groups have in some cases prioritised randomised controlled trials (RCTs) over other forms of study design, but in other cases have prioritised observational studies and real-world evidence (RWE) over randomised evidence, depending on which data are judged most relevant to the decision problem. The NICE Health Technology Evaluation manual (3) makes reference to literature searching being conducted in an iterative, hierarchical way, particularly when searching beyond RCTs for treatment effectiveness; this may involve searching first for more robust forms of evidence before searching for less reliable study designs (section 3.3.3). There may also be a need for assessment groups to make decisions about which of the outcomes specified in an assessment scope to prioritise in a review. The Cochrane methods guidance for rapid reviews of effectiveness recommends rating outcomes by importance (recommendation 3.2) (4). Meanwhile, reviews for the NICE IP programme are typically done in-house by NICE, with a focus on highlighting the most valid and relevant studies for detailed presentation to committee. Process and methods are described in the IP programme manual (5).

Guidance and a clear approach that EAGs could follow to make and defend decisions about prioritisation of studies, either within the review protocol or during the review itself, whilst noting any limitations and risks of such prioritisation, would be valuable.

1.4. Focus of this report in terms of review process and timing

The focus of this report is the development and refinement of eligibility criteria (generally led by EAGs or the NICE IP team) whilst developing the review protocol and undertaking the review itself, *after* the production of the NICE Scope. This report does not cover initial development of eligibility criteria within the NICE Scope.

1.5. Research question and Objective

Research question: What approach(es) should assessment groups follow to prioritise studies and outcomes for consideration in assessments in order to further narrow or widen eligibility criteria beyond the original review Scope, when this is needed (for example when numbers of studies for review in the time available is likely to be higher or lower than anticipated)?

Objective: To develop a set of approaches to follow when making decisions about studies and outcomes to prioritise, for consideration by EAGs and technical teams when developing review protocols and conducting evidence reviews for the NICE HealthTech programme (this report does not cover other NICE assessment types such as drug evaluations).

For the purposes of this work, the features of a 'study' that might inform prioritisation were both the study's design (e.g. RCT, cohort, case-control) and its characteristics, e.g. population, intervention, comparator, outcomes, setting, and publication date. As a result, 'outcomes' were considered within and alongside other study characteristics. As noted above, this work relates to refinement of eligibility criteria during development of the review protocol and the review itself, *after* production of the NICE Scope.

2. METHODS

This work consisted of three separate but related stages:

1. A narrative review of the key rapid review methods literature, as well as NICE methods guidance documents, to develop a framework of recognised approaches to prioritising studies within HealthTech Evaluations and rapid reviews;
2. A review of approaches to prioritisation conducted within a purposive sample of NICE assessments included in the HealthTech programme categorised using the framework developed for Stage 1;
3. A series of consultations with authors of a sample of these NICE assessments, as well as NICE committee members and members of the NICE IP team, to explore the approaches undertaken in the sample of NICE assessments analysed in Stage 2 and to provide feedback on the proposed framework.

The findings from the stages are collated and reported below, and a final evidence-based framework of approaches to prioritising evidence for HealthTech evaluations, which may be used as general guidance by review teams conducting such assessments, is then presented.

2.1. Stage 1: Narrative review of key rapid review methods literature and NICE methods guidance

This work involved identifying and summarising published guidance documents for conducting rapid reviews, including NICE methods documents. Relevant rapid review methods publications were identified via non-systematic searches by the authors in MEDLINE and Google Scholar, consideration of the Cochrane Rapid Reviews Methods Group list of publications, reference checking of included methods publications, and consultation with rapid review experts in the field (Professor Andrew Booth, Dr Fiona Campbell, Mr Abdullah Pandor). The relevant NICE methods documents were provided by the technical team at NICE.

To be eligible for this review, methods guidance had to describe at least one approach to prioritising evidence for a review based on a study's characteristics (such as population, intervention, comparator, outcomes, study design, location, publication date, etc).

The relevant domains in the recent Cochrane Rapid Reviews Methods Guidance(4) provided an *a priori* framework of approaches for prioritising study inclusion by a study's design or characteristics. The findings or recommendations of other literature and methods guides were coded against this initial framework and, where relevant, further domains were added based on other rapid review publications. A small number of items were added based on discussions with NICE and the authors of this report. This coding was completed by two of the authors and any discrepancies discussed and resolved. The *a priori* framework was then revised and developed based on the approaches recommended within this broad evidence base and discussions among the authors.

2.2. Stage 2: A review of approaches to prioritisation reported in a sample of NICE assessments

The aim of this stage was to explore which approaches to prioritisation of studies had been undertaken in literature reviews within NICE assessments, and the reasons behind these choices of approach, taking note of the assessment type and evidence base concerned, as well as identifying any potential approaches listed in the framework that were not being used or reported.

This work involved a high-level content analysis to explore the approaches to prioritising studies reported by NICE technical teams and EAGs in a purposive sample of 15 NICE assessments.

These 15 assessments were selected by NICE to incorporate a sample that included most types of evaluation to be included in the HealthTech programmes, i.e. Interventional Procedures Guidance (IPGs), Early Value Assessments (EVAs), Late-Stage Assessments (LSAs) and Diagnostic Guidance (DGs). The following documents were provided by NICE for each assessment, where available: Draft / Final Scope; Final protocol; EAG report or Evidence Overview (latter for IPGs); Committee papers; Company comments and responses; and Draft / Final guidance.

The relevant sections of each document (as appropriate and available) were checked for any statements relating to prioritising certain study designs or characteristics with the purpose of narrowing or widening study inclusion in comparison with the specifications of the assessment's decision problem. Relevant statements were extracted into the framework developed in Stage 1 to explore examples of each approach to evidence prioritisation as evidenced in a real-world sample of HealthTech programme case studies. Two authors each independently piloted the framework-based extraction form (in Excel) on the same two case studies in order to clarify processes and data fields. Resulting queries were resolved by discussion. Following this process, 7 of the extractions were conducted by a single author, and 8 were double-checked by a second author (double-checking was therefore performed for 53% of the total sample).

2.3. Stage 3: Consultation with EAG authors of NICE assessment reports, NICE committee members and the Interventional Procedures team, to understand decision-making around evidence prioritisation and to gain feedback on the proposed framework

The aims of this stage were to use real-world experience to better understand:

- The prioritisation decisions identified in a purposive sample of the Stage 2 case studies;
- The implications of prioritisation decisions for EAGs and NICE committees;
- How the process might be improved;
- The clarity and value of the draft framework.

In order to achieve these objectives, the authors (two per discussion) conducted a series of consultations (discussions) with a purposive sample of authors from the case study EAGs (at least one EVA, one LSA, one DA), the NICE IP Team, and NICE committee members. EAGs and committee members were all approached with an explanation of the project and a request for their individual participation in a discussion (to be up to one hour) regarding their experiences of prioritisation in NICE assessments. All of those approached agreed to participate. Each then received a follow-up email including a brief discussion guide and a copy

of the short (1-page) version of the draft framework for prioritising studies. EAGs were also given a brief summary of the extracted data on prioritisations implemented in their case studies, derived from Stage 2.

The discussion guide questions submitted to EAGs and used as an interview guide during the consultations were as follows:

- Thoughts on the draft framework for prioritising studies;
- Whether our case study summary accurately reflected the prioritisation approaches used within the EAG report;
- EAG choice of prioritisation approaches and why they were chosen;
- How any prioritisation methods were received by the NICE committee and any companies;
- Whether the EAG would do anything differently in hindsight
- Issues with and benefits of prioritising studies.

The discussion guide questions submitted to NICE committee members and used as an interview guide during the consultations were as follows:

- Any instances during committee where the clinical effectiveness literature review has prioritised some efficacy and/or safety evidence over other evidence?
- How well did this work? Any major issues?
- What would be the committee's preferred way to prioritise evidence in the clinical literature review, when there are a lot of studies or time is short?
- Thoughts on our draft framework for prioritising studies.

All discussions were recorded or transcribed to ensure that there was an accurate record of the meeting in the event of any lack of clarity when it came to analysis, and notes of the meeting were also taken by the authors of this report. These notes formed the principal basis of a summary of key points from the discussions, which was the main output from this stage of the research.

3. RESULTS

3.1. Stage 1 results: Narrative review of the key rapid review methods literature and development of framework

The literature searches and expert consultation identified 16 key rapid review guidance documents outlining approaches to prioritising review evidence based on study design and characteristics. These were generated by four centres or organisations - the Cochrane

Collaboration, World Health Organization (WHO), McMaster University (Canada), and the Joanna Briggs Institute (Australia) - as well as from a range of international research groups. This was supplemented by eight NICE methods guidance documents. Brief details of these guidance documents are presented in **Table 1.**

Table 1 Included rapid review guidance documents

Organisation	Citation
Cochrane Rapid Review Methods Group	— Garritty C, Hamel C, Trivella M, Gartlehner G, Nussbaumer-Streit B, Devane D*, et al.* Updated recommendations for the Cochrane rapid review methods guidance for rapid reviews of effectiveness. *BMJ* 2024a;384:e076335.(4) — Garritty C, Tricco AC, Smith M, Pollock D, Kamel C, King VJ*, et al.* Rapid Reviews Methods Series: Involving patient and public partners, healthcare providers and policymakers as knowledge users. *BMJ Evid Based Med* 2024b;29(1):55-61.(6) — Campbell F, Sutton A, Pollock D, Garritty C, Tricco AC, Schmidt L, et al. Rapid reviews methods series (paper 7): guidance on rapid scoping, mapping and evidence and gap map ('Big Picture Reviews'). *BMJ Evid Based Med* 2025; 10.1136/bmjebm-2023-112389.(7) — Stevens A, Hersi M, Garritty C, Hartling L, Shea BJ, Stewart LA*, et al.* Rapid review method series: interim guidance for the reporting of rapid reviews. *BMJ Evid Based Med* 2025; 2025;30(2):118-23.(8) — King VJ, Stevens A, Nussbaumer-Streit B, Kamel C, Garritty C. Paper 2: Performing rapid reviews. *Syst Rev* 2022;11(1):151.(9) — Arevalo-Rodriguez I, Baxter S, Steingart KR, Tricco AC, Nussbaumer-Streit B, Kaunelis D*, et al.* How to develop rapid reviews of diagnostic tests according to experts: A qualitative exploration of researcher views. *Cochrane Evidence Synthesis* 2023;1:e12006.(10)
WHO	— Tricco AC, Langlois EV, Straus SE. Rapid reviews to strengthen health policy and systems: A practical guide. World Health Organization (WHO); 2017.(11) — Tricco AC, Garritty CM, Boulos L, Lockwood C, Wilson M, McGowan J, et al. Rapid review methods more challenging during COVID-19: commentary with a focus on 8 knowledge synthesis steps. *J Clin Epidemiol* 2020;126:177-83.(12) — World Health Organization (WHO). WHO Handbook for Guideline Development; 2014.(13)
McMaster	— Dobbins M. Rapid Review Guidebook: Steps for conducting a rapid review. National Collaborating Centre for Methods and Tools (NCCMT), McMaster University; 2017.(14)
JBI	— Tricco AC, Khalil H, Holly C, Feyissa G, Godfrey C, Evans C, et al. Rapid reviews and the methodological rigor of evidence synthesis: a JBI position statement. *JBI Evid Synth* 2022;20(4):944-49.(15)
Other	— Haby MM, Barreto JOM, Kim JYH, Peiris S, Mansilla C, Torres M, et al. What are the best methods for rapid reviews of the research evidence? A systematic review of reviews and primary studies. *Res Synth Methods* 2024;15:2-20.(16) — Pandor A, Kaltenthaler E, Martyn-St James M, Wong R, Cooper K, Dimairo M, et al. Delphi consensus reached to produce a decision tool for SelecTing Approaches for Rapid Reviews (STARR). *J Clin Epidemiol* 2019;114:22-9.(17) — Pandor A. et al. STARR tool and user guide (supplement), *J Clin Epidemiol* 2019;114:22-9.(17)

Organisation	Citation
	— Smela B, Toumi M, Swierk K, Francois C, Biernikiewicz M, Clay E, et al. Rapid literature review: definition and methodology. *J Mark Access Health Policy* 2023;11:2241234.(18) — Wilson MG, Oliver S, Melendez-Torres GJ, Lavis JN, Waddell K, Dickson K. Paper 3: Selecting rapid review methods for complex questions related to health policy and system issues. *Syst Rev* 2021;10:286.(19)
NICE	— National Institute for Health and Care Excellence (NICE). Interim methods and process statement for late-stage assessment. 2024a.(20) — National Institute for Health and Care Excellence (NICE). Interim methods and process statement for late-stage assessment: Consultation on draft. 2024b.(21) — National Institute for Health and Care Excellence (NICE). NICE HealthTech programme manual: Draft manual consultation. 2024c.(22) — National Institute for Health and Care Excellence (NICE). Economic evaluation of multi-indication health technologies: proposed approaches. HTA Innovation Laboratory Report. 2024d.(2) — National Institute for Health and Care Excellence (NICE). NICE health technology evaluations: the manual. 2022a.(3) — National Institute for Health and Care Excellence (NICE). Early value assessment interim statement. 2022b.(23) — National Institute for Health and Care Excellence (NICE). Interventional procedures programme manual. 2016.(5) — National Institute for Health and Care Excellence (NICE). Developing NICE guidelines: the manual; 2014.(24)

HTA: health technology assessment; JBI: Joanna Briggs Institute; NICE: National Institute of Health and Care Excellence (NICE); WHO: World Health Organization (WHO).

3.2. Overview of the framework

The initial framework of approaches to prioritising by study design and outcome resulting from the content analysis of the rapid review methods documents is presented in **Table 2**. A version of this table with example quotes from the rapid review methods literature (and from the NICE methods guidance) is available in Appendix 1.

Table 2: Initial framework of approaches to prioritising by study design and characteristics, based on rapid review literature

Domains	Items	Further Explanations	Supporting guidance
PRINCIPLE	*Set clearly defined eligibility criteria*	*Clearly define the review question and eligibility criteria, including any restrictions or limits (e.g. using PICOS) that meet the evidential requirements of the assessment in terms of rigour and relevance and will be deliverable within time and resource constraints*	*Garritty 2024a (4), Campbell 2025 (7), Arevalo-Rodriguez 2023 (10), Haby 2023 (16), King 2022 (9), Pandor 2019 (17), Dobbins 2017 (14), Tricco 2017 (11), WHO 2014 (13)* *NICE 2024a, b & c (20-22), NICE 2022a & b (3, 23), NICE 2016 (5)*
PROCESS: *Consulting stakeholders and assessment of the evidence*	*Use stakeholder input to refine initial eligibility criteria*	*Initial consultation with relevant stakeholders (review commissioners, policy makers, clinicians, specialist advisers, patients, manufacturers, knowledge users) to determine the most relevant evidence to inform the scope and eligibility criteria*	*Garritty 2024a & b (4, 6), Campbell 2025 (7), Stevens 2025 (8), Arevalo-Rodriguez 2023 (10), Haby 2023 (16), Smela 2023 (18), King 2022 (9), Pandor 2019 (17), Wilson 2021 (19), Tricco 2017 & 2020 (11, 12)* *NICE 2024a (20)*
	Consider formal scoping or mapping of the literature (what existing knowledge is available)	*Scoping of the literature may help to gauge the volume and type of evidence available*	*Campbell 2025 (7), Smela 2023 (18), King 2022 (9), Wilson 2021 (19), Pandor 2019 (17), Dobbins 2017 (14), Tricco 2017 (11), WHO 2014 (13)*
	Use repeated (iterative) stakeholder input to refine eligibility criteria	*Consultation with relevant stakeholders at more than one timepoint to determine the most relevant evidence to inform any changes to the scope and eligibility criteria*	*Garritty 2024a (4), Wilson 2021 (19), King 2022 (9), Pandor 2019 (17), Tricco 2017 (11)* *NICE 2016 (5)*
	Consider repeated (iterative) refinement of eligibility criteria	*Iterative refinement of eligibility criteria in response to the quantity and quality of the evidence may help prioritise the most relevant evidence whilst ensuring the review is manageable in the timeframe*	*Garritty 2024a (4), Stevens 2025 (8), WHO 2014 (13)* *NICE 2014 (24)*
	Consider data requirements for cost-effectiveness analysis	*Discussion of the structure and required inputs of any cost-effectiveness analysis may inform the prioritisation of evidence*	*From discussions between NICE and authors of this report*
REFINING CRITERIA	*Consider focusing (or expanding) by population*	*Reduce or expand initial population to identify group(s) most directly relevant to the review question or decision problem*	*Arevalo-Rodriguez 2023 (10)* *NICE 2024c (22)*

Domains	Items	Further Explanations	Supporting guidance
	Consider focusing (or expanding) by interventions and comparators	*Reduce or expand initial list of interventions or comparators to focus on the available evidence considered most relevant to the review question or decision problem*	*Garritty 2024a (4), Arevalo-Rodriguez 2023 (10)*
	Consider focusing (or expanding) by outcome	*Reduce or expand initial list of outcomes to focus on the available evidence considered most relevant to patients, clinicians and decision-makers (e.g. clinical rather than surrogate outcomes)*	*Garritty 2024a (4), Arevalo-Rodriguez 2023 (10), Haby 2023 (16), King 2022 (9), Pandor 2019 (17), Tricco 2017 & 2020 (11, 12), WHO 2014 (13)* *NICE 2024c (22), NICE 2022a & b (3, 23), NICE 2016 (5)*
	Consider focusing (or expanding) by study design and publication type	*Select the most relevant evidence for the decision problem (e.g. RCT for effectiveness, non-RCT studies for long-term safety) and, in the event of such evidence being insufficient, expand selection to identify other study designs of most relevance to the review question or decision problem (e.g. real-world evidence etc.) Selection may also be made according to publication type e.g. exclusion of conference abstracts.*	*Garritty 2024a (4), Campbell 2025 (7), Arevalo-Rodriguez 2023 (10), Haby 2023 (16), Pandor 2019 (17), Wilson 2021 (19), Tricco 2020 (12), WHO 2014 (13)* *NICE 2024 a & b (20, 21), NICE 2022a (3), NICE 2016 (5)*
	Consider focusing (or expanding) by setting	*Reduce or expand initial setting to focus on the available evidence considered most relevant to the review question or decision problem (e.g. UK only, Europe only, secondary care only)*	*Garritty 2024a (4), Campbell 2025 (7), Arevalo-Rodriguez 2023 (10), Pandor 2019 (17)* *NICE 2024c (22)*
	Consider focusing (or expanding) by date	*Apply or expand a date limit depending on presence or absence of evidence most relevant to the review question or decision problem*	*Garritty 2024a (4), Campbell 2025 (7), Arevalo-Rodriguez 2023 (10), Haby 2023 (16), Pandor 2019 (17); NICE 2016 (5)*
	Consider which criteria to prioritise and how criteria interact	*Consider which criteria to prioritise over others, and how the different criteria interact. For example, studies may be initially prioritised by study design (e.g. RCTs prioritised), but alternative study designs (e.g. observational studies) may be prioritised if they address a different criterion such as outcomes (e.g. report safety data) or setting (e.g. UK studies). As another example, given a lack of studies with the right population and comparator, one may choose to expand to a wider population, or wider comparator definition, or both. Final decisions will depend on the specific review question and clinical context.*	*From discussions between NICE and authors of this report*

Domains	Items	Further Explanations	Supporting guidance
REPORTING	*Explain and justify all decisions taken*	*Clear transparency in reporting of approaches and decisions taken (explanation and justification) in selection and/or refinement of eligibility criteria, and possible impact of any decisions on findings*	*Garritty 2024a (4), Campbell 2025 (7), Stevens 2025 (8), Arevalo-Rodriguez 2023 (10), Haby 2023 (16), Smela 2023 (18), Pandor 2019 (17), Tricco 2022 (15), WHO 2014 (13) NICE 2024b (21), NICE 2016 (5)*

PICOS: Population, Intervention, Comparators, Outcomes, Study types; RCT: randomised controlled trial.

3.3. Principles and processes in the framework

As noted earlier, the framework outlines approaches to narrowing or widening eligibility criteria beyond the original brief (or NICE Scope), during development of the review protocol or during the review itself. The processes described in this section refer to recommended approaches around prioritisation by study design and characteristics within rapid reviews generally, rather than the specific NICE process. The framework presents principles and processes as follows.

Key principle: As for any review applying systematic methods, the main principle is to establish or refine some clearly defined and justified eligibility criteria to facilitate answering the review question or addressing the decision problem in the original brief or NICE Scope, whilst being deliverable within time and resource constraints. Other key functions of eligibility criteria are to minimise scope creep and prevent the introduction of selection biases. With any further prioritisation of review criteria after the start of the review, it is especially important to ensure this process does not introduce bias.

Processes: The processes to establish and justify the review criteria generally involve: firstly, consulting key stakeholders, and secondly, scoping the literature to obtain an idea of the volume and type of evidence available.

Timing of prioritisation processes: Stakeholder consultation and scoping of the literature during protocol development might enable a review team to establish a protocol with a set of clearly defined eligibility criteria, prioritising certain studies, from the very start of a review. Conversely, the stakeholder consultation and refinement of eligibility criteria may occur throughout the course of the review, in response to the quantity and quality of the evidence. This might then lead to an iterative process of criteria refinement, to prioritise those studies of most relevance to the decision problem whilst ensuring the review is manageable in the timeframe.

Refining criteria: The next stage involves refining the eligibility criteria for the review in response to these consultations and explorations of the evidence base. Within the framework, this process is captured by the items listing the full range of individual criteria (PICOS elements) that might be revised to prioritise the literature. Some items in the framework were supported by multiple guidance documents (e.g. *Set clearly defined eligibility criteria* and *Use (iterative) stakeholder input*), while others were supported by only one or two such documents (e.g. *Consider formal scoping of the literature* and *Consider iterative scoping of the literature)*.

Reporting: The framework also highlights the importance of clearly reporting the prioritisation approaches taken, justification of these, and potential impact on review findings.

3.4. Narrowing or widening of criteria

While prioritisation might principally involve 'focusing' or 'narrowing' a review's eligibility criteria, e.g. including only certain study designs, or only studies conducted in certain locations or after certain dates, it was noteworthy that prioritisation could also involve widening the original criteria to fill evidence gaps and provide additional 'useful' data. For this reason, the *Refining criteria* items report the need to consider 'expanding' as well as 'focusing' certain criteria. Any focussing or expansion should be done with consideration of whether the search strategy and study selection process remain fit for purpose.

3.5. Other considerations in the framework

Finally, while the majority of the items in the framework were identified from the rapid review methods literature, two items were identified following discussions between the authors and NICE. The first highlighted the process of refining criteria in response to the data requirements of the economic evaluations that accompany the NICE HealthTech assessments (except for IP). The absence of this criterion from the literature is no surprise given the context in which the literature anticipates the production of rapid reviews, which is generally as 'stand-alone' outputs. The second concerned the need to consider which criteria to prioritise and how criteria interact, in order to ensure certain key data are included. For example, a process of refining criteria by prioritising high-quality study designs (e.g. RCTs) might lead to relevant outcome data, such as quality of life or certain adverse events, being excluded; this may lead to a decision to also prioritise certain non-RCT studies on the condition that they include these important outcomes of interest. It is important to note that the literature does not recommend any hierarchy in terms of applying these criteria when seeking to prioritise some studies over others (e.g. study design first, outcomes last). This is because some criteria will be more relevant to some review questions than others, and this selection might be influenced as much by practical issues around reporting and data availability, as relevance. The literature and resulting framework can therefore only provide a list of options that should be considered in prioritising studies in any given evaluation. However, a potential recommendation in terms of order of prioritisation criteria is covered in the Discussion.

3.6. Stage 2 results: Review of approaches to prioritisation in a sample of NICE HealthTech evaluations

As described in the Methods, NICE provided 15 case studies for consideration. This sample included most types of evaluation to be included in the HealthTech programme, i.e. EVAs (n=6), IPGs (n=5), LSAs (n=2) and DGs (n=2). Brief details of these case studies are presented in **Table 3**.

Table 3: Brief details of the sample of NICE case studies analysed

Type of Health Technology Evaluation	Title	Final Guidance Date
Early Value Assessment (EVA)		
EVA HTE5	ProKnow cloud-based system for radiotherapy data archiving, communication and management	2023*
EVA HTE7	Point of care tests for urinary tract infections (UTI) to reduce antimicrobial resistance: a systematic review and conceptual economic model to inform Early Value Assessment	2023
EVA HTE9	Digitally Enabled Therapies for Adults with Anxiety Disorder	2023
EVA HTE11	Artificial intelligence auto-contouring to aid radiotherapy treatment planning: early value assessment	2023
EVA HTE18	Digital technologies to deliver pulmonary rehabilitation programmes for adults with COPD	2024
EVA HTE19	Digital technologies to support self-management of COPD: early value assessment	2024†
Interventional procedure (IP)		
IPG586	Transcatheter aortic valve implantation (TAVI) for aortic stenosis	2017
IPG599	Transvaginal mesh repair of anterior or posterior vaginal wall prolapse	2017
IPG686	Minimally invasive radical hysterectomy for early stage cervical cancer	2021
IPG688	Cytoreduction surgery with hyperthermic intraoperative peritoneal chemotherapy for peritoneal carcinomatosis	2021
IPG777	Interventional procedure overview of percutaneous transarterial carotid artery stent placement for asymptomatic extracranial carotid stenosis	2023
Late Stage Assessment (LSA)		
LSA	Drug-eluting stents for treating coronary artery disease	2025
LSA	Transcatheter heart valves for transcatheter aortic valve implantation (TAVI) in people with aortic stenosis	2024 (draft guidance)
Diagnostic Assessment (DA)		
DG39	Tests to help assess risk of acute kidney injury for people being considered for critical care admission (ARCHITECT and Alinity i Urine NGAL assays, BioPorto NGAL test and NephroCheck test)	2020
DG58	Tumour profiling tests to guide adjuvant chemotherapy decisions in lymph node positive early breast cancer	2024

*With 2024 update. †With 2025 update.
DA: Diagnostic Assessment; EVA: Early Value Assessment; IPG: Interventional Procedures Guidance; LSA: Late-Stage Assessment.

3.7. Prioritisation approaches reported in NICE case studies

A summary of the results of coding the relevant content from the NICE case studies against the prioritisation framework developed from Stage 1 is presented in **Table 4** and **Table 5**. A more detailed version of these tables is available in **Appendix 2**. Some illustrative examples of prioritisation approaches within the NICE case studies are presented in **Table 6**.

It should be noted that the processes detailed below around scoping and stakeholder involvement do not refer to the initial work conducted by NICE to develop the decision problem and NICE Scope, which may or may not involve the EAG. Rather, they refer to processes of scoping and stakeholder involvement which specifically involve the EAG or technical review team *after* the production of the NICE scope, including the development of the review protocol by the EAG and the production of the literature review itself.

Table 4: Prioritisation approaches reported in clinical effectiveness protocols and reviews within NICE case studies (EVAs and DGs)

Domains and Items / Reports	EVA HTE5	EVA HTE7	EVA HTE9	EVA HTE11	EVA HTE18	EVA HTE19	DG39	DG58
Topic (date)	*ProKnow for radiotherapy data (2023)*	*Point of care tests for UTIs (2023)*	*Digital therapies for anxiety (2023)*	*AI in radiotherapy (2023)*	*Digital technologies pulmonary rehab in COPD (2024)*	*Digital self-management in COPD (2024)*	*Acute kidney injury (2020)*	*Tumour profiling tests in breast cancer (2024)*
PRINCIPLE								
Set clearly defined eligibility criteria	✓	✓	✓	✓	✓	✓	✓	✓
PROCESSES								
Use stakeholder input to refine initial eligibility criteria					✓	✓		
Consider formal scoping of the literature (knowledge available)				✓				
Use repeated (iterative) stakeholder input to refine eligibility criteria								
Consider repeated (iterative) scoping of the literature								
Consider data requirements for cost-effectiveness analysis								✓*a*
REFINING CRITERIA								
General		✓	✓✓	✓✓	✓	✓		

Domains and Items / Reports	EVA HTE5	EVA HTE7	EVA HTE9	EVA HTE11	EVA HTE18	EVA HTE19	DG39	DG58
Consider focusing (or expanding) by population			✓		✓		✓	✓
Consider focusing (or expanding) by interventions and comparators		✓	✓			✓		✓
Consider focusing (or expanding) by outcome		✓	✓✓[b]		✓[a]	✓		✓
Consider focusing (or expanding) by study design and publication type		✓[b]	✓	✓	✓	✓		✓✓[a]
Consider focusing (or expanding) by setting		✓[b]	✓		✓	✓		✓
Consider focusing (or expanding) by date		✓			✓			✓[a]
INTERACTIONS BETWEEN CRITERIA								
Consider which criteria to prioritise and how criteria interact				✓				

Prioritisation principally involved narrowing criteria, but underline indicates instances that included widening criteria beyond the scope (two ticks, one underlined one not, indicates both narrowing and widening).

[a]Plan for prioritisation reported but unclear if applied. [b]Unclear whether the limits applied were simply an application of the protocol rather than prioritisation.

DG: Diagnostic Guidance; EVA: Early Value Assessment.

Table 5: Prioritisation approaches reported in clinical effectiveness protocols and reviews within NICE case studies (IPGs* and LSAs)

Domains and Items / Reports	**IPG586**	**IPG599**	**IPG686**	**IPG688**	**IPG777**	**LSA (TAVI)**	**LSA (DES)**
Topic (year)	*TAVI for aortic stenosis (2017)*	*Transvaginal mesh repair (2017)*	*Hysterectomy for cervical cancer (2021)*	*Cytoreduction surgery (2021)*	*Carotid artery stents (2023)*	*TAVI for aortic stenosis (2024)*	*Drug-eluting stents (2025)*
PRINCIPLE							
Set clearly defined eligibility criteria	✓	✓	✓	✓	✓	✓	✓
PROCESSES							
Use stakeholder input to refine initial eligibility criteria						✓[a]	✓
Consider formal scoping of the literature (knowledge available)						✓	
Use repeated (iterative) stakeholder input to refine eligibility criteria							✓
Consider repeated (iterative) scoping of the literature							
Consider data requirements for cost-effectiveness analysis	*N/A*	*N/A*	*N/A*	*N/A*	*N/A*	✓	✓
REFINING CRITERIA							
General	✓[a]	✓	✓	✓	✓		✓
Consider focusing (or expanding) by population		✓	✓		✓	✓[a]	✓

Domains and Items / Reports	IPG586	IPG599	IPG686	IPG688	IPG777	LSA (TAVI)	LSA (DES)
Consider focusing (or expanding) by interventions and comparators		✓	✓		✓	✓✓	✓✓
Consider focusing (or expanding) by outcome	✓	✓	✓		✓	✓	✓
Consider focusing (or expanding) by study design and publication type	✓	✓	✓	✓	✓	✓	✓
Consider focusing (or expanding) by setting						✓	✓
Consider focusing (or expanding) by date	✓	✓	✓	✓	✓		
INTERACTIONS BETWEEN CRITERIA							
Consider which criteria to prioritise and how criteria interact			✓	✓	✓		✓

*IPG data refer to the prioritisation applied to the *Evidence overview* unless specified.

Prioritisation principally involved narrowing criteria, but underline indicates instances that involved widening criteria beyond the scope (two ticks – one underlined, one not, indicates both narrowing and widening).

[a]Plan for prioritisation reported, but unclear if applied.

IPG: Interventional Procedures Guidance; LSA: Late-Stage Assessment; N/A: not applicable.

Table 6: Examples of prioritisation approaches within NICE case studies

Criteria for prioritisation	Examples from NICE case studies
Consider focusing (or expanding) by population	DG 39: Final guidance 3.1: Although the population in the scope was people being considered for critical care admission, to maximise the available data the EAG included data from studies that enrolled patients already admitted to critical care
	DG58 EAG report 3.1.2: Where studies included patients who were out of scope, if ≤20% were out of scope then the study was included (and heterogeneity was considered), whilst if >20% were out of scope then the study was excluded. Exceptions to this were that some studies did not report HER2 status, whilst some studies included LN+ patients but >20% had >3 positive nodes; these studies were included to ensure inclusion of sufficient relevant evidence, but these limitations were noted.
Consider focusing (or expanding) by interventions and comparators	DG 58: EAG report 3.1.2: Excluded studies which do not use the commercial versions of the four tests.
	LSA Drug-eluting stents: Section 4.1.1, six RCTs deprioritised as the company indicated that evidence for these two generations (Endeavor Resolute and Resolute Integrity) is no longer used to support the clinical efficacy or safety of the Onyx Frontier device, due to availability of evidence for the third generation device Resolute Onyx.
	HTE7 (EVA): Report 4.3 and Protocol pp.15-16: Protocol changes: In addition to Flexicult human, we identified a number of studies of ID Flexicult. This test was not specifically in the scope but is included in the review as we consider it possible that ID Flexicult identifies the same information as the control field of Flexicult human, however, this has not been confirmed by the company.
	HTE9 (EVA): Report Table 1: Although excluded from the scope, if evidence comparing with standard interventions is limited, the EAG will consider studies comparing technologies with waitlist controls and other non-standard comparators. This will be done on a technology by technology basis.
	HTE19 (EVA): Committee papers 1: Table 1.1. Due to the volume of literature identified, this EVA was limited to evaluating the listed 12 interventions only (the list was not seen as exhaustive from the scope, just that the technologies 'may include' these 12).
Consider focusing (or expanding) by outcome	LSA Drug-eluting stents: Report 3.2: Clinical experts advised that clinical endpoints (or 'clinically meaningful' endpoints) should be prioritised (e.g. mortality, myocardial infarction (MI), target lesion revascularisation (TLR) and stent thrombosis (ST)) over short-term outcomes measured via angiography such as late lumen loss, minimal luminal diameter and neointimal healing. This influenced the pragmatic study selection criteria used by the EAG, which is described in Section 4.1.3.

Criteria for prioritisation	Examples from NICE case studies
Consider focusing (or expanding) by study design and publication type	DG58 Protocol 4.6: End-to-end studies comparing decision-making based on the test versus decision-making using current tools may not be available, in which case different evidence types will be sought and will be linked via the health economic model [widening] Protocol 4.6: For prognostic and predictive outcomes: RCTs and trial reanalyses to be included; observational studies to be included initially, but if the volume of data is large then priority will be given to higher quality data (e.g., larger studies, more applicable to practice in England, longer follow-up, data on multiple risk groups) [narrowing].
	EVA HTE7: Section 4.1: For Objective 1 (impact on clinical outcomes), studies had to be RCTs or non-randomised studies of interventions ... For Objective 2 (test accuracy), only diagnostic test accuracy studies were eligible for inclusion. Studies of any design were eligible for objective 3 (test performance).
	HTE18: EAG report 7.2: Randomised controlled trials were prioritised for inclusion where they were available. This was supplemented with additional data from other studies where it was considered appropriate. Where no prospective studies were available for a given technology, the most relevant retrospective studies were sought. If no retrospective studies were available, then conference abstracts were reviewed. If retrospective studies were available for a technology with one or more prospective studies, a brief commentary on these were provided.
	IPG777: IP Evidence Overview: The following study designs were excluded from the main evidence table (but listed in Appendix): * Observational studies with fewer than 1,000 people (apart from case reports of adverse events) * Smaller studies, or those with small numbers in intervention group, where larger studies are included * Studies with shorter follow-up, where studies with longer term outcomes included * Studies where the study or its primary data is already covered in an included review * Systematic reviews without meta-analysis
Consider focusing (or expanding) by setting	HTE18 (EVA): Protocol: 1.4.3: Priority will be given to … studies … with a UK NHS setting.
	DG58: Protocol 4.6 and EAG report 3.1.2: For the outcome relating to impact on chemotherapy use only: restricted to studies conducted in the UK or Europe due to differing rates of chemotherapy use worldwide.
	HTE18 (EVA): Protocol: 1.4.3: Priority will be given to more recent studies ….

Criteria for prioritisation	Examples from NICE case studies
Consider focusing (or expanding) by date	IPG599: The following studies were excluded from the main evidence table (but listed in Appendix A): Older studies where more recent studies were included.
Consider which criteria to prioritise and how criteria interact	Interaction between prioritising by study design and outcome: IPG586: EAG SLR 5.2 Table 1: For evidence on efficacy: published systematic reviews, randomised or non-randomised controlled trials, and comparative observational studies will be included. For evidence on safety: in addition to the types of studies above-mentioned, non-comparative observational studies will be included if they report longer follow-up outcomes than those reported in comparative studies or systematic reviews for long term patient survival, and short and long term valve function/durability, or if they report important outcomes that are not covered in the included comparative studies and systematic reviews.

3.8. Principal findings from review of NICE case studies

The main findings from the review of NICE case studies were as follows:

- The draft framework captured all of the main approaches to prioritisation by study design and characteristics (including outcomes) recorded in the documents analysed for the 15 case studies;
- Stakeholder consultation and literature scoping processes conducted by EAGs during the production of the protocols and reviews of clinical evidence (after the production of the NICE Scope) were generally not reported in the case study documents, with the exception of the two LSA case studies, where they were recorded in both assessments;
- In each case, a NICE Scope set out the eligibility criteria for the decision problem and review, but some further prioritisation beyond these initial criteria was conducted in every case study except one (HTE5). Prioritisation by some aspect of population, intervention, comparator, outcome, study design or setting was therefore recorded in the vast majority of assessments, regardless of type of evaluation (IP, EVA, LSA, DA). Indeed, such refinements were often made to more than one criterion in each case study;
- Prioritisation informed by the requirements of the economic evaluation was relatively uncommonly reported within the clinical review report, but was reported within LSAs (noting prioritisation of outcome data required for the network meta-analysis and economic model) and within a DG (prioritisation of studies reporting on multiple relevant interventions for use in the economic model);
- Consideration of which criteria to prioritise and how criteria interact was also less commonly reported, but was sometimes reported for EVAs, IPGs and LSAs.

This stage therefore confirmed the appropriateness of the breadth and content of the framework, and the broadly consistent nature of the prioritisations applied and recorded in a range of HealthTech assessments, which frequently encompassed multiple criteria. The next stage explored these decisions – and committee responses to such decisions – in more depth.

3.9. Stage 3 results: Discussions with EAGs (from a sample of NICE HealthTech evaluations), the Interventional Procedures team, and NICE committee members, around approaches to prioritisation

This stage aimed to gain further insight into the process of refining eligibility criteria beyond those in the NICE Scope, while developing the review protocol and the review itself. In addition, some points were also raised in relation to the development of the initial Scope (reported here despite not being the main focus of this report). This stage involved discussions with four EAGs (Aberdeen, Exeter, York, Cardiff) covering six of the case study assessments, the NICE IP team, and three independent but highly experienced NICE committee members (each having a minimum of six years of committee experience). Each discussion was conducted by two of the authors of this report and lasted for at least one hour. A summary of the key findings from the discussions, where they add to or elaborate on the details provided in the draft framework, is presented in **Table 7**. Comments are not attributed to individual EAGs, the IP team or Committee members; the aim was to gain a more in-depth understanding of the application of prioritisation approaches from a sample of those with real-world experiences, and without the risk of bias in interpretation.

Table 7: Prioritisation approaches from discussions (supplementary to the draft framework)

Principles and processes in framework	**Key points from conversations**
PROCESS: Initial prioritisation *- Use stakeholder input to refine initial eligibility criteria* *- Consider formal scoping or mapping of the literature*	Comprehensive *a priori* scoping and stakeholder consultation is the preferred approach: - Scoping and prioritisation may be conducted by review commissioners whilst developing the review Scope, and/or by review teams whilst developing the protocol; - Appropriate time and resources are required for scoping and prioritisation (whether conducted by commissioner and/or review team) - Ideally, a fit-for-purpose protocol with clearly defined inclusion and exclusion criteria, manageable within the timeframes, is developed before commencing the review. Scoping: - Comprehensive scoping searches in preliminary stages aid understanding of size and nature of evidence base, and inform pragmatic prioritisation decisions; Stakeholder involvement: - Review team attendance at NICE scoping workshops can facilitate prioritisation decisions; - Careful use of stakeholder consultation from early stages informs prioritisation (NICE, clinicians, economic modellers, specialist advisers, users of technology e.g. patients or healthcare professionals); - Inclusion of specialist clinical advisers aids identification of pathways, populations, comparators, outcomes and 'equivalence of use' scenarios (e.g. prioritise international evidence alongside UK evidence if populations and services likely to be similar);

Principles and processes in framework	Key points from conversations
	- Inclusion of users of technology (e.g. patients or healthcare staff) aids identification of relevant outcomes for prioritisation (e.g. PROMs and usability); Company involvement: - Earlier involvement of companies may mitigate later work at consultation to address exclusions as a result of prioritisation (e.g., allow companies to comment on protocol before review commences to manage expectations of what will be included); - Company evidence submissions should be provided early with clear sets of studies, so that potential exclusions due to prioritisation can be anticipated; - Request that companies specify exact purpose of technology, to understand relevant outcomes.
PROCESS: Ongoing iterative prioritisation *- Use repeated (iterative) stakeholder input to refine eligibility criteria* *- Consider repeated (iterative) refinement of eligibility criteria*	Iterative prioritisation: Where the evidence base remains large despite initial scoping and consultation, prioritisation may be an 'ongoing' iterative process during the review itself: - In some cases, a broad initial review protocol may allow for later prioritisations during the review itself (both narrowing and expanding) - Ideally this potential for later criteria refinement would be pre-specified in the protocol; - A larger evidence base than anticipated may require further narrowing of criteria during the review process itself; - A smaller evidence base than anticipated may require widening of criteria ('best evidence' often preferred to 'no evidence'); - Iterative use of stakeholders can inform and validate prioritisations: NICE, clinicians, economic modellers, specialist advisers, users (relevant staff and patients).
PROCESS: Consider data requirements for cost-effectiveness analysis	Requirements for cost-effectiveness or statistical analyses: - Data requirements for subsequent analyses, e.g. economic model and requirement for a network meta-analysis, may inform prioritisation of evidence, especially outcomes; - Prioritisation must take into account coherence between the evidence used in the clinical and economic sections.
PROCESS (NEW): Choose appropriate methods to organise literature for iterative prioritisation	Processes for iterative prioritisation during the review itself: - Use of evidence 'mapping' may aid understanding of volume, type and quality of evidence (study designs and numbers of studies) for each technology, to inform pragmatic decisions around further prioritisation. - Mapping may be conducted via tabulation, or using tags in reference management software for key study characteristics; - Alternatively, generate additional inclusion/exclusion criteria in response to the literature without formal mapping, apply to initial full text includes, and provide list of studies excluded at "second level" of prioritisation, with reasons; - May use different levels of data extraction depending on prioritisation, e.g. prioritised studies fully extracted; and other studies reported as short summary or simply as a recorded list of other relevant studies.
REFINING CRITERIA	General points about refining criteria: - Overarching aim is to prioritise by quality and relevance of evidence. State these principles explicitly, and that they will guide further prioritisation; - Decisions are required on whether there is too much or too little evidence; this will inform narrowing or widening of criteria; - Pragmatic consideration of how many studies can realistically be reviewed, or considered by committee, in available timeframe. Commissioners or review teams may set limits on the number of studies to include (overall or for each technology).

Principles and processes in framework	Key points from conversations
	Interventions: generations or versions of a technology: - Different generations or versions of a technology often requires decisions on which should be included or prioritised, noting that earlier versions may have useful longer-term evidence; this requires input from stakeholders and companies; - Prioritisation criteria applied may be different for different technologies within the same HealthTech assessment depending on the volume and type of evidence available for each technology; Which criteria to prioritise and how criteria interact: - Prioritisation tends to focus on higher levels of study design (e.g RCTs),but can also include lower-level designs if they have particular types of outcome data (e.g., safety data especially for rare but serious adverse events; PROMs) or longer follow-up (e.g. cohort studies, registries, post-marketing surveillance studies), which is missing from other, higher-level prioritised evidence. - Prioritisation decisions on various criteria might also take into account the rarity or frequency of the condition of interest; Publication type: - Exclusion of conference abstracts on the basis of publication type was a common approach where the evidence base was large or time was short.
Issues arising from prioritisation	Potential issues: - Prioritisation beyond the initial protocol may lead to bias; - Companies may take issue with exclusion of certain studies due to prioritisation; - Alteration of initial protocol can leave EAGs open to criticism on methodological grounds; - Publication of reviews where extensive prioritisation has occurred can be jeopardised on methodological grounds and due to lack of international relevance; - EVAs generate information on evidence gaps, but an identified gap might actually be covered within non-prioritised studies (this would often be acknowledged during consultation); - Some topics are large and cannot reasonably be prioritised into a manageable size.

PROMs: Patient-Reported Outcome Measures; RCT: Randomised Controlled Trials; RWE: Real-World Evidence.

3.10. Approaches to prioritisation: additional points from discussions

With the exception of some suggested minor revisions, the discussions found the draft framework to be useful and to represent accurately the types of prioritisation approach by study design and characteristics (e.g. population, intervention, outcomes and setting) undertaken by EAGs or equivalent groups when conducting EVAs, LSAs, DGs and IP assessments for NICE committees. The conversations with EAGs also confirmed the prioritisation approaches identified by the authors in their respective case studies.

However, the discussions also stressed the following items as crucial in practice:

- Data quality and relevance (e.g. transferability to the UK setting) were constant and key considerations;

- The role of stakeholders – in particular specialist advisers, clinicians, users of the technology (including patients and/or healthcare professionals), economic modellers, and companies - in facilitating prioritisation decisions around the criteria, i.e. the most relevant study designs and characteristics;
- The preference for adequate stakeholder consultation and scoping of the literature prior to the conduct of the clinical evidence review, to identify appropriate prioritisations *a priori* and develop a fit-for-purpose protocol;
- The inevitable iterative process of prioritisation in response to the evidence base, sometimes during the review itself, including the importance of iterative stakeholder involvement;
- The consideration and challenges for prioritisation by different criteria, including interventions (e.g. with different generations or versions of the same technology); comparators; outcomes, and settings (including identifying possible 'equivalence of use' scenarios), especially where there are choices around which criteria are most appropriate to prioritise; when there are different levels of evidence for different interventions or indications; and where relevant data may be missed by the exclusion of some studies;
- The importance of concordance or coherence in the evidence presented for the clinical effectiveness review and the economic model, and how the economic model could be used to facilitate prioritisation of outcomes for the clinical effectiveness review.

Major points from the discussions can be summarised as follows:

1) the vital role of stakeholder involvement in prioritisation choices (earlier is better, but also needs to be responsive to the quantity and relevance or coverage of the evidence base identified during the review);
2) the importance of addressing the unique challenges represented by having multiple generations or versions of a HealthTech, and
3) the important role of any associated economic evaluation for informing prioritisation decisions in the clinical effectiveness review.

These last two elements especially are absent from the majority of the published rapid review guidance.

3.11. Timing of prioritisation processes during the review

There are multiple points during the lifecycle of a review where the iterative process of stakeholder consultation, scoping searches and refinement of the eligibility criteria to prioritise

the evidence can occur. The first timepoint (which is not the main focus of this report) is the scoping and consultation that occurs during development of the initial NICE Scope, with or without input from the review team. This may lead to a Scope that can be converted to a review protocol by the review team with minimal refinement of the eligibility criteria defined in the Scope's decision problem.

However, where the commissioner's Scope is broad, or knowledge of the available literature is limited, refinement of eligibility criteria may be required after the Scope has been finalised, whilst the review team prepare the protocol. In addition, while the Scope generally specifies the PICO, it doesn't usually specify the study type to be included, so this needs to be clarified in the protocol. In some cases, the Scope and protocol may be developed concurrently. Initial stakeholder consultation and scoping of the literature enables a review team to establish a protocol with a set of clearly defined eligibility criteria, prioritising certain studies, from the very start of a review, which can be applied without revision through to the completion of the review.

Understanding the evidence base, and criteria refinement, at these two timepoints (development of Scope and/or protocol) should be considered best practice and are likely to make the subsequent review more robust and less open to criticism.

However, it should be noted that, by necessity (e.g., timescales, budgets, commissioner processes, unexpected volume of literature), this might not prove to be such a linear, sequential process. The stakeholder consultation and criteria refinement processes can in such cases occur throughout the course of the review, in response to the quantity and quality of the evidence. This might entail an iterative process of criteria refinement, to prioritise those studies of most relevance to the decision problem whilst keeping the review manageable. Such refinements may necessitate formal protocol revisions (where a protocol is registered), and may leave a review open to criticism and the introduction of bias. An approach to mitigate this bias is to pre-specify in the protocol that further criteria refinement may occur and how this will likely be done; for example, that if the volume of evidence is higher or lower than expected, studies will be prioritised according to e.g. study design, setting, outcomes reported, etc (specific criteria for prioritisation will depend on the review context).

4. DISCUSSION AND FINAL FRAMEWORK

4.1. Framework and Guide for prioritisation of studies in NICE HealthTech evaluations

A final framework and visual guide to the prioritisation of studies in NICE HealthTech evaluations are presented in **Table 8** and **Figure 1**. As noted earlier, a distinction needs to be made between the NICE Scope and the work of the EAG or technical review team in producing the clinical evidence review. It should be noted that this framework refers to the processes of stakeholder involvement and criteria refinement which specifically involve the EAG or technical review team *after* the production of the NICE scope (including the production of a separate review protocol by the EAG and production of the review itself).

Table 8: Guidance framework of approaches to consider when prioritising by study design and characteristics

Domains	Items	Further Explanations
PRINCIPLE	*Set clearly defined eligibility criteria a priori (before commencing the review)*	*Clearly define the review question and eligibility criteria, including any restrictions or limits (e.g. using PICOS) that meet the evidential requirements of the assessment in terms of rigour and relevance and will be deliverable within time and resource constraints.*
PROCESS *Consulting stakeholders and assessment of the evidence a priori*	*Use stakeholder input to refine eligibility criteria a priori (before commencing the review)*	*Initial consultation with relevant stakeholders (review commissioners, policy makers, clinicians, specialist advisers, patients, manufacturers, knowledge users, economists, economic modellers, companies) to determine the most relevant evidence to inform the scope and eligibility criteria*
	Consider formal scoping or mapping of literature a priori (before commencing review)	*Scoping of the literature may help to gauge the volume and type of evidence available and inform pragmatic prioritisation decisions*
	Consider data requirements for cost-effectiveness analysis	*Discussion of the structure and required inputs of any cost-effectiveness analysis may inform the prioritisation of evidence. It is important that there is coherence in the evidence presented for the clinical effectiveness review and the economic model.*
PRINCIPLE *(if required)*	*Prioritisation can be an ongoing process if necessary*	*Consultation with relevant stakeholders should occur in the earliest stages of a review to inform definition of eligibility criteria, but it can also occur on multiple occasions throughout the review in order to inform pragmatic decisions on prioritisation based on relevance and rigour in response to the scale and nature of the evidence.* *Initial criteria in the protocol may be broad in order to provide scope for possible later prioritisations (both narrowing and expanding)*
PROCESS *Consulting stakeholders and assessment of the evidence throughout review*	*Use repeated (iterative) stakeholder input to refine eligibility criteria*	*Consultation with relevant stakeholders at more than one timepoint to determine the most relevant evidence to inform any changes to the scope and eligibility criteria*
	Consider repeated (iterative) refinement of eligibility criteria	*Iterative refinement of eligibility criteria in response to the quantity and quality of the evidence may help prioritise the most relevant evidence whilst ensuring the review is manageable in the timeframe*

Domains	Items	Further Explanations
(if required)	*Consider data requirements for cost-effectiveness analysis*	*Discussion of the structure and required inputs of any cost-effectiveness analysis may inform the prioritisation of evidence. It is important that there is coherence in the evidence presented for the clinical effectiveness review and the economic model.*
	Choose appropriate methods to organise literature for iterative prioritisation	*Various methods can be used, including tagging of key characteristics in reference management software, formal mapping (tabulation by key characteristics), or lists grouping studies by type*
REFINING CRITERIA *Criteria that may be adapted in order to prioritise the inclusion of studies of highest rigor and relevance*	*Consider focusing (or expanding) by population*	*Reduce or expand initial population to focus on the available evidence considered most relevant to the review question or decision problem*
	Consider focusing (or expanding) by interventions and comparators	*Reduce or expand initial list of interventions or comparators to focus on the available evidence considered most relevant to the review question or decision problem; this might include prioritising only certain generations or versions of a technology.*
	Consider focusing (or expanding) by outcome	*Reduce or expand initial list of outcomes to focus on the available evidence considered most relevant to patients, clinicians and decision-makers (e.g. clinical rather than surrogate outcomes)*
	Consider focusing (or expanding) by study design and publication type	*Select the most relevant evidence for the decision problem (e.g. RCT for effectiveness, non-RCT studies for diagnostics or long-term safety) and, in the event of such evidence being insufficient, expand selection to identify other study designs of most relevance to the review question or decision problem (e.g. systematic review, real-world evidence etc.). The study designs prioritised may be different for different technologies within an assessment (e.g. not all technologies might have an RCT) and for different outcome data (e.g. prioritisation of RWE, case-reports (rare but serious events) and post-marketing surveillance studies for safety outcomes). Selection may also be made according to publication type e.g. exclusion of conference abstracts.*
	Consider focusing (or expanding) by setting	*Reduce or expand initial setting to focus on the available evidence considered most relevant to the review question or decision problem (e.g. UK only, Europe only, secondary care only, including awareness of 'equivalence of use' scenarios, that might enable the prioritisation of alternative locations and settings while maintaining relevance)*

Domains	Items	Further Explanations
	Consider focusing (or expanding) by date	*Apply or expand a date limit depending on presence or absence of evidence most directly relevant to the review question or decision problem (e.g. only evidence after a date when a key diagnostic test became available, or only the most recent evidence if the body of evidence otherwise satisfying the criteria is too large to be reviewed within time limits, and the evidence covers a substantial time period and is otherwise homogenous).*
	Consider which criteria to prioritise and how criteria interact	*Consider which criteria to prioritise over others, and how the different criteria interact. For example, studies may be initially prioritised by study design (e.g. RCTs prioritised), but alternative study designs (e.g. observational studies) may be prioritised if they address a different criterion such as outcomes (e.g. report safety data) or setting (e.g. UK studies). As another example, given a lack of studies with the right population and comparator, one may choose to expand to a wider population, or wider comparator definition, or both. Final decisions will depend on the specific review question and clinical context.*
Reporting	*Explain and justify all decisions taken*	*Clear transparency in reporting of approaches and decisions taken (explanation and justification) in selection and/or refinement of eligibility criteria, and possible impact of any decisions on findings. Any post hoc changes updated in the protocol (If registered).*

Green: initial scoping and consultation to enable criteria refinement during protocol development; Orange: iterative criteria refinement during the review; Blue: criteria for refinement; Purple: reporting and justification.

4.2. Key principles, processes and criteria in the framework

Three key domains were identified: *principles, processes* and *criteria*.

The *principle* driving the prioritisation *process* is the need to establish or refine a set of clearly defined eligibility *criteria* that meet the evidential requirements of the assessment in terms of rigour and relevance and will be deliverable within time and resource constraints.

The recommended *process* for achieving this is:

- During protocol development, early consultation with all key stakeholders and preliminary scoping of the literature to refine the eligibility *criteria*, including consideration of any associated economic evaluation, and the production of a relevant protocol.

However, iterative prioritisation as the review progresses can also be very valuable, especially where time for initial scoping is short, or the evidence base is large or difficult to scope. Where pragmatic decisions about study eligibility might need to be made after the protocol stage, the *process* for achieving this might include:

- Pre-specifying in the protocol that further *criteria* refinement may occur at one or more later points in the review, ideally specifying the general approaches to prioritisation; for example, in the event of a large volume of evidence, studies will be prioritised according to the *criteria* of study design (e.g. RCTs) or setting (e.g. UK studies). These general approaches to later prioritisation can be informed by stakeholders at the protocol stage;
- Organisation of the available evidence using tabulation (mapping), tags in reference management software or simple lists;
- Ongoing (iterative) consultation with key stakeholders to refine *criteria* considering the available evidence, and the requirements of any associated economic evaluation;
- Explicit reporting (description and justification) of any further refinements applied to the eligibility criteria outlined in the NICE Scope and/or in the review protocol.

4.3. Visual Guide to the prioritisation process

The overall prioritisation process is depicted in **Figure 1**. This highlights that the *principle* of establishing or refining a set of clearly defined eligibility criteria beyond those outlined in the NICE Scope is a circular *process* in which the prioritisation is informed by the quantity and relevance of the evidence and consultation with key stakeholders.

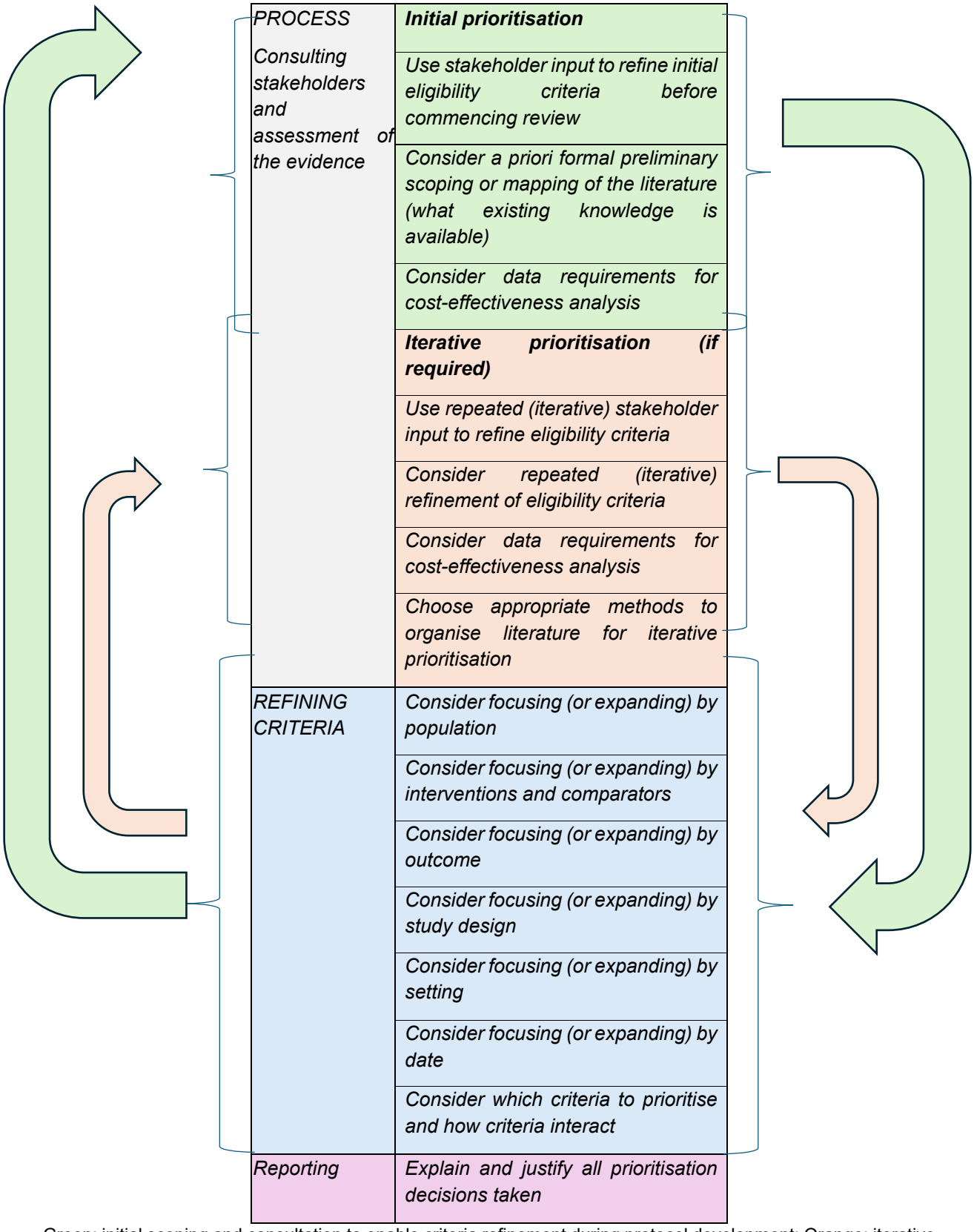
The key stakeholder consultations and literature scoping are very important in determining the need and nature of any specific prioritisations (based on the *criteria*). These consultations should include NICE, relevant clinicians, specialist advisers, economic modellers, likely users of the technology, and companies (to establish the purpose of the technology being evaluated, the most relevant generations or versions of a technology, and those studies deemed most relevant by the company), and should be used to inform decisions on prioritisation criteria. Some form of scoping of the literature should also be performed, to gauge the size and nature of the relevant literature. Stakeholder consultation and scoping are often iterative, circular processes which inform each other.

Ideally, a single cycle of initial scoping and consultation processes during protocol development by the EAG will enable any necessary refinement of review criteria as set-out in the NICE Scope (represented by the green domains and large green arrows on **Figure 1**). Sufficient time and resources should be allowed for this process. A protocol for the review can then be produced, which includes any resulting prioritisation decisions within the criteria.

However, the prioritisation process potentially might require one or more iterations involving further refining of criteria (narrowing or widening) during the review, depending on the evidence base identified (especially its quantity) and its relevance to the decision problem. This process is represented by the orange domains and the smaller, orange arrows. While consultations and assessment of the available literature might occur at any point, the earlier these processes are conducted, the greater the ability to anticipate issues likely to be raised later in the process and avert any later criticisms of the process. Given the nature of HealthTech evaluations, the latter process of iterative consultation and refinement of criteria might frequently apply. If the size and nature of the evidence base is uncertain or anticipated to be large, a sensible option may be to pre-specify in the protocol that further criteria refinement during the review may occur, how this will likely be done, and based on which criteria.

All processes and decisions concerning prioritisation of studies, including iterations of stakeholder consultation, should be reported and justified clearly within the Methods section of review reports. This is especially important to pre-empt criticisms and to satisfy a key aim of all systematic reviews: to be transparent.

Figure 1: Visual guide to the prioritisation process



Green: initial scoping and consultation to enable criteria refinement during protocol development; Orange: iterative criteria refinement during the review; Blue: criteria for refinement; Purple: reporting and justification.

4.4. Reporting checklist for study prioritisation

To facilitate reporting of any prioritisation processes undertaken, and criteria applied, during the review of evidence for a HealthTech evaluation, the following reporting checklist (**Table 9**), based on the framework guidance, is also proposed.

Table 9: Reporting checklist for any approaches applied in prioritising study selection by study design and characteristics

Domains	Items	Tick and give details of any process or criteria applied
PRINCIPLE	*Set clearly defined eligibility criteria a priori (before commencing the review)*	
PROCESS *Consulting stakeholders and assessment of the evidence a priori*	*Stakeholder input to refine eligibility criteria a priori (before commencing the review)*	
	Formal scoping or mapping of literature a priori (before commencing review)	
	Consideration of data requirements for cost-effectiveness analysis	
PROCESS *Consulting stakeholders and assessment of the evidence throughout review (if required)*	*Use of repeated (iterative) stakeholder input to refine eligibility criteria*	
	Use of repeated (iterative) refinement of eligibility criteria	
	Consideration of data requirements for cost-effectiveness analysis	
	Application of methods to organise literature for iterative prioritisation (e.g. mapping)	
REFINING CRITERIA *Criteria that may be adapted in order to prioritise the inclusion of studies of highest rigour and relevance*	*Focused (or expanded) by population*	
	Focused (or expanded) by interventions and comparators	
	Focused (or expanded) by outcome	
	Focused (or expanded) by study design and publication type	
	Focused (or expanded) by setting	
	Focused (or expanded) by date	
	Consider which criteria to prioritise and how criteria interact	
Reporting	*Explain and justify all prioritisation decisions taken*	

Green: initial scoping and consultation to enable criteria refinement during protocol development; Orange: iterative criteria refinement during the review; Blue: criteria for refinement; Purple: reporting and justification.

4.5. Potential hierarchy of criteria

The framework and guide do not mandate a hierarchy of criteria for prioritisation of studies. Rather they present a choice of *processes* and *criteria* that should be considered by review teams in the event that they are required to prioritise some studies over others in an assessment, due to the quantity and relevance of the available evidence. In this sense, the framework and guide should be seen as a 'compass' rather than an 'anchor'. None of the methods guidance literature appears to recommend selecting one criterion ahead of the others, when seeking to prioritise studies in a review.

However, there is an argument for proposing study design as the initial criterion of choice in any prioritisation decision (before population, intervention, comparator, outcome, date or setting). The rationale might be summarised as follows: 1) Study design is recognised as a potential proxy for study quality. Depending on the question, certain designs are accepted as offering the best potential evidence, e.g. RCTs for questions relating to clinical effectiveness. The study design criterion is also inherently flexible because it permits the prioritisation of the **best available** study design from a large evidence base of potentially relevant studies for each technology or intervention within a review (rather than prioritising only a single design, such as an RCT, across an entire review). While this approach has limitations - e.g. an RCT might be chosen based on its design, but has been poorly conducted - it offers a straightforward criterion for the first round of prioritisation decisions. 2) Given that study design is a methodological criterion expertly understood by EAGs and technical review teams, which can be easily applied as an initial, 'first round' approach to prioritisation, it potentially reduces the need for iterative stakeholder involvement and literature searching to refine other criteria. Also, the NICE Scope generally specifies only the following criteria: population, intervention, comparator and outcomes (PICO) of relevance to the decision problem. By considering study design as a first criterion in any necessary prioritisation, the integrity of the NICE scope, and the relevance of the clinical evidence review to the decision problem, is maintained. In this sense, an argument might also be made for considering setting (UK or equivalence) as a highly relevant prioritisation criterion of choice in any necessary second round of prioritisation decisions.

However, which criteria are most important will greatly depend on the individual review context.

4.6. Advantages and disadvantages of prioritisation

Prioritisation at an early stage of the review (i.e. during protocol development) can help reviewers focus on the data of most relevance to a committee or commissioner, with the highest methodological rigour. It can speed up the review process by enabling more focussed literature searches, less time screening studies, and limiting the number of studies from which

data are extracted. It can also facilitate stakeholder input throughout the review process, which keeps the review relevant. Prioritisation after the review protocol is finalised (i.e. during the review itself) can be useful where an evidence base is (unexpectedly) large as it can enable review teams to focus efforts on the most valuable literature, so that high quality, relevant work can be produced on time.

Prioritisation after the protocol is written can also be associated with various risks, including considerations about the methodological process following best practice; potential difficulties with publication in peer-reviewed journals; the potential for missing important and relevant data; and lower generalisability of findings outside of the UK context. As noted above, these risks may be mitigated by pre-specifying in the protocol how further criteria refinement during the review may occur, and through consultation on EAG reports and corresponding NICE guidance to highlight any gaps and omissions. It also introduces an additional layer of complexity for EAGs preparing these reports. Whilst prioritisation can save time in terms of data extraction and writing up, time has to be invested in the prioritisation process, and it is unclear to what extent in-process prioritisation saves time compared to a more extensive Scope and protocol development stage. For example, a more tightly-defined Scope and protocol will generally result in a more focussed search strategy with fewer citations retrieved, and less time spent by an EAG screening the results and considering the relevance of articles that ultimately become excluded. All these considerations should be borne in mind and consideration given to ensuring the initial Scope and protocol are as well-defined as possible. Where the evidence base is particularly large, it may be beneficial to make allowances for exceptions to standard NICE processes in terms of timelines and resources.

4.7. The wider reviewing context

It is important to acknowledge the wider context relating to advances in evidence synthesis technologies using artificial intelligence (AI). This is a very rapidly developing and active space, with the advent of large language models such as ChatGPT, and the availability of an ever-increasing number of commercial systematic review platforms that utilise AI in all aspects of the review process. The very recent Cochrane-backed Responsible AI use in Evidence Synthesis (RAISE) guidelines suggest that these tools could be useful, but crucially, that they should be evaluated and used responsibly. As the evidence base about these tools develops, it may be possible in the future to use them to truncate timelines significantly and safely, meaning more evidence can be included in a shorter timeframe, potentially negating the need for significant prioritisation. An eye should be kept on this rapidly evolving area of development.

5. SUMMARY

This piece of research involved three stages to identify a set of principles, processes and criteria to facilitate the refinement of eligibility criteria and prioritisation of studies by teams conducting clinical effectiveness reviews for HealthTech evaluations for NICE. The three stages involved: 1) the development of an initial framework based on an assessment of the relevant published literature on prioritisation of studies using rapid review approaches; 2) the testing and evolution of that framework using evidence on the types of prioritisations adopted in a set of real-world 15 HealthTech evaluations conducted for NICE; 3) an exploration of decisions behind, and the implications arising from, approaches to prioritisation based on consultations with a purpose sample of EAGs and NICE committee members, in order to bring greater depth and breadth to the final framework guidance.

The products of this work were:

- **A Guidance Framework of approaches to consider in prioritising study selection by study design and characteristics**
- **A Visual Guide to the prioritisation process**
- **A Reporting Checklist for any approaches applied in prioritising study selection by study design and characteristics.**

The key findings from this work were:

- Following the production of the NICE Scope and decision problem, work by an EAG or technical review team to further narrow or widen eligibility criteria should ideally be done early in the review process, e.g. during protocol development.
- Literature scoping work by the EAG or technical review team is a circular process including stakeholder input and assessing the volume and type of available evidence;
- The scoping process should be afforded as much time as is feasible, to facilitate production of a review that can be achieved within available timescales;
- If the EAG's literature scoping stage for the review is necessarily short or the size of the literature unexpectedly large, prioritisation may be conducted after the protocol has been finalised, i.e. during the review itself;
- In such circumstances, scoping work by the EAG or technical review team becomes an iterative, circular decision-making process including stakeholder input and the available evidence;
- Pre-specifying in the protocol whether and how further criteria refinement may occur during the review may avoid the need for post-hoc protocol amendments;

- Consideration should be given to the following criteria when seeking to prioritise studies: population, intervention (including different versions of a technology), comparators, outcomes, study design and publication types, possibly date, and the needs of the economic evaluation.

The prioritisation of some studies over others has both advantages and disadvantages, but can be a way of ensuring reviews focus on the evidence of highest rigour and relevance, and enable them to be completed on time

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APPENDICES

Appendix 1: Framework of approaches to prioritising studies for inclusion in a review, with example quotes from methods literature

Items	Domains	Example quotes from rapid review methods literature and NICE methods guidance
PRINCIPLE	***Set clearly defined eligibility criteria*** Clearly define the review question and eligibility criteria, including any restrictions or limits (e.g. using PICOS) that meet the evidential requirements of the assessment in terms of rigour and relevance and will be deliverable within resource constraints	Various restrictions can be applied to eligibility criteria (e.g. PICOs, timing, settings, date) (Garritty 2024a)(4) Streamline the request to focus on a limited number of high priority questions and outcomes (King 2022)(9) When there is a large amount of relevant evidence … the EAG can prioritise the studies or data it considers most valid and relevant to the decision problem ... Specific details of the prioritisation approach will be adapted to the needs of the topic and the evidence available. This will be initially described in the assessment protocol and refined if required in the assessment report (NICE LSA interim 2024 and consultation)(20, 21) Limits the studies … to those most likely to be relevant and informative (NICE IPP manual 2016)(5) If no evidence directly relevant … is available, inclusion criteria should be expanded to look at a broader evidence base (NICE EVA interim 2022)(23)
PROCESS	***Use stakeholder input to refine initial eligibility criteria*** Initial consultation with relevant stakeholders (*review commissioners,* policy makers, clinicians, specialist advisers, patients, manufacturers, knowledge users) to determine the most relevant evidence to inform the scope and eligibility criteria	Involve knowledge users to set and refine the review question, eligibility criteria, and outcomes of interest, with consultation at various stages of the review (Garritty 2024a)(4)
PROCESS	***Consider formal scoping or mapping of the literature***	Scoping work … to understand the volume and type of evidence available … may include brief database or web searches, examination of existing reviews, and/or discussions with experts (Pandor 2019)(17)

Items	Domains	Example quotes from rapid review methods literature and NICE methods guidance
	Scoping of the literature may help to gauge the volume and type of evidence available	A large number [of citations] retrieved may require you to refine your search question or inclusion/exclusion criteria (Dobbins 2017)(14)
PROCESS	***Use repeated (iterative) stakeholder input to refine eligibility criteria*** Consultation with relevant stakeholders at more than one timepoint to determine the most relevant evidence to inform any changes to the scope and eligibility criteria	Rapid reviews involve an iterative process … allow for post hoc changes to the protocol. Substantial changes should be discussed with knowledge users … any amendments should be tracked and reported (Garritty 2024a)(4) Report whether an iterative process (ideally specified in the protocol) was used (Stevens 2025)(8) Interaction with commissioners is an iterative process throughout the planning and conduct of the rapid review (Pandor 2019)(17) [In] the two-stage reviewing process … the stakeholder touch points [include]: at inception, to agree on key concepts and … principles about the evidence required; after the initial search, to gauge the scale and depth of the literature; and, optionally, after the final search (Tricco 2017)(11) A number of checks are used to establish whether the right studies have been selected for inclusion, including using the expertise and knowledge of the specialist advisers, the notifier of the procedure, the specialist Committee member, and … consultation on the draft guidance (NICE IPP manual 2016)(5)
PROCESS	***Consider repeated (iterative) refinement of eligibility criteria*** Iterative refinement of eligibility criteria in response to the quantity and quality of the evidence may help prioritise the most relevant evidence whilst ensuring the review is manageable in the timeframe.	In an iterative approach, searching is done in several stages, with each search considering the evidence that has already been retrieved. Searching in stages allows the reviewers to review the most relevant, high-quality information first and then make decisions for identifying additional evidence if needed (NICE guideline manual 2014)(24)
PROCESS	***Consider data requirements for cost-effectiveness analysis***	N/A

Items	Domains	Example quotes from rapid review methods literature and NICE methods guidance
	Discussion of the structure and required inputs of any cost-effectiveness analysis may inform the prioritisation of evidence.	
REFINING CRITERIA	***Consider focusing (or expanding) by population*** Reduce or expand initial population to focus on the available evidence considered most relevant to the review question or decision problem	Limiting the review question by population … was considered acceptable (Arevalo-Rodriguez 2023)(10) If no evidence is identified that is directly relevant to the decision question, a broader evidence base should be considered. For example, evidence … in a different population or setting (NICE HTP manual draft 2024)(22)
REFINING CRITERIA	***Consider focusing (or expanding) by interventions and comparators*** Reduce or expand initial list of interventions or comparators to focus on the available evidence considered most relevant to the review question or decision problem	Limit the number of interventions and comparators (Garritty 2024a)(4)
REFINING CRITERIA	***Consider focusing (or expanding) by outcome*** Reduce or expand initial list of outcomes to focus on the available evidence considered most relevant to patients, clinicians and decision-makers (e.g. clinical rather than surrogate outcomes)	Limit the number of outcomes, focusing on those most important for decision making (Garritty 2024a)(4) … Outcomes being relevant to the research question and of importance to patients, clinicians and policymakers (Arevalo-Rodriguez 2023)(10) Patient-focused efficacy and safety outcomes … are considered particularly important (NICE IPP manual 2016)(5)
REFINING CRITERIA	***Consider focusing (or expanding) by study design and publication type*** Select the most relevant evidence for the decision problem (e.g. RCT for effectiveness, non-RCT studies for long-term safety) and, in the event of such evidence being insufficient, expand	Prioritise the inclusion of high-quality study designs relevant to the review question or objective … ensure the decision is well explained (Garritty 2024a)(4) Identifying existing systematic reviews was valuable to the rapid review process (Arevalo-Rodriguez 2023)(10)

Items	Domains	Example quotes from rapid review methods literature and NICE methods guidance
	selection to identify other study designs of most direct relevance to the decision problem (including systematic review, real-world evidence etc.) Selection may also be made according to publication type e.g. exclusion of conference abstracts.	For relative treatment effects there is a strong preference for high-quality RCTs. Non-randomised studies may complement RCTs when evidence is limited, or form the primary source of evidence when there is no RCT evidence, [or] be used to contextualise results. The need to search beyond RCTs should be informed by the residual uncertainties … and the practicalities of the evidence search (NICE HTE manual 2022)(3) The highest value has traditionally been placed on evidence from systematic reviews or meta-analysis of RCTs, or one or more well-designed and executed RCT. However, the level of evidence is only one dimension when considering validity and relevance … priority is usually given to studies that include larger numbers of patients … [and] with longer and more complete follow-up (NICE IPP manual 2016)(5)
REFINING CRITERIA	***Consider focusing (or expanding) by setting*** *Reduce or expand initial setting to focus on the available evidence considered most relevant to the review question or decision problem (e.g. UK only, Europe only, secondary care only*)	Limit the setting, with justification … may be related to geographical areas or regions … [or] where the study is conducted, such as in the community or in a hospital (Garritty 2024a)(4) If no evidence is identified that is directly relevant … a broader evidence base should be considered. For example, evidence … in a different population or setting (NICE HTP manual draft 2024)(22)
REFINING CRITERIA	***Consider focusing (or expanding) by date*** Apply or expand a date limit depending on presence or absence of evidence most directly relevant to the decision problem	Consider restriction of the search date, with clinical or methodological justification provided (Garritty 2024a)(4) Date restrictions … are applied only in particular situations, for example, when a technology has evolved, when there is an exceptionally large amount of literature (NICE IPP manual 2016)(5)
REFINING CRITERIA	***Consider which criteria to prioritise and how criteria interact*** Consider which criteria to prioritise over others, and how the different criteria interact. For example, studies may be initially prioritised by study design (e.g. RCTs prioritised), but alternative study designs (e.g. observational studies) may be prioritised if they address a different criterion such as outcomes (e.g. report	N/A

Items	Domains	Example quotes from rapid review methods literature and NICE methods guidance
	safety data) or setting (e.g. UK studies). As another example, given a lack of studies with the right population and comparator, one may choose to expand to a wider population, or wider comparator definition, or both. Final decisions will depend on the specific review question and clinical context.	
PROCESS: Reporting	***Explain and justify all decisions taken*** Clear transparency in reporting of approaches and decisions taken (explanation and justification) in selection and/or refinement of eligibility criteria, and possible impact of any decisions on findings	Provide a clear description of the selected review approach … [and] discuss the potential limitations (Garritty 2024a)(4) Preliminary reporting items for rapid reviews include … a priori-defined iterative methods … distinguishing the rapid review from a systematic review … and knowledge user involvement (Stevens 2025)(8) The prioritisation approach … will be initially described in the assessment protocol and refined if required in the assessment report. Reasons for de-prioritising or excluding studies will be outlined (NICE LSA interim 2024 and consultation)(20, 21)

Appendix 2a: More detailed table of prioritisation approaches within NICE case studies (EVAs and DGs)

Domains and Items / Reports	**EVA HTE5**	**EVA HTE7**	**EVA HTE9**	**EVA HTE11**	**EVA HTE18**	**EVA HTE19**	**DG39**	**DG58**
Topic (date)	*ProKnow for radiotherapy data (2023)*	*Point of care tests for UTIs (2023)*	*Digital therapies for anxiety (2023)*	*AI in radiotherapy (2023)*	*Digital technologies pulmonary rehab in COPD (2024)*	*Digital self-management in COPD (2024)*	*Acute kidney injury (2020)*	*Tumour profiling tests in breast cancer (2024)*
PRINCIPLE								
Set clearly defined eligibility criteria	*Reported*	*Reported*	*Reported*	*Reported*	*Reported*	*Reported*	*Reported*	*Reported*
PROCESSES								
*Use **stakeholder input** to refine initial eligibility criteria*								
*Use repeated **(iterative) stakeholder input** to refine eligibility criteria*								
*Consider formal **scoping** of the literature (what existing knowledge is available)*				*Directly relevant SLRs not found*				
*Consider repeated **(iterative) scoping** of the literature*								
*Consider data **requirements for cost-effectiveness** analysis*								*Potential prioritisation of studies that include more than one relevant test[a]*

Domains and Items / Reports	EVA HTE5	EVA HTE7	EVA HTE9	EVA HTE11	EVA HTE18	EVA HTE19	DG39	DG58
REFINING CRITERIA								
General		*Prioritise by tests and populations 'where evidence is greatest'*	*Inclusion criteria in protocol broadened beyond scope to address evidence gaps. Final report: narrowing rather than broadening as large evidence base.*	*If evidence base large, prioritise by quality and relevance; if small, broaden beyond scope, e.g. in terms of population or comparator*	*Limit to between 1 and 3 studies per intervention*	*Prioritised by their relevance to the decision problem, UK setting and their quality (study design)*		
Consider focusing (or expanding) by ***population***	*Summary included of a study excluded by population due to possible data linkage*[a]		*If relevant data lacking, studies from age group (<18 years) not in scope will be included*		*Prioritisation based on relevance of population*		*Population expanded 'to maximise available data'*	*Some 'mixed populations' studies included based on certain criteria*
Consider focusing (or expanding) by ***interventions and comparators***		*A related test not in scope added as data considered potentially relevant*	*When relevant data lacking, studies with non-standard controls included*	*Studies with 'out of scope' comparators included if they offered 'useful information'*		*Studies deprioritised due to not being in the final list of 12 interventions (as set out by the final NICE scope); earlier generations of listed interventions deprioritised (because very different in nature), and studies with non-standard of care comparators*		*Limited to commercial versions of tests only*
Consider focusing (or expanding) by ***date***		*2000 onwards only, to restrict review due to tight timelines*			*Prioritisation based on 'recency'*			*Update of a 2017 review (the source for pre-2017 studies)*[a]

Domains and Items / Reports	EVA HTE5	EVA HTE7	EVA HTE9	EVA HTE11	EVA HTE18	EVA HTE19	DG39	DG58
*Consider focusing (or expanding) by **setting***		*Only those studies set in primary care or community[b]*	*Prioritisation by UK location, specific UK service or technologies provided by a specific UK service*		*Prioritisation based on conduct of studies in a UK or NHS setting*	*Prioritisation based on conduct of studies in a UK setting*		*Limited to UK and European studies (due to differing rates of certain chemotherapy use worldwide)*
*Consider focusing (or expanding) by **study design** and **publication type***		*Limiting of study designs depending on outcome (e.g. efficacy or test accuracy or performance)[b]*	*Prioritisation by sample size (>100) unless data deemed relevant*	*Prioritised by design (prospective studies); selected, higher quality retrospective studies or abstracts also included in absence of full prospective study*	*Prioritisation based on study design (RCT), supplemented with additional data from other studies as appropriate*	*RCTs were prioritised over nonrandomised comparative studies, comparative studies over non-comparative, and prospective over retrospective non-comparative studies*		*If the volume of data is large then priority will be given to higher quality data (e.g., larger studies, more applicable to practice in England, longer follow-up, data on multiple risk groups) <u>Additional 'evidence types' to be sought in the absence of certain data</u>*
*Consider focusing (or expanding) by **outcome***	*<u>Summary included of studies initially excluded by outcome</u>, due to a lack of data for some outcomes[a]*	*<u>Test performance studies expanded</u> to include any design due to small number of studies identified in scope*	*Prioritisation by outcomes (if reported combined rather than discrete outcomes, but only included on a case-by-case basis)*	*<u>Studies with 'out of scope' outcomes included if they offered 'useful information'</u>*	*Two outcomes specified as 'high priority'[a]*			*<u>Studies with 'out of scope' populations included to provide HRQoL data</u>*
INTERACTIONS BETWEEN CRITERIA								
*Consider which criteria to **prioritise** and how criteria **interact***						*By prioritising by study design (RCT) some patient outcomes are missing (deprioritised)*		

Prioritisation principally involved narrowing criteria, but <u>underline</u> indicates instances that also included widening criteria beyond the scope.
[a]Plan for prioritisation reported, but unclear if applied.
[b]Unclear whether the limits applied were simply an application of the protocol rather than prioritisation.
DG: Diagnostic Guidance; EVA: Early Value Assessment.

Appendix 2b: More detailed table of prioritisation approaches within NICE case studies (IPGs* and LSAs)

Domains and Items / Reports	**IPG586**	**IPG599**	**IPG686**	**IPG688**	**IPG777**	**LSA (TAVI)**	**LSA (DES)**
Topic (year)	*TAVI for aortic stenosis (2017)*	*Transvaginal mesh repair (2017)*	*Hysterectomy for cervical cancer (2021)*	*Cytoreduction surgery (2021)*	*Carotid artery stents (2023)*	*TAVI for aortic stenosis (2024)*	*Drug-eluting stents (2025)*
PRINCIPLE							
Set clearly defined eligibility criteria	*Reported*	*Reported*	*Reported*	*Reported*	*Reported*	*Reported*	*Reported*
PROCESSES							
*Use **stakeholder input** to refine initial eligibility criteria*						*Liaise with clinical experts to identify any additional subgroups*	*Clinical experts and NICE consulted to provide clarification and guidance on interpreting and prioritising evidence that has been identified as relevant to the assessment, where necessary*
*Use repeated **(iterative) stakeholder input** to refine eligibility criteria*							*NICE will be consulted during the process to provide clarification and guidance on interpreting and prioritising evidence that has been identified as relevant to the assessment, where necessary*
*Consider formal **scoping** of the literature (what existing knowledge is available)*						*Directly relevant SLRs not found (but others might be used to address gaps in prioritised data)*	
*Consider repeated **(iterative) scoping** of the literature*							
*Consider data **requirements for cost-effectiveness** analysis*						*Cited the model's focus on particular clinical outcomes*	*Clinical evidence was prioritised based on its suitability for providing appropriate inputs for the network meta-analysis and economic model*

Domains and Items / Reports	IPG586	IPG599	IPG686	IPG688	IPG777	LSA (TAVI)	LSA (DES)
REFINING CRITERIA							
General	*EAG report: Scope complies with a previous rapid review[a]*	*Overview. Prioritise by publication type or study design*	*Overview. Prioritise by publication type or study design*	*Overview. Prioritise by publication type or study design*	*Overview. Prioritise by publication type or study design*		*'Pragmatic approach' taken in line with LSA methods guide prioritising evidence considered most relevant to the decision problem and highest quality*
*Consider focusing (or expanding) by **population***		*Overview, Appendix. Other relevant studies excluded as less relevant population or only a subset of population relevant*	*Overview, Appendix. Other relevant studies excluded due to smaller numbers of patients, and mixed populations*		*Overview, Appendix. Other relevant studies excluded due to smaller numbers of patients, and mixed populations*	*Additional subgroups to be included if feasible and as considered appropriate by clinical experts[a]*	*Studies deprioritised if a subgroup*
*Consider focusing (or expanding) by **interventions and comparators***		*Studies deprioritised as use multiple or different interventions/ devices/kits or techniques*	*Overview, Appendix. Other relevant studies excluded due to focusing only on a specific device or technique*		*Overview, Appendix. Other relevant studies excluded due to focusing only on a specific device or technique*	*Expand technologies to those 'out of scope' by indication (where not specifically contra-indicated) or generation of device (but only 'where generalisable' and noting limitations)*	*Prioritised studies that included both intervention and comparator in scope, and studies with the most recent generation of a technology*
*Consider focusing (or expanding) by **date***	*EAG report: Update of a previous review[a]*	*Overview, Appendix. Other relevant studies excluded due to more recent studies being available*	*Overview, Appendix. Other relevant studies excluded due to more recent studies being available*	*Overview, Appendix. Other relevant studies excluded due to more recent studies being available*	*Overview, Appendix. Other relevant studies excluded due to more recent studies being available*		
*Consider focusing (or expanding) by **setting***						*Prioritised by UK and NHS data where large amounts of evidence*	*Prioritised by generalisability to UK*

Domains and Items / Reports	IPG586	IPG599	IPG686	IPG688	IPG777	LSA (TAVI)	LSA (DES)
*Consider focusing (or expanding) by **study design** and **publication type***	*Overview, Appendix. Other relevant studies excluded due to not being RCTs/SLRs, being smaller, type of analysis (exploratory analyses excluded), quality of SLR (lower quality excluded)*	*Overview, Appendix. Other relevant studies excluded due to not being RCTs, or being smaller and/or having shorter-term data than included studies, having higher drop-out rates than included studies, or being included in an included SLR*	*Overview, Appendix. Other relevant studies excluded due to being smaller and/or having shorter-term data than included studies, reporting data cited in included studies, or being included in an included SLR*	*Overview, Appendix. Other relevant studies excluded due to not being an SLR or RCT, or being smaller, less relevant or less comprehensive, or having shorter follow-up, than included studies*	*Overview, Appendix. Other relevant studies excluded due to being smaller and/or having shorter-term data than included studies, and/or reporting data cited in included studies or not reporting a meta-analysis (for SLRs)*	*Prioritised by hierarchy: UK real-world and observational data; by sample size; length of follow-up; comparative studies; availability of AE data*	*Prioritisation of studies to be included may be based on factors such as type of study design (RCTs, studies with longest follow-up), sample size. Deprioritised conference abstracts.*
*Consider focusing (or expanding) by **outcome***	*EAG report and Final Guidance: Only included studies that reported outcomes by risk level of patients* *Overview, Appendix A. prioritised studies of rare AEs*	*Other relevant studies excluded due to having less relevant outcomes, or outcomes covered in included studies*	*Overview, Appendix. Other relevant studies excluded due to having 'less relevant outcomes' than included studies, or only reporting AEs already reported in included studies. Abstracts and smaller studies generally excluded, but included if reporting specific AEs not available in other studies*	*Abstracts and smaller studies generally excluded, but included if reporting specific AEs not available in other studies*	*Overview, Appendix. Abstracts Other relevant studies excluded due to having 'less relevant outcomes' than included studies, or only reporting AEs reported in included studies. Abstracts generally excluded, but included if reporting specific AEs not available in other studies*	*Prioritised by reporting of AE data and adjustment of confounders for patient-level data*	*Prioritisation of outcomes that were 'clinically meaningful' (rather than short-term), consistently reported for use in NMA, and directly attributable to stents. This influenced the pragmatic study selection criteria used.*
INTERACTIONS BETWEEN CRITERIA							
*Consider which criteria to **prioritise** and how criteria **interact***			*Study design (or publication type) and outcomes: Excluded most abstracts and smaller studies, but included if reported AE not covered elsewhere*	*Study design (or publication type) and outcomes: Excluded most abstracts and smaller studies, but included if reported AE not covered elsewhere*	*Study design (or publication type) and outcomes: Excluded most abstracts and smaller studies, but included if reported AE not covered elsewhere*		*Most recent publication prioritised and for multiple publications of same study (longest follow-up)*

*IPG data refer to the prioritisation applied to the *Evidence overview* unless specified.
Prioritisation principally involved narrowing criteria, but underline indicates instances that involved widening criteria beyond the scope.

[a]Plan for prioritisation reported, but unclear if applied.
IPG: Interventional Procedures Guidance; LSA: Late-Stage Assessment.