NICE National Institute for Health and Care Excellence

Early value assessment interim statement

NICE process and methods
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Contents

1 Introduction 3

2 Strategy for medical technologies topic intelligence 5

The vision 5

Topic intelligence for early value assessment 6

Topic intelligence process 6

Topic priority: the problem 7

Identification of technologies 8

Filtering technologies 8

Understanding the data collection landscape 9

System validation 9

Commercial surveillance 9

Topic feeds and outputs within NICE 10

Engagement framework 10

3 Interim process and methods for early value assessment 11

Intention 11

Topic selection 12

Scoping 12

Evidence 13

Economic evaluation 14

Decision making 16

4 A new approach to evidence generation for medical and digital health technologies 19

Intention 19

Stakeholder roles 20

Guiding principles 22

The stages of the evidence generation approach 22

1 Introduction

1.1 Early value assessment is a new evidence-based approach designed to improve the care of people and effective use of NHS resources through quicker access to promising health technologies that address national unmet need. It champions stronger partnership working between regulatory, healthcare and research organisations to benefit people and better support innovators while ensuring value for money for the NHS.

1.2 There are 4 key aims of the early value assessment approach:

- To focus on promising innovations that meet the needs and priorities of people, and the health and social care systems.
- To enable earlier access to useful innovations through faster assessments and timely guidance production.
- To better support adoption and evidence generation by embedding early value assessment in cross-partnership working.
- To check the benefits of promising innovations are realised and ensure value for money for the health and social care systems.

1.3 To develop early value assessments, NICE is adopting a 'test and learn' approach and running at least 10 pilots of different use cases. Approaches being tested are outlined in appendix 1 table 3 and include assessments of varying length with a clinical gap analysis and various approaches to economic analysis such as reviewing economic literature or early conceptual modelling. Each early value assessment will include relevant technologies that are used for a specific purpose or indication. Early value assessment recommendations will refer to each technology individually.

1.4 This interim statement outlines:

- the vision for the new topic intelligence function and how pilot topics have been identified
- the process and methods that are being tested for assessing early value and

producing sound and timely guidance

- the approaches for evidence generation that are being tested to support further evidence generation for technologies that have been conditionally recommended through the early value assessment process.

1.5 The approaches outlined in this statement are iterative and may change to fit the needs of the project. Learnings from the tested approaches will inform the final design of early value assessment and will then be documented in a final manual.

2 Strategy for medical technologies topic intelligence

2.1 Topic intelligence describes the activity done to proactively and systematically gather information on an agreed subject focus. The aims of this activity are to rapidly identify priority areas for health and social care and corresponding medical technologies which are suitable for national evaluation and validate these topics and technologies with a range of stakeholders in the health and care system. Technologies will then be considered for advice or guidance.

2.2 The topic intelligence process brings together 3 domains (see appendix 1, figure A):

- Issues in health and social care – an understanding of unmet or partially met clinical, system or service user needs, identified through strategic engagement with the health and care system.
- Top health and care policy priorities, established and validated through broad engagement with key policy teams in the NHS and social care sectors.
- Suitable technologies, which are systematically searched for from a variety of sources and filtered for evaluation by NICE.

The vision

2.3 NICE will take a deliberative and systematic approach, selecting and supporting relevant health system priorities. This will help ensure NICE resources are focused on areas of greatest need for new innovations to improve care.

2.4 The topic intelligence function aims to deliver this vision by providing a capability within NICE to:

- develop networks to generate intelligence streams on key topic areas to better understand system priorities (service or clinical needs).

- proactively scan for devices, diagnostics, and digital health technologies which meet system priorities.
- carry out targeted engagement with the wider system to confirm the right topics are being considered for various work programmes, helping NICE to focus resources on the most impactful outputs.

  This structured approach to topic intelligence will optimise the inward flow of technologies to NICE for the benefit of the health and care system.

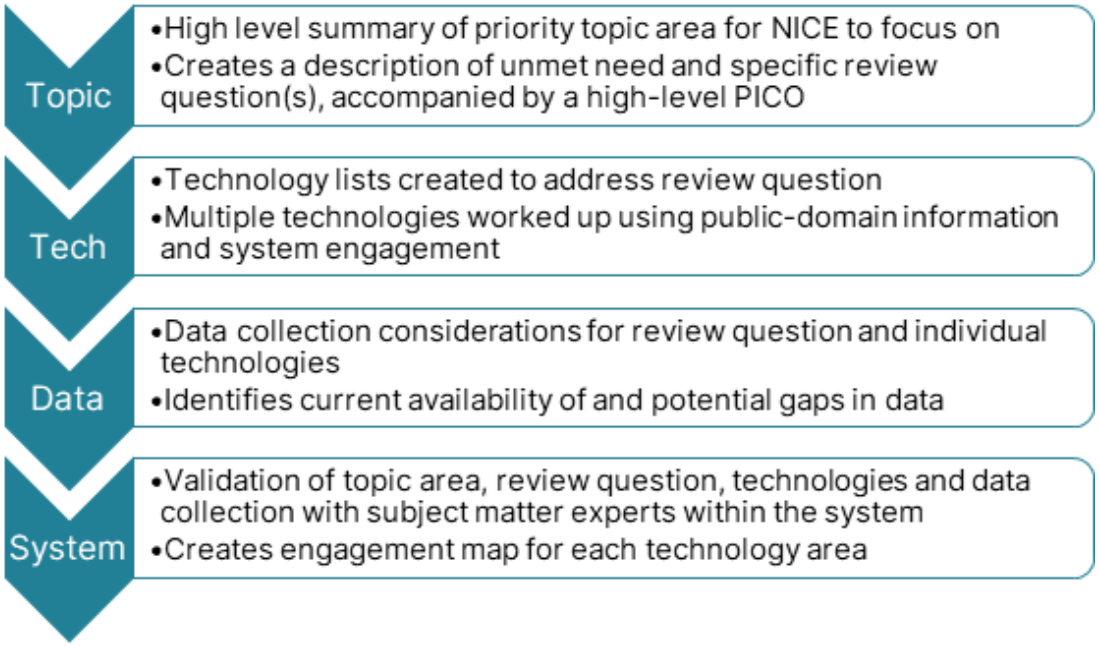
Topic intelligence for early value assessment

2.5 The initial focus for topic intelligence was on rapidly identifying digital health technologies that would address system priorities in cardiovascular disease, mental health, and post-COVID system recovery.

Topic intelligence process

2.6 The topic intelligence process is a 4-step process to produce a comprehensive output that is useful to multiple NICE teams. The process involves different teams gathering information on the domains shown in figure 1.

Figure 1. Summary of topic intelligence process



Abbreviations: PICO – population, intervention, comparator, and outcomes

Topic priority: the problem

2.7 Topic intelligence activity must begin with identifying a clinical, system or service user problem to help direct NICE resource to topics which will be of greatest value to the health and social care system.

2.8 This activity will build intelligence on the following areas:

- Priority topic areas, for example, by health inequality, clinical specialty, or system pressure, incorporating key national policy priorities, activity data from the system, epidemiology data on burden of disease.
- Unmet need for the topic area, for example, lack of access to diagnostics or treatments, long waiting lists, suboptimal outcomes with current standard of care.
- Scale and impact of the problem, for example, national compared with regional compared with local and implications for inequalities.

2.9 Each topic area is described as an unmet clinical need in a specialty area (for example, cancer, ophthalmology) or a system need (for example, system recovery, long referral-to-treatment times). This information should ideally

correspond to national priorities such as the NHS Long Term Plan and core NHS strategies such as Core20plus5.

2.10 Each area of need is focused into a specific review question and articulated further using a population, intervention, comparator and outcome (PICO) framework or other relevant frameworks, considering the scale and potential impact on the system.

2.11 Topic priorities are identified through engagement at a senior level with the health and social care system.

Identification of technologies

2.12 The topic intelligence hub database will support the systematic logging of all topic intelligence activity for both technology trawls and engagement.

2.13 A search for appropriate technologies which could meet unmet needs of the health and care system will be done through extensive external and internal engagement with the organisations listed in appendix 1, table 1. High-level criteria are used to initially identify the technologies, with minimum requirements as follows:

- The technology meets appropriate regulatory requirements (for example, UKCA or CE mark) appropriate to the function.
- The technology falls within a priority area.
- The technology is currently being used in the NHS or being planned for uptake in the coming 6 months.

Filtering technologies

2.14 Technologies are filtered based on priority area, regulatory information, use in the NHS and social care, funding and evidence (see appendix 1, table 2). Information on these criteria is extracted from public domain sources wherever possible, to

avoid generating expectations from companies. Technologies will subsequently be reviewed by the topic selection oversight panel.

Understanding the data collection landscape

2.15 The current availability of data and plans for collecting data are both important considerations around assessing technologies and making appropriate recommendations on future evidence generation. Where available, this will be included in the topic intelligence activity.

System validation

2.16 The validation of the topic areas and technologies with policy drivers and system leaders will ensure NICE is moving cohesively with the health and care system. It is more likely that such priorities will get system support, either through resource, funding, or consensus agreement.

2.17 Additionally, system engagement at the ground level is critical for generating consensus among key stakeholders on the topic areas and technology lists and may help identify testbeds for the programme outputs from NICE.

Commercial surveillance

2.18 Surveillance of commercial activity in the devices, diagnostics, and digital health technologies sector is not routinely done within NICE. There has been ad hoc reporting of large-scale industrial investment in areas such as virtual wards, done by the strategy team. This type of intelligence is useful for signalling where there is likely to be a surge in activity after large investment in a particular sector, hence may benefit from topic intelligence activity. NICE topic intelligence and strategy teams can jointly support this activity.

Topic feeds and outputs within NICE

2.19 The NHS Innovation Service, launched in July 2022, is the centralised source of innovation information for the health and care system and is being referred to accordingly. This will become a key source of intelligence for NICE work programmes and provide a means through which to engage with system partners on common priorities.

2.20 There are also existing internal topic feeds for topic intelligence within NICE from current workstreams, for example, from the Office for Market Access team, Interventional Procedures programme, Scientific Advice and so on. These will continue to be used as sources for both topic areas and technology feeds.

2.21 Summaries of the topic intelligence activity will be shared with NICE's Medical Technologies Evaluation Programme and Diagnostic Assessment Programme, Centre for Guidelines, NICE Scientific Advice and Office for Market Access as relevant.

2.22 Different work programmes will have different requirements of the information provided, and identified technologies will be managed in line with NICE's topic selection process and methods. The topic selection oversight panel will remain responsible for topic selection including selection of early value assessment topics.

Engagement framework

2.23 The topic intelligence team routinely engages with relevant networks (see table 1 in the appendix). These information sources have been invaluable for gathering insights on technologies and for understanding how different NICE programmes could align to the system, and vice versa.

3 Interim process and methods for early value assessment

Intention

3.1 This section of the early value assessment interim statement describes the processes and methods that are being used for the early value assessment pilots. Different approaches are being tested to identify where efficiencies can be made and where alternative approaches could be used, see table 3 in the appendix for different approaches being tested for each topic. The intention of this statement is to provide an overview of the methods and processes but not be prescriptive in detail, to allow flexibility to adapt and change approaches during the pilots. It should be read alongside NICE health technology evaluations: the manual (relevant sections of the manual have been referenced throughout this document).

3.2 The objectives of the early value assessment process and methods are to:

- identify the evidence that is available on the technologies
- explore if technologies have the potential to address the identified unmet need
- identify important evidence gaps to help direct evidence generation
- determine if technologies should be used while further evidence is generated.

3.3 The overall timeframe of an early value assessment is approximately 6 months. This includes 8 weeks for scoping, stakeholder identification and specialist committee member recruitment; 9 weeks for external assessment; and 7 weeks for guidance production and public consultation.

3.4 The following section outlines the stages of an early value assessment and the key areas for pilots (for a summary of the types of approaches being trialled per

pilot see tables 3 and 4 in the appendix).

Topic selection

3.5 Topics for the early value assessment pilots include technologies that address an unmet need or priority area, different types of technology, different purposes or use cases and differing availability of infrastructure for real world data collection. The aim of selecting a wide variety of topics encompassing these aspects is to test that early value assessment is a useful approach for all different types of health technology and use cases, and to show proof of principle of what could be achieved through early value assessment when strong partnerships are in place.

Scoping

3.6 Technologies selected for early value assessment will be scoped in line with section 2 of NICE's health technology evaluations: the manual, except for the following process changes:

- An advert for specialist committee members will be posted on the NICE website for 4 weeks. The panel for shortlisting and interviewing applicants will consist of the committee chair or vice chair and an associate director or their appointed deputy.
- Consultation of the scope may take place. When a consultation period is deemed necessary, it can take place before or after the scoping workshop.
- Where a scoping workshop is needed, all registered stakeholders will be invited to attend. After this, special committee members will be invited to an assessment subgroup workshop where the draft scope and key consultation comments will be discussed before final scope amendment and release. The scoping process will be expedited for the early value assessment pilot process.

Evidence

3.7 The standard approach to assessing the evidence for a NICE evaluation is outlined in section 3 of NICE health technology evaluations: the manual. The way that NICE assesses evidence has been amended for the purpose of the early value assessment pilots.

3.8 The evidence assessment processes being piloted include:

- an external assessment group producing an assessment report for the early value assessment pilot projects in 8 to 10 weeks
- the assessment report may be released to stakeholders for comment before the committee discussion
- stakeholders being informed of the dates of any comment period at least 1 week before documents are released
- a streamlined approach to internal approval of final documents within NICE and the need for a resolution period.

3.9 The remainder of this section outlines the methodology for reviewing the evidence for an early value assessment.

3.10 It is expected that there will not be a comprehensive evidence base available for technologies included in early value assessment. The evidence considered by the committee should be relevant to the evaluation in terms of patient groups, comparators, perspective, outcomes and resource use as defined in the scope wherever possible. The aim of the evidence review is to identify the most relevant evidence relating to the decision question defined in the scope. If no evidence directly relevant to the evaluation is available, inclusion criteria should be expanded to look at a broader evidence base.

3.11 In addition to reviewing the evidence on the technologies, additional reviews may be needed to look for studies that report on relevant information, but do not include the intervention technologies. For example, evidence on treatment effect for a condition in which people have a biomarker identified by the new technology or evidence on a relationship between surrogate and final clinical

outcomes. Identifying whether there is such evidence will help the committee identify whether there are data gaps across the care pathway that would lead to uncertainties in a future model.

3.12 Broad evidence mapping searches may need to be done to identify evidence on the technologies because articles may be published in less well-known journals, studies may not be well indexed or may only be presented as conference abstracts. Unpublished data provided by companies and other stakeholders could be considered.

3.13 The evidence reviews may be done using pragmatic approaches in order for the assessment to be done in the time available. For example, using rapid review methods such as single screening and data extraction. For evidence reviews of outcomes where a large amount of data could be available, a restricted number of databases could be searched or a review of review done.

3.14 Searches for ongoing studies should be done. Any ongoing studies that were identified should be checked to see if they will help to fill key evidence gaps.

3.15 A full critical appraisal of studies using a validated tool is not needed, but there should be discussion on the potential biases in key studies and how the risk of bias could affect key outcomes. The report should explicitly detail the potential sources of bias such as the main confounding factors. Comments on the generalisability of the results to clinical practice in the NHS should also be made.

3.16 Evidence synthesis of the key findings should be provided in a simple narrative and descriptive format, a quantitative meta-analysis is not expected. Where the direction of the effect (and associated confidence intervals) is reported in the literature it should be included. A cautious interpretation of the findings should be provided. The report should include a discussion of the evidence gaps and uncertainties in the identified evidence and suggestions of outcomes to focus on in future evidence generation.

Economic evaluation

3.17 Economic analyses for early value assessment may differ from the standard

approach for guidance products. The standard approach is outlined in section 4 of NICE health technology evaluation: the manual. For early value assessment, the economic evaluation work that is likely to be most beneficial for committee decision making is likely to vary by topic, needing flexibility from assessment groups doing the work. Proposed work should be discussed between the NICE team and the external assessment group from an early stage to inform development of the protocol for the assessment.

3.18 The objectives of the economic evaluation are to:

- identify likely impacts of using technologies (while further data is collected) on:
  - people with the condition and, when relevant, carers
  - the NHS and personal social services (including costs)
- identify additional uncertainties that would not be apparent from technology related studies; for example, related to the structure of, or parameters used in, models that are anticipated to be needed for future guidance.
- identify uncertainties that are likely to be key drivers of model results and decision-uncertainty to inform decision making about further evidence generation.

3.19 The cost of reversing a decision to adopt the technologies while further evidence is generated may also be considered. This is to assess the potential implications if, after an initial decision by NICE to recommend use of the technologies while further evidence is generated, a later assessment (after this evidence is collected) shows the technology not to be cost effective or cost saving. This could include any costs that could not be recouped related to implementation such as fixed or up-front costs related to the purchase of equipment, training costs or changes to organisation of care pathways.

3.20 Efforts should be made to identify relevant economic evaluations related to the technologies or disease area that could inform the work. For example, through targeted literature searches or work highlighted by experts or stakeholders as potentially relevant. Any models highlighted or submitted by companies could be considered.

3.21 Economic evaluation should as a minimum consider model structure(s) that would be needed for a future analysis to support NICE committee decision making. Relevant experts (for example appointed specialist committee members) should be consulted to validate this. Comparisons should also be made with any existing model structures identified where they are deemed relevant or robust (see section 3.19).

3.22 Development of a preliminary or early coded model (that is, a model implemented in a software platform) should be considered to help meet the objectives in section 3.17, particularly to explore uncertainty with the aim of identifying key drivers of the model results to inform decision making about further evidence generation. Existing models could be used here, if considered suitable and an agreement is in place to allow models developed by third parties to be made available to stakeholders.

3.23 The reference case will be the same as described in section 4.2 of NICE health technology evaluations: the manual.

3.24 Guidance for presenting data and results of models is described in section 4.10 of NICE health technology evaluations: the manual. Outputs of models should be presented to easily allow clinicians to validate model results and the extent of work done to validate model outcomes should be described.

3.25 If no coded model is produced (see section 3.21), targeted searches should still be done to attempt to identify data (and highlight where there may be a paucity of data) for model parameters considered likely to be key drivers of future cost-utility analysis (see section 3.9 and section 3.10).

Decision making

3.26 New approaches to decision making are being piloted for early value assessment. NICE's usual approach to decision making and committee recommendations is outlined in section 6 of NICE health technology evaluations: the manual. The key points are outlined below.

3.27 Decision making will be the responsibility of one of the following:

- the diagnostic advisory committee
- medical technologies advisory committee
- decision panel.

Specialist committee members will also be invited to be decision makers for early value assessment.

3.28 When making decisions the committee should consider:

- the extent of the evidence that supports the likelihood of the technology addressing unmet need in the system
- the views and experiences of people using the technology
- any barriers to implementation and how these can be addressed as part of further evidence generation
- the key evidence gaps where further data is needed to resolve uncertainty for future decision making
- if further evidence generation, either from ongoing or new research or from real-world data, will sufficiently resolve the key evidence gaps
- if any identified risks or uncertainties could be mitigated if the technology is used while further data is generated (for example, by specifying how the device should be used or further research [with defined outcomes] that would need to be done before wider use, or by reductions in technology cost or ways in which the technology is charged for)
- the likelihood and size of impact of adopting the technologies for people using the technologies (and their carers) and the NHS personal social services while further data is collected, in terms of both potential benefits and risks
- whether provision should be made for special safety monitoring measures.

3.29 When multiple technologies are considered in a topic, each should be assessed independently. For example, considering any difference between technologies in

terms of whether they can solve the specified unmet need and any differences in further evidence needs.

3.30 The committee or panel can make the following types of recommendations (specific wording subject to change):

- Conditionally recommended for use while further evidence is generated.
  - Made when the committee or panel consider it is plausible that the technology will address the unmet need and it is acceptable for the technology to be used in practice (potentially with measures in place to mitigate risks) while further evidence is generated. How evidence is to be collected (for example, collected while the technology is used in practice or from a research study) will be determined in the evidence generation plan developed (see section 4).
- Recommended in research
  - Made when the committee or panel are uncertain if the technology has the potential to solve the unmet need, or if the committee do not think it is acceptable for the technology to be widely used in practice while further evidence is generated. For example, if it is too uncertain about the extent to which the potential benefits of use outweigh the potential risks.
- Not recommended for use
  - Made where the committee or panel do not believe a technology has the potential to meet the unmet need, or where there are concerns about the potential harms associated with using the technology even in a research context.

    Figure B in the appendix illustrates the main considerations that will impact the recommendations.

3.31 For the conditional recommendation, the outcomes that the committee need further data on to support future decision making should be listed and include a focus on outcomes which are fundamental to decision making.

4 A new approach to evidence generation for medical and digital health technologies

Intention

4.1 The early value assessment evidence generation approach is designed to help technology developers to work with patients and clinicians, along with NHS data custodians and analytical partners who can generate the new evidence needed either from new or ongoing research or from real-world data. The approaches outlined are iterative and may change to fit the needs of the project.

4.2 The aims of this approach are:

- to collaborate on evidence generation with opportunities to use real-world evidence in line with NICE's 5-year strategy.
- advice and support to identify proportionate and pragmatic approaches to evidence generation
- collaborative engagement between a wide range of stakeholders to help adoption with evidence generation.

4.3 For technologies conditionally recommended through early value assessment, NICE will support development of a plan for new evidence generation by:

- Engaging with companies about the evidence already available and any evidence gaps that could be addressed to identify opportunities for further evidence generation.
- Assess the evidence gaps that would need to be addressed for a routine recommendation, identifying existing and ongoing sources of data and evidence that could address these
- Producing clear statements about what new evidence generation could

sufficiently address the evidential gaps

- Broker relationships on behalf of the technology developer with:
  - NHS real-world data custodians, who hold data that can assist in addressing evidence gaps.
  - Analytical or research partners, who can advise on or do analyses to generate evidence.
  - Voluntary and community sector organisations, who can reach people who might like access to new technologies.
  - Clinical networks, who can provide information and guidance to the NHS about using these products and any data collection needs to support evidence generation.

Stakeholder roles

NICE's role

4.4 NICE's role around evidence generation for digital health and medical technologies will be to:

- Identify what additional evidence is needed for NICE to support using the technology in the NHS.
- Work with the technology developer to:
  - identify system partners who may be able to support the design and delivery of an evidence generation plan, and to broker relationships, as needed, with potential data controllers and research funders.
  - identify and engage with experts who can provide advice around evidence generation.
  - determine what should be included in an evidence generation plan, including guidance on suitable approaches to generating the evidence.

  - develop a proportionate and pragmatic approach to evidence generation with consideration for the burden on patients, healthcare professionals and the wider system.
  - help the development of evidence generation plans through multi-stakeholder engagements.
- Share the published final evidence generation plan with stakeholders.
- Link technology developers with potential research funding partners.

Technology developer's role

4.5 The technology developer's role will be to:

- Support evidence reviews to identify the most relevant evidence and information relating to the decision question defined in the scope.
- Engage with relevant stakeholders to help develop and implement an evidence generation plan, to:
  - Identify robust approaches to evidence generation, consider aspects such as study design, data quality and suitability.
  - Work with potential evidence sources to establish approaches to generating evidence.
  - Ensure new evidence is generated in accordance with all applicable data protection legislation.

Clinician, patient, carer, and data custodian role

4.6 Clinician, patient, carer, and data custodian input will inform the early value assessment by:

- Providing the technology developer with relevant and constructive contributions, based on their experience, expertise, and knowledge to

influence the evidence generation plan. These contributions could include feedback on the placement of the technology, its potential value, its acceptability or feasibility and its implementation. They could also incorporate reviewing any potential evidence generation plans around their feasibility and appropriateness.

- Providing input to assess the burden of data collection to ensure it is deliverable.
- Identifying potential implementation barriers which would need to be addressed as part of the evidence generation plan.

Guiding principles

4.7 These guiding principles are important because they help the early value assessment process to produce the high-quality information necessary to support NICE decision making and make sure that patients and the NHS can benefit from new technologies. These guiding principles should be used by all stakeholders when considering the early value assessment evidence generation process.

4.8 The principles that will guide our approach to evidence generation for medical technologies are outlined in table 5 of the appendix.

The stages of the evidence generation approach

4.9 There will be multiple opportunities throughout the early value assessment process to consider the evidence and gaps which could be resolved with further evidence generation. The objective of this evidence generation approach will be to produce a plan which the technology developer will be able to take forward in partnership with key stakeholders to generate the new evidence that will support a future NICE guidance.

Evidence review

4.10 During scoping and the evidence review, the NICE technical team, external assessment group and committee will identify areas of potential evidence gaps and inform the evidence generation team of these. The evidence generation team will then investigate and consider the data collection landscape around the technology in the NHS (through literature review and expert elicitation) to see if there are any suitable initiatives that could support evidence generation in an early value assessment. The evidence generation team will also seek to identify and work with independent academic advisors and representatives of the NICE committee to form the evidence generation panel.

4.11 The assessment by NICEs external academic partners will identify potential evidence gaps. Before the early value assessment recommendations are published, the evidence generation panel will consider the evidence gaps and create an outline of possible approaches to addressing them.

Formulation of preliminary evidence generation plan

4.12 If the committee or panel considering the topic makes a recommendation for conditional use with evidence generation, they will identify the evidence gaps that need to be addressed for the topic to be considered for a full recommendation. The evidence generation team will then liaise with the technology developers and stakeholders of ongoing studies involved in the topic to discuss the evidence generation process and how they can support it. The evidence generation panel will then meet and develop the initial evidence generation plan.

Multi-stakeholder engagement

4.13 Once a plan has been developed by the evidence generation panel with input from the technology developers it will be finalised through a multi-stakeholder engagement. Stakeholders involved in this could include:

- evidence generation partners such as national registries and regional

integrated data repositories

- potential funders for early value assessment evidence generation
- NHS England and Integrated Care Board commissioners
- Academic Health Science Networks (AHSNs)
- National Institute for Health and Care Research (NIHR)
- clinicians and patient representatives
- third-party data experts where relevant
- patient groups and service users.

4.14 The evidence generation plan will be published alongside publication of the committee recommendations after it has been confirmed by multi-stakeholder engagement.

Pilot phase

4.15 The early value assessment pilot phase will inform the development of the evidence generation process, so evidence generation plans may be published later than committee recommendations.

The evidence generation plan

4.16 The evidence generation plan will refer and link to the sections of the NICE guidance document that summarise the existing evidence and describes the evidence gaps identified by committee. It will then propose how the evidence gaps can be addressed. It will be developed through a systematic approach, addressing practical considerations and challenges in generating new evidence.

4.17 The evidence generation plan is not a research protocol, a research or data collection contract, nor is it an undertaking from NICE to lead the subsequent data collection and analysis.

4.18 The evidence generation plan seeks to be an outline which the developer can use to produce a research protocol and engage with potential funders and evidence generation partners.

Developer created evidence generation plans

4.19 Evidence generation plans created by the developer and submitted to NICE for consideration will be welcomed. The evidence generation team will work with developers to support their creation of plans.

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