Technoleg Iechyd Cymru
Health Technology Wales

Health Technology Wales

Appraisal Process Guide

Contents

Abbreviations

ASCOT	Adult Social Care Outcome Toolkit
AWMSG	All Wales Medicines Strategy Group
BNF	British National Formulary
CEVR	Center for Evaluation of Value and Risk in Health
eMIT	electronic Market Information Tool
EQ-5D	EuroQol Five-Dimensions
ICER	Incremental Cost-Effectiveness Ratio
MIMS	Monthly Index of Medical Specialities
NICE	National Institute for Health and Care Excellence
PSSRU	Personal Social Services Research Unit
QALY	Quality-Adjusted Life Year
SF-36	36-Item Short Form Health Survey

1. Purpose of this document

This guide describes the processes that Health Technology Wales follows when carrying out appraisals for health and social care.

The aim is to provide a high-level summary of our methods and processes in an accessible and transparent format for anyone with an interest in our work, to support engagement with the organisation and contribution to our work.

A shorter, plain language summary of our process is also available on our website.

2. Introduction to Health Technology Wales and our process

Health Technology Wales is a national health technology assessment body working to improve the quality of health and social care by issuing independent, authoritative guidance to health and social care providers in Wales, based on existing evidence regarding effectiveness and cost effectiveness. We do not undertake any primary research.

Our remit covers the evaluation of health and social care technologies and models of care and support. For health, this could include medical devices, diagnostics, procedures, and interventions by allied health professionals; Health Technology Wales does not appraise medicines. For social care, this could include equipment and environmental design, or different models of care for supporting families, children, adults, and the workforce.

This document explains the process we use for appraisals, including:

- Initial topic submission and selection
- Production of a Topic Exploration Report
- Selection of topics for further work, in the form of an Evidence Appraisal Report
- Production of an Evidence Appraisal Report
- Production of guidance

It also describes what happens after an appraisal: how we monitor the impact and adoption of our guidance, and the circumstances under which we might change or update guidance.

Our overall process is summarised in the flow diagram below.

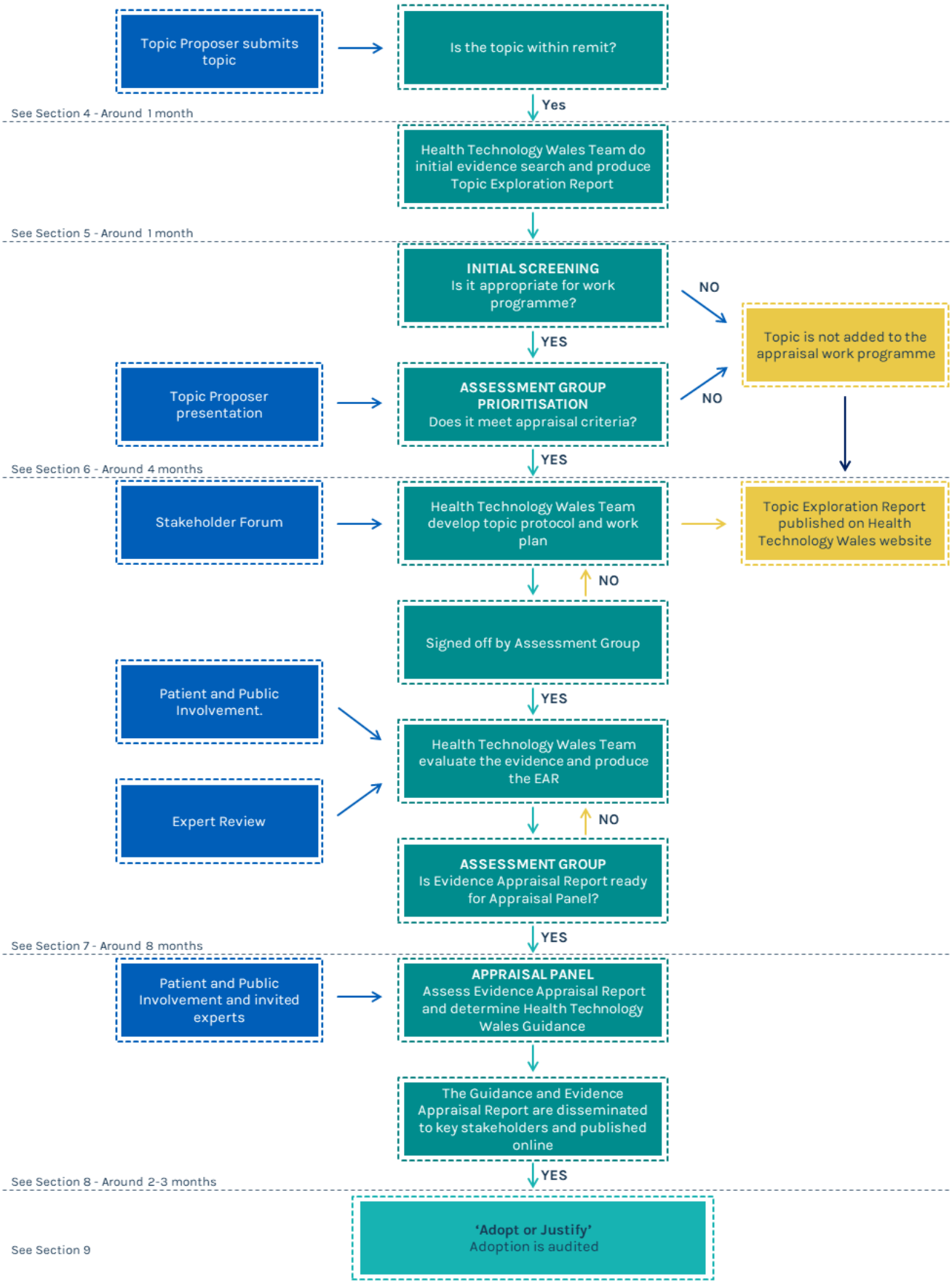

Figure 1 – Appraisal process flow diagram

3. Who is involved and how

This section outlines the people or groups involved in our appraisal work. Their input will vary depending on the stage of the process, and will be detailed under the relevant process section of this document. Governance requirements such as declarations of interest and confidentiality statements are also covered.

3.1 Participants in the process

3.1.1 Health Technology Wales decision-making committees, advisory groups, and staff

3.1.1.1 Health Technology Wales staff

Health Technology Wales staff are a multidisciplinary group made up of Researchers, Health Economists, Information Specialists, Patient and Public Involvement professionals, and staff with expertise in communications, project and programme management, and administration. Specific project teams are established for each appraisal topic.

3.1.1.2 The Assessment Group

The Assessment Group oversees the production of Health Technology Wales appraisal outputs, ensuring methodological and scientific rigour in our work and adherence to agreed processes. The Assessment Group also advises us on what technologies and models of care and support should be selected for appraisal, and agrees the research methods for each appraisal.

Current membership of the Assessment Group, along with terms of reference, is published on the Health Technology Wales website. The membership of the Assessment Group is determined by the Health Technology Wales Chair and Health Technology Wales Director, normally via nominations invited from relevant peer groups. As far as possible, membership includes representatives offering geographical spread across North, South West, South East, and Mid Wales, and representatives from both health and social care, including from each Health Board, the Welsh Ambulance Services NHS Trust, the Welsh Health Specialised Services Committee, local authorities, and other social care organisations. Membership also includes two Public Partners from the Patient and Public Involvement Standing Group. We are committed to the values of equality, diversity, and inclusion, and we welcome nominations for membership of the Assessment Group from all sectors of the community.

Although the Assessment Group seeks the views of organisations representing health and social care professionals, patients, carers, people accessing care and support, companies, and government, its guidance is independent.

3.1.1.3 The Patient and Public Involvement Standing Group

Our Patient and Public Involvement Standing Group advises us on all aspects of our Patient and Public Involvement work.

Patient and Public Involvement Standing Group members have diverse experience and knowledge of the involvement that patients and people who access care and support can have in research, Patient and Public Involvement in health technology assessment, patient networks

and organisations across the UK and internationally, patient consultancy, and Patient and Public Involvement processes across a range of different organisations.

Current membership of the Patient and Public Involvement Standing Group, along with terms of reference, is published on the Health Technology Wales website.

3.1.1.4 The Appraisal Panel

The Appraisal Panel is the decision-making body of Health Technology Wales that generates evidence-based guidance on health and social care technologies and models of care and support. This guidance is used to inform decisions about implementation and adoption of technologies and models of care and support appraised across Wales.

We publish current membership of the Appraisal Panel, along with terms of reference, on our website. The membership of the Appraisal Panel is determined by the Health Technology Wales Chair and Health Technology Wales Director, normally via nominations invited from relevant peer groups. As far as possible, membership includes representatives offering geographical spread across North, South West, South East, and Mid Wales, and representatives from both health and social care, including from each Local Health Board, the Welsh Ambulance Services NHS Trust, the Welsh Health Specialised Services Committee, local authorities, and other social care organisations. Membership also includes three Public Partners from the Patient and Public Involvement Standing Group. We are committed to the values of equality, diversity, and inclusion, and we welcome nominations for membership of the Appraisal Panel from all sectors of the community.

Although the Appraisal Panel seeks the views of organisations representing health and social care professionals, patients, people who access social care and support, unpaid carers, industry, and government, its guidance is independent.

3.1.2 Stakeholders outside of Health Technology Wales

3.1.2.1 Topic proposer

The topic proposer is the person who originally suggested the topic for the appraisal work programme. Anyone can suggest a topic that they think we could appraise, and we receive suggestions from people and organisations with a wide range of backgrounds, including clinicians or other health and social care professionals, commissioners, third sector organisations, industry representatives, academics, and the general public. Topics are normally submitted via a form on our website. We also use the NHS Innovation Service to identify potential topics. In this case, the person who submitted the topic to the NHS Innovation Service would act as the topic proposer.

3.1.2.2 Industry representatives

These are representatives of manufacturers or suppliers of technologies relevant to the topic being appraised. They may be identified from our own research, or because they have registered an interest in a particular topic. Our advisory Industry User Group may also assist with identifying relevant organisations (see Glossary).

3.1.2.3 Subject experts

Subject experts provide independent advice and scrutiny during our work. Depending on the type of topic being considered, they can be health and social care professionals, academic researchers, or other groups or individuals with expertise and experience relevant to the topic being considered. We identify subject experts from our own research and networks, or because they have registered an interest in a particular topic. As far as possible, we endeavour to include representatives from all relevant disciplines, offering geographical spread across Wales, as well as from other parts of the UK. We also approach relevant organisations or individuals representing health and social care professionals (for example, Royal Colleges, societies, clinical networks, directors of services in social care) and any relevant groups developing clinical and social care guidelines, or public health guidance.

3.1.2.4 Patient and Public Involvement representatives

Patient and Public Involvement provides a valuable dimension to our work. Patient and Public Involvement can include individual patients, carers, and people who access care and support, along with organisations representing them, as well as public communities and patient groups.

3.1.2.5 Wider stakeholders

Depending on the topic, we may also involve other Welsh, UK-based, or international stakeholders. This can include collaboration or data sharing with other UK health technology assessment bodies during topic identification and when planning an appraisal, and consulting stakeholders with a key role in implementing our guidance (such as Welsh Government, Local Health Boards, local authorities, or other social care organisations such as providers or third sector organisations), either during an appraisal or after guidance is produced.

3.2 How participants are involved

3.2.1 Health Technology Wales decision-making committees, advisory boards, and staff

3.2.1.1 Health Technology Wales Staff

For each potential appraisal, Health Technology Wales staff:

- Carry out initial assessment of suggested topics to determine whether they are within our remit;
- Carry out exploratory research into the available evidence (a Topic Exploration Report) to inform the Assessment Group's decision on which topics should be selected for appraisal;
- Identify and liaise with specific stakeholders who can contribute to the appraisal process;
- Organise and manage meetings of the Assessment Group, the Appraisal Panel, the Patient and Public Involvement Standing Group, and our other relevant groups;
- Research and write the Evidence Appraisal Report;
- Support the Appraisal Panel in producing guidance on a topic, providing them with input and advice on interpretation of the evidence;
- Manage the timelines for each appraisal, communicating any changes to our key groups and to other stakeholders.

3.2.1.2 The Assessment Group

The Assessment Group:

- Advises Health Technology Wales on topic selection and prioritises topics for the appraisal work programme when necessary;
- Advises on potential sources of topic identification;
- Agrees the research question(s) to be answered during an appraisal and the methods to be used;
- Reviews and quality assures Evidence Appraisal Reports on behalf of the Appraisal Panel. Assures the Appraisal Panel on methodological and scientific rigour;
- Agrees on stakeholder input and consultations required during an appraisal;
- Reviews consultation comments on Evidence Appraisal Reports, and advises Health Technology Wales on revisions and further actions needed;
- Assesses whether the Evidence Appraisal Report should be considered by the Appraisal Panel and guidance developed;
- Inputs into changes or updates to our methodology and processes.

Two Public Partners sit on the Assessment Group. Public Partner attendance at the Assessment Group is essential to:

- Ensure that any decisions made do not, or will not, unfairly impact on patients, people who access social care, unpaid carers, individuals, and public communities;
- Ensure that appropriate measures are taken to address issues of interest to patients, people who access social care, unpaid carers, and the public;
- Have oversight of our Patient and Public Involvement work;
- Help ensure that the views of members of the public, carers, individuals and patients, and their families are considered.

3.2.1.3 The Patient and Public Involvement Standing Group

The Patient and Public Involvement Standing Group has three main areas of work:

- Determining the mechanism of Patient and Public Involvement for all new topics,
- Advising on our ongoing Patient and Public Involvement activities, and
- Contributing to the writing of plain language summaries for all topics.

In addition, the Patient and Public Involvement Standing Group supports the development of our Patient and Public Involvement process, mechanisms, documents and tools, events, and training. Members also assist with our engagement activities and advise on accessibility, diversity, and inclusivity of our Patient and Public Involvement and wider organisational activities.

Nominated Public Partners from the group are also members of the Assessment Group or the Appraisal Panel. If nominated Public Partners are not able to attend an Assessment Group or Appraisal Panel meeting, their place can be deputised by any member of the Patient and Public Involvement Standing Group to make sure this perspective is considered appropriately at meetings.

3.2.1.4 The Appraisal Panel

The Appraisal Panel:

- Considers the case for adoption of health and social care technologies and models of care and support that are undergoing appraisal. The Appraisal Panel provides recommendations in the form of Health Technology Wales guidance, based on:
    - the evidence presented within our Evidence Appraisal Report,
    - expert input, via comments on our Evidence Appraisal Report and discussions with independent experts attending the Appraisal Panel meeting,
    - Patient and Public Involvement, provided via the mechanisms determined by our Patient and Public Involvement Standing Group, and
    - the context of the topic within health and social care in Wales.

Three Public Partners sit on the Appraisal Panel on a rota basis, so that at least two representatives are present for each meeting. Public Partner attendance at the Appraisal Panel is essential to ensure:

- All elements of the Patient and Public Involvement work gathered in the Evidence Appraisal Report are effectively and properly addressed by the Appraisal Panel during proceedings;
- There is governance over contributions from invited patient representatives;
- Any decisions made do not, or will not, unfairly impact on patients, carers, people accessing care and support, and public communities;
- The views of members of the public, unpaid carers, individuals, patients, people who access social care, and their families are considered when decisions are made.

3.2.2 Stakeholders outside of Health Technology Wales

3.2.2.1 Topic proposer

As and when required by our project team, the topic proposer may be engaged in the development of the protocol, as well as assisting with any queries Health Technology Wales staff may have at other stages. We will also invite them to participate in the expert review stage of the appraisal (see Section 7.7.3), subject to relevant declaration of interest and confidentiality paperwork being completed.

The topic proposer may opt out of the process at any time, although we will still conduct the appraisal.

3.2.2.2 Industry representatives

We will invite manufacturers or suppliers of relevant technologies to participate in the expert review stage of the appraisal (see Section 7.7.3), subject to relevant declaration of interest and confidentiality paperwork being completed. Earlier in the appraisal process, we may seek their input on an ad-hoc basis in relation to protocol development and to clarify any other queries.

There is no requirement for industry experts to supply us with an evidence dossier for an appraisal. As with all our stakeholders, we welcome submission or highlighting of potentially relevant evidence, and we will consider this for inclusion in an appraisal on a case-by-case basis in line with the methods used to select evidence.

Please see expert review guidance (Section 7.7.3) for further details on eligibility and requirements.

3.2.2.3 Subject experts

Subject experts provide a view on the technology or model of care and support in relation to current practice, and help to put evidence used during the appraisal into context by, for example, commenting on its direct relevance to practice in Wales, and commenting on the importance of any uncertainties or limitations of the evidence.

We will invite subject experts to participate in the expert review stage of the appraisal (see Section 7.7.3), subject to relevant declaration of interest and confidentiality paperwork being completed. We may also invite them to attend the Appraisal Panel meeting to act as an independent expert. During this meeting, they will have the opportunity to give their views on the appraised topic and to respond to any queries that Appraisal Panel members may have. Subject experts are not involved in drafting or agreeing guidance, which is the sole responsibility of the Appraisal Panel.

Earlier in the appraisal process, we may seek subject expert input on an ad-hoc basis in relation to the protocol development and to clarify any queries.

Invited experts can opt out of the process at any time, although we will still conduct the appraisal.

Please see expert review guidance (Section 7.7.3) for further details on eligibility and requirements.

3.2.2.4 Patient and Public Involvement representatives

Patient and Public Involvement seeks to incorporate the views, experiences, perspectives, and values of patients, individuals, carers, and their families to the appraisal process. We will actively seek to engage Patient and Public Involvement input into our appraisals though our Patient and Public Involvement mechanisms, but also welcome expressions of interest from individuals and groups. We also welcome topic submissions from patients, individuals, carers, and their families.

3.2.2.5 Other stakeholders

All stakeholders can register an interest in a topic via our website.

We distribute completed guidance to all stakeholders registered for our guidance alerts, as well as key NHS peer groups. We also publish guidance on our website and disseminate it via our social media channels.

3.3 Declarations of interest and confidentiality

To ensure our appraisals are as unbiased and transparent as possible, we require self-reported declarations of interest from all stakeholders involved in the process. This includes all members of our advisory and decision-making committees and staff, as well as anyone contributing to an Evidence Appraisal Report as a topic or industry expert, or from a Patient and Public Involvement perspective.

Table 1 provides an overview of how we process relevant declarations of interest.

Table 1 – Process for handling relevant declarations of interest

Potentially relevant declaration of interest from:	Action
Member of Health Technology Wales staff	Considered by Health Technology Wales staff with support from the Assessment Group if required. A staff member will not be involved in the project team for an appraisal where there is deemed to be a conflict of interest.
Member of decision-making and advisory groups	Considered by the Chair of the relevant group. If required, members with a relevant declaration of interest will not take part in discussion of the relevant appraisal and may be required to leave the meeting for these discussions.
External reviewer of the Evidence Appraisal Report	Declarations of interest from subject experts or others invited to review the Evidence Appraisal Report will be reviewed by the Health Technology Wales project team, who will ensure these are clearly documented. Declarations of interest do not prevent stakeholders from reviewing the Evidence Appraisal Report and submitting comments and feedback, but they are taken into consideration when comments are reviewed and actioned. Any declarations of interest will be documented in the collated summary of responses and shared with our decision makers. They may also be included in published documentation but will not be specifically attributed to a named individual.

We also require confidentiality agreements from all staff and committee members, as well as anyone with access to draft copies of the Evidence Appraisal Report, such as those participating in expert review.

4. Initial topic submission and selection

This section summarises the first stage of our appraisal process, outlining what topics are covered within our remit and how we receive topics for consideration on our appraisal work programme.

4.1 Health Technology Wales's remit

Our remit covers any technology or model of care and support in health and social care that is not a medicine.

For health, this could include things like:

- medical devices,
- diagnostics, f
- procedures,
- interventions by allied health professionals.

For social care, this could include things like:

- equipment,
- different models for supporting families, children, adults, and the workforce.

In Wales, appraisal of medicines is done by either the All Wales Medicines Strategy Group (AWMSG) or the National Institute for Health and Care Excellence (NICE).

4.2 Sources of topics

4.2.1 Suggest a Topic form

Anyone can suggest a topic for Health Technology Wales appraisal through the Suggest a Topic form on our website.

We receive suggestions from a wide range of people, including the public. Our Suggest a Topic form aims to be suitable for everyone and should take around 15 minutes to complete.

Previous suggestions have come from people:

- working in health or social care,
- accessing health or social care services,
- providing care to a family member or friend,
- developing or researching technologies and models of care and support for health or social care,
- supporting people through third sector and voluntary organisations.

Health Technology Wales staff are available to discuss potential topics with topic proposers before submission; however, all topics will still need to be formally submitted via the online Suggest a Topic form, or via the NHS Innovation Service (see Section 4.2.2).

4.2.2 NHS Innovation Service

Companies or developers of a technology or model of care and support can also submit a topic to us through the NHS Innovation Service.

We review the NHS Innovation Service whenever we receive a notification that a relevant topic has been submitted. Topics may also be referred to other health technology assessment organisations in the UK, in which case we will liaise with these bodies to ensure we are not duplicating each other's work.

We will consider all topics received via the NHS Innovation Service in line with the process outlined in Section 4.3, as with any other topic referrals.

We will communicate with topic proposers for topics received through the NHS Innovation Service via the NHS Innovation Service portal.

4.2.3 Other sources of topics

We also seek topics through routes other than the referrals described above. We monitor guidance outputs of other UK health technology assessment organisations and consider where similar guidance may be useful for health and social care in Wales. We also consult with stakeholders on broader priorities or areas of unmet need for health and social care in Wales and use this to identify potential topics.

When identified, we consider such topics in line with our standard topic prioritisation processes as outlined in Section 6.

4.3 Topic selection for further exploration

4.3.1 Topic eligibility for topic exploration

Topics must meet certain criteria to be potentially suitable for appraisal. We will consider a topic for appraisal if:

- It is a technology or model of care and support that falls within our remit,
- It has the potential to directly impact patients, people who access social care, or unpaid carers, and
- It has appropriate regulatory approval, or is expected to have regulatory approval within the next 12 months.

A topic will not usually be considered suitable for appraisal if:

- It is a medicine,
- Its use does not directly influence the outcomes, wellbeing, or experience of patients or people accessing care and support,
- It is still a prototype or still under development.

Although we would not usually consider topics that meet any of these exclusion criteria suitable for full appraisal, we may still produce a Topic Exploration Report (see Section 5). This means we can provide health and social care stakeholders in Wales with a high-level evidence overview, without developing an Evidence Appraisal Report or guidance.

4.3.2 Reviewing topic submissions for eligibility and further appraisal

Health Technology Wales staff review new topic submissions and use them to determine whether the topic meets our eligibility criteria (see Section 4.3.1). A member of our team will contact the topic proposer if further clarification or information is needed to determine this.

If the topic meets our eligibility criteria, the topic proceeds to topic exploration and a Topic Exploration Report is produced.

We aim to review topics submitted within a two-week period; however, decision making may be delayed if there are any queries or uncertainties that need to be explored by carrying out initial background research, or by contacting the topic proposer or other stakeholders.

If a topic does not meet our eligibility criteria, we may flag the support available via our Scientific Advice Service (see Glossary).

5. The Topic Exploration Report

This section outlines the first type of report we produce on a topic, the Topic Exploration Report. This report is researched and written by a Health Technology Wales Researcher. Health Technology Wales staff and the Assessment Group use the Topic Exploration Report to determine whether further appraisal work is appropriate, and whether it would be likely that guidance could be produced using available evidence.

5.1 Topic Exploration Report contents

Topic Exploration Reports provide a high-level summary of a topic and an overview of the evidence available. The main objectives are to:

- Determine the quantity of evidence available for a technology or model of care and support,
- Identify any gaps or uncertainties in the evidence,
- Inform decisions on whether the topic warrants further appraisal by Health Technology Wales, in the form of an Evidence Appraisal Report.

The Topic Exploration Report focusses on the quantity of evidence, the type of evidence (for example, systematic reviews, randomised controlled trials, observational studies) and any uncertainties or gaps in the evidence. If gaps are identified, the Researcher will check for any ongoing studies that may address these gaps.

The Topic Exploration Report will list any evidence identified, typically in the following areas:

- Health technology assessments and guidance,
- Evidence reviews and economic evaluations,
- Individual studies,
- Ongoing research.

During preparation of the Topic Exploration Report, Health Technology Wales staff will also draft potential research questions and evidence selection criteria for the topic if it were to progress to full Evidence Appraisal Report.

5.2 Topic Exploration Report process

Searches for evidence to inform a Topic Exploration Report are carried out by a single Researcher, with Information Specialist input if needed. The purpose of the search is to:

- Ascertain whether there is published evidence that could be used to address the question of interest as understood from the topic suggestion;
- Provide a non-exhaustive overview of the types of evidence that exist, and any uncertainties or gaps in the evidence.

We gather evidence by a high-level scan of the literature. This is not a systematic search, although similar sources to those used for a full systematic literature search would be used. This means that a Topic Exploration Report may not cover all the evidence that exists on a topic, particularly in cases where the evidence base is extensive. Instead, the aim is to give an overview of the evidence that exists, sometimes with a focus on sources that are most recent or relevant. Searches and the evidence presented in the Topic Exploration Report may also prioritise certain types of evidence. For example, if we identify robust and recent sources of secondary evidence that address the question of interest, the Topic Exploration Report may only report these and not the findings of individual studies. Each Topic Exploration Report will briefly explain the methodology used for searching and justify any inclusion or exclusion of sources of evidence.

In some cases, the Researcher may contact the topic proposer to clarify any outstanding queries about the topic before or during topic exploration. Where initial searching indicates that the evidence covers a wide range of different populations, settings, or comparisons, we may also work with the topic proposer to identify one or more areas of focus. It may also be appropriate for the Researcher to contact other stakeholders if they have any specific questions at this stage.

The completed Topic Exploration Report is then reviewed for quality assurance purposes by a senior member of our team and any required amendments completed.

It takes around four weeks for a Topic Exploration Report to be prepared. We send the draft Topic Exploration Report to the topic proposer before publication. This is an opportunity for the topic proposer to highlight any perceived inaccuracies or errors in the report, including interpretation of the evidence, and to highlight any additional sources of evidence they believe should be included. The topic proposer will be given two weeks (10 working days) to respond. Comments on the Topic Exploration Report should be submitted in writing to ensure they are documented clearly along with our responses to them.

If the topic proposer is not best placed to comment on the report (for example, if they are not an expert in the use of the technology or model of care and support, or the relevant area of health and social care), another representative may comment on the Topic Exploration Report and respond to our queries. This person could be nominated by the topic proposer or sought by Health Technology Wales.

Health Technology Wales staff will review any comments and, if appropriate, revise the Topic Exploration Report before publication. If necessary, Health Technology Wales staff will discuss any proposed changes with the Assessment Group. We may also send the topic proposer a summary of responses to their comments and any changes made.

We will publish finalised Topic Exploration Reports on our website once they have been considered for prioritisation onto the appraisal work programme by the Assessment Group, along with the outcome of whether a topic has progressed or not. Timescales for publication will vary as this will be dependent on when a topic has been reviewed by the Assessment Group at a Health Technology Wales prioritisation meeting. We will send a notification email to the topic proposer to advise when the report is available online.

6. Topic selection and prioritisation for the appraisal work programme

The next stage is to use the Topic Exploration Report to establish if the topic is suitable for full appraisal.

In circumstances where the number of topics suitable for appraisal exceeds the capacity of the appraisal work programme, topics are ranked by their likely impact and importance to health and social care in Wales, and prioritised accordingly.

The Topic Exploration Report is used to establish if the topic is suitable for full appraisal. Reasons a topic may be deemed unsuitable include:

- There is insufficient evidence for an appraisal,
- There is ongoing research likely to be critical to decision making,
- The same topic is currently undergoing appraisal by another UK health technology assessment organisation.

In some cases, we may decide not to progress a topic at this stage. This may be where there is very little evidence, the evidence indicates the technology or model of care and support is unlikely to offer advantages over current care, or the topic proposer and Health Technology Wales staff are unable to define a suitable research question for a more detailed evidence search. Whilst a topic proposer's input will be considered, the Assessment Group's decision is final.

Where appraisal is ongoing elsewhere in the UK, we do not commence work until this work has been completed, to avoid duplication and research waste. Depending on the type of appraisal, we then consider whether its findings are applicable in Wales, or whether the work can be adapted to produce guidance for Wales.

If a topic is considered suitable for full appraisal based on initial screening, it is then considered in more detail by Health Technology Wales staff, who will assess it in terms of:

- Impact: The potential for the technology or model of care and support to have an impact on outcomes (benefits and harms);
- Budget impact: The impact of the technology or model of care and support on health and social care spending;
- Burden of disease: The nature of the condition involved, and the size of the population that would be affected by the technology or model of care and support;
- Stakeholder interest: The level of known or anticipated demand for the technology or model of care and support, and the likelihood that advice will be adopted;
- Equity: The potential of the technology or model of care and support to introduce, increase, or decrease equity.

In addition to monthly Assessment Group meetings, we hold a separate prioritisation meeting on a quarterly basis. It is at this meeting that the Assessment Group agrees which topics should be taken onto the appraisal work programme, and the priority with which they should be considered.

A summary of all topics considered for prioritisation is submitted to the Assessment Group, along with copies of Topic Exploration Reports for review.

The Assessment Group will consider all submitted topics, including those which did not progress through initial screening, to ensure the Assessment Group agree with the recommendations of Health Technology Wales staff.

To aid the prioritisation process, we may invite topic proposers for potential topics to the meeting to briefly introduce and discuss their suggested technology or model of care and support and the potential benefits of an appraisal, undertaking a question-and-answer session with Assessment Group members.

Topics are discussed in detail, and a decision is made by the Assessment Group based on the Topic Exploration Report content, our prioritisation assessment, and discussion with the topic proposer.

The Assessment Group may make one of the following decisions, outlined in Table 2.

Table 2 – Potential topic outcomes following Assessment Group discussion

Topic prioritised for Health Technology Wales appraisal	The topic will progress to the appraisal work programme.
Topic is not suitable for Health Technology Wales appraisal	The topic will not progress past the Topic Exploration Report stage. The topic proposer is welcome to resubmit the topic for further assessment should they become aware of any changes in the future, for example, publication of new evidence.
Further information is needed	Topic is potentially suitable for Evidence Appraisal Report and guidance, but more information is needed before a final decision can be made. Questions will be addressed outside of the meeting, and the topic will be reconsidered at a future prioritisation meeting.
Topic potentially suitable for appraisal, but not prioritised at this time	There may be occasions when a topic is potentially suitable for appraisal, but other topics under consideration are deemed a higher priority and there is not a slot on the appraisal work programme at that time. The topic will be reconsidered in the next prioritisation meeting.

Following the prioritisation meeting, we notify topic proposers of the Assessment Group's decision via email. We also publish the decision on our website alongside the completed Topic Exploration Report. This process can take around four weeks as queries are addressed and Topic Exploration Reports finalised for publication.

7. Production of an Evidence Appraisal Report

This section outlines the various stages of producing our second type of report, the Evidence Appraisal Report, and describes the information included in more detail.

Once a topic is selected for the appraisal work programme, an Evidence Appraisal Report will be developed. The Evidence Appraisal Report summarises:

- The context or area of unmet need, and how the technology or model of care and support aims to improve outcomes in this area;
- The background on current care in this area, and if this varies within Wales or across the wider UK;
- The synthesis of available evidence on the effectiveness of the appraised technology or model of care and support;
- The available economic evidence on the technology or model of care and support and any economic analysis carried out by Health Technology Wales;
- The Patient and Public Involvement input and evidence relevant to the topic;
- Any other relevant factors that would need to be considered if the technology or model of care and support were to be adopted.

To identify evidence for the report, we conduct a type of review called a rapid evidence review. Whilst there is no universally accepted definition of rapid evidence reviews, it is generally accepted that they involve a more streamlined, accelerated version of systematic review (see Glossary).

The Evidence Appraisal Report is considered, along with other supporting documents and information, by our Appraisal Panel in the development of Health Technology Wales guidance.

7.1 Planning the appraisal

Once a topic is accepted onto the appraisal work programme, a team will be appointed comprising:

- a Health Economist
- a Senior Health Economist
- a Health Services Researcher
- a Senior Health Services Researcher
- an Information Specialist
- a Patient and Public Involvement Manager
- a Communications Manager
- a Project Manager.

This is referred to as the Health Technology Wales project team.

The team will start by developing a detailed plan for the appraisal. This includes defining the scope of the project by drafting a topic protocol and economic plan, determining the most appropriate methods for engaging with patients, people who access care and support, and the public, and establishing timescales for the project.

It normally takes around six weeks from a topic being accepted onto the appraisal work programme to plans being agreed and finalised, though this may vary dependent on Assessment Group meeting dates.

7.1.1 Topic protocol

The topic protocol outlines how we plan to search for and identify evidence on a topic that has been accepted onto the appraisal work programme. This ensures the evidence included, and the justification for this, is transparently documented and selected in a way that minimises bias.

The main objectives of the topic protocol are to:

- Give a brief overview of the topic in question,
- Outline the proposed research question,
- Provide the study selection criteria, which are used to identify relevant evidence.

A protocol will usually include one review question. In exceptional cases, two related questions may be considered. The title of the Evidence Appraisal Report reflects the content of the review question(s).

7.1.1.1 Protocol contents

The protocol provides specific detail on what is in and out of scope for the topic, covering areas including selection criteria, study design, and the type of evidence that will be considered.

The selection criteria normally include the following:

- The target population.
- The intervention of interest, that is, the technology or model of care and support being appraised.
- The comparator or comparison being made. Usually, comparators are limited to those that best represent standard care in Wales.
- The outcomes of interest. As we undertake rapid evidence reviews, we focus on the outcomes that are considered most important and relevant for decision making in Wales.
- A reference standard (if considering diagnostics).

In addition to being used to select evidence, the protocol determines what evidence will be reported in the Evidence Appraisal Report: reporting on effectiveness of a technology or model of care and support should encompass all elements of the eligibility criteria (for example, all possible target populations, outcomes, and possible control or comparison groups of interest) specified in the protocol. Where no evidence is found for a particular criterion, this should be clearly stated alongside the evidence found.

Topic protocols are agreed with our Assessment Group to ensure they are methodologically robust and their scope is appropriate. On occasion, based on Assessment Group input, we may seek stakeholder advice on the development of the protocol, requesting views from the stakeholders or the topic proposer on planned criteria. In all cases, we circulate draft protocols to our Stakeholder Forum (see Glossary) for comment to ensure they reflect the priorities of health and social care in Wales.

7.1.2 Economic plan

We carry out reviews of the existing economic literature as part of the appraisal process. Where the existing economic evidence is inadequate or inconclusive, additional economic analysis is often required to assess cost effectiveness. However, conducting de novo economic analyses is time consuming and so it may not be practical to do this for every topic we appraise. We therefore

need to focus our efforts on those topics where economic analysis has the potential to be of most value.

We develop an economic plan to determine the priority level for a topic and this informs the economic analysis that will be undertaken. The economic plan provides a clear framework for making considerations on the priority level, as well as an outline of the proposed methods for evaluating cost effectiveness. This framework considers the expected budget impact, whether the cost effectiveness of the intervention (or technology) is currently uncertain, and whether this uncertainty could feasibly be reduced by undertaking de novo economic analysis.

7.1.3 Patient and Public Involvement mechanism

Patient and Public Involvement is a crucial aspect of all our appraisal work. The most appropriate way to undertake Patient and Public Involvement will vary for each topic.

When we accept a topic onto the appraisal work programme, the Patient and Public Involvement Standing Group determines what the appropriate mechanism of Patient and Public Involvement is for that topic. This is called the Patient and Public Involvement mechanism plan. At this stage, we may engage early with organisations representing patients and people who access care and support to inform our decision on the most appropriate approach. In some cases, the Patient and Public Involvement Standing Group will decide that a topic is unsuitable for detailed Patient and Public Involvement activity.

The Patient and Public Involvement mechanism allows for several approaches to gathering Patient and Public Involvement for an appraisal, including:

- submissions from patients, people who access care and support, and unpaid carers (via a representative organisation),
- questionnaires or surveys (via a patient or carer organisation),
- focus groups (via a patient or carer organisation),
- literature searches that look specifically for Patient and Public Involvement evidence.

For each appraisal, the Patient and Public Involvement Standing Group can select one or more approaches, and we can engage with multiple organisations representing patients and people who access care and support. If the chosen approaches are unsuccessful, for example if we are unable to engage with suitable organisations representing patients and people who access care and support, the Patient and Public Involvement Standing Group may decide to amend the mechanism planned. This flexibility ensures that our appraisals include effective Patient and Public Involvement wherever possible and in the most appropriate form.

7.1.4 Timelines and project plans

All topics taken onto the appraisal work programme will receive a detailed project plan outlining key deadlines and milestones, in particular noting when the topic will be considered for guidance by our Appraisal Panel.

Factors considered when planning timelines include:

- Nature and complexity of the evidence review, economic analysis, and Patient and Public Involvement work required
- Anticipated volume and complexity of published evidence
- Any known external dependencies, such as publication of major studies that will impact findings

- Prioritisation of topics on the appraisal work programme
- Overlap with other topics on the appraisal work programme

7.1.5 Sign off

Around six to eight weeks after we have accepted a topic onto the appraisal work programme, the topic protocol, economic plan, Patient and Public Involvement mechanism, and proposed timelines are submitted to the Assessment Group for sign off. This is to ensure they reflect the priorities of health and social care in Wales, and are methodologically robust.

7.1.5.1 Protocol amendments

On occasions, it may be necessary to amend aspects of our proposed approaches and methods after the appraisal has commenced. Examples of when this could be necessary include:

- When input from subject experts indicates a need to focus on particular aspects of the planned research question (such as narrowing to a particular population where there is the most unmet need, or amending the outcomes for which data are collected and reported to ensure these are the ones that matter most to people).
- Where initial searches indicate the availability of high volumes of evidence, restricting the evidence that we search for or synthesise to focus on that which offers the most certainty, or is most relevant to decision making.
- Amending the planned evidence searches to ensure they identify evidence to inform health economic analysis, or planned mechanisms of Patient and Public Involvement.

Such changes may result in amendments to the protocol or economic plan. Any such changes will be agreed by the Assessment Group, and documented, along with the rationale for the amendments, in our published Evidence Appraisal Report.

7.2 Evidence identification

Once we have planned the methods for an appraisal, we need to identify as much relevant evidence as possible. This evidence can come from our own searches (see Section 7.2.1) or from other sources (see Section 7.2.2).

7.2.1 Searching for the evidence (literature searching)

We adopt a flexible approach for the searches we run to support the confines of our rapid evidence review timelines. Literature searches for our rapid evidence reviews aim to identify the best available evidence to address the review question, without producing an unmanageable volume of results. In this section we outline how we plan, execute, and document our literature searching activities.

7.2.1.1 Planning the search

Literature search strategies are directly informed by the selection criteria listed within the appraisal protocol.

7.2.1.2 Sources

Our Information Specialists have developed and maintain checklists specific to the type of search being undertaken, based on the characteristics of the technology or model of care and support, including whether it is used in health or social care settings. The checklists include core bibliographic databases (searched for all appraisals), specialised databases (used as and when considered appropriate to the topic or research area), and clinical trials registries, as well as relevant grey literature sources and websites. We have developed the checklists to ensure adequate coverage of the relevant literature and to balance comprehensiveness with pragmatism.

7.2.1.3 Writing and running the search

Searches are written and run by our Information Specialists.

As well as the protocol, other sources used to inform search development include the Topic Exploration Report and information provided by the topic proposer. We use these, and any relevant literature they contain, to develop specific search terms. We may also use other relevant published search strategies to inform our search strategy.

Development of the strategy is an iterative process that includes testing different potential search terms and checking the results for relevancy, as well as ensuring known relevant records are retrieved by the search. Quality assurance of literature search strategies is also undertaken, either internally within our Information Specialist team or via our external networks of information or subject specialists.

The final search strategy for each source is then run and the retrieved results downloaded or manually recorded. All the retrieved results are processed together and saved using reference management software.

7.2.1.4 Updating searches prior to publication

Literature searches for Evidence Appraisal Reports are re-run towards the end of the development timeline, to identify any further evidence that has been published since the search was last run.

7.2.1.5 Documenting the search

To ensure transparency and reproducibility, a search report is produced for the full search and update searches. This ensures that there is a record of all sources included in the search, as well as details of the database host and its date range. In addition, any key decisions pertaining to the search are recorded, including decisions on search methods, specific terms that are included or excluded, date limits, and study design filters used. The full search strategies for each source are also included along with numbers of results retrieved.

A summary of the key points from the search report (including the date of both the main and update searches) is included in the Evidence Appraisal Report. The Medline database search strategy is also included in the Evidence Appraisal Report and other search strategies are available on request.

7.2.2 Other sources

We will also consider, if appropriate, unpublished sources provided by stakeholders such as primary studies, economic modelling, or audit data. As with sources identified from the literature search, our project team will select what evidence should be included based on our inclusion and exclusion criteria.

We aim to make all information we use in our decision making publicly available, so we work with the authors or owners of unpublished sources to incorporate these data, without redaction, into the published version of our Evidence Appraisal Report wherever possible. Confidential information is considered in exceptional circumstances with appropriate justification and, where this is included, it is redacted from the published version of our documentation.

7.3 Selection, synthesis, and presentation of effectiveness evidence

For every appraisal, we carry out a rapid evidence review to assess the effectiveness of the appraised technology or model of care and support. This review aims to identify all relevant evidence, assess its reliability and certainty, and summarise the overall effectiveness of the technology or model of care and support, in comparison with current treatment or care options.

For our rapid evidence reviews, the key steps in the evidence selection and synthesis process are:

- Selecting sources of evidence from the literature search according to the predefined inclusion and exclusion criteria in the protocol (see Section 7.1.1);
- Extracting relevant data from relevant sources of evidence;
- Synthesising the evidence.

These steps are common to all rapid evidence reviews, whether conducted by Health Technology Wales or others. Earlier steps in the process, such as defining the research question, the topic protocol, and searching for evidence, are covered above in Section 7.1.1 and Section 7.2.1.

Our methods for evidence selection and synthesis are based on and adapted from the Cochrane Rapid Reviews Methods Group (Garritty et al. 2021) and the NICE guidelines manual (NICE 2023b). An overview of the process is given in the following sections.

7.3.1 Study selection

A single Researcher carries out evidence selection based on the criteria outlined in the protocol (see Section 7.1.1). During quality assurance, a second Researcher checks the choice of included studies against the protocol and may also check excluded full texts and reasons for exclusion.

7.3.1.1 Types of evidence included

We consider all types of evidence as potentially relevant to our rapid evidence reviews. However, we give priority to evidence that compares the effectiveness of a technology or model of care and support with current treatment or care options, and that measures effectiveness in as unbiased a manner as possible. For example, if we identify relevant and well-conducted randomised controlled trials, we may choose to report only results from these and not from non-randomised or observational studies. Similarly, where randomised controlled trials are unavailable or not feasible, we look for other sources of evidence from non-randomised or observational studies that compare the technology or model of care and support of interest with current practice or

standard care. We will usually only include data from single-arm studies (where there is no control group) if no comparative evidence is available. For appraisals relating to social care topics, it may be appropriate to include UK-based non-randomised or observational studies alongside randomised controlled trials to explore the generalisability of findings.

We will also prioritise evidence from well-conducted secondary studies, such as systematic reviews or health technology assessments undertaken by other agencies, where these are available. Depending on their exact relevance to our work, they can be used as a source of existing individual studies (helping to limit the amount of literature searching carried out by our Researchers) or as a source of study design and outcome data to be used directly in our own evidence synthesis.

7.3.2 Data extraction

A single reviewer extracts data from selected, relevant studies. Data extraction is limited to a minimal set of required data items, usually covering the design of each study, the characteristics of study participants, and the outcomes measured. If necessary, a pilot of data extraction is done to resolve or clarify any issues or uncertainties.

Where available, the reviewer uses data from existing relevant and well-conducted systematic reviews to reduce the time spent on study selection and data extraction. For example, where a relevant and well-conducted systematic review is found, we may report the findings from this review and only search for and include individual studies published since the searches for this review were carried out.

During quality assurance (see Section 7.7.1), a second Researcher checks at least a proportion of data extraction. Volume of evidence and timescales for review production mean checking of all data is not always possible.

7.3.2.1 Assessment of certainty of the evidence

Critical appraisal is not formally reported using tools or checklists, and full risk-of-bias judgements for each source of evidence are not documented. However, an informal assessment is made by members of the Health Technology Wales project team, and any issues with risk of bias or evidence certainty are reported either alongside study details or as part of the Conclusions and Summary.

7.3.3 Synthesis

Evidence is usually synthesised narratively. Meta-analysis adds to the time and resource needed to conduct an evidence review, so we only carry out meta-analysis when it is feasible, appropriate, and relevant to decision making, for example:

- An existing meta-analysis is available and it is appropriate and feasible to update it to incorporate any newer individual studies published since it was carried out.
- An existing meta-analysis is available but includes studies that are not relevant to our evidence review, and it is appropriate and feasible to carry out pooled analysis using only the studies of relevance to our review.
- There are multiple individual studies that are similar enough in their characteristics and design to minimise the potential for heterogeneity and report consistent outcomes that can be pooled without data transformation.

The way that effectiveness evidence is structured in each Evidence Appraisal Report will vary, depending on the topic, the type of evidence, and the volume of evidence. However, all Evidence Appraisal Reports include:

- The selection criteria used to search for and identify relevant evidence for the review.
- An explanation of the relevant evidence identified, including any decisions on how existing systematic reviews or other sources of secondary evidence have been adapted, and decisions on whether to include only studies of a certain design.
- The design and characteristics of the evidence, including aspects that affect their reliability, certainty, or relevance to the review question.
- The evidence available for each outcome of interest, and the sources from which this was derived.
- Judgements on the overall certainty and reliability of the evidence, including any 'evidence gaps' where no or very limited evidence was found to address part of the review question or decision problem.

7.4 Economic evidence

Our Evidence Appraisal Reports include a review of existing economic evidence identified as part of the rapid evidence review and an overview of any original economic analyses undertaken to inform the review question. Both the critical appraisal of existing studies and the development of original economic analyses are informed by the NICE Reference Case (NICE 2013).

7.4.1 Types of economic evaluation

Economic evaluations aim to provide a comparative analysis of alternative courses of action in terms of both their costs and consequences (Drummond et al. 2015). However, economic analyses vary in terms of the costs and consequences they consider, and these differences can be used to classify the different types of analysis. Different decision problems may merit different types of economic evaluation.

In situations where a new intervention (or technology or model of care and support) is known to be associated with higher effectiveness than current standard care, a simple cost analysis may be the only requirement. However, if the intervention is also associated with a higher cost, a more complex modelling approach, such as cost–utility analysis, may be necessary.

The type of economic evaluation that we undertake depends on the level of available evidence and the expected outcomes of the new intervention. The main types of economic evaluations are described below:

- Cost–utility analysis: Consequences are expressed in terms of quantity and quality of life using quality-adjusted life years (QALYs).
- Cost-effectiveness analysis: Consequences of interventions are measured in non-monetary terms using a single outcome. Interventions are compared as cost per unit of effectiveness (for example, cost per life year gained).
- Cost–consequence analysis: Costs and consequences of different interventions are compared but outcomes are not summarised in a single measure or in financial terms.
- Cost–benefit analysis: Costs and outcomes of an intervention are expressed in monetary terms.
- Cost-minimisation analysis: Costs of interventions that are equally effective are compared to determine the least costly approach.

7.4.1.1 Choice of comparator

An economic evaluation should include all relevant comparators to the intervention in question. It is particularly important to include those interventions being routinely used in the NHS and in social care in Wales.

7.4.1.2 Perspective of analysis

The NHS and personal social services perspective will be adopted in most economic analyses. This perspective is chosen as it is the most applicable to the appraisals that we typically undertake. However, we may consider wider perspectives for technologies that are expected to have significant health and cost consequences beyond the NHS, such as social care technologies or models of care and support.

7.4.1.3 Time horizon

The time horizon selected for analysis should be long enough to reflect all important differences in costs and outcomes between the interventions being compared. For example, if a new intervention is expected to reduce a patient's risk of stroke, this is likely to have impacts on outcomes for the lifetime of the patient, and so a lifetime horizon should be modelled.

7.4.1.4 Discounting

Discounting is a means of giving less weight to future costs and benefits compared with costs incurred or benefits gained in the present, to reflect the view that people generally prefer to receive benefits or goods now but pay for them later. In our analyses, discounting is applied at an annual rate of 3.5% for both costs and benefits.

7.4.2 Model inputs

Economic analyses are underpinned by different types of evidence for the alternative courses of action being evaluated. For example, this could include evidence relating to:

- anticipated course of disease or developing need for care,
- the relationship between short- and long-term outcomes,
- quality of life,
- adverse events,
- resource use and costs.

While economic analyses should be populated with the best available evidence, these data are often from differing sources and vary in their applicability and quality. We undertake a rapid evidence review to identify effectiveness evidence as outlined in Section 7.3. However, as our Evidence Appraisal Reports follow a rapid evidence review model, it is not possible to undertake systematic literature reviews to inform every model input. Economic analyses should be populated with the best quality evidence available that underpins the research question. In addition to the rapid evidence review to identify effectiveness evidence (Section 7.3), additional methods are used to identify model inputs, which may vary for different research questions.

7.4.2.1 Effectiveness

Effectiveness inputs should reflect the effectiveness evidence presented in the Evidence Appraisal Report as far as possible and any deviations from this approach should be highlighted for the consideration of decision makers.

Typically, the key effectiveness input for an economic evaluation is an estimate of the relative effectiveness of the intervention in comparison with standard care, often expressed as a relative risk or hazard ratio. The outcomes considered vary depending on the topic under consideration but should include those aspects expected to have an impact on costs, survival, or quality of life. For example, an economic analysis considering an intervention for cancer would likely include outcomes such as overall survival, disease-specific survival, and treatment-related adverse events.

In addition to considering any disease-specific mortality, we typically consider background mortality for the general population, which we source from Office for National Statistics life tables (ONS 2021).

7.4.2.2 Quality of life

Where possible, quality-of-life data for the health economic model are sourced from the effectiveness evidence identified in the Evidence Appraisal Report. However, in most cases, such data are not identified, and alternative approaches are required. There are several resources that can be used to identify appropriate values, such as the Tufts Cost-Effectiveness Analysis Registry (CEVR) and the NICE Decision Support Unit's technical support documents (NICE DSU). Alternatively, values may be sourced from published economic analyses considering the same or closely related populations.

Generic measures of quality of life are preferred for economic analyses as they are applicable across disease areas and conditions. There is a particular preference for the EuroQol Five-Dimensions (EQ-5D) survey. However, alternative measures such as the 36-Item Short Form Health Survey (SF-36) may be used and mapped to EQ-5D using published mapping algorithms. Where possible, quality of life should have been reported directly by patients, carers, or people accessing care and support.

In some cases, outcomes of interest may be broader than those captured by standard utility measures, and preference-weighted measures could be applied instead. For example, specific quality-of-life measures that can be used for the analysis of interventions for social care are recognised, such as the Adult Social Care Outcomes Toolkit (ASCOT) set of instruments used by the Department of Health and Social Care in the Adult Social Care Outcomes Framework indicator on social care-related quality of life.

7.4.2.3 Resource use and costs

Resource use and costs used within the economic model should reflect the perspective of the analysis and all relevant costs should be included. Data may be from several different sources and choices should be justified within the Evidence Appraisal Report. There should be a preference for recent cost data, from countries most applicable to the UK. If required, costs used in the model should be converted to GBP and inflated to the current cost year.

Resource use data may be available within studies reported in the effectiveness section of the Evidence Appraisal Report. Alternatively, data may be available in published economic analyses. Information on resource impact costings can be found in NICE's process guide on resource

impact assessment (NICE 2023a). Some information about public services may be better obtained from national statistics or databases, rather than from published studies. It may be necessary to elicit assumptions from experts if no data are available.

There are several resources that could be used for specific costs. Two key sources of national unit costs are the Personal Social Services Research Unit (PSSRU), which reports unit costs of health and social care, and NHS Reference Costs (NHS England), which reports the average costs for procedures and services provided to patients. Public list prices can be used to source costs of specific devices where available. Where this is not possible, costs of devices can usually be obtained from the manufacturer. Costs of specific medicines can be sourced from the British National Formulary (BNF) or the Monthly Index of Medical Specialities (MIMS) or the electronic market information tool (eMIT).

7.4.3 Interpreting results

The results of the analysis should be presented in a transparent way. Key results of a cost-utility analysis should be presented in a table outlining the total costs, total life years, and total QALYs for each intervention arm, in addition to incremental results between model arms, including the corresponding incremental cost-effectiveness ratio (ICER).

The results of the analysis vary depending on the type of analysis that has been conducted. However, it will typically include an estimation of total costs and effectiveness for the intervention and comparators over the modelled time horizon. If a cost-effectiveness analysis has been conducted, then the results will also include an estimation of the ICER expressed as a 'cost per unit of effectiveness'. If a cost-utility analysis has been conducted, then this ICER will be expressed as a cost per QALY. In such cases, the ICER is compared against our chosen cost-effectiveness threshold of £20,000 per QALY. An intervention which provides an additional QALY for less than £20,000 would therefore be considered cost effective.

7.4.4 Uncertainty and sensitivity analysis

The results of any modelled analysis will be subject to uncertainty. We conduct sensitivity and scenario analyses to explore uncertainty and measure the impact that uncertainty could have on modelled results.

7.4.4.1 Deterministic sensitivity analysis

We use deterministic sensitivity analysis to explore the uncertainty around an individual input parameter in the model. This involves independently varying an input parameter to assess the impact that the change has on the modelled results.

7.4.4.2 Probabilistic sensitivity analysis

We use probabilistic sensitivity analysis to explore the combined uncertainty around model inputs. In this analysis, the mean values used in the base case are replaced with values drawn from distributions around the mean values. Changes to inputs are made simultaneously with an entirely new set of inputs for each model run. This process is repeated until modelled results converge, and average results of the analysis are presented.

7.4.4.3 Scenario analysis

Scenario analyses are useful for testing assumptions made in the model and can determine whether using alternative assumptions would impact the conclusions of the analysis. Common scenario analyses include subgroup analysis to explore whether the intervention may be more cost effective in a particular subgroup of the population (such as a 'high risk' subgroup).

7.5 Patient and Public Involvement

For each Evidence Appraisal Report, Patient and Public Involvement mechanisms are determined in line with the process outlined in Section 7.1.3.

This section outlines what is involved for different Patient and Public Involvement mechanisms, and how this information is incorporated into the Evidence Appraisal Report.

Patient and Public Involvement mechanisms include:

- submissions from patients, carers, and people accessing care and support (via a representative organisation),
- questionnaires or surveys (via an organisation representing patients, carers, or people accessing care and support),
- focus groups (via an organisation representing patients, carers, or people accessing care and support),
- Patient and Public Involvement literature searches.

Any patient literature identified through the clinical evidence searches, such as evidence on patient experiences and perspectives, is also included in the Evidence Appraisal Report for all topics. In addition, Public Partner input is always considered at the Assessment Group and Appraisal Panel meetings. It may also be appropriate for patient or carer organisations to participate in the Assessment Group and/or Appraisal Panel meetings, although this is not routinely requested.

7.5.1 Engagement with organisations representing patients, carers, and people who access care and support

The Patient and Public Involvement evidence represents the views, opinions, and experiences of organisations and their networks of patients and people who access care and support, and therefore does not represent the view or position of Health Technology Wales. Any form of Patient and Public Involvement obtained through engagement with an organisation, regardless of additional support from us, must be approved by the organisation involved before it can be included in the Evidence Appraisal Report. By taking this approach, our Patient and Public Involvement is subject to the UK National Standards for Public Involvement and the standards set out by Participation Cymru.

As rapid health technology assessment is not primary research, Patient and Public Involvement contributions to the Evidence Appraisal Report are made in the name of the organisation representing the views, interests, and rights of patients, their families, carers, or individuals. Relevant organisations are identified through recommendation from the Patient and Public Involvement Standing Group or by searches based on our standardised list of sources, which includes relevant reviews undertaken by other health technology assessment organisations.

Once identified, organisations are approached with a formal request to take part in an appraisal. Organisations must complete a declaration of interest form, but they do not need to complete a confidentiality agreement unless they see a draft of the Evidence Appraisal Report.

We work with the organisation to get the most appropriate form of engagement wherever possible. This may include taking a more flexible approach to evidence collection and providing additional support to the organisation for the data collection and report writing.

Each Evidence Appraisal Report may involve engagement with a number of different organisations representing patients, carers, and people who access care and support, and their preferred method of engagement may vary.

7.5.1.1 Submissions by patients, carers, and people who access care and support

Our submission template for patients, carers, and people who access care and support is the most frequently used form of participation we offer. It includes a mix of standard and tailored questions for the topic under appraisal. These submissions are completed by a representative of the patient, service-user, or carer organisation.

A summary of the submissions, written by the Patient and Public Involvement Manager, is included in the main body of the Evidence Appraisal Report. The summary includes points from each submission that are relevant to:

- the health condition or need for care,
- the health or social care technology or model of care and support, and
- patient-reported outcomes and any other points of relevance.

The full submission from the organisation, or a summary of it, is also included in the appendices of the Evidence Appraisal Report.

7.5.1.2 Direct patient evidence

Organisations representing patients, carers, or people accessing care and support may feel that they wish to collect data directly from their own groups of patients, people who access social care, or unpaid carers for a submission. This may take the form of questionnaires, surveys, or focus groups. In most cases, these submissions are coordinated by the organisation representing patients, carers, or people accessing care and support, rather than us. However, we often work with the organisation to co-produce the questions that people are asked. Any direct evidence from patients, carers, or people accessing care and support is anonymised and summarised as a report by the representative organisation. Reports will contain a summary of methods, the results of the engagement activity, and conclusions or key messages. These reports will be included in full in the Evidence Appraisal Report.

7.5.2 Patient and Public Involvement literature reviews

There are two methods for summarising existing Patient and Public Involvement literature. The first is an ‘easy access’ review, where an existing, recent health technology assessment from another agency has been identified in the clinical evidence review and includes Patient and Public Involvement evidence. The patient evidence or Patient and Public Involvement from the previous health technology assessment is summarised in the Evidence Appraisal Report and adapted where necessary. For example, where the previous health technology assessment is on

a wider population or different intervention, we would focus on the aspects specific to our own appraisal. This eliminates the need to perform a literature search for relevant Patient and Public Involvement articles.

The second method is to perform a search for relevant Patient and Public Involvement-related articles. Search strategies are determined and reflect the basic structure of the submission by patients, carers, and people who access care and support, in that information can be gathered on:

- the health condition or need for care,
- the health or social care technology or model of care and support,
- patient outcomes, patient decision making, and patient-related behaviours that may impact the success of the intervention.

A Patient and Public Involvement literature search considers the outcomes of the Evidence Appraisal Report and how it can add to and support the effectiveness evidence. It considers broader perspectives and experiences that would not be included in the effectiveness evidence, but would still add value to the appraisal. These can include:

- What it is like to live with the health condition or need for care.
- What the current barriers are for people who try to access care.
- What the current situation is for people with these needs in Wales.
- How patients or people who access social care make decisions about their care and what influences them (for example, would they be put off by social stigma, would they have to travel far, is there a type of intervention that they would consider unfeasible).
- How attitudes and behaviours impact how successful care might be.

It may be appropriate to broaden the scope of the Patient and Public Involvement search to include different populations if the technology or model of care and support is the same and the experiences of these people would be relevant. For example, if the population under appraisal is people with gestational diabetes, and patient evidence is available for people with type 1 diabetes, but all variables around the use of the device remain the same.

The selection criteria for Patient and Public Involvement evidence are different to the criteria used to identify effectiveness and cost-effectiveness evidence. Articles are excluded if they are not qualitative in nature (for example, clinical patient-related outcomes, such as satisfaction rates, adherence rates, scales, and statistical analyses) and if they do not represent the view of patients, people who access social care, and unpaid carers (for example, the views of healthcare professionals or other stakeholders). The amount of relevant Patient and Public Involvement evidence is often limited; therefore, we do not apply search date limitations to Patient and Public Involvement literature searches, and we do not limit by study size or relevancy to Welsh populations. Any relevant evidence identified in the Patient and Public Involvement literature searches is shared with the Researchers in the project team to ensure there is no cross over or duplication with the effectiveness evidence.

Once selected, the Patient and Public Involvement evidence from the literature search is summarised narratively and included in the Evidence Appraisal Report.

7.6 Additional considerations

Inclusion of additional considerations that provide contextual information alongside other parts of the Evidence Appraisal Report may be appropriate. Additional considerations may relate to

service structure and delivery, training requirements, workforce, equity, environmental sustainability, or other issues relevant to provision of health and social care in Wales.

Additional considerations will be taken into account where they are raised by the topic proposer, by our Assessment Group, or during expert review, or where they are identified in the literature. Considerations identified during these stages of our process will be included in the Evidence Appraisal Report where they are judged to be relevant for decision making and sufficient supporting evidence has been identified.

Additional considerations may also arise during our Appraisal Panel discussions and have an impact on decision making. These will be reported in the guidance document within the Appraisal Panel considerations section.

7.7 Quality assurance, oversight, and external review

During the appraisal process, an Evidence Appraisal Report undergoes several forms of quality assurance and review.

7.7.1 Quality assurance

Each appraisal is overseen by a Senior Health Economist and Senior Health Services Researcher. These staff members are responsible for internal quality assurance, which includes:

- checking the overall structure of the report is logical and complete,
- checking the effectiveness and cost-effectiveness sections use appropriate methods and document these clearly,
- checking that all key information needed to interpret these sections is present,
- checking that data have been reported appropriately and accurately,
- checking that appropriate conclusions have been drawn.

As well as carrying out a formal check of these issues, those responsible for quality assurance provide ongoing guidance and oversight to other members of the project team during drafting of the report.

7.7.2 Review by the Assessment Group

As noted in Section 3.2.1.2 it is the responsibility of the Assessment Group to review and quality assure the Evidence Appraisal Reports on behalf of our Appraisal Panel, as well as provide assurance on methodological and scientific rigour.

Each Evidence Appraisal Report is seen by the Assessment Group on at least three occasions:

- Prior to expert review: A draft report is prepared and discussed with the Assessment Group; discussion focusses on any uncertainties and how to address them, any suggestions for other changes, nominations for subject experts to review the Evidence Appraisal Report, and potential questions for experts.
- Post-expert review: Once all expert comments are received, proposed changes are submitted to the Assessment Group for consideration, and agreement is reached on updates required to the Evidence Appraisal Report.

- Final Evidence Appraisal Report: Prior to submission to the Appraisal Panel, the Assessment Group receives a final copy of the Evidence Appraisal Report, following incorporation of changes agreed and the updated literature review, for sign off.

7.7.3 External expert review

As part of our appraisal process, we invite subject experts to review our work. We ask reviewers to critically read the Evidence Appraisal Report and provide comment, either on specific issues or uncertainties that Health Technology Wales staff need help clarifying, or on the general content of the report and its robustness. We provide a response document with some key questions to assist with this. Participants in the process are selected as outlined in Section 3.

A list of subject experts who respond to external review will be listed in the Evidence Appraisal Report appendices. In addition, stakeholders who were asked to comment but did not return a response, will also be included in the appendices without personal information.

Contributions from expert reviewers will be considered by our Assessment Group and Appraisal Panel. Expert reviewers will have no role in authorship or editorial control; we reserve the right to make significant changes to the final publication following consideration of comments received. The views expressed in the final publication will be those of Health Technology Wales.

Where feedback from experts or the Assessment Group, or other circumstances, result in major revisions or delays to the Evidence Appraisal Report, more than one round of expert review may be undertaken. This will be agreed with the Assessment Group where necessary and the original experts will be invited to review the updated Evidence Appraisal Report, along with any additional experts identified in the interim.

7.8 Finalising the Evidence Appraisal Report

7.8.1 Updating the literature review

Researching and writing an Evidence Appraisal Report typically takes three to six months, so to ensure the evidence is as current as possible, an update to the literature search is carried out, approximately one to two months prior to publication. The aim of this is to identify any evidence published since the original search that could impact on the findings of the Evidence Appraisal Report.

Any evidence found by the update search will be considered using the same inclusion and exclusion criteria used throughout the appraisal. Any new sources of evidence will be incorporated into the Evidence Appraisal Report and their implications for the overall findings of the Evidence Appraisal Report considered, initially by our project team. If there are concerns that newly identified sources of evidence are critical to decision making, or independent input is needed into their relevance or implications on decision making, the updated Evidence Appraisal Report undergoes further discussion with the Assessment Group and, in exceptional circumstances, may be reviewed again by subject experts before proceeding to the Appraisal Panel.

7.8.2 Agreement to progress to guidance

On their final review of the Evidence Appraisal Report, the Assessment Group will determine that they are satisfied that all expert review comments and other outstanding recommendations of the Assessment Group have been or can be addressed prior to the Appraisal Panel.

In exceptional cases, the Assessment Group will decide that it is inappropriate to progress to the Appraisal Panel or to produce guidance. In these cases, a summary is produced along with the Evidence Appraisal Report. This does not contain any guidance recommendations, and explains the rationale for not producing guidance. The summary of the evidence is written by our project team and signed off by the Assessment Group prior to publication on our website.

8. Production of Health Technology Wales guidance

Health Technology Wales guidance outlines the effectiveness, safety, and cost effectiveness of the technology or model of care and support being appraised, within the context of the Welsh health and social care system.

The status of Health Technology Wales guidance is that NHS Wales, local authorities, and social care providers should adopt this guidance. However, Health Technology Wales guidance is not mandatory. There may be instances where there are reasons for not following recommendations and it is acknowledged that the guidance constitutes only one of the sources needed for decision making and planning in NHS and social care services in Wales. Health Technology Wales guidance does not override the responsibility of health and social care professionals to consider the circumstances of individuals in their care and exercise appropriate judgement in consultation with the person being cared for and/or their guardian or carer.

8.1 The Appraisal Panel

Once an Evidence Appraisal Report is completed and the Assessment Group have agreed that it is appropriate for Health Technology Wales guidance on the topic to be produced, it will be considered at an Appraisal Panel meeting. It is at this meeting that guidance is drafted, deliberated, and agreed.

The Appraisal Panel considers our Evidence Appraisal Report, as well as views and comments provided by clinical and Patient and Public Involvement experts during the meeting, to ensure that the implications for NHS Wales and the social care sector in Wales are given due consideration.

Key factors considered by the Appraisal Panel when drafting guidance include:

- Evidence of effectiveness: the number of studies and the number of patients studied to address the question of interest. Is evidence available that allows direct comparison of the technology or model of care and support with current alternatives, and is evidence available for all relevant outcomes?
- Certainty of the evidence: the extent to which studies are protected from potential biases that may impact upon the relationship between an intervention and an outcome.
- Consistency of the evidence: the degree to which different study results are in agreement for the same outcome.
- Applicability and generalisability of the evidence: the degree to which populations and pathways in studies reflect the Welsh context and practice.

8.1.1 Meeting attendees

Membership of our Appraisal Panel is outlined in Section 3.1.1.4. In addition to Appraisal Panel members, additional people are invited to provide members with further detail on the topic. This includes:

- Representatives of organisations for patients, carers, and people accessing care and support
- Subject experts

The Appraisal Panel meeting is open to public observers (except for confidential discussions). Members of the public who wish to observe the meeting must sign up in advance via our website.

8.1.2 Format of meetings

The Appraisal Panel will consider up to two topics per meeting. For each topic, the meeting commences with an introduction to the topic and a summary of the evidence presented in the Evidence Appraisal Report, including Patient and Public Involvement considerations. Members will then undertake a question-and-answer session with our project team and invited experts and Patient and Public Involvement contributors.

This will then be followed by a closed panel discussion during which the guidance will be formulated.

8.1.3 Potential outcomes

Health Technology Wales drafts guidance considering the specific circumstances of the technology or model of care and support, and the population being appraised. We do not use set wording and formatting for our guidance but, in general terms, there are five main types of guidance outcome:

- Evidence supports routine adoption: The evidence suggests that the technology or model of care and support is effective and cost effective for the full population being considered in the guidance. Therefore, it is recommended that the technology or model of care and support is routinely adopted.
- Evidence supports partial adoption: The evidence suggests that the technology or model of care and support is effective and cost effective for a subgroup or subset of the population being considered in the guidance. Therefore, it is recommended that the technology or model of care and support is selectively adopted in the indicated population.
- Evidence partially supports adoption: There is some evidence to suggest that the technology or model of care and support is effective and cost effective but there is uncertainty around the evidence base. For example, there may be evidence to suggest that the technology or model of care and support is effective but there may be uncertainty around cost effectiveness.
- Insufficient evidence to support adoption: There is not enough evidence to determine whether the technology or model of care and support is effective and cost effective. In some cases, this may reflect a general paucity of evidence, whereas in other cases it may reflect uncertainty in the outcomes from studies identified in the evidence base.
- Evidence does not support adoption: The evidence identified suggests that the technology or model of care and support is not effective and/or cost effective. Therefore, it is recommended that the technology or model of care and support is not adopted.

8.2 Drafting the guidance

Following the Appraisal Panel meeting, the first full draft of the Health Technology Wales guidance document is prepared by the Health Technology Wales project team in line with the discussions in the Appraisal Panel meeting.

This document includes:

- The Health Technology Wales guidance recommendation
- The reasons that the topic was considered for appraisal
- A summary of the evidence from the Evidence Appraisal Report
- A summary of the Appraisal Panel's considerations
- The responsibilities for consideration of the guidance

The document will also outline any suggestions or considerations for further research put forward by the Appraisal Panel.

8.3 Guidance sign off

The draft guidance is initially reviewed by the Health Technology Wales Chair.

Once the Health Technology Wales Chair has reviewed the guidance document, it is circulated to all Appraisal Panel members for further comment or clarification. Any revisions are incorporated into a final draft by the project team and signed off by the Health Technology Wales Chair.

8.4 Publication and dissemination of guidance

The following are available on our website when guidance is published:

- The outcome of the appraisal: this summarises key findings of the Health Technology Wales guidance in terms of whether a technology or model of care and support should be adopted and the rationale for this.
- Why the topic was appraised: this summarises the health problem or need for care, how the technology or model of care and support addresses it, and if relevant, why guidance was needed and who requested it.
- A plain language summary: this combines the information in the above two sections and is published alongside them.

The following documentation is published (alongside any previously published Topic Exploration Report) which expands on the information above:

- Guidance
- Evidence Appraisal Report

The outcomes of the appraisal, the reasons the topic was appraised, the plain language summary, and the guidance document are published in Welsh and English. Other documents are published in English but available in Welsh upon request. Where necessary, any confidential information will be redacted from the Evidence Appraisal Report or other supporting documents before publication.

Once our guidance is published, we disseminate it via social media and publication of a news story on our website. A guidance alert is sent to contacts who have subscribed to receive them. We also contact any organisations who our guidance may impact upon (such as Local Health

Boards, local authorities, social care providers, third sector organisations, trade or industry bodies, and professional organisations).

8.5 Challenges to guidance

The methodology adopted in the development of Health Technology Wales guidance includes consulting with relevant experts and stakeholders throughout the process, with the aim of minimising disagreements on the content of the final published guidance. However, it is recognised that there may be occasions when challenges will arise. An individual or organisation may consider that Health Technology Wales has:

- Misinterpreted the evidence contained within the Evidence Appraisal Report on which the Health Technology Wales guidance is based;
- Given insufficient attention to, or misused, relevant contextual material; or
- Deviated significantly from due Health Technology Wales process when preparing the advice.

If so, the organisation or individual should contact us in writing, setting out their concerns. These concerns will be considered by the Health Technology Wales Chair, our senior team, and the Chair of our Assessment Group.

If concerns cannot be resolved informally by discussion, they will be considered by our Assessment Group. As a minimum, the Assessment Group will review the original guidance and the accompanying Evidence Appraisal Report.

If concerns remain unresolved, an organisation or individual has the option of requesting a formal review, through the constitution of an Independent Review Panel. A request to set up an Independent Review Panel must be made in writing to Health Technology Wales within three months of the publication of the Health Technology Wales guidance.

The decision to convene an Independent Review Panel will be considered by the Director of Health Technology Wales and the Health Technology Wales Chair. If the decision is not to proceed with an Independent Review Panel, the individual or organisation that requested the review will be informed within three months. They will be given the reasons on which the decision was based.

If the decision is to convene an Independent Review Panel, this will be held within three months of receiving the request. The Independent Review Panel shall comprise a minimum of four members:

- An independent Chair for the Independent Review Panel.
- Two or more members, appointed by the Independent Review Panel Chair, who are recognised experts in the relevant scientific field, and who have not been involved in our Evidence Appraisal Report or guidance production.
- One or more independent member(s), for example, a public or industry partner, or former member(s) of the Appraisal Panel.

Declarations of interest will be recorded for all Independent Review Panel participants.

A note will be made on our website that the Health Technology Wales guidance is under review.

The Independent Review Panel will review the original guidance, the expert review comments received and our response to these comments, the accompanying Evidence Appraisal Report, the original topic referral form, and the papers of the Assessment Group and Appraisal Panel meetings at which the topic was discussed. The Independent Review Panel may also consider evidence from the individual or organisation who is challenging the Health Technology Wales

guidance, but this evidence should remain relevant to the appraisal review question, and cannot include any new evidence published since the original appraisal concluded. Where evidence is not considered relevant, we may choose to exclude it, with justification for doing so.

Independent Review Panel members will vote on the decision to amend the guidance or not. Each member will have one vote and the Chair will be given a casting vote.

The person or organisation submitting the review request will be informed in writing of the results of the review within two weeks of the date of the Independent Review Panel meeting. If the Independent Review Panel believe that due process has been followed and that evidence and contextual information has been appropriately interpreted, then no action will be taken. If the Independent Review Panel believe that amendments are required, their conclusions and recommendations will be reviewed at a subsequent Appraisal Panel meeting and revised guidance issued.

9. Impact and adoption of guidance

We monitor the impact of our appraisals, guidance, and wider work on improving health, wellbeing, and value for people in Wales. To track and report on the impact of our work, we use a contribution analysis-based approach (developed by the external company Matter of Focus).

Contribution analysis is a theory of change approach that acknowledges that change and outcomes are not driven by direct cause and effect. This works well when you are evaluating actions within a complex system, like the Welsh health and social care system, where there are many different factors that influence the outcomes. Evidence of our impact is captured via multiple quantitative and qualitative data sources.

We also monitor the uptake of our guidance, via the annual adoption audit. Through the adoption audit, we assess and report on the extent to which relevant commissioners have considered guidance, made steps towards adoption, and justified non-adoption. For details on our adoption audit methodology, please see our annual adoption audit reports on our website.

10. Review and reassessment

We aim to ensure that our outputs stay current and relevant after publication. Therefore, stakeholders or anyone with a wider interest in the appraised technology or model of care and support can contact us if they believe an Evidence Appraisal Report or associated guidance requires updating. We refer to updates to the Evidence Appraisal Report or associated guidance as 'reassessment'.

Working with stakeholders, we will consider whether there is a need for reassessment, and make recommendations to the Assessment Group accordingly. There must be a strong likelihood that guidance, or the conclusions of an associated Evidence Appraisal Report, will need to be changed. Further detail on the factors considered in this decision making are described below.

Reassessment of a topic follows our standard rapid evidence review process once accepted onto the appraisal work programme.

10.1 Determining the need for reassessment

When reassessment is considered or requested, Health Technology Wales staff will contact stakeholders to ascertain whether the research question is still relevant and if there have been any developments to the evidence base. These stakeholders include:

- The original appraisal stakeholders
- Anyone relevant who has accessed the original Health Technology Wales guidance on our website, and given their permission to be contacted
- Any new patient or public organisation contacts suggested by the Patient and Public Involvement Standing Group
- Welsh NICE Health Network
- Health Technology Wales Stakeholder Forum

Where necessary, Health Technology Wales staff also undertake a high-level literature search to provide an update on the available evidence on a topic.

Stakeholder feedback and any newly identified evidence are considered by the Assessment Group, who will recommend whether guidance should be updated.

10.2 Decision to update Evidence Appraisal Report or guidance

Reassessment will be done in instances where the Assessment Group decide that either the conclusions of our Evidence Appraisal Report, or the associated guidance statements, need to be reviewed in full and are likely to change. Circumstances could include:

- The identification of substantial new evidence that is likely to alter the conclusions of the Evidence Appraisal Report or guidance in terms of the effectiveness, or cost-effectiveness, of the appraised technology or model of care and support. This new evidence may be in areas where different evidence existed, or the new evidence may resolve gaps and uncertainties highlighted in the original Evidence Appraisal Report or guidance.
- A fundamental shift in clinical practice which means the place of the appraised technology or model of care or support in the care pathway needs to be reviewed.
- Availability of new comparators or changes to standard care that could alter the effectiveness or cost effectiveness of the technology or model of care or support.

10.3 Decision not to update Evidence Appraisal Report or guidance

The Assessment Group may decide that reassessment is not appropriate, because there is insufficient new information to warrant it.

The availability of new evidence may not always be considered a sufficient reason for reassessment, if this evidence is not likely to alter the conclusion of the Evidence Appraisal Report or guidance. Examples of what the Assessment Group might consider sufficient evidence to warrant reassessment are given above under ‘decision to update Evidence Appraisal Report or guidance’.

10.4 Reassessment process

Following consideration by the Assessment Group, a decision will be taken on whether to progress with reassessment, and stakeholders will be informed of the outcome by email.

Where the Assessment Group decide that the Evidence Appraisal Report and any associated guidance should be updated, we will inform all stakeholders who contributed to the original appraisal. The later stages of the appraisal process are then followed. The scope of the appraisal will be discussed with the Assessment Group, using the original scope as a starting point, and incorporating any changes flagged by stakeholders or the Assessment Group. A new rapid evidence review and health economic analysis is then undertaken, using the original Evidence Appraisal Report where possible but fully updating the evidence where this is necessary. Patient and Public Involvement is to be considered in the same manner as a new topic appraisal.

Once the Evidence Appraisal Report is complete it will be discussed with the Assessment Group (before and after expert review) and with the Appraisal Panel, who will consider it and produce guidance.

Where an Evidence Appraisal Report and guidance exist for a topic, reassessment always involves updating both. Where reassessment is carried out on an Evidence Appraisal Report with no associated guidance, the principles in Section 7.8.2 apply, and the Assessment Group may or may not recommend that guidance is produced for the topic.

Glossary

Bias

A systematic error that may distort the results of a study because of weaknesses in its design, analysis, or reporting.

Budget impact

The financial impact of the introduction of a technology or model of care and support on the capital and operating budgets of a government or health and social care system.

Comparator

The standard (for example, another intervention or usual care) against which technology or model of care and support is compared in a study. The comparator can also be no intervention.

Cost-effectiveness

Whether the additional cost of a technology or model of care and support is justified by the additional benefit, when compared with the alternative course(s) of action.

Cost-effectiveness analysis

An economic evaluation consisting of comparing various options, in which costs are measured in monetary units, then aggregated, and outcomes are expressed in natural (non-monetary) units.

Cost-minimisation analysis

An economic evaluation consisting of comparing the costs of various options presumed to produce equivalent outcomes and determining the least costly of those options.

Cost-utility analysis

An economic evaluation consisting of comparing various options, in which costs are measured in monetary units and outcomes are measured in utility units, usually in terms of utility to the patient (using quality-adjusted life years [QALYs], for example).

This is a form of cost-effectiveness analysis in which the effectiveness of an option is adjusted on the basis of quality of life.

This type of analysis is useful where a technology or model of care and support is expected to either provide more benefit to patient, but at an increased cost, or provide less benefit to a patient at a reduced cost.

Economic evaluation

The comparative analysis of the costs and consequences of two or more possible options.

Depending on whether the consequences are expressed as monetary, physical, or qualitative variables, the analysis may be a cost-benefit, cost-effectiveness, or cost-utility analysis.

Economic model

A simplified representation of the real world that can support decision-making. A health economic model uses clinical, epidemiological, and economical evidence from appropriate (and different) sources to give estimates for specific outcomes.

Equity

The absence of unfair, avoidable, or remediable differences among groups of people. These groups could be defined socially, economically, demographically, or geographically or by other dimensions of inequality (e.g. sex, gender, ethnicity, disability, or sexual orientation).

Health economics

Health economics is a field of economics that focuses on the analysis and understanding of efficiency, effectiveness, values, and behaviours involved in the production and consumption of health and healthcare.

Health technology

An intervention developed to prevent, diagnose, or treat medical conditions; promote health; provide rehabilitation; or organise healthcare delivery. The intervention can be a test, device, medicine, vaccine, procedure, program, or system.

The Health Technology Wales remit covers the evaluation of non-medicine health and social care technologies and models of care and support.

Health technology assessment

Health technology assessment is a systematic and multidisciplinary evaluation of health technologies and interventions covering both their direct and indirect consequences. It aims to determine the value of a health technology and to inform guidance on how these technologies can be used in the health and social care system.

The value of a health technology may be assessed by examining the intended and unintended consequences of using a health technology compared to existing alternatives. These dimensions often include effectiveness, safety, costs and economic implications, ethical, social, cultural and legal issues, organisational and environmental aspects, as well as wider implications for the patient, relatives, caregivers, and the population. The process uses systematic and transparent methods to consider the best available evidence.

Health technology assessment can be applied at different points in the lifecycle of a health technology, i.e., pre-market, during market approval, post-market, through to the disinvestment of a health technology.

Incremental cost-effectiveness ratio (ICER)

The additional cost of the more expensive intervention compared with the less expensive intervention, divided by the difference between the effects of the interventions on the patients (the additional cost per quality-adjusted life year [QALY], for example).

Meta-analysis

Statistical combination of results from multiple studies to obtain a single estimate of effect of a particular intervention or variable.

Model of care and support

See “Non-medicine health and social care technologies and models of care and support”.

Non-medicine health and social care technologies and models of care and support

The Health Technology Wales remit covers the evaluation of non-medicine health and social care technologies and models of care and support. For health, this could include medical devices, diagnostics, procedures, and psychological therapies; Health Technology Wales does not appraise medicines. For social care, this could include equipment and environmental design, or different models for supporting families, children, adults, and the workforce.

A model of care and support is used to guide the delivery of health and social care services, to ensure the right care and support is delivered, at the right time, in the right place, by the right people.

Outcome

A measurable component or consequence observed after an intervention has been applied.

Primary research/study/evidence

An investigation in which the data are collected for the first time directly from patients (randomised controlled trial, observational study, case series, etc.).

The term “primary research” is often used to distinguish this type of research from “secondary research,” which is synthesis research (re-analysis of previously collected data), meta-analyses and other ways of combining studies (such as economic analysis and decision analysis).

Qualitative research and sources

Qualitative research and sources explore people's beliefs, experiences, attitudes, behaviour, and interactions. It asks questions about how and why. For example, why people want to stop smoking, rather than asking how many people have tried to stop. It generates non-numerical data, such as a person's description of their pain rather than a measure of pain.

Quantitative research and sources

Quantitative research and sources involve data that can be quantified, with a numerical value that can be analysed mathematically.

Quality-adjusted life year (QALY)

A unit of outcome of an intervention where gains (or losses) of years of life subsequent to this intervention are adjusted on the basis of the quality of life during those years. This parameter can provide a common unit for comparing cost-utility across different interventions and health problems.

Randomised controlled trial

A study comparing at least two interventions, in which the eligible participants are allocated randomly to the intervention group, or groups, and the control group. The control may be a standard practice, a placebo, other active intervention, or no intervention. Participants may be individuals or groups (e.g. unit of randomisation in a cluster randomised controlled trial).

Rapid evidence review

An evidence review that aims to be rigorous, but more streamlined and accelerated than a systematic review.

Scientific Advice Service

Support for developers and innovators to generate evidence and demonstrate value that meets the needs of care commissioners, care providers, patients, , carers, or people accessing care and support.

Secondary research/study/evidence

A type of research that does not produce original data, but that involves the qualitative or quantitative synthesis of information from multiple original studies.

Literature reviews, meta-analyses, decision analyses, and consensus reports are examples of secondary research. Health technology assessment is also secondary research, and our Topic Exploration Reports and Evidence Appraisal Reports both fall within this category.

Sensitivity analysis

A means for evaluating the robustness of a mathematical model by testing a plausible range of estimates of key independent variables to determine whether such variations result in meaningful changes in the model's results.

Sensitivity analysis can also be used for other study types, such as clinical trials analysis, to determine whether inclusion or exclusion of certain data changes the results, and meta-analysis, to determine whether inclusion or exclusion of certain studies changes the results.

Single-arm trial/study

A trial in which there was no parallel comparison group and all the subjects received the same intervention.

Stakeholder Forum

The aim of the Stakeholder Forum is to ensure that Health Technology Wales understands the views of stakeholders and these views are able to influence the work of Health Technology Wales in identifying, evaluating, and adopting technologies and models of care and support that could improve the lives of patients in Wales. As well as supporting the Health Technology Wales work programme, the Stakeholder Forum provides guidance on priorities for care services in Wales.

The membership of the Stakeholder Forum is drawn from key care sector stakeholders and ensures involvement from a range of bodies. Each member organisation is invited to send a representative who will fairly articulate the views and interests of their stakeholder community.

Standard of care

Technologies, interventions, or ways of working routinely used in the NHS, including those regarded as best practice.

Systematic review

A synthesis that collates all empirical evidence fitting pre-specified eligibility criteria in order to answer a specific research question. Systematic reviews are conducted according to a pre-specified protocol. The methods used are selected with a view to minimising bias, thus providing more reliable findings from which conclusions can be drawn and decisions made. Systematic reviews may use formal methods such as meta-analyses to synthesise the evidence found.

Time horizon

The time period over which the main differences in effects and the use of resources between interventions in health and social care are expected to be experienced, taking into account the limitations of the supporting evidence.

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