Technoleg Iechyd Cymru
Health Technology Wales

Health Technology Wales

Appraisal Process Guide

Contents

1. Purpose of this document

This guide describes the processes that Health Technology Wales (HTW) 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.

2. Introduction to HTW and our process

HTW is a national health technology assessment (HTA) 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.

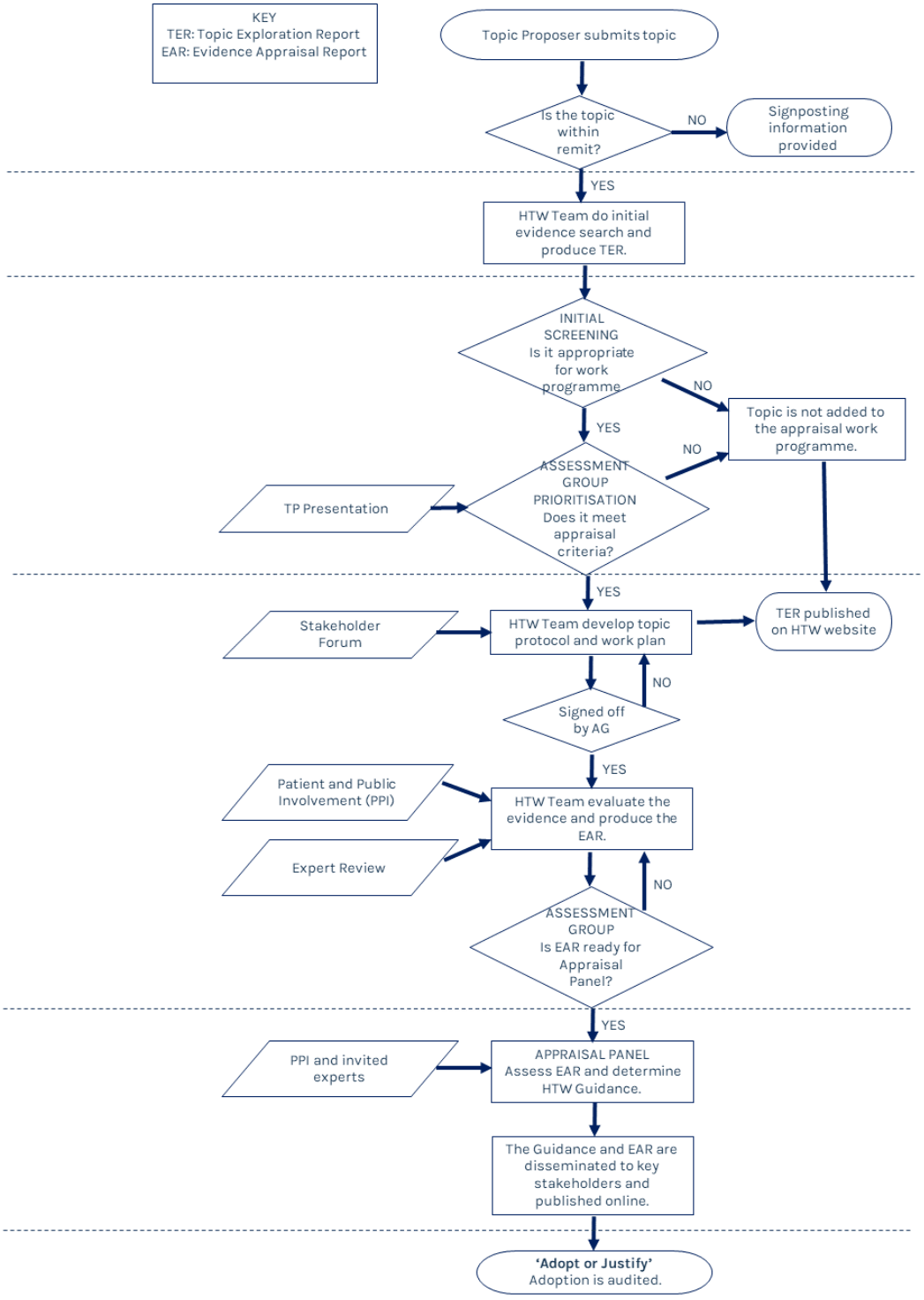
Our remit covers the evaluation of health and social care technologies and models of care and support. For health, this could include medical devices, diagnostics, procedures, and interventions by allied health professionals. For social care, this could include equipment and environmental design, or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

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

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

It also describes some of what happens after an appraisal: how we monitor the impact and adoption of our guidance, and the circumstances under which guidance may be changed or updated.

146 Our overall process is summarised in the flow diagram below.



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149 Figure 1. Appraisals process flow diagram

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3: Who's involved and how

This section outlines the people or groups involved in HTW's 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 (DoIs) and confidentiality statements are also covered.

3.1 Participants in the process

3.1.1 HTW decision-making committees, advisory groups, and staff

3.1.1.1 HTW Staff

HTW's staff are a multidisciplinary group made up of Researchers, Health Economists, Information Specialists, and Patient and Public Involvement (PPI) professionals, working alongside 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 HTW appraisal outputs, ensures methodological and scientific rigour in the work of HTW and adherence to agreed HTW processes. The Assessment Group also advises HTW on what technologies and models of care and support should be selected for appraisal, and agrees the research question(s) and methods for each appraisal.

Current membership of the Assessment Group, along with terms of reference, is published on the HTW website. The membership of the Assessment Group is determined by the HTW Chair and HTW Director, normally via nominations invited from relevant peer groups. As far as possible, membership endeavours to include 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, and local authorities. Membership also includes two Public Partners from the Patient and Public Involvement Standing Group (PPISG). HTW is committed to the values of equality, diversity, and inclusion, and welcomes 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, companies, and government, its guidance is independent.

3.1.1.3 The PPISG

HTW's PPISG advises HTW on all aspects of our PPI work.

PPISG members have diverse experience and knowledge of patient and service-user involvement in research, PPI in HTA, patient networks and organisations across the UK and internationally, patient consultancy, and PPI processes across a range of different organisations.

Members are initially appointed for a period of 18 months before their role on the PPISG is formally reviewed. Normal appointment lengths are three years, after which a second review is conducted, with a maximum one-term renewal.

3.1.1.4 The Appraisal Panel

The Appraisal Panel is the decision-making body of HTW 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.

Current membership of the Appraisal Panel, along with terms of reference, is published on the HTW website. The membership of the Appraisal Panel is determined by the HTW Chair and HTW Director, normally via nominations invited from relevant peer groups. As far as possible, membership endeavours to include 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, and local authorities. Membership also includes three Public Partners from the PPISG. HTW is committed to the values of equality, diversity and inclusion and welcomes 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, users of social care, informal carers, industry, and government, its guidance is independent.

3.1.2 Stakeholders outside of HTW

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 health innovations. 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. These 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.

3.1.2.3 Subject experts

Subject experts provide independent advice and scrutiny during our work. Depending on the type of topic considered, they can be health and social care professionals, academic researchers, or other groups or individuals with expertise and experience relevant to the topic considered. Subject experts are identified from our own research and networks, or because they have registered an interest in a particular topic. As far as possible, HTW endeavours 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 PPI representatives

PPI provides a valuable dimension to our work. PPI can include individual patients, carers, and service users, along with organisations representing them, as well as public communities and patient groups.

3.1.2.5 Wider stakeholders

Depending on the topic, HTW may also involve other Welsh, UK-based, or international stakeholders. This can include collaboration or data sharing with other UK HTA 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 providers) either during an appraisal or after guidance is produced.

3.2 How participants are involved

3.2.1 HTW decision-making committees, advisory boards, and staff

3.2.1.1 HTW Staff

For each potential appraisal, HTW staff:

- Carry out initial assessment of suggested topics to determine whether they are within HTW's remit;
- Carry out exploratory research into the available evidence (a TER) to inform the Assessment Group 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, and HTW's other relevant groups;
- Research and write the EAR;
- 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 HTW's key groups and to other stakeholders.

3.2.1.2 The Assessment Group

The Assessment Group:

- Advises HTW on topic selection and prioritises topics for the appraisal work programme when necessary. Advises on horizon scanning and other potential sources of topic identification;
- Agrees the research question(s) to be answered during an appraisal and the methods used to do so;
- Reviews and quality assures EARs 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 EARs, and advises HTW on revisions and further actions needed;
- Assesses whether the EAR should be considered by the Appraisal Panel and guidance developed;
- Inputs into changes or updates to HTW's 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, users of social care, informal carers, individuals, and public communities;
- Ensure that appropriate measures are taken to address issues of interest to patients, users of social care, informal carers, and the public;
- Have oversight of HTW's PPI 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 PPISG

The PPISG has three main areas of work:

- determining the mechanism of PPI for all new topics,
- advising on HTW's ongoing PPI activities, and
- contributing to the writing of plain language summaries for all topics.

In addition, the PPISG supports the development of HTW's PPI process, mechanisms, documents and tools, events, and training. Members also assist with our engagement activities and advise on accessibility, diversity, and inclusivity of HTW's PPI 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 PPISG 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 on this in the form of HTW guidance, based on:
    - the evidence presented within HTW's EAR,
    - expert input, via comments on HTW's EAR and discussions with independent experts attending the Appraisal Panel meeting,
    - PPI, provided via the mechanisms determined by HTW's PPISG, 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 PPI work gathered in the EAR 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, individuals, and public communities;
- The views of members of the public, informal carers, individuals, patients, users of social care, and their families are considered when decisions are made.

3.2.2 Stakeholders outside of HTW

3.2.2.1 Topic proposer

As and when required by the HTW project team, the topic proposer may be engaged in the development of the protocol, as well as assisting with any queries HTW staff may have at other stages. They will also be invited to participate in the expert review stage of the appraisal (see Section 7.7.3), subject to relevant DoI and confidentiality paperwork being completed.

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

3.2.2.2 Industry representatives

Manufacturers or suppliers of relevant technologies will be invited to participate in the expert review stage of the appraisal (see Section 7.7.3), subject to relevant DoI and confidentiality paperwork being completed. Earlier in the appraisal process, their input may be sought 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 HTW with an evidence dossier for an appraisal. As with all our stakeholders, submission or highlighting of potentially relevant

evidence is welcomed and will be considered 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.

Subject experts will be invited to participate in the expert review stage of the appraisal (see Section 7.7.3), subject to relevant DoI and confidentiality paperwork being completed. They may also be invited 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, subject expert input may be sought 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.

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

3.2.2.4 PPI representatives

PPI 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 PPI input into our appraisals though our PPI 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 are able to register an interest in a topic via our website.

Completed guidance will be distributed to all stakeholders registered for our guidance alerts, as well as key NHS peer groups. Guidance will also be published on our website and disseminated via our social media channels.

3.3 DoIs and confidentiality

To ensure our appraisals are as unbiased and transparent as possible, we require self-reported DoIs from all stakeholders involved in the process. This includes all members of

HTW advisory and decision-making committees and staff, as well as anyone contributing to an EAR as a topic or industry expert, or from a PPI perspective. We also require confidentiality agreements from all staff and committee members, as well as anyone with access to draft copies of the EAR, such as those participating in expert review. Table 1 provides an overview of how relevant DoIs will be processed.

Table 1. Process for handling relevant DoIs

Potentially relevant DoI from:	**Action**
Member of HTW staff	Considered by HTW 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 DoI 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 EAR	DoIs of subject experts or others invited to review the EAR will be reviewed by the HTW project team, who will ensure these are clearly documented. DoIs do not prevent stakeholders from reviewing the EAR and submitting comments and feedback but they are taken into consideration when comments are reviewed and actioned. Any DoIs 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.

4. Initial topic submission and selection

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

4.1 HTW's remit

HTW's 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,
- 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 HTW 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.

HTW 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.

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 (link once live).

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 HTA organisations in the UK, in which case we will liaise with these bodies to ensure we are not duplicating each other's work.

All topics received via the NHS Innovation Service will then be considered in line with the process outlined in Section 4.3, as with any other topic referrals.

Communication with topic proposers for topics coming via the NHS Innovation Service will be undertaken via the NHS Innovation Service portal.

4.2.3 Other sources of topics

HTW also seeks topics through routes other than the referrals described above. We monitor guidance outputs of other UK HTA 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, such topics will be considered 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 HTW's remit,
- It has the potential to directly impact patients, users of social care, or informal 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,
- use of the technology or model of care and support does not directly influence patient outcomes, wellbeing, or experience,
- 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 TER (see Section 4.3). This provides health and social care stakeholders in Wales with a high-level evidence overview, without developing an EAR or guidance.

4.3.2 Reviewing topic submissions for eligibility and further appraisal

New topic submissions are reviewed by HTW staff and are used to determine whether the topic meets HTW eligibility criteria (see Section 4.3.1). A member of the HTW team will contact the topic proposer if further clarification or information is needed to determine this.

If the topic meets HTW's eligibility criteria, the topic proceeds to topic exploration and a TER 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.

4.3.3 Topics not suitable for topic exploration

If a topic does not meet our eligibility criteria, it may be directed to our Signposting Group (see Glossary). If it is established that this route may be suitable, permission for referral will be requested from the topic proposer.

If permission is agreed, the Signposting Group will be sent details of the topic proposed, with a request to respond in three weeks, and will provide HTW with any suggestions for potential next steps for the topic proposer. HTW will collate these comments and communicate them to the topic proposer. The Signposting Group may not always be able to provide any suggestions for further action if a topic does not fall within the scope of individual members.

HTW may also flag the support available via the HTW Scientific Advice Service (see Glossary).

5. Production of a TER

This section outlines the first type of report we produce on a topic, the TER. It covers the type of information we include in this report, and how we get this information. A TER is used by HTW staff and the HTW Assessment Group to determine whether further appraisal work is appropriate, and whether it would be likely that guidance could be produced using available evidence.

5.1 TER contents

TERs are designed to 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 HTW, in the form of an EAR.

The TER focusses on the quantity of evidence, the type of evidence (for example, systematic reviews, randomised controlled trials [RCTs], 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 TER will list any evidence identified, typically in the following areas:

- HTAs and guidance,
- Evidence reviews and economic evaluations,
- Individual studies,
- Ongoing research.

As part of preparing the TER, HTW staff will also draft potential research questions and selection criteria for the topic if it were to progress to full EAR.

5.2 TER process

Searches for evidence to inform a TER 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 referral form;
- Provide a non-exhaustive overview of the types of evidence that exist, and any uncertainties or gaps in the evidence.

Evidence is gathered 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 searched and checked. This means that a TER 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 TER may also prioritise certain types of evidence. For example, if robust and recent sources of secondary evidence are identified that address the question of interest, the TER may only report these and not the findings of individual studies. Each TER will briefly explain the methodology used for searching and justify any inclusion or omission 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 TER is then reviewed for quality assurance purposes by a senior member of the HTW team and any required amendments completed.

It is anticipated that it takes around four weeks for a TER to be prepared. The draft TER will be sent 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 TER 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), they may also nominate another representative to comment on the TER and respond to our queries. This person could be nominated by the topic proposer or sought by HTW.

HTW staff will review any comments and, if appropriate, revise the TER before publication. If necessary, HTW staff will discuss any proposed changes with the Assessment Group. HTW may also send the topic proposer a summary of responses to their comments and any changes made.

Finalised TERs will be published on the HTW 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 an HTW prioritisation meeting. A notification email will be sent to the topic proposer to advise when the report is available online.

6. Topic selection and prioritisation for the appraisal work programme

This section outlines the process used to select topics for the appraisal work programme, including how we engage stakeholders at this stage.

Each TER is used by HTW staff and the HTW Assessment Group to determine whether further appraisal work is appropriate, and whether it would be likely that guidance could be produced using this evidence. This step may also involve prioritising topics for addition to the appraisal work programme when necessary.

6.1 Why is prioritisation important?

HTW only has capacity to carry out a finite number of appraisals each year, according to staff resources and scheduling of sufficient meetings of the Assessment Group and Appraisal Panel. In circumstances where the number of potential topics suitable for the appraisal work programme exceeds the capacity of the appraisal work programme, prioritisation is used to rank topics by their likely impact and importance to health and social care in Wales, with the highest-ranking topics taken onto the appraisal work programme first.

6.2 Prioritisation process

Once a TER is completed, it is reviewed by HTW staff and the Assessment Group to determine if it is appropriate for progression onto the appraisal work programme.

HTW staff will use the TER 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 HTA organisation.

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

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 HTW 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.

If a topic is considered suitable based on initial screening, it is then considered in more detail by HTW 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 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, a separate prioritisation meeting is scheduled 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 TERs for review.

All submitted topics will be considered by the Assessment Group, including those which did not progress through initial screening to ensure the Assessment Group agree with the recommendations of HTW staff.

To aid the prioritisation process, topic proposers for potential topics may be invited to the meeting to briefly introduce and discuss their 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 will be discussed in detail, and a decision will be made by the Assessment Group based on the TER content, HTW's 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 HTW appraisal	The topic will progress to the appraisal work programme.
Topic is not suitable for HTW appraisal	The topic will not progress past the TER 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 EAR 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 resubmitted to 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, topic proposers will be notified of the Assessment Group's decision via email. The decision will also be published on the website alongside

the completed TER. This process can take around four weeks as queries are addressed and TERs finalised for publication.

7. Production of an EAR

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

Once a topic is selected for the appraisal work programme, an EAR will be developed. The EAR 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 HTW;
- The PPI 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 [Garrity Cochrane RRG https://doi.org/10.1016/j.jclinepi.2020.10.007].

The EAR is considered, along with other supporting documents and information, by our Appraisal Panel in the development of HTW 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
- a PPI Manager
- a Communications Manager
- a Project Manager.

This is referred to as the HTW 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 of patient, service user, and public engagement, 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 some exceptional cases, two related questions may be considered. The title of the EAR should reflect 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 that has been submitted for appraisal
- The comparator or comparison being made. Usually, comparators are limited to those that are of most interest and best represent standard care in Wales
- The outcomes of interest. As HTW undertake rapid evidence reviews, we focus on the outcomes that are considered most important and relevant for decision making in Wales
- With diagnostics, a reference standard is also included.

In addition to being used to select evidence, the protocol determines what evidence will be reported in the EAR: 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, HTW

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, draft protocols will be circulated 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

HTW carries 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 appraised by HTW. There is therefore a need to prioritise our efforts on those topics where economic analysis has the potential to be of most value.

We develop an economic plan to identify the likely 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 likely 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 is currently uncertain, and whether this uncertainty could feasibly be reduced by undertaking de novo economic analysis.

7.1.3 PPI mechanism

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

When a topic is accepted onto the appraisal work programme, the PPISG determines what the appropriate mechanism of PPI is for that topic. This is called the PPI mechanism plan. At this stage, we may engage early with patient or service-user organisations to inform our decision on the most appropriate approach. In some cases, the PPISG will decide that a topic is unsuitable for detailed PPI activity.

The PPI mechanism allows for several approaches to gathering PPI for an appraisal, including:

- submissions from patients, users of social care, and informal carers (via a patient or carer organisation)
- questionnaires or surveys (via a patient or carer organisation)
- focus groups (via a patient or carer organisation)
- literature searches that look specifically for PPI evidence.

For each appraisal, the PPISG can select one or more approaches, and HTW can engage with multiple patient and service user organisations. If the chosen approaches are unsuccessful, for example if HTW is unable to engage with suitable patient and service-user organisations, the PPISG may decide to amend the mechanism plan. This flexibility ensures that HTW appraisals include PPI 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 PPI 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 a topic has been accepted onto the appraisal work programme, the topic protocol, economic plan, PPI mechanism, and proposed timelines will be 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 is searched for or synthesised 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 PPI.

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 EAR.

7.2 Evidence identification

Once the methods for an appraisal are planned, as much evidence as possible relevant to the appraisal needs to be identified. 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 appraisals 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

HTW 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. The checklists have been developed to ensure adequate coverage of the relevant literature and to balance comprehensiveness with pragmatism.

7.2.1.4 Writing and running the search

Searches are written and run by HTW's information specialists.

As well as the protocol, other sources used to inform search development include the TER and information provided by the topic proposer. These, and any relevant literature they contain, are used to develop specific search terms. Other relevant published search strategies may also be used to inform the search strategy.

Development of the strategy is an iterative process, including 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 the information specialist team at HTW 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.

7.2.1.5 Updating searches prior to publication

Literature searches for EARs 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.

7.2.1.6 Documenting the search

To ensure transparency and reproducibility of the search, a search report is produced for the full search and update(s). 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 HTW EAR. The Medline search strategy is also included in the EAR 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 our literature search, the HTW 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 will work with the authors or owners of unpublished sources to incorporate these data, without redaction, into the published version of our EAR 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 HTW 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 HTW or others. Earlier steps in the process, such as defining the research question, the topic protocol, and searching for evidence, are covered above in Sections 7.1.1 and 7.2.1.

HTW's methods for evidence selection and synthesis are based on and adapted from [Garrity Cochrane RRMG, https://doi.org/10.1016/j.jclinepi.2020.10.007] and [NICE Guidelines

Manual PMG20, https://www.nice.org.uk/process/pmg20]. 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. If we identify relevant and well-conducted RCTs, we may choose to report only results from these and not from non-randomised or observational studies. Similarly, where RCTs are unavailable or not feasible, we will 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 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 RCTs to explore the generalisability of findings.

We will also prioritise evidence from well-conducted secondary studies, such as systematic reviews or HTAs 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 HTW 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 HTW 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 will 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 EAR will vary, depending on the topic, the type of evidence, and the volume of evidence. However, all EARs 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

HTW EARs include a review of existing economic evidence identified as part of the systematic 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 (see Glossary).

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). 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 analyses. Different decision problems may merit different types of economic evaluation.

In situations where a new intervention 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 will be undertaken by HTW 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 HTW typically undertakes. However, wider perspectives will be considered 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

Base case results of analyses should be discounted 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:

- disease prognosis 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 disparate sources and vary in their applicability and quality. HTW undertakes a systematic review to identify effectiveness evidence as outlined in Section 7.3. However, as HTW EARs 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 systematic 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 EAR 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 (ONS) life tables.

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 EAR. 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 and the NICE Decision Support Unit's technical support documents. 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 people using the service or their carers.

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 EAR. 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 EAR. 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. Some information about public services may be better obtained from national statistics or databases, rather than from published studies. Philips et al. (2004) provide a useful guide to searching for data for use in economic models. 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, 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 PPI

For each EAR, PPI mechanisms will be determined in line with the process outlined in Section 7.1.3. This section outlines what is involved for different PPI mechanisms, and how this information is incorporated into the EAR.

PPI mechanisms include:

- patient and carer submissions (via a patient or carer organisation)
- questionnaires or surveys (via a patient or carer organisation)
- focus groups (via a patient or carer organisation)
- PPI literature searches

Any patient literature identified through the clinical evidence searches, such as evidence on patient experiences and perspectives, is also included in the EAR for all topics.

7.5.1 Engagement with patient and carer organisations

The PPI evidence represents the views, opinions, and experiences of organisations and their networks of patients and users of social care, and therefore does not represent the view or position of HTW. Any form of PPI obtained through engagement with an organisation, regardless of additional support from HTW, must be approved by the organisation involved before it can be included in the EAR. By taking this approach, HTW's PPI is subject to the UK National Standards for Public Involvement and the standards set out by Participation Cymru.

As rapid HTA is not primary research, PPI contributions to the EAR 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 PPISG or by searches based on HTW's standardised list of sources, which includes relevant reviews undertaken by other HTA organisations.

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

HTW works 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 EAR may involve engagement with a number of different patient, service-user, and carer organisations, and their preferred method of engagement may vary.

7.5.1.1 Patient and carer submissions

HTW's Patient and Carer Submission template 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 PPI Manager, is included in the main body of the EAR. 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 is also included in the appendices of the EAR.

7.5.1.2 Direct patient evidence

A patient, service-user, or carer organisation may feel that they wish to collect data directly from their own groups of patients, users of social care, and informal carers for a submission. This may take the form of questionnaires, surveys, or focus groups. In most cases, these submissions are coordinated by the patient, service-user, or carer organisation, rather than HTW. However, HTW often work with the organisation to co-produce the questions that people are asked. Any direct evidence from patients or users of social care is anonymised and summarised as a report by the patient, service-user, or carer 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 EAR.

7.5.2 PPI literature reviews

There are two methods for summarising existing PPI literature. The first is an 'easy access' review, where an existing, recent HTA from another agency has been identified in the clinical evidence review and includes PPI evidence. The patient evidence or PPI from the previous HTA is summarised in the EAR and adapted where necessary. For example, where the previous HTA 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 PPI articles.

The second method is to perform a search for relevant PPI-related articles. Search strategies are determined and reflect the basic structure of the patient and carer submission, 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 PPI literature search considers the outcomes of the EAR 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 users of 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 PPI 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 PPI 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, users of social care, and informal carers (for example, the views of healthcare professionals or other stakeholders). The amount of relevant PPI evidence is often limited; therefore, we do not apply search date limitations to PPI literature searches, and we do not limit by study size or relevancy to Welsh populations. Any relevant evidence identified in the PPI 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 PPI evidence is summarised narratively and included in the EAR.

7.6 Additional considerations

Inclusion of additional considerations that provide contextual information alongside other parts of the EAR 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 the HTW 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 EAR where they are judged to be relevant for decision making and sufficient supporting evidence has been identified.

Additional considerations may also arise during HTW 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 EAR 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.

In addition, information specialists quality assure the references of each EAR, to ensure that each citation is correct and follows HTW's citation style.

7.7.2. Review by the HTW Assessment Group

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

Each EAR 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 EAR, 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 EAR.
- Final EAR: Prior to submission to the Appraisal Panel, the Assessment Group receives a final copy of the EAR, 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 experts in the field of a particular topic to review our work. We ask reviewers to critically read the EAR and provide comment, either on specific issues or uncertainties that HTW staff need help clarifying, or 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 experts who respond to external review will be listed in the EAR 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 the HTW Assessment Group and the HTW Appraisal Panel. Expert reviewers will have no role in authorship or editorial control; HTW reserves 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 HTW.

Where feedback from experts or the Assessment Group or other circumstances result in major revisions or delays to the EAR, 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 EAR, along with any additional experts identified in the interim.

7.8 Finalising the EAR

7.8.1 Update literature review

Researching and writing an EAR 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 EAR.

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 EAR and their implications for the overall findings of the EAR considered, initially by the HTW 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 EAR will undergo further discussion with the Assessment Group and, in exceptional circumstances, may be re-reviewed by subject experts before proceeding to the Appraisal Panel.

7.8.2 Agreement to progress to guidance

On their final review of the EAR, 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 EAR. This does not contain any guidance recommendations, and explains the rationale for not producing guidance. The summary of the evidence is written by the HTW project team and signed off by the Assessment Group prior to publication on our website.

8. Production of HTW guidance

HTW guidance outlines the view of HTW on 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.

HTW guidance has a status of “adopt or justify” and there is an expectation from Welsh Government that our guidance is considered by relevant commissioners. However, HTW guidance is not mandatory. There may be instances where there are reasons for not following recommendations and it is acknowledged that HTW guidance constitutes only one of the sources needed for decision making and planning in NHS and social care services in Wales. HTW 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 HTW Appraisal Panel

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

The Appraisal Panel considers the EAR produced by HTW, as well as views and comments provided by clinical and PPI 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. A high-quality study is more likely to protect the integrity of this relationship.
- 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.

8.1.2 Meeting attendees

Membership of the HTW Appraisal Panel is outlined in Section 3. In addition to Appraisal Panel members, additional guests will be invited to provide members with further detail on the topic. This includes:

- Patient and carer organisation representatives
- Subject matter experts

The HTW 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.

8.1.3 Format of meetings

Appraisal Panel meetings are scheduled virtually each month. 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 EAR, including PPI considerations. Members will then undertake a question-and-answer session with the HTW project team and invited experts and PPI contributors.

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

8.1.4 Potential outcomes

HTW 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 HTW guidance document is prepared by the HTW project team in line with the discussions in the Appraisal Panel meeting.

This document includes:

- The HTW guidance recommendation
- Why the topic was considered for appraisal
- A summary of the evidence from the EAR
- 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 emailed to the HTW Chair for initial review.

Once the HTW Chair has reviewed the HTW 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 HTW project team and signed off by the HTW Chair.

8.4 Publication and dissemination of guidance

The following are available on the HTW website when guidance is published:

- The outcome of the appraisal: this summarises key findings of the HTW 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 is also provided. This combines the information in the above two sections and is published alongside them.

The following documentation is published which expands on the information above:

- Guidance
- EAR

The outcomes of the appraisal, why the topic was appraised, a 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 EAR 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 our guidance alerts. We also contact any organisations who our guidance may impact upon (such as health boards, local authorities, trade or industry bodies, third sector organisations, and professional organisations).

8.5. Challenges to guidance

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

- Misinterpreted the evidence contained within the EAR on which the HTW guidance is based;
- Given insufficient attention to, or misused, relevant contextual material; or
- Deviated significantly from due HTW process when preparing the advice.

If so, the organisation or individual should contact HTW in writing (healthtechnology@wales.nhs.uk), setting out their concerns. These concerns will be considered by the HTW Chair, HTW's senior team, and the Chair of the HTW Assessment Group.

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

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

The decision to convene an IRP will be considered by the Director of HTW and HTW Chair. If the decision is not to proceed with an IRP, 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 IRP , this will be held within three months of receiving the request. The IRP shall comprise a minimum of four members:

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

DoIs will be recorded for all IRP participants.

A note will be made on the HTW website that the HTW guidance is under review.

The IRP will review the original guidance, the expert review comments received and response of HTW to these comments, the accompanying EAR, the original topic referral form, and the papers of the Assessment Group and Appraisal Panel meetings at which the topic was discussed. The IRP may also consider evidence from the individual or organisation who is challenging the HTW guidance, but this evidence should remain relevant to the appraisal review question, and cannot include any evidence published since the original appraisal concluded. Where evidence is not considered relevant, HTW may choose to exclude it, with justification for doing so.

IRP 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. Should support and advice be required then this will be provided by the HTW Programme Office.

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 IRP meeting. If the IRP 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 IRP believe that amendments are required, their conclusions and recommendations will be reviewed at a subsequent HTW Appraisal Panel meeting and revised HTW guidance issued.

9. Impact and adoption of guidance

HTW monitors the impact of our appraisals, guidance, and wider work on improving the 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 ecosystem, where there are many different factors that influence the outcomes. Evidence of HTW's 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, HTW assesses and reports 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.

10. Review and re-assessment

HTW aims to ensure our guidance remains current and relevant after publication. We will consider guidance for re-assessment either at the request of stakeholders, or where our own intelligence indicates the guidance may require updating. Such circumstances could include:

- Substantial new evidence that is likely to alter conclusions on the effectiveness or cost effectiveness of the appraised technology or model of care and support
- A shift in practice which means the appraised technology or model of care and support's place in the care pathway needs to be reviewed
- Changes to standard care that could alter the effectiveness or cost effectiveness of the appraised technology or model of care and support

When re-assessment is considered or requested, HTW 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 HTW guidance on the HTW website, and given their permission to be contacted
- Any new patient or public organisation contacts suggested by the PPISG
- Welsh NICE Health Network
- HTW Stakeholder Forum

Stakeholders will be updated by email on the decision of whether to progress with a reassessment on the topic, following consideration by the Assessment Group.

Where necessary, HTW 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. When the decision is to update guidance, the topic will follow the standard HTW appraisal process described earlier in this document. Existing appraisal documentation such as the EAR will be re-used and updated as necessary.

11. Abbreviations

AP Appraisal Panel

AG Assessment Group

ASCOT Adult Social Care Outcome Toolkit

AWMSG All Wales Medicines Strategy Group

BNF British National Formulary

DoI declaration of interest

EAR Evidence Appraisal Report

eMIT electronic market information tool

EQ-5D EuroQol Five-Dimensions

HTA health technology assessment

HTW Health Technology Wales

ICER incremental cost-effectiveness ratio

IRP Independent Review Panel

MIMS Monthly Index of Medical Specialities

ONS Office for National Statistics

PPI patient and public involvement

PPISG Patient and Public Involvement Standing Group

PSSRU Personal Social Services Research Unit

QALY quality-adjusted life year

RCT randomised controlled trial

SF-36 36-Item Short Form Health Survey

TER Topic Exploration Report

[DOCUMENT HISTORY]

[ACKNOWLEDGEMENTS]

[REFERENCES]

[GLOSSARY TO BE ADDED]

1587 [ANY OTHER APPENDICES]