

Developing an Evidence Gaps Tool for Developers of Digital Health Technologies (DHTs): A Scoping Review of Evidence Requirements for Evaluating the Value of DHTs

Bowie D, Garrett Z, Chalkidou A.

National Institute for Health and Care Excellence (NICE)

Background

There is evidence suggesting that health technology assessment (HTA) frameworks typically do not consider the unique evidence requirements for evaluating DHTs and may not specify evidence criteria that need extra consideration when assessing the relative benefits and risks of these technologies¹. We aim to address this by developing an online tool to help developers to understand the quality of their existing evidence, identify important evidence gaps, and address these through robust evidence generation plans. This tool is part of the ASSESS DHT project, which aims to develop an assessment framework and toolkit for assessing DHTs across Europe.

Our approach

We are conducting a scoping review of evidence requirements for DHTs in European HTA agency documents and existing HTA frameworks. We define 'evidence' in this context as information on which a decision or guidance is based².

Between July to September 2024, we reviewed 11 HTA agency documents for DHTs. Data on evidence requirements was extracted and synthesised across assessment domains³ and, where applicable, types of DHTs and stage in the assessment lifecycle. Here, we present preliminary findings from this review.

Next, we will expand the scoping review to explore evidence requirements in other HTA frameworks for evaluating DHTs. Results of the review will inform the development of a practical online tool to help developers to understand the evidence requirements for their specific DHTs and to identify gaps in their supporting evidence before assessment.

Early findings

We reviewed evidence requirements for 9 European countries: Belgium (RIZIV-INAMI), England (NICE), Finland (FinCCHTA), France (HAS), Germany (BfArM), Italy (AGENAS), Scotland (SHTG), Spain (AQuAS) and Wales (HTW).

Three of the 11 documents described different categories of DHTs, but only 2 presented specific requirements based on these subgroups. Three documents focused on specific DHTs, namely telemonitoring and artificial intelligence (AI). Four documents were technology agnostic, while 2 provided additional criteria for assessing AI.

All documents outlined technical information needed for the assessment of DHTs. Most also outlined requirements for clinical effectiveness, organisational impact, current and intended use, safety, and economics. Almost half of the documents adapted or incorporated information from other frameworks such as the HTA Core Model, NICE Evidence Standards Framework (ESF), and NHS Digital Technology Assessment Criteria (DTAC).

The tool and its impact

The results from the review will be used to create a comprehensive database of evidence requirements for assessing DHTs across Europe. This 'library' will form the core of the evidence gaps tool (Figure 1).

The primary audience for the tool will be developers of DHTs who wish to understand specific evidence requirements for their technology. This will help them to better prepare and generate evidence prior to the evaluation of their DHTs by: (1) identifying evidence requirements based on technology type and stage in lifecycle, (2) assessing and developing their evidence generation plans, (3) considering options for real-world evidence generation, (4) prioritising outcomes for further evidence generation, and (5) considering if further expert input is needed.

The tool will also advance the evaluation of DHTs by facilitating targeted evidence generation and HTA submissions. This will help HTA agencies evaluating the value of DHTs across Europe to produce more timely and relevant assessments which will hopefully increase access to innovative and effective DHTs.

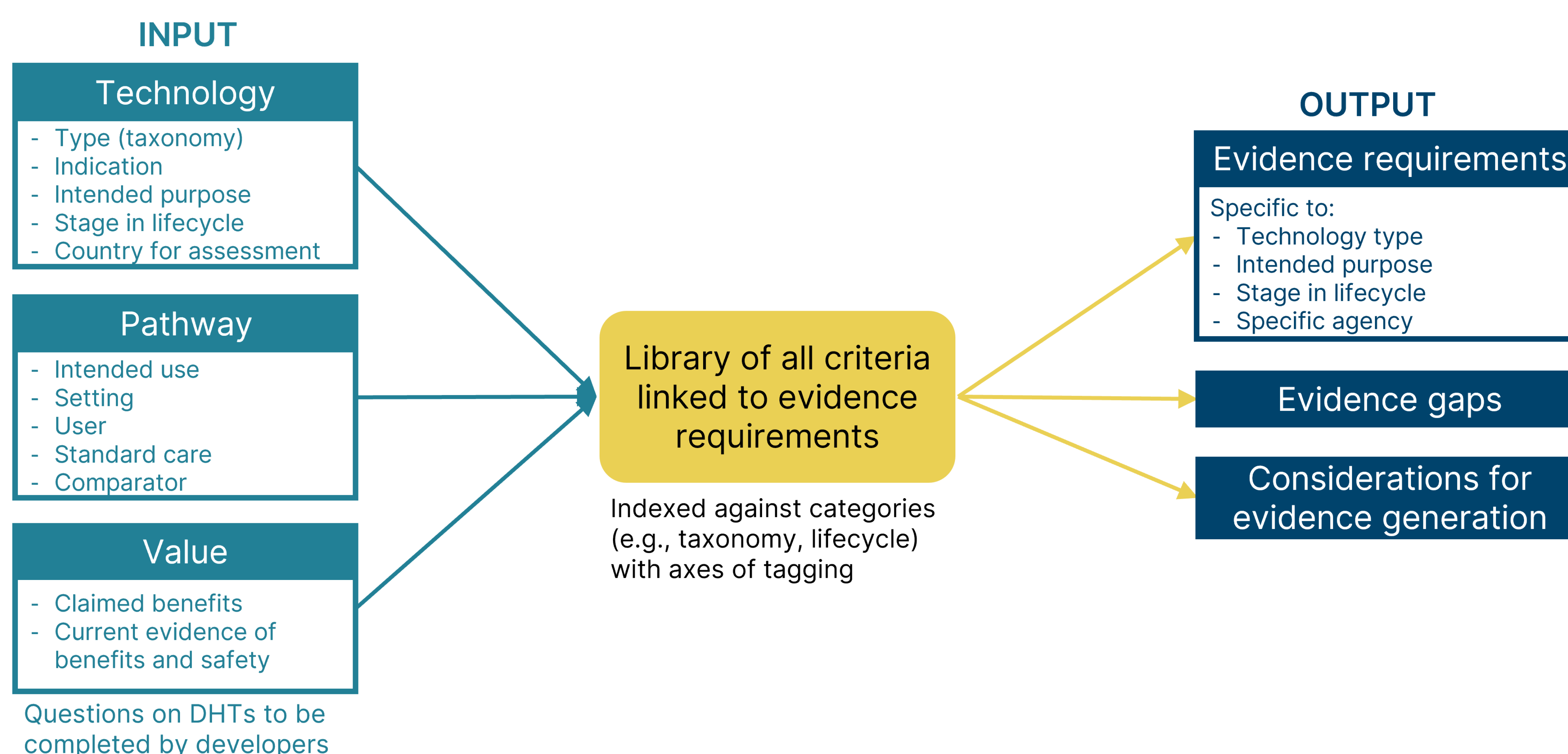


Figure 1. Proposed structure of evidence gaps tool

References

- Silberman, J. (2023). *npj Digital Medicine*, 6.
- NICE, Glossary. <https://www.nice.org.uk/Glossary>
- EUnetHTA, HTA Core Model. <https://www.eunetha.eu/hta-core-model/>

Corresponding author:

Dionne Bowie (Dionne.Bowie@nice.org.uk)

Views and opinions expressed are those of the authors only and do not necessarily reflect those of the European Union, HaDEA or NICE. Neither the European Union nor the granting authority can be held responsible for them.

To learn more about ASSESS DHT, visit our project website:

