

# Challenges in Health Technology Assessment of Complex Health Technologies

**Challenges in Health Technology Assessment of Complex Health Technologies**  
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**Our aim:**  
 With more advanced health technologies (HTs) entering the health care market, also the procedures for health technology assessment (HTA) to decide on reimbursement require changes.  
 Therefore, the aim of this study was to assess:  
 • which assessment issues are considered challenging by European HTA organisations and  
 • which HTs are perceived as complex.  
 The overarching goal is to gain further understanding of the needs for new HTA methods and requirements for advanced HTs.

**Challenges in HTA:**  
 For the case studies, most challenging issues were reported to occur in the relative effectiveness assessment (REA) and cost-effectiveness assessment (CEA).  
 In the open questions, however, organisations reported most often data related challenges, including absent, insufficient, immature or low-quality data. These initial data issues are often represented during the REA and CEA and ultimately complicate decision-making, according to 13 organisations. Policy and organisational challenges, as well as societal or political pressure, were reported by respectively 8 and 4 organisations. Direct modelling issues were least often reported.

**Complex technologies:**  
 ATMPs were considered as the types of therapies in HTA that of course posed special issues, the technology-independent therapies.

**Responding organisations:**  
 Out of 33 invited HTA organisations, 22 organisations completed the questionnaire.

**The questionnaire:**  
 To identify which HTs are perceived as complex and what challenges are faced during HTA, a questionnaire was sent out to HTA organisations throughout Europe. The questionnaire used relevant case studies and was validated and tested for reliability by an expert panel and it was pilot tested before dissemination. A schematic structure of this questionnaire is shown here.

Despite where challenges are expressed during HTA, the majority of these challenges root in the (un)availability of data at time of assessment.  
 ATMPs are considered the most complex therapies for HTA.

This research was performed as part of the HTA project, designed to support funding from the European Union Horizon 2020 research and innovation programme under grant agreement No 101019182.

CHAT | ABSTRACT | REFERENCES | CONTACT AUTHOR | GET IPOSTER

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PRESENTED AT:



## OUR AIM

With more advanced health technologies (HTs) entering the health care market, also the procedures for health technology assessment (HTA) to decide on reimbursement require changes.

Therefore, the aim of this study was to assess:

- which assessment issues are considered challenging by European HTA organizations and
- which HTs are perceived as complex.

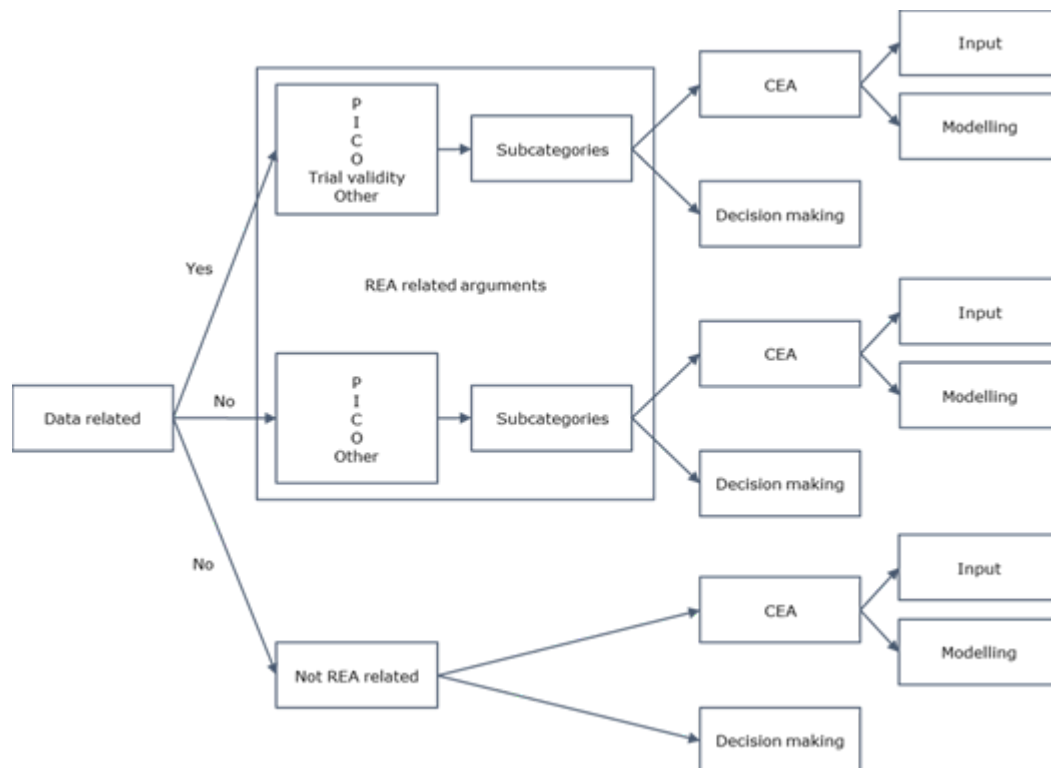
The overarching goal is to gain better understanding of the needs for new HTA methods and requirements for advanced HTs.

## THE QUESTIONNAIRE

To identify which HTs are perceived as complex and what challenges are faced during HTA, a questionnaire was sent out to HTA organizations throughout Europe. The questionnaire used relevant case studies and was validated and tested for reliability by an expert panel and it was pilot tested before dissemination. A schematic structure of this questionnaire is shown here:

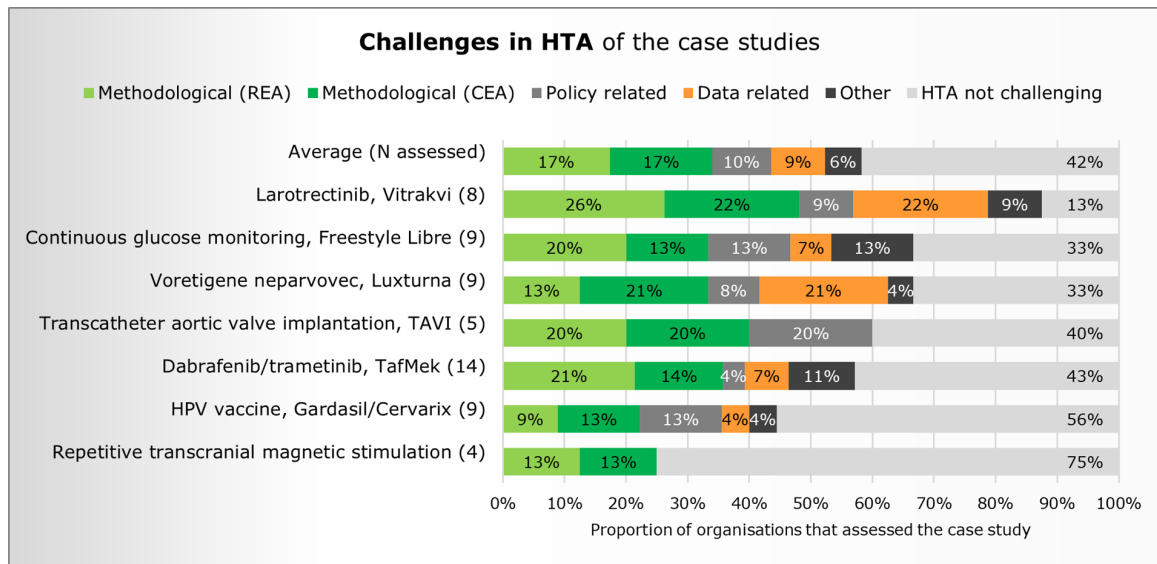
Research question	Gap analysis of challenging HTAs	
Sub-questions	What health technologies are perceived as difficult?	Which issues contribute to challenging HTAs
Specificity	Part 1 - How often are prespecified HTs perceived as challenging?	1-5 Likert scale
Validating specificity	Part 2 - Case studies	
	a. Was case study difficult to assess?	Binary (Yes/No)
		b. What contributed to difficulty?
		Multiple choice
		c. Detailed explanation of difficulties?
		Open
Sensitivity	Part 3 - Additional complex health technologies and contributing complicating factors	
		Open

The open questions were assessed using NVivo according to a predefined node tree as displayed below.

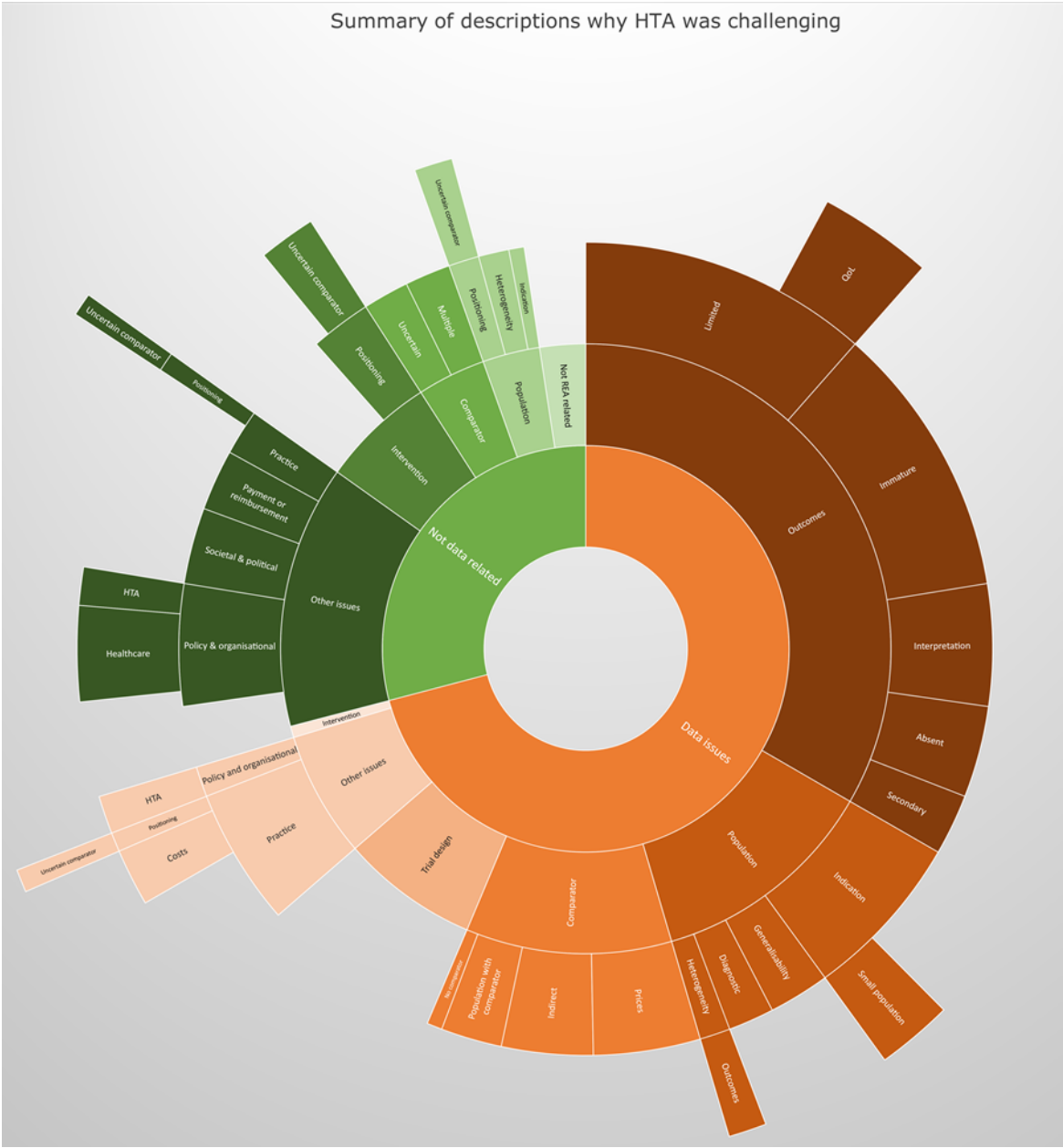


## CHALLENGES IN HTA

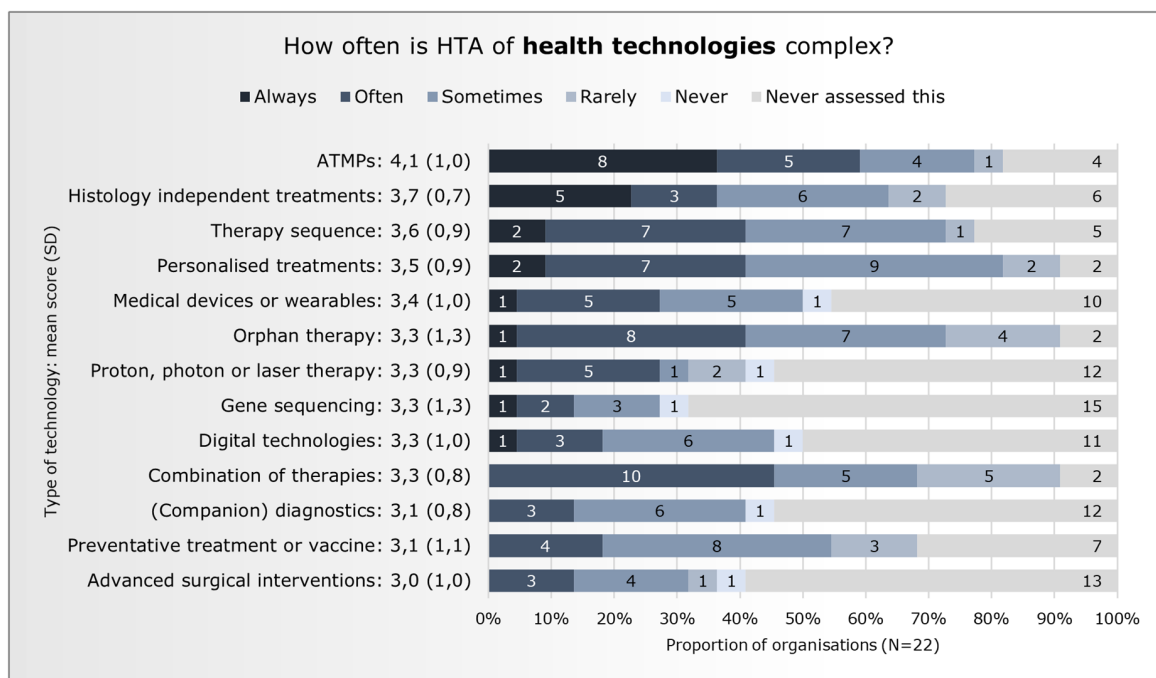
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In the open questions, however, organizations reported most often data related challenges, including absent, insufficient, immature or low-quality data. These initial data issues are often expressed during the REA and CEA and ultimately complicate decision-making, according to 13 organizations. Policy and organizational challenges, as well as societal or political pressure, were reported by respectively 8 and 4 organizations. Direct modelling issues were least often reported.



## COMPLEX TECHNOLOGIES



ATMPs were considered as the types of therapies in HTA. Out of seven prespecified case studies, the histology independent therapy was reported as most challenging by organizations that had assessed it. Additionally reported complex HTs by the organizations were mostly pharmaceuticals, oncology products, orphan medicines, personalized treatments and combinations of treatments.

## RESPONDING ORGANISATIONS

Out of 33 invited HTA organizations, 22 organizations completed the questionnaire.



Despite where challenges are expressed during HTA, the majority of these challenges root in the (un)availability of data at time of assessment.

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ATMPs are considered the most complex therapies for HTA.

This research was performed as part of the HTx project. The project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 825162.



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## ABSTRACT

**OBJECTIVES** With more advanced health technologies (HTs) entering the health care market, also the procedures for health technology assessment (HTA) to decide on reimbursement require changes. Therefore, the aim of this study was to assess which HTs are perceived as complex and which assessment issues are considered challenging by European HTA organizations. The overarching objective is to gain better understanding of what the needs are for new HTA methods and requirements for advanced HTs.

**METHODS** To identify which HTs are perceived as complex and what challenges are faced during HTA, a questionnaire was send out to HTA organizations throughout Europe. The questionnaire used relevant case studies and was validated and tested for reliability by an expert panel and it was pilot tested before dissemination.

**RESULTS** Out of 33 invited HTA organizations, 22 organizations completed the questionnaire. ATMPs were considered as the types of therapies most challenging for HTA. Out of seven prespecified case studies, the histology independent therapy was reported as most challenging by organizations that had assessed it. Additionally reported complex HTs by the organizations were mostly pharmaceuticals, oncology products, orphan medicines, personalized treatments and combinations of treatments.

For the case studies, most challenging issues were reported to occur in the relative effectiveness assessment (REA) and cost-effectiveness assessment (CEA). In the open questions, however, organizations reported most often data related challenges, including absent, insufficient, immature or low-quality data. These initial data issues are often expressed during the REA and CEA and ultimately complicate decision-making, according to 13 organizations. Policy and organizational challenges, as well as societal or political pressure, were reported by respectively 8 and 4 organizations. Direct modelling issues were least often reported.

**CONCLUSION** Challenges in HTA of complex HTs mainly root from data insufficiencies and result in outcome uncertainties in the REA and parameter uncertainty in the CEA, ultimately complicating decision making. Complex HTs, for example gene therapies, sometimes inherently cause data insufficiencies, making some complex HTs more challenging for HTA. These results therefore highlight the importance of the methodological work that is done in the HTx project.

## REFERENCES

<https://www.htx-h2020.eu/publications/>