

Investigation of factors considered in the Health Technology Assessment conducted by regulatory authorities in eight countries



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INTRODUCTION

Health Technology Assessment (HTA) organizations play a crucial role in optimizing the healthcare resources and using the budget allocated for its medical care sector. Recommendations made by HTA organizations may vary across countries for a single intervention. Hence, analyzing the factors considered by different HTA organizations on the decision-making becomes important.

OBJECTIVES

To understand the differences in the process and factors involved in decision-making by HTA organizations across eight countries.

METHODS

A targeted literature review (TLR) was conducted from two sources for HTAs that were evaluated up until August 2019 – HTA Accelerator (HTAA; IQVIA's HTA dossier literature platform) and evidence or dossiers available on HTA organizations' webpage. Descriptive statistics were used to measure the frequencies and correspondence analysis was conducted.

Table 1. Data evaluated in the present study

Population/intervention/comparison/outcome/study design (PICOS) criteria		Number of dossiers included per HTA organization			
Target drugs	Hepatitis C: Daklinza®, Sunvepra®, Viekirax®, Harvoni®, Sovaldi® Cancer: Opdivo®, Keytruda®, Kadcyla®, Ibrance®	Organization	Cancer	Hepatitis C	Total
Target HTA organizations	AETSA (Spain), AIFA (Italy), C2H/Chuiyo* referred to as C2H (Japan), CADTH/pCODR** (Canada), HAS (France), IQWiG (Germany), NICE (UK), PBAC (Australia),				
Evaluated factors	Economic evaluations: Incremental cost-effectiveness ratio (ICER) with QALY, cost only, not available	AETSA	5	7 [#]	12
	Clinical uncertainties and issues: clinical benefit, comparator, population and generalizability, safety, sample size and study design	AIFA	8	0	8
	Disease considerations: disease nature/severity, end of life, rare/orphan status, national priority	CADTH/pCODR	21	7	28
	Population considerations: children, disadvantaged population and stakeholder persuasion	C2H	2	5	7
Treatment considerations: complex pathways, innovation, indirect benefit from the treatment, issues around current alternative treatment, manageable/non-significant adverse events (AEs) and unmet needs	HAS	22	7	29	
Future elements of value (suggested by ISPOR special task force): adherence-improving factors, equity, fear of contagion, insurance value, real option value, scientific spillovers, value of reduction of uncertainty due to a new diagnostic and value of hope	IQWiG	23	6	29	
	NICE	23	2	25	
	PBAC	43	8 ^{##}	51	
		Total	147	42	189

*Due to recent changes in the organization of HTAs in Japan, documents from both C2H and Chuiyo documents were used as references
**In Canada, cancer technologies are evaluated by pCODR and other diseases are evaluated by CADTH
#Daklinza, Exviera, Harvoni, Holkira Pak, Olysio, Sovaldi, Viekirax are evaluated in one dossier for AETSA
##Daklinza and Sunvepra are evaluated in one dossier for PBAC

RESULTS

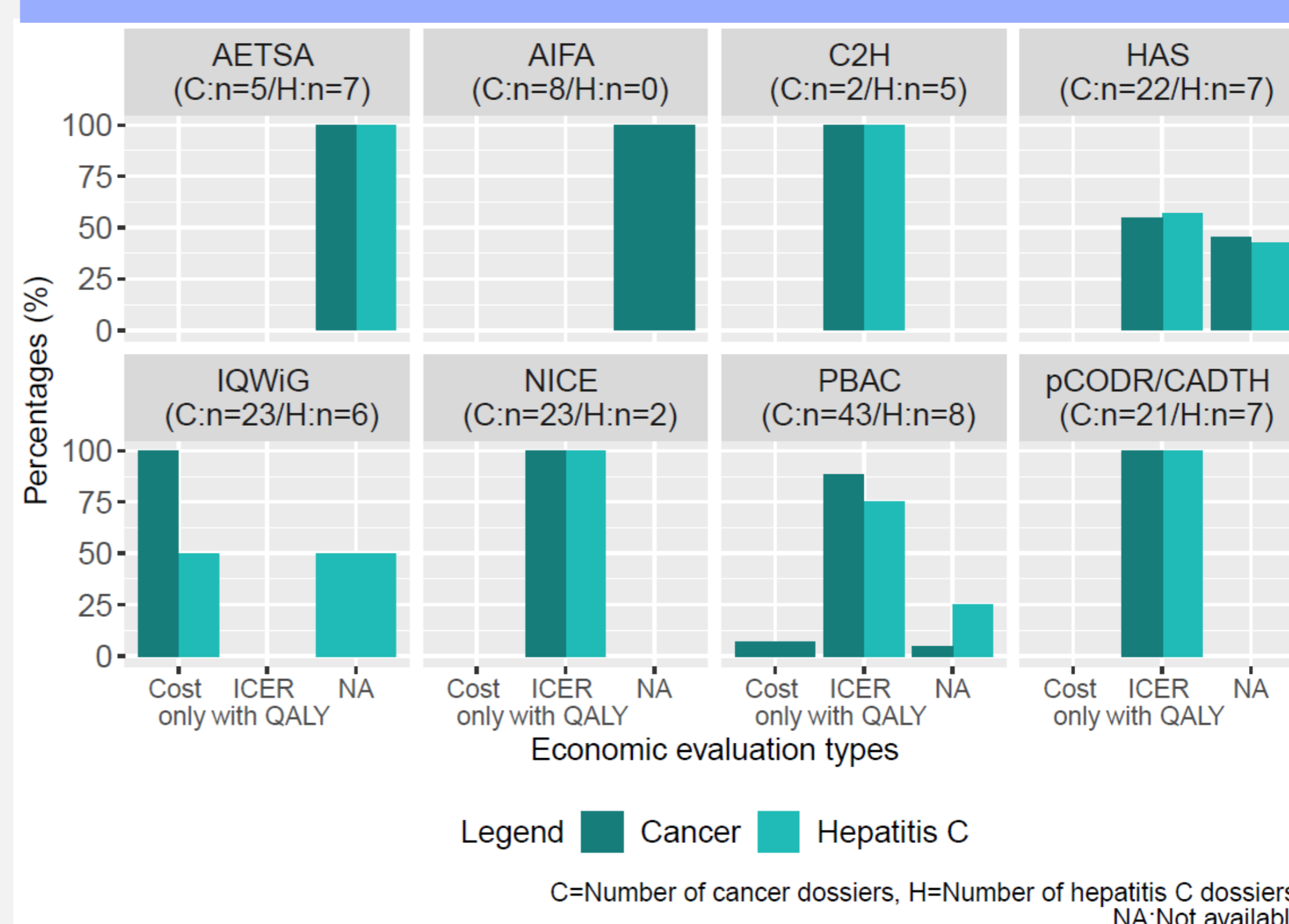
Economic evaluations

- Irrespective of the disease, all or most dossiers by the NICE, the CADTH/pCODR, the C2H and the PBAC used ICER with QALY
- For the IQWiG, all cancer-related dossiers were evaluated using cost only analysis. For the HAS, about 55% of dossiers showed cost-effectiveness analysis using ICER with QALY (Figure 1)

Consideration factors

- The NICE is the only organization to report end-of-life and rare/orphan status; and nearly all factors related to treatment considerations
- For population considerations, stakeholder persuasion and unmet needs were the most common factors reported across HTA organizations
- Correspondence analysis showed the most common attributes observed were unmet needs, stakeholder persuasion, disease nature/severity and indirect benefit. The NICE was distinguished from other organizations for noting additional factors, such as issues around alternative treatment, end-of-life and innovation. The IQWiG, on the other hand, was uniquely associated with manageable or non-significant AEs (Figure 3)

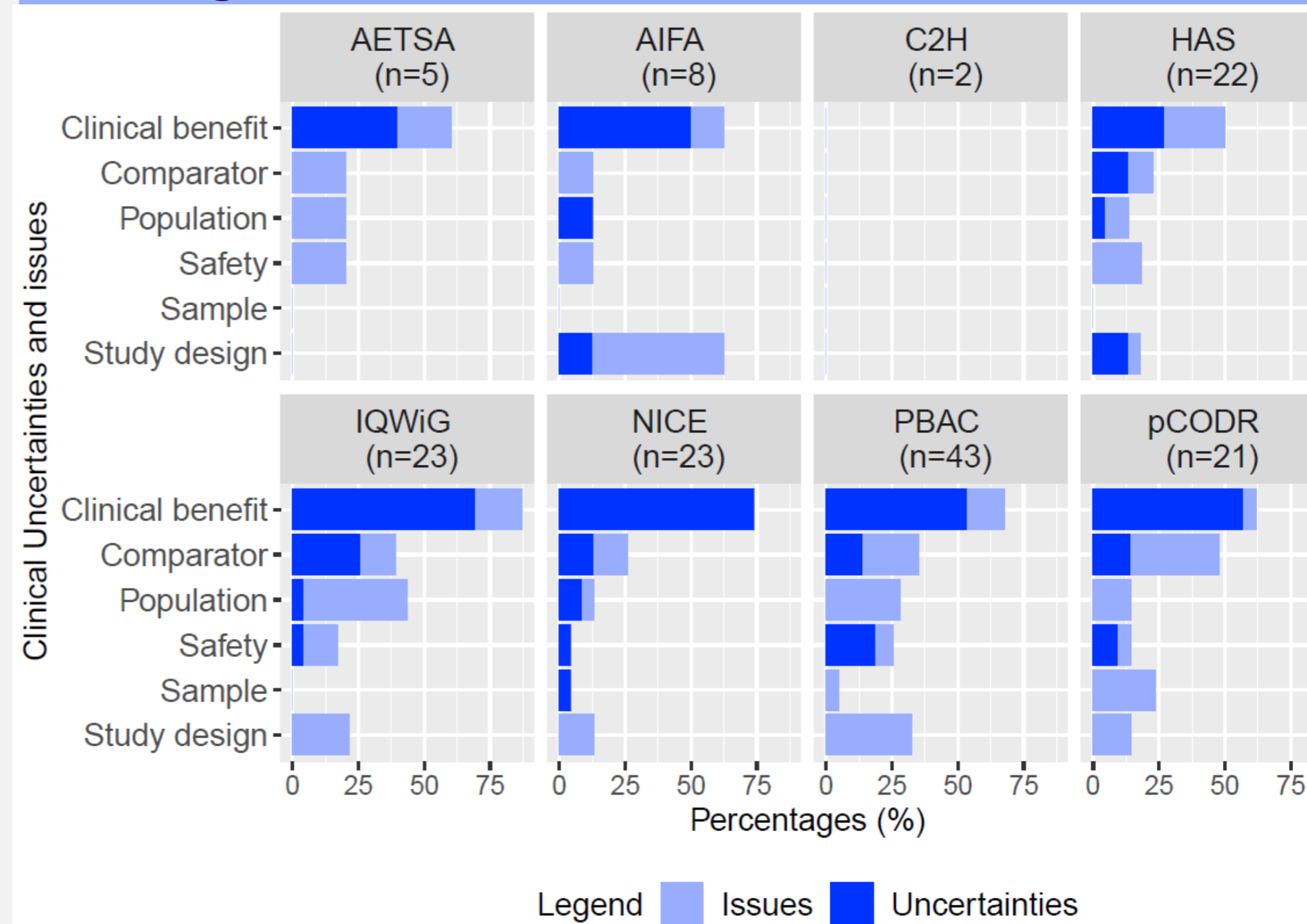
Figure 1. Economic evaluation types by HTA organization and disease



Clinical uncertainties and issues

- For cancer, the highest number of uncertainties observed were related to clinical benefits followed by comparator while the issues reported across organizations were variable (Figure 2)
- For Hepatitis C, similar trends as cancer dossiers were observed.

Figure 2. Cancer clinical uncertainties and issues by HTA organization



Future elements of value

- The PBAC mentioned the most number of additional factors recommended by ISPOR's Special Task Force
- The most common additional elements of value considered by the PBAC included fear of contagion, equity and scientific spillover (Figure 4)

Figure 3. Correspondence analysis for cancer drug evaluation consideration factors

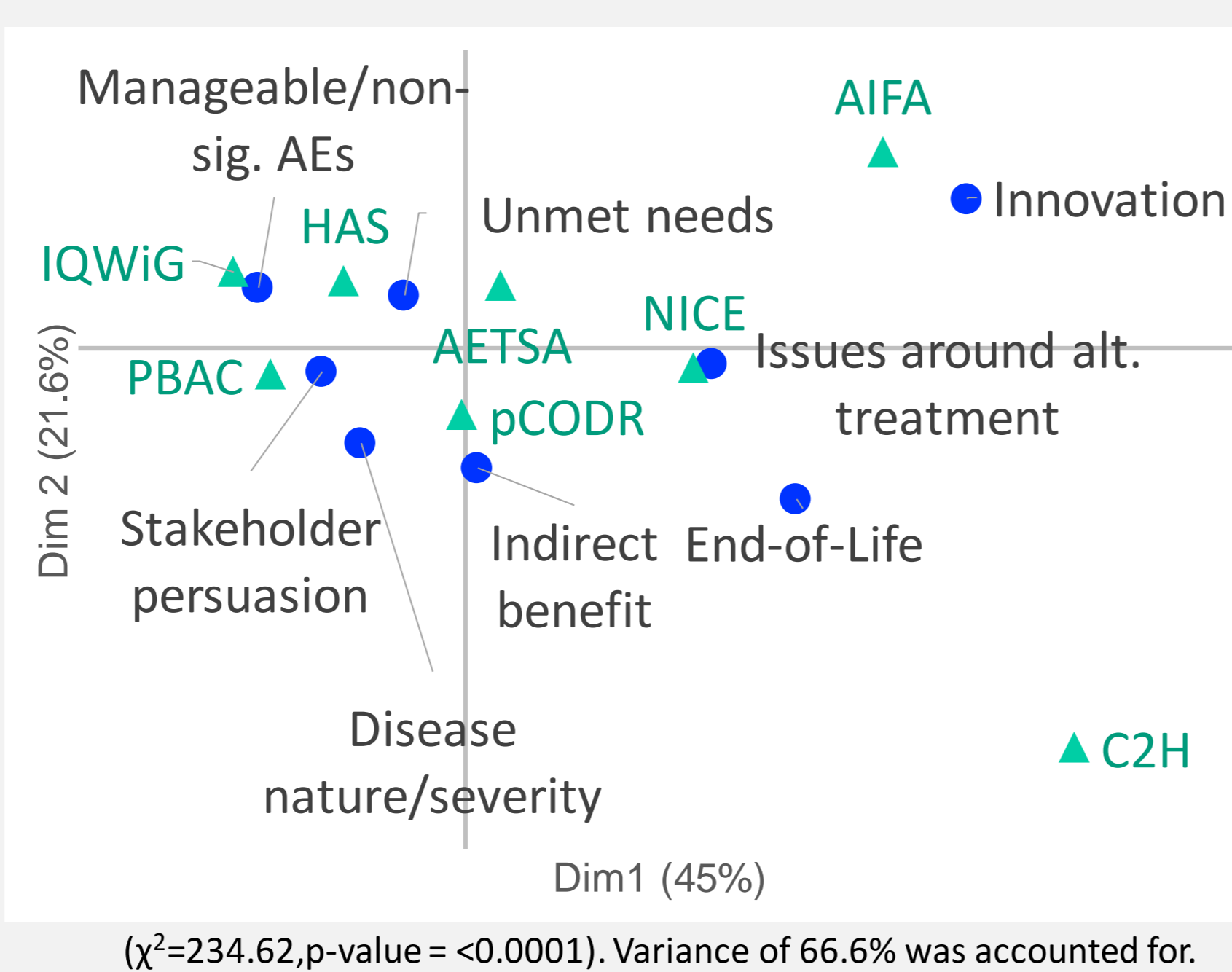
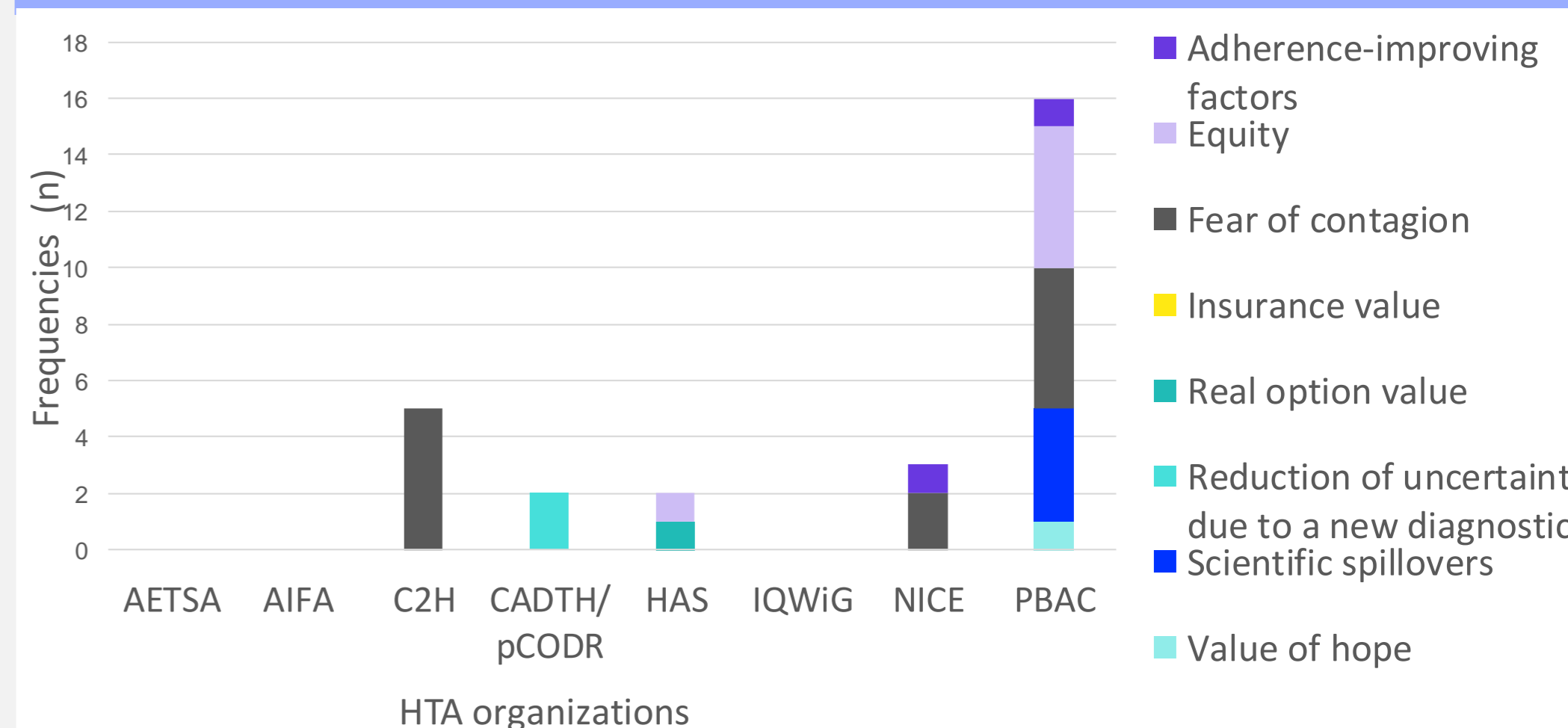


Figure 4. Additional elements of value



Discussion

- Due to the small sample size no definite observations are made
- Due to limitations to publicly available information in HTA dossiers, the study could not determine which factors were included/absent with certainty for decision-making

Conclusion

- Although clinical factors play a predominant role in the decision to reimburse medicine, the NICE and the PBAC were found to be the HTA organizations with the most comprehensive list of additional criteria
- If the decision-making process of HTA were clearly outlined with more transparency into the considered factors, there would be more transparency in HTA systems leading to better understanding amongst stakeholders about decision-making