A Call for Standardisation: Navigating the Inconsistency in European HTA Pharmacoeconomic Guideline Reporting

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METHODS CONSIDERATIONS FOR HTA

Health technology assessment (HTA) processes are applied throughout Europe to evaluate the comparative clinical and economic value of novel health technologies to inform evidence-based resource allocation decisions. The appraisal approach is multidisciplinary, considering the economic, medical, social and ethical impact of introducing and reimbursing novel technologies [1]. Economic evaluations enable policymakers, payers, healthcare professionals, patients and the general population to access information about the costs, benefits and consequences associated with reimbursement decision-making [1].

However, such evaluations necessitate numerous decisions from the analyst and decision-maker concerning the appropriate evaluation framework, evidentiary requirements and the methods used to generate said evidence. For instance…

COST UTILITY ANALYSIS CONSIDERATIONS

If HRQoL data are required, the analyst must determine…

- Which preference-based instrument?
- Is there a preferred source of population norms?
- Whose valuations should inform scoring?
- How should paediatric data be estimation?
- Is a preferred tariff available?
- Should caregiver data be considered?
- What methods should be used if the preferred approach is inappropriate (i.e. psychometric performance)?

PHARMACOECONOMIC GUIDANCE IN EUROPE

Agencies have developed pharmacoeconomic (PE) guidelines to address this uncertainty.

In England and Wales, for instance, the NICE 'Manual' outlines the appraisal processes, timelines and accepted methods for evidence synthesis and economic evaluations [2].

Jurisdictions may, however, specify differences in, for instance, what costs and resources should be considered, what evaluation frameworks are appropriate and how health benefits should be quantified [3]. For example, NICE guidelines specify health effects must be expressed as quality-adjusted life years (QALY), generated using scoring algorithms based on valuations from the general population [2]. In contrast, the Swedish Dental and Pharmaceuticals Benefits Agency (TLV) explicitly states utilities should be derived using tariffs based on the appraisals of people in the health state being valued [4]. Despite this distinction, Burström *et al.* note most applied economic evaluations in Sweden, including those supporting TLV appraisals, utilise the UK version of the EQ-5D-3L value set, creating uncertainty as to accepted practices [5].

There is no standardised template for reporting PE guidelines. Between-country variation in the format and depth of information provided present a barrier for companies developing evidence-generation plans. For instance, varying degrees of information are available for alternative methods of estimating health effects (e.g. where recommended instruments display insufficient psychometric performance). The NICE manual specifies a hierarchy of preferred methods, including the conditions where non-reference case methods such as statistical mapping or direct elicitation methods are appropriate [2]. Other agencies, such as TLV and Fimea (Finland), do not specify alternative methods when deviating from the preferred approach [4, 6].

Table 1: European TA Guidelines

Parameter	England and Wales	Scotland	France	Germany	Denmark	Sweden	Norway	Finland
Agency	NICE	SMC	HAS	IQWiG	DMC & Amgros	TLV	NoMA	Fimea and HILA
Date of Publication	2022 (updated 2023)	2022	2020	2023	2021	2017	2020	2023
Preferred Framework	CUA	CUA	CUA or CEA	CUA or CEA	CUA	CUA	CUA	CUA
Perspective	NHS and personal social services	NHS Scotland and social work	Collective	Statutory health-insured community	Societal	Societal	Extended health service	Health service and societal
Time Horizon	Capture all relevant effects							
Discounting	3.5%, costs and health effects	3.5%, costs and health effects	Public discount rate*	3.0%, costs and health effects	Dynamic, costs and health effects	3.0%, costs and health effects	4.0%, costs and health effects	3.0%, costs and health effects
Primary Health Effect	QALY	QALY	QALY (CUA) or LY (CEA)	Patient relevant outcomes	QALY	QALY	QALY	QALY
Preferred Elicitation Method	EQ-5D-3L	Unspecified generic PBM	EQ-5D-5L	Not specified	EQ-5D-5L	Direct measurement	EQ-5D-3L, UK value set	Unspecified generic PBM
WTP Threshold	£20,000 to £30,000	No formal threshold	No formal threshold	No formal threshold**	No formal threshold	No formal threshold	No formal threshold	No formal threshold

* Gradual decreasing discount rate to 1.5% (>30 years). ** A proportional rule system is employed, whereby the ICER of a new intervention compared to the next effective intervention should not be higher than the ICER of the next effective intervention compared to its next effective alternative.

A CALL FOR STANDARDISED REPORTING

While pharmacoeconomic evaluation is not included in the ongoing implementation of EU HTA Regulation 2022, joint clinical assessments signal increased collaboration between member states for the regulatory approval and reimbursement of novel health technologies [7]. Accordingly, stakeholders must determine in advance which patient outcomes are required and which methods are accepted for marketing authorisation and technology appraisal submissions in the target countries when developing research protocols. The lack of a standardised PE guideline reporting template has necessitated comparative analyses examining between-country differences [8]. This process could be supported and streamlined with standardised reporting formats, saving time and potentially improving the quality of submitted evidence. Consensus across EU HTA agencies may also inform standards for less established agencies, encouraging collaboration to address methodological uncertainty while respecting valid jurisdictional differences.

CONCLUSIONS

Checklists such as CHEERS and PRISMA have been developed to inform the standards and minimum evidence required to facilitate consistent reporting for economic evaluations and systematic literature reviews [1, 9]. However, similar consideration is not given when reporting PE guidelines, and between-country variation limits their comparability and transferability. Jurisdictional differences may be valid, reflecting the stated goals of the appraisal process and the beliefs of stakeholders and decision-makers. However, a standardised reporting template concerning, for instance, the preferred economic evaluation framework, source of clinical efficacy and safety, analysis perspective and method of quantifying health benefits would supplement the a priori generation of research protocols. Organisations such as the European Network for HTA (EUnetHTA) and ISPOR have developed resources outlining the primary features of PE guidelines across Europe [8, 10]. This work, alongside other comparative analyses, may form the basis of a standardised reporting template.

REFERENCES

1. Husereau *et al.* CHEERS 2022 statement: updated reporting guidance for health economic evaluations. MDM Policy & Practice. 2022. **2.** National Institute of Health and Care Excellence. NICE health technology evaluations: the manual. 2023. **3.** EUnetHTA. Practical considerations when critically assessing economic evaluations. 2020. **4.** Dental and Pharmaceuticals Benefits Agency. Ändring i Tandvårds- och läkemedelsförmånsverkets allmänna råd (TLVAR 2003:2) om ekonomiska Utvärderingar. 2017. **5.** Burström et al. Experience-Based Swedish TTO and VAS Value Sets for EQ-5D-5L Health States. PharmacoEconomics. 2020. **6.** Pharmaceuticals Pricing Board (HILA). Preparing a Health Economic Evaluation to be Attached to the Application for Reimbursement Status and Wholesale Price for a Medicinal Product. 2023. **7.** European Union. Regulation (EU) 2021/2282. 2021. **8.** EUnetHTA Joint Action 2. Is There a European View on Health Economic Evaluations? Results from a Synopsis of Methodological Guidelines Used in the EUnetHTA Partner Countries? Pharmacoeconomics. 2016. **9.** Page et al. The PRISMA 2020 statement: an updated guideline for reporting systematic reviews. BMJ. 2021. **10.** ISPOR. Pharmacoeconomic Guidelines Around the World.

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