Building quality in HTA process and decision making: Can key performance measures of good practices in HTA be identified?

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Introduction

Health Technology Assessment (HTA) is increasingly used to assess new medicines in order to inform coverage decision making for efficient allocation of healthcare resources. While there is considerable diversity between HTA organisations and methodologies utilized in HTA assessment in different countries, the HTA agencies are evolving to adopt the best tools and to improve their decision making infrastructures to make high quality decisions. As agency strive to improve their assessment and appraisal process a key element of this is to have quality submissions from companies. The complex environment represents a challenge for the agencies to learn from each other and improve their own process to make better decision, as well as for the industry to adjust their development and submission strategy accordingly.

The Centre for Innovation in Regulatory Science (CIRS) undertakes a series of metrics programmes among HTA agencies and pharmaceutical companies to evaluate both the influence of HTA requirements on development as well as, timelines, procedures and transparency, with the aim to understand and improve the HTA decision making process within companies and agencies.

However one aspect which is critical to good HTA review practices by agencies and good submission practice from companies is to understand just how companies can build quality submission and how agencies can build quality into the HTA process and decision making.

Objectives

- ❑ To establish a working definition of "quality" in the HTA context;
- ❑ To identify the key features of good-quality dossier for submission in an evolving HTA environment;
- ❑ To identify performance indicators to measure the quality of HTA review;
- ❑ To recommend key features to be considered for best practice in HTA process and decision making.

Methods

This study was initiated by developing a working definition of quality in the context of HTA; common elements that underpin a quality submission dossier, and a set of key performance indicators of HTA review processes that companies could provide feedback on as markers of either good quality interaction or HTA review.

International experts representing HTA/coverage agencies, academics and pharmaceutical companies were invited to discuss the definition of quality and identified parameters from diverse viewpoints. The key discussion points and recommendations for performance indicators are outlined herein.

Results

QUALITY

Quality itself is difficult to define and a working definition of quality was developed as "meeting expectations". In the context of HTA, this refers to the expectation of the companies in relation to the quality of an HTA review and of the agencies in relation to the quality of the HTA submissions.

The elements of a quality review and a quality submission can be defined and measured but this requires agencies to provide feedback to companies and vice versa to ensure that each stakeholder is "meeting expectations".

- Four elements of a quality submission dossier were identified. (Figures1 and 2).
- Four main areas of the review process from HTA agencies' perspectives (Figure 3) and ten performance indicators considered important from companies' perspectives (Figure 4) were identified.
- Quality can also be built into HTA review and submissions by ensuring the use of quality management tools designed to ensure or to support good-quality processes such as internal and external peer reviews, audits, standard operating procedures and procedures for learning and feedback.

Quality of HTA submission

Figure 1: Elements of a good quality dossier

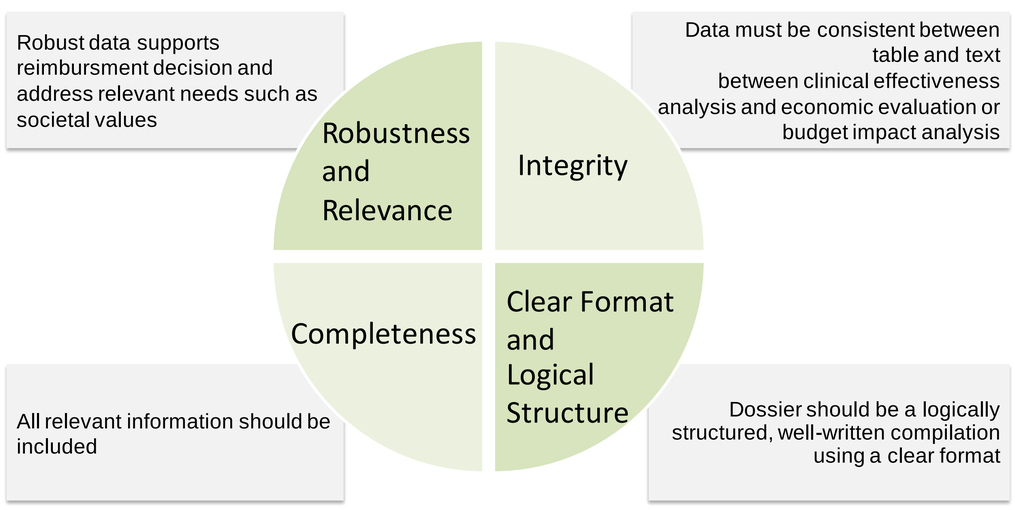

Figure 2: Key consideration when preparing a quality submission and areas for which an HTA agency could provide feedback

Meet HTA requirements

- ❑How scientific advice was incorporated
- ❑Provide justification for not taking /following scientific advice
- ❑Answer all concerns when expressed

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Use objective measures

- ❑Specification of overall quality and robustness of evidence
- ❑Subgroup analysis to be supported and the quality of support details
- ❑Address societal needs adequately
- ❑Cost-effectiveness to be well-proved
- ❑Provide justification for quality of life surrogates
- ❑Present patient perspective

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Tell the story well

- ❑Show where the most benefit will be relevant in the local context
- ❑Explain assumptions made behind dealing with uncertainties
- ❑Be transparent and proactive in addressing the shortcomings

Quality of HTA review

Figure 3: Main areas considered from HTA agencies' perspectives

TIMELINE

- Timeliness is a key measurable indicator
- Queue management – prioritisation techniques
- Special review procedures such as parallel review, rapid HTA

RELEVANCE

- Customer focus - stakeholder engagement with patients, payers and industry
- Transparency in decision making – communication of the attributes taken into account in the deliberative process
- Forum for dialogue to improve processes

CREDIBILITY

- Robust methods
- Consistency and predictability of process
- Availability of guidance documents on detailing HTA process and methods
- Unmet need and public health priorities encompassed in decision making

IMPACT

- Important to understand the impact of HTA on the actual payer
- Assess impact by evaluating the expertise to diffuse technology

Figure 4: Measuring agency performance : Areas for focus considered from companies' perspectives

Item to be considered	Types of areas that could be measured or a company could provide feedback on
Pre-submission dialogue	The extent to which the advice was useful for the submission of the dossier and for avoiding/reducing objections being raised by the agency during review
Scientific advice (if appropriate)	The extent to which the advice aided development and reduced/avoided objections during review
Consistency of the HTA during the review	The extent to which the authority follows its own guidance and process and is in line with previous precedents when reviewing similar products
Process timeliness	Meeting the agency target times
Professional and scientific competence of the authority	Knowledge and experience of the reviewer or agency in the therapeutic area
Nature of questions asked by the authority	Extent to which the question was relevant and clear
The quality of the assessment report	Quality of different parts of the assessment report: Clinical assessment ; Economic assessment
The recommendation	The extent the ultimate recommendation decision was driven by science; the opportunity for discussion and negotiation with the HTA agency in order to reach the optimal product decision
Communication	Accessibility, transparency and professionalism of the HTA authority
Overall assessment of the review process	Overall rate for the quality of the review process

Conclusions

- A key outcome of this research was a clear understanding of what could be markers of a "quality" HTA review or submission from the perspectives of both company and agency stakeholders.
- These key factors, irrespective of the diversity of HTA agencies, could be used to measure if an agency had a quality review process and companies were submitting a quality dossier.
- The next phase of the research will be to develop an instrument to measure the quality of HTA process and submission based on the identified KPIs and to be piloted and validated by key stakeholders.

Bibliography

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