Stage 3: Quality Decision

The instrument was tested for content validity using a panel of experts to rate language clarity, completeness, and relevance. Several themes relating to overconfidence and use of ‘intuition/gut feeling’ emerged as those that influence decision making. For the purpose of clarity, the results are presented in three stages.

Stage 1: Qualitative phase

- The semi-structured interviews were transcribed verbatim and the thematic analysis was performed using NVivo (qualitative analysis software). Examples of the themes are shown in Figure 2.
- The thematic analysis yielded 94-item version of the QoDoS with a 5-point Likert scale response option.
- The instrument was tested for content validity using a panel of experts to rate language clarity, completeness, and relevance and scaling of each item on a 5-point scale (Strongly agree, agree, disagree, and strongly disagree). The agreement among the panel members was high, with an intra-class correlation coefficient value of 0.85 (95% confidence interval = 0.56, 0.93).
- A 75-item instrument (version 2) resulted from content validation.

Figure 2: Three example themes identified through semi-structured interviews

Several themes relating to overconfidence and use of ‘intuition/gut feeling’ emerged as those that influence decision making. For the purpose of clarity, the results are presented in three stages.

Stage 2: Psychometric evaluation

- Factor analysis was performed on the version 2 (75-item) instrument and produced a 47-item measure (QoDoS) with four domains grouped into two parts:
- The 47-item QoDoS (version 3) showed high internal consistency (n = 120, Cronbach’s alpha = 0.89), high reproducibility (r = 0.90, intra-class correlation = 0.77) and a mean completion time of 10 minutes (Figure 3).
- This suggests that the QoDoS is a practical instrument possessing strong psychometric properties of validity and reliability.

Figure 3: Quality of Decision-Making Orientation Scheme (QoDoS): Questionnaire items 1-12 out of 47 shown

For the purpose of clarity, the results are presented in three stages.

Stage 3: Quality Decision-Making Practices

A major outcome of this study has also been the identification of the 10 quality decision-making practices that underpin a quality process (Figure 4). The 47 QoDoS individual and organisational items can be grouped according to these 10 practices.

Figure 4: The 10 quality decision-making practices

The 10 Quality Decision-Making Practices

1. Consider uncertainty
2. Ensure transparency
3. Examine alternative decision-making approaches
4. Evaluate ethical, social, and environmental implications
5. Examine alternative decision-making approaches
6. Examine alternative decision-making approaches
7. Examine alternative decision-making approaches
8. Perform impact analysis
9. Evaluate ethical, social, and environmental implications
10. Examine alternative decision-making approaches

Conclusions

- Although decision-making during the development and regulatory review of medicines influences the delivery of new products, there appears to be no suitable instrument that can be used to assess the process of QDM. This poster describes the development and initial psychometric properties of a new tool that aims to address this unmet need using a standardised methodology.
- Factor analysis was followed by construct validation, examining convergence (evidence that different measurement methods of a closely related constructs correlate) and discriminant/divergent validity (ability to differentiate the construct from other distantly related constructs of the QoDoS). The results showed that the instrument possesses strong measurement properties of reliability and validity, which should provide confidence for its use in the scenarios outlined above.
- The QoDoS can therefore be used to increase awareness of the biases and influences that need to be considered when making decisions, as well as the best practices that should be incorporated into a decision-making framework such as having a systematic, structured approach to aid decision making; assigning values and relative importance to decision criteria; evaluating internal and external influences/biases; considering uncertainty; performing impact analysis; and ensuring transparency. Such practices could lead the EMA to new recommendations to establish "the science of therapeutic regulatory decision making" (Edladivitch and Salmon, 2015).

References


Disclosure