

Factors Influencing Quality Decision Making in Medicines Development and Regulatory Review: Biases and Best Practices



Magdalena Bujar (first year PhD student)^{1,2} • Neil McAuslane² • Sam Salek¹ • Stuart Walker²
 1. University of Hertfordshire, Hatfield, UK; 2. Centre for Innovation in Regulatory Science (CIRS), London UK



Introduction

- Problem:** The various decisions made by pharmaceutical companies and regulatory agencies throughout the life cycle of medicines are critical for ensuring that relatively safe medicines become available in a timely and efficient manner. Despite this, there is a paucity of research into the quality aspect of decision making in medicines research and development.
- Approach:** An organisation that seeks to improve its productivity should also routinely measure the quality of its decision making (Kahneman, 2011). However, decisions with high uncertainty should be judged by the quality of the process, not just by the consequences. Nevertheless, decisions underpinned by a quality process should lead to better outcomes (CIRS, 2004). Consequently, there is a need to develop, validate and employ frameworks and tools to build quality into the decision-making process in drug development and the regulatory review.
- Previous research:** Prior studies have led to the identification of 10 quality decision-making practices (QDMPs) that underpin a quality decision-making process (Figure 1). These were generally considered as relevant by both pharmaceutical companies and regulatory agencies (Bujar et al., 2016). In order to further improve the quality of outcomes in medicines development, the degree of incorporation of these 10 QDMPs into agency and company processes needs to be evaluated.

Figure 1: The 10 quality decision-making practices (QDMPs).



Objectives

- The objectives of this study were to assess the quality of decision making (QDM) by individuals and organisations in order to:
- Identify their strengths and weaknesses
 - Increase awareness of biases and best practices
 - Evaluate differences in decision-making behaviours between pharmaceutical companies and regulatory agencies



Methods

- The Quality of Decision-Making Orientation Scheme (QoDoS) consisting of 47 items that measure individual and organisational decision-making approach and influences (Donelan et al. 2015, 2013) was completed by 76 participants from regulatory agencies and pharmaceutical companies
- All participants were asked to respond to each of the QoDoS 47 statements using a 5-point Likert scale, where 0 = not at all, 1 = sometimes, 2 = frequently, 3 = often and 4 = always
- The data were analysed using descriptive statistics



Results

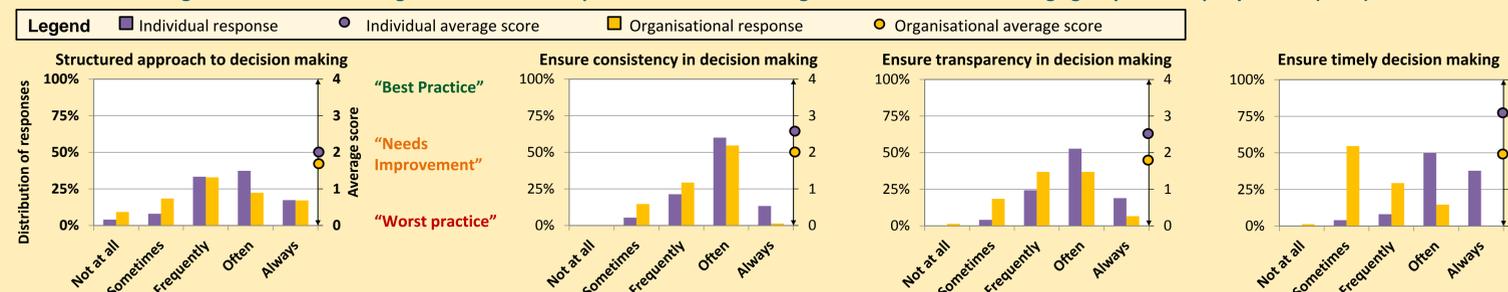
Characteristics of the study participants

Thirty-eight individuals (male=27, female=11) from 12 regulatory agencies and 38 (male=22, female=16) from 23 pharmaceutical companies with varying levels of professional experience (range= 2-40 years) representing medium-sized and large organisations participated in the study.

Individual and organisational decision making

- There were four QoDoS items that were common to both the individuals and organisations namely: structured approach; ensuring consistency; transparency; and timeliness (Figure 2)
- Combined agency and company responses for these items were evaluated to uncover differences between individual practices compared with those of an organisation
- The results show that all four items were incorporated more at the individual level (72%) rather than organisational level of decision making (38%).

Figure 2: Individual and organisational-level responses across four analogous QoDoS items combining agency and company results (n=76).



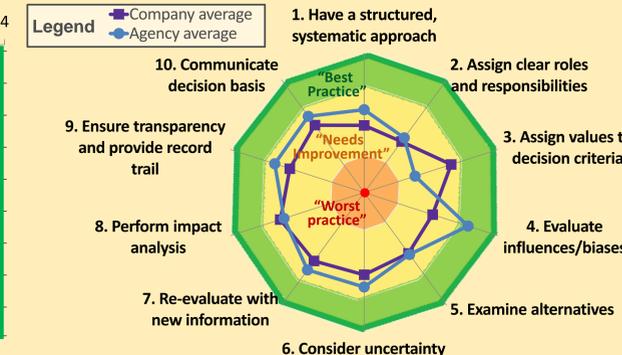
Pharmaceutical regulatory agency and company decision making

- An assessment of agency and company responses identified differences between the two stakeholders. Both groups considered evaluating the impact of the decisions as an important factor, with agencies using a structured, systematic approach to decision making more frequently than companies. Conversely, there was a general tendency for biases, due to politics, competitors or incentives, to have more impact on decision making for companies compared with agencies. Whilst it was recognized that the science of decision making is important, training in this area was rarely provided (Figure 3). All responders from agencies and 92% from companies felt that they could make better decisions
- The organisational-level agency and company responses were mapped against the 10 QDMPs confirming the need for improvement and training in decision making (Figure 4).

Figure 3: Agency and company organisational-level responses across nine QoDoS items (n=76).



Figure 4: Agency and company responses mapped to the 10 QDMPs (n=76)



Conclusions

- QoDoS applicability:** The findings of this study demonstrate that the QoDoS has the ability to identify differences in decision making between individuals and their organisation as well as differences between companies and agencies. It would be of value to initiate additional QoDoS studies in order to further explore and validate the findings of this study.
- Increasing awareness:** The overall benefit of assessing the quality of decision-making practices is to enable an increased awareness of biases and best practices but also to provide the ability to measure change over time in order to determine the impact of improvement initiatives.
- Improving QDM:** Furthermore, such measurements of QDM will enable trust, consistency, transparency and timeliness to be built into critical decisions in medicines development and review.

How good is your decision making?

Assess yourself or your organisation!

References

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Disclosure

Author(s) of this presentation have the following to disclose concerning possible financial or personal relationships with commercial entities that may have a direct or indirect interest in the subject matter of this presentation: Magda Bujar: nothing to disclose; Neil McAuslane: nothing to disclose; Sam Salek: nothing to disclose; Stuart Walker: nothing to disclose;