5 — Framework for improving quality decision-making practices and building institutional knowledge management (KM)

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**Note** — *This presentation describes the work undertaken by the Centre for Regulatory Science (CIRS) in the area of quality decision-making, which has also been the focus of my doctoral research.*

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### 1. Introduction to CIRS

The Centre for Innovation in Regulatory Science (CIRS) is a neutral, independently managed UK-based subsidiary company, forming part of Clarivate Analytics (UK) Limited. CIRS’s mission is to maintain a leadership role in identifying and applying scientific principles for the purpose of advancing regulatory and health technology assessment (HTA) policies and processes. CIRS provides an international forum for industry, regulators, HTA and other healthcare stakeholders to meet, debate and develop regulatory and reimbursement policy through the innovative application of regulatory science and to facilitate access to medical products through these activities. CIRS key international stakeholder organisations include many of those who attended the seminar in the Dublin Institute of Technology in October 2018 on which this monograph is based.

The CIRS quality decision-making programme (*Figure 5.1*) represents a natural evolution of CIRS’s work which has initially focused on performance metrics to benchmark regulatory agency and company process timeliness, followed by focussed research in the area of good submission and good review practices, and lastly benefit-risk assessment of medicines, where CIRS developed a framework for documenting this process. CIRS initiated work in the area of quality decision-making in 2011 with an aim of developing a framework for improving quality decision-making during the lifecycle of medicines.
2. The importance of decision-making

Most companies and agencies currently focus on decision-making outcomes as opposed to the process for making the decision. Nevertheless, as noted in Smart Choices (1999), “Decisions under uncertainty should be judged by the quality of the decision making, not by the quality of the consequences.”. Furthermore, as noted by Professor Larry Phillips, Lecturer and Consultant in Decision Analysis (LSE), “In an uncertain world it is perfectly possible to take a good decision that has poor consequences and equally to make a bad decision and come up with a good outcome. On balance, however, the long-running use of good systems for making decisions will generally give better outcomes”.

The focus of CIRS’s work has been therefore on the process of decision-making to enable quality and ultimately to increase the probability of favourable outcomes. The programme aims to improve awareness of biases and best practices in decision-making in companies and agencies, develop, publish and validate frameworks and tools for use by organisations, and ultimately help organisations to incorporate quality into key strategic decision-making processes.
3. The development of best practices in decision making

In 2010, CIRS and Dr Ronan Donelan, in collaboration with Professor Stuart Walker, Professor Sam Salek and Cardiff University, initiated a study to develop best practices for quality decision-making. In the qualitative stage of the research, in-depth structured interviews were conducted with 29 key opinion leaders from the European Medicines Agency (EMA), the European Union (EU) National Regulatory Agencies, EU and US pharmaceutical companies and US Contract Research Organisations regarding their understanding of the approaches and influences in individual and organisational decision-making during the lifecycle of medicines.

Analysis of the output from these interviews using NVivo 8© software resulted in the identification of 32 major and 97 sub-themes, which were consolidated into 19 overarching themes, as exemplified with quotes from interviews below:

**Example Theme 1: Experience in previous decision-making**

“What qualifies a person to make decisions? Is it scientific or professional training? It is a subjective matter and worth investigating” Pharmaceutical Company.

**Example Theme 2: Individual versus corporate decision-making**

“There is a difference between the corporate decision-making process and that of the individual. We have a good understanding of how a committee makes a decision, but we do not necessarily understand how individuals on that committee have made their own decision” Regulatory agency.

**Example Theme 3: Education and awareness of evolving decision-making techniques**

“It is important that we are trained in decision-making. We also need an understanding and practical application of the tools that can assist our decision-making” Pharmaceutical company.

These themes were further distilled into ten Quality Decision-Making Practices (QDMPs) which can be structured into four areas: Structure and Approach, Evaluation, Impact and Transparency and Communication.

Although these may seem like common sense to organisations, they are not always common practice, as demonstrated through subsequent studies.
4. Evaluation of decision-making processes, challenges and solutions

In 2015-2017 CIRS carried out studies with pharmaceutical companies (regulatory and health outcome departments) as well as regulatory and HTA agencies using structured questionnaires to determine the processes, challenges and solutions to quality decision making. As many decisions are made within these organisations on a daily basis the study was anchored to specific high-level decisions made by the organisations, namely the submission and assessment of medicines. Questionnaires on reimbursement decision making were sent to 16 HTA agencies in Australia, Europe, Canada and Latin America and 24 multinational companies. The responses were compared with published results of questionnaires sent to 25 companies and 14 regulatory agencies in Australia, Asia, Europe and North America. An average response rate of approximately 65% was received from the four groups, which suggested interest in this topic.

Some similarities were identified between the decision-making processes of pharmaceutical companies, regulatory authorities and HTA agencies, such as the use of committees, and having a primarily mixed (qualitative/quantitative) internal decision-making system. Nevertheless, the results indicate differences as companies and agencies use diverse processes to arrive at the final decision, either through consensus,

through majority vote, or an individual making the decision. Secondly, the study evaluated the use of frameworks to structure the decision-making processes within companies, regulatory authorities and HTA agencies. Importantly, although the majority of agencies and companies have a framework in place that forms the basis of their respective decision-making process, a formally defined and codified framework was not always used within organisations, particularly within companies, whereas a number of participants used an informal framework which had never been clearly agreed but over time became practice (by “custom and practice”).

The only way organisations can learn how to make better decisions is by first evaluating the quality of their decision-making. Consequently, companies and agencies were asked whether there are evaluations in place to periodically measure the quality of decision-making. The results indicated that companies and agencies did not generally have such formal assessment in place, despite recognising the need to improve how they currently make decisions.

The following key challenges for quality decision-making were identified from the questionnaires:

- Occurrence of biases: optimism, stability and historical biases from previous decisions
- Misalignment and competing interests
  - Internally, for example, within companies - between HTA and regulatory functions and requirements (focus primarily on registration)
  - Externally, for example, relating to agency requirements and standards – local versus global; HTA versus regulatory
- Time pressure – need to decide quickly and reluctance to start early.

Furthermore, the respondents proposed the following solutions to address those challenges:

- More formal review of decision-making process, outcomes (both positive and negative) and feedback from stakeholders
- Establish or implement a structured DM framework/method that requires values/preferences/uncertainty to be made explicit
- Education and training regarding decision-making and communication.
5. Development of an instrument for assessing quality decision-making practices

CIRS has been contributing to a number of solutions identified by the questionnaires, particularly regarding having a “more formal review of decision-making process” by developing a diagnostic tool for this purpose, the Quality of Decision-Making Orientations Scheme (QoDoS). This project has been initiated in collaboration with Cardiff University and is now continued through a collaboration with the University of Hertfordshire. The QoDoS items were generated from face-to-face semi-structured interviews that were also used to develop the ten QDMPs, as described earlier. Psychometric evaluations including factor analysis, reliability and construct validation were also performed. This study resulted in a 47-item QoDoS instrument organised into four sections namely:

i. organisational decision-making approaches
ii. organisational decision-making culture
iii. individual decision-making competencies
iv. individual decision-making style.

The 47 QoDoS items can be assessed on a 5-point Likert scale. The questionnaire can be completed in 10-15 minutes. The QoDoS item responses have also been mapped to the 10 QDMPs.

Finally, the practicality and applicability of QoDoS to evaluate quality decision-making was assessed through a study with 76 participants from the pharmaceutical industry and regulatory agencies. The results of this pilot study revealed that 39% of participants said that their organisation never, or only sometimes, used a structured approach to decision-making and that 70% indicated that they have never or only sometimes received training in decision-making. Furthermore, the findings demonstrated 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.

CIRS is currently undertaking a number of in-depth case studies with companies, regulatory and HTA agencies, using QoDoS to assess the quality of decision making across various committees and teams within the participating organisations. The objectives are twofold: firstly to raise awareness of biases and practices in decision-making, and secondly to identify strengths and areas for improvement and to assess incorporation of best practices within review teams. High level results from selected case studies are currently being prepared for a publication.

What QoDoS does very well is letting individuals see their short-comings in decision-making. Nevertheless, understanding shortcomings is not enough to fix them as it is hard to correct a bias in our decision-making process just by being aware of it. Consequently, it is important that, following a QoDoS study that may highlight potential weaknesses, an organisation’s select frameworks and tools to improve quality and counter the most relevant biases, as well as embedding practices in formal processes to ensure they are applied consistently.
6. Documentation of practices for better decision-making and enabling knowledge management

Building on the past research, CIRS is now seeking to determine what should be documented at the time of decision to improve knowledge management and future decision-making. Indeed, companies and agencies are continually evaluating how to improve their internal decision-making practices and are evolving systems and processes to ensure that not only is quality built into the process but also that accurate information from past decisions is available to inform current and future decisions. As such, companies and agencies want to correlate their decision-making with outcomes, but this can only be done by documenting what would be the expected outcome of the decision at the time the decision is made. Such documentation would enable a comparison of the expected outcome with the actual result and the impact of the decision without “hindsight bias.” This information can help improve future decision-making, and indeed is a way of ensuring that knowledge gleaned is fed back into a learning system, or what today may be called “institutional knowledge management”.

FDA Commissioner, Scott Gottlieb, has also recently highlighted the importance of documentation of quality decision-making for improving institutional knowledge management:

“Right now, if you asked me how we made a particular review decision in the past, I’d begin by asking our review staff if they’ve confronted a similar clinical circumstance, how it was decided and why. We have limited options to query review decisions to extract how we reached certain conclusions. We can’t store and interrogate the scientific precedent we establish every day. This sort of knowledge management system is essential to how we’re modernising medical product review programmes and establish scientific precedents established every day.”

Over the last three years, CIRS, as part of its research into what practices companies and agencies should consider when building quality into the decision-making process, has reviewed what should be documented at the time of a decision. This was deliberated at a CIRS workshop in 2017 when a Syndicate Group identified internal considerations for measuring the processes and outcomes of decision making, as follows:

- Perform status quo analysis of an organisation’s decision-making process and continue to re-evaluate it in future particularly with process improvement initiatives
- Ensure the availability of documentation at the time of a decision
- Examine and highlight the importance of the rationale for quality decision making not just the methodology
- Document the expected outcome at the time of the decision so that there is a basis for comparison
- Assess the quality of decision-making across multiple decisions.
CIRS is currently undertaking research to develop methods for documenting quality decision making, including a checklist-based approach, to ensure the implementation of quality decision-making practices at the time the decision is made.

7. Conclusion

The methods and approaches developed and validated during this programme of research, namely the questionnaires, the QoDoS and the checklist, led to the development of a roadmap for improving the quality of decision-making processes within companies and agencies for key strategic decisions. This roadmap therefore describes the steps an organisation could undertake to improve the quality of key decision-making processes, namely by first defining the decision, evaluating the ten QDMPs and subsequently better incorporating them into their organisational framework, illustrated in Figure 5.3 below.

**Roadmap for Improving Quality Decision-Making Practices and Building Institutional Knowledge Management**

![Roadmap for Improving Quality Decision-Making](image)

This ongoing CIRS programme of research in the area of quality decision-making marks a milestone in addressing the gap between the well-recognised science of decision-making with that addressed in the area of regulation and reimbursement of medicines. This could revolutionise the way companies and agencies
make and document decisions, which may ultimately increase the probability of good quality outcomes as well as lead to improved organisational knowledge management. Furthermore, as described by one of the CIRS questionnaire participants “the value of quality decision-making is not only just for the decision (and its implications), but to the effectiveness of teams, better productivity between teams and leadership, and to ensure a level of trust across the broader organisation as well as between various stakeholders”.