Quality Improvement (QI) in health care is, at its core, a focus on improving the processes by which services are brought to and applied to people who may need that care.

BACKGROUND & RATIONAL: Pfizer has a dedicated Medical Outcomes Specialists (MOS) team within Medical Affairs that supports quality improvement and real-world research in U.S. healthcare organizations. Increasingly, there has been greater demand from healthcare organizations to conduct innovative QI projects and non-interventional studies focused on assessing quality of care, designing and implementing interventions, and measuring change in healthcare processes and patient outcomes.

THE CHALLENGE: Pfizer Medical Affairs has observed variation and some challenges across U.S. healthcare organizations in the determination of processes to execute QI projects versus research. This variation includes differences in approval and IRB processes, assignment of institutional resources, and publication requirements.

OBJECTIVE: To build a well-referenced tool as an aid to support the U.S. healthcare community in:

- Making the distinction between QI and research
- Considering project elements that may influence classification as QI or research (or both) in a local setting

METHODS: Conduct a targeted literature review, survey U.S. healthcare systems and interview Pfizer field-based MOS colleagues to understand challenges experienced in conducting QI projects within health systems. Use findings to inform QI tool content and design to aid healthcare systems in decision making and “fact finding” about QI processes within their own organizations. Develop a QI Decision Support Tool and obtain initial clinician feedback, with a plan to introduce to health systems in 2019.

LITERATURE REVIEW AND ENVIRONMENTAL SCAN IDENTIFIED:

- SQUIRE as a guide to formulation and documentation of QI
- Ambiguity in research regulations
- Uncertainty about the merits of QI

INTERVIEWS WITH PFIZER FIELD MEDICAL COLLEAGUES WORKING WITH HEALTH SYSTEMS CONFIRMED:

- Differences in the definition of QI versus research categories across systems
- Differences in approval processes (IRB, other) across organizations
- Challenges in working with research contracting parties for QI projects
- Lack of clarity around QI program evaluation

An internet survey of 25 geographically dispersed U.S. health systems with at least 1000 health care providers (HCPIs) was conducted by Pfizer Medical Affairs in December 2018. Respondents were all HCPIs including physicians, physician assistants, nurse practitioners, nurses, or pharmacists who had been involved with the conduct of a QI project within their health system in the past 12 months.

The QI Decision Support Tool diagram, five color-coded decision points and/or guidelines exist that determine whether local systems. The survey was designed to gain feedback on practices in U.S. healthcare systems. The survey was modeled from a national survey conducted to determine whether local guidelines exist that distinguish QI from research, and if so, what criteria were used to guide decision-making.

The literature, survey, and observational data illuminated the need for a process tool that could serve as an aid in supporting QI versus research determination in the local healthcare setting. Pfizer Medical Affairs colleagues, with the support of the Altarum project team, developed the QI Decision Support Tool. This tool is intended to help guide the health care community in classifying projects as quality improvement, research, or possibly both.

In the QI Decision Support Tool diagram, five color-coded decision points and/or considerations can be reviewed while making this determination. These decision points are described in the numbered and color-matched corresponding “supporting information” elements.

The QI Decision Support Tool is an aid to aid U.S. healthcare systems in decision making and organizational fact-finding in making the distinction between QI and research.

Comments included consideration that “yes/no” responses to inquiries at some decision points might more accurately be described as “more or less likely” research versus QI. In addition, if publication or sharing of results outside of an organization are strong drivers of intent to conduct the project, this may tend more toward a research rather than QI classification. Furthermore, the decision to publish often requires departmental scientific review and a corresponding protocol or IRB approval identifier in many institutions.

In continuation of this project, Pfizer Medical Affairs will work with the U.S. healthcare community to gain feedback on The QI Decision Support Tool with the aim of continuous improvement and evolution.

REFERENCES


