What Makes the ABO Risk Based Decision Making Framework Unique?

The ABO Risk Based Decision Making Project is a two-phase project that will provide an overall risk framework with health economics and outcomes tools specially designed for blood safety; stakeholder engagement guidelines; and a web portal. Phase I (April 2013 to March 2014) is devoted to developing a draft framework that will be used as a catalyst for consultation with key stakeholders in Phase II (beginning April 2014).

There are many comprehensive, credible, and time-tested risk frameworks available. What makes the ABO risk framework currently under development different from the others? Designed specifically for blood safety risk assessment, the framework will gauge quantitative and qualitative risk and overall risk tolerance in the context of patient and donor safety. It will also contain guidance regarding the use of health economic and outcomes assessments in the evaluation of risk and mitigation options. And to achieve transparency and optimal input, the framework will include guidelines to enable stakeholder engagement on considerations such as possible gaps and problems, risks, opportunities, alternate solutions, unintended consequences, resources, linkages, and implementation implications. The framework will enable the integration of all of these dimensions into an overall risk profile in order to inform the decision-making process.

Where are we?

As the project moves into the last quarter of Phase I, we made good progress on achieving the goals we set for ourselves in early 2013. So far we have:

- Constructed the overall risk framework, obtained initial feedback on it, and refined it significantly based on the feedback;
- Developed stakeholder engagement guiding principles and step-by-step guidelines for ensuring appropriate and timely stakeholder involvement in the decision-making process;
- Selected the health economic and assessment tools most appropriate for blood safety decisions, and begun development of the assessment guidelines;
- Completed the design of the ABO website (which will house information about blood safety risk-based decision-making) and begun to build the site.

We are on track to have the risk framework and accompanying tools completed and ready to begin feasibility testing and stakeholder consultation as of April, 2014.
Communication

A multi-pronged communication plan has been created to keep stakeholders up-to-date on progress and to socialize the concepts and approaches upon which the framework has been built. Communication of the framework will include channels such as publication of commentaries and manuscripts in industry journals, presentations at meetings and conferences, and updates in newsletters and on the ABO website.

What happens next?

April 1 begins Phase II of the RBDM project. This phase will be dedicated to consulting with stakeholders such as patient groups, blood operators, regulators, and others who have been identified over the past several months. Consultation will be broad and will take a variety of formats including online consultation, face-to-face interviews, and group workshops. The purpose of the consultation will be to obtain feedback that will be used to strengthen and refine the framework. A second important activity in Phase II will be a “stress testing” exercise that will challenge the practical application of the framework to potential risk scenarios. Again, the purpose is to strengthen the framework and its tools by identifying gaps or areas for improvement, prior to its final release in 2015.

Questions? Suggestions?

Questions about the project or suggestions about how we can better communicate with you can be directed to the RBDM project team.