

FINAL REPORT

Project title: **Probabilistic Risk Assessment Chicago Transplant Inquiry Study (PRACTIS)**

Principal Investigators and Team Members:

Richard Cook, MD, University of Chicago
John Wreathall, PhD, Wreathall Associates
James Reason, PhD, Wreathall Associates
Robert Harland, MD, University of Chicago
Jai Raiman, MD, University of Chicago
Allison Smith, Gift of Hope Organ & Tissue Donor Network
Ozzie Rivero, University of Chicago
Christopher Nemeth, PhD, University of Chicago

Organization: The University of Chicago, Chicago, Illinois

Inclusive Dates of Project:

September 1, 2003, thru October 1, 2005

Federal Project Officer:

James Battles, PhD

Acknowledgement of Agency Support:

The investigators gratefully acknowledge the support of both the Agency for Healthcare Research and Quality and the Biological Sciences Division of the University of Chicago. The two institutions provided equal support for the PRACTIS project.

Grant Award Number:

UC1 HS14261-01

STRUCTURED ABSTRACT

Purpose: The purposes of the PRACTIS project were to produce a probabilistic risk assessment of transplant donor/recipient mismatch, to evaluate the sensitivity of probabilistic risk assessment to individual event probability estimates and model changes, to characterize the risk of transplant donor/recipient mismatch, to predict the conditions and processes in which improvements would have significant value, to evaluate the risk assessment results and possible process and condition changes, and to provide a model for successful probabilistic risk assessment to advance patient safety.

Scope: The project addressed the organ transplantation process as it existed in the United States between 2003 and 2004, specifically the aspects of the process relating to blood type compatibility between donor organs and potential recipients.

Methods: The project used probabilistic risk assessment to model the transplantation system. The model was developed in collaboration with transplantation experts and used to estimate the likelihood of ABO incompatible thoracic organ implantation under three conditions: (1) prior to March 2003, (2) between March 2003 and October 2004, and (3) after October 2004.

Results: The predicted rate of ABO-incompatible thoracic organ implantation in the U.S. transplantation system prior to March 2003 was 2.6×10^{-5} per transplanted organ. Changes in the transplantation process mandated by the United Network for Organ Sharing in March 2003 and October 2004 reduced the predicted rate to 3.1×10^{-6} and 2.2×10^{-7} per transplanted organ. Probabilistic risk assessment is a useful means for assessing selected processes in healthcare.

Key Words: risk, risk assessment, transplantation, complications, patient safety, probabilistic risk assessment, mathematical model, accident, human error, mistake

2. Purpose

The narrow purpose of the PRACTIS project was to understand the factors that contribute to the risk of ABO incompatible organ implantation in order to gauge the effects of the countermeasures that have been undertaken to reduce that risk. The broader purpose of the project was to demonstrate the use of a detailed, quantitative method for risk assessment in healthcare and to provide a model for other risk assessments. The specific aims of the project included producing a probabilistic risk assessment of transplant donor/recipient mismatch, evaluating the sensitivity of probabilistic risk assessment to individual event probability estimates and model changes, characterizing the risk of transplant donor/recipient mismatch, predicting the conditions and processes in which improvements would have significant value, and evaluating the risk assessment results and possible process and condition changes in order to provide a model for successful probabilistic risk assessment to advance patient safety.

This project demonstrates one method for producing a quantitative risk assessment. Although the technique used here appears simple, its application requires substantial skill and expertise in order to produce high-quality results. The project itself reflects a small-scale use of the method for a limited purpose. Even in this limited study, the method used represents a significant advance in the handling of risk. It makes explicit the causal relationships under consideration and encourages exploration of these relationships and their sources.

3. Scope

The project addressed the organ transplantation process as it existed in the United States between 2003 and 2004, specifically the aspects of the process relating to blood type compatibility between donor organs and potential recipients. The time periods correspond to the era of transplantation leading up to the Duke University Medical Center accident, a period covering an interim process change instituted by UNOS, and the time since UNOS rules have mandated a process intended to make the likelihood of Duke-like events negligible.

The project provided an opportunity to employ a specific type of risk assessment, *probabilistic risk assessment* (PRA), in a healthcare setting. The quality of PRA models depends on the expertise of the modelers and, in particular, their ability to discover the details of contingencies and operational processes that underlie notional descriptions of how the system works. The PRA model for a system represents a crystallization of the critical relationships in that system and the output of the PRA depend entirely on how well that succinct representation reflects the actual operational system. The exploratory work need for modeling provides important insights that extend beyond model details. These insights are likely to be as valuable or, in some cases, more valuable than the model output *per se*.

There are few examples of successful PRA application in healthcare, and this project is intended to serve as a model and demonstration of a deliberate and carefully controlled application of the technique to an important and controversial topic. In this case, the exploration reveals the tension that exists between the need to ensure biological compatibility between donor and recipient and the need to ensure that donated organs are used equitably throughout the United States.

It is this tension that leads the system to have the features that the model contains and that creates the opportunities for the failures that have been observed.

4. Methods:

The project used probabilistic risk assessment to model the transplantation system. Detailed exploration of the transplantation process was undertaken, including all phases of donor and recipient processing. The exploration included examination of the pressures and demands placed on workers and focused intensively on the processes associated with the generation of the list of potential recipients and the handling of information related to the selection of the designated individual recipient and coordination of organ recovery and implantation.

A review of the history of transplantation accidents was made using newspaper databases and journal articles. A detailed inquiry was done into the most recent ABO-type accident (the “Duke event” of 2003), including reconstruction of the timeline and communications between participants. The details of this reconstructed view of that accident are included in the referenced publication.

The PRA model was developed in collaboration with transplantation experts and used to estimate the likelihood of ABO-incompatible thoracic organ implantation under three conditions: (1) prior to March 2003, (2) between March 2003 and October 2004, and (3) after October 2004.

The results of these studies were presented at a meeting for invited transplantation experts and stakeholders in October 2004. The results form the basis of several presentations, a journal article now being reviewed, and a book chapter that will appear in 2006.

5. Results:

The predicted rate of ABO-incompatible thoracic organ implantation in the U.S. transplantation system prior to March 2003 was 2.6×10^{-5} per transplanted organ. Changes in the transplantation process mandated by the United Network for Organ Sharing in March 2003 and October 2004 reduced the predicted rate to 3.1×10^{-6} and 2.2×10^{-7} per transplanted organ.

The underlying tensions that create the opportunity for this form of failure remain at the center of the transplantation process, and it is likely that these tensions will give rise to other forms of failure. Delineating these new forms of failure is not within the scope of the current project, but they could be addressed by a more detailed, but considerably more expensive, study.

Probabilistic risk assessment is a useful means for assessing selected processes in healthcare.

6. List of Publications and Products:

PRACTIS Workshop Meeting, Gift of Hope Organ & Tissue Donor Network, Elmhurst, IL, October 21-22, 2004. Thirty attendees, including representatives from UNOS.

Cook RI. "Hobson's Choices: Matching and Mismatching and Transplantation Work Processes" in Wailoo K, Livingston J, Guarnaccia P, ed.s, *A DEATH RETOLD: Jessica Santillan, The Bungled Transplant, and Paradoxes of Medical Citizenship* (Chapel Hill: University of North Carolina Press, in press)

Wreathall J, Cook R, Battles J. PRA & Patient Safety: A Trial Application to the Risks of Organ Mismatches in Transplantation. PSAM 8, Proceedings of the International Conference on Probabilistic Safety Assessment and Management 2006 Annual Meeting, New Orleans, LA. (in press)

Cook RI, et al. Probabilistic Risk Assessment of Unintended ABO Incompatible Organ Transplant. (in review at JAMA)

Cook RI. *Other People's Problems: Estimating the Risk of Human Organ Transplantation Miss-Match (Duke-like) Events*. NASA Risk Management Conference 2005 (RMC VI), December 6-8, 2005, Orlando, FL.