



Transplant Information Services Newsletter

A partnership: University of Minnesota Academic Health Center, UMPHysicians, Fairview-University Medical Center

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Mission Statement

Transplant Information Services (TIS) is the limited liability corporation (LLC) formed by the Academic Health Center at the University of Minnesota, Fairview Health Services, and UMPHysicians to support the collection, coordination and dissemination of information about individuals waiting for transplant, organ transplant recipients, and living donors. It does this by managing the information system used for clinical care, conducting hypothesis-driven outcomes research, and managing the database and data warehouse for exploratory transplant research.

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From the Director

With the arrival of the Transplant Information Services Newsletter, the OTTR Islet Module has moved into production within The Diabetes Institute for Immunology and Transplantation (DIIT). Staff will be trained in use of the system during the week of July 12th by Robin Jevne, our DIIT “super-user.”

To say that “Go Live” meant significant work on the part of staff from DIIT and Fairview Information Services is an understatement. Besides the configuration of new software, meticulous testing had to be completed for the myriad of “what if” scenarios that a user could encounter in their daily use of the new system. Staff deserves commendations and kudos for their fine work and attention to detail.

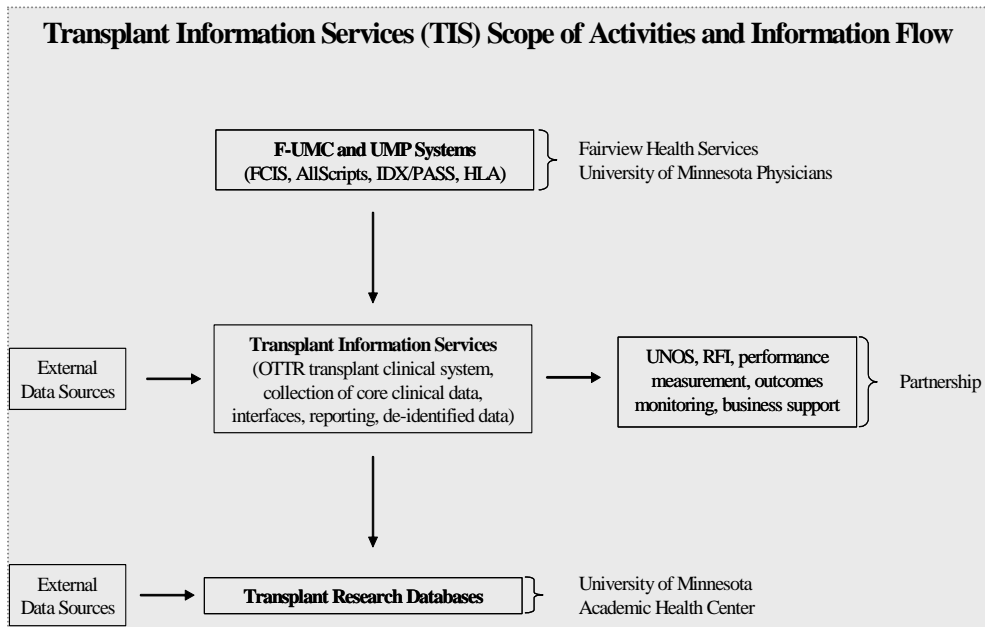
Concomitant with our Islet rollout, we are in the early stages of implementing the OTTR Heart/Lung Module. The process of implementation becomes more complex for obvious reasons: more users, conversion of clinical data, and workflow changes.

Finally, the Protocol Review and Data Use (PRDU) Committee has reviewed and made recommendations on twenty-five solid organ transplant research projects since the Committee’s inception August 2002. Lisa Pulkrabek, who is the administrative coordinator for PRDU, explains the Committee’s function and process for reviewing transplant research protocols.

David M. Radosevich, Ph.D., R.N.

How OTTR Works

The diagram depicts how OTTR fits into the scope of TIS activities and information flow.



Within the present scope of work, electronic interfaces are planned between the OTTR system (center box) and IDX, HLA immunology and laboratory (upper box). OTTR will replace the SOTA system, a number of free-standing databases built over the years, and supplemental records used in the Transplant Office. Once fully operational, OTTR will be used for regulatory reporting, business support, quality assurance and improvement, and outcomes monitoring. Core data from OTTR will be used by faculty investigators for hypothesis driven research that has been approved by the Institutional Review Board.

David M. Radosevich, PhD, R. N.

The Islet Module Nears Completion

The Islet Processing Core, Immunology Core and Clinical Core members have diligently participated in redefining and customizing the configuration of the Organ Transplant Tracking Record (OTTR) application. The configuration process, by both Fairview and OTTR's vendor, Hickman-Kenyon Systems (HKS), is near completion. Staff members at The Diabetes Institute for Immunology and Transplantation (DIIT) are enthusiastically anticipating implementation of the software.

Training for DIIT staff members will occur within the next week while we move forward into testing the Islet production Go-Live segment of this process. The interface for the Collaborative Islet Transplant Registry (CITR) and UNOS are not part of this stage. However, upon completion, we anticipate elimination of duplicate entry and more efficient reporting mechanisms.

Go-live for the Islet Module will ensue in the next week. The islet team will be provided with a comprehensive real-time interface to patient data.

The six major areas will include demographics, diagnosis, medication, flow sheets, actions, and progress notes. At any given moment, the medical staff will have a complete picture of a patient's medical status.

Robin Jevne, PhD

Heart-/Lung Module Rollout

The Heart/Lung rollout is well underway. Lisa Cunningham and Marci Knaak have presented OTTR demonstrations to the clinical leads in the programs. David Radosevich has been coordinating clinical data conversion for the Heart- Lung groups.

Marci has been working closely with the Transplant Coordinators to evaluate their current workflow and determine what is important to have in OTTR. The OTTR vendor (HKS) was on site on June 29th and June 30th to meet with both groups to determine configuration needs and will meet with Randy Mathowitz to complete the configuration.

On July 14th and 15th, HKS will conduct training for the Heart and Lung groups. This will include two Super Users chosen from their respective groups. The Super Users, Barb Sampson from Heart Transplant and Diane Elmajri from Lung Transplant, will be responsible for training other people within their transplant group.

Implementation of the Heart-Lung Module is scheduled for August 2004.

Lisa Cunningham RN, BSN

Protocol Review and Data Use Committee (PRDU)

The mission of the Protocol Review and Data Use (PRDU) Committee is to evaluate, prioritize, approve, monitor, and review all University of Minnesota clinical transplant research protocols and to make recommendations regarding the use of data from the transplant clinical system. In evaluating research protocols, the following are considered: (1) scientific relevance, (2) validity of the hypothesis, (3) adequacy of the study design, (4) patient survey design and methods, (5) biostatistical validity, and (6) feasibility of timely completion of the study. All results, preliminary or final, will be reviewed by the PRDU prior to public dissemination, including non-funding agencies or press. This review does not include professional conference presentations.

The Committee received formal approval from the Transplant Information Services Board of Directors on June 11, 2002. This standing committee is independent of the Institutional Review Board (IRB). It specifically does not compete or overlap with the IRB, but does assist the IRB by providing a scientific review of all solid organ and tissue transplant protocols. Final approval before implementation of any protocol rests with the IRB.

PRDU began its conduct of scientific review of all solid organ transplant research protocols in August of 2002. To apply for PRDU review, the investigator or designee must submit a copy of the IRB application and other study materials, such as case report forms and survey instruments. The due date for submission of review materials is ten working days prior to the next PRDU meeting (the first Friday of each month). Members consist of transplant surgeons and physicians, as well as public health research staff. The committee's non-voting members are from the staff of the Institutional Review Board (IRB) and the Academic Health Center's Office of Regulatory Affairs.

The committee typically reviews two submissions a month and often suggests improvements to and revisions of the scientific questions and study methods to support higher quality research. Applicants should submit all materials for review to Lisa Pulkrabek at intercampus mail address 925 Delaware St, Suite 150.

Lisa Pulkrabek, RN, BAN
