OPTN/UNOS OPO Technology Consensus Conference
San Antonio, Texas
March 1-2, 2005

Conference Summary

This document summarizes the events, deliberations and outcomes of the second OPTN/UNOS OPO Technology Consensus Conference which was held in San Antonio, Texas, on March 1 and 2, 2005. Attached documents provide the details of presentations and group work, as well as the results of the conference evaluations. The conference agenda is included as *Attachment 1*.

The two-day conference was attended by 81 individuals, representing 41 organ procurement organizations (OPOs), 4 transplant centers, the Department of Health and Human Services, UNOS and several OPO data system companies. The list of conference participants is included as *Attachment 2*.

Day 1 –

The morning began with welcome and introductory comments by Berkeley Keck, Assistant Executive Director of Information Technology at UNOS. Mr. Keck reviewed the progress that was made during the initial OPO Technology Consensus Conference that was held in Chicago in December 2004. He noted that the consensus issues resulting from that meeting were the focus of this two-day conference. Mr. Keck commended the OPOs for the progress that was made in December and their commitment to participating in this process.

Brian Lunde, Information Systems Manager at LifeSource and Chairman of the OPTN Technology Subcommittee, followed with a welcome and an overview of the agenda for Day 1. As Moderator for Day 1, he introduced the plenary presentations related to the following areas:
- Data Model Case Studies
- Healthcare Data Security & Privacy Issues
- Successful Strategies in Obtaining Internet Access in Donor Hospitals

The presentation on Data Model Case Studies was provided by Ed Pierson, Chief Information Officer and Vice-President of Healthvision, an Irving, Texas-based, healthcare technology company. Mr. Pierson provided an explanation of what a data model is and why it is important in defining how data and information is shared. He provided examples of three data models and explained the benefits and limitations of each type of system. The three models illustrated included the Pointer Model, Longitudinal Data Repository Model and a Blended Model. Mr. Pierson's presentation is included as *Attachment 3*.

Mark Brown, Chief Information Security Officer for the Health Resources and Services Administration (HRSA), an agency of the U.S. Department of Health and Human Services (DHHS), spoke on Healthcare Data Security & Privacy Issues. His presentation addressed the definition of system interconnection, covered associated requirements as specified by National Institutes of Standards and Technology (NIST) guidelines, and outlined privacy issues related to the Privacy Act of 1974 and the DHHS Privacy Impact Assessment Guide. Mr. Brown offered several valuable resources to the participants for more information on these issues. His presentation is labeled *Attachment 4*.

A panel presentation led by Dave Gee, Director of Information Services at Gift Of Life Michigan, focused on Successful Strategies in Obtaining Internet Access in Donor Hospitals. Mr. Gee provided case studies of two local donor hospitals in which the OPO was able to gain Internet access by working with the donor hospital administration and information technology staff. He also noted that recently their organization has updated memorandums of understanding with each donor hospital to include the requirement that a high-speed internet connection be provided. His presentation (*Attachment 5*) concluded with points of advice for other OPOs. Mr. Gee was followed by Carolyn Olivarez, the Director of QA, Risk Management and Regulatory Compliance at LifeGift

Organ Donation Center. The focus of her OPO's strategy was based on utilizing the assistance of in-hospital coordinators to make contact with the appropriate hospital staff, and provide information and education to the management and staff of the donor hospital related to the benefits associated with the OPO having access to the Internet. Ms. Olivarez also concluded her presentation (*Attachment 6*) with helpful advice for effecting these changes. The final member of the panel to speak was Todd Jennings, the Director of Information Technology for the Transplant Resources Center of Maryland. Mr. Jennings related how their data system accommodates multiple routes of communication via the Internet depending on the donor hospital or situation, to connect with the data system server maintained at their headquarters. He concluded his presentation (*Attachment 7*) by noting that his OPO is in the process of updating their memorandums of understanding with each donor hospital to include the requirement that a high-speed internet connection be provided. This is similar to a strategy that was also mentioned by Dave Gee during his presentation.

Following the plenary sessions, participants were divided into four Data Model working groups. Groups were instructed to use the information provided during Mr. Pierson's presentation and any other information they possess to formulate a list of benefits and disadvantages for each of the various data models, and from this discussion reach a consensus on one model, providing rationale to share with the larger group.

The four Data Model work groups deliberated independently for nearly three hours. Each group provided their findings to the reconvened full session of participants. The points made by each group during their presentations have been collated into *Attachment 8*. All four work groups independently reached the same conclusion that a "Hybrid Data Model" will currently best serve the transplant community. The consistent themes that were discussed and for which there was general agreement by the full attendance are summarized as follows:

- Adopt a Hybrid Data Model, which is based on the Longitudinal Model for Offer with the OPTN as the repository of organ offer data, but in which the OPO uses their own systems for donor data collection
- Need to develop standardized donor data set
- Need to survey OPO's and Transplant Centers regarding how this model would function for them
- As it currently stands, there cannot be a single OPO data system that is utilized by every OPO
- A standard should be published that all OPO data systems (purchased or developed) must meet
- Handheld technology will only become easier to use and cheaper to buy
- Surgeons may welcome the change since offers will take less time and will require fewer pages and calls
- There should be a single display of donor information with a common language and look that is accessible by all OPOs, accepting surgeons/physicians, and tissue banks
- There could be work-in-progress data sets, which can be updated, coexisting with the ultimately validated final version
- An approach discussed by the group to implement the data model is as follows:
  - o OPO captures data electronically at the bedside as specified by the OPO's data system
    - ▪ The OPO's data system must to include or meet a standardized donor data set
    - ▪ The system should include validation of minimum acceptable business rules
  - o Donor data would be communicated to the central repository in a standardized format but the OPOs need to have the ability to communicate data through other means as a contingency plan
    - ▪ Organ specific data sets should be defined by OPTN organ specific committees
  - o Notification algorithm developed (when, how and conditions) and implemented in the UNet[sm] match system
    - ▪ Automated multiple organ offers
    - ▪ Acknowledgment of offer (read receipt) is needed
    - ▪ Current policy needs to be changed to allow transplant centers to enter refusal codes
    - ▪ Notify centers of all of their listed patients by order on the match
    - ▪ On-demand update of acceptance criteria by transplant centers for individual candidates and their full list of candidates.
  - o Automatically populated Deceased Donor Registration and Donor Feedback from the centralized repository data.

Day 1 of the conference adjourned following consensus on these themes.

Day 2 –

The second morning of the Consensus Conference began with a plenary gathering of the participants. Todd Jennings, Director of Information Technology and Communications and Chairman of the AOPO Information Technology Subcommittee, was the Moderator for Day 2. Mr. Jennings welcomed the participants and provided an overview of the second day's agenda. He invited the participants to continue their stay in order to attend the AOPO Quality Improvement Council and Information Technology Subcommittee meetings that would be held on the two days following the Consensus Conference. Mr. Jennings instructed the participants to break into their respective impact breakout groups. The groups were as follows:

- Data
- Technology
- Security & Privacy
- Processes

He challenged the groups to work toward developing consensus on ideas and plans related to their assigned subject that could be integrated with the consensus "hybrid" data model agreed upon the preceding day.

The Impact Breakout Groups relocated to their assigned meeting rooms, and deliberated for approximately three hours. Following a brief lunch break, participants reconvened for a plenary session where each group presented their topic-specific conclusions. A full summary of the points presented by each group is included as *Attachment 9*. Abbreviated summaries are included below:

Technology Group –
The Technology Group concentrated on a possible model for use of technology in the process. This model is based on the OPO capturing donor data at the bedside via OPO-specific protocol and data system. Each OPO data system must include a standardize data set for communication of donor data with the central repository (OPTN) and include other means of donor data communication as a contingency plan. The standardized data set would be established using OPTN/UNOS Policy direction and guidance from the OPTN organ-specific committees. The Group discussed ways in which organ offers could be communicated in an automated, electronic manner. They also discussed the challenges in implementing a technology-based methodology for making organ offers and communicating donor information.

Security and Privacy –
The Security and Privacy Group identified the guiding principles of:

- Confidentiality – "Preserving authorized restrictions on information access and disclosure, including means for protecting personal privacy and proprietary information"
- Integrity – "Guarding against improper information modification or destruction and includes ensuring information non-repudiation and authenticity"
- Availability – "Ensuring timely and reliable access to and use of information"

The Group discussed the process for implementing the "Hybrid" data model and focused on regulations and requirements that govern interconnectivity of data systems. It was agreed that a set of all-inclusive applicable regulations should be collected and distributed to all OPOs. Additionally, the OPTN IT subcommittee and AOPO IT Subcommittee should encourage OPOs to follow the highest standards - even for OPOs not interconnecting with the OPTN system. The Group determined that preferred security measures should be shared among the OPOs, and that one way to do this may be to host a *Live Meeting* to discuss results of different tools. All agreed that a goal was not to reinvent the wheel. In conclusion, the Group encouraged every OPO to take advantage of the following resources: National Institute for Standards and Technology, www.nist.gov; Mark Brown with HRSA, mbrown@hrsa.gov; Blaine Hess with UNOS, hessbt@unos.org; and the AOPO Sharepoint site (Todd Jennings, Brian Lunde, David Gee).

Process Group –
The Process Group began their presentation by illustrating the current serial process utilized for organ placement. The group focused their discussions on how an electronic parallel organ placement process could be implemented using the consensus data model. This process would be based on the current OPTN allocation system utilizing a parallel offering methodology where simultaneous organ offers could be made to a grouping of transplant candidates

in the current match run sequence. Offers would be made electronically through the OPTN system to transplant personnel who are on-call for program of the listed candidate. An electronic notification algorithm would be utilized to determine the size of the group to be notified simultaneously and to make the initial electronic communication of the organ offer. The Group felt it would be best if the OPTN/UNOS organ specific committees developed the notification guidelines to support the decision of the OPO coordinator. In concluding their presentation, the Group identified challenges to implementing this system that include: OPO and transplant center resistance to change; having enough resources (personnel and/or finances) to accomplish the required tasks; and having transplant centers adopt technologies for notification of organ offers that complements their current system. In discussion of the points of this presentation, it was noted that a potential secondary effect of high volume parallel organ offers will be that transplant candidate listing criteria will be indicated in the OPTN system more appropriate to the patient's condition and to the center's acceptance criteria, as well as more organs may be utilized for candidates who are best suited for the available organ which may lessen the need for aggressive placement efforts.

Data Group –
The Data Group concentrated on the type of donor data that must be transferred. To facilitate their discussion the group viewed various donor data points including a smaller data set of > 100 fields that is being trialed in an organ placement pilot project between UNOS and several OPOs. It was agreed that using this "short form" data was a good starting point. The Group also agreed that it would be necessary to continue to review ongoing data standardization efforts, and to eventually adopt national standards such as the National Heath Record Standards as they are codified. The Group concluded that will be necessary to get a consensus on all of the data elements before they are compiled and distributed as the industry standard.

Following presentations by each breakout group, Berkeley Keck moderated a plenary discussion of the points of consensus that were established during the conference. There were many questions and opinions expressed by the participants. These focused on:
- Factors influencing the implementation of a system for parallel organ placement
- The need for more input and participation from transplant centers in the planning and implementation process of such a system
- How best to keep this momentum and to make the data model and parallel placement system a reality.
- What is the next step?

Mr. Keck informed the participants that UNOS IT staff will modify future development plans for UNet[sm] and DonorNet[sm] to facilitate the desired "Hybrid" data model. He also noted that UNOS was beginning a pilot project with three OPOs and five transplant centers to demonstrate the communication of donor data from the OPOs' data systems to DonorNet[sm] where it will be posted in association with the donor record for review by participating transplant centers when an organ offer is made. He further stated that development of a parallel organ placement system is a goal of UNOS and a desire of HRSA. To continue this positive momentum, OPOs were encouraged, if they have not already done so, to implement a donor data system whether it is developed in-house or purchased. Additionally, it was recommended that all OPOs work with their primary donor hospitals to obtain on-site Internet access. These two achievements will prepare the OPO for implementing the consensus systems when they are available. In closing, there was an overwhelming sentiment that there should be another consensus conference to continue work on these issues. In addition, the need to include transplant centers in the next conference and obtain their perspective was noted. Participants also agreed that they would be willing to pay a registration fee in order to defray the cost of the conference. Mr. Keck stated that another conference would likely not be possible until the fall. The participants agreed.

Conference evaluation forms were distributed on the second day to the participants. Of the 81 total participants, 52 evaluation forms (64%) were returned and tabulated. All respondents (52) felt the conference was productive and informative, and most all (50) indicated that a future consensus conference would be beneficial. A summary of the conference evaluations is included as *Attachment 10*.