Attachment 1

OPTN/UNOS OPO Technology Consensus Conference

La Mansion del Rio Hotel
San Antonio, Texas
March 1 – 2, 2005

Agenda

DAY 1 -

Continental Breakfast Provided from 7:00 - 8:00 a.m.

8:00 a.m. **Welcome & Opening Remarks**
Berkeley Keck, UNOS
Brian Lunde, OPTN Technology Subcommittee

8:30 a.m. **Opening Plenary Sessions**
- Data Model Case Studies
  Ed Pierson, CIO & VP, Healthvision
- Healthcare Data Security & Privacy Issues
  Mark Brown, ISS Program Manager, HRSA
- Successful Strategies In Obtaining Internet Access In Donor Hospitals
  Panel Presentation – David Gee, Moderator

11:30 a.m. **Data Model Breakout Group Briefing**
Breakout Group Instructions and Assignments

12:00 noon **Lunch**

1:00 p.m. **Data Model Breakout Sessions**
Data Model Breakout Groups will:
- Formulate a pro and con list for various data models
- Gain consensus on one model and provide rationale

3:30 p.m. **Data Model Breakout Group Presentations**
Each group will present their deliberations, followed by discussion & consensus building by the full attendance

5:00 p.m. **Adjournment**

Agenda

DAY 2 -

Continental Breakfast Provided from 7:00 - 8:00 a.m.

8:00 a.m. **Opening Remarks**
Todd Jennings, AOPO IT Subcommittee
- Impact Breakout Group Instructions

8:30 a.m. **Impact Breakout Sessions**
Participants will divide into the following four Impact Breakout Groups to discuss how their assigned subject will integrate with the selected data model
- Data
- Technology
- Security & Privacy
- Processes

12:00 noon **Lunch**

1:00 p.m. **Impact Breakout Group Presentations**
Each Impact Breakout Group will present their deliberations, followed by discussion & consensus building by the full attendance

4:00 p.m. **Closing Remarks**
- Consensus statements reviewed
- Next steps outlined

5:00 p.m. **Adjournment**

March 3 & 4 - AOPO Spring Quality Improvement Council Educational Forum and Business Meeting of Quality & IT Representatives

Attachment 2

OPTN/UNOS OPO Technology Consensus Conference
March 1-2, 2005
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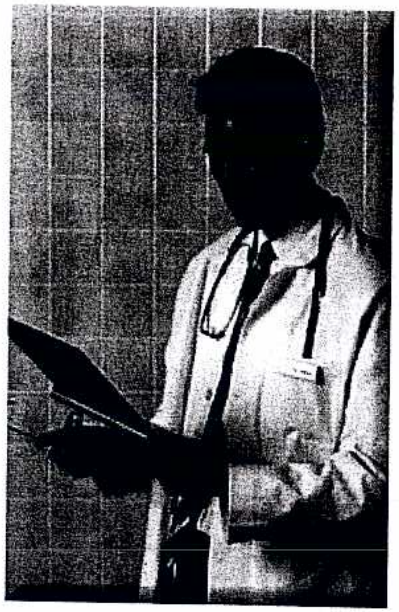
Attachment 3

Imagine A Connected Organ Donation Community

Our Healthcare System in Crisis

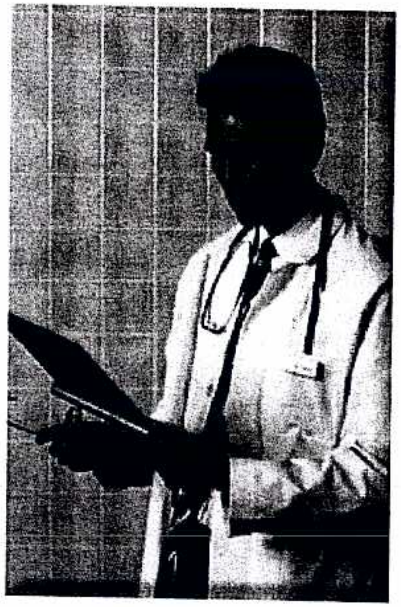
"...*the most remarkable feature of this twenty-first century medicine is that we hold it together with nineteenth-century paperwork"*

Tommy G. Thompson
Former Secretary,
Department of Health and Human Services



Our Healthcare System in Crisis

Each day, about 70 people receive an organ transplant. However, 16 people die each day waiting for transplants that can't take place because of the shortage of donated organs.



Your donor's file is in here... *somewhere.*

What are Data Models and why are they important?

- Data models are attempts at organizing information in a useful way.
- The intended use of the data and the difficulty in gathering the data impact the right solution.
- The type of individual needing the data is a critical factor in the design.
- The urgency of the data is a huge factor.
- How many different groups need to update the data is a factor
- The source of the data (electronic, paper, scanned) is also a key factor.

So what are the possible ways to structure a solution..... Lets look at what other systems are using....

Healthcare based

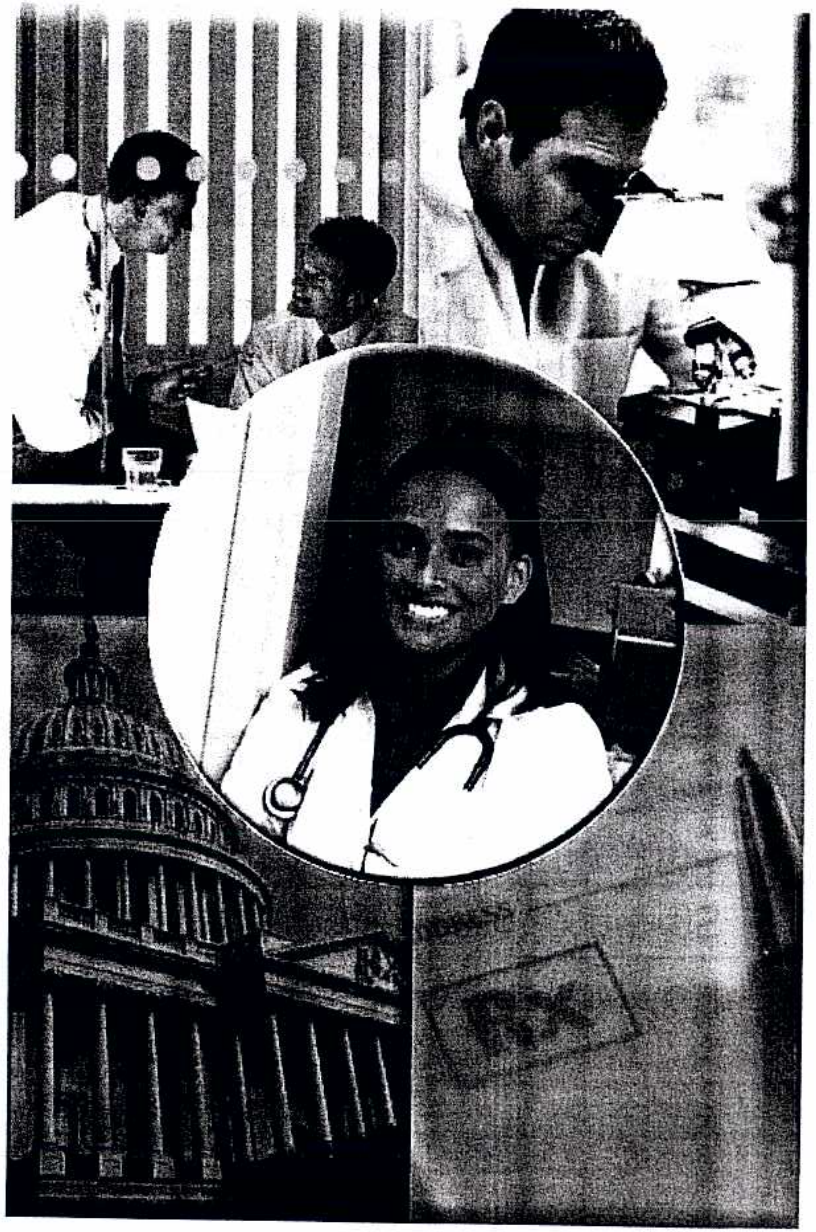
- Pointer Model (used by Santa Barbara County Care Data Exchange)
  (Google approach)
  (Internet DNS approach)
  (Criminal records research – access police records)
- Longitudinal Data Repository (used by Taconic IPA / MedAllies in New York)
  (Library of Congress approach)
  (Federal Reserve approach)
  (Banking / ATM approach)

Key Issues Table

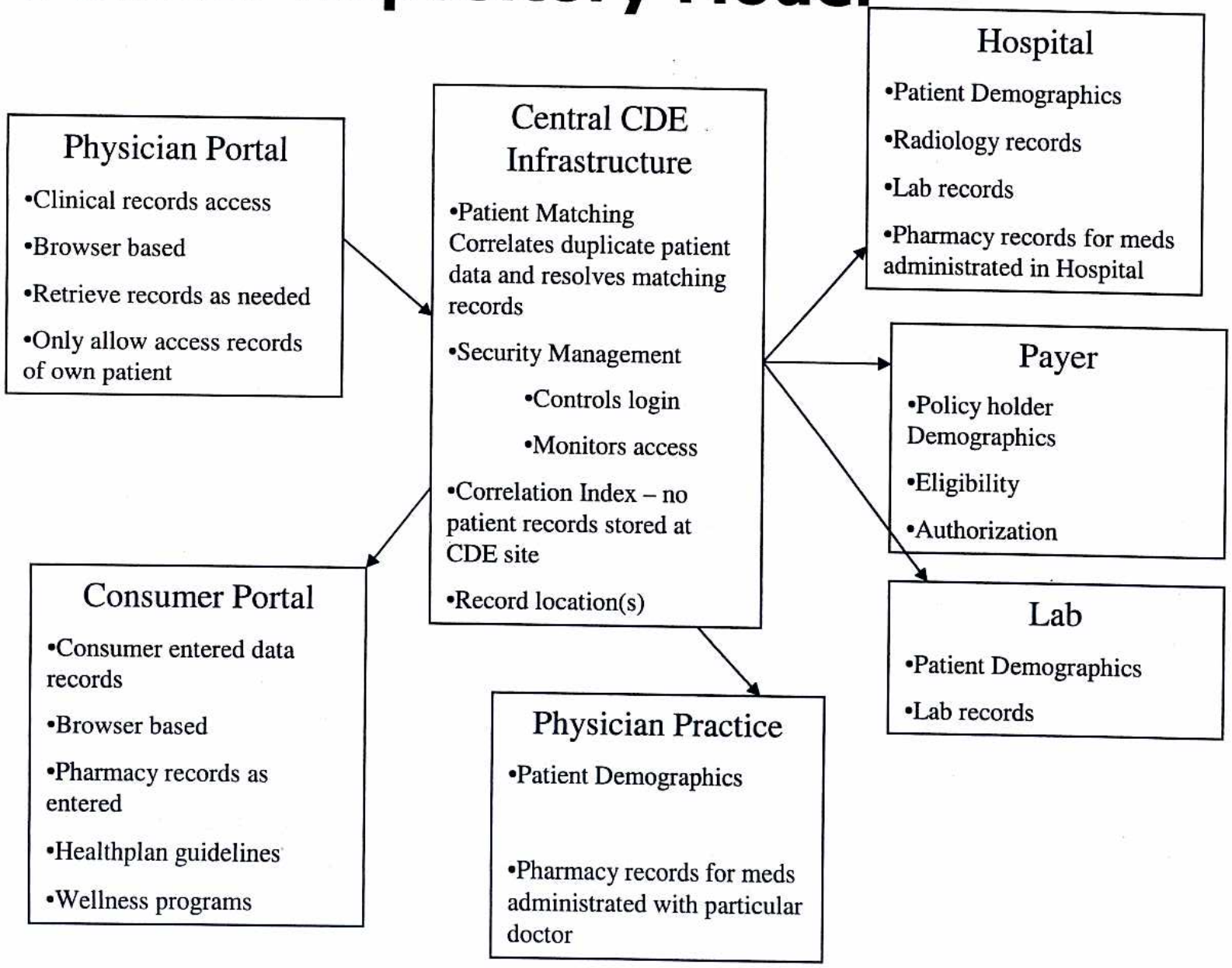
Security	Ease of Access	Locating the right data
Control of data	Updating of data	Consistency of data
Speed of locating data	Backup / recovery	Recovery of data
How much data	How long is the data stored	Who needs the data
Auditing of access	Maintaining System to System connectivity	Scalability of systems

CHC Funding Examples

- State-Run Initiatives
  - Maine
  - Rhode Island
  - Nebraska
  - Hawaii
- IPA Initiatives
  - Taconic
- Hospital-Led Consortiums
  - Houston
  - Southern California
- Stand-Alone RHIOs
  - Eastern Tennessee
  - Santa Barbra Initiative
- Payer Initiatives
  - Wellpoint
  - BC/BS Massachusetts

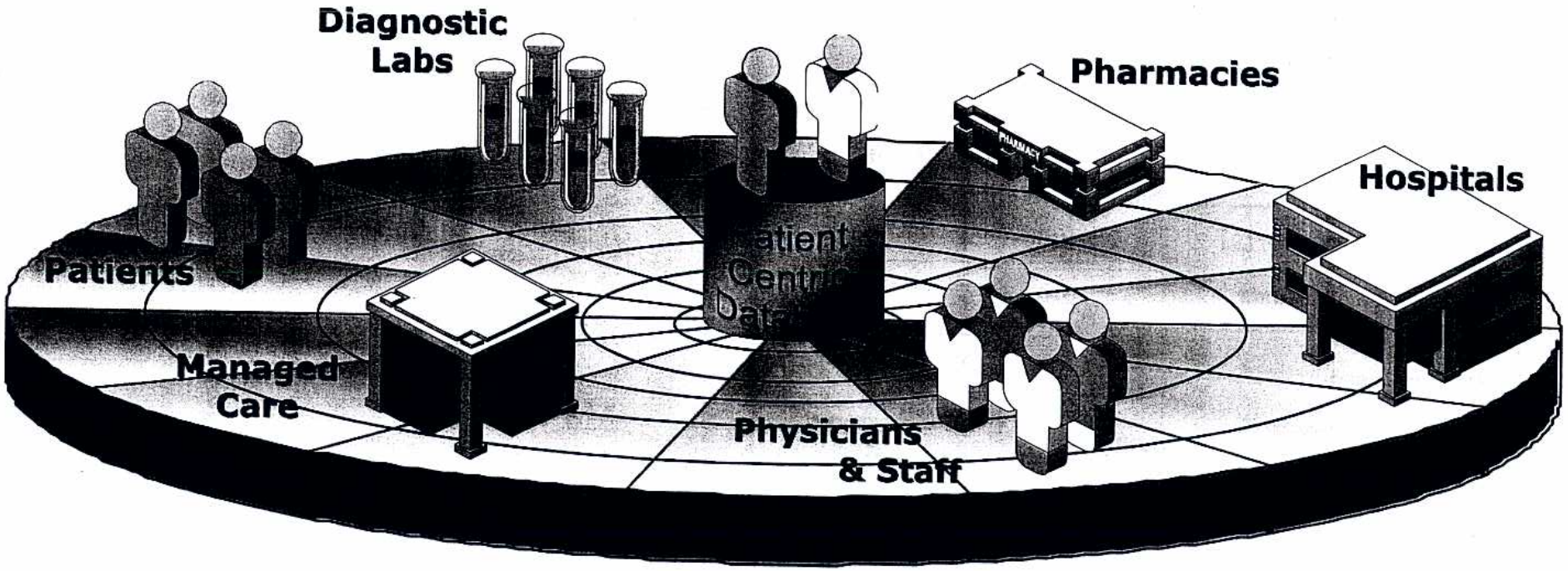


The Connected Healthcare Community Pointer Repository Model



The Connected Healthcare Community Central Repository Model

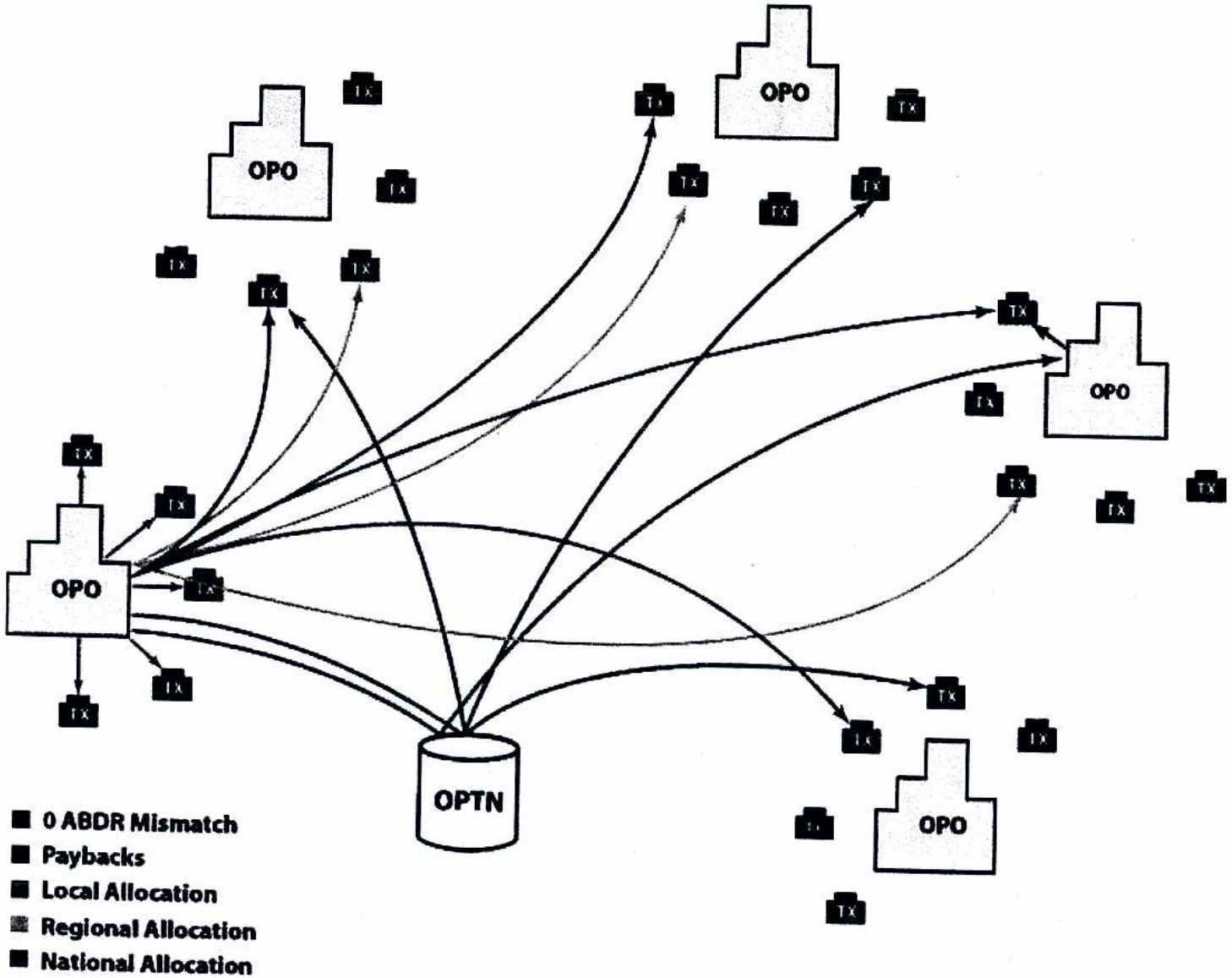
- Patient-centric design
- Disparate IT systems are unified through a shared information architecture
- Collaborative Care Model
- All providers have access to complete, up-to-date patient information



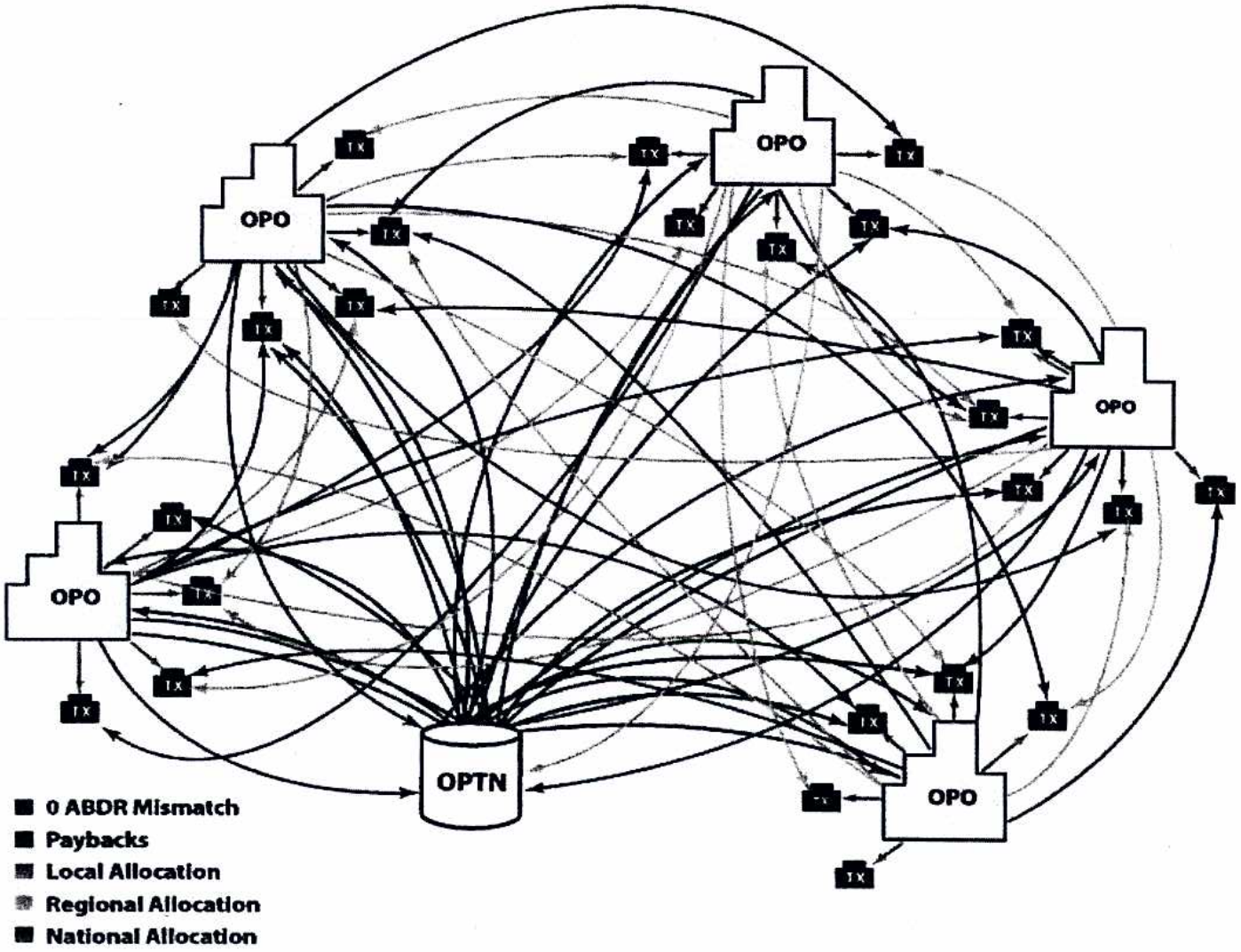
The Connected Transplant Community

- Problem to solve – How to place organs more quickly and efficiently.
- Issues
  - How to get the "No" faster.
  - How to get current data
  - How to share current data
  - How to see and share the full record
  - How to deal with security and regulatory issues

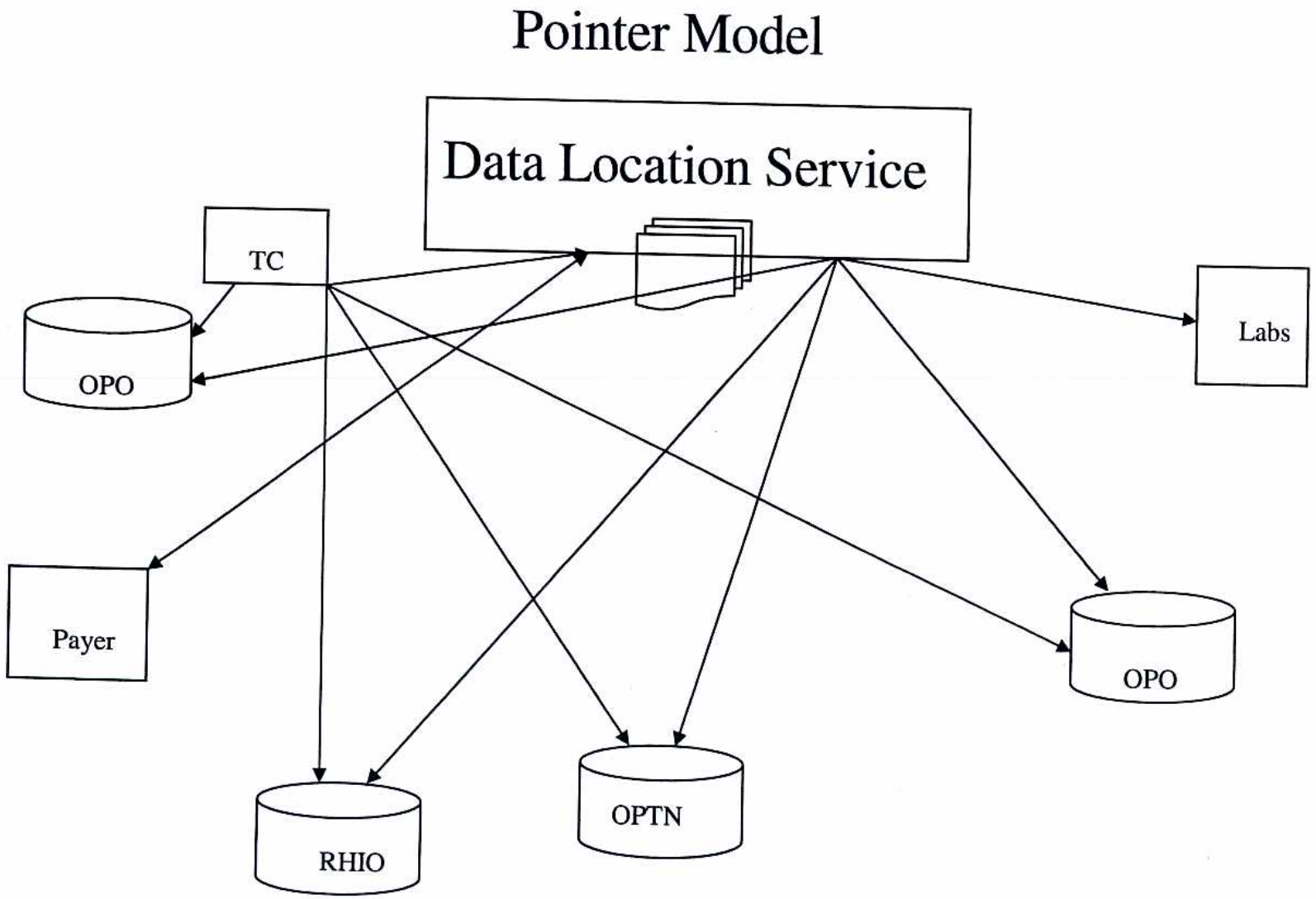
The Connected Transplant Community
Current Model Version 1



The Connected Transplant Community
Current Model (what it feels like)

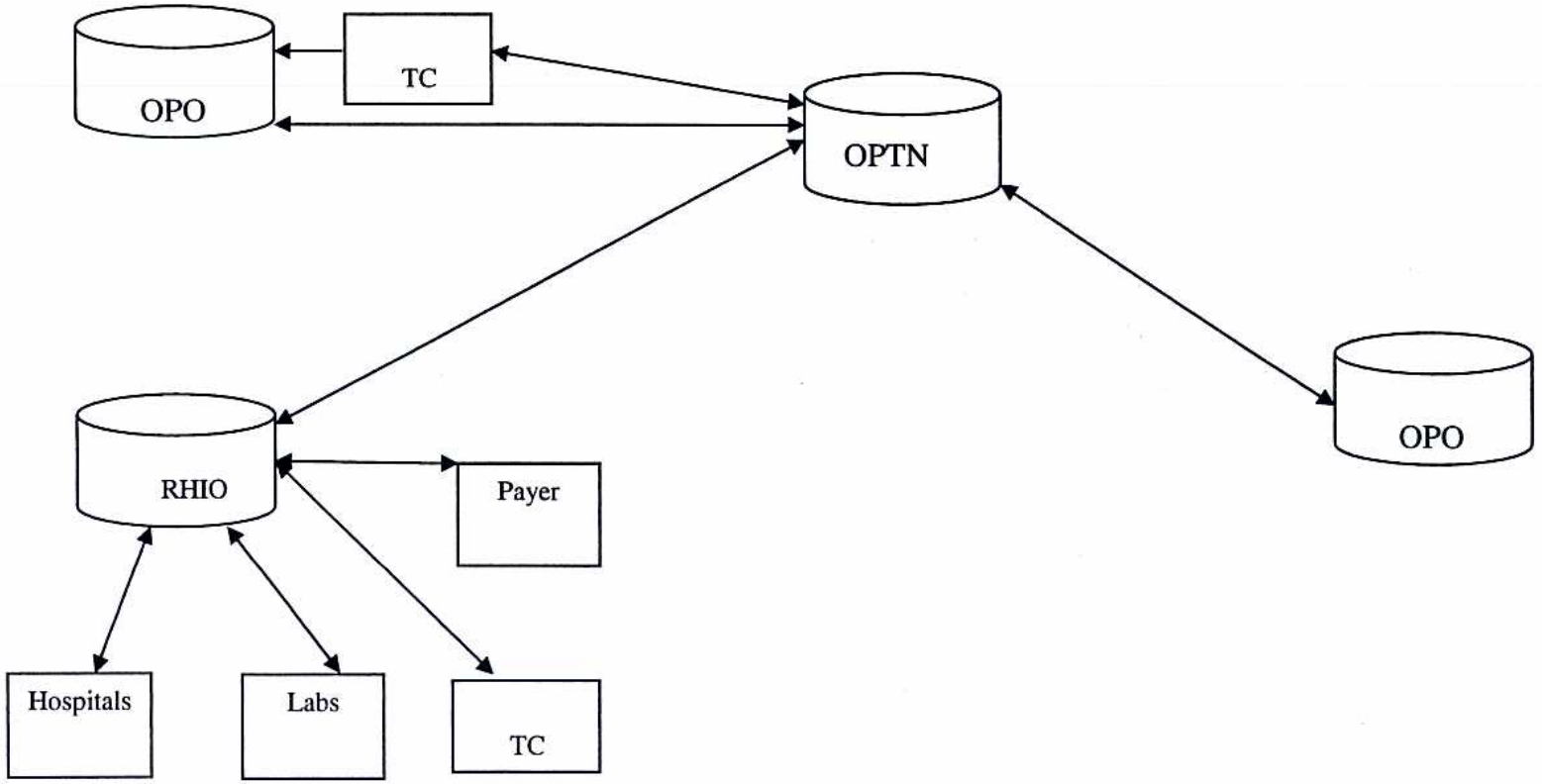


So what could it look like

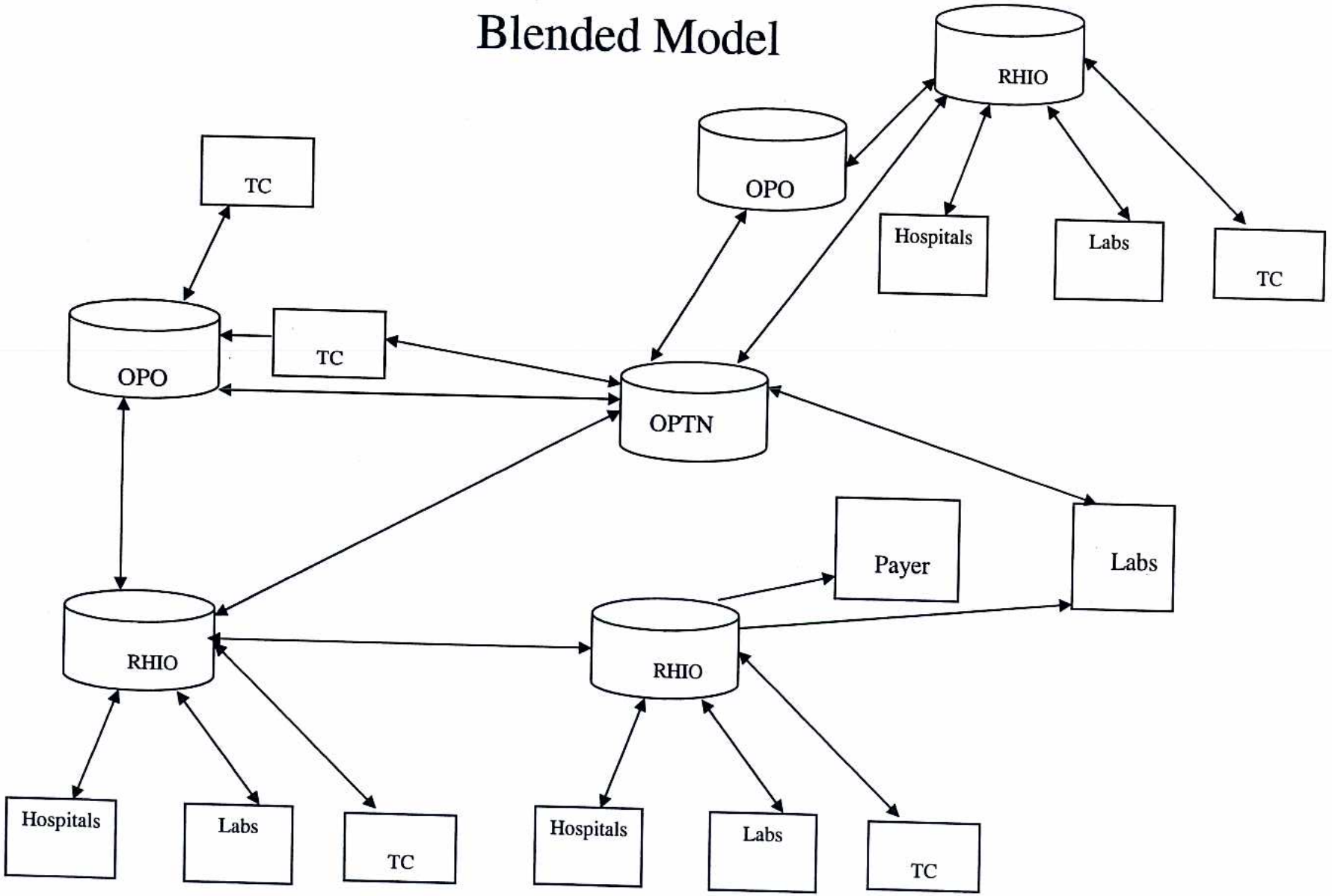


So what could it look like

Longitudinal Data Repository Model



So what could it look like



Conclusions and Recommendations for Discussion / Follow up /Question

- Make sure to look at the long term direction for technology
  - Mobile access
  - The need to see the full history of donor
  - The potential emergence of RHIOs
  - Increasing changes to regulatory events
  - The ability to lower the cost of connections.
  - Acceptance of data exchange standards. (HL7, CCR, etc)
- Questions

The Healthvision Network

- 7.5 million longitudinal patient records
- 4 million consumer users
- 1.2 million electronic prescriptions
- 800,000 patient records
- 310,000 clinical transactions each day day
- 25,000 clinician users
- 1,000 hospitals and IDNs as clients
- Installed in over 25 communities

Healthcare Data Security and Privacy

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HRSA

HRSA: America's Health Care Safety Net

We work to:

- Expand access to high-quality, culturally sensitive health care;
- Improve health outcomes among America's minority communities; and
- Prepare communities to treat victims of a bioterrorist attack.

HRSA

How HRSA Serves America

- **Bureau of Health Professions** ($882 million in FY 2005): In many areas, health care professionals are in short supply. BHPr helps train physicians, nurses and other providers and places them where they are needed most.
- **HIV/AIDS Bureau** ($2.05 billion): HAB's 600-plus Ryan White CARE Act grantees provide life-saving medication, health care and support services to almost 600,000 low-income people with HIV/AIDS.
- **Maternal and Child Health Bureau** ($866 million): In partnership with States, MCH programs expand access to health care for more than 28 million women, infants and children.

HRSA

How HRSA Serves America

- **Bureau of Primary Health Care** ($1.84 billion): 3,650 BPHC-supported health centers and clinics deliver preventive and primary health care to some 13.2 million low-income and uninsured individuals.
- **Office of Rural Health Policy** ($145 million): ORHP grants and technical assistance help rural health care providers build coordinated systems of care that improve local residents' access to medical services.
- **Healthcare Systems Bureau** ($1.14 billion): HSB oversees the Nation's transplant systems, helps communities respond to mass casualty events, and compensates families of children harmed by vaccines.

HRSA

HRSA's Role in Organ and Tissue Donation

- Plays a key role in funding and overseeing Federal efforts to improve methods, standards and outcomes
- All OPTN functions performed under HRSA contract
- In partnership with OPTN, seeks to:
  - Increase the number of organs made available for transplant
  - Support the continued improvement of national organ allocation policies
  - Continually evaluate and improve the performance of the national transplant systems

HRSA

The Issue At Hand...

- There exists significant inefficiencies in the current OPTN – Transplantation Community interface:
  - Data entry redundancy
  - Data quality/data validation challenges
  - Use of technical lowest common denominator
  - Inability for OPOs to interface donor information with their internal business systems

HRSA

The Solutions

- Develop standards for:
  - Data
  - Technologies
  - Security
  - Processes
- Through use of technology, improve interconnectivity, data sharing capabilities, and in turn, several process and functions.

HRSA

To Interconnect or Not To Interconnect...that is the question!!!

- The key to many of the improvements identified a the Chicago OPO Technology Consensus Conference centered around real-time access to donor information.
- Interconnectivity between OPTN and the transplantation community appears to be the only viable solution.
- But what does that mean for everyone involved?

HRSA

Two Levels of Interfacing with OPTN

- Manual Authentication
  - Logging onto the OPTN system
  - Remaining within OPTN system infrastructure and security controls
  - Utilizing OPTN system utilities to access and transmit data
- Automated Interconnectivity
  - Authenticating to entity system
  - Remaining with entity system's infrastructure and security controls
  - Transparent and bi-directional access to data via local applications using secure handshake

HRSA

Interconnectivity and the Transplantation Community

- Both options require:
  - Planning
  - Proper Implementation
  - Maintenance

HRSA

Primary Issues of Interconnectivity

- Accounting for the management and monitoring of information which leaves the control of one entity and formally passing the responsibility to manage and monitor that information to another entity
- Ensuring that required security controls are maintained throughout the transaction

HRSA

Primary Issues of Interconnectivity

- Establishing Interconnection Security Agreement (ISA) and Memorandums of Understanding (MOU)
  - The ISA specifies the technical and security requirements for establishing, operating, and maintaining the interconnection
  - The MOU documents the terms and conditions for sharing data and information resources in a secure manner

HRSA

The National Institutes of Standards and Technology (NIST)

In Title III of the E-Government Act (Public Law 107-347), entitled the Federal Information Systems Security Management Act of 2002, the National Institute of Standards and Technology (NIST), in the U.S. Department of Commerce, was charged with the mission of:

- developing standards, guidelines, and associated methods and techniques for information systems;
- developing standards and guidelines, including minimum requirements, for information systems used or operated by an agency or by a contractor of an agency or other organization on behalf of an agency, other than national security systems and
- developing standards and guidelines, including minimum requirements, for providing adequate information security for all agency operations and assets, but such standards and guidelines shall not apply to national security systems.

HRSA

NIST SP800-47 "Security Guide for Interconnecting IT Systems"

A system interconnection is defined as the direct connection of two or more IT systems for the purpose of sharing data and other information resources

HRSA

Interconnectivity and the Transplantation Community

- Users utilizing OPTN exclusively:
  - Establish proper agreements
  - Educate users on agreement particulars and rules of the system
  - Ensure compliance to all of the above

HRSA

Interconnectivity and the Transplantation Community

- Users that establish true interconnection must comply with NIST guidelines
- NIST Special Publication 800-47:
  - Planning for the system interconnection
  - Establishing a system interconnection
  - Maintaining a system interconnection
  - Disconnecting a system interconnection

HRSA

Planning for a System Interconnection

- Establish a Joint Planning Team
- Define the Business Case
- Perform Certification and Accreditation
- Determine Interconnection Requirements
- Document Interconnection Agreement
- Approve or Reject System Interconnection

HRSA

Establishing A System Interconnection

- Develop an Implementation Plan
  - Describe IT systems that will be connected
  - Identify personnel who will establish and maintain the interconnection, and specify responsibilities
  - Identify and describe security controls
  - Establish test procedures to ensure proper and secure operations
  - Specify training requirements

HRSA

Establishing A System Interconnection (cont.)

- Execute the Implementation Plan
  - Implement or configure security controls (SP800-53)
  - Install or configure hardware and software required to establish the interconnection
  - Integrate applications
  - Conduct operational and security testing (SP800-42)
  - Conduct security training and awareness (SP800-50)
  - Update system security plan (SP800-18)
  - Obtain management approval to operate (SP800-37)
- Activate the interconnection

HRSA

Maintaining A System Interconnection

- Maintain clear lines of communication
- Maintain equipment
- Manage user profiles
- Conduct security reviews
- Analyze audit logs
- Report and respond to security incidents
- Coordinate contingency planning activities
- Perform change management
- Maintain system security plans (SP800-18)

HRSA

Disconnecting A System Interconnection

- Planned Disconnection
  - Changed business needs
  - Failed security audits
  - Inability to abide by technical specifications
  - Changes in system configuration
- Emergency Disconnection
  - Attacks, intrusion attempts, exploits
  - Have procedures in place
- Restoration of Interconnection

HRSA

Privacy

- The Privacy Act of 1974 is the primary act that regulates the federal government's use of personal information.
- Major provisions of the Privacy Act:
  - Collecting only necessary information.
  - Providing public notice.
  - Providing for informed consent.
  - Protecting against adverse determinations through maintaining accuracy of personal information.

HRSA

Privacy

- Major provisions of the Privacy Act (cont.):
  - Safeguarding information.
  - Accounting for disclosures of records.
  - Training employees.
  - Providing notice of exemptions of systems of records.
  - Providing for civil remedies and criminal penalties for violating the rights granted by the Privacy Act.

HRSA

Privacy

- **Personal information:**
  - All information associated with an individual, both *identifying* and *nonidentifying*:
    - Identifying information can be used to locate or identify someone
      - **Identifying:** name, aliases, social security number, e-mail address, drivers license identification number, agency-assigned case number
      - **Nonidentifying:** age, education, finances, criminal history, physical attributes, gender

HRSA

Privacy Impact Assessment

- Since the Department handles a large amount of information in identifiable form (IIF) that is protected by federal law, the Department must follow federal privacy guidelines. Private and public sector organizations interacting with HHS and/or the Operating Divisions (OPDIV) must be assured that sensitive information is protected in a manner that will ensure its confidentiality.

HRSA

Privacy Impact Assessment

- **U.S. DHHS Privacy Impact Assessment (PIA) Guide - 2004-04** (7/19/2004) outlines a standard approach for conducing an IT Privacy Impact Assessment (PIA) on all Departmental general support systems and major applications. It identifies the E-Government Act of 2002, Section 208 PIA requirements with which the Department must comply. In addition, the guide provides a Privacy Analysis Worksheet and Summary Template.

HRSA

Healthcare Data Security and Privacy

- In conclusion:
  - Develop formal, structured interconnection guidelines
  - Implement supporting processes
  - Update current practices
  - Educate, educate, educate
  - Constant evaluation and improvement

HRSA

Healthcare Data Security and Privacy

Contact information:

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Rockville, MD 20857
Office: 301-443-9660
Email: MBrown@hrsa.gov

HRSA

GIFT OF LIFE

Hospitals & Broadband for Donation Coordinators

Recent success stories and future plans at Gift Of Life Michigan

University of Michigan

- The Situation
  - 700+ beds, 24 organ donors in 2004
  - Large investment in wireless infrastructure throughout the entire hospital campus
  - No direct Internet access for our donation coordinators
    - Using "Aircard" cellular modems

University of Michigan

- The Opening
  - Hospital donation staff & managers obtained wireless
  - Asked our HDA why she was using an Aircard when high-speed wireless was available
  - Offered to run interference with the Information Technology department

University of Michigan

- The Process
  - A donation specialist called a personal friend in the IT group
  - The IT person coached us on how to approach management
  - We agreed to very strict limitations for security purposes
  - We needed to remind them of the special HIPAA rules for donation

University of Michigan

- The Result
  - Our coordinators have complete wireless access to the Internet
  - For security, access is limited to certain pre-specified Ethernet card addresses
    - We must tell them the address of every wireless card that we want to use

Spectrum Butterworth

- The Situation
  - 1100 beds on three campuses
  - 32 organ donors in 2004
  - $100M new facility opened Fall 2004
    - Fully wireless enabled
  - No direct Internet access for our donation coordinators
    - Using "Aircard" cellular modems

Spectrum Butterworth

- The Opening
  - We trained staff to use the StatTrac hospital analysis reports
    - They understood the value of the data collection that we do
  - Our Liaison asked how we work during donations
  - She offered to put us in contact with the IT people

Spectrum Butterworth

- The First Approach
  - Contact was with a network administrator
  - Answer was emphatic: "NO"
    - Described unlikely freezing conditions
  - Stated objection: Security
    - But objection was not sustained when it was challenged
  - Suspected objection: Change

Spectrum Butterworth

- The Re-Approach
  - Our HDA made contact with the Chief Information Officer
    - Non-technical explanation
  - Reaction: "Why are we talking about this? Make it Happen."
  - Hospital IT staff called us the same day to work out details

Spectrum Butterworth

- The Result
  - Our donation coordinators have restricted access to wireless Internet
  - Security Restrictions: We can only access certain sites
    - Lotus Notes server at Gift of Life
    - StatTrac
    - UNOS

Building on Success

- StatTrac Reports
  - Training hospital staff on the use of the reports really opens their eyes
  - Working with their own data makes them favorable to increasing access
  - Clinical people and quality people are very eager to help us

Building on Success

- Contract Language
  - The new CMS regulations require all hospitals to renew their contracts
  - We have added a standard clause:
    - *... provide Gift of Life organ procurement coordinators with access to a wired or wireless high speed internet connection, where available, for the purpose of facilitating statewide and national organ placement ...*

Building on Success

- Positive References
  - As stories are told about successful experiences at U-M and Butterworth, other hospitals are inquiring
  - How can they help us get the access we need

Thank You

LifeGift Organ Donation Center

Carolyn Olivarez
Director of QA, Risk Mgmt. & Reg. Compliance

Our Approach

- Started with two primary donor hospitals
- IHC's assistance
  - Familiar with Hospital dynamics/players
  - Known to Hospital Staff
  - History of relationship

Approach

Way's to benefit the hospital just not the OPO

- Assist bedside nurse (historical involvement)
  - Entering labs
  - Retrieving Labs
- Expedite donor process
  - The sooner we're gone the sooner they get the bed back
- Reduction of incoming phone calls
- Lessen unit fax machine being tied up

Education

- IHC's have access to upper management
  - ❖Willing to support donation process
  - ❖Both hospitals heavily involved in Collaborative
    - ❖Use of "connections"
  - ❖Again, show the benefit to the hospital
  - ❖Very helpful in also a transplant center
    - ❖Use those connections

UNET

"Validate" UNOS/UNET

- ❖In-service on how accessing UNET is done
- ❖What it can offer to them (public site)
- ❖List explanation
- ❖History of organization

Where to begin!!!

- ❖180 hospitals
- ❖Core hospitals 90% set up
- ❖Non Core hospitals 60% set up
  - ❖Urgency dependent on organ potential

Hindrances

- Location, location, location
- What's remodeled, what's not??
- Competition to hospital unit PC's

- If failure to connect…what's the back up?

Communications Overview

Transplant Resource Center of Maryland
OTIS
(Organ Tissue Information System)

Challenges and New Possibilities

Changing times...

New technology always reshapes the way we interact, creating new expectations and new organizational paradigms.

It was January 01 2004 when the Transplant Resource Center of Maryland went 100% live with our Organ Tissue Information System. The first and most obvious hurdle we had to overcome was how our remote users would be able to access and update the centralized system in real time as much as possible.

DONATE LIFE

Process Overview

- Referral data is imported into OTIS from Statline.
- Initial Referral information is pushed to handheld PDA's to inform clinical staff & Administrator on Call (AOC) of all new referrals and new donor cases.
- Clinical Coordinators capture clinical information on site. Gathered information is pushed to central database
- Family Advocates can review case information, enter Med Soc and other pertinent information real time in the field
- Transplant centers / OPO's / UNOS can view the complete clinical chart online in real time.
- Clinical chart and documents can be faxed directly from OTIS to Transplant centers / OPO's / UNOS

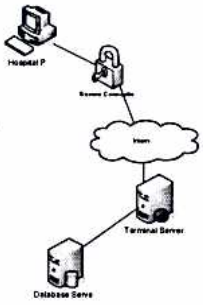
DONATE LIFE

Current OTIS Connectivity

Hospital Workstations

At TRC we provide staff members in the field several connectivity options depending on the hospital they are visiting and the environment they are in we have tried to cover all connectivity options.

At 90% of our hospitals in Maryland a computer within the unit/nurses station is the primary connection method. This is accomplished with a secure connection via web browser to our Terminal Server Interface.

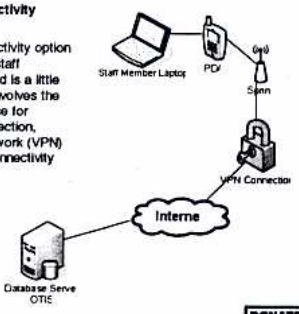


DONATE LIFE

Current OTIS Connectivity

PDA/Wireless Connectivity

The second connectivity option we provide to our staff members in the field is a little more complex. It involves the use of a PDA device for wireless data connection, Virtual Private Network (VPN) client for secure connectivity and a laptop.

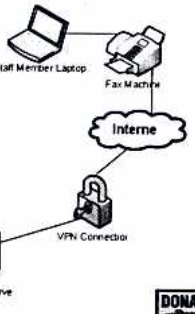


DONATE LIFE

Current OTIS Connectivity

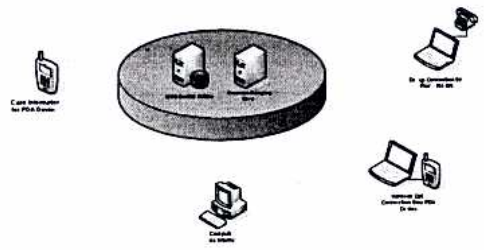
Dial-up Connectivity

The last connectivity option we provide to our staff members in the field is a basic dial-up connection. Staff members will use any standard analog phone connection. Ideally this is the fax machine connection in the nurses station.



DONATE LIFE

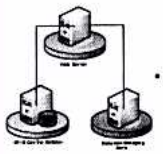
OTIS Connectivity Overview



* Note all internet connections are via Secure VPN connection.

DONATE LIFE

Security

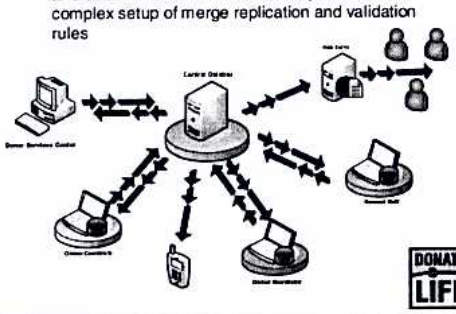


- TRC Laptops incorporate:
  - (CyberAngel) This product provides data encryption and lo-jack type tracking of stolen equipment.
  - Cable locks to physically secure the device
  - Connections to OTIS made via Secure Socket Layer (SSL) / Virtual Private Network (VPN) connections
- Database, Document Imaging server physically separated on separate servers. Creating additional security layers
  - Application, Windows Active Directory & SQL Server authentication required

DONATE LIFE

Record Access

- The overall design of OTIS allows multiple individuals to not only access donor information but to update and edit information. This is accomplished thru a complex setup of merge replication and validation rules



DONATE LIFE

Future Hospital Connectivity

TRC is currently in the process of updating our agreements with each hospital. Within our agreements we are including verbiage to state that the hospitals will provide to TRC high speed internet connection where available. This connectivity would be outside of the hospitals network for security. TRC would provide all equipment to facilitate this process.

DONATE LIFE

Conclusions & Questions

THANK YOU

DONATE LIFE

Attachment 8

This document summarizes the Day 1 deliberations of the second OPTN/UNOS OPO Technology Consensus Conference, March 1-2, 2005. During the morning of March 1, three presentations were given to outline the possible models and considerations in selecting the model. The participants were assigned to four working groups and given instructions to outline the pros and cons of the pointer model (decentralized), longitudinal model (centralized), and requested decide on the best model to proceed towards implementation. For purposes of this document, the following definitions apply:

Pointer Model: The OPTN and/or the OPOS act as a repository of links to OPO systems and Transplant Center systems where the data actually resides. Either the OPTN or the OPO could offer using these links.
Longitudinal Model: The OPTN acts a central repository of data for presentation of the offer from a single OPO system
Hybrid Model: Same as Longitudinal except data comes from many OPO systems

The following is a consolidated list of the results reached by each working group and presented to the plenary session in the afternoon. Duplicate comments have been consolidated into single comments for brevity.

Pointer Model -

- Cons
  - May not know most recent information
  - Could present multiple values from multiple systems
  - Relies upon many independent systems to be available
  - Security issues; need multiple access points to systems
  - Training issues; learning where to find the information
  - Pointer model may slow down arrival at the long-term goal
  - Limited data exchange
  - Mat create broken links when data is moved
  - No standardization of location or nature of data
  - Reliability of information is not assured
- Pros:
  - Initial investments and change to existing systems are minimal
  - Initial implementation time is faster than longitudinal model.
  - Allows OPOS to maintain control over data.
  - Allows expedited placement without going through organ center
  - Doesn't necessitate a specific language or technology

Longitudinal Model -

- Pros:
  - May allow for financial incentives for partners
  - Few limits on scalability
  - Allows for predictable manipulation of data
    - Reduces amount of application customization needed on OPO
  - Training issues are consistent
  - Ownership of data should not be an issue at the OPO level

  - Security would be easier to manage with a longitudinal model
  - Location of master data needs high level of availability and redundancy, and disaster recovery
  - Allows for national comparison of your OPO performance
    - Leads to faster overall improvement
  - Higher ROI
  - Most Cost-Effective
  - Easiest Model to Implement (some data is already at OPTN.)
  - Better possibility of achieving standardized data
  - Initial implementation would allow us to get back more control of the process.
  - OPTN may be better situated to get buy-in from transplant centers
- Cons
  - Longer implementation
  - Risk of stifling innovation (needs to stay flexible)
  - More agreements needed on standards
  - Possible higher initial costs
  - We are past this as a possibility
  - No longer feasible due to private sector fulfilling the niche

Hybrid Model -

- Pros
  - Increased flexibility
  - Faster initial implementation
  - Core data set is defined; everything external to the core utilizes the pointer model
  - Could provides evolutionary path / phased approach for OPOs
  - Supports different software programs
  - Allows use of different data points
  - Allows OPOs to have more control of placement process
  - Allows OPOs freedom to innovate
  - Ability to synthesize information, but also link to other information that is necessary
  - More extensive information would be available if needed.
  - One data repository that could be queried.
  - Reduce overhead in storing medical imaging large file formats.
  - UNOS is the template for presentation purposes
  - A single identification for access
  - Permanent log-in for surgeons maintained by the OPTN
  - Standard presentation of information
  - Trust of surgeons built on fact, not coordinator opinion
  - Stop inputting data into multiple sources
- Cons
  - Training issues
  - Disparate systems

  - May cause less information to be standardized (i.e. only data sent to OPTN)
  - Different levels of the same interface would have to developed during the implementation
  - Is it feasible to transmit Echoes, X-rays, ect?

General Comments -

- There may be many regulations which must be adhered to: NIST, HIPAA, FDA, CGTP.
- Safeguards in OPTN contract would need to exist regarding ownership of the data submitted to OPTN
- Standardization is the key for any model you go toward.
  - Assists with communication to new partners
  - Sets expectations for all parties
- Common data interchange / data standards will lead to an evolution of our data systems
  - Integration to hospital/tx center IS systems
  - Complete electronic donor record
  - Industry efficiencies
- Would OPOs be able to house a superset of data wherever the centralized repository is?
- What would the reporting model be against the repository?
- Could develop combination system (Voice & Data)
- Will All Players buy into system? (Surgeons, Transplant Centers, OPO's, OPTN, etc.)
- Transplant centers need to be putting in accurate information on the potential recipient lists

Consensus -

- 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
- 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
- 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.
- Automatically populated Deceased Donor Registration and Donor Feedback from the centralized repository data.

Attachment 9

This document summarizes the Day 2 deliberations of the second OPTN/UNOS OPO Technology Consensus Conference, March 1-2, 2005. During the morning of March 2, participants were divided into four groups: Technology, Security, Process, and Data.

Included below are the deliberations of each working group which were presented to the plenary session in the afternoon.

1. **Technology Group**
    a. The Technology Group concentrated on a possible model for use of technology in the process. The details of the model are as follows:
        i. OPO captures data at the bedside specified as per the OPO
            1. Solution has to meet a standardize data set (UNOS policy)
            2. Validation of minimum acceptable business rules
            3. It has to be communicated to a central repository in a standardized format but the OPO need to have the ability to communicate data as a contingency plan
            4. Organ specific data set has be defined across organ specific UNOS organ committee
        ii. Notification algorithm (when, how and conditions)
            1. Automated refusal codes
            2. Acknowledgment – (read receipt)
            3. Current policy needs to be changed to allow transplant centers to enter refusal codes
            4. Notify centers of all listed patients by listed order
            5. On-demand update of acceptance criteria by transplant centers updateable the by transplant centers
            6. Automated Deceased Donor Registration and donor feedback from the Centralized repository
        iii. Challenges
            1. Legal implications
            2. Policy changes
            3. Culture change
            4. For Tissue electronic data capture and exchange, design of system and validation must conform to Part 11 as it relates to Tissues on OPO level

2. **Security & Privacy**
    a. Guiding Principals
        i. **Confidentiality** – "Preserving authorized restrictions on information access and disclosure, including means for protecting personal privacy and proprietary information"
        ii. **Integrity** – "Guarding against improper information modification or destruction and includes ensuring information non-repudiation and authenticity"
        iii. **Availability** – "Ensuring timely and reliable access to and use of information"

iv. From 44 U.S.C. SEC 3542

b. Items to consider
   i. What is the process of implementation?
   ii. Who performs the audits?
   iii. Who is interconnected?
   iv. How are the new regulations applied?
   v. Is HRSA available to aid in the implementation process for currently non-compliant OPOs?
   vi. What happens if your organization is compromised? How do we elicit change from above?
   vii. What happens if you can't transplant? What happens if you can't operate?
   viii. Do we need these regulations in place to complete recertification?
   ix. Are we going to be told how to meet these regulations?
   x. Will the transplant centers be able to meet these new standards?
   xi. Are the standards for AOPO, the FDA, and HIPPA different?
   xii. How can OPTN assist in getting us compliant?
   xiii. Do you have a disaster recovery plan? Are you prepared to disconnect and reconnect?
   xiv. Is wireless equipment governed by the new regulations?

c. Good News
   i. Keep the gold standard
   ii. UNOS or an outside agency could issue a certification for outside organizations (i.e. vendors) that we share an interconnect with that guarantees compliancy
   iii. OPTN could help educate the OPOs and their directors
   iv. Help define terms and instruct how UNOS fulfilled these new standards
   v. Following these regulations will assist compliance with ISO 17799
   vi. An outside agency will perform the audits – so you don't have to!
   vii. This is the new cost of doing business
   viii. We have an ethical reason for protecting donor and recipient data – not just a legal one
   ix. We can make a difference!

d. Next Steps
   i. Create a set of all-inclusive regulations
   ii. IT-subcommittee which encourages the gold standard even for OPOs not interconnecting with UNOS
   iii. Share with each other preferred security measures; host a live-action meeting to discuss results of different tools
   iv. We needn't recreate each other's errors
   v. Resources
   vi. National Institute for Standards and Technology www.nist.gov
   vii. Mark Brown with HRSA mbrown@hrsa.gov
   viii. Blaine Hess with UNOS hessbt@unos.org
   ix. AOPO Sharepoint site (Todd Jennings, Brian Lunde, David Gee)

3. Process Group -

a. Analogy
   i. In the Electronic world circuits can function in serial or parallel mode
   ii. Serial mode – a switch has to be thrown before you can proceed to the next signal of transmission
   iii. Parallel mode – require switch however multiple signals are sent at the same

b. Current Process
   i. Currently organs are offered in serial mode by individual organ type dictated by match run
   ii. After an offer is made to a potential transplant candidate, transplant center has one hour to accept or decline the organ
   iii. Offerings are made in serial mode to local, regional and national candidates according to allocation policies.

c. Parallel Process in the Transplant Community
   i. Propose the current allocation system utilizing a parallel offering methodology
   ii. Simultaneous offering of a donor organ to a grouping of transplant candidates in the current match run sequence of allocation
   iii. Relies on an electronic notification algorithm
   iv. How will this be accomplished
   v. UNOS organ specific committees develop guidelines to support transplant coordinator

d. Recommendations
   i. Organ specific UNOS committees to work out guidelines
   ii. Initially to recommend a range or grouping of candidates by organ type for parallel offers
   iii. Allows OPO's staff to operate within this range for specific organ donor situations

e. Challenges
   i. Cultural – there are OPOs and transplant centers that will be resistant to change
   ii. Having enough personnel and/or finances to accomplish the required tasks however the use of technology will help streamline current processes
   iii. The key will be to get the transplant center to adopt the technology for notification that complements their current system. The transplant center will need select one or two notification systems that will work best for them.
   iv. Should the process be implemented one organ at a time or all at once?

f. Features and Benefits
   i. Quicker progression through the allocation sequence – get to the no's faster

ii. Allow program for high risk interest calls – this is a benefit. Example donors with a history of high risk behaviors or positive serology

4. Data Group -

a. The data group concentrated on the type of data that must be transferred
b. It was agreed that using the OPO short form was a good starting point
c. It was agreed that it would be necessary to continue to review ongoing data standardization efforts and to adopt national standards such as the National Heath Record Standards as they are codified
d. It is necessary to get consensus on all of the data elements

Attachment 10

OPO Technology Consensus Conference Evaluation - March 1 - 2, 2005

Did the Consensus Conference meet your expectations?	Was this a productive meeting?	Did you gain useful information from the Conference?	Were the Conference location and facilities satisfactory?	Would future Consensus Conferences be beneficial?	If yes, what areas need further resolution?	Areas for further resolution?
yes	yes	yes	yes	yes	yes	Continue the focus of expedited placement and improving feedback
blank	yes	yes	yes	yes	yes	
yes	yes	yes	yes	yes	yes	
no	yes	yes	yes	yes	yes	
neutral	yes	yes	see comment	yes	yes	security implementation& guidelines
neutral	yes	yes	yes	yes	yes	drilling down on Data,Finalization of system
yes	yes	yes	yes	yes	yes	
yes	yes	yes	yes	yes	yes	
yes	yes	yes	yes	yes	yes	
yes	yes	yes	yes	yes	yes	
yes	yes	yes	yes	yes	yes	Credentialing of OPO i.e I.T.
no	yes	yes	yes	yes	yes	Transplant Center participation
yes	yes	yes	yes	yes	yes	
yes	yes	yes	yes	yes	yes	
yes	yes	yes	yes	yes	yes	
yes	yes	yes	yes	yes	yes	
yes	yes	yes	yes	yes	no	
yes	yes	yes	yes	yes	yes	
yes	yes	yes	**no**	yes	yes	Security, Process, Standard Definition Draft
yes	yes	yes	yes	yes	yes	good networking
yes	yes	yes	yes	yes	yes	
yes	yes	yes	yes	*blank*	*blank*	
yes	yes	yes	yes	*blank*	*blank*	Security Implementation
yes	yes	yes	yes	yes	*blank*	
yes	yes	yes	yes	yes	yes	Process and Data Model
yes	yes	yes	yes	yes	yes	Implementation
yes	yes	yes	yes	yes	yes	Implementation
yes	yes	yes	yes	yes	yes	
yes	yes	yes	yes	yes	yes	
yes	yes	yes	yes	yes	yes	Implementation
yes	yes	yes	yes	yes	yes	Wireless Communication
yes	yes	yes	yes	yes	yes	Further Data Standards
yes	yes	yes	yes	yes	yes	Data Elements/Technology Application

yes	yes	yes	yes	yes	yes	combine all groups
yes	yes	yes	yes	yes	yes	actual implementation
yes	yes	yes	yes	yes	yes	security education
yes	yes	yes	yes	yes	yes	IT & Security Standards
yes	yes	yes	yes	yes	yes	
yes	yes	yes	yes	yes	yes	Security Standards/Resources
yes	yes	yes	yes	yes	yes	Best practices in IT
yes	yes	yes	yes	yes	yes	
yes	yes	yes	yes	yes	yes	
yes	yes	yes	yes	yes	yes	
yes	yes	yes	yes	yes	yes	
yes	yes	yes	yes	yes	yes	get feedback
yes	yes	yes	yes	yes	yes	
yes	yes	yes	yes	yes	yes	Follow up to next steps
yes	yes	yes	yes	yes	yes	finalized data standards
yes	yes	yes	yes	yes	yes	
yes	yes	yes	yes	yes	yes	
yes	yes	yes	yes	yes	yes	
yes	yes	yes	yes	yes	yes	
Totals	*Totals*	*Totals*	*Totals*	*Totals*	*Totals*	
47 - Yes	**52- Yes**	**52-Yes**	**50 - Yes**	**50- Yes**	**48- Yes**	
2 - No			**1- No**	**2- Blank**	**1- No**	
2- Neutral			**1-see comment**		**3- Blank**	
1- Blank						