The ERA of Regulatory Oversight in Solid Organ Transplantation

*Does Your Program Have the Right Stuff?*

Improving People's Lives through innovations in personalized health care
Disclosure Information

- No financial conflicts to disclose.

- (I am as confused as you are)
UNOS is a…

1. Part of the federal government
2. A contractor for transplant programs
3. A trade organization
4. United Network of Surgeons
OPTN is…

1. Organ Procurement and Transplant Network
2. A unionized labor program
3. State-run transplant program
4. Organ Processing Tissue Network
SRTR reports…

1. Only to patients and recipients
2. Makes policies governing transplant
3. Enforces the OPTN bylaws
4. Patient/organ survival after transplant
Insurance contracts are based on…

1. Cost of transplant at center
2. Length of stay
3. Quality metrics
4. Survival rates
5. All of the above
“The Right Stuff”
The Key to Transplant Success in the Current Regulatory Environment

- History - How did we get here?

- Current regulatory requirements
  - OPTN/UNOS
  - CMS

- Building a successful program
  - Quality assessment/Process Improvement (QAPI)
Iconic Role Models

“We do not learn from vain exultation of successes, but from our failures.”
Many Sleepless Nights

“Ask the Question”
Pharos, 1982

“Be Brave”
Mens Room, PresbyHosp Pgh.
TRANSPLANTATION- Quality and Quantity of LIFE
Transplant Success

GOOD DONOR

GOOD RECIPIENT

GOOD OUTCOME
The Regulatory oversight of Transplantation…*it’s Alphabet Soup!*
Transplant History

Fantastic Firsts in Our field

1950
First Heart Value and Artery Transplants

1954
First Successful Kidney Transplant

1955
First Heart Value and Artery Transplants

1962
First Cadaveric Kidney Transplant

1963
First Successful Lung Transplant

1967
First Successful Liver Transplant

1968
First Successful Heart Transplants in the U.S.

1969
First Single Lung Transplant

1970
First Long-Term Artificial Heart Implanted

1973
First Successful Bone Marrow Transplant

1981
First Successful Heart-Lung Transplant

1982
First Long-Term Artificial Heart Implanted

1983
First Successful Liver Transplant

1984
The U.S.’s National Transplant Network is Established

1989
First Successful Living Donor Lung Transplant

1990
First Successful Living Donor Lung Transplant

1998
First Successful Living Donor Lung Transplant

1999
First Successful Tissue Engineered Bladder Transplant

2008
First Successful Complete Full Double Arm Transplant

2010
First Full Facial Transplant

2011
First Successful Tissue Engineered Bladder Transplant

September 2003
18 People Die Each Day on the Waiting List

Source: www.UNOS.org
GIFT OF A HUMAN HEART

A dying man lives with a dead girl’s heart

Louis Washkansky, recipient of the historic transplant, smiles after regaining consciousness.
Development of Heart Transplantation

Figure 1–8. Norman Shumway, regarded by most investigators as the major contributor to successful heart transplantation, is shown here in 1968, soon after his initial human heart transplant procedure.

Figure 1–5. Principals in the experimental laboratory at Stanford University in 1960. Norman Shumway (left), Richard Lower (right), and Raymond Stoffer (right lower) with a long-term surviving dog heart transplant patient.

reality at the University of Capetown in South Africa.
Figure 12-8. The implantation procedure is begun with the left atrial anastomosis.
<table>
<thead>
<tr>
<th>Time</th>
<th>Event</th>
</tr>
</thead>
<tbody>
<tr>
<td>May 24, 1968</td>
<td>Admitted to MCV</td>
</tr>
<tr>
<td></td>
<td>Unconscious unaccompanied by Family or friend</td>
</tr>
<tr>
<td>May 25th, 6:05pm</td>
<td>Tracheotomy</td>
</tr>
<tr>
<td></td>
<td>discuss transplant ME present</td>
</tr>
<tr>
<td>May 25th, 2:05am</td>
<td>Neurological consult</td>
</tr>
<tr>
<td></td>
<td>EEG flat, exam</td>
</tr>
<tr>
<td></td>
<td>“brain death”, stable VS</td>
</tr>
<tr>
<td>May 25th, 1:00pm</td>
<td>Dr. Hume seeks ME</td>
</tr>
<tr>
<td></td>
<td>Permission to release “unclaimed body”</td>
</tr>
<tr>
<td>May 25th, 1:45pm</td>
<td>Name of brother, business address, phone #</td>
</tr>
<tr>
<td></td>
<td>Friend of Tucker Family makes inquiry about medical information</td>
</tr>
<tr>
<td>May 25th, 2:00pm</td>
<td>No family found</td>
</tr>
<tr>
<td></td>
<td>ME releases body</td>
</tr>
<tr>
<td>May 25th, 3:45pm</td>
<td>Makes inquiry about medical information</td>
</tr>
</tbody>
</table>
Time line: William Tucker v. Dr. Richard Lower et al

--- May 25th ------------------ May 26th ------------------------------- May 31st

3:33pm
16th heart transplant in world/ 1st in VA

May 26th

Bruce Tucker’s body given to family, no disclosure of transplantation

Recipent dies

--- January 1970 --------------------------------- May 26th 1970 ---

Claim filed against MCV Surgeons under Wrongful Death Act

After seven-day trial, jury delivers verdict
At Issue

- Was Bruce Tucker legally dead when Dr. Lower removed his heart?
- Did Dr. Lower kill Tucker by removing his heart?

Key Question for Jury
Is ‘Moment’ of Death

By JIM MASON

A seven-man Law and Equity Court jury was expected to begin deliberating later today on a verdict in the heart transplant case.

And its verdict is likely to turn on the jury’s answer to the key question in the trial: When did Bruce O. Tucker, the donor in Virginia’s first heart transplant, die?

Was it when his brain ceased functioning, some three hours before his heart was transplanted, as doctors argued that the words “defined by physicians” imply that the legal concept of death is based on the definition of death by physicians?

Accordingly, as the physicians’ definition changes, so too must the legal definition,” Russell contended.

Assistant Atty. Gen. Theodore J. Markov, who represents the other defendant in the case, a doctor who formerly was on the staff of the chief state medical examiner here, also touched on this year’s arguments and refused their motion to dismiss the suit. Any change in Virginia law, which would incorporate brain death as a criterion of legal death, must be made by the legislature, not the courts, the judge said.

In addition to the medical and legal definitions of death, references have also been made during the course of the trial to “biological” and “theological” death.

Biological death, as ex-
Medical Definition of Death Upheld in Transplant Case

By JAMES N. WOODSON

A contemporary medical definition of death as being brain death was upheld in its first known test here yesterday by a jury of 10, who returned a verdict that transplant surgeons at the Medical College of Virginia played no role in the death of a donor in a 1968 heart transplant operation.

The jury, which the plaintiffs indicated would be appealed, rejected to have medical and legal arguments around the nation since it lent a lawyer's affirmation that it is a question for medical judgment, rather than strictly a legal definition.

In the Tucker case, the jurors were told that they could consider several elements, any one or more of which they might feel from the evidence to be controlling.

Those elements were: the time of the total stopping of the circulation of the blood, the time of the total cessation of the other vital functions consequent therefrom, such as respiration and pulsation, the time of complete and irreversible loss of all function of the brain, and, whether or not the aforesaid functions were spontaneous or were being maintained artificially or mechanically.

THE JURORS deliberated only 47 minutes in reaching their decision at the end of a seven-day trial, believed to be the first anywhere on a lawsuit alleging wrongful death of a donor in a heart transplant. The plaintiff, a Richmond shoe repairman, William E. Tucker, had filed the suit as administrator of the estate of his deceased brother, Bruce D. Tucker, a 54-year-old laborer here and the donor in Virginia's first heart transplant on May 25, 1968 at MCV.

Bruce Tucker entered MCV Hospital on the night of May 24, 1968, with massive head injuries sustained in an accident.

Doctors at the hospital said Tucker died the next day, some hours before the transplant of brain tissue had been received.

But William Tucker alleged that the brain which breathed, pulse, blood pressure and body temperature. Russell said afterwards: "The verdict of the jury clearly indicates that, not only were we not guilty, but it's also a clear indication that the time and determination of death is a judgment call, and that the medical profession decided in the case of death.

"As to this particular case," he said, "it served the purpose. The doctors were right as to the time. We have the case where a person or an individual, which was when his brain worked, and irreversibly ceased to function."

State Sen. L. Douglas Wilder, Tucker's lawyer, said the legal definition of death first adopted by Judge A. Christian Compton when he rejected a defense demurrer movice two days ago is "a fact, submitted to the correct definition of evidence and relies chiefly upon medical testimony."

IN AN UNEXPECTED last-minute move yesterday, Judge Compton broadened the definition of death that he ultimately gave the jury as applicable to the case, including the medical as well as the legal definition and allowing the jury to choose either of the two or a combination of them.

Wilder said, "It's an awfully difficult fly in the face of the system. Doctors are presumed to be done of good and people picture them in their white coats with no potential for wrong.

"And yet," he added, "medical history is replete with instances of malpractice, though the proof required is so often impossible to come by. The closed fraternity rules out any such thing."

That instruction said the time of death is when life ceases, a "ceasing to exist" that isn't continuing but occurs at a precise time that must be established according to the facts in each specific case.

In determining the time of death in the Tucker case, the jurors were told that they could consider several elements, any one or more of which they might feel from the evidence to be controlling.
Heart Transplantation

*Rags to Riches* . . .

**Timeline**


1967 - Christian Barnard performs first human to human heart transplant in 54 year old man with severe heart disease

- 24 year old donor injured in car accident; removed from respirator and heart removed after it stops
- Patient succumbs 18 days after surgery 2° to pneumonia

1968 - Shumway performs first heart transplant in U.S.
1968 - 102 transplants performed at 52 centers

- 30% (30/108) alive at 12 weeks after surgery

1981 - Cyclosporine immunosuppression introduced
Heart Transplantation
“Growing Pains”

Questions raised by early experience

1. What about the donor?
   Was she dead or did we facilitate death?
   What are the criteria of death?

2. Who should perform transplants
   Where should they be done?

3. How do we proceed with potentially lifesaving technology? (with bad early results)
National Organ Transplant Act
42 USCS, 273 et seq. (1984)

- Passed as response to continuing shortage of organs
- Creates Organ Procurement and Transplantation Network (OPTN)
- Establishes system for matching donor organs with potential patients in need and developing policies for equitable allocation of organs
- Supervised by Dept of Health and Human Services
The Federal Government’s Role in Transplantation

Department of Health and Human Services (DHHS)

Advisory Committee on Transplantation (ACOT)

Other Agencies

Health Resources and Services Administration (HRSA)

Centers for Medicare & Medicaid Services (CMS)

Healthcare Systems Bureau (HSB)

Division of Transplantation (DOT)

SR Contractor

OPTN Contractor (UNOS)

CWBYCTP

Medical Center
Obama’s health care plan is awful! It would put the government between you and your doctor!!
United Network for Organ Sharing (UNOS)

- Originated from South Eastern Organ Procurement Foundation (SEOPF) in 1986
- Sole bid for OPTN contract in 1987
- Direct reporting /oversight from HRSA/HHS
- 300+ employees
- As a contractor, UNOS has specific “deliverables” as part of it’s responsibilities
UNOS Membership

- **248 Transplant Centers**
  - Kidney - 238
  - Liver – 134 (72 Living)
  - Heart - 132
  - Heart/Lung - 50
  - Intestine - 43
  - Lung - 66
  - Pancreas Islet Cell - 23
  - Pancreas – 143

- **58 Organ Procurement Organizations (OPOs)**

- **158 Histocompatibility Labs**

- **Other Organizations**

5,795 hospitals in the US. Only 4% have a transplant program!
The OPTN as a Component of the American Health Care System

- OPTN one of many components
- State boards of medicine – licensure and discipline of individuals
  - OPTN has no authority over individual practitioners
- State health departments – licensure & inspection of facilities
  - OPTN has no authority to limit the number of centers
- HRSA requirements in Final Rule for centers and OPOs
- CMS conditions of participation for centers and OPOs
- Joint Commission
- State coroners and prosecutors; US Justice – criminal behavior
- State courts and malpractice claims
OPTN Scope

- All patients awaiting organ transplant: kidneys, liver, heart, lungs, pancreas, intestine
- All living and deceased organ donors
- All deceased organ donor/candidate matches
- All organ transplants
- All OPOs
- All transplant centers
UNOS-Organ Center
The Problem

Demand

Supply
Difficult decisions about Extending the Donor Pool

A balance:

The risks of death on the waiting list versus the risks of surgical complications or primary graft dysfunction.
Goal of Every Transplant Program

Optimal Timing of Transplantation with the most suitable organ leading to good quality of life with event free survival

Reality of Transplant Today

Many patients die on the waiting list while the ideal donor is rare

Informed consent of every possible donor related risk factor is a CMS mandate
60 Lives, 30 Kidneys, All Linked
Donor family member (left) and transplant recipient (right).
Transplant Program Requirements

- Surgeon (+/- fellowship)
- Physician
- RN Coordinator
- Financial Consultant
- Social Worker/Mental Health
- OPO Affiliation/support
- Histocompatibility Lab
- Operating room anesthesia/nursing
- ICU Critical care/nursing
- Pharmacy
- Blood bank
- Infectious disease
Compliance and Continuity of Care in Transplantation…

Why is it important?

- Preoperative condition of patient on waitlist impacts outcomes
- Outcomes are tracked by federal regulatory agencies and CMS
- These agencies have expectations at 1 and 3 years for survival which is reflective of follow-up care
- Lapses in perioperative and follow-up care may have significant financial impact on hospital and professional reimbursement
Transplant Care Coordination Model

- Pre Transplant period
- Waitlist period
- Transplant admission
- Post Transplant period
Quality Committees

- Each organ group has a designated quality committee.

- Each committee does routine monitoring of key elements of care utilized in the inpatient setting that are important in the transition of care to the post transplant/ambulatory care setting (Hemoglobin at the time of d/c, Creatine at the time of d/c).

- Results of this monitoring are shared on a quarterly basis as part of the monthly quality committee activities. Committee members discuss results of these monitoring activities, identify any trends/issue if applicable, perform root cause analysis for any issues identified and develop/implement solutions to address problems identified.

- The quality committees are multidisciplinary. Membership includes:
  - Transplant Physician
  - Transplant Surgeon
  - Quality Representative
  - Post Transplant Coordinator
  - Transplant Infectious Disease
  - Transplant Administration
  - Transplant Nurse Manager
  - Pre Transplant Coordinator
  - Transplant Pharmacy
UNOS/OPTN Membership and Professional Standards Committee
Transplant Outcomes

- Membership and Professional Standards Committee (MPSC) associated Data Subcommittee (DSC) conducts routine reviews of all transplant program performance by monitoring program outcomes and activity.
- DSC meets four times a year, prior to each MPSC meeting.
- Scientific Registry of Transplant Recipients (SRTR), works in partnership with the MSPC and its Data Subcommittee.
- DSC utilizes the SRTR statistical model for programs that perform ten or more transplants, over a contiguous 2.5 year period (referred to as Large Volume Programs).
MPSC Composition

- 12 Surgeons
- 10 Physicians
- 4 OPO Representatives
- 1 Transplant Administrator
- 1 Lab Director
- 1 Transplant Coordinator
- 2 Transplant Recipients
# Post transplant Outcomes

<table>
<thead>
<tr>
<th>Organ</th>
<th>1 year patient survival</th>
<th>1 year graft survival</th>
<th>5 year patient survival</th>
<th>5 year graft survival</th>
</tr>
</thead>
<tbody>
<tr>
<td>Liver-deceased donor</td>
<td>86.9%</td>
<td>82.4%</td>
<td>73.4%</td>
<td>67.4%</td>
</tr>
<tr>
<td>Liver-living donor</td>
<td>91.2%</td>
<td>84%</td>
<td>76.8%</td>
<td>68.8%</td>
</tr>
<tr>
<td>Kidney-deceased donor</td>
<td>94.7%</td>
<td>89.5%</td>
<td>80.7%</td>
<td>67.1%</td>
</tr>
<tr>
<td>Kidney-living donor</td>
<td>98%</td>
<td>95.1%</td>
<td>90.4%</td>
<td>80.3%</td>
</tr>
<tr>
<td>Kidney-pancreas</td>
<td>95.1%</td>
<td>85.2%</td>
<td>85.8%</td>
<td>71.1%</td>
</tr>
</tbody>
</table>
Transplant Review Process

**MPSC/DSC Review Process**

- Once a program is identified for review, the program is sent a survey. This survey requests a validation of the data submitted into Unet system.

- A synopsis of the deaths and/or graft failures that occurred within one year of transplant is also requested for review. The DSC considers changes in key personnel, changes to processes and procedures within the transplant program.

- Potential recommendations for programs under review: Release from reporting, Continue to report, Peer Visit, Informal Discussion.
OPTN Compliance Process

Unifying Themes

- Member organizations, programs, OPO’s, and practitioners encouraged to fully understand and voluntarily comply with bylaws, policies, and procedures of OPTN.

- Membership and Professional Standards Committee provides specific oversight for non-adverse actions and reports adverse actions to Board of Directors, HRSA, HHS.

- *Ultimate goal is to enhance clinical care, patient safety and process improvement through peer-review and consensus development.*
Role of CMS
Changes in place after botched surgery
Failed kidney transplant at UTMC prompts new safeguards

BY JENNIFER FEEHAN
BLADE STAFF WRITER

Lead surgical nurse Sara King placed a small metal bowl into the icy slush that sat just a few feet from the operating table inside Operating Room 5 at the University of Toledo Medical Center.

Ed Hall promptly replaced the metal basin with a square plastic box marked "donor kidney," explaining that this is the new container to be used for organs awaiting transplant.

"Simple is good," said Mr. Hall, administrator of surgical services for UTMC, the former Medical College of Ohio.

PHOTO GALLERY: UTMC kidney transplant tour

The new container, which has both a lid and a label, is a small but significant change in the way UTMC surgical teams are to perform kidney transplants in the aftermath of an Aug. 10 surgery in which a viable kidney was removed from a young man, cleaned, placed in a metal basin, stored in the slush machine to await transplant, and then inadvertently thrown away by a nurse who apparently was unaware the organ was in the slush.

Although the mistake was quickly discovered, it took nearly two hours for the kidney to be retrieved from the hospital's medical waste system, and it could not be safely implanted into the waiting patient, the donor's sister.

The mistake — deemed "baffling" by a medical reviewer and "an inexplicable human error" by UT President Dr. Lloyd Jacobs — has prompted a complete review of policies and procedures in the surgery department at UTMC and at hospitals across the country where organ transplants are performed. UTMC's living-donor kidney transplant program remains on voluntary suspension.

"We know what happened. Why it happened is baffling, and that's the human error element of it, which we've been unable to explain," Mr. Hall said during a tour of the operating room where the incident occurred. "Why does anyone make a mistake at any point in the day? Distraction? Having a bad day?

"What we try to do here, regardless of this incident, is to put processes in place to reduce the risk of human error, and unfortunately we had this terrible incident," he said. "We're taking it very seriously. We looked at everything we do with a fine-toothed comb. We changed some of the things we do."

Among the new policies and the changes:
- Nothing may leave the operating room until the patient has been removed after surgery.
- Members of the surgical team must check with the surgeon before going on break.
- An infrared motion detector has been mounted near the slush machine that sounds an alarm when anyone gets close to it.
- A ring-shaped magnetic device has been designed to fit on top of the slush machine. It will have a visual and auditory alarm that will go off when it is lifted.

"Mistakes spur innovation and improvement, and I think they have begun to do that already," Dr. Jacobs told The Blade last week. Mr. Hall, who was temporarily placed on paid leave after the incident and then was reinstated, said no one in the transplant community had heard of a viable organ being discarded before it happened at UTMC.

"This exact incident isn't on anybody's radar screen in the country — lots of other issues are — so nobody was walking around saying, 'How can we prevent this exact type of incident?' " Mr. Hall said. "This showed us that it could happen."

Checks and balances

Still, Dr. Robert Higgins, director of the comprehensive transplant center at Ohio State University Wexner Medical Center and a former president of the United Network for Organ Sharing, said there is a reason this kind of aberration has not occurred before.

"The fact that this hasn't happened anywhere else is probably because there are already checks and balances in place," he said, explaining that OSU requires that donor organs be packaged and labeled after removal and that they not leave the sight or control of the operating surgeon.

Still, Dr. Higgins said the entire transplant community is following what happened in Toledo, and his own medical center has taken a look at its policies in light of the incident.

"We've reinforced our senses to what we should be doing and how we should be conducting our affairs," Dr. Higgins said.

UTMC said that is a constant process — mistake or no.
Role of CMS

All currently approved transplant centers that continue to participate in Medicare, are required to submit a request for initial approval. Once approved by Medicare, transplant centers are eligible for re-approval every 3 years.
CMS Conditions of Participation (COPs)

- **Standard: Data submission (CTC-007)**
  - No later than 90 days after the due date established by the OPTN, a transplant center must submit to the OPTN at least 95 percent of required data on all transplants

- **Standard: Clinical experience (CTC-007)**
  - Annual volume for the following types of transplant centers is required:
    - Heart, kidney, liver & lung transplant centers – 10 transplants
    - No annual volume requirement for heart-lung, and pancreas centers, and centers that primarily perform pediatric transplants

- **Standard: Outcome measures (CTC-007)**
  - A center’s (risk-adjusted) expected 1-year patient survival and 1-year graft survival will be compared to its observed 1-year patient survival and 1-year graft survival, based on the following non-compliance thresholds:
    - $O - E > 3$
    - $O/E > 1.5$
    - $1$-sided $p < 0.05$
CMS Conditions of Participation

Clinical Experience

- Annual volumes requirements for the following types of transplant centers:
  - Heart, intestine, kidney, liver & lung transplant centers = 10 transplants
  - No annual volume requirement for heart-lung, and pancreas centers, and centers that primarily perform pediatric transplants.
CMS Conditions of Participation

Patient and Living Donor Selection

Patient selection criteria must:

- Assure fair and nondiscriminatory distribution of organs
- Include a psychosocial evaluation
- Include documentation in the patient’s medical record that the candidate’s blood type has been determined on at least two separate occasions
- Include documentation in the patient’s medical record of the patient selection criteria used
- Selection criteria must be available upon request

Living donor selection

- The living donor selection criteria must be consistent with the general principles of medical ethics.

Transplant centers must:

- Ensure that a prospective living donor receives a medical & psychosocial evaluation prior to donation
- Document in the living donor’s medical records the living donor’s suitability for donation
- Document that the living donor has given informed consent, as required.
Case in Point

- You are recruited to established academic transplant program
- Past observed outcomes in kidney (N=50) are not meeting expected outcomes (5 graft losses, 4 deaths from MI, PE, head trauma and infection)
- Quality improvement process has addressed patient care issues but outcomes still not meeting expectations
- OPTN/CMS “flag” your program 2 consecutive cycles
- CMS contacts program director requesting explanation
- Your team submits rationale explanations saying transplant (like life) isn't perfect!
"Hi, I'm here about the Arena Events job listing?"
Process For Requesting Consideration of Mitigating Factors in CMS' Determination of Medicare Approval of Organ Transplant Centers

A. Background

Under the authority of 42 CFR §488.61 (a)(4), (b)(2) and (c)(4), a transplant program may request that the Centers for Medicare & Medicaid Services (CMS) consider mitigating factors in the initial approval and re-approval of a transplant program that does not meet one or more Conditions of Participation.

The regulation describes three general areas that will be reviewed in determining whether or not a program can be approved based on mitigating factors. These areas include (but are not limited to): 1) the extent to which outcome measures are met or exceeded; 2) the availability of Medicare-approved transplant centers in the area; and 3) extenuating circumstances that may have a temporary effect on meeting the Conditions of Participation.

In most cases CMS will schedule a conference call with the hospital to discuss the results of the CMS review about 30 days after CMS’ receipt of the completed request for consideration of mitigating factors.
Process For Requesting Consideration of Mitigating Factors in CMS’ Determination of Medicare Approval of Organ Transplant Centers

B. Requesting Approval Based on Mitigating Factors

A transplant program seeking approval based on the presence of mitigating factors should:

1) Submit a formal written request for approval to the CMS Central Office contact and address specified below **within 10 calendar days from the notification date on the letter accompanying the CMS-2567 form** (this form outlines survey results) in order to get timely attention before any possible enforcement action is taken on the cited deficiencies.

2) Submit any final (additional) explanatory materials **within 30 calendar days following the date of the notice accompanying the CMS-2567 form**.
CMS Regulatory IMPACT

• Program Actual outcomes below Expected outcomes
  • Based on SRTR data cohort from 1/1/09-6/30/2011
  • 2 times in the past 30 months with one of two times being most recent cohort
  • Next report to be published January 2014 (7/1/10-12/31/12)

• Systems Improvement Agreement
  • Facilitate quality system improvements that will enhance the existing program
  • Enter into agreement (hospital pays for ALL activities)
  • 12 month agreement

• Independent Peer Review
  • Panel of transplant professionals (surgeon, physician, SW, Txp. Admin, RN, QA)
  • Provide recommendations that become the Quality Action Plan

• Ongoing Consultant guidance
  • 6 days/month on site for EACH program
  • Assist with execution of Quality Action Plan
  • Connectivity back to CMS re: program’s progress
CMS SIA Update

General Themes:

- Multi disciplinary rounding … daily
- Transition post operative care during inpatient admission from Surgery to Medicine after patient moved out of ICU care
- Improve Medical and Surgical collaboration
- Social Work, Dietary, Pharmacy involved across entire care continuum
- Electronic medical record development
- Root Cause Analysis (RCA) on every death and graft loss
- PSC to be multidisciplinary with all disciplines present and voicing their opinions. Needs to go GREEN with real time documentation.
- Surgeons/Physicians involved with UNET data collection
Keys to Success in The Current clinical and regulatory environment

- Understand the OPTN, CMS requirements
- Develop a strong, prospective administrative understanding and or role
- Accurate data submission is critical to appropriate risk adjustment
- Quality Assessment and Process Improvement (QAPI) program - fix problems in real time
- Do Good work - there is no replacement for good patient selection, appropriate donor management and selection, outstanding surgical/medical expertise and comprehensive follow-up
Transplant Signature Program
Teamwork committed to Quality and Quantity of Life – OSUMC 2010