

Coroner's, Medical Examiner's and Organ and Tissue Donation

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Organ and Tissue Donation

Hospital Deaths

1998 CMS Conditions of participation:
Required to work with Federally designated OPO, select tissue, eye bank and refer all potential donors and all deaths to OPO

State and Local Oversight

Hospital Leadership Ethics committee

Selects Tissue Bank Specific criteria

Hospital

Referral

Organ Procurement Organization OPO

Triages

Tissue Bank

Out-of-Hospital Deaths

No Federal Regulations

Problem 1

No State or Local Oversight

Selects Tissue bank ? Criteria

Coroners/ Medical Examiners

"releases"

Problem 2

Referral

Problem 4

**Problem 3
Jurisdiction**

Tissue Bank

Problem 1- Lack of Federal, State and local oversight

Problem 2- Denial of Life Saving Organ Transplants

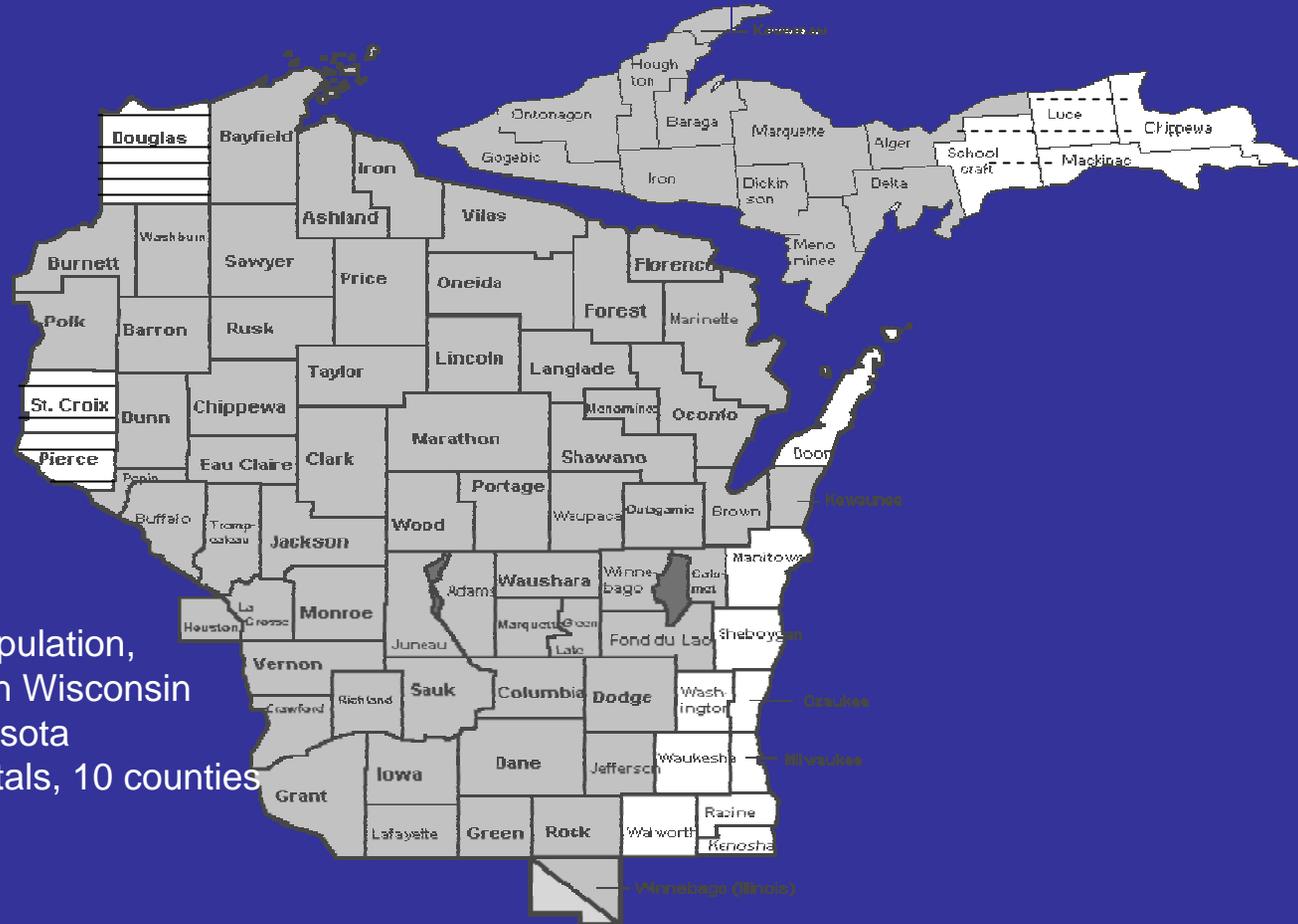
Problem 3- Circumvents Hospital's choice of Tissue Bank

Problem 4- Lack of oversight and transparency in tissue referral

Organ Procurement Organizations (OPO's)

- OPO's are responsible the recovery of heart, lungs, liver, kidney,pancreas and intestine for transplantation
- OPO's serve federally designated donation service areas(DSA) based upon counties
 - All hospitals within the designated group of counties are mandated to work with the assigned OPO
 - Two OPO's in the state UW OPO and Wisconsin Donor Network(WIDN)
- OPO's are regulated by the Center's of Medicare and Medicaid Services (CMS) and the United Network for Organ Sharing (UNOS)
- 1998 CMS conditions of participation requires all hospitals to work with the Federally designated OPO, select a tissue and eye bank to work with and refer all deaths and potential donors to the OPO

UWHC and WIDN OPO Donation Service Areas



-  **UWHC-OPO**- 3.2 million population, 100 hospitals, 72 counties in Wisconsin
-  Michigan, Illinois and Minnesota
-  **WIDN**- 2.2 million, 45 hospitals, 10 counties In Wisconsin
-  Minnesota OPO
-  Michigan OPO

Tissue Banks

- Tissue Banks are responsible the recovery of bone, skin, tendons, and heart valves
- There are four tissue banks operating in Wisconsin
 - MTF Wisconsin Tissue Services, Wisconsin Tissue Bank, RTI Tissue Services (formerly Allograft Resources of Wisconsin), and American Tissue Services Foundation
- Tissue Banks are subject to the FDA's Good Tissue Practices Standards and may be certified by the American Association of Tissue Banks(AATB)
- Tissue Banks usually have three operations: Recovery, Processing and Distribution

Tissue Banks

- The Tissue Banks send the tissue recovered to be processed into usable “grafts”
- The business structures of tissue banks vary
 - some recovery operations of tissue banks are non-profit but send tissues to for-profit tissue processors others are affiliated with not-for-profit tissue processors
- Tissue processors then distribute the processed “grafts” to hospitals for surgical implantation or treatment of burn patients
- Tissue Banks contract with hospitals
 - the Medicare Conditions of Participation require that all hospitals have a relationship with a tissue and eye bank and develop criteria by which to select a tissue bank

Tissue Bank Selection Criteria-UWHC

Hospital Leadership and Ethics Committee

- UWHC looked at the profit and non-profit status of not only the recovery operation of the tissue bank but of the processing and distribution operations of the tissue bank. While most tissue banks have a non-profit recovery operation many have for profit processing and distribution operations. We chose a tissue bank that is a 501(c)3 organization and non-profit in all three areas
- UWHC looked at the national reputation of the tissue banks and their history of service to hospitals and to the communities they served. We chose to work with a tissue bank that sent processed tissue back to the same community for use by local surgeons before it was sent elsewhere.
- UWHC chose a tissue bank that prioritized the use of its tissue for medically therapeutic uses and not for cosmetic uses.
- UWHC also chose a tissue bank that was certified by the American Association of Tissue Banks(AATB) not just for recovery but for processing and distribution.

Coroners, Medical Examiners and Out-of -Hospital Deaths

- Out-of-hospital deaths account for the majority of deaths that occur in a county
- Coroners and ME's are not required by federal regulations to report out-of-hospital deaths to a donation agency nor are they required to offer the option of donation
- Historically, coroners and ME's have had informal relationships with tissue banks not subject to any regulation by federal, state or local government
- Federal regulations and well as State Statutes did not foresee the relationships that would develop between coroners, ME's and tissue banks after CMS introduced Conditions of Participation in 1998

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Coroner and Medical Examiner Denials for Organ Donation: The National Landscape

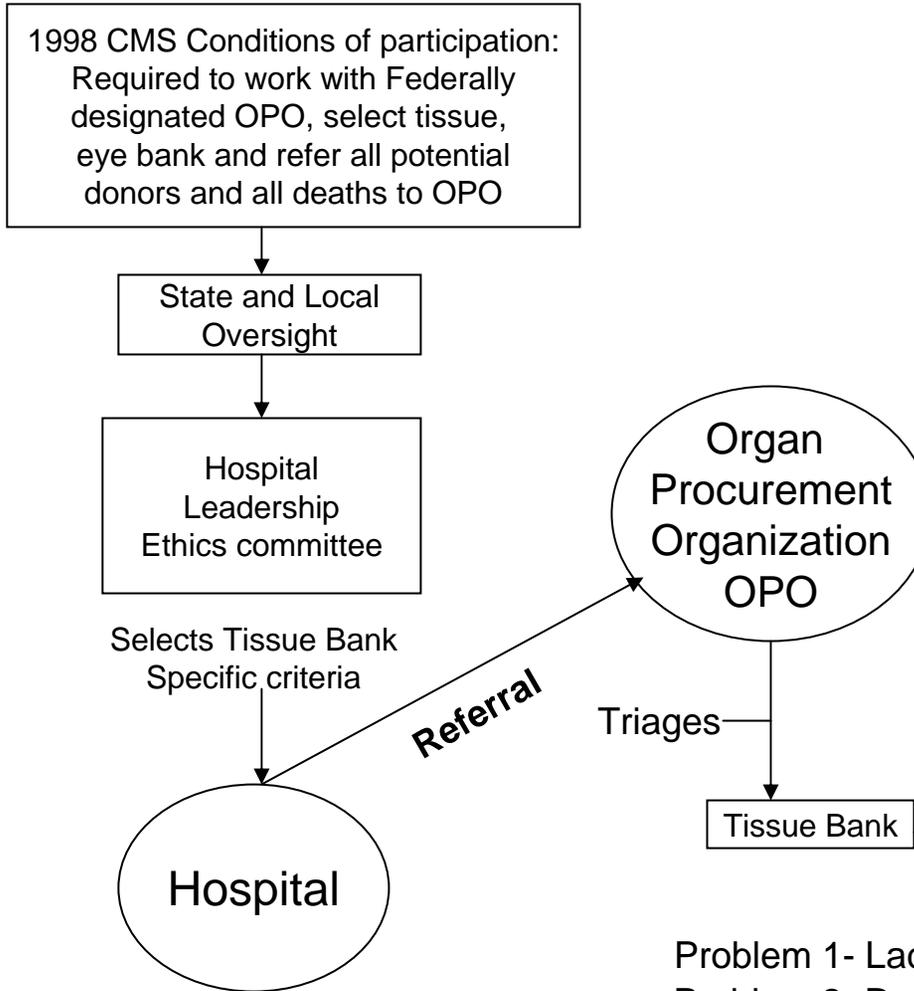
- The National Association of Medical Examiners set a national goal for zero denials of organ donation. ***“It is now the official policy of the National Association of Medical Examiners to support not only the concept of zero denials, but to make it a reality.”*** Dr. Michael Graham, President National Association of Medical Examiners, April 2004
- Case law demonstrates that organ donation and successful prosecution are **not** mutually exclusive
 - Criminal Investigations and Prosecutions Not Adversely Affected by Organ Donation: A Case Law Review
Medicine and Law Committee Newsletter, Summer 1994
- Medical publications demonstrate that organ donation has never precluded prosecution of a suspect and many areas of the country have zero coroner/me denials
 - Vital Role of Medical Examiners and Coroners in Organ Transplantation
American Journal of Transplantation, 2003

Coroner and Medical Examiner Denials for Organ Donation: The National Landscape

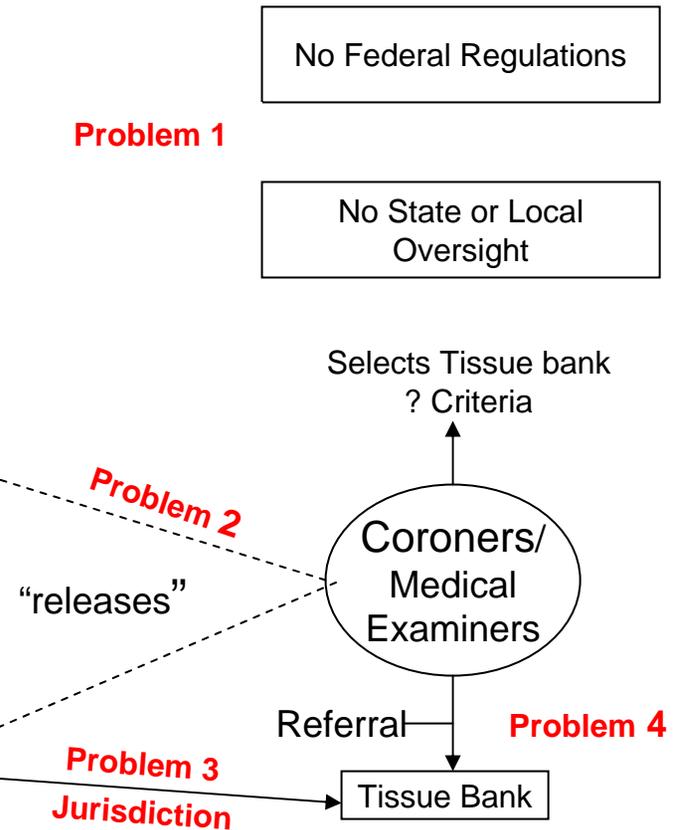
- Unfortunately, Coroner and ME denial of organ donation still occurs and for that reason several states have enacted legislation
- States **requiring** coroner/me release:
 - New York, Tennessee, Mississippi
- States **restricting** circumstances of denial- coroner/me required to be in surgery if considering denying organ recovery:
 - New Jersey, Texas, California, Rhode Island, Arkansas
 - Michigan's legislation passed Assembly Aug. 2005
- In a 10 month period from July 2004 thru May 2005 there were four coroner/me organ donation denials and the loss of 20 life saving transplants
 - additionally four families suffered a second loss when told that the coroner was not going to allow donation
 - Denials were from Wood, Winnebago, Marathon and Barron Counties

Organ and Tissue Donation

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Out-of-Hospital Deaths



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Jurisdiction of Coroner's and Medical Examiner's vs. Federal Regulation

- Although Federal regulations require all hospitals to have an agreement with a tissue bank, some Wisconsin coroners and ME's believe their statutory authority allows them to refer to the tissue bank of their choice thereby disregarding the Federally mandated choice of the Hospital.
 - Some of the 30 coroner's and medical examiners who have sent letters notifying the OPO that all donors from their counties will be referred to the American Tissue Services Foundation are now redirecting tissue donors who die within the hospital, and that they take jurisdiction of, to American Tissue Services Foundation regardless of the hospital's contractual relationship with other tissue banks

Concerns with Re-direction of Hospital Tissue Donors by Coroner's and Medical Examiner's

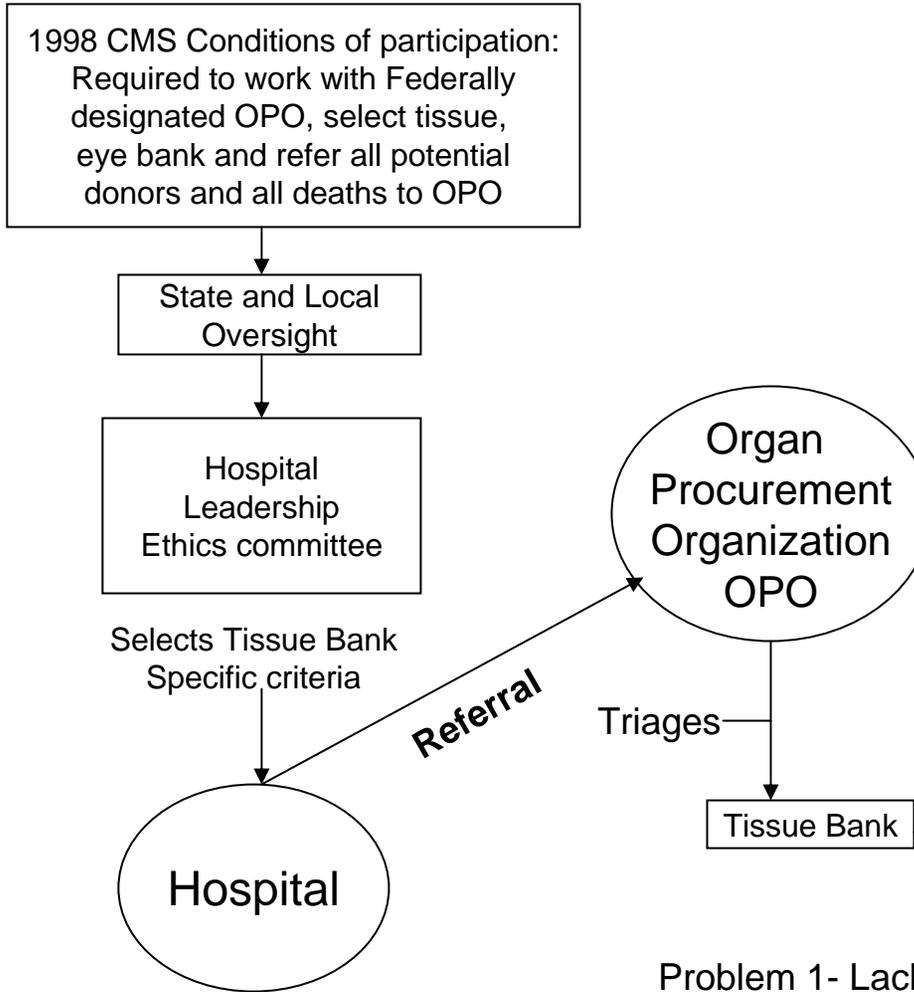
- Hospitals have contractual relationships which require that all deaths within the hospital will be referred to the recovery agency with whom they contract
- Each hospital contracts with a tissue bank based upon criteria by which they have determined will best serve donor families within their organization
- Consent forms for tissue donation used within the hospital for tissue donation are specific to the tissue bank with whom the hospital contracts
 - When a coroner or medical examiner redirects a tissue donor the consent form used by the hospital may not reflect the business practices of the Coroner's or medical examiner's chosen tissue bank
- Tissue Banks require information from the patient's medical record for donation to proceed. If the hospital doesn't have a contractual relationship with the company that the coroner has chosen, then the hospital is not compliant with JCAHO, HIPAA and state statutes which require hospital's to have specific contractual language addressing confidentiality of released medical information.

What Does CMS Say about this Practice?

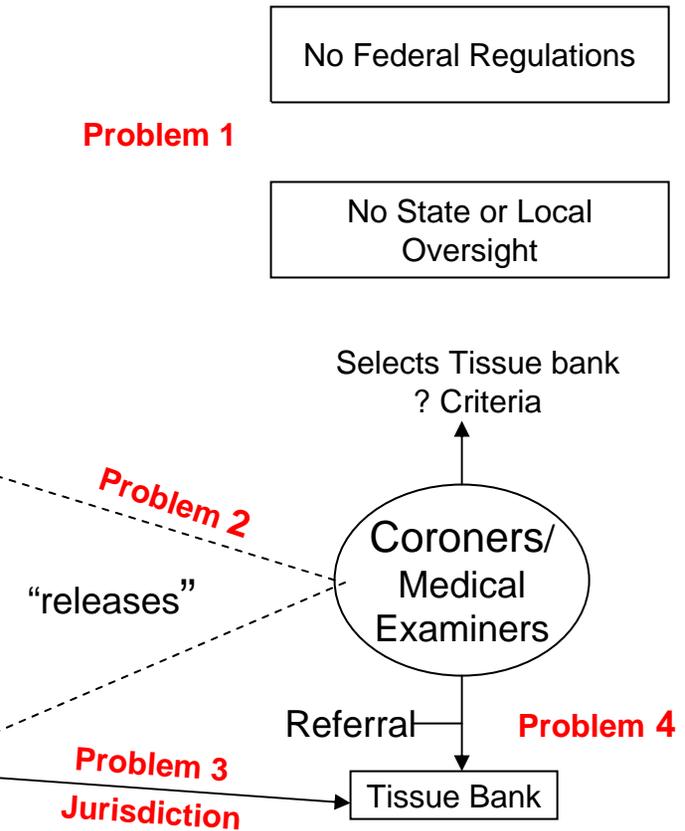
- In a letter dated August 4, 2005 to the Dane County Coroner:
 - ...The OPO may serve as gatekeeper receiving notification about every hospital death and should notify the tissue bank or eye bank **chosen by the hospital** about potential tissue and eye donors. For the medical examiner or coroner to circumvent the hospital's arrangement with its designated tissue bank, risks putting the hospital out of compliance with Federal Regulation, as well as compromising the integrity and outcomes of the organ and tissue donation process...
 - ...it appears that physical custody of a deceased individual is being taken within the hospital for purposes beyond determination of the cause of death and/or the performance of an autopsy...

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Lack of Oversight and Transparency for Out-of-Hospital Tissue Donor Referral

Since the majority of deaths occur out-of-hospital

- What are the selection criteria coroner's and me's use to exclusively work with one tissue bank for out-of-hospital deaths ?
- How many out-of-hospital deaths occur in a county?
- How many are referred for tissue donation?
- Which tissue bank received the referral for tissue recovery?