



Jagger's Statement

- “Today our focus is on the Santillan family. My own heart is with them as they face a loss at the end of a process that began with so much hope. I have known Jesica and her family since May of 2002, when her condition deteriorated to a level where only a transplant could prolong her life. She was placed on a transplant list due to the fact that she was extremely ill with a congenital heart defect that was eventually going to kill her in a relatively short period of time....”

Jagger's Statement



- Despite the large # of seriously ill people who would benefit from a transplant, less than 30 H-L transplants are performed in the US each year. Most patients on the H-L transplant list die without getting organs. As Jessica's surgeon, I had hoped to prolong & improve her life with a H-L transplant....

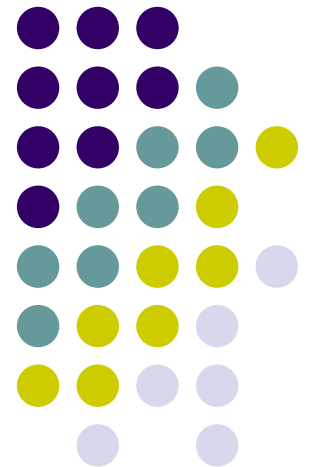
Jagger's Statement



- The process of matching donors to recipients is a very complex one and involves multiple steps & organizations. The organ procurement agencies manage the donors, screen the organs & allocate those organs to appropriate recipients based upon nationally approved guidelines. The other parties include the transplant center, the patients and their families. Unfortunately, in this case human errors were made during the process. As Jessica's surgeon, I am ultimately responsible for the team and for this error"

Case

A Mismatched Heart - Lung Transplant





Lessons Learned

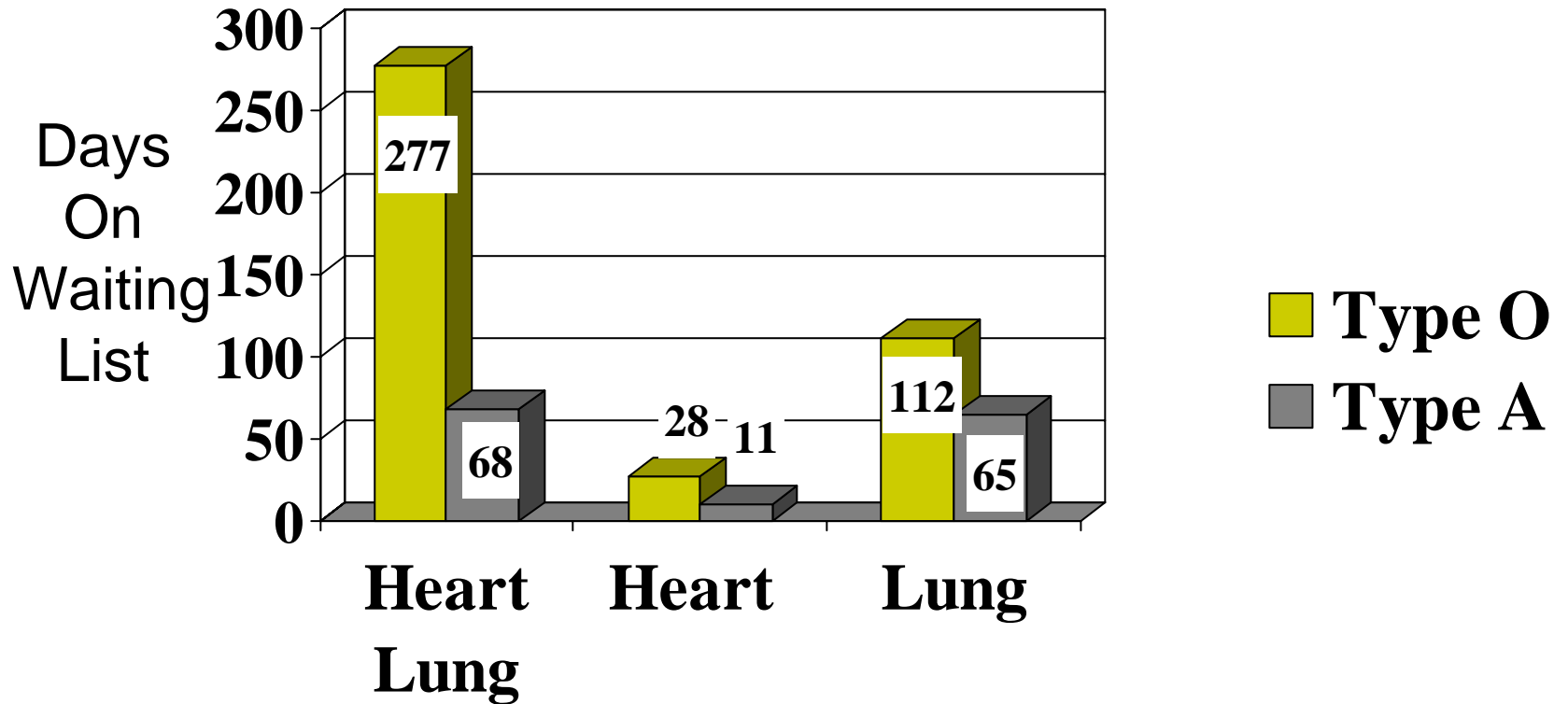
- Chronology of events leading to error
- Were appropriate checks in place?
 - Why did it fail?
 - Solutions?
- Chronology of events post error
 - PYA
 - Competing Interests
 - Dealing with the Media



Heart-Lung Transplants

- United Network for Organ Sharing (UNOS) Data - 2001-02
 - 55 heart-lung transplants world wide
 - 197 on the waiting list
 - 5 Pediatric

UNOS Data: Days for 10% of listed Patients to be Transplanted



Chronology of Events



- Carolina Donor Services - Contacted adult heart surgeon re 7 year old donor heart in Massachusetts. Referred to Dr. Jaggers for a specific peds pt.
- Heart declined for that pt. Inquiry made for heart-lung block for Jessica. CDS organ procurement coordinator offered to check and call back



Chronology of Events

- 3AM return call offered Jesica organs
 - Organ function, size discussed
- Duke: 2 harvests ongoing
 - Adult heart
 - Liver, Lung, pancreas, small bowel
 - A CT surgical fellow not on transplant service sent for procurement. Did not know Jesica's blood type.

Chronology of Events



- Snow storm in Boston - delays flight
- Jessica's heart and lungs were removed upon landing at RDU
- After weaning from CPB
 - Duke's Clinical Transplant Immunology Lab reported incompatible blood type
 - Immune modulation started in OR

Transplant confirmation system at Duke failed at 6 points



- CDS: Can not offer organs to patients not on UNOS match list
- Surgeon
- Transplant Coordinator
- Harvesting Surgeon
- Clinical Transplant Immunology Lab
- Tag on cooler containing organs has donor blood type listed

Redundancy without Accountability



- Redundancy - Yes
 - 6 levels
- Accountability -No
 - No signed document confirming match
 - Process does not stop without confirmation
 - Specific, limited check off sheet
 - Less than 10 items preferably 5



Organ Procurement Org. Responsibility

Host OPO must secure a minimal check list including ABO type

- Regional OPO (CDS) offers compatible organs to transplant centers in their region
 - Match: UNOS computer data base
 - The computer run is confirmed by two individuals in the regional OPO
 - Jesica was not on computer list
- No document to confirm compatibility by CDS



Surgeon Responsibility

- Confirm Match: No signature document listing donor / recipient blood type
- CDS offer came at 3AM
- Surgeon assumed match
- Did not have access to list at home
- No Pediatric Transplant coordinator
- Institution does five or six peds heart transplants/yr

Nurse Coordinator



- Confirm Compatibility
- Communicate with Surgeon, OR, Transport Service, Harvesting Hospital and Transplant Immun. Lab
- No Confirmation of Organ Compatibility
- No check list to confirm compliance

Harvesting Surgeon



- Not on Transplant Service
- 2 other harvests ongoing
- Did not have Institutional list or knowledge of recipient blood type
- Did not think to ask
- Was told donor blood type 3x
- No confirmation with signature before harvest begins

Clinical Transplant Immunology Lab

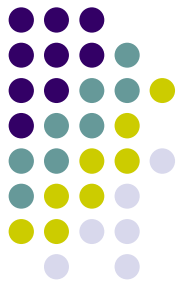


- Confirm blood type match
- Did not receive call from nurse coordinator
- Paged coordinator three times
- No match confirmation made
- Did not communicate failure to confirm to transplant team



Weather

- Two hour delay at Logan Airport
- Elected to remove Jessica's heart and lungs when Jet touched down at Raleigh Durham Airport
- Organs "in bucket" when harvested organ block arrived
- No option to confirm blood type when organ arrived in OR
- OR confirmation was not part of confirmation process



CDS Failure to Confirm

- For Profit Org
- Cardiothoracic Transplant Service at Duke one of three largest in US
- Relationship with CDS to place organs
- Duke prioritized after first run
 - Take suboptimal organs
 - Large waiting list
 - No pts died waiting
 - Peds unaware of relationship

Surgeon



- Transplant small part of practice (1.5%)
- No pediatric coordinator
- Majority of transplants adult
- Communication and Operational practice of adult transplantation service differed from pediatric practice

Adult Nurse Coordinator



- Did not check UNOS list
- Distracted by 2 other transplants & weather
- Did not call or return page of Clinical Immunology Lab



Medical Errors - Patient Injury

- Series of Errors, not a single mistake
- Unpredictable: Predictable - don't occur
- Airline Industry - Safety Check Lists
 - Formalized
 - Regulated
 - Confirmed and Signed
- Transplant Process at Duke
 - Redundant but not formalized, or regulated, confirmed signature



Process Change at Duke

- Signed Confirmation and Check List for Compatibility
- CDS
- Surgeon
- Transplant Coordinator Must Call OR
 - Confirm blood type and UNOS number with Circulating Nurse and Anesthesiologist
 - Prior to Organ Harvest
 - Documented in 2 computer records at Duke

Example of Other Sensationalized Medical Errors

Untreated Intractable Seizure resulting in
Brain Death at Boston Children's Hospital



The Boston Globe



Doctors were unsure of roles as boy died at
Children's By Anne Barnard, Globe Staff, 9/19/2003

“The 5-year-old boy had just had electrodes implanted in his skull to track his epilepsy when a massive seizure struck. Though he was in intensive care at Children's Hospital in Boston, one of the world's top pediatric centers, no one ordered the aggressive treatment that could have saved his life.”

Childrens Hospital, Boston

POINTING THE FINGER

Both doctors at the scene and those in supervisory roles told federal investigators that other individuals or departments were responsible for managing the patient's treatment during the seizure. The patient did receive anti-seizure drugs, but not in high enough dosages.

Neurosurgeon

Said epilepsy staff or medical intensive care unit (MICU) staff are responsible for post-operative care.

Neurosurgery resident

Assumed the seizure was being managed by the MICU fellow and the epilepsy fellow on the phone.

MICU director

Said MICU staff don't assume responsibility for surgical patients; the responsibility belongs to the surgical staff.

MICU attending

Said neurological staff was responsible for managing care during the seizure.

MICU fellow

Thought the seizure was being managed by neurosurgical resident at bedside and epilepsy fellow on the telephone.

Epilepsy specialist #1

Said MICU staff or neurosurgical team were responsible for managing care during the seizure.

On call that night

Epilepsy specialist #2

Said MICU staff was responsible for care.

Patient's primary doctor, but not on call that night

Epilepsy fellow

Said she was only a consultant. She was not at the hospital and assumed bedside doctors would manage care.

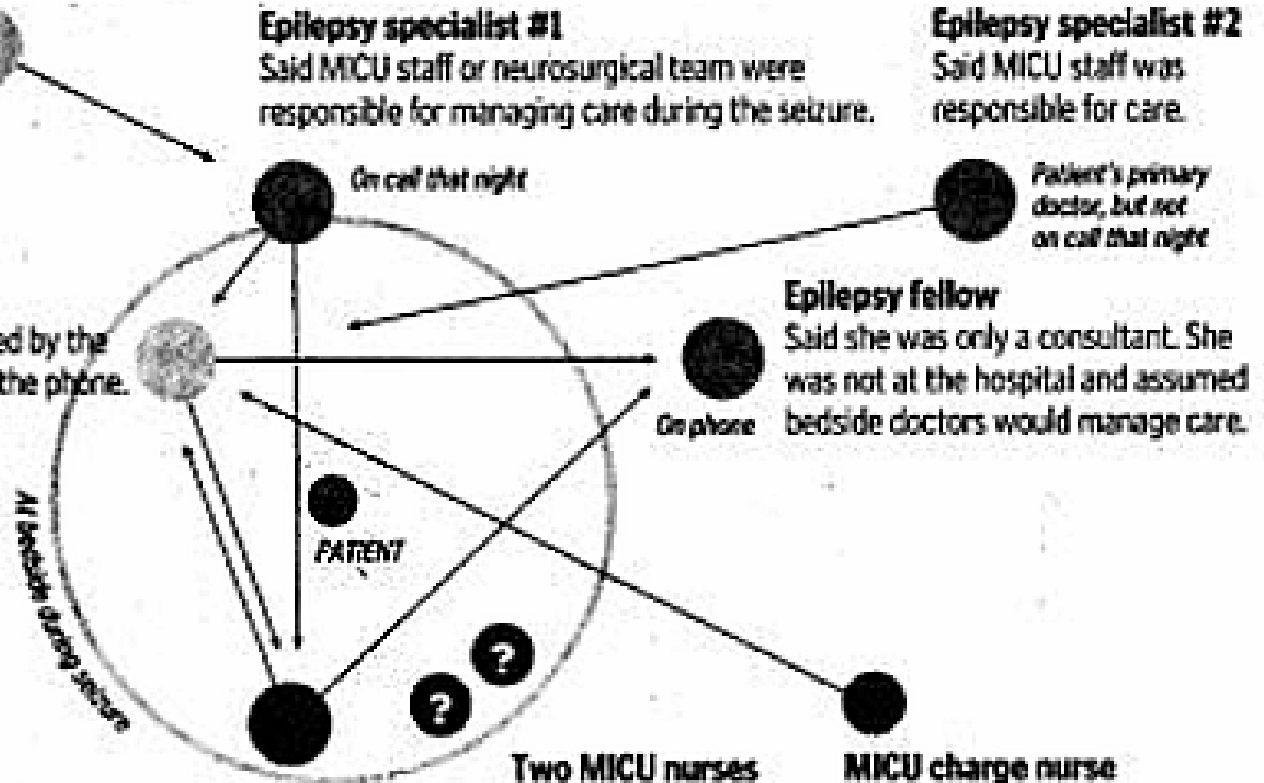
On phone

Two MICU nurses

Could not recall who was managing the patient's seizure.

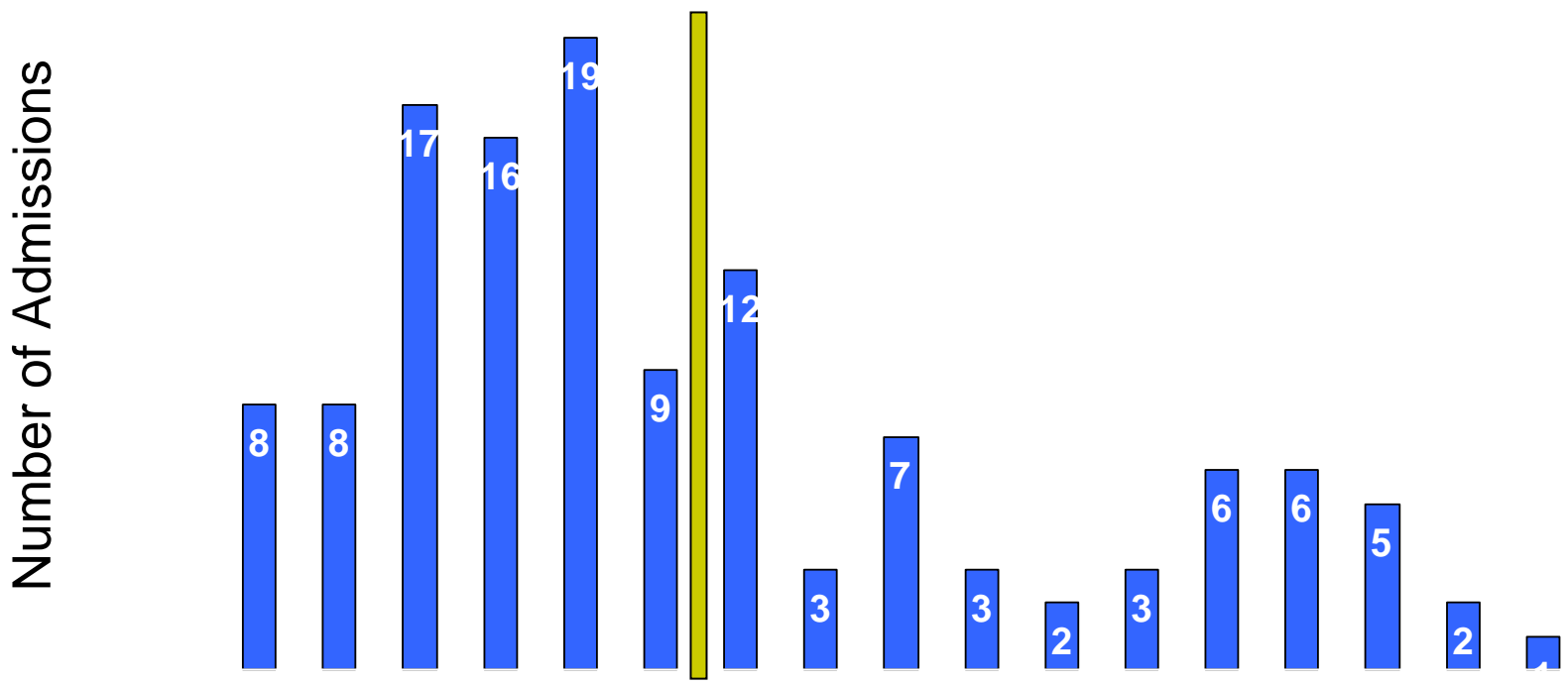
MICU charge nurse

Said surgical teams are responsible for surgical patients.





Miscommunication Events / Admit



Number of Miscommunication Events per Admission (mean 6.56)

Miscommunications



- No correlation with:
 - Level of training
 - Anesthesia
 - ICU
 - Nursing
 - Workload - hours
- Streamlined check list driven sign out

Translocational Research

Wachter AHRQ



Strategy	Non-health care example	Study demonstrating value in health care	Impetus for wider implementation
Improved ratios of providers to “customers”	Teacher-to-student ratios (ie, class-size initiatives)	Aiken, 2002 (2)	California legislation; other pressure
Decrease provider fatigue	Consecutive work-hour limitations for pilots, truck drivers	Landrigan, 2004 (4)	ACGME regulations limiting duty hours
Improve teamwork and communication	Crew resource management in aviation	Morey, 2002 (6)	None yet, but on the horizon if evidence becomes more robust
Use of simulators	Simulator use in aviation and the military	Reznek, 2003 (7)	Now required for credentialing for certain procedures; growing interest
Executive walk rounds	“Management by Walking Around” in business	Thomas, 2005 (8)	Not required, but increasingly popular practice
Bar coding	Use of bar coding in manufacturing, retail, and food sales	Poon, 2005 (9)	U.S. FDA requires medications; bar coding (or radiofrequency identification) may be required in many identification processes

Post Transplant Management



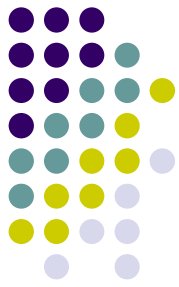
- Steroids
- Plasmaphoresis
- Immunotherapy
- Antibody levels remained low



Extubation Attempt POD 2

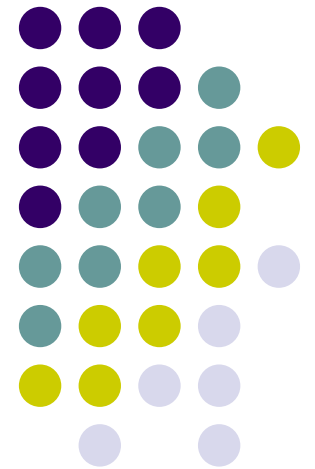
- After 6 hours
- Dramatic worsening in oxygenation & ventilation
- Failed in succession
 - Conventional ventilation
 - HFOV
 - VV ECMO
- VA ECMO -Retransplantation

Autopsy of Lung Explant

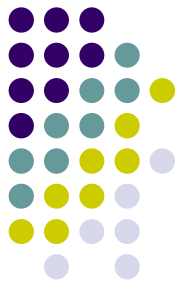


- No evidence of Rejection
- Acute Lung Injury
 - Overdistension Injury?
 - 7 yr olds lungs in 17 yr old
 - Size was right on edge
 - Extubated post op day 2
 - Pleural spaces primarily air filled

Protecting Your Self



Do an Assessment



- Who are your Enemies?
- Who are Your Friends?
 - Are you sure?
 - Will they be your friend tomorrow?
 - Does helping you hurt them?
 - Does helping them hurt you?

Patient, Family, 3rd Party Advocate

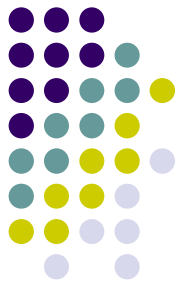


- Is the Patient or Family reasonable?
 - Involvement of lawyer(s) or media --No
 - Be careful in taking blame
 - Anything you say or write can and will be used against you!

The Hospital / Health System



- Just because the Hospital insures you is it on your side?
- Its interests may differ from yours
 - Bad Publicity -- Med Center Reputation
 - Priorities: Protect Hospital, CEO, Chancellor of Health Affairs
 - Consultant: Bad Hospital vs. “Bad Apple”
 - Are you the bad apple?



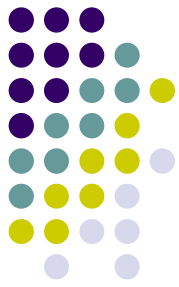
Other Involved Parties: OPO

- General Principles
 - No one wants to take blame
 - No one wants to pay for mistakes
 - If it's you or them, it's you!
- Statement: New England Organ Bank
 - "A review of our medical files related to this case shows that correct blood type information was indeed provided by the New England Organ Bank to the transplant team in North Carolina."



Others: Chief Thoracic Transplant

- Protect program & relationship with CDS
 - “I would say that it is routine for those of us who do this on a regular basis to ask what the blood type is”
 - “it wasn't the Harvesting Surgeon's fault that he didn't know, because that information wasn't conveyed to him”
 - “there was an initial misassumption, and no one went back to check it. The initial mistake, was made by Dr. Jagers.”
- Highly profitable program



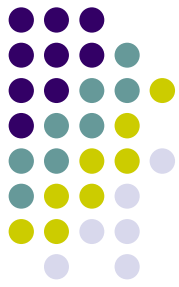
Media

- 24 Hour News
- Like a Shark:
 - Stops swimming it dies
 - Prefers to feed constantly
- Santillan Family Representative and Lawyers feed the media constantly
- Duke hunkered down “investigating” and “protecting patient confidentiality”
- Santillan view point updated hourly



Should You talk to “The Media”

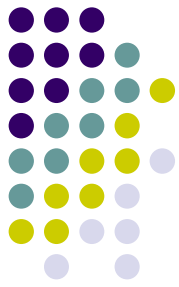
- Five Top Media Lies:
 - 5) I want to be fair
 - 4) I want to give you a chance to tell your side
 - 3) I’m writing a story about how doctors are misunderstood
 - 2) I just want to verify a few facts
 - 1) I’m from “60 Minutes” and I’m here to help



Media Spokesperson

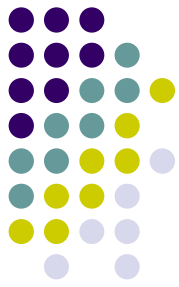
- NOT YOU!
 - Medicine controlled environment
 - Good at Medicine does not make you good at Media
- Media has own agenda
 - Maintain Story/ fuel fire/ quotes out of context
- Media Savvy - not hospital person
- Should consult with Legal Counsel

Undivided Loyalty

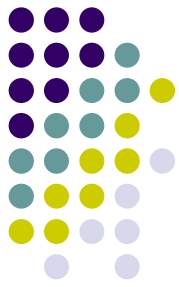


- Get Your Own Lawyer
- Physician Group ±
 - Depending on other physician involvement
 - Risk to Group

Survival?



- Jagers review by Hospital, State Medical Board, American College of Surgeons
- Interviewed, reviewed every surgical case
- Reviewed using NY State Classification
 - Adult cases: received highest score ever recorded for adults
 - Peds: case outcome was $> 100\%$ above the mean for like surgeons placing him in the highest category of congenital heart surgeons in the US



Conclusion

- Insight into a tragedy
- Redundancy without accountability, documentation, or communication
- Safety concepts
- Protecting yourself
- Dealing with Media