

Disclosing Medical Error to the Family

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 The Canadian Healthcare Safety Symposium: Healthcare and the Law

Conflict of Interest Disclosure

Mayo Clinic Division of Cardiovascular Surgery

Research funding within the past year:

AstraZeneca	Jarvik Heart
Atricure	Medtronic
Avant Immunotherapeutics	St. Jude Medical
Baxter	Thoratec Corporation
Carbomedics/Sorin Group	TransTech Pharma
CryoLife	W.L. Gore and Associates

No personal equity, patents, or licensing, agreements with the medical device or pharmaceutical industry.

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Objective

- *Generate Discussion*

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Errors or Adverse Events?

- Disclosure
 - “process by which an adverse event is communicated”
- Adverse event
 - “event which results in unintended harm...related to the care of the patient....”

CMPPA

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Definition of Error

- “failure of a planned action to be completed as intended

or

- the use of a wrong plan to achieve an aim”

per Institute of Medicine

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Definitions: "Patient Safety"



Our Definitions
(approved by the NPSF[®] Board July 2003)

- **PATIENT SAFETY**
The prevention of healthcare errors, and the elimination or mitigation of patient injury caused by healthcare errors.

Assumption: "Patient Safety" will result from reduced errors...

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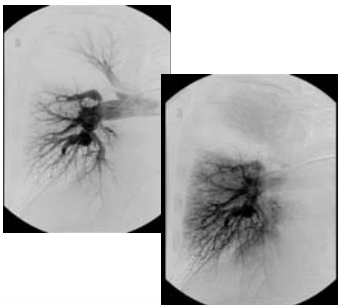
What Families Want

- Acknowledgment that something has happened
- The facts
- What is to happen to care for the individual harmed
- Expression of care, concern and regret
- Assurances that corrective measures are being undertaken to prevent it from happening to others

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What Went Wrong?

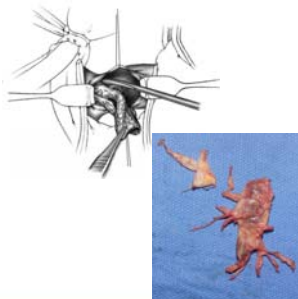
- 46 year old woman
- Morbidly obese
- Chronic Pulmonary Emboli
- Supra-systemic pulmonary pressures



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What Went Wrong?

- Bilateral Pulmonary Thrombo-endarterectomy under profound hypothermia with circulatory arrest
- Bypass time 232 minutes



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What Went Wrong?

- Weaned from bypass but unable to exchange CO₂
- Venovenous ECMO initiated
- Supported 7 days with gradual improvement
- PA pressures in the 30's on prostacyclin



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What Went Wrong?

- Brought to OR
- Successfully weaned from ECMO
- Large venous outflow cannula in femoral vein removed by cut-down
- Small venous inflow cannula removed from neck...which kept bleeding
- Heparin maintained to protect pulmonary bed..."how about a topical hemostatic agent?"

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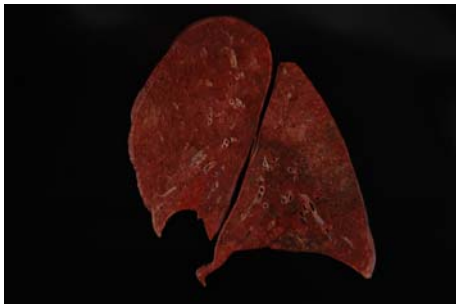
What Went Wrong?

- Topical Agent applied
- Within 5 minutes supra-systemic pulmonary artery pressures
- Unresponsive to all maneuvers
- Return to ICU, gradual decline to death



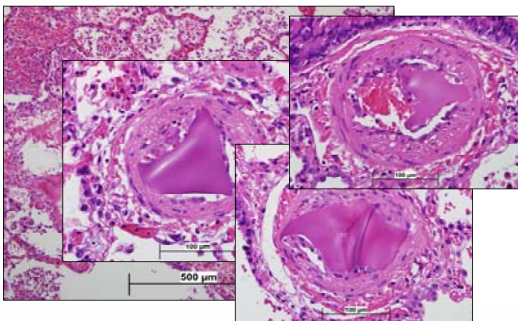
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Post-Mortem



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Post-Mortem



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The Price of Error

Dear Dr. Sundt,

We, the family of L. P. would like to thank you for inviting us to go over the autopsy report with yourself and Dr. Michael Rock, the Chair of the Hospital Practice Committee, on June 3, 2008. We greatly appreciate your openness and honesty in regards to the results of the autopsy.


It was with much hurt and sadness that we learned of the 4-5 cc's of the topical glue that was inadvertently injected into a vessel in L. 's neck which then went into her blood stream and then to her lungs. L. then had no chance of recovery.

Prior to the removal of the ECMO machine, the nursing staff, doctors and individuals running the machine, along with C. and myself, were in almost a celebratory mood. L. had done so well with the weaning off the ECKMO machine the day before, and coming off totally was a giant step in her recovery. We do feel that L. had an excellent chance. It was not to be.

A horrible though unintentional mistake was made. Our family has neither the desire nor the heart to file a malpractice suit. No amount of money can heal our hearts or bring L. back. However we have incurred additional expenses ie; funeral expenses, legal fees, custodial fees, moving expenses etc. L. 's life was of much value and we miss her desperately! Would it be within reason to request a monetary sum to offset some of the hardship?

Laurie liked and respected you very much. She was so positive and had such high hopes.

Sincerely,



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We greatly appreciate your openness and honesty....Prior to the removal...the nursing staff, doctors...[my sister and I] were in almost a celebratory mood....A horrible though unintentional mistake was made....Our family has neither the desire nor heart to file a malpractice suit....

Laurie liked and respected you very much. She was so positive and had such high hopes.

Sincerely,



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What went wrong?

- Clearly the material was used incorrectly....
- Did he not know it was topical agent?
- Was he not paying attention?
- Is he *stupid*?
- Does he *not care*?

- And what is the solution...

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The Price of Errors

From: [Redacted] Sent: Fri 8/22/2008 1:17 PM
 To: [Redacted]
 Cc: [Redacted]
 Subject: RE: [Redacted]

Thank you very much Dr Sundt

You always think the best for the situation and I would be happy to go in that direction.

I am still depressed about the patient and the family, but I would be happy staying behind my responsibility and the truth. It happened unfortunately but now I am thinking whatever the best for patient family, Mayo and you to handle this event in a correct way should be the way of my thinking also.

Thanks again,

[Redacted]

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Understanding Error in Surgical Culture

Forgive and Remember, Charles Bosk

- Technical Errors
- Judgment Errors
- Normative Errors
- Quasi-Normative Errors

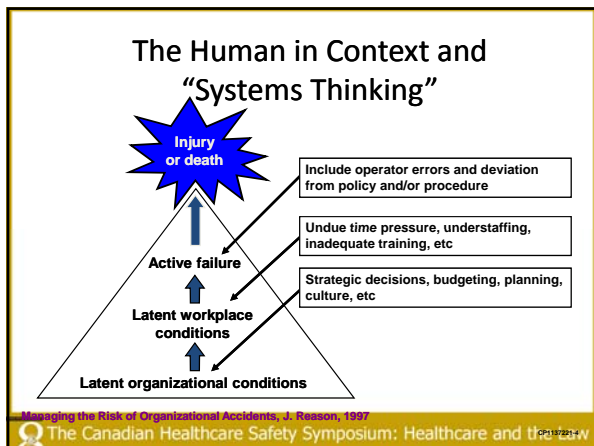
- ...Cognitive Errors....

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Understanding Harm

- Inherent risks of investigation/treatment
- System failures
- Provider performance

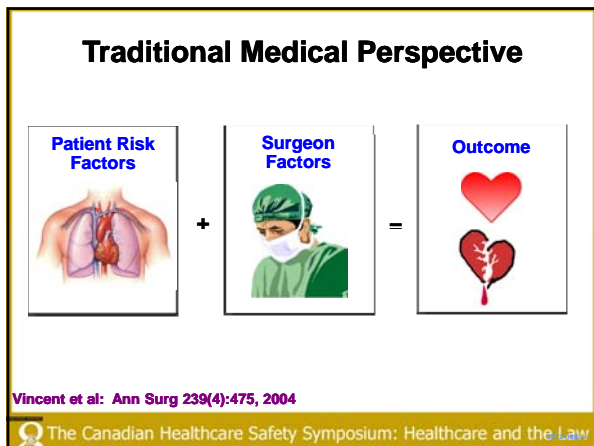
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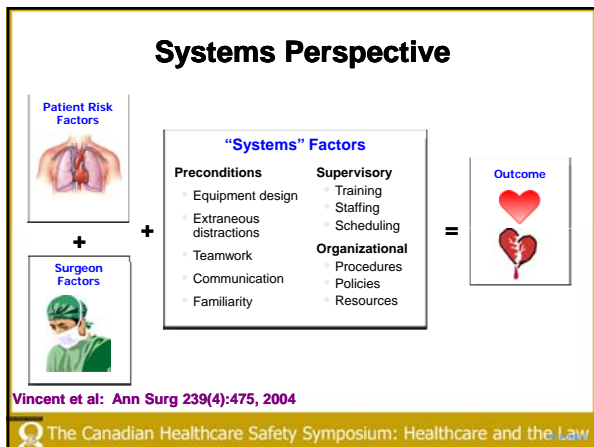


- ### Provider performance
- Gap in knowledge or skills
 - Violation/departure from policy/protocol
 - Poor performance due to health of provider
 - Malicious harm
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- ### Provider performance
- Gap in knowledge or skills
 - Violation/departure from policy/protocol
 - Poor performance due to health of provider
 - Malicious harm


 - Do any of these explain the event?
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The Spectrum of Error: Case #2

- 56 year old man
- s/p massive heart attack
- Shock
- Left-Ventricular Assist Device
- Listed for Transplant



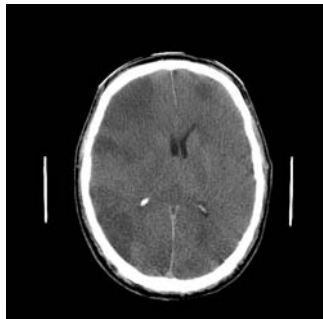
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The Spectrum of Error: Case #2

- > 3 months waiting in-hospital
- Donor heart became available
- Transplant performed by 2 staff surgeons
- Transplanted heart functioning normally

...but he patient did not wake up

Postoperative head CT scan



Preventable Death?

- Complex case
- Sick patient
- But was it preventable?

Case # 2 cont.

- What happened?
 - Massive air embolus
 - Multiple individuals thought an error was occurring
 - Nobody spoke up



Disclose What?

- Air Embolus?
- Air from the VAD (technical error)
- Failure to crossclamp the aorta early (procedural error)
- Command to pump the VAD (Cognitive Error...or is it technical...does it matter?)
- Failure to speak-up
- Blameworthiness?
- What is "fixable" – checklists? Mindfulness?

Understanding the Cause ...so we can prevent it

- Systems Error?
- Provider Error?
 - Gap in knowledge or skills
 - Violation/departure from policy/protocol
 - Poor performance due to health of provider
 - Malicious harm
- Or Human Nature?

Understanding Errors in Complex Environments



B17 – “too much plane for one man to fly”

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Origins of Human Factors

WWII... emphasis on
“*designing the human
to fit the machine*” ...
selection and training
(person-centered)



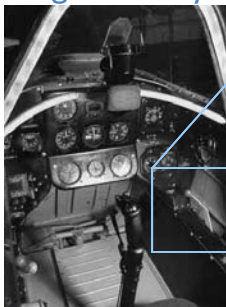
but planes kept
crashing...



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Human Factors

Cognitive Psychology + Engineering



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Physicians Resist the Aviation Analogy



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The Analogy is Pilot and Surgeon



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Medicine is Complex



“Normal Errors” are inevitable in complex environments

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From Cause and Effect to Chaos

PHILOSOPHIÆ NATURALIS PRINCIPIA MATHEMATICA

THE END of CERTAINTY

ILYA PRIGOGINE

And humans make errors

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"Swiss Cheese" Model of Error

Organizational influences

Supervisory factors

Preconditions

Errors

Failed or absent defenses

Adverse event

HFACS Wiegmann & Shappell
Adapted from Reason, 1990

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The Spectrum: Case #3

- 40 year old father of 2
- s/p XRT and chemo for Hodgkins at age 11
- s/p chemo for recurrent Hodgkins at age 32
- s/p 8/06
 - CABG x 2
 - AVR with patch closure of calcified ascending aorta
 - MVR
 - anterior pericardiectomy
- Struggled out of hospital with CHF

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Case #3 cont.

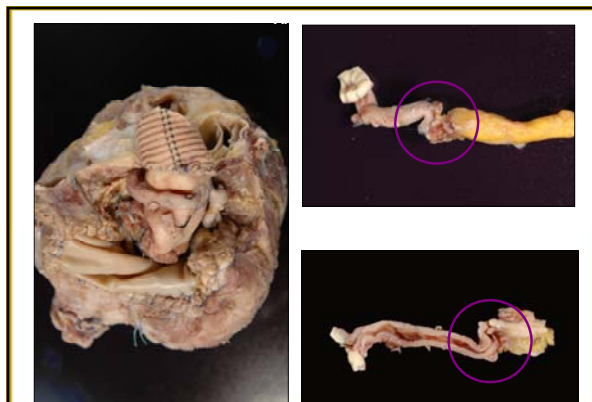
- Admitted 4 months later with endocarditis
- Sunday afternoon ECHO – AR progressing
- Emergent
 - Repeat sternotomy
 - Double valve replacement
 - Pericardial patch reconstruction of mitral annulus, LVOT
 - Aortic homograft
 - Cabrol coronary reconstruction (SV)
 - Graft replacement of ascending aorta

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Case #3 cont.

- 2:00 AM
- Weaned from bypass without difficulty
- Protamine administered
- Decannulated
- Progressive RV dysfunction, then biventricular dysfunction
- RVAD
- Death

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What Went Wrong?

- Technical Error?
- Cognitive Error?
 - Note: I administer the boards!
- Fatigue?
- “Time of Day”?
- What can be done to fix the problem?

Questions I struggle with...

- How to recognize vulnerability to making an error
 - not procedures and protocols
 - Cannot anticipate all potential errors
 - Cannot get the work done!
- How to optimize error capture
- How to optimize error recovery

Error Management

- Prevention
 - e.g. checklists
- Capture
 - Teamwork/
Communication
- Recovery
 - Traditional focus



Our Culture



- “Collaboration” in Medical School is called...
cheating
- The day after graduation it is “*teamwork*”

In The School of Hard Knocks



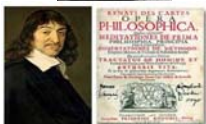
- The ABC’s:
 - Assess
 - Blame
 - Criticize
- Individual Responsibility
- “It is good to be loved but better to be feared”

Western Attitude Toward Errors



- Deeply rooted in Western culture
- Human suffering due to human fault and human choice
- Free Will
- Original Sin

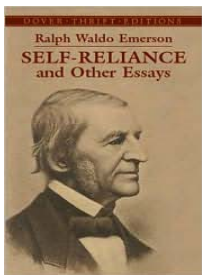
Western Attitude Toward Errors



- Power of Individualism
- Failures are Deviant
- We have control... therefore errors can be corrected/prevented
- *May be wrong, but better wrong than afraid*

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Teamwork or Individuality?



- *Insist on yourself; never imitate. Your own gift you can present every moment with the cumulative force of a whole life's cultivation; but of the adopted talent of another you have only an extemporaneous half possession. That which each can do best, none but his Maker can teach him.*

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Teamwork or Individuality?



- *I shall be telling this with a sigh
Somewhere ages and ages hence:
Two roads diverged in a wood, and I—
I took the one less traveled by,
And that has made all the difference*

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Personal Responsibility



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Alex cartoon
Picture galleries

Friendly fire death 'unlawful and criminal'

By Stewart Payne
Last updated: 4:04pm GMT 16/02/2007

- Video: Widow's reaction | MoD statement in full
- Video: The cockpit footage that the US tried to suppress
- Transcript of the 'friendly fire' video

The killing of a British soldier when American warplanes opened fire on his convoy in Iraq was unlawful and an act of criminality, a coroner ruled today.

At the end of a lengthy and controversial inquest into the death of Lance Corporal of Horse Matty Hull, 25, Andrew Walker, the assistant deputy coroner for Oxfordshire said: "I don't think this was a case of honest mistake."

"I find there was no lawful authority to fire on the convoy. The attack on the convoy therefore amounted to an assault. It was unlawful because there was no lawful reason for it and in that respect it was criminal."

LCpl Hull's widow, Susan, 30, burst into tears as the coroner delivered his verdict.

Afterwards she said it was the right verdict and demonstrated that her husband's death was "entirely avoidable".



LCpl Hull in military uniform, shot at despite clear markings

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Are We Really Ready For "Systems Thinking"?

Afterwards she said it was the right verdict and demonstrated that her husband's death was "entirely avoidable".

Mr Walker said: "The pilots chose not to take steps to confirm the identity of the vehicles in the convoy." Such steps could easily have been taken, he said.

"The pilot chose to interpret the orange panels as (Iraqi) rockets without taking steps to identify the vehicles as friendly."

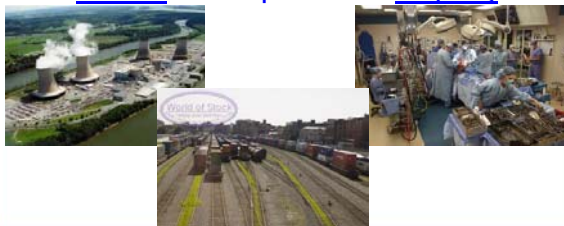
The pilots, a major and a lieutenant colonel of the 190th Fighter Squadron, the Idaho Air National Guard, who had no combat experience, said they could see orange panels on top of the vehicles but convinced themselves they were enemy rocket launchers.

Referring to the pilots she said: "I hope that they are at peace in themselves and that they can move on with their lives. I'm sure they are full of remorse for what they did, I hope so, anyway."

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High Consequence Industries and High Reliability Organizations (HRO)

HRO: An organization that consistently avoids catastrophes in an environment where normal accidents can be expected due to complexity



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High Reliability Organizations

- High consequence – must **function reliably**
- **Expect the unexpected** to occur
- Organized to better **recognize** the unexpected
- Mindfully **manage** the unexpected
- Focus is on **containing** the unexpected

- *This is **Resilience***

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High Reliability Organizations

- **Characterized by**
Mindfulness

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Detection Phase is Increased by Interaction

- Interaction among individuals with diverse expectations increases mindfulness by decreasing simplification
- Weick and Sutcliffe

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Pre-Procedure Briefing

- Long utilized in aviation and military combat units to reduce errors and improve teamwork.
- In surgery briefings have been shown to reduce nurse turnover and increase employee satisfaction. (DeFontes, 2003)



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OR Preoperative Briefing Trial Version 1

1. RESIDENT (Surgeon) History <ul style="list-style-type: none"> • Diagnosis • Planned Procedure • Significant past history <ul style="list-style-type: none"> ◦ Low EF ◦ Rads <ul style="list-style-type: none"> • CABG • Valve ◦ Previous vein stripping • Allergies 	4. PROFESSIONIST <ul style="list-style-type: none"> • Perfusion Pressure • Perfusion Temperature • Cannula Size • Circulatory Arrest <ul style="list-style-type: none"> ◦ Cool down temperature
2. SURGEON (Resident) <ul style="list-style-type: none"> • Circulation <ul style="list-style-type: none"> ◦ Arterial Cannula <ul style="list-style-type: none"> • Placement <ul style="list-style-type: none"> • Aortic • Ascending • Axillary • Femoral ◦ Venous Cannula <ul style="list-style-type: none"> • Placement • Type <ul style="list-style-type: none"> • Bi-caval • Two stage 	5. SURGICAL TECH <ul style="list-style-type: none"> • Suture • Instrumentation
3. SURGICAL ASSISTANT <ul style="list-style-type: none"> • Length of Vein • Positioning (if Atypical) • Prep (if Atypical) 	6. RN <ul style="list-style-type: none"> • Valve type • Orals • Patch • Special Precautions • Concerns
	7. ANESTHESIA/CRNA <ul style="list-style-type: none"> • Line Placement <ul style="list-style-type: none"> ◦ Arterial Line <ul style="list-style-type: none"> • Right • Left • Femoral • Radial • Antifibrolytics <ul style="list-style-type: none"> ◦ Aprotinin ◦ Tranexamic Acid • OR list management plan for the day
	8. OTHER CONCERNS- UNIQUE TO THIS CASE

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Obstacles

- Tacit assumptions regarding leadership
 - Background
 - Role models
 - Education
- Practical issues regarding
 - Start times
 - Shift changes
 - Multiple cases
- Challenges in evaluating the impact
 - Endpoints
 - Control groups

Teamwork

- “The **best interest of the patient** is the only interest to be considered, and in order that the sick may have the benefit of advancing knowledge, **union of forces** is necessary....It has become necessary to develop medicine as **a cooperative science.**”
- Will Mayo 1910




Disclosure...What and When?

- Adverse events or errors?
 - Does this pertain to all deaths?
 - “unexpected” deaths?
 - Low risk/high risk patients?
 - Preventable deaths?
- Do we disclose all errors?
- “Near Misses”?
- What about multiple errors? (the rule)

What Families Want

- Acknowledgment that something has happened
- **The facts**
- What is to happen to care for the individual harmed
- Expression of care, concern and regret
- **Assurances that corrective measures are being undertaken to prevent it from happening to others**

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