



The Heart of Great Medicine

***Healthcare Compliance issues from
Administration to Point of care***

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To Do No Harm

Objectives

- The participant will:
 - Understand the ***standards of practice*** designed to assist clinician in providing safe effective patient care
 - List ***important behaviors*** that will assist the inpatient clinician to remain in compliance with current legal requirements
 - List potential legal and ethical consequences of professional negligence

Standards of Practice...

Understand the standards of practice designed to assist clinician in providing safe effective patient care

- Regulatory Agencies
- Policy and Procedure
- Professional Organizations
- State Board of Nursing – Credentialing Body

Congress Focuses on Safety

- Congress commissioned the Institute of Medicine to do a study on healthcare



- Dr. Lucian Leape, with Harvard School of Public Health was the lead investigator



INSTITUTE OF MEDICINE
OF THE NATIONAL ACADEMIES



HARVARD
School of Public Health

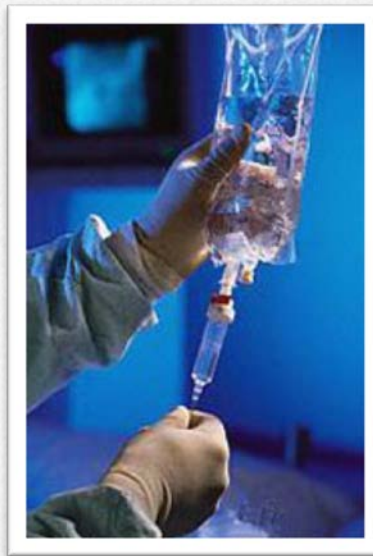


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To Err is Human



The risk of death
on a domestic
flights = 1 in
8,000,000 flights



Adverse Event in a Hospital =
1 in every 27 - 34 Admits



Death in
Hospitals from
Medical Errors =
1 in every 343 -
764 Admits

The Cost of Medical Mistakes

- The fiscal impact is astounding¹
 - 18 types of medical errors account for 2.4 million extra hospital days
 - \$9.3 billion in excess charges

¹The Journal of American Medical Association (JAMA), *Excess Length of Stay, Charges, Mortality Attributable to Medical Injuries During Hospitalization*, 2003

To Err is Human

The number of deaths from medical error each year were comparable to more than one jumbo jet crashing every single day of the year killing every passenger on board



Where Are We Now?

“Unfortunately, I do not think we can honestly say that health care is now appreciably safer than it was 10 years ago.”

“I think we’re a little bit safer than we were back then. The data are not very good to help us answer the question. I remember in the original report, the analogy was made that the equivalent of a jumbo jet going down every day was how many people died of medical mistakes. We’re probably down to a Boeing 727. That represents progress. That’s a lot of lives saved from what we’ve done, but it’s still completely unacceptable.”

- *Lucian Leape, M.D. Interview, 2009*



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Joint Commission Standards

- Consist of a set of rules we must follow to maintain our accreditation and are a basis of an objective evaluation process that can help measure, assess, and improve performance
- **These rules ensure we practice safe care for our patients and have high quality outcomes**
- The National Patient Safety Goals are standards that are mandatory without exception to maintain patient safety

National Patient Safety Goals

- Goal 1 – Improve the accuracy of patient identification.
- Goal 2 – Improve the effectiveness of communication among caregivers.
- Goal 3 – Improve the safety of using medications.
- Goal 6 – **New Jan 2014** – Improve the safety of clinical alarm systems
- Goal 7 – Reduce the risk of health care–associated infections.
- Goal 8 – Accurately and completely reconcile medications across the continuum of care.
- Goal 9 – Reduce the risk of patient harm resulting from falls.
- Goal 14 – Prevent health care–associated pressure ulcers
- Goal 15 – The organization identifies safety risks inherent in its patient population.

Improving Patient identification accuracy:

- 2 identifiers:
 - Name/DOB
 - Room number?



If not: hard stop! No procedure/no test/ no care

Communication With Caregivers:

- ***Handoffs:***

- Communication between shifts
- Between disciplines
- Bringing a patient back from a test:
 - They have arrived back on the floor
 - No problems
 - No requests: Did they request pain medication?
 - Did they have any problems?
 - Where did you put them? In the chair/back in the bed?
 - Did you leave all of their necessary items close at hand?



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Time out process:

- Any procedure: in OR at bedside requires time out
 - Everyone must participate
 - Everything must stop
 - Must be done prior to the procedure beginning
 - **Consent:**
 - Must be obtained for both the procedure and the sedation PRIOR to the procedure
 - By the individual performing the procedure

Informed Consent Policy:

Title : Informed **Consent**

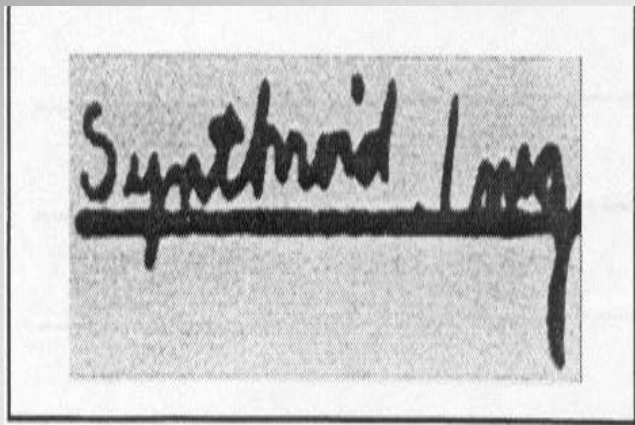
Policy Number : 1233

- A. Informed **consent** for operative, invasive, noninvasive procedures that place the patient at risk, anesthesia, and planned blood administration are obtained by the physicians. Nursing staff may have **consent** forms signed after informed **consent** is obtained. **Consent** forms must be obtained prior to the operative procedure. These are valid during the entire hospital stay. Each subsequent operative, invasive, noninvasive procedure that place the patient at risk and/or anesthesia (even during same period of hospitalization) must have a separate **consent** form for operative procedure.
- B. The physician performing the procedure will inform the patient of the procedure, alternative procedures and risks of each procedure. The physician should document this discussion in detail and sign operative permit.

“Do Not Use Abbreviations”

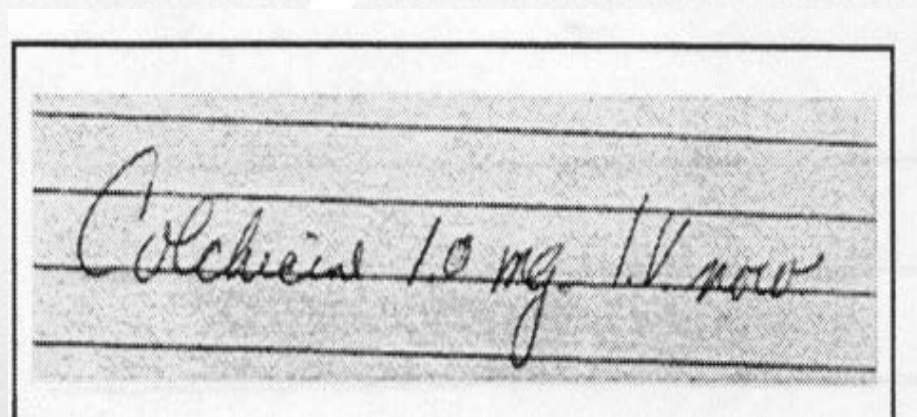
- u, iu
- qd, qod, d
- Must have leading zero (0.5)
- Never have trailing zero (5.0)
- MS, MSO4, MgSO4
- μ , g

Do not use naked decimals (.1mg) or trailing zeros (1.0 mg).



Synthroid 1mg

A rectangular box containing a handwritten prescription. The text "Synthroid 1mg" is written in black ink on a light-colored background. A thick horizontal line is drawn under the word "Synthroid".



Colchicine 10 mg IV now

A rectangular box containing a handwritten prescription on lined paper. The text "Colchicine 10 mg IV now" is written in black ink across three lines.

Labeling of medications/solutions:

- Any time of solution poured into another container – must be labeled!
- Any syringe drawn up must be labeled immediately unless it is going directly to the patient
- Single unit vials – cannot use one vial for multiple patients
- Example: cleaning solution on crash cart

Improve the safety of clinical alarm systems

- Phase 1 – Hospitals will be required to establish alarms as an organization priority and identify the most important alarms to manage based on their internal situation
- Phase 2 (beginning January 1, 2016) – Hospitals will be required to develop and implement specific components of policies and procedures. Education of those in the organization about alarm system management
- Example: patient dies from lack of response to an alarm

Reduce the risk of healthcare associated infections

- Hand washing: in and out of a patient's room
- Hand Foam vs. soap and water
- Isolation rooms?

Communication: Verbal Orders

- Write it Down: Read it Back
- Verbal Orders
- High risk behavior!
- High opportunity for error
- Risk for patient and caregiver
- Emergencies only
- Name and Date of Birth
- Written: exactly and read back PRIOR to hanging up the phone
- Drug, concentration, dosage, route – no assumptions

Fall Prevention: National Patient Safety Goal

Why A Patient Is At Risk Of A Fall?

- Medical Condition (Arthritis, Diabetes, Incontinence, Parkinson's Disease, Cardiovascular Disease)
- **Medications** (Pain Meds, Blood Pressure Meds, Diuretics)
- Physical Condition (muscle weakness, poor balance or gait, use of assistive devices)
- Mental Status (Confusion, Dementia, Memory Loss)
- Behavior (fear of falling, takes small steps, moves slowly, refuses to ask for help)
- Age (Over 65 years old)
- Environmental Conditions (IV poles, clutter, not enough space)



Standards:

- **Know the standards**
 - Regulatory
 - Professional organization
- **Teach students to refer to organizational policy and procedure** – not “just” their textbook (need both)
- **Examples:**
 - Armband: patient’s family request
 - Assignments by room number
 - How do we hardwire the handoff?
 - The nurse told me.... Vs. CHECK the MD order

Objective 2: Behaviors

List *important behaviors* that will assist the inpatient clinician to remain in compliance with current legal requirements

- Culture of Safety
- Near Miss Reporting
- Evidence Based Medicine/Core Measures
- Process Improvement Focus: LEAN
- Use of safety devices and technology
- Documentation

How Do We Protect Our Patients?

- Eliminate Risky Behaviors
- Revise an Environment of Risk
- Call a Stop for Safety
- No Tolerance for Disruptive Behavior
- Grow a Culture of Safety

According to The Joint commission:

A safety culture is:

- Expressed in the beliefs, attitudes and values of an organization's employees regarding the pursuit of safety
- Present in the organization's structure, practices, controls and policies
- Characterized by a continual drive toward the goal of maximal attainable safety
- Rooted in the **processes and in the structure**, rather than in the behavior of the individual

Ask yourself:

***How might the next patient be harmed?
Continually Seek Potential Failure Points***

Quality and Safety Hotline

- 931-7722 (QSCC)



Occurrence Reporting...

When in doubt... fill it out!

- *Using the Occurrence system to identify actual and **potential patient safety concerns** and to CHASE ZERO*
- *Training staff to “see” potential problems*
- *Focus on Near Miss!*
- *Look what “almost” happened*

Chasing

WINNING THE WAR ON HEALTHCARE HARM

Zero

Incorporate evidence-based medicine

Patient care that research has shown to result in better outcomes for patients, such as lower:

- Mortality and morbidity
- Disability
- Length of stay
- Readmissions



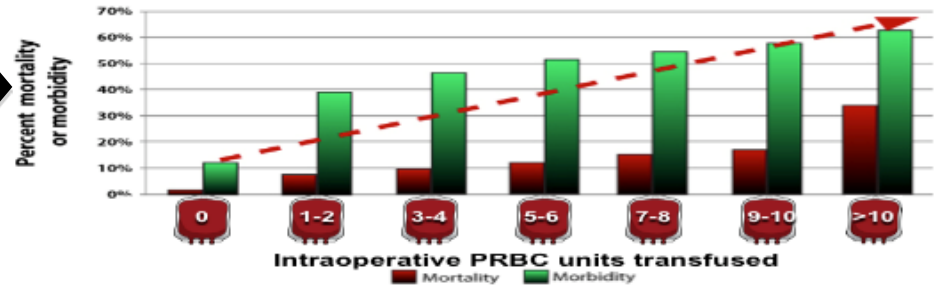
Why give 2, when 1 will do?

Complications associated with transfusions are dose-dependent

LESS
is
MORE

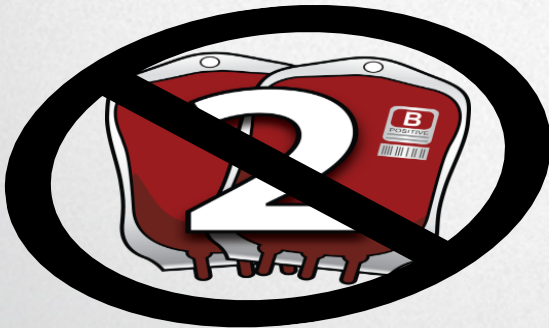


Impact of Blood Transfusion on Surgical Outcomes:
NSQIP Database

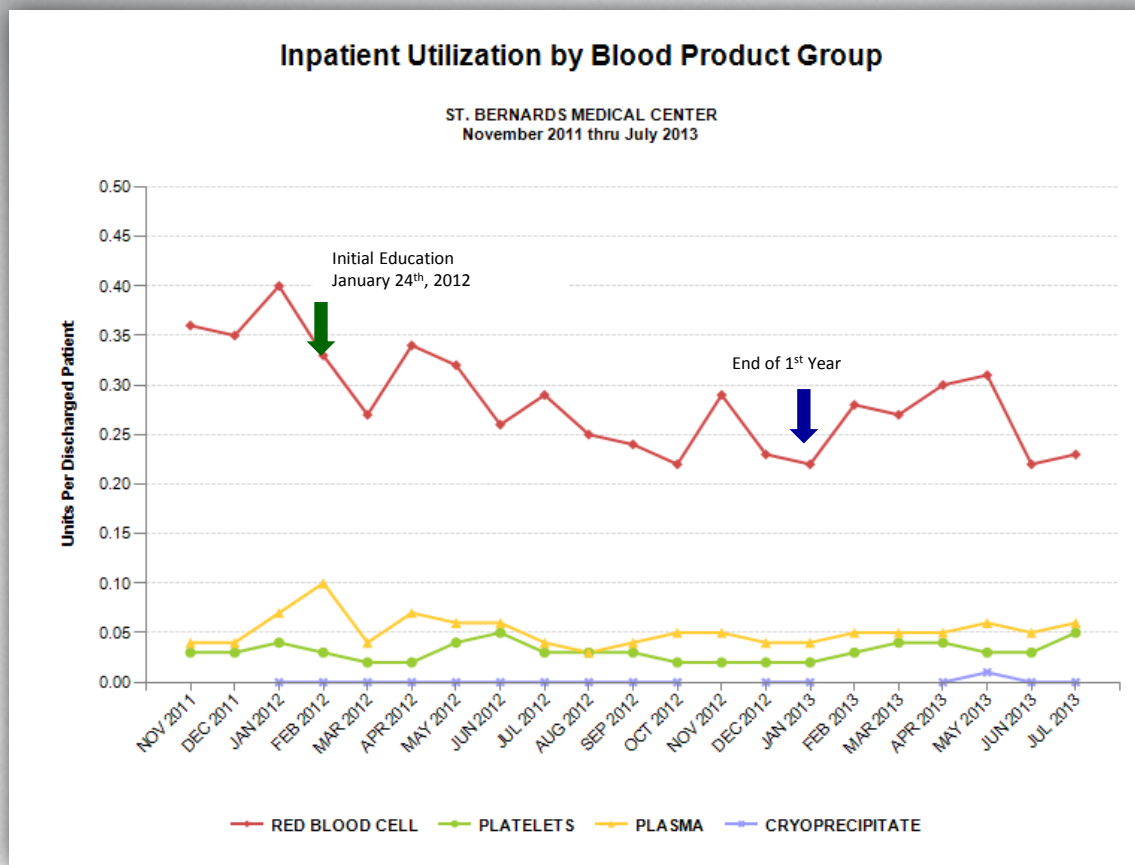


Recent studies associate blood transfusions with an increased risk of renal injury, lung injury, surgical site infection, sepsis and even mortality.^{1,2}

1. Koch, et al, CritCareMed 2006; 34(6)
2. Ferraris et al, Arch Surg. 2012;147(1)
3. Napolitano et al, CritCareMed 2009;37(12)



BLOOD PRODUCT UTILIZATION



28% reduction in Red Blood Cells (3,552 units)*

32% reduction in Platelets (476 units)*

19% reduction in Plasma (343 units)*

19% reduction in Cryoprecipitate (13 pools)*

**Includes reductions in outpatient volume*

Know: core measures

The percentage of eligible patients that receive care represented by the measure.

Example: Percentage of AMI patients that receive aspirin on arrival.

Proved Best Practice

Core Measure example: Acute Myocardial Infarction

Acute Myocardial Infarction	FYTD2014	Oct	Nov
Aspirin on Arrival	96.5	100.0	93.1
Statin Prescribed at Discharge	100.0	100.0	100.0
Aspirin on Discharge	100.0	100.0	100.0
ACEI or ARB for LVSD	100.0	100.0	100.0
Beta Blocker at Discharge	100.0	100.0	100.0
PCI within 90 Minutes of Arrival	100.0	100.0	100.0

Top 10%	Nat. Ave.	State
NA	NA	NA
100.0	98.00	97.0
100.0	99.00	99.0
NA	NA	NA
NA	NA	NA
100.0	95.00	94.0



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FOCUS ON **P**ROCESS

IMPROVEMENT: LEAN

Lean Defined

Results

Create Value For Customers

Measure What Matters
Align Behaviors With Performance
Identify Cause and Effect Relationships

Create Constancy Of Purpose
Think Systemically

Enterprise Alignment

See Reality
Focus On Long Term
Align Systems
Align Strategy
Standardize Daily Management

Focus On Processes
Embrace Scientific Thinking
Flow & Pull Value
Assure Quality At The Source
Seek Perfection

Continuous Process Improvement

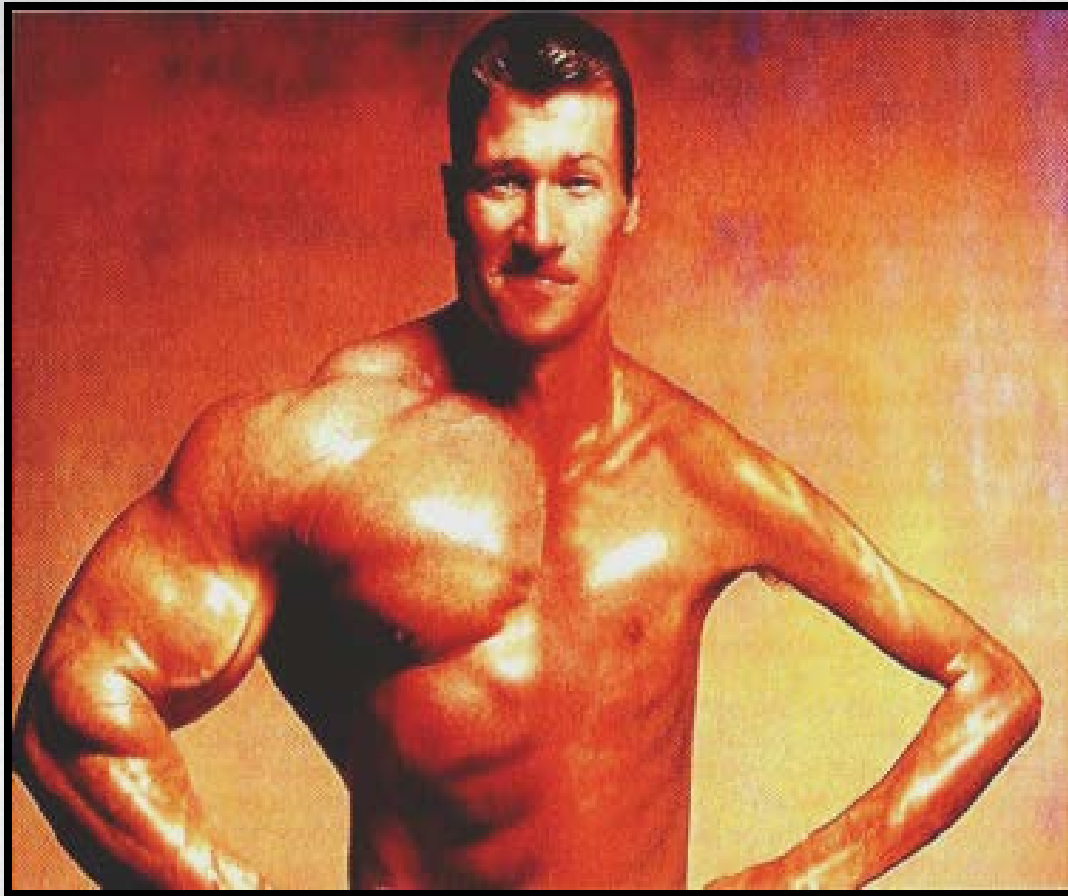
Stabilize Processes
Rely On Facts & Data
Standardize Processes
Insist On Direct Observation
Focus On Value Stream
Keep It Simple & Visual
Identify & Eliminate Waste

Lead With Humility
Respect Every Individual

Cultural Enablers

Assure A Safe Environment
Develop People
Empower & Involve Everyone

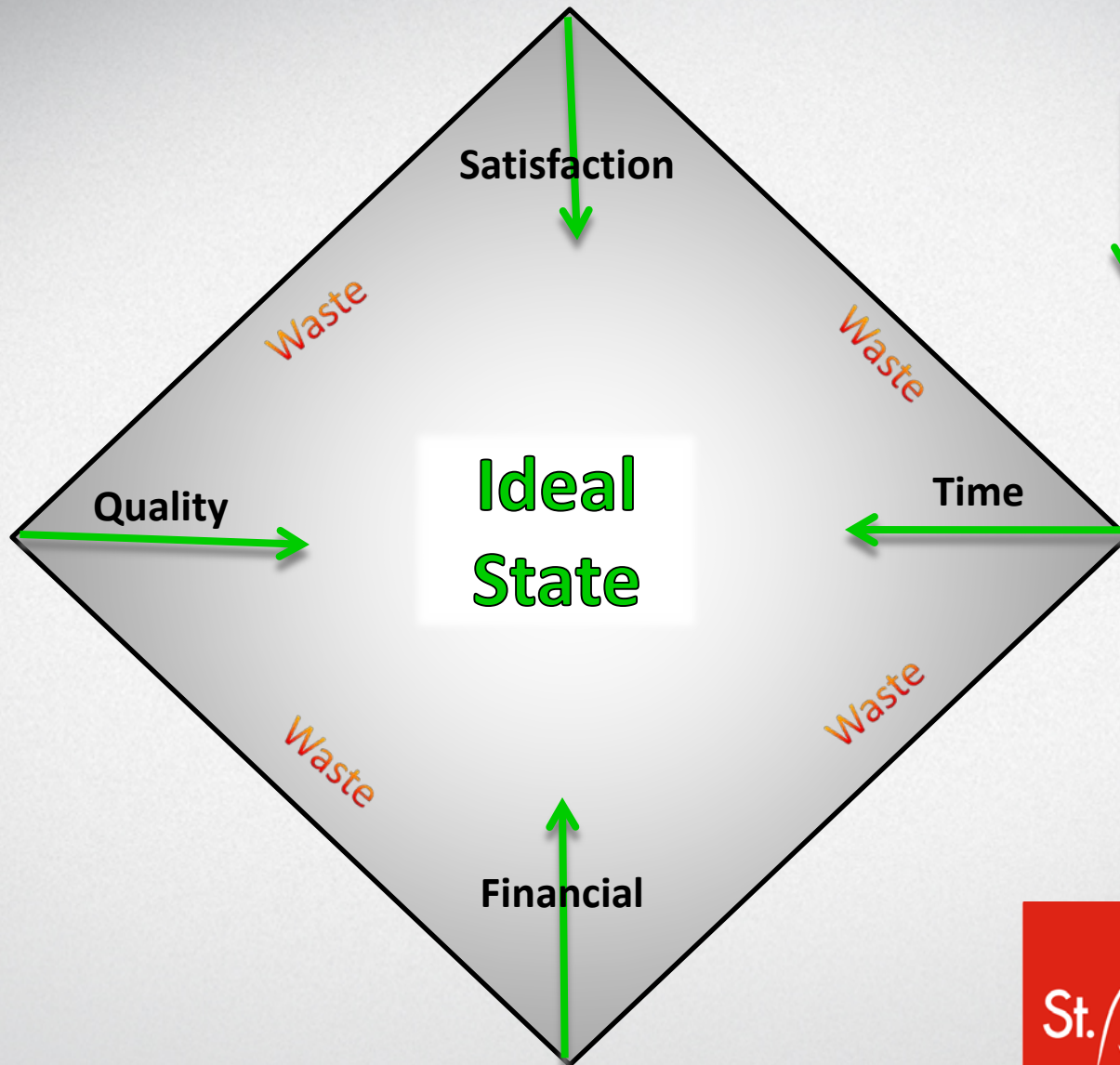
Current State of Healthcare Organizations



Technology

Processes &
Delivery
System

Value Diamond (Focus: Elimination of Waste)



Eliminating Waste
improves all metrics.
No trade-off thinking.

Before Lean



- Unorganized work areas
- Process flow not obvious
- Time wasted looking for things
- Hoarding of supplies

- Poor utilization of space
- General clutter
- Supply shortages and “hidden” inventories

After Lean



USE TECHNOLOGY



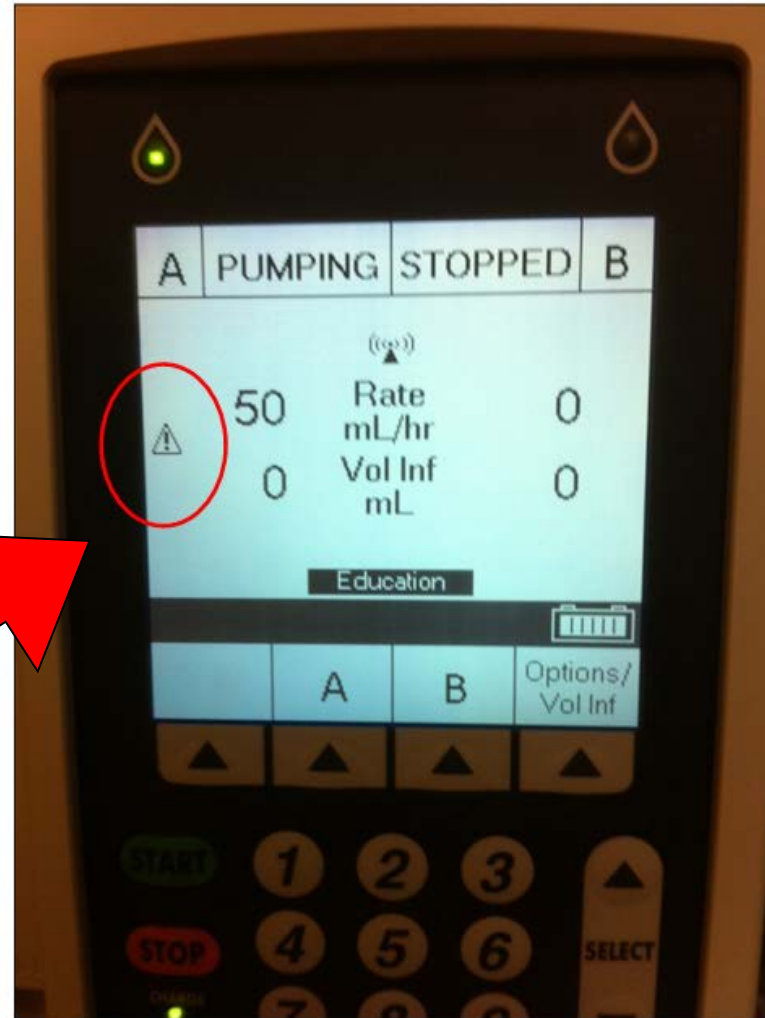
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Smart Pump

Remember to select medications from the drug library.

The yield sign means that Line A was programmed to run, without choosing a med from the drug library.



Barcode scanning



DOCUMENTATION



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Documentation: New Challenges:

Same Truth....



**Meani
ngful
Use**

**If you didn't
document it...
you didn't do
it!**

**Art/Science
of
documentation**

**Audit
Trails**

**Realtime
documentation:
vs. notes on a
napkin**

Operational Excellence

Quality

Safety

Customer service

Cost

People

Together we will: Chase Zero!



LEGAL & ETHICAL CONSEQUENCES OF PROFESSIONAL NEGLIGENCE



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Health Care Malpractice

- Legal Actions
 - Patients cannot successfully sue health care providers (HCPs) simply because they experience “bad” outcomes
 - Legal bases of health care malpractice liability are:
 - Professional negligence
 - Intentional misconduct
 - Breach of contract
 - Strict product liability for injury from providing dangerously defective products
 - Strict liability incident for abnormally dangerous activities

Health-care facilities & HCPs may be named as malpractice defendants



Professional Negligence

The vast majority of health care malpractice claims & lawsuits are grounded exclusively in the allegations of professional negligence or substandard care.

A patient-plaintiff in a professional negligence health care malpractice legal action must prove four elements by a preponderance of evidence.

Professional Negligence Elements of Proof

- The HCP owed the patient a legal duty of care.
- The HCP violated or breached the duty owed in some way.
- The breach of duty caused injury to the patient.
- The patient sustained the kinds of losses for which a court may award compensation in the form of monetary “damages”.

Intentional Misconduct

Cases alleging intentional misconduct are frequently highlighted by the media & include such claims as battery (inappropriate touching of a patient without patient consent) & invasion of privacy.

The intentional wrong publicizing of private information about a patient (invasion of privacy) also constitutes an ethics violation.

Consequences of Intentional Misconduct

- Civil Court
 - Malpractice
- Criminal Court
 - Felonious misconduct
- Administrative hearing
 - Adverse licensure or certification action



HIPAA & PATIENT CONFIDENTIALITY

- A major purpose of the HIPAA Privacy Rule is to define & limit the circumstances in which an individual's protected health information (PHI) may be used or disclosed by covered entities.
- Treatment, payment & health care operations exceptions

Knock Knock!
~Who's there?
HIPAA!
~HIPAA Who?

I can't tell you
THAT!



ROTTENeCARDS

Maintaining HIPAA Compliance



Areas of Concern

- Information Technology - computer systems, electronic health records, cell phones, fax machines, email
- Physical Security of PHI
- Loose Talk
- Social Media
- Snooping

St. Vincent Medical Center

SHOPTALK

Three Sentenced for Privacy Violations in Pressly Case

By Andrew Gauthier on October 27, 2009 12:00 AM

Arkansas News



A federal judge sentenced a doctor and two former hospital employees to a year's probation each today after they admitted to violating federal privacy laws by looking at the medical records of slain TV reporter **Anne Pressly**.

Dr. **Jay Holland** of Little Rock also was fined \$5,000 and ordered to perform 50 hours of community service educating professionals on the importance of patient privacy under the

federal [Health Insurance Portability and Accountability Act](#), also known as HIPAA.

Sarah Elizabeth Miller of England, a former account representative at the St. Vincent Medical Center in Sherwood, was fined \$2,500 and **Candida Griffin**, a former emergency room unit coordinator at St. Vincents main hospital in Little Rock, was fined \$1,500.

The three pleaded guilty in July to misdemeanor violations of the health information privacy

U.S. Department of Justice



U.S. Department of Justice

United States Attorney
Eastern District of Arkansas

FOR IMMEDIATE RELEASE
July 20, 2009

CONTACT: Jane Duke
United States Attorney
501-340-2600

DOCTOR AND TWO FORMER HOSPITAL EMPLOYEES PLEAD GUILTY TO HIPAA VIOLATION

Little Rock – Jane W. Duke, United States Attorney for the Eastern District of Arkansas, along with Thomas J. Browne, Special-Agent-in-Charge of the Little Rock Division of the Federal Bureau of Investigation, announced today the guilty pleas of Dr. Jay Holland, age 56, of Little Rock, Arkansas; Sarah Elizabeth Miller, age 28, of England Arkansas; and Candida Griffin, age 34 of Little Rock, Arkansas. Each pled to a misdemeanor violation of the health information privacy provisions of the Health Insurance Portability and Accountability Act (HIPAA) based on their accessing a patient's record without any legitimate purpose. The pleas were accepted by United States Magistrate Judge Henry L. Jones, Jr.

Dr. Holland, Medical Director of Select Specialty Hospital, located on the 6th floor of the St. Vincent Infirmary Medical Center (SVIMC), admitted that after watching news reports on television, he logged on to the SVIMC patient records from his computer at home and accessed a



U.S. Department of Justice

United States Attorney
Eastern District of Arkansas

FOR IMMEDIATE RELEASE
October 26, 2009

CONTACT: Jane Duke
United States Attorney
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Holland, Miller, and Griffin pleaded guilty on July 20, 2009 to misdemeanor violations of the health information privacy provisions of the Health Insurance Portability and Accountability Act (HIPAA) based on their accessing a patient's records without any legitimate purpose.

“The HIPAA privacy protections are real, and we hope that through vigorous enforcement of HIPAA’s right-to-privacy provisions and swift prosecution of those who violate HIPAA, we can deter those in the medical industry who have access to protected health information from searching others’ medical records merely to satisfy their own curiosity.”

Jane Duke

United States Attorney

7/20/2009

Following HIPAA regulations is not only the law, it is also the right thing to do for patients as it supports the trusting relationships that are essential to providing quality care.

Legal & ethical behavior is essential for every health care organization & health care provider.

ST. BERNARDS

