A Systems Approach to Analyzing and Preventing Hospital Adverse Events

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A Brief History of Accident Investigation and Patient Safety

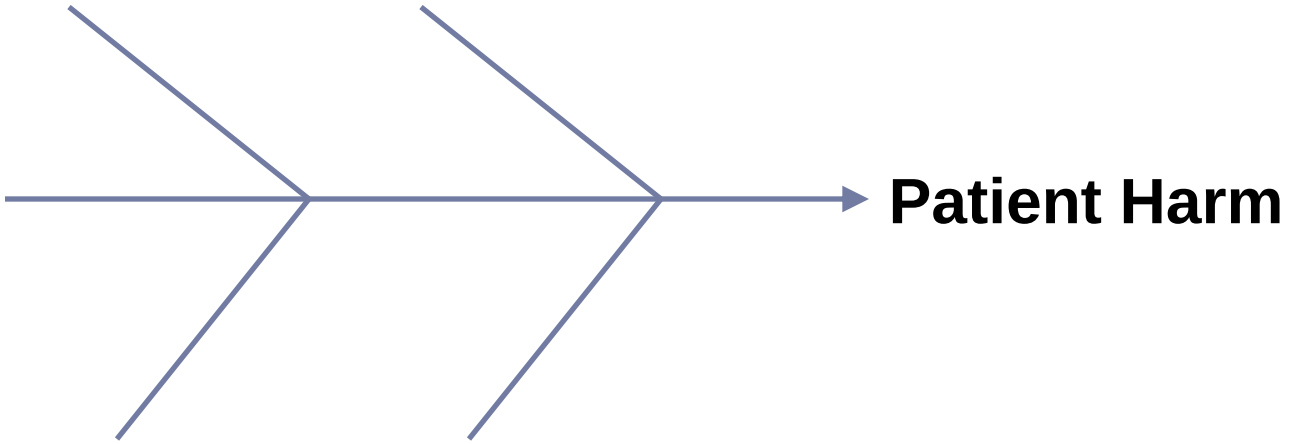
- Hospitals are dangerous places
  - IOM report in 1999 said the US health system kills **49,000 – 98,000** patients per year (Kohn, 1999)
  - Revised predictions now say the number is actually **210,000-400,000 per year** in the US alone (James, 2013)
- Before 1990s, accidents were considered to be the fault of the clinician and were a major source of shame
- In the 1990s, healthcare adopted the idea of a Root Cause Analysis (RCA) from system engineering
  - Joint Commission required hospitals to perform RCAs on accidents as part of their accreditation starting in **1997**

So how does a hospital do an RCA?

- Incredibly heterogeneous in methodology and quality
  - 7 regions in England: 2 "exemplary", 3 "less rigor", 2 "scant evidence of … RCAs" (Wallace, 2006)
  - Anecdotally, many hospitals focus on uncovering the "most fundamental" cause of the accident (Wu, 2008)
    - Even the name "Root Cause Analysis" pushes people to think they must find one root cause
  - No one accepted methodology across the industry

Common RCA Methodologies

- Fishbone Diagramming



- 5 Whys?
  - Typical guidance offered is to keep asking why until you get to the root cause or have asked it at least five times
- VA RCA Process

VA RCA Process

- Event, environment, human factors
  - Uses guided questions to bring analysts to an understanding of the accident (*VA RCA Tools*, 2015)
- Pros:
  - Stresses system failures, not human failures
  - Promotes the idea of changing the system to prevent future accidents
- Cons:
  - Based on linear chain of event causality models
  - Promotes adding barriers and complexity instead of adding feedback and clarity
  - No common system model to promote a common mental model amongst analysts

Are we safer because of these RCAs?

- Safety comes from learning from accidents fully and making changes to the system
  - 68.1% of RCAs for suicide attempts at the VA had full implementation of their recommendations (Mills, 2006)
  - In a study of RCAs for falls at the VA, 64.1% of actions were fully implemented, while 20.9% had been partially implemented (Mills, 2005)
  - BUT… in both studies, the vast majority of recommendations were reeducation or policy changes

Big Picture

- Measuring safety in healthcare is hard, but common consensus is that we have not improved
  - Despite increased awareness and increased funding
- Wide-variability in how accidents are investigated and preventive measures are implemented
- No healthcare equivalent to the NTSB
  - Accidents are investigated locally and lessons stay local
    - Some organizations are trying to make national incident databases, but the information tends to be superficial at best
  - There is no team of safety experts – accidents are investigated by clinicians in their "spare" time

We believe that we can do better with STAMP and CAST

- Based on a systems theoretic view of accident causality
  - Allow us to identify more nuanced views of accident causes
  - Identify stronger system changes
  - Stronger understanding of how indirect actions, like managerial decisions, impact accidents
- Analysis is built around a system model
  - Analysts can have a shared mental model of the system and accident
  - There are insights to be gained simply by creating this model that a fishbone would miss

Project Goals and Objectives

- Analyzed 280 consecutive cardiac surgeries over 24 months
  - Identified 30 adverse events
- Use CAST to re-analyze these events retrospectively
  - Identify causal factors and potential solutions specific to the accident and local conditions
  - Identify common causal factors across a wide variety of accidents

Incident Overviews

Incident Category	Number (%)
Miscommunication during staff handoff throughout the procedure	4 (13.3)
Missing medication prior to incision	4 (13.3)
Missing instrumentation leading to intra-operative delay	8 (26.7)
Missing implants leading to delays and sub-optimal implants being used	3 (10.0)
Broken and/or improperly handled specialized instruments	9 (30.0)
Miscellaneous incidents	2 (13.3)

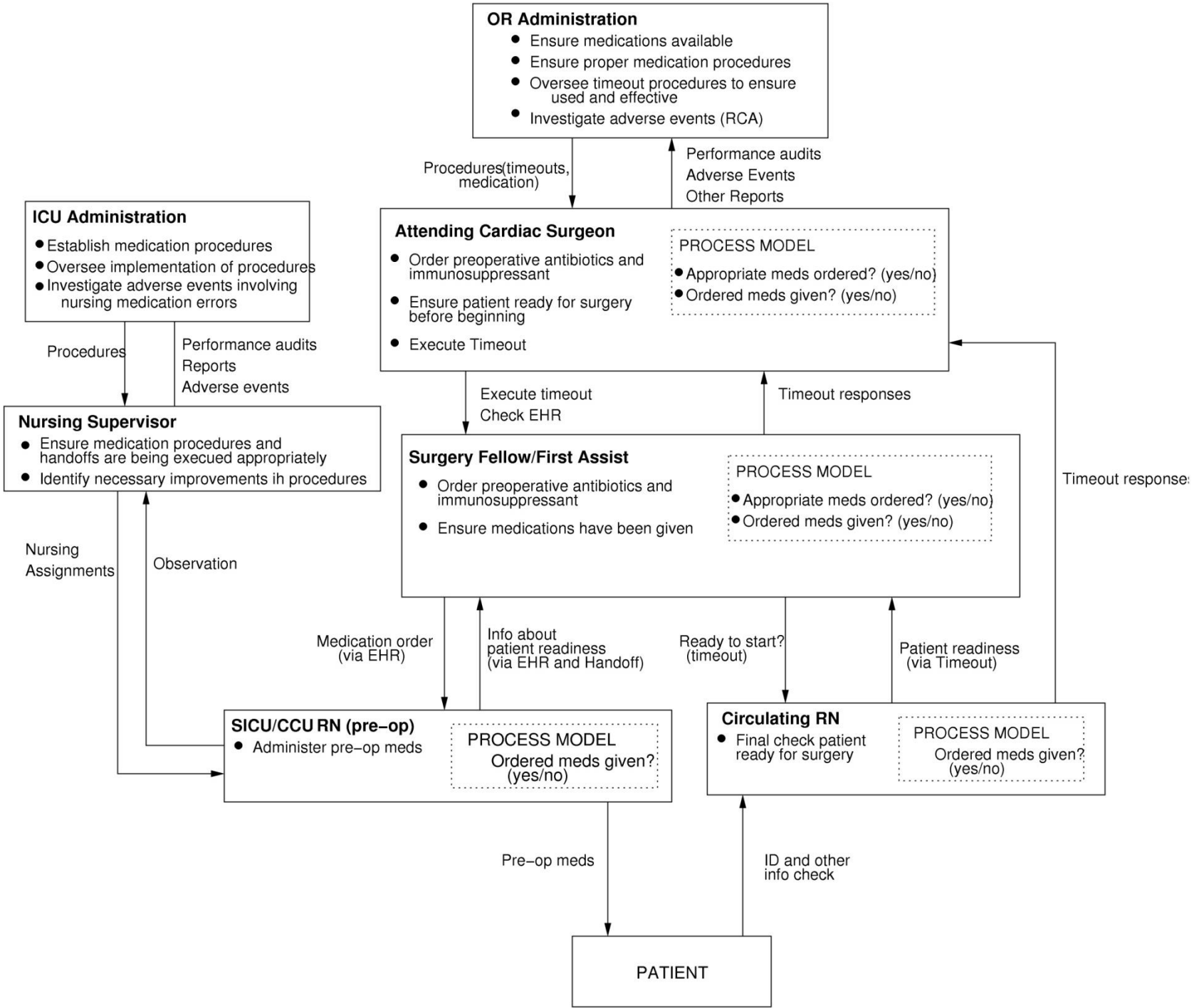
Incident Overviews

Patient Outcomes	Number (%)
Death	2 (7.7)
Prolonged Hospitalization	1 (3.8)
Prolonged "on-pump" time	3 (11.5)
Prolonged anesthetic (off-pump)	16 (61.5)
Aborted Procedure	2 (7.7)
No clinical or sub-clinical consequences	2 (7.7)

*Missing outcome data on 4 cases

Incident Summary

- 56 year old male patient
- History of heart failure treated with a *Left Ventricular Assist Device*
  - Implanted pump that assists the heart
- Donor heart becomes available and transplant is completed
  - Pre-operative time out completed
  - Textbook surgery with no intraoperative complications
- Within hours, heart function dropped
  - Within days, the patient died
- Retrospective chart analysis revealed that patient never received pre-operative immunosuppressive medications
  - This was discovered **several months** after the case


OR Administration
Ensure medications available
Ensure proper medication procedures
Oversee timeout procedures to ensure used and effective
Investigate adverse events (RCA)
Procedures(timeouts, medication)
Performance audits
Adverse Events
Other Reports
ICU Administration
Establish medication procedures
Oversee implementation of procedures
Investigate adverse events involving nursing medication errors
Attending Cardiac Surgeon
Order preoperative antibiotics and immunosuppressant
Ensure patient ready for surgery before beginning
Execute Timeout
PROCESS MODEL
Appropriate meds ordered? (yes/no)
Ordered meds given? (yes/no)
Procedures
Performance audits
Reports
Adverse events
Nursing Supervisor
Ensure medication procedures and handoffs are being execued appropriately
Identify necessary improvements ih procedures
Execute timeout
Check EHR
Timeout responses
Surgery Fellow/First Assist
Order preoperative antibiotics and immunosuppressant
Ensure medications have been given
PROCESS MODEL
Appropriate meds ordered? (yes/no)
Ordered meds given? (yes/no)
Timeout responses
Nursing Assignments
Observation
Medication order (via EHR)
Info about patient readiness (via EHR and Handoff)
Ready to start? (timeout)
Patient readiness (via Timeout)
SICU/CCU RN (pre-op)
Administer pre-op meds
PROCESS MODEL
Ordered meds given? (yes/no)
Circulating RN
Final check patient ready for surgery
PROCESS MODEL
Ordered meds given? (yes/no)
Pre-op meds
ID and other info check
PATIENT

Analysis of Controllers

- Safety Responsibilities
  - What are they responsible for doing to maintain a safe system
- Unsafe Control Action
  - What happened in this accident that in retrospect was unsafe?
  - We are not blaming the controller here! We are trying to understand the events that occurred
- Process Model Flaws
  - Why did the controller believe that the unsafe action was actually the correct action?
- Contextual Factors
  - Why was the controller's process model flawed?
  - What external factors drove the controller to make the wrong decision?

Analysis of Controllers – SICU RN

- Safety Responsibilities
  - Administer pre-operative medications
  - Report concerns about patient to the surgical team
- Unsafe Control Actions
  - Did not give pre-operative immunosuppression
  - Did not tell the surgical team that the patient had not received the medication
- Process Model Flaws
  - Not aware that they needed to give the medication

Analysis of Controllers – SICU RN (cont)

- Contextual Factors
  - New leadership in cardiac surgery pushing cardiac transplants after several years of doing them infrequently
    - Nurses and staff were not familiar with this operation
  - Not all pre-operative medications that are ordered in the EHR are the responsibility of the SICU RN
    - For example, antibiotics are in the pre-operative order set but they are given in the OR by the anesthesiologist
  - There is no distinction in the orders between pre-operative medications to be given in the SICU versus in the OR
  - This EHR does not send any alert if an order has not been fulfilled

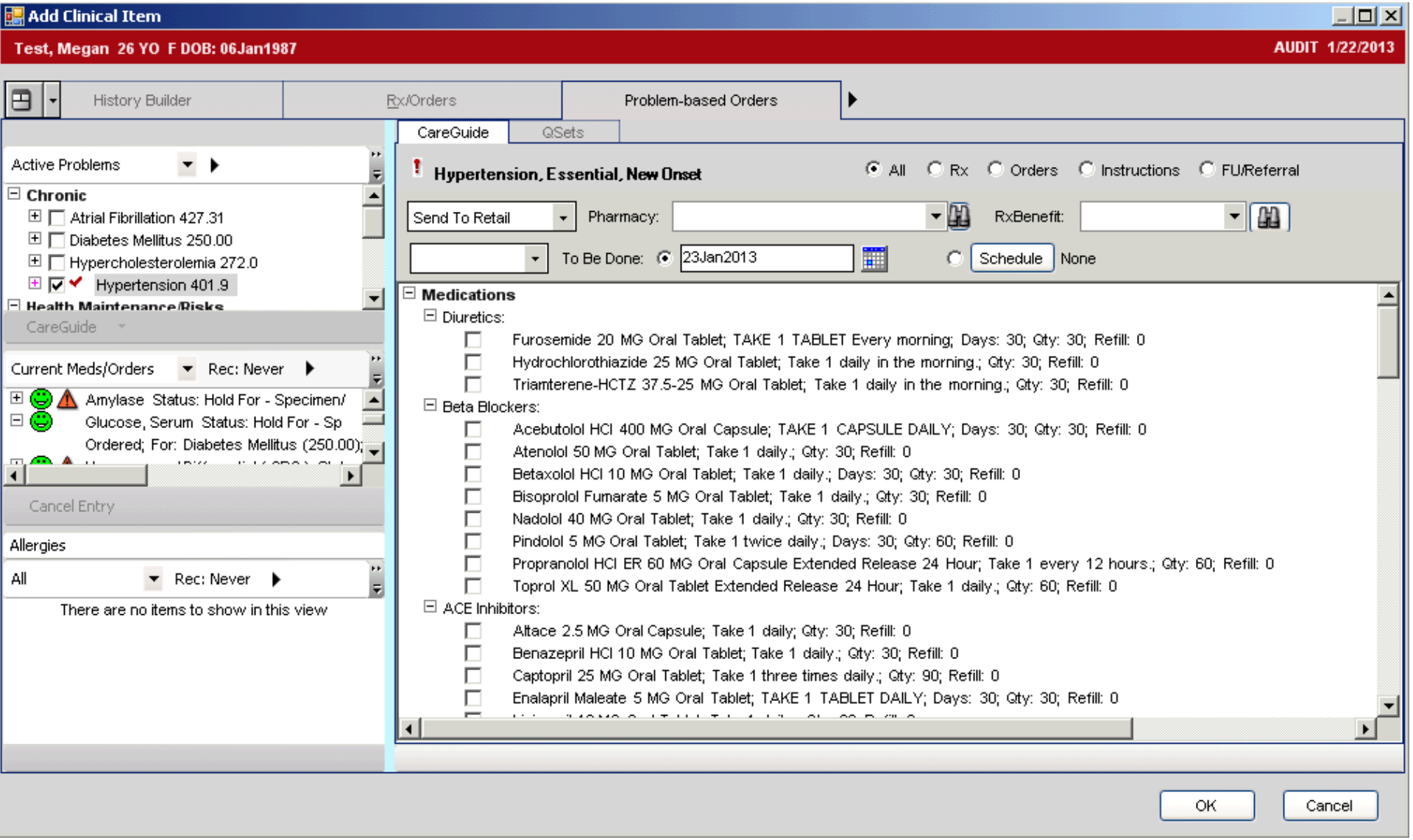
Analysis of Controllers – Surgery Attending

- Safety Responsibilities
  - Order pre-operative antibiotics and immunosuppression
  - Ensure that the patient is ready for surgery before beginning
  - Supervise the surgical fellow
- Unsafe Control Actions
  - Began surgery without the patient having received prophylactic immunosuppression
- Process Model Flaws
  - Believed that because he had ordered the medication that it had been given

Analysis of Controllers – Surgery Attending (cont)

- Contextual Factors
  - On the order screen of the EHR there is no record of whether an order has been carried out
    - The order screen and the administered screen are two separate areas of the EHR. Physicians only look at ordering. Nurses only look at administering.
  - Almost all cardiac patients are in the SICU pre-operatively, so the surgical team knows and trusts the nursing team without feeling the need to question or second-guess their work

Sample Order Screen



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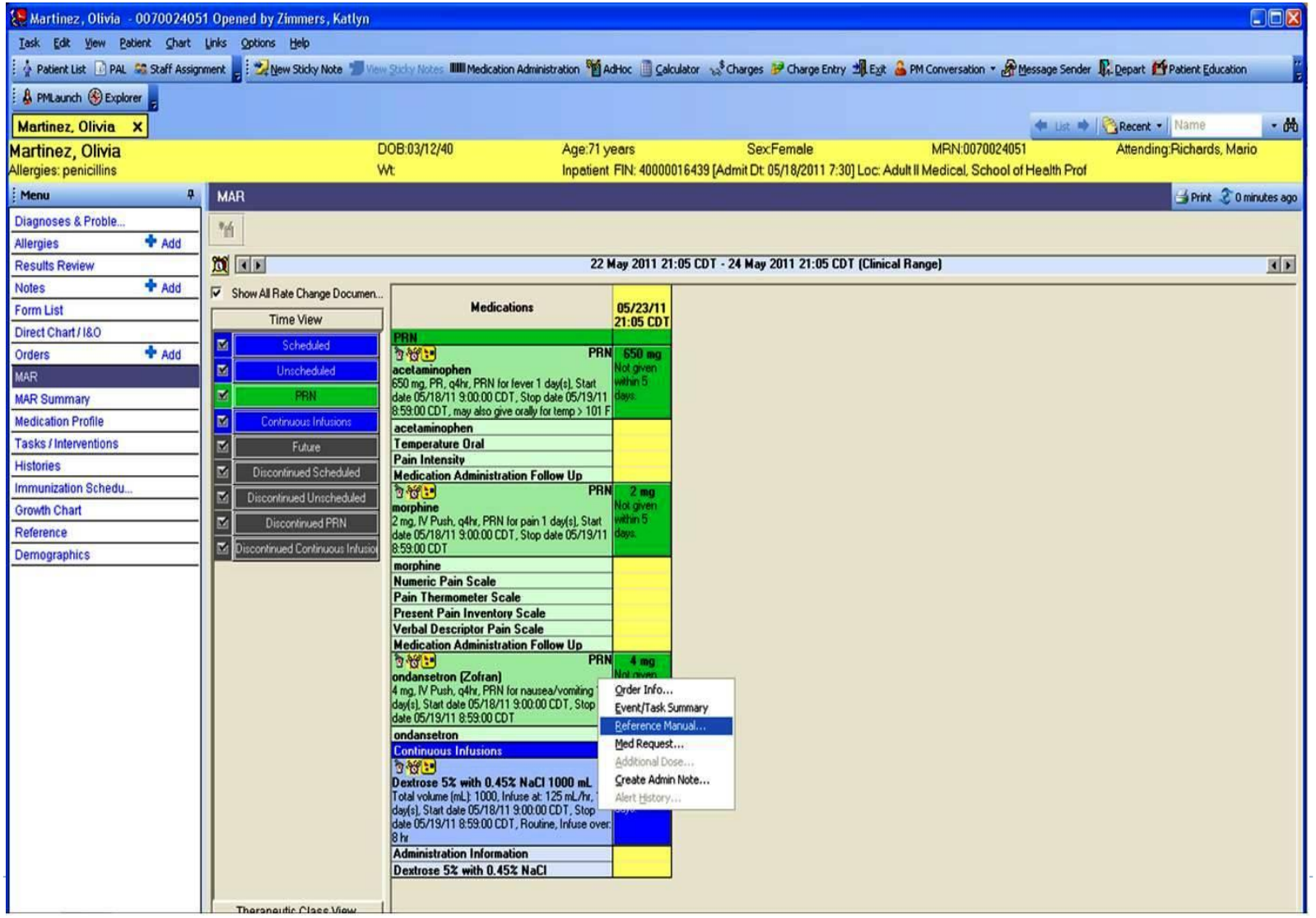
Sample Electronic Medication Administration Record



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Analysis of Controllers – OR Administration

- Safety Requirements
  - Ensure safe practices in the OR
  - Maintain medication supplies
  - Investigate accidents
- Unsafe Control Actions
  - Did not ensure safe practices in the OR
  - Did not thoroughly investigate the accident
    - This happened another two times
- Process Model Flaws
  - Believed that staff knew how to order and administer all medications
  - Unaware of this incident until several months later

Analysis of Controllers – OR Administration (cont)

- Contextual Factors
  - Separate management silos for surgery and intensive care complicate communication between the two departments
  - New surgical management
    - Unfamiliar with the department and their background and experience
  - Most incidents are never written up as incident reports
    - The majority of these incidents were identified through the assistance of a PA doing chart reviews on cases

Recommendations

- Change the EHR
  - Provide more obvious feedback on both screens if an order has not been carried out
- Change the process for placing pre-operative orders
  - Order sets are good to prevent forgetting orders, but bad when they cause ambiguity
  - Break up the large order set into orders for the SICU team and orders for the OR team
- Institute a formal handoff procedure between the SICU and the surgical team
  - Include explicit mention of all of the preoperative medications and labs

Recommendations (continued)

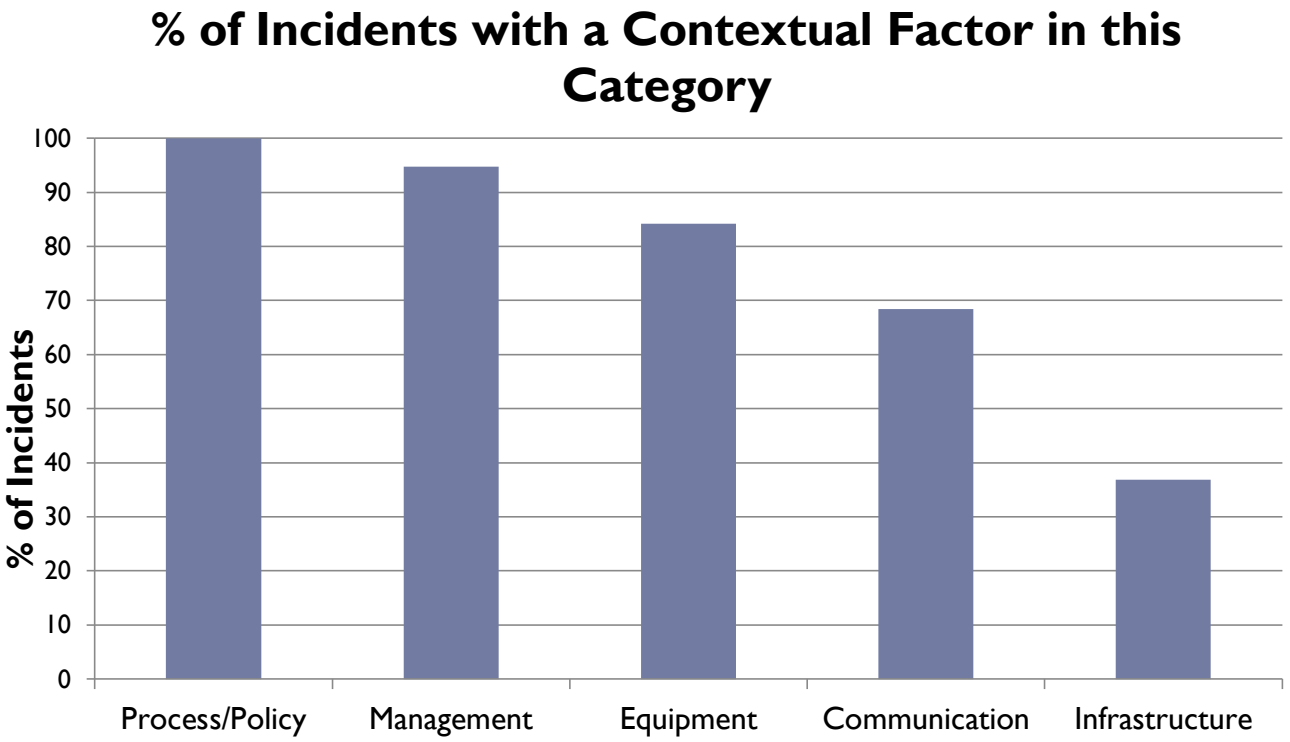
- Implement a formal Management of Change Protocol
  - This will aid in changes of leadership, ensuring that everyone understands the expectations and assumptions
- Create a robust incident reporting system
  - Make it easy to write up and access the reporting system
  - Show people that you take their reports seriously and are doing something to make changes
- Weekly management meetings between the SICU and the Cardiac Surgery leadership
  - Promote communication and create policies for interactions between the departments

Coded Categories of Contextual Factors

- Equipment
  - Poor EHR design
- Process/Policy
  - No standardized process for calling a consult
- Infrastructure
  - Blood bank is ½ mile away from the ICU
- Communication
  - Equipment referred to by many different eponyms
- Management
  - Financial pressure leads to cutting overtime and placing staff in jobs they are not trained for

Aggregate Contextual Factors

- Average of 6.9 contextual factors per incident
  - Far more than one root cause



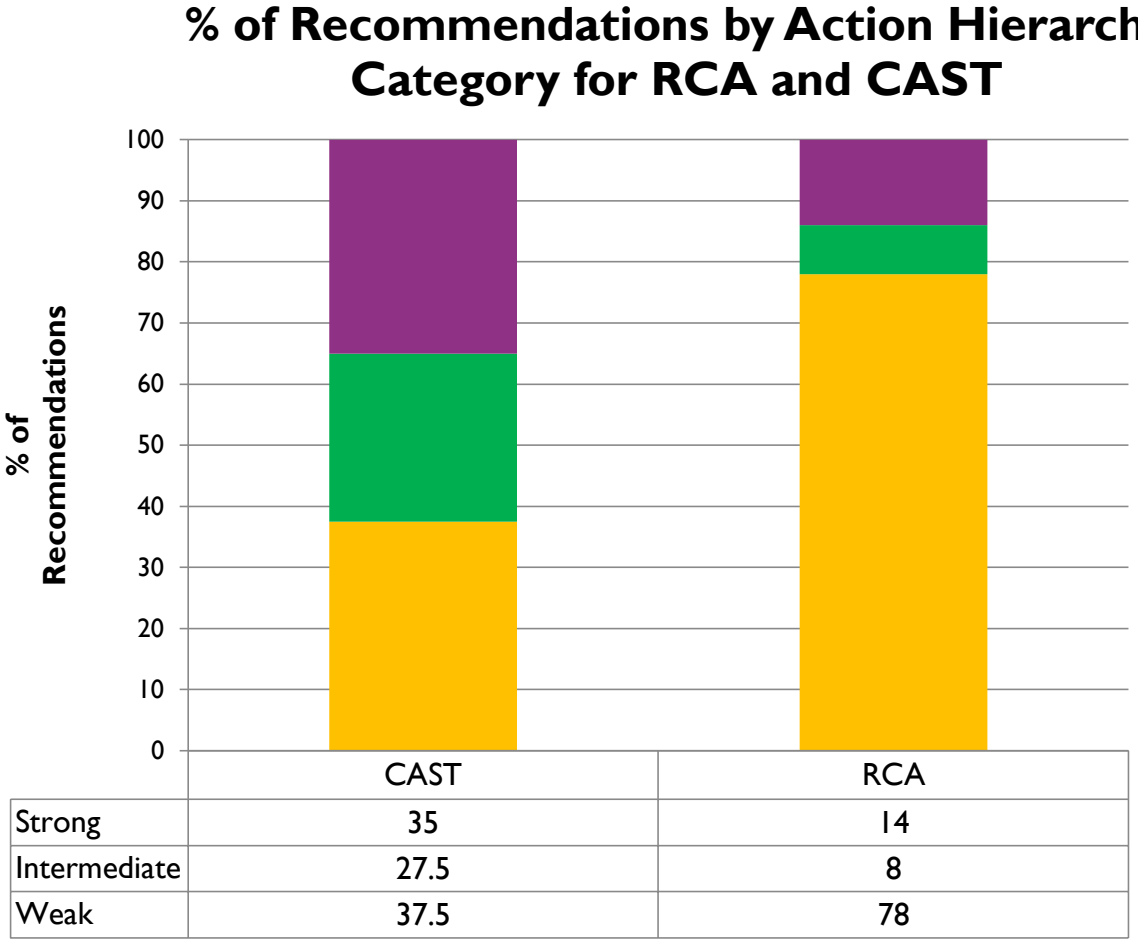
VA Action Hierarchy

ACTION	PAC GLOSSARY
Stronger Actions	• Architectural/physical plant changes • New devices with usability testing before purchasing • Engineering control, interlock, forcing functions • Simplify the process and remove unnecessary steps • Standardize on equipment or process or care maps • Tangible involvement and action by leadership in support of patient safety
Intermediate Actions	• Redundancy/back-up systems • Increase in staffing/decrease in workload • Software enhancements/modifications • Eliminate/reduce distractions • Checklist/cognitive aid • Eliminate look- and sound-alikes • Enhanced documentation/communication
Weaker Actions	• Double checks • Warnings and labels • New procedure/memorandum/policy • Training • Additional study/analysis

From the VA RCA tool, 2015.

Recommendations – RCA vs. CAST

- Average of 3.9 recommendations per incident with CAST



	CAST	RCA
Strong	35	14
Intermediate	27.5	8
Weak	37.5	78

RCA data from (Mills, 2006), a study on RCA in patient suicidal behavior incidents

Conclusions

- CAST, as a system based accident analysis technique, can be easily adopted for use in healthcare accidents
- Potential benefits of CAST over other RCA forms include:
  - Shared mental model of the system across the analytic team
  - Potential to identify impacts of management and regulatory bodies
  - Potential to identify contextual factors common across many incidents
  - Potential to create a higher percentage of "strong" recommendations to prevent future accidents

Parting Thoughts

- I shared some stories of horrible accidents with you here
  - Don't walk away thinking that this medical center is egregiously unsafe
  - **Every hospital has these stories**
- Sharing these mistakes and lessons learned takes courage, but until every hospital is willing to be as open we will continue to harm patients
  - We can only move forward and prevent accidents when we are open about our mistakes and share our lessons

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