Update on National Patient Safety Goal 6: Reduce the harm associated with clinical alarm systems

AAMI Foundation Annual Forum

Hot Topics in Patient Safety

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Disclosures

- Nothing to disclose

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Joint Commission Enterprise

- The Joint Commission
  - Accreditation in the US, standards
  - Sentinel events, quality measurement
- Joint Commission Resources
  - Publication, education, consulting
  - International standards and accreditation
- Center for Transforming Healthcare
  - Partners with US hospitals and systems
  - Creates interventions

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Recommendations and Requirements

- Standards
- *Sentinel Event Alerts*
- National Patient Safety Goals

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A PSA about mental models…

- Highlight critical features and how they are related
- Easier to understand new concepts if it is built around an existing model

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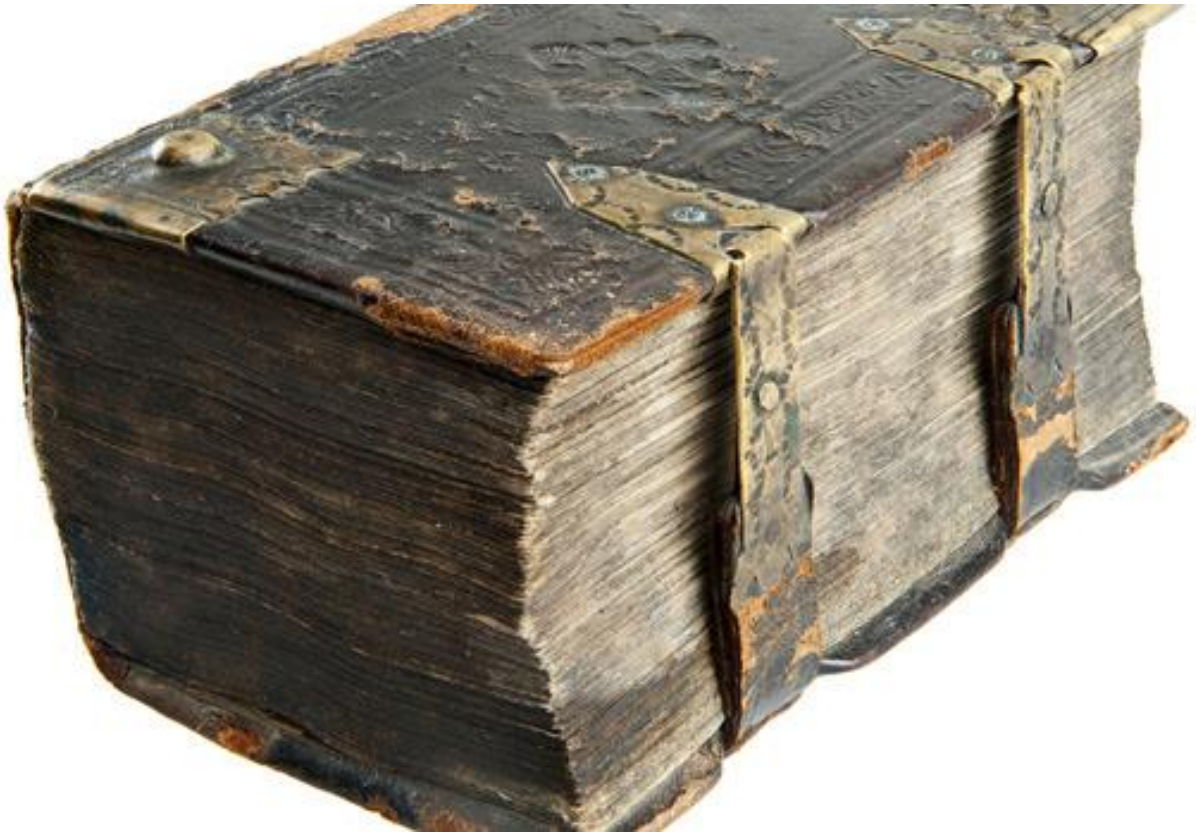
Joint Commission Standards



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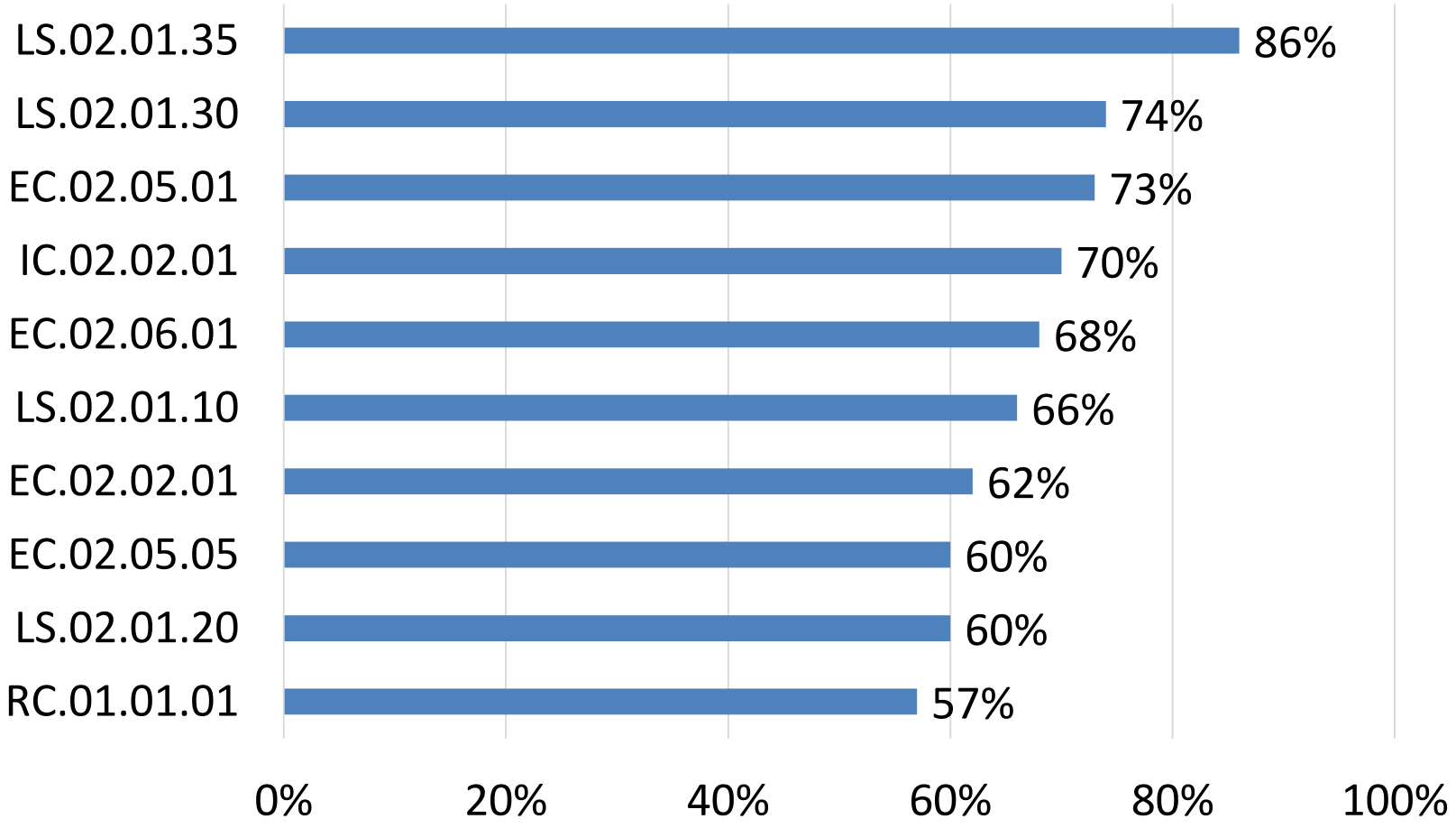
Top Ten Standards Scored 2017



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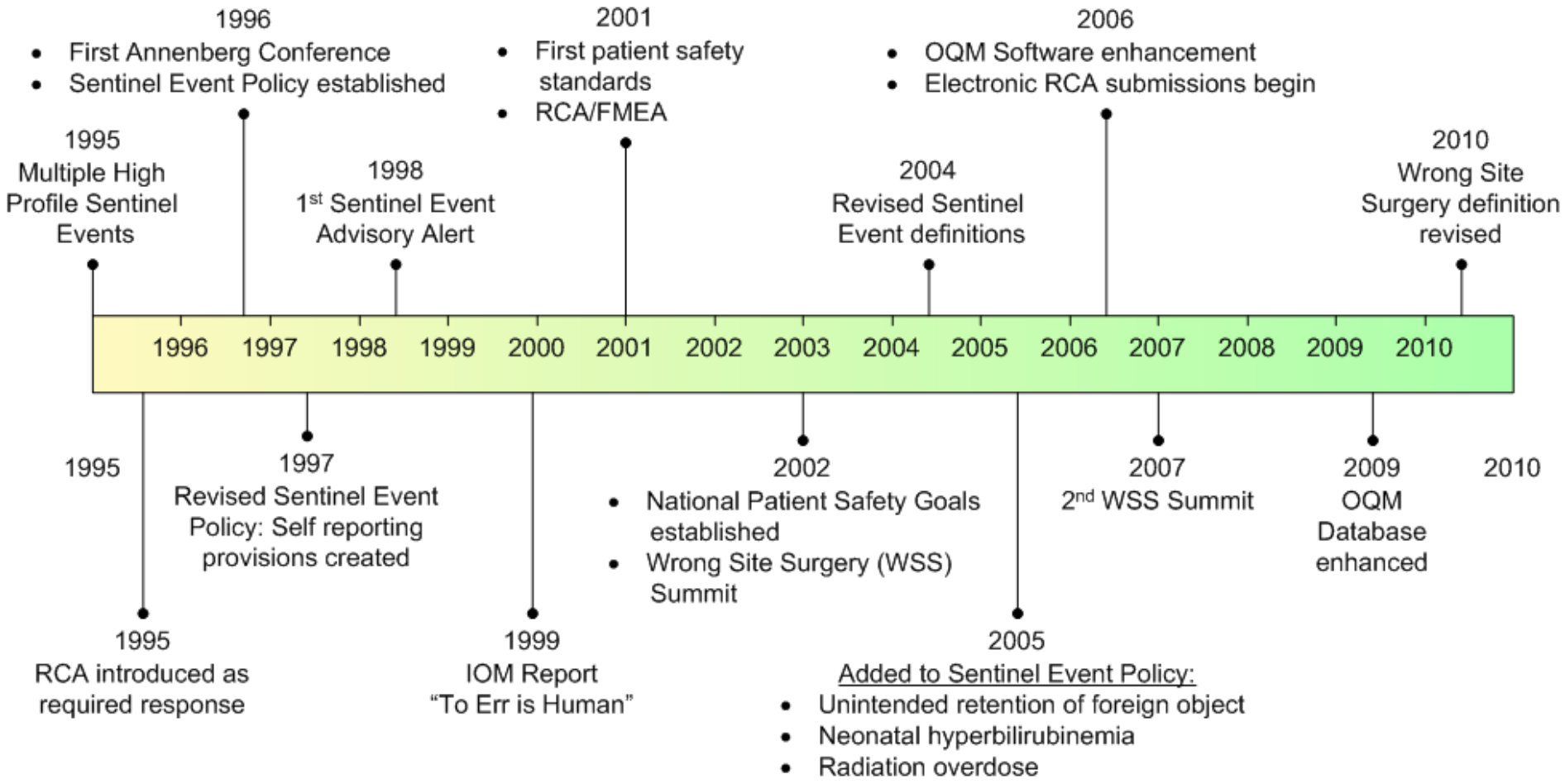
History


1996
First Annenberg Conference
Sentinel Event Policy established
2001
First patient safety standards
RCA/FMEA
2006
OQM Software enhancement
Electronic RCA submissions begin
1995
Multiple High Profile Sentinel Events
1998
1st Sentinel Event Advisory Alert
2004
Revised Sentinel Event definitions
2010
Wrong Site Surgery definition revised
1996 1997 1998 1999 2000 2001 2002 2003 2004 2005 2006 2007 2008 2009 2010
1995
1995
RCA introduced as required response
1997
Revised Sentinel Event Policy: Self reporting provisions created
1999
IOM Report
"To Err is Human"
2002
National Patient Safety Goals established
Wrong Site Surgery (WSS) Summit
2005
Added to Sentinel Event Policy:
Unintended retention of foreign object
Neonatal hyperbilirubinemia
Radiation overdose
2007
2nd WSS Summit
2009
OQM Database enhanced
2010

Sentinel Event Alerts (SEAs)

Sentinel Event Alert Issue 50: Medical device alarm safety in hospitals

April 8, 2013

Download This File

Many medical devices have alarm systems. These alarm-equipped devices are essential to providing safe care to patients in many health care settings; clinicians depend on these devices for information they need to deliver appropriate care and to guide treatment decisions. However, these devices present a multitude of challenges and opportunities for health care organizations when their alarms create similar sounds, when their default settings are not changed, and when there is a failure to respond to their alarm signals.

Additional resource:

Sentinel Event Alert Issue 50: Medical device alarm safety in hospitals, highlights important issues and approaches to improving safety surrounding alarm-equipped medical devices in hospitals. To stimulate further discussion on this important patient safety issue, The Joint Commission held a web conference featuring an ECRI Institute representative and staff from Boston Medical Center who discussed their successful Cardiac Alarm Management Pilot.

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Recommendations from Alarm Management SEA

- Leadership
- Inventory
- Establish guidelines for alarm settings
- Establish guidelines for changing alarm settings
- Inspect, check, test, and maintain equipment and settings

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National Patient Safety Goals (NPSGs)

- Promote specific improvements in patient safety
- Highlight problematic areas in healthcare
- Derived from *Sentinel Event Alerts* and recommendations from safety organizations, professional societies, and the Patient Safety Advisory Group

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Examples of NPSGs

Goal 1 Use at least two patient identifiers when providing care, treatment, and service

Goal 7 Comply with either the CDC hand hygiene guidelines or the WHO hand hygiene guidelines.

Universal Protocol

Preprocedure verification process

Mark the procedure site

A time-out is performed before the procedure

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Retired NPSGs

Goal 3 Improve the safety of using high-alert medications

3A - Remove concentrated electrolytes (including, but not limited to, potassium chloride, potassium phosphate, sodium chloride >0.9%) from patient care units.

Goal 5 Improve the safety of using infusion pumps

5A - Ensure free-flow protection on all general-use and PCA (patient controlled analgesia) intravenous infusion pumps used in the organization.

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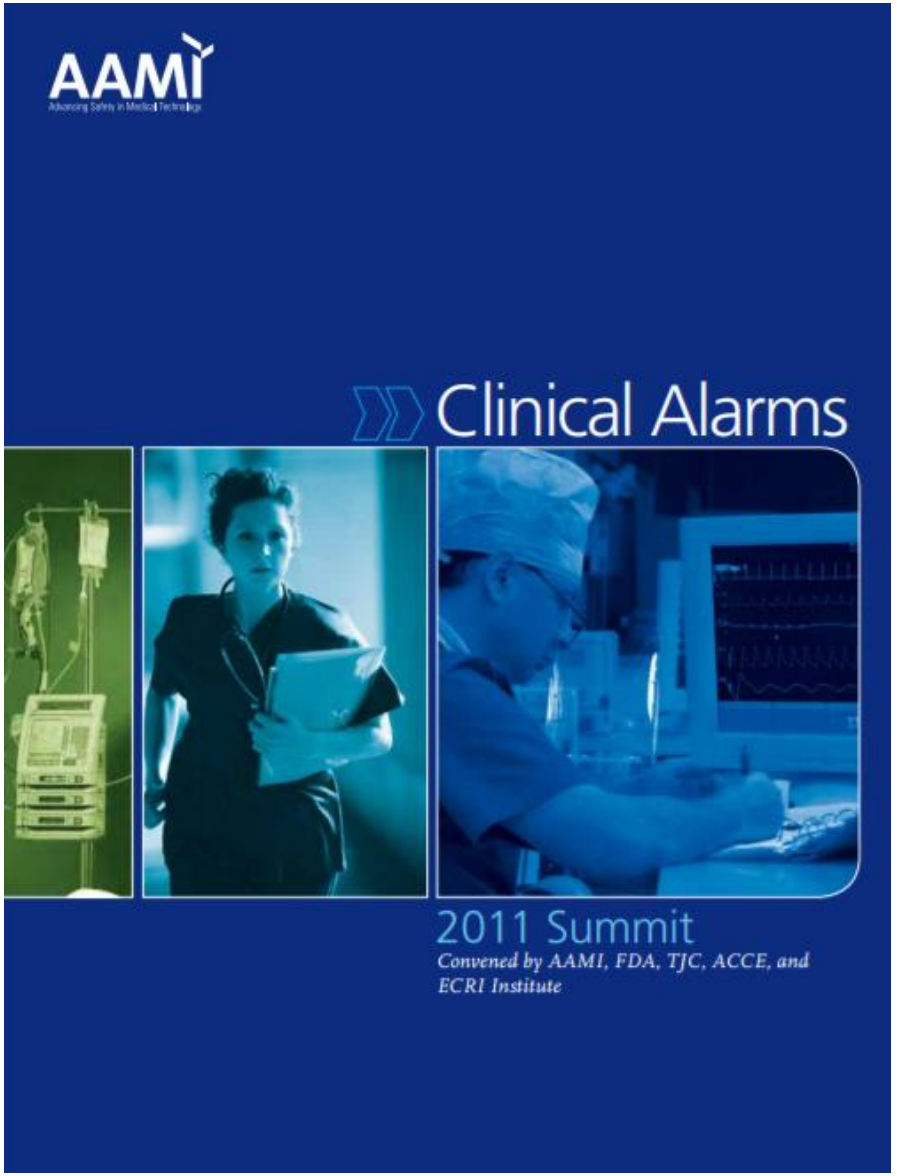
AAMI Clinical Alarms Summit 2011



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Requirement

National Patient Safety Goal on Alarm Management

APPLICABLE TO HOSPITALS AND CRITICAL ACCESS HOSPITALS

Effective January 1, 2014

National Patient Safety Goal (NPSG)

NPSG.06.01.01
Improve the safety of clinical alarm systems.

Rationale for NPSG.06.01.01
Clinical alarm systems are intended to alert caregivers of potential patient problems, but if they are not properly managed, they can compromise patient safety. This is a multifaceted problem. In some situations, individual alarm signals are difficult to detect. At the same time, many patient care areas have numerous alarm signals and the resulting noise and displayed information tends to desensitize staff and cause them to miss or ignore alarm signals or even disable them. Other issues associated with effective clinical alarm system management include too many devices with alarms, default settings that are not at an actionable level, and alarm limits that are too narrow. These issues vary greatly among hospitals and even within different units in a single hospital.

There is general agreement that this is an important safety issue. Universal solutions have yet to be identified, but it is important for a hospital to understand its own situation and to develop a systematic, coordinated approach to clinical alarm system management. Standardization contributes to safe alarm system management, but it is recognized that solutions may have to be customized for specific clinical units, groups of patients, or individual patients. This NPSG focuses on managing clinical alarm systems that have the most direct relationship to patient safety. As alarm system management solutions are identified, this NPSG will be updated to reflect best practices.*

Elements of Performance for NPSG.06.01.01

A 1. As of July 1, 2014, leaders establish alarm system safety as a [critical access] hospital priority. **R**

A 2. During 2014, identify the most important alarm signals to manage based on the following: **R**

- Input from the medical staff and clinical departments
- Risk to patients if the alarm signal is not attended to or if it malfunctions
- Whether specific alarm signals are needed or unnecessarily contribute to alarm noise and alarm fatigue
- Potential for patient harm based on internal incident history
- Published best practices and guidelines

(For more information on managing medical equipment risks, refer to Standard EC.02.04.01.)

A 3. As of January 1, 2016, establish policies and procedures for managing the alarms identified in EP 2 above that, at a minimum, address the following: **R**

- Clinically appropriate settings for alarm signals
- When alarm signals can be disabled
- When alarm parameters can be changed

* Additional information on alarm safety can be found on the AAMI website http://www.aami.org/htsi/alarms/. Also, the ECRI Institute has identified alarm hazards as one of the top technology hazards for 2013; more information on this hazard list can be found at http://www.ecri.org/Forms/Pages/Alarm_Safety_Resource.aspx.

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Rolling EP Effective Dates

1. As of July 1, 2014 establish alarm safety as a hospital priority.
2. During 2014 identify the most important alarm signals to manage
3. As of January 1, 2016 establish policies and procedures for managing the alarms identified in EP 2.
4. As of January 1, 2016 educate staff and licensed independent practitioners about the purpose and proper operation of alarm systems for which they are responsible.

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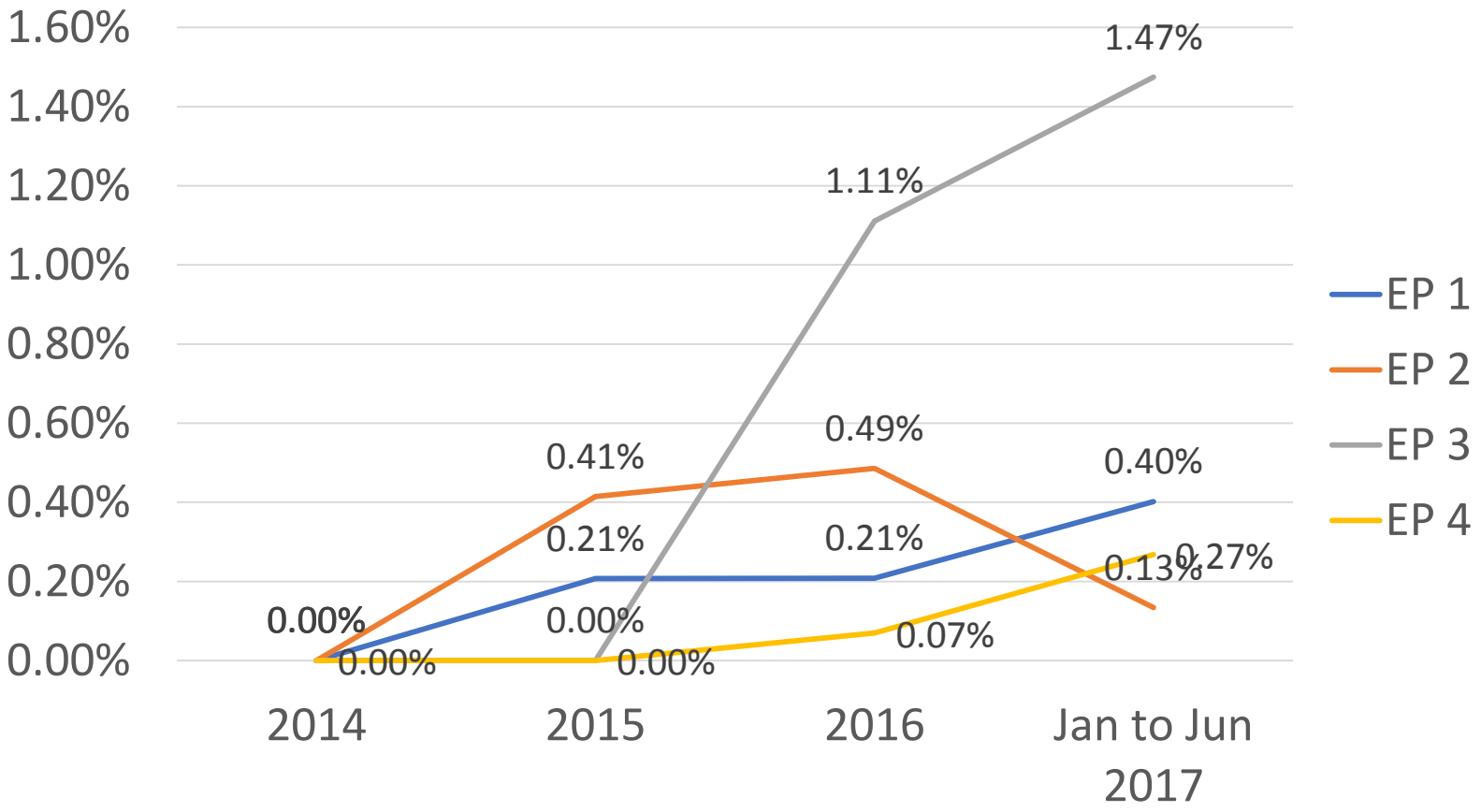
NPSG.06.01.01 Scoring



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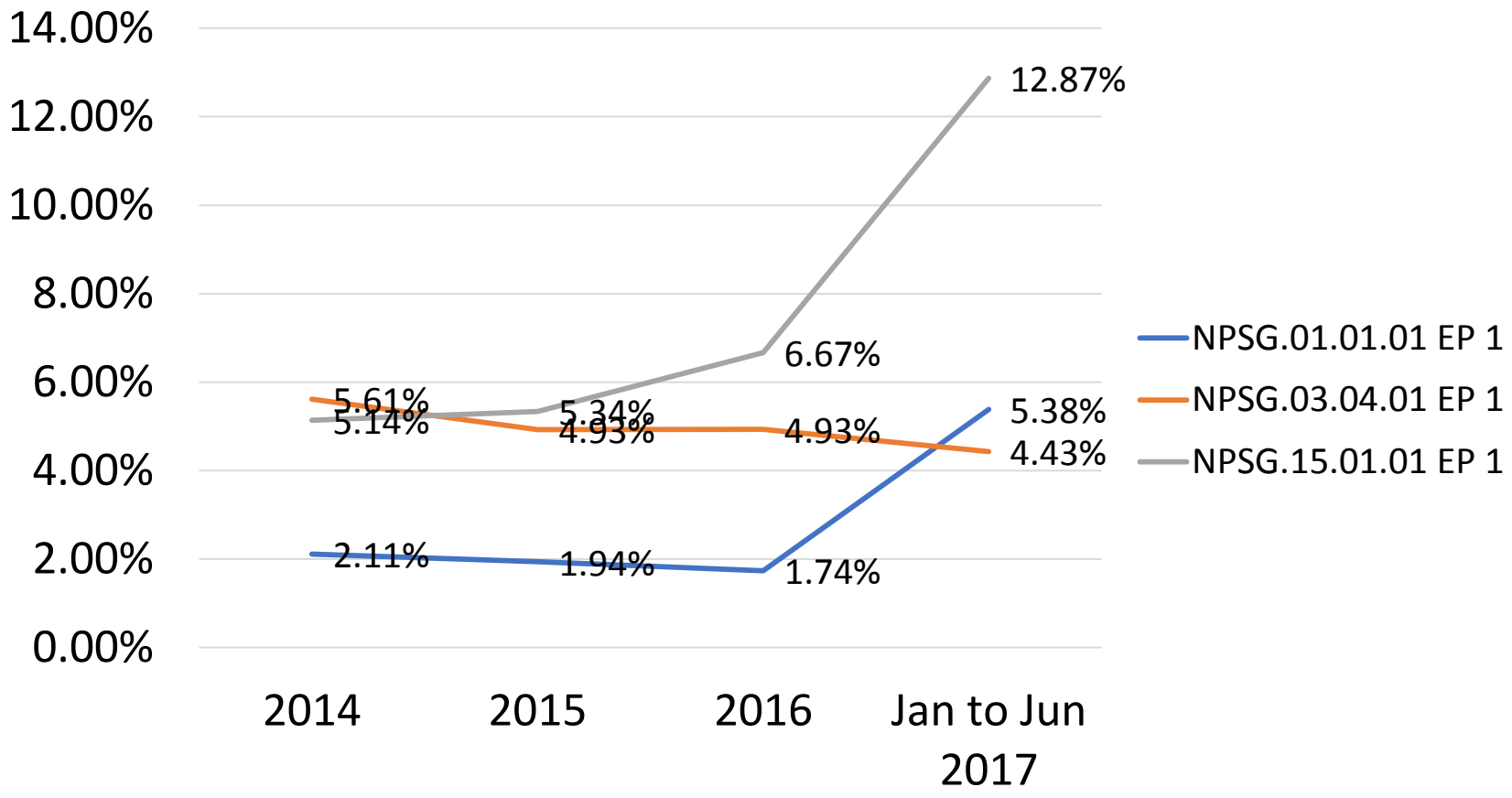
Scoring compared to other NPSG



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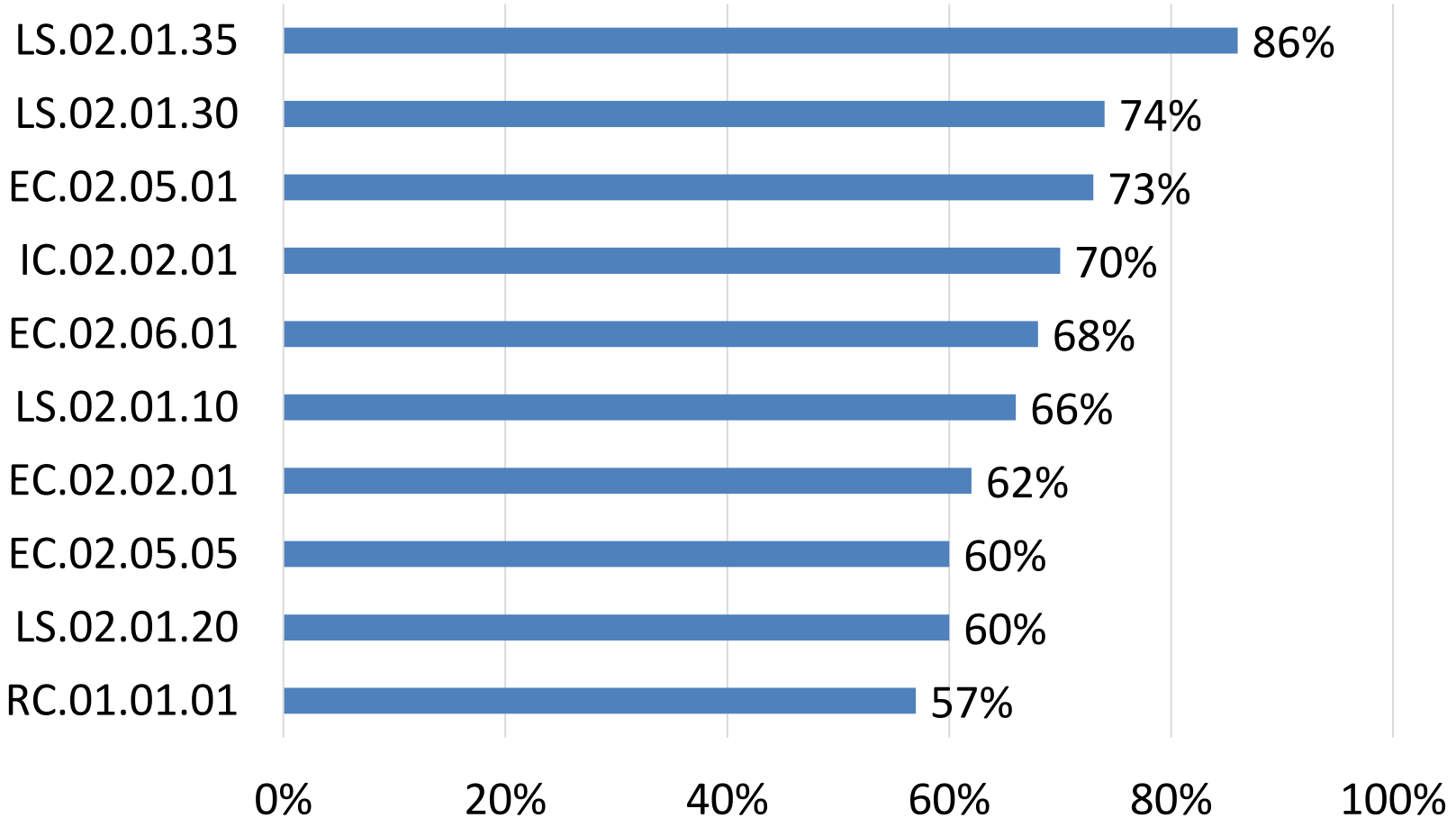
Top Ten Standards Scored 2017



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What does this look like?

1. Establish alarm safety as a hospital priority
2. Identify the most important alarm signals to manage
3. Establish policies and procedures
4. Educate staff and licensed independent practitioners about the purpose and proper operation of alarm systems for which they are responsible.

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Strength of Intervention

More Effective

1. Forcing functions
2. Automation, computerization
3. Protocols and preprinted orders
4. Checklists
5. Rules and double-checking
6. Education
7. Information

Less Effective

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Corrective Actions: Strong

	Action Category	Example
Stronger Actions (these tasks require less reliance on humans to remember to perform the task correctly)	Architectural/physical plant changes	Replace revolving doors at the main patient entrance into the building with powered sliding or swinging doors to reduce patient falls.
	New devices with usability testing	Perform heuristic tests of outpatient blood glucose meters and test strips and select the most appropriate for the patient population being served.
	Engineering control (forcing function)	Eliminate the use of universal adaptors and peripheral devices for medical equipment and use tubing/fittings that can only be connected the correct way (e.g., IV tubing and connectors that cannot physically be connected to sequential compression devices or SCDs).
	Simplify process	Remove unnecessary steps in a process.
	Standardize on equipment or process	Standardize on the make and model of medication pumps used throughout the institution. Use bar coding for medication administration.
	Tangible involvement by leadership	Participate in unit patient safety evaluations and interact with staff; support the RCA^2 process; purchase needed equipment; ensure staffing and workload are balanced.

Source: National Patient Safety Foundation. *RCA2: Improving Root Cause Analyses and Actions to Prevent Harm.* Boston: National Patient Safety Foundation, 2015

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Corrective Actions: Intermediate

Intermediate Actions	Redundancy	Use two RNs to independently calculate high-risk medication dosages.
	Increase in staffing/decrease in workload	Make float staff available to assist when workloads peak during the day.
	Software enhancements, modifications	Use computer alerts for drug-drug interactions.
	Eliminate/reduce distractions	Provide quiet rooms for programming PCA pumps; remove distractions for nurses when programming medication pumps.
	Education using simulation-based training, with periodic refresher sessions and observations	Conduct patient handoffs in a simulation lab/environment, with after action critiques and debriefing.
	Checklist/cognitive aids	Use pre-induction and pre-incision checklists in operating rooms. Use a checklist when reprocessing flexible fiber optic endoscopes.
	Eliminate look- and sound-alikes	Do not store look-alikes next to one another in the unit medication room.
	Standardized communication tools	Use read-back for all critical lab values. Use read-back or repeat-back for all verbal medication orders. Use a standardized patient handoff format.
	Enhanced documentation, communication	Highlight medication name and dose on IV bags.

Source: National Patient Safety Foundation. RCA2: Improving Root Cause Analyses and Actions to Prevent Harm. Boston: National Patient Safety Foundation, 2015

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Corrective Actions: Weak

Weaker Actions (these tasks require more reliance on humans to remember to perform the task correctly)	Double checks	One person calculates dosage, another person reviews their calculation.
	Warnings	Add audible alarms or caution labels.
	New procedure/ memorandum/policy	Remember to check IV sites every 2 hours.
	Training	Demonstrate correct usage of hard-to-use medical equipment.

Action Hierarchy levels and categories are based on *Root Cause Analysis Tools*, VA National Center for Patient Safety, http://www.patientsafety.va.gov/docs/joe/rca_tools_2_15.pdf. Examples are provided here.

Source: National Patient Safety Foundation. RCA2: Improving Root Cause Analyses and Actions to Prevent Harm. Boston: National Patient Safety Foundation, 2015

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Questions to Consider

- How is leadership involved?
  - How has the organization demonstrated leadership commitment to the action plan?
- Does the action correspond to the identified risk?
- Has the organization considered other common causes/risk, impact to other processes, other areas in which action can be leveraged, unintended consequences of action?
- How will the action be measured for effectiveness and sustained over time?

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Enhancing Actions

- New procedure/policy
  - Weak if process was actually already in place and there's no particular change to process other than reinforcement
  - Stronger if new procedure has removed unnecessary steps or serves to standardize
  - Stronger if procedure/policy includes front-line staff and supported by leadership (culture)

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Enhancing Actions

- Training/Education
  - Weak if re-educating, reminding, reiterating a process that was already in place
  - Weak if it is an education module, reading a policy, or similar review
  - Stronger if training includes practice opportunities (simulation)

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Enhancing Actions

- Audit/Observation
  - This is not an action per se but a measurement strategy. Asking “what does the audit/observation address?” will reveal the action.
  - If an organization has found a process has drifted and are using an audit for assessment, remaining questions to ponder are why did the process drift, how can it be improved to increase consistency, etc.

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Enhancing Actions

- Leadership support as an action
  - Weak if leadership support is limited to "signing off" on action
  - Stronger if strategies include tangible commitment and inclusion of leadership (e.g., executive walk-rounds, standing "town hall" meetings, resources and support)

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Strategies for Implementation and Sustainment

- Leadership Support and Active Involvement
  - Provide necessary support, resources time
  - Evaluate quality/thoroughness of analysis
  - Approve/disapprove actions and intervene when RCA does not meet expectations (at least one intermediate or strong action recommended)
- Effective Measurement
  - Process and outcome measures
- Ongoing Assessment
  - Avoiding Drift
  - Routine progress reporting to board (standing agenda)

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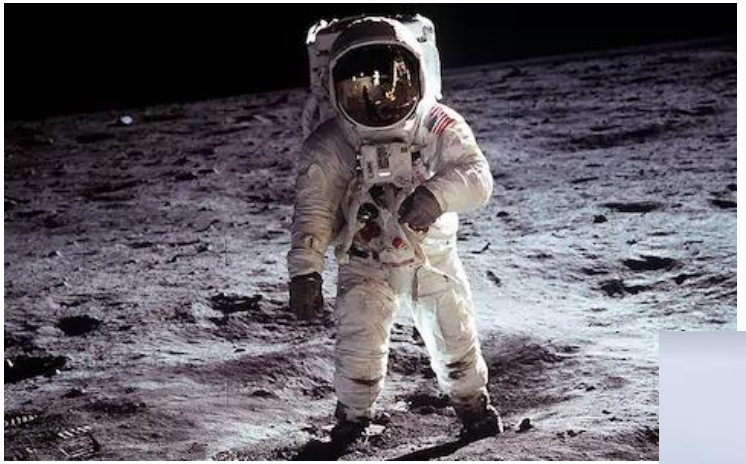
Complexity Theory

Simple



Complicated

Complex

Gawande, Atul. *The Checklist Manifesto: How To Get Things Right*. New York, N.Y. : Metropolitan Books, 2010.

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Today…

AAMI FOUNDATION

PIM Postgraduate Institute for Medicine

2017 AAMI Foundation **Annual Forum**

HOT TOPICS IN PATIENT SAFETY

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Thank You!

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