The New Jersey Patient Safety Act and Reporting

New Jersey Department of Health

Patient Safety Reporting System

Mary Noble, MD, MPH
Sara Day, RN, BSN, CPM

NJAASC Annual Meeting
Hyatt Regency
October 10, 2014

Objectives

- Review legislation and rules
- Review reporting requirements
- Review reporting process
- Review Root Cause Analysis requirements
- Allow time for discussion and questions

NJ Health
New Jersey Department of Health

The Patient Safety Act

- C.26:2H-12.23 Enacted in April 2004
  - Enhance Patient Safety
  - Minimize Number of Adverse Events
  - Minimize Patient Harm
  - Improve System/Facility Performance

NJ Health
New Jersey Department of Health

Confidentiality Protection

- Patient Safety Act encourages honest, critical self-analysis and restricts:
  - Discoverability
  - Admissibility
  - Disclosure of documents, materials and information
    - Be clear about separation between Patient Safety and Quality Improvement activities

NJ Health
New Jersey Department of Health

Patient Safety in NJ

- We all want the same thing for the patients of NJ:
  - The best care that they can receive
  - Prevention of adverse events

NJ Health
New Jersey Department of Health

Patient Safety in NJ

- Let's promote a culture of safety
  - Open-minded to change and improvement
  - Blame-free environment
  - Collaboration between all levels and disciplines of staff
  - Strive for "Zero" adverse events, not just better than the national average
  - Commit resources to improvement

NJ Health
New Jersey Department of Health

Patient Safety in NJ

- The NJ Patient Safety Reporting System (PSRS) tries to make patient safety:
  - Non-Punitive
    - No public reports are issued by PSRS about patient safety that list individual facilities
  - Educational
    - Encourage literature review for best practices
  - Collegial

NJ Health
New Jersey Department of Health

Patient Safety Rules and Requirements

- N.J.A.C. 8:43E Subchapter 10 requires facilities to do the following:
  - Establish Patient Safety Committee
  - Establish Patient Safety Plan
  - Report Adverse Events to DOH or DHS
  - Conduct Analyses of Adverse Events
  - Submit Analyses of Adverse Events to DOH or DHS

NJ Health
New Jersey Department of Health

Facility Administrators

- PSRS requests a minimum of 2 facility administrative users (FacAdmins)
- FacAdmins must sign a User Agreement
- FacAdmins receive emails sent through the system
- FacAdmins expected to cover for days off
  - Report Readers and Writers who are not FacAdmins do not receive emails in the system

NJ Health
New Jersey Department of Health

Reporting Requirements

- Event Report entered into the online Patient Safety Reporting System (PSRS) within 5 business days of discovery
  - The physician or surgeon is a member of the healthcare team.
  - If the physician or anyone associated with the ASC becomes aware of an adverse event, this is considered the date and time of discovery.

NJ Health
New Jersey Department of Health

Reporting Requirements

- PSRS reviews event report in online system
  - PSRS determines whether a Root Cause Analysis (RCA) is required based on the rules and regulations and notifies the facility
- If event accepted by PSRS, RCA submitted to PSRS within 45 calendar days from initial event report

NJ Health
New Jersey Department of Health

Extensions

- Extensions for events and RCAs may be granted upon request—Send request with rationale as a comment through online system for that Event/RCA

- Some extensions granted automatically if time frame for event review is lengthy

NJ Health
New Jersey Department of Health

General Reporting Recommendations for ASCs

- Surgical events (wrong site, procedure, etc.)
- Aspiration
- Pneumothorax
- Perforation of an organ
- Cardiac and/or respiratory issues
- Moderate to severe bleeding
- Infections that require intervention
- Falls with injury

NJ Health
New Jersey Department of Health

General Reporting Recommendations for ASCs Cont'd

- Any patient transferred to the Emergency Department
  - Transfer from ASC directly to ED
  - Visit to ED or other health care facility (Urgent Care Center, etc.) after discharge from ASC
- Recommend reporting **all** adverse events
  - PSRS will determine whether event meets criteria for acceptance

NJ Health
New Jersey Department of Health

Choosing a Category

- Surgical—Intra/Post-op Coma/Death/Other
  - Includes cases where anesthesia was administered regardless of whether the planned procedure was carried out
  - Includes cases where adverse events occur within 24 hours of the procedure
- Surgical—Other
  - Generally used for infections and any other surgical event that does not fit into the previous surgical event category

NJ Health
New Jersey Department of Health

Choosing a Category Cont'd

- The following surgical event types have no threshold of injury:
  - Retained Foreign Object
  - Wrong Site
  - Wrong Procedure
  - Wrong Patient

Threshold of Injury

- Certain surgical events have a "threshold of injury" requirement in the regulations
  - Coma, death, loss of body part, disability or loss of bodily function lasting more than seven days or still present at discharge
- Important for PSRS to determine if the event meets the "threshold of injury" when deciding whether the event will require an RCA

NJ Health
New Jersey Department of Health

Threshold of Injury Cont'd

- Often need information from hospital about what happened once the patient was transferred or presented for treatment after surgery
- PSRS needs to determine how this event affected the patient
- Include this information in the Event Report

NJ Health
New Jersey Department of Health

Suggestions for Obtaining Information from Hospitals

- Contact performance improvement or quality assurance department and ask for the person who handles patient safety
- Physicians if this is their patient and they have privileges
- If consistent with your practices, have patient sign consent for medical record release as part of routine practice (May want to check with your legal advisors)

NJ Health
New Jersey Department of Health

The Online System for Reporting Adverse Events

- The two-hour window
- The 2 hour window
- The 2° window
- The 2h window
- Did I mention the two hour window?

NJ Health
New Jersey Department of Health

The Online System for Reporting Adverse Events

- Choose the correct event type
- Complete the fields
  - May want to work in a word processing document (cut and paste)
  - Description of the event is unlimited field
  - PSRS was not there and we don't know what happened
- Save your work (within the 2h window)
- Submit to PSRS

NJ Health
New Jersey Department of Health

Online System Demo

- How to enter an event
- View the communication log
- View comments
- Respond to comments by editing the event
- Submit/resubmit to PSRS
- Resource Tab—Event Specific Questions

NJ Health
New Jersey Department of Health

Root Cause Analysis

- A process to improve patient safety
- Emphasis on improving and redesigning systems and processes
- Emphasis not on individual performance
- Educational opportunity
- Nonpunitive

NJ Health
New Jersey Department of Health

RCA Required Components

- A description of the event
- An analysis of why the event happened
- The corrective actions for the patient

RCA Required Components Cont'd

- Method to identify other patients having potential to be affected by the same event and corrective action(s)
- Systemic changes to reduce likelihood of similar events
- How the corrective actions will be monitored

RCA Team

- Ad hoc under Patient Safety Committee
- Distinct from QI activities
- Multidisciplinary and diverse
  - Staff knowledgeable about processes
  - Front line staff
  - Staff involved in event?
- Commitment to RCA Process

NJ Health
New Jersey Department of Health

Facts of the Event

- Detailed chronological narrative
- Who, what, when, where and how
- Clear, complete and understandable
- Provide enough detail so that a person unfamiliar with the event can understand what happened
- Document all systems/processes reviewed

NJ Health
New Jersey Department of Health

Identifying a Root Cause

- Use the Facts of the Event to examine why the event occurred
- Start with a broad review of all systems/processes
  - No process is above scrutiny
  - No preconceived beliefs
  - Honest and open discussion
- Focus on prevention

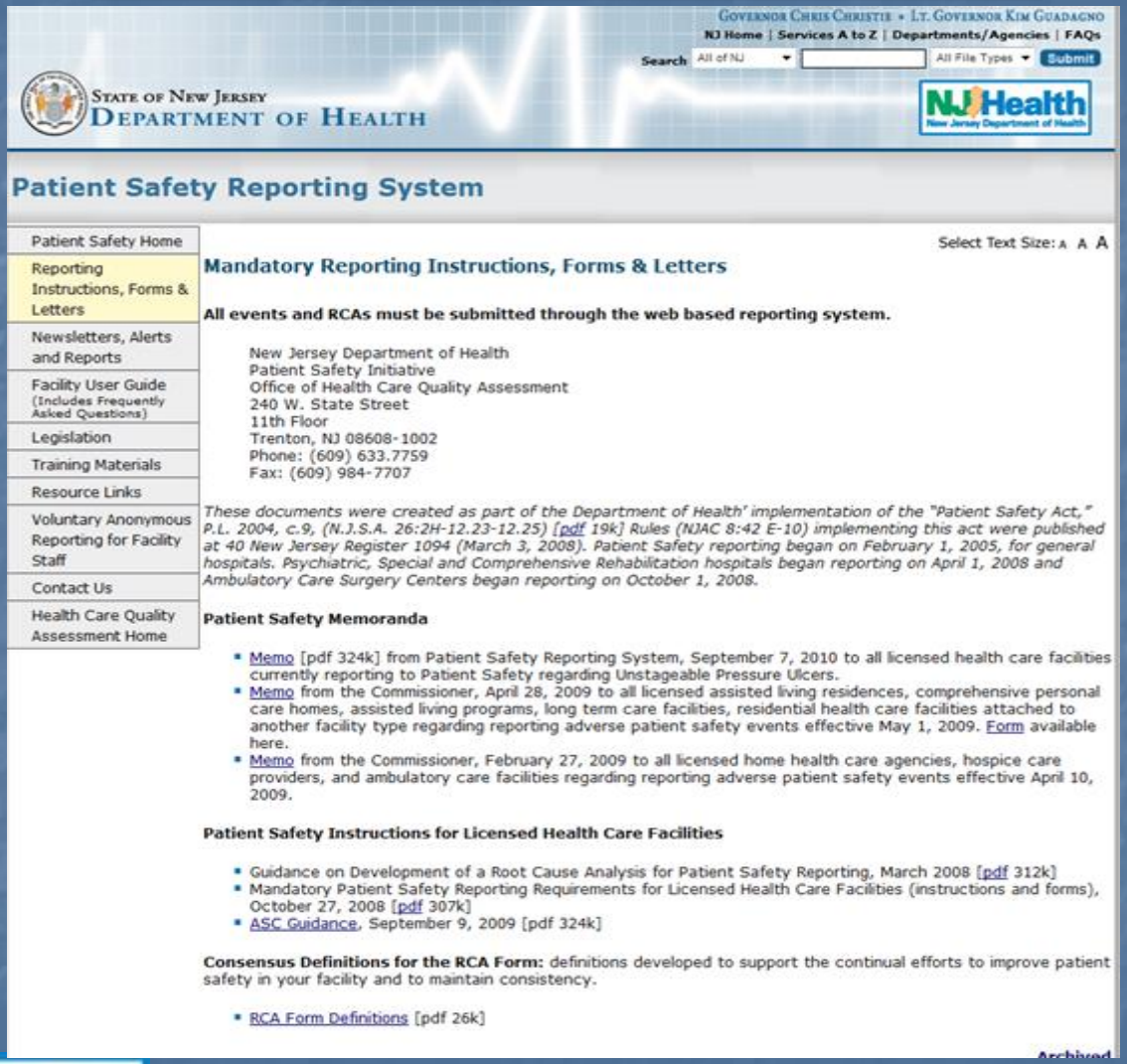
NJ Health
New Jersey Department of Health

Identifying a Root Cause Cont'd

- Look for Modifiable Risk Factors
- Evidence-based literature review
- Human error and violations of procedure must have a preceding system cause
- Facts of the Event should connect to the root cause
- Often more than 1 root cause

NJ Health
New Jersey Department of Health

RCA Form Definitions



Governor Chris Christie • Lt. Governor Kim Guadagno
NJ Home | Services A to Z | Departments/Agencies | FAQs
Search All of NJ All File Types Submit

State of New Jersey
Department of Health

NJ Health
New Jersey Department of Health

Patient Safety Reporting System

- Patient Safety Home
- Reporting Instructions, Forms & Letters
- Newsletters, Alerts and Reports
- Facility User Guide (Includes Frequently Asked Questions)
- Legislation
- Training Materials
- Resource Links
- Voluntary Anonymous Reporting for Facility Staff
- Contact Us
- Health Care Quality Assessment Home

Select Text Size: A A A

Mandatory Reporting Instructions, Forms & Letters

All events and RCAs must be submitted through the web based reporting system.

New Jersey Department of Health
Patient Safety Initiative
Office of Health Care Quality Assessment
240 W. State Street
11th Floor
Trenton, NJ 08608-1002
Phone: (609) 633.7759
Fax: (609) 984-7707

These documents were created as part of the Department of Health' implementation of the "Patient Safety Act," P.L. 2004, c.9, (N.J.S.A. 26:2H-12.23-12.25) [pdf 19k] Rules (NJAC 8:42 E-10) implementing this act were published at 40 New Jersey Register 1094 (March 3, 2008). Patient Safety reporting began on February 1, 2005, for general hospitals. Psychiatric, Special and Comprehensive Rehabilitation hospitals began reporting on April 1, 2008 and Ambulatory Care Surgery Centers began reporting on October 1, 2008.

Patient Safety Memoranda

- Memo [pdf 324k] from Patient Safety Reporting System, September 7, 2010 to all licensed health care facilities currently reporting to Patient Safety regarding Unstageable Pressure Ulcers.
- Memo from the Commissioner, April 28, 2009 to all licensed assisted living residences, comprehensive personal care homes, assisted living programs, long term care facilities, residential health care facilities attached to another facility type regarding reporting adverse patient safety events effective May 1, 2009. Form available here.
- Memo from the Commissioner, February 27, 2009 to all licensed home health care agencies, hospice care providers, and ambulatory care facilities regarding reporting adverse patient safety events effective April 10, 2009.

Patient Safety Instructions for Licensed Health Care Facilities

- Guidance on Development of a Root Cause Analysis for Patient Safety Reporting, March 2008 [pdf 312k]
- Mandatory Patient Safety Reporting Requirements for Licensed Health Care Facilities (instructions and forms), October 27, 2008 [pdf 307k]
- ASC Guidance, September 9, 2009 [pdf 324k]

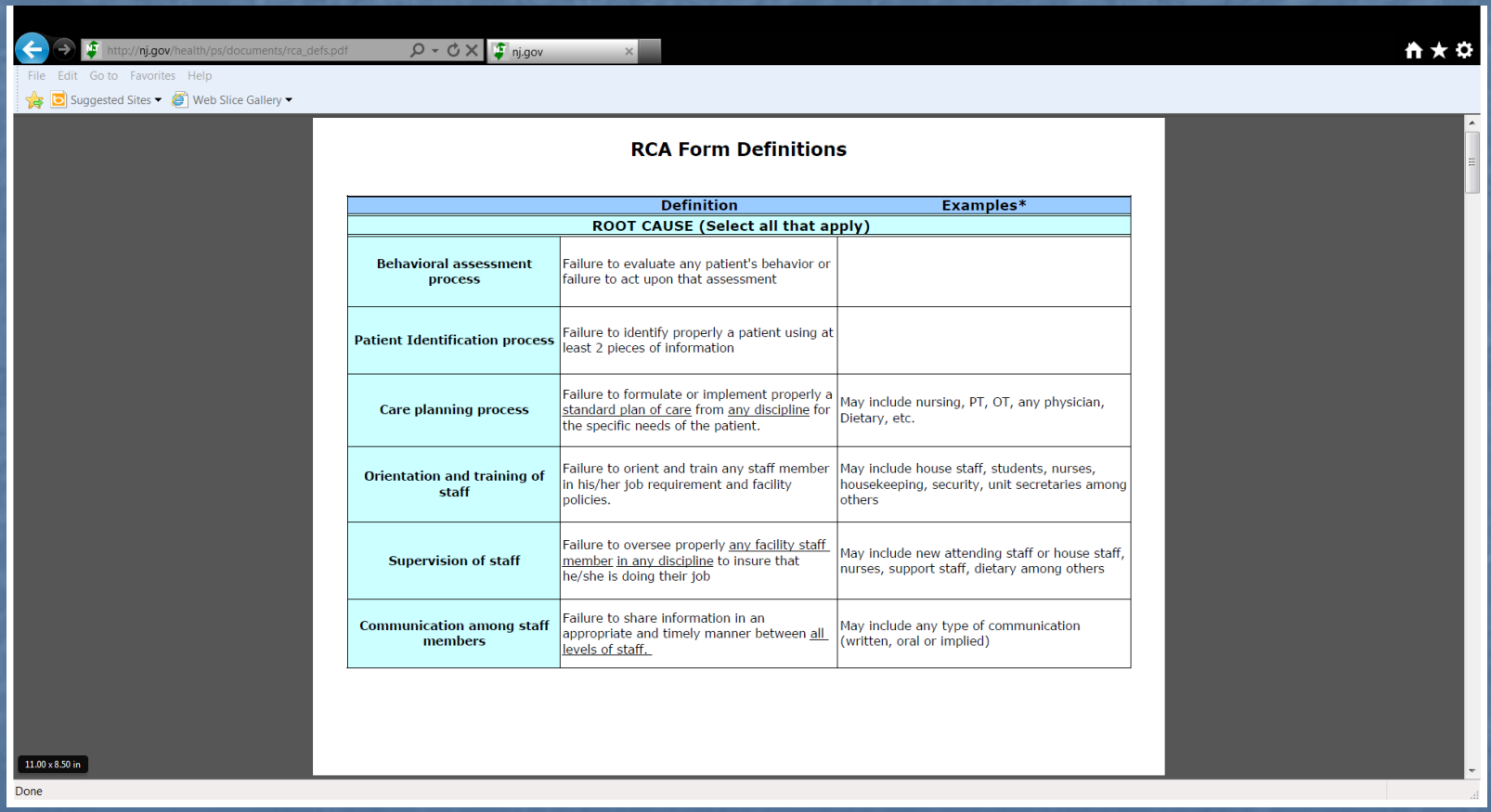
Consensus Definitions for the RCA Form: definitions developed to support the continual efforts to improve patient safety in your facility and to maintain consistency.

- RCA Form Definitions [pdf 26k]

Archived

NJ Health
New Jersey Department of Health

RCA Form Definitions Cont'd



RCA Form Definitions

	Definition	Examples*
ROOT CAUSE (Select all that apply)		
Behavioral assessment process	Failure to evaluate any patient's behavior or failure to act upon that assessment	
Patient Identification process	Failure to identify properly a patient using at least 2 pieces of information	
Care planning process	Failure to formulate or implement properly a standard plan of care from any discipline for the specific needs of the patient.	May include nursing, PT, OT, any physician, Dietary, etc.
Orientation and training of staff	Failure to orient and train any staff member in his/her job requirement and facility policies.	May include house staff, students, nurses, housekeeping, security, unit secretaries among others
Supervision of staff	Failure to oversee properly any facility staff member in any discipline to insure that he/she is doing their job	May include new attending staff or house staff, nurses, support staff, dietary among others
Communication among staff members	Failure to share information in an appropriate and timely manner between all levels of staff.	May include any type of communication (written, oral or implied)

NJ Health
New Jersey Department of Health

Care Planning Process

- Failure to formulate or implement properly a standard plan of care from any discipline for the specific needs of the patient.
- May include nursing, PT, OT, any physician, Dietary, etc.

NJ Health
New Jersey Department of Health

Care Planning Process Cont'd

- May also include the lack of a single, comprehensive and individualized care plan that incorporates aspects of each discipline's care plan
  - Nursing
  - Surgeon
  - Anesthesiologist

Obstacles on the road to the Root Cause

- Motivation
- Resources
- Time
- Safe Environment
- Team Dynamics
- Commitment

NJ Health
New Jersey Department of Health

Root Causes
Common Myths

- Accidental injury
- Policies and procedures in place
- Infection rate lower than national average
- The nurse/tech/physician did not…
- Patient noncompliance/characteristics
- Act of God
- No Root Cause

NJ Health
New Jersey Department of Health

Actions/Prevention Strategies

- Specific, doable and measurable
- Should prevent or decrease future adverse events
- Stronger actions compared to weaker actions
- Permanent actions over temporary actions
- Each root cause may have multiple actions

NJ Health
New Jersey Department of Health

Monitoring

- Describes how the effectiveness of each action will be measured and communicated.
- States what will be monitored, by whom, and for how long.
- Specific for each action

NJ Health
New Jersey Department of Health

Common Pitfalls: Action Plans and Monitoring

- General and unmeasurable actions
  - What are you measuring
- Education or review of policy without observation of implementation
  - Attendance at educational sessions does not demonstrate understanding or a change in behavior

NJ Health
New Jersey Department of Health

Common Pitfalls: Action Plans and Monitoring Cont'd

- Delayed Implementation of Actions
  - New events/injuries not prevented
- Insufficient timeframe for monitoring
  - Compliance wanes over time

NJ Health
New Jersey Department of Health

RCA Review

- Each RCA is reviewed by one or more clinical Reviewers
- Reviewer must understand what occurred
- RCA must include required components
- RCA must be thorough and credible

NJ Health
New Jersey Department of Health

RCA Review Cont'd

- RCA may be closed on initial review with comments
- RCA may be returned for additional information
- RCA must be returned for modification if it does not contain the required components of an RCA

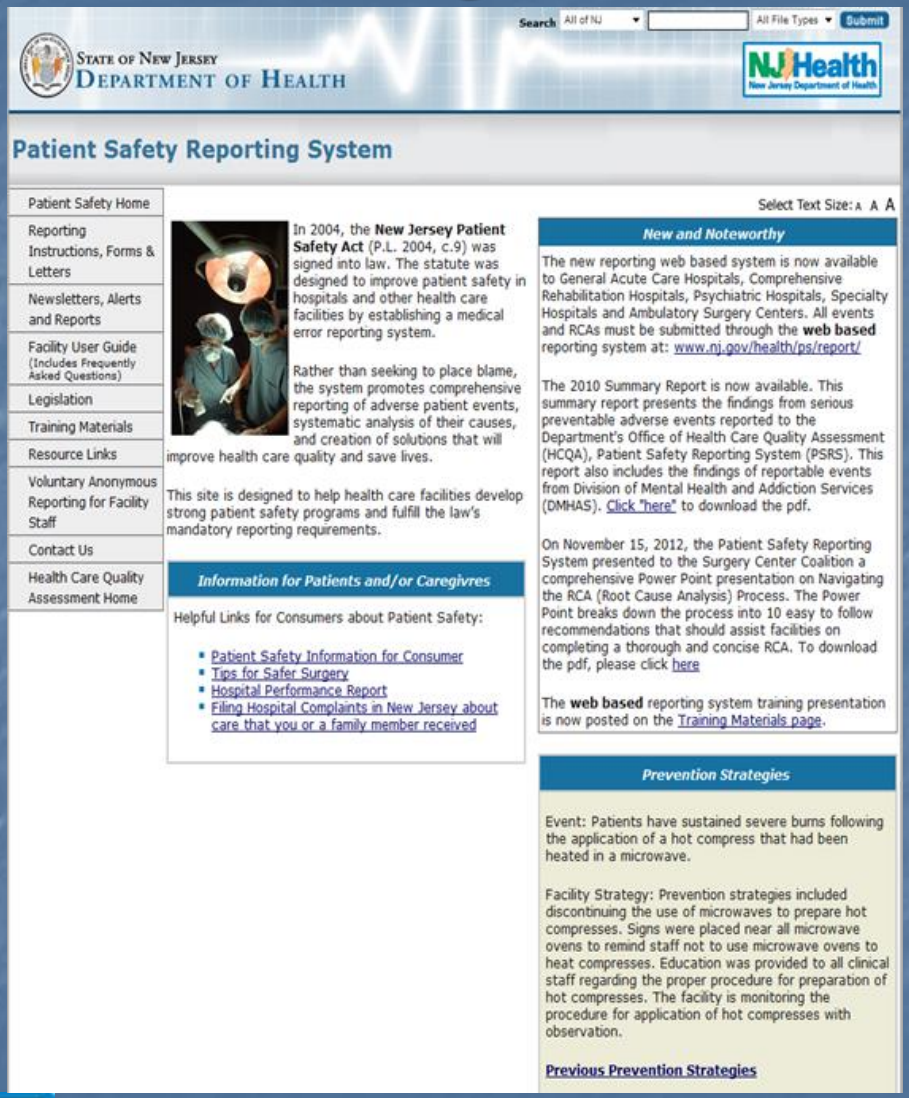
NJ Health
New Jersey Department of Health

Training on the Patient Safety Reporting System

- Familiarity with the system associated with frequency of use
- Staff wear many hats
- Multiple reporting requirements
  - e.g., NHSN
- Staff turnover inevitable

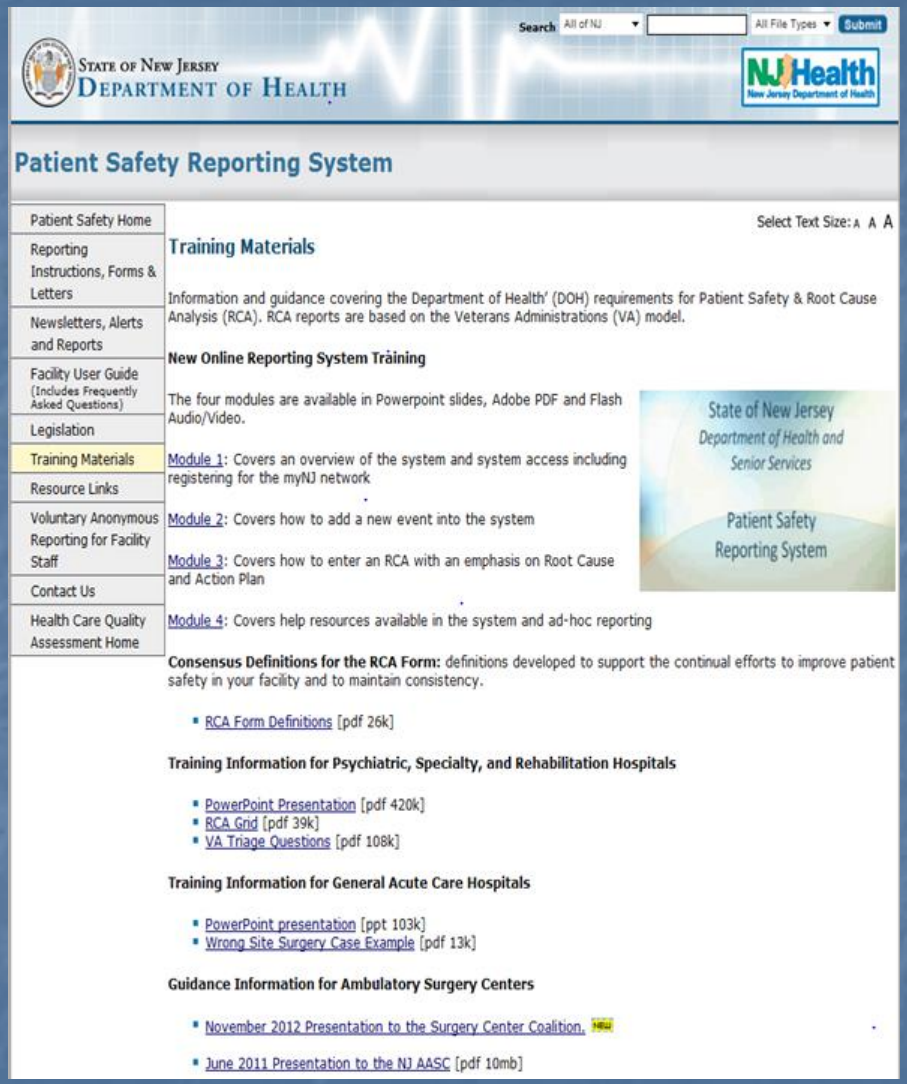
NJ Health
New Jersey Department of Health

Training Cont'd



NJ Health
New Jersey Department of Health

Training Cont'd



State of New Jersey Department of Health

Search All of NJ All File Types Submit

NJ Health New Jersey Department of Health

Patient Safety Reporting System

- Patient Safety Home
- Reporting Instructions, Forms & Letters
- Newsletters, Alerts and Reports
- Facility User Guide (Includes Frequently Asked Questions)
- Legislation
- Training Materials
- Resource Links
- Voluntary Anonymous Reporting for Facility Staff
- Contact Us
- Health Care Quality Assessment Home

Select Text Size: A A A

Training Materials

Information and guidance covering the Department of Health' (DOH) requirements for Patient Safety & Root Cause Analysis (RCA). RCA reports are based on the Veterans Administrations (VA) model.

New Online Reporting System Training

The four modules are available in Powerpoint slides, Adobe PDF and Flash Audio/Video.

State of New Jersey
Department of Health and Senior Services
Patient Safety Reporting System

Module 1: Covers an overview of the system and system access including registering for the myNJ network

Module 2: Covers how to add a new event into the system

Module 3: Covers how to enter an RCA with an emphasis on Root Cause and Action Plan

Module 4: Covers help resources available in the system and ad-hoc reporting

Consensus Definitions for the RCA Form: definitions developed to support the continual efforts to improve patient safety in your facility and to maintain consistency.

- RCA Form Definitions [pdf 26k]

Training Information for Psychiatric, Specialty, and Rehabilitation Hospitals

- PowerPoint Presentation [pdf 420k]
- RCA Grid [pdf 39k]
- VA Triage Questions [pdf 108k]

Training Information for General Acute Care Hospitals

- PowerPoint presentation [ppt 103k]
- Wrong Site Surgery Case Example [pdf 13k]

Guidance Information for Ambulatory Surgery Centers

- November 2012 Presentation to the Surgery Center Coalition. NEW
- June 2011 Presentation to the NJ AASC [pdf 10mb]

NJ Health New Jersey Department of Health

Resources

- NJ Patient Safety Website
  - http://nj.gov/health/ps/index.shtml
- VA National Center for Patient Safety (NCPS)
  - http://www.patientsafety.va.gov/
- AHRQ Patient Safety Network (PSNet)
  - http://psnet.ahrq.gov/
- National Quality Forum
  - http://www.qualityforum.org

NJ Health
New Jersey Department of Health

PSRS Contact Information

- PSRS Telephone: 609-633-7759
- PSRS Website **http://nj.gov/health/ps**

- PSRS Staff:
  - **Mary Noble, MD, MPH,** ***Clinical Director***
    - **Mary.Noble@doh.state.nj.us**
  - **Sara Day, RN, BSN, CPM,** ***Supervising Health Care Evaluator***
    - **Sara.Day@doh.state.nj.us**
  - **Regina Smith, RN, BSN, MA,** ***Health Science Specialist***
    - **Regina.Smith@doh.state.nj.us**
  - **Eva Besserman, DO, MBA, FCCM,** ***Clinical Consultant***
    - **Eva.Besserman@doh.state.nj.us**
  - **Adan Olmeda,** ***Administrative Support***
    - **Adan.Olmeda@doh.state.nj.us**

NJ Health
New Jersey Department of Health

In Perspective

- The significant problems we face cannot be solved at the same level of thinking we were at when we created them

–Albert Einstein (attributed)
US (German-born) physicist (1879 - 1955)

NJ Health
New Jersey Department of Health

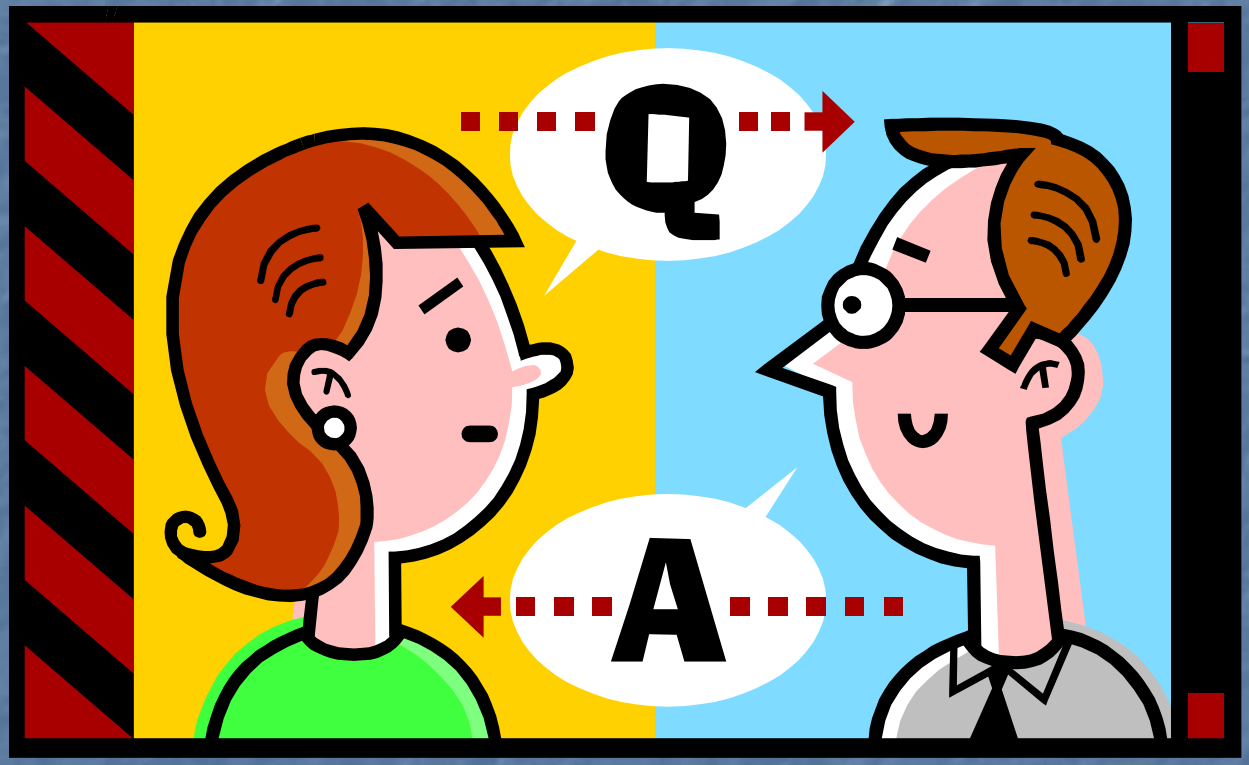
Insanity

Doing the same thing over and over again
And expecting different results.

–Albert Einstein (attributed)
US (German-born) physicist (1879 - 1955)

NJ Health
New Jersey Department of Health

Discussion and Questions



NJ Health
New Jersey Department of Health