The Patient Safety Act
Reporting and RCA Requirements

Patient Safety Initiative
Health Care Quality Assessment
NJ Department of Health and Senior Services
Goals for Workshop Today

- Review legislation and rules
- Review implementation of reporting system
- Review reportable events/reporting process
- Review RCA development requirements
- Review Example of a falls RCA
GOALS FOR LEGISLATION

• Strengthen patient safety
• Promote a systematic analysis
• Emphasize confidentiality
• Sets up reporting system
Legislative Requirements

- Patient Safety Plans
- Patient Safety Committee
- Inform patient
- Mandatory reporting of serious preventable events
- Anonymous voluntary reporting of less serious events
Implementation: Mandatory Reporting

• Acute care hospitals in February 2005

• Other types of hospitals in April 2008

• Phase in for all licensed facilities
New Approach to Reporting

- An error viewed as a systems issue
- Facility examines system and corrects
- Not restricted to enforcing regulations
- Submit RCA including monitoring plan
Confidentiality

• Major component of system
• Protections for facility deliberations under Patient Safety Committee
• Protection of reports to DHSS
• Different from earlier reporting system
• Different from DHSS response for complaints
How Will Information be Used?

• Facility review of events & RCA
• DHSS review of events & RCA
• Summary of reports
• Newsletters and Alerts
• Work with facilities
**Event Reporting**

- Definition of a reportable event
- Types of events to report
- Time frame: 5 business days
- Continuation of other reporting
Process for Reviewing Event Reports/RCAs

- Using forms and fax to report
- Review each form submitted
- May ask for additional information
- Confirm receipt of event form
- RCA due in 45 calendar days
- Also confirm receipt of RCA
- Review RCA—may ask questions
- Confirm that RCA is accepted
Reporting Form Issues

• Download forms:
  www.NJ.gov/health/ps
• “Brief Event Description” (question 2)
• “Incident Date and Date Discovered” (question 2)
• “How was event discovered” (question 3)
• The patient safety liaison
NQF Reporting Categories

- Care Management
- Environmental
- Product or Device
- Surgery-Related
- Patient Protection
The RCA Process

RCA 101
Culture of Safety

An organization’s commitment to patient safety as a top-level priority.
Culture of Safety

• Acknowledgment of high-risk, error-prone nature of organization’s activities
• Blame-free environment
• Expectation of collaboration across ranks
• Willingness to direct resources to address safety concerns

AHRQ
Culture of Safety
RCA Process

*Emphasis* on improving and redesigning systems and processes

Emphasis is *not* on individual performance

VA NCPS
Root Cause Analysis (RCA)

- A process to identify the basic or contributing causal factors that underlie variations in performance associated with Adverse Events

- A specific type of focused review

- A tool for identifying prevention strategies

VA NCPS
RCA Goals

- Identify *what* happened
- Identify *why* it happened
- Identify *how* to prevent recurrence
RCA Team

- Ad hoc under Patient Safety Committee

- Interdisciplinary & diverse
  - Staff knowledgeable about processes involved in the event
  - Front line staff
  - Staff involved in event (?)

- Commitment to RCA process
RCA Components

1. Facts of Event
2. Causality Statements
3. Action Plan
4. Monitoring
Component 1: Facts of Event

- Patient history *related to event*
- Chronological order
- Specific details of event
  - *date, time, location*
- Effect on patient
- Identify staff by title
- Similar event in the past 3 years
Case Example

Narrative

68 y.o. obese female, recently widowed, hard of hearing, history of TBI, HTN, asthma, fall with S/P ORIF, depression with suicide attempt


On 5/28/08, patient diagnosed with UTI. At 2 PM. Patient received dose of Bactrim. At 4 PM, patient complained of flushing, pruritis and chest tightness. During Nursing assessment, patient became severely SOB and then unresponsive.

BLS was instituted. Patient was emergently transferred to acute care hospital ED. Patient expired.
Narrative Timeline

- Patient admitted on 5/25/08 at 1800
- Physician phoned verbal orders without read back
- Nurse transcribed incorrect allergy information (Biaxin in place of Bactrim)
- Patient diagnosed with UTI on 5/28/08
- Patient received Bactrim at 1400
- At 1600, patient c/o chest tightness, flushing; became SOB and unresponsive
- BLS initiated and patient was transferred to ED; patient expired
Event Flow Diagram

Nurse Transcribed Incorrect medication → Patient given Incorrect medication → Patient developed anaphylaxis; not recognized → Patient became unresponsive
Component 2: Causality Statements

Most often, a root cause is a known or unknown system vulnerability

Human weakness is almost never a root cause
Identify Root Causes

• Broad review: Areas of Causality

• Narrow analysis to relevant areas

• Focus on most significant areas
Patient identification

• Shared information
  • Assessments, documentation
• Co-worker to co-worker
• Management to front line staff
  • Policies/procedures, technical information
• Staff to patient/family

(Beige paper)
Human Factors Training

- Training program
- Training provided
- Monitored
- Adequate
- Procedures/Equipment
  - Related to staff need, experience, work space

(Pink paper)
Human Factors
Fatigue/Scheduling

- Environmental conditions
- Environmental stressors
- Adequate sleep
  - Scheduling issues
- Staff to workload ratio
- Level of automation

(Yellow paper)
Environment Equipment

- Environment appropriate to function
- Environmental risk assessment
- Environment stress levels
- Equipment design
- Equipment maintenance program
- Safely evaluations/reviews
- Codes/specifications/regulations

(Green paper)
Rules/Policies/Procedures

- Risk management plan
- Quality control system
- Prior audit, results & interventions
- Facility’s mission, expertise & services
- Qualifications/training/orientation
- Up-to-date policies & procedures
  - Functional
  - Obstacles
(Purple paper)
Barriers

- Design of barriers
  - Patients, staff, equipment, environment
  - Patient risk
- Were barriers in place
  - Prevention of event
- Maintenance
- Pre-implementation testing

(Blue paper)
Identify Root Causes

• Ask *why, why, why* event occurred

• Use answers to focus on areas of causality

• *Beware of hindsight bias*
Event Flow Diagram Revisited

Patient hard of hearing (Bactrim vs Biaxin)

Nurse Transcribed Incorrect medication

Patient given Incorrect medication

Patient developed anaphylaxis; not recognized

Patient became unresponsive

No read back

Nurses station busy when orders phoned

Another patient recently treated with Biaxin

Nurse unfamiliar with S/S anaphylaxis

Patient with Hx asthma

35
Area of Causality Example

- Human Factors-Communication
- Human Factors-Training
- Human Factors-Fatigue/Scheduling
- Environment/Equipment
- Rules/Policies/Procedures
- Barriers
5 Rules of Causation

- Must clearly show “cause and effect”
- Avoid negative descriptions
- Human error must have a preceding cause
  - System cause of the error
- Violations of procedure must have a preceding cause
  - Positive & negative incentives
- Failure to act only if pre-existing duty
Causality Statement

[Something] increased the likelihood of [something] happening, which led to the adverse event
Causality Statement #1
The practice of providing verbal admissions orders increased the probability that the nurse would transcribe the incorrect allergy information, which increased the probability that the patient would receive the wrong medication.
Component 3: Action Plan

• Addresses the root causes

• Specific and concrete

• Doable

• Consult process owners
Levels of Action Plans

- Weaker actions
- Intermediate actions
- Stronger actions
Action Plan

• Examine each causal statement & create action plans for each
• Specific and concrete
• Action plans should prevent or decrease the possibility of future adverse events
  • Decrease the injury if the event occurs.
• Identify stronger compared to weaker actions.
• Choose permanent over temporary actions.
The practice of providing verbal admissions orders increased the probability that the nurse would transcribe the incorrect allergy information, which increased the probability that the patient would receive the wrong medication.
Action Plan for Causal Statement #1
Action Plan #1
Weaker

• The Nursing Managers will issue a memorandum alerting all nursing staff to this issue by 7/15/08.
Action Plan #2
STRONGER

• By 7/1/08, all Admission Orders, including allergy information, will be entered into the computer by the physician.
Action Plans

• Weaker ➔ Memo
• Intermediate ➔ Remove LASA meds
• Stronger ➔ Direct order entry
Review Action Plans

- Do these actions address the cause?
- Will they prevent or reduce the probability of future events?
- Are actions doable?
Component 4: Monitoring

- Outcome measures
  - Assess the action’s effect to prevent/minimize additional events
- Specific
- Quantifiable
- Timeframe
Monitoring for Action Plan

#2
Monitoring for Action Plan

#2

• The Performance Improvement Nurse Manager will review 15 charts per week for compliance for 3 months.
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)
Psychological Perspective

Insanity:

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

—Albert Einstein, (attributed)
US (German-born) physicist (1879 - 1955)
PRACTICE SESSION

From Adverse Event Report

To

Root Cause Analysis Report
Serious Preventable Adverse Event

Serious
Preventable
Adverse
Event
New Jersey Department of Health and Senior Services

REPORT OF SERIOUS PREVENTABLE ADVERSE EVENT IN A NEW JERSEY LICENSED HEALTH CARE FACILITY

This form must be completed for any serious preventable adverse event, which results in death or loss of a body part, or disability or loss of bodily function lasting more than seven (7) days or present at discharge. All information is protected based on the provisions of the Patient Safety Act (N.J.S.A. 26:24H-13.20).

In is a revision of an earlier report to the Patient Safety Initiative for the same event? □ Yes □ No
If yes, give DOHSS Report Number:
Facility Internal Tracking Number of this incident, if known:

SECTION A - GENERAL INFORMATION

1. FACILITY IDENTIFICATION
Facility Name: __________________________ Facility License No.: __________________________
Facility Street Address: __________________________ County: __________________________
City: __________________________ State: __________________________ Zip Code: __________________________
Name of Person Submitting: __________________________ Telephone No.: __________________________
Title or Position: __________________________ Fax No.: __________________________
Email Address: __________________________

2. PLEASE SUPPLY A SIMPLE AND CLEAR DESCRIPTION OF THE EVENT OR SITUATION YOU ARE REPORTING:

Incident Information:
Incident Date: __________________________ Time: __________________________ □ AM □ PM
Date Discovered: __________________________ Time: __________________________ □ AM □ PM

3. HOW WAS EVENT DISCOVERED? (Check only one)
1. Report by staff/physician
2. Report by family/visitor
3. Report by patient/resident
4. Assessment of patient/resident after event
5. Review of chart/record
6. Other: __________________________

4. PATIENT/RESIDENT INFORMATION
□ Inpatient or □ Outpatient
Admission through: □ ED □ Direct □ Transfer from Acute Care General Hospital □ Transfer from LTC
Patient/Resident Billing Number: __________________________
Patient/Resident Name: __________________________ Medical Record No.: __________________________
Street Address: __________________________ City: __________________________ State: __________________________ Zip Code: __________________________
Date of Birth: __________________________ Gender: __________________________
Admission Date or Date of Ambulatory Encounter: __________________________
Primary Diagnosis: __________________________
Race: □ Caucasian □ Amer. Indian/Alaskan Native □ Native Hawaiian/Pacific Islander □ Other:
□ Black □ Asian □ Unable to Determine
Ethnicity: □ Non-Hispanic/Unable to Determine □ Hispanic

Must Be Reported Within 5 Business days!
### B. EVENT DETAILS

#### 5. TYPES OF SERIOUS PREVENTABLE ADVERSE EVENTS (Check only one)

- **A. CARE MANAGEMENT EVENTS in a Health Care Facility**
  - 1. Patient/resident death/harm due to a medication error
  - 2. Patient/resident death/harm due to a hemolytic reaction due to the administration of ABO-incompatible blood or blood products
  - 3. Maternal death/harm due to labor delivery in a low-risk pregnancy
  - 4. Patient/resident death/harm due to hypoglycemia
  - 5. Patient/resident death/harm due to failure to identify and treat hyperbilirubinemia in neonates
  - 6. Stage 3 or 4 pressure ulcers acquired after admission
  - 7. Patient/resident death/harm due to spinal manipulative therapy
  - 8. Other event causing patient/resident death or harm that lasts seven days or is present at discharge

- **B. ENVIRONMENTAL EVENTS in a Health Care Facility**
  - 1. Patient/resident death/harm due to an electric shock
  - 2. Any event in which a line designated for oxygen/other gas to be delivered to a patient/resident contains the wrong gas or is contaminated by toxic substances
  - 3. Patient/resident death/harm due to a burn incurred from any source
  - 4. Patient/resident death/harm due to a fall
  - 5. Patient/resident death/harm due to the use of restraints or bedrails
  - 6. Other event causing patient/resident death or harm that lasts seven days or is present at discharge

- **C. PRODUCT OR DEVICE EVENTS in a Health Care Facility**
  - 1. Patient/resident death/harm due to the use of contaminated drugs/devices/biologicals
  - 2. Patient/resident death/harm due to the dysfunction of a device in patient/resident care in which the device is used/functions other than as intended
  - 3. Patient/resident death/harm due to intravascular air embolism
  - 4. Patient/resident death/harm due to the use of a single-use device in which the device is used/functions other than as intended
    - new single-use device
    - reprocessed single-use device
  - 5. Other event causing patient/resident death or harm that lasts seven days or is present at discharge

- **D. SURGERY-RELATED EVENTS**
  - 1. Surgery performed on the wrong body part
  - 2. Surgery performed on the wrong patient
  - 3. Wrong surgical procedure performed on a patient
  - 4. Retention of a foreign object in a patient after surgery or other procedure
  - 5. Intraoperative or immediately post-operative cardiac or death in an ASA Class 1 patient or ASA Class same day surgery patient or outpatient
  - 6. Other event causing patient death or harm that lasts seven days or is present at discharge

- **E. PATIENT/RESIDENT PROTECTION EVENTS in a Health Care Facility**
  - 1. Infant discharged to the wrong person
  - 2. Patient/resident death/harm due to patient allopment
  - 3. Patient/resident suicide/attempted suicide
  - 4. Other event causing patient/resident death or harm that lasts seven days or is present at discharge
ACTIONS FOR THE PATIENT
NJDHSS Reporting Initiative

• Reports of Preventable Adverse Events began in February, 2005

• Falls with Serious Injury and Pressure Ulcers are the most reported event types for the last two years

<table>
<thead>
<tr>
<th>YEAR</th>
<th>ADVERSE EVENTS</th>
<th>FALLS</th>
<th>PRESSURE ULCERS</th>
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<tbody>
<tr>
<td>2005</td>
<td>376</td>
<td>125</td>
<td>77</td>
</tr>
<tr>
<td>2006</td>
<td>450</td>
<td>165</td>
<td>129</td>
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</table>
Root Cause Analysis

Purpose:

To identify the factor or factors that led to and caused the serious preventable adverse event.

Conducting and writing an RCA is an opportunity to examine how the systems for providing care function.
RCA COMPONENTS

The RCA must have four components:

1) Facts of the Event
2) Causality Statements
3) Prevention Strategies or Actions
4) Monitoring
Component One

FACTS OF THE EVENT
The RCA Team

- Multidisciplinary
- Ad Hoc Members
- Subject Matter Experts
Potential Team Members

- Medical Director
- Director of Psychiatric Medicine
- Director of Nursing
- Performance Improvement
- Risk Management
- Patient Safety Liaison
- Clinical Pharmacist
Potential Team Members

- Nurse Manager of Behavioral Health Unit
- Patient Caregivers (RN, LPN, PCA, Tech)

Other Examples:
- Engineering
- Dietary
- Housekeeping
- Occupational Health and Safety
- Physical Therapy
- Transportation
- Respiratory Therapy
Component Two

Causality Statement
Causality Statement

[Something] increased the likelihood of [something] happening, which led to the adverse event
Searching for Root Causes

The Facts of the Event are reviewed by the entire RCA Team.

Tools such as the NCPS Triage Questions for RCA, a detailed timeline, or a flow diagram/chart may be used to explore potential root causes.
Areas of Causality

• Human Factors – Communication
• Human Factors – Training
• Human Factors – Fatigue/Scheduling
• Environment/Equipment
• Rules/Policies/Procedures
• Barriers
Other Tools

DETAILED TIMELINE
Facts of the Event with specific dates and times

DIAGRAMS
Event Flow Diagram
Intermediate Event Flow Diagram
Final Flow Diagram
Different assessment methodologies may be used for determining root causes but they always involve repeatedly asking “Why”.
Areas of Causality
Causality Statement

Definition

The Causality Statement is a brief, succinct sentence that connects an identified factor with the adverse event.

The Facts of the Event information is used to examine the processes involved in the event in order to identify WHY the event occurred.

WHY the adverse event occurred, the underlying reason(s), is the root cause.
Rules of Causation

• Five Rules

• Designed to improve the RCA Process by minimizing the very real biases we all bring to an investigation

• Create minimum standards for how an RCA investigation and its results should be documented
5 Rules of Causation

Rule 1: Root Cause Statements must clearly show the “cause and effect” relationship.

Rule 2: Negative descriptors are not used in causal statements.

Rule 3: Each human error must have a preceding cause.

Rule 4: Each procedural deviation must have a preceding cause.

Rule 5: Failure to act is only causal when there was a pre-existing duty to act.

-NCPS
Causality Statements

“The lack of (insert the process or system) related to (insert the reason it happened, the root cause) may have led to (name the type of adverse event)”

Examples

“The lack of proper implementation of the Falls Prevention strategies for high risk fall patients, related to the absence of a cross training program for float staff, may have led to the fall with serious injury.”
# Causality Statements

<table>
<thead>
<tr>
<th>Causality Statement</th>
<th>Action or Prevention Strategy</th>
<th>Monitoring</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Cause and Effect Relationship</td>
<td>• Specific, measurable actions, implemented within 45 days of incident, or are currently being implemented</td>
<td>• Includes specific time frames and responsible staff</td>
</tr>
<tr>
<td>• No negative descriptions</td>
<td>• Include time frames, responsible staff</td>
<td>• Need to Confirm actions have taken place</td>
</tr>
<tr>
<td>• Human Errors/Policy Violations- must have a preceding cause</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Procedures deviations</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Failure to Act only Causal if there is pre-existing Duty to Act</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

- Specific, measurable actions, implemented within 45 days of incident, or are currently being implemented
- Include time frames, responsible staff
- Need to Confirm actions have taken place
Component Three

Actions/Prevention Strategies
Prevention strategies or actions describe what will be done to address an identified root cause.

- Root cause may have more than one action in the action plan
- Action(s) should be clearly defined, measurable, and relate to a specific root cause
- Specified time frames for implementation and a designated person responsible for implementation should be stated
**Actions/Prevention Strategies**

- Actions should prevent or decrease the possibility of future adverse events
- Implement stronger actions, if possible, as compared to weaker actions
- Implement permanent actions over temporary actions, if possible
# Actions/Prevention Strategies

<table>
<thead>
<tr>
<th>Causality Statement</th>
<th>Action or Prevention Strategy</th>
<th>Monitoring</th>
</tr>
</thead>
</table>
| - Cause and Effect Relationship  
- No negative descriptions  
- Human Errors/Policy Violations- must have a preceding cause  
- Procedures deviations  
- Failure to Act only Causal if there is pre-existing Duty to Act | - Specific, measurable actions, implemented within 45 days of incident, or are currently being implemented  
- Include time frames, responsible staff | - Includes specific time frames and responsible staff  
- Need to Confirm actions have taken place |
Component four

Monitoring
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
## Monitoring

### Causality Statement
- Cause and Effect Relationship
- No negative descriptions
- Human Errors/Policy Violations - must have a preceding cause
- Procedures deviations
- Failure to Act only Causal if there is pre-existing Duty to Act

### Action or Prevention Strategy
- Specific, measurable actions, implemented within 45 days of incident, or are currently being implemented
- Include time frames, responsible staff

### Monitoring
- Includes specific time frames and responsible staff
- Need to Confirm actions have taken place
### Section A - General Information

<table>
<thead>
<tr>
<th>Field</th>
<th>Details</th>
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</thead>
<tbody>
<tr>
<td>Facility Name</td>
<td>Facility License No.</td>
</tr>
<tr>
<td>Facility Street Address</td>
<td>County</td>
</tr>
<tr>
<td>City</td>
<td>State</td>
</tr>
<tr>
<td>Zip Code</td>
<td>Telephone No.</td>
</tr>
<tr>
<td>Name of Person Submitting</td>
<td>Title or Position</td>
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<tr>
<td>Fax No.</td>
<td>Email Address</td>
</tr>
</tbody>
</table>

### Section B - Incident Information

<table>
<thead>
<tr>
<th>Field</th>
<th>Details</th>
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</thead>
<tbody>
<tr>
<td>Incident Date Date/Initial Report Date</td>
<td>DMSS Report Number</td>
</tr>
<tr>
<td>Time</td>
<td>Patient Safety Initiative: Assigned by DMSS</td>
</tr>
<tr>
<td>Medical Record Number</td>
<td>Patient/Resident Billing Number</td>
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### Section C - Root Cause Analysis

<table>
<thead>
<tr>
<th>Field</th>
<th>Details</th>
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<tbody>
<tr>
<td>Behavioral assessment process</td>
<td>Physical assessment process</td>
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<tr>
<td>Patient Identification process</td>
<td>Patient observation procedures</td>
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<tr>
<td>Care planning process</td>
<td>Staffing levels</td>
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<tr>
<td>Orientation &amp; training of staff</td>
<td>Competency assessment/credentialing</td>
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<tr>
<td>Supervision of staff</td>
<td>Communication with patient/family</td>
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<tr>
<td>Communication among staff members</td>
<td>Availability of information</td>
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<tr>
<td>Adequacy of technical support</td>
<td>Equipment maintenance/management</td>
</tr>
<tr>
<td>Physical environment</td>
<td>Security systems and processes</td>
</tr>
<tr>
<td>Control of medications (storage/access)</td>
<td>Labeling of medications</td>
</tr>
<tr>
<td>Other</td>
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</table>

### Section D - Impact of Event for Patient/Resident

<table>
<thead>
<tr>
<th>Field</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Loss of libido</td>
<td>Additional patient monitoring in current location</td>
</tr>
<tr>
<td>Loss of dexterity</td>
<td>Transfer to more intensive level of care</td>
</tr>
<tr>
<td>Loss of ability to eat</td>
<td>Increased length of stay</td>
</tr>
<tr>
<td>Loss of bowel function</td>
<td>Minor surgery</td>
</tr>
<tr>
<td>Loss of sensory function</td>
<td>Major surgery</td>
</tr>
<tr>
<td>Loss of bodily function</td>
<td>System or processes delay care to a patient</td>
</tr>
<tr>
<td>Disability - physical or mental impairment</td>
<td>To be determined</td>
</tr>
<tr>
<td>Other additional diagnostic tests</td>
<td></td>
</tr>
</tbody>
</table>

### Note

- 45 Calendar Days
- Form must be completed for any serious preventable adverse event, which results in death or loss of a body part, or disability or loss of bodily function lasting more than seven (7) days or present at discharge.
Contacts

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Support Materials

• NJ Patient Safety web site:  
  http://nj.gov/health/ps/

• Institute for HealthCare Improvement (IHI)  
  http://www.ihi.org/ihi

• National Center for Patient Safety (NCPS)  
  www.patientsafety.gov/tools/html

• AHRQ Patient Safety Network (PSNet)  
  http://psnet.ahrq.gov/