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 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





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







Identify what happened

Identify why it happened

Identify *how* to prevent recurrence

VA NCPS



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

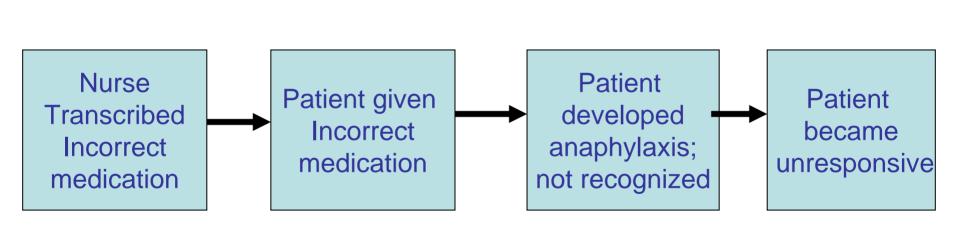
- 68 y.o. obese female, recently widowed, hard of hearing, history of TBI, HTN, asthma, fall with S/P ORIF, depression with suicide attempt
- Admitted for follow-up care on 5/25/08. Verbal Admitting orders. Nurse transcribed incorrect allergy (Biaxin in place of Bactrim).
- On 5/28/08, patient diagnosed 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





COMPONENT 2: CAUSALITY STATEMENTS

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

Human weakness is almost never a root cause

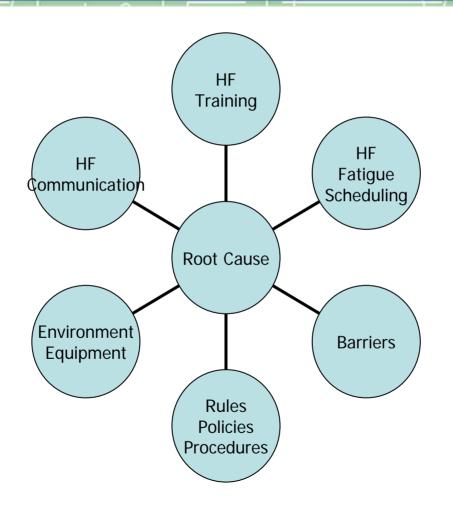


IDENTIFY ROOT CAUSES

- Broad review: Areas of Causality
- Narrow analysis to relevant areas
- Focus on most significant areas



AREAS OF CAUSALITY





HUMAN FACTORS COMMUNICATION

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

(Peurple paper)



BARRIERS

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



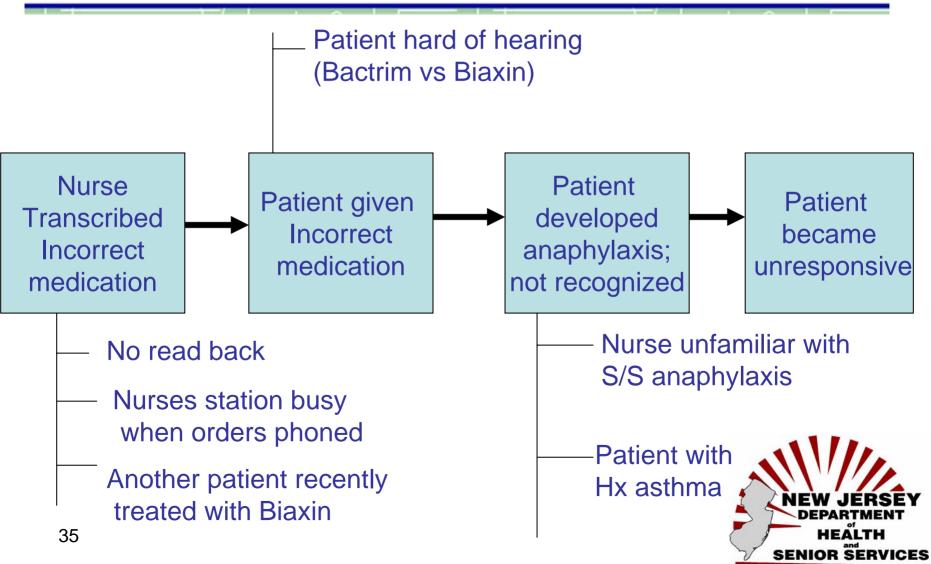
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IDENTIFY ROOT CAUSES

- Ask why, why, why event occurred
- Use answers to focus on areas of causality
- Beware of hindsight bias



EVENT FLOW DIAGRAM REVISITED



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



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.



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.



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
- 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.



IN PERSPECTIVE

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

–<u>Albert Einstein</u>, (attributed) US (German-born) physicist (1879 - 1955)



PSYCHOLOGICAL PERSPECTIVE

Insanity:

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

–<u>Albert Einstein</u>, (attributed) US (German-born) physicist (1879 - 1955)



PRACTICE SESSION

From Adverse Event Report



Root Cause Analysis Report



SERIOUS PREVENTABLE ADVERSE EVENT



PREVENTABLE

ADVERSE





New Jercey Department of Health and Senior Services

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

NUDHSS INTERNAL USE ONLY



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 leating 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. 20:2H-12:25()]

Is this a revision of an earlier report to the Patient Safety initiative for the same event?	Facility Internal Tracking Number of this incident, if known:
Yes No	

SECTION A - GENERAL INFORMATION				
1. FACILITY IDENTIFICATION				
Facility Name:	Facility License No.:			
Facility Street Address:	County:			
City:	State: Zip Code:			
Name of Person Submitting				
Title or Position:	Fex No.:			
Email Address:				
2. PLEASE SUPPLY A SIMPLE AND CLEAR DESC	RIPTION OF THE EVENT OR SITUATION YOU ARE REPORTING:			
Incident Information:				
Incident Date:				
Date Discovered:	Time: AM PM			
3. HOW WAS EVENT DISCOVERED? (Check only 1. Report by staffphysician	4. Assessment of patient/resident after event.			
2. Report by family/visitor 3. Report by patient/resident	 5. Review of chart/record 6. Other: 			
Patient/Resident Billing Number:				
	Medical Record No.:			
	County:			
	State: Zip Code:			
Admission Date of Ambulatory Encounter.				
Primary Diagnosis:				
Race:				
Caucasian Amer. Indian/Alaskan Nath	ive Intervalian/Pacific Islander Other:			
Ethnicity: Non-Hispanic/Unable to De	etermine Hispanic			



New Jercey Department of Health and Senior Services REPORT OF SERIOUS PREVENTABLE ADVERSE EVENT IN A NEW JERSEY LICENSED HEALTH CARE FACILITY Continued

NJDHSS INTERNAL USE ONLY Report No.

SECTION B - EVENT DETAILS

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

- A. CARE MANAGEMENT EVENTS in a Health Care Facility
- 1. Patient/vesident death/harm due to a medication error
- 2. Patient/resident death/harm due to a hemolytic reaction due to the administration of ABC-incompatible blood or blood products.
- 3. Maternal death/harm due to labor/delivery in a low-risk pregnancy
- 4. Patient/vesident death/harm due to hypoglycemia.
- 5. Patient/valident death/harm due to failure to identify and treat hyperbilinubinemia in reonates
- 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/hesident confains the wrong gas or is contaminated by toxic substances
 - 3. Patient/vesident death/harm due to a burn incurred from any source
 - 4. Patient/resident death/harm due to a fail
 - 5. Patient/resident death/harm due to the use of restraints or bedrails
 - 6. Other event causing patient/teoident death or harm that lasts seven days or is present at discharge

- C. PRODUCT OR DEVICE EVENTS in a Health Care Facility
 - Patient/resident death/harm due to the use of contaminated drugs/devices/biologics
- 2. Patient/resident death/harm due to the use/function of a device in patient/resident care in which the device is used/functions other than as intended
- 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 interded.
 - 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
- Surgery performed on the wrong body part.
- 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 come or death in an ASA Class I inpatient or <u>any</u> 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
- Infant discharged to the wrong person
- 2. Patient/resident dealty/harm due to patient elopement.
- 3. Patient/resident suickle/attempted suicide
- 4. Other event causing patient/resident death or harm that lasts seven days or is present at discharge

Adopted from The National Quality Forum

NEVER EVENTS



	New Jercey Department of Health and Senior Services REPORT OF SERIOUS PREVENTABLE ADVERSE EVENT IN A NEW JERSEY LICENSED HEALTH CARE FACILITY Continued	NJDHSS INTERNAL USE ONLY Report No.	
	6. IF <u>5.A.1</u> WAS SELECTED, COMPLETE THIS SECTION: What type of medication error occurred? (<i>Obeck all that apply</i>) Whong Datient Wrong Dose Wrong Route Wrong Frequency Wrong Time Combation Administration After Order Discontinued/Expired Wrong Diluent/Concentration/Dosage Form Monitoring Error Other:		
	BrandProduct Name (If Applicable): Genetic Name: 7. WHERE WAS THE PATIENT/RESIDENT WHEN THE EVENT OCCURRED? (Check only one) Patient/Resident Room Emergency Department Radiology Laboratory Coperating Room Cardiac Catheterization Laboratory		
	Labor and Delivery Nursery Recovery Room Rehabilitation Areas In Transit ICU / CCU / TCU Step Down Unit Telemetry Unit NICU Haltway or Other Common Area Other:		
ACTIONS	DIATE CORRECTIVE ACTION(S) TAKEN:		
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PATIENT			NEW JERSEY
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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

YEAR	ADVERSE EVENTS	FALLS	PRESSURE
2005	376	125	77
2006	450	165	129



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

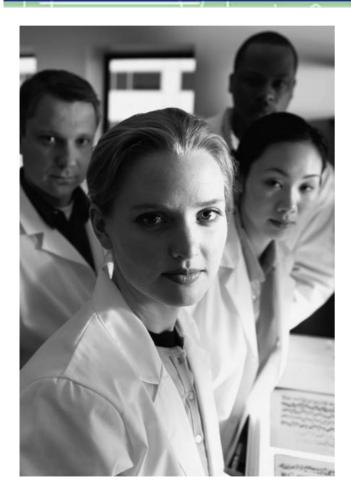


COMPONENT ONE

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





CAUSALITY STATEMENT



CAUSALITY STATEMENT

[*Something*] increased the likelihood of [*something*] happening, which led to the adverse event



SEARCHING FOR ROOT CAUSES



Tools such as the NCPS Triage Questio 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



Methodologies

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 preexisting 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

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
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HEALTH

SENIOR SERVICES



Actions/Prevention Strategies



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

Ausality 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

HEALTH SENIOR SERVICES



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	Action or Prevention Strategy • Specific, measurable actions, implemented	Monitoring Includes specific time frames and
No negative descriptions Human Errors/Policy Violations- must have preceding cause Procedures deviations Failure to Act only Causal if there is pre- xisting Duty to Act	within 45 days of incident, or are currently being implemented •Include time frames, responsible staff	responsible staff •Need to Confirm actions have taken place
85	1	

SENIOR SERVICES

New Jercey Department of Health and Senior Services

REPORT OF SERIOUS PREVENTABLE ADVERSE EVENT IN A NEW JERSEY LICENSED HEALTH CARE FACILITY: ROOT CAUSE ANALYSIS (RCA)

This form must be completed for any serious preventable adverse event, which results in death or loss of a body part, or disability or ioss 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 ML 3 S. 26 20-12 25/01

SEC	TION A - GENERAL INFORMATIO	DN		
1. FACILITY IDENTIFICATION				
Facility Name:	Facility	License No.:		
Facility Street Address:				
City:				
Name of Person Submitting				
	Fax No.:			
Email Address:				
8EC	TION B - INCIDENT INFORMATIO	DN .		
2. INCIDENT DATE:	Time:			
Date Initial Report Sent	DHSS Report Number			
	to Pallent Safety initiative: (Assigned by DHSS):			
Medical Record Number:	Patient/Realdent Billing	g Number:		
Patien/Resident Name:				
8EC	TION C - ROOT CAUSE ANALYS	18		
3. SELECT ROOT CAUSE (Select all that apply	\$			
Behavioral assessment process	Physical assessment process			
Patient identification process	Patient observation procedures			
Care planning process	Statting levels			
Orientation & training of staff	Competency assessment/credentialing			
Supervision of staff	Communication with patient/family			
Communication among staff members	Availability of information			
Adequacy of technical support	Equipment maintenance/management			
Physical environment	Seculty systems and processes			
Control of medications (Storage/access)	Labeling of medications			
Other				

New Jercey Department of Health and Senior Services REPORT OF SERIOUS PREVENTABLE ADVERSE EVENT IN A NEW JERSEY LICENSED HEALTH CARE FACILITY: ROOT CAUSE ANALYSIS (RCA) (Continued)

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Page 2 of 2 Pages.

Report No.

4. WHAT WERE THE CONTRIBUTING FACTORS TO EVE	ENT (Select all that apply):		
Team factors	Work environment		
Task factors	Staff factors		
Patient characteristics	Organizational/management		
Medical Device	Medications		
Procedures	Transportation		
Equipment	Home Care		
Patient record documentation	Imaging and X-rays		□Imaging and X-rays
Laboratory and diagnostics	Other (Specify):		
5. EVALUATE IMPACT OF EVENT FOR PATIENT/RESID	ENT (Select all that apply):		
Loss of limb(s)	Additional patient monitoring in current location		
Loss of digits)	Visit to Emergency Department		
Loss of body part(s)	Hospital admission		
Loss of organ(s)	☐ Transfer to more intensive level of care ☐ Increased length of stary ☐ Minor surgery ☐ Major surgery ☐ System or processes datay care to a patient.		
Loss of sensory function(s)			
Loss of bodily function(s)			
Disability - physical or mental impairment			
Additional laboratory testing or diagnostic imaging			
Other additional diagnostic testing	To be determined		
Other (Specify):	Death		
6. DESCRIBE ROOT CAUSE ANALYSIS: (Allach the RCA.)			
	1.5		
Calendar			

OCT 08

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SUPPORT MATERIALS

- NJ Patient Safety web site: <u>http://nj.gov/health/ps/</u>
- Institute for HealthCare Improvement (IHI) <u>http://www.ihi.org/ihi</u>
- National Center for Patient Safety (NCPS) <u>www.patientsafety.gov/tools/html</u>
- AHRQ Patient Safety Network (PSNet) <u>http://psnet.ahrq.gov/</u>

