The New Jersey Patient Safety Act And Reporting Process

Patient Safety Reporting System

End Stage Renal Disease Facility
Training Webinar
March 21, 2019

Patient Safety Reporting System

The Presentation will Review

1. **Patient Safety Act and Reporting Requirements**
2. **Adverse Event Reporting Process**
3. **Root Cause Analysis Reporting Process**
4. **Questions???**

1. The Patient Safety Act and Reporting Requirements

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**

* Link available on the NJ Patient Safety website

1. The Patient Safety Act and Reporting Requirements

Patient Safety Act *continued*

- **Adverse events are inherent in all systems**
- **The great majority of medical errors result from systems problems**
  - **Not individual incompetence**
- **Well designed systems have processes to**
  - **Minimize errors**
  - **Detect those that occur**
  - **Incorporate mechanisms to continually improve performance**

1. The Patient Safety Act and Reporting Requirements

Patient Safety Act *continued*

- **The goal is to craft a health care delivery system that minimizes, to the greatest extent feasible, the harm to patients from the delivery system itself**

- **An important component is a feedback mechanism that allows detection and analysis of adverse events and near misses**

1. The Patient Safety Act and Reporting Requirements

Patient Safety Act *continued*

- **Promotes a Non-Punitive Culture**
  - **Focuses on improving processes rather than assigning blame**
  - **Promotes accountability**
  - **Promotes exchange of information**
  - **Encourages disclosure**
  - **No public reports are issued by PSRS that list individual facilities**

1. The Patient Safety Act and Reporting Requirements

Patient Safety Act *continued*

- **Provides Confidentiality Protection**
  - **Encourages honest, critical self-analysis**
  - **Restricts**
    - **Discoverability**
    - **Admissibility**
    - **Disclosure of documents, materials and information**

Be clear about separation between Patient Safety and Quality Improvement activities

1. The Patient Safety Act and Reporting Requirements

Patient Safety Act *continued*

- **Promotes a culture of safety and includes**
  - **A process to conduct ongoing analysis and application of evidence based patient safety practices**
  - **A process to conduct analyses of serious preventable events, adverse events and near misses**
  - **A process for provision of ongoing patient safety training for facility personnel**

1. The Patient Safety Act and Reporting Requirements

Patient Safety Act *continued*

NJ Licensed healthcare facilities (including ESRD centers) must report every serious preventable adverse event

- A negative consequence of care that results in unintended injury or illness
- Discrete, auditable and clearly defined occurrence
- Preventable: an event that could have been anticipated and prepared against, but occurs because of an error or other system failure.
  - Frequently unable to make this determination at time of event
- Results in death or loss of a body part, or disability or loss of bodily function
  - Some event types have no threshold of injury such as Intravascular Air Embolism
- Lasts more than 7 days or present at discharge from a health care facility

1. The Patient Safety Act and Reporting Requirements

Patient Safety Regulations (N.J.A.C. 8:43E-10*) require facilities to:**

- **Establish a Patient Safety Committee**
  - Conduct ongoing analysis and application of evidence-based patient safety practices
  - Conduct analyses of near-misses, with particular attention to serious preventable adverse events
  - Foster attitudes, beliefs and behaviors supporting open communication in the facility
  - Review results of each RCA and, as appropriate, recommend modifications of systems, technology, policies or procedures

* Link available on the NJ Patient Safety website

** List is not inclusive

1. The Patient Safety Act and Reporting Requirements

Patient Safety Regulations *continued*

- **Develop a Patient Safety Plan**

- **Report Serious Preventable Adverse Events that occur in the facility to DOH or DHS**
  - If a facility discovers an event subject to mandatory reporting that occurred in a different facility, the discovering facility shall notify DOH but does not need to perform an RCA
  - The identity of the facility at which the event occurred should be reported to DOH if known

- **Conduct Root Cause Analyses (RCAs) of Serious Preventable Adverse Events**

1. The Patient Safety Act and Reporting Requirements

Patient Safety Regulations *continued*

- **Submit Root Cause Analyses of Serious Preventable Adverse Events to DOH or DHS**

- **Disclose the Serious Preventable Adverse Event to the Patient or Health Care Representative *within 24 hours of discovery***
  - Record the time, date, and individuals present when disclosure was made and to whom it was disclosed in the medical record
  - Record a statement that the occurrence of a serious preventable adverse event was disclosed in the medical record

- **Inform employees/health care professionals about their option to file anonymous reports of preventable adverse events**

1. The Patient Safety Act and Reporting Requirements

Patient Safety Regulations *continued*

Event Report must be submitted into the online Patient Safety Reporting System no later than 5 ***business* days after discovery**

- The date and time of discovery is the date and time ***anyone*** associated with the ESRD center (including the physician) becomes aware of a serious preventable adverse event

- The physician is a member of the healthcare team.

1. The Patient Safety Act and Reporting Requirements

Patient Safety Regulations *continued*

- **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 the event is reportable, the RCA must be submitted to PSRS within 45 *calendar* days from initial event report**

2. Adverse Event Reporting Process

Reporting Categories*

- **Care Management**
- **Environmental**
- **Product or Device**
- **Surgery-Related**
- **Patient Protection**

* **List of reportable events are located in the Patient Safety Regulations**

2. Adverse Event Reporting Process

Care Management Events* Examples

- **Medication Errors**
- **ABO/HLA-incompatible blood or blood products**

*** List of reportable events are located in the Patient Safety Regulations**

2. Adverse Event Reporting Process

Environmental Events* Examples

- **Electric Shock**
- **Burn**
- **Fall**

*** List of reportable events are located in the Patient Safety Regulations**

2. Adverse Event Reporting Process

Product or Medical-Device related Events* Examples

- **Contaminated Drugs/Devices/Biologics**
  - **Regardless of the source of contamination or product**
  - **Water handling/contamination issues**
- **Device Use/Malfunction**
- **Intravascular Air Embolism**

*** List of reportable events are located in the Patient Safety Regulations**

2. Adverse Event Reporting Process

‘Other’ Events

A facility shall report in the appropriate category events that are not specifically listed that meet the definition of a serious preventable adverse event.

Care Management Other

Environmental Other

Product or Device-Related Other

Surgery-Related Other

Patient Protection Other

2. Adverse Event Reporting Process

‘Care Management-Other’ Potential Events

- **Failure to follow Physician’s Prescription, policy or protocol**
- **Needle dislodgement**
- **Catheter disconnection**

2. Adverse Event Reporting Process

'Care Management-Other' Potential Events cont.

- **Access related issues requiring replacement**
- **Infection related events**
  - **CLABSIs**
- **Seroconversions**
  - **Continue current reporting to CDS/Local Health/Other**
  - **Confirmed new acute infection**
  - **Determined likely related to the provision of healthcare at the center**

2. Adverse Event Reporting Process

Other Indicators of Potential Reportable Events

- **Transfer to hospital/ED**
- **Unplanned hospital admission**
- **Visit to ED or other healthcare facility (e.g., Urgent Care Center) for suspected ESRD treatment related issues**
- **Symptoms associated with ESRD treatments requiring medical intervention**

2. Adverse Event Reporting Process

Threshold of Injury

- **Some event types have no threshold of injury such as**
  - **Intravascular Air Embolism**
  - **Retained Foreign Object**

- **Most event types 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 from a health care facility**

2. Adverse Event Reporting Process

Threshold of Injury *continued*

- **Important for PSRS to determine if the event meets the "threshold of injury" when deciding whether the event will require an RCA**
- **PSRS needs to determine how this event affected the patient**
- **Include this information in the Event Report**

2. Adverse Event Reporting Process

Description of the Adverse Event

- **The Initial Event submission should contain details about the impact on the patient:**
  - **The type of injury/harm to the patient**
  - **The severity of the injury/harm**
  - **Duration of injury/harm**
  - **Pertinent lab and imaging results**
  - **Impact on the patient's Activities of Daily Living and function**
  - **Chronological timeline**

- **Often need information from hospital about what happened once the patient was transferred or presented for treatment after dialysis**

2. Adverse Event Reporting Process

Description of the Adverse Event *continued*

- **If a patient is either transferred, or subsequently presents to a different facility for care following the event, additional information from that facility providing follow-up care may be required.**
  - Examples may include transfer from a dialysis center to a hospital or an emergency department visit.

- **In these situations, the facility at which the event occurred may need to reach out to the facility that provided follow-up treatment *through appropriate channels consistent with the facility's policies* to obtain the required information.**

2. Adverse Event Reporting Process

Description of the Adverse Event *continued*

The following information <u>from the facility providing follow-up care</u> may be required:

- Date/time of the transfer/admission and discharge
- Diagnosis upon presentation and the discharge diagnosis
- Results of pertinent diagnostic testing
- Treatments received including any new medications prescribed at discharge

2. Adverse Event Reporting Process

Immediate Clinical Actions

Provide the clinical actions taken for the patient following the event

- Describe the immediate treatment provided to the patient in response to the event
- Timeline
- Clinical outcome

2. Adverse Event Reporting Process

Immediate Corrective Actions

- **Provide the immediate corrective actions taken in response to the event.**
- **Should include the specific procedures implemented to reduce the likelihood of recurrence of this event**
- **List any additional reports provided to other organizations concerning this event**
  - oversight organizations, e.g., Renal Network/Hippocrates/CDS
  - equipment/pharmaceutical manufacturers

2. Adverse Event Reporting Process

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?**

2. Adverse Event Reporting Process

Event Review by PSRS

Possible Review Outcomes:

1. **Reportable RCA Required**
2. **Reportable RCA Not Required**
3. **Not Reportable**
4. **Less Serious or Near Miss**
5. **Need More Information**

2. Adverse Event Reporting Process

1. Reportable RCA Required

- **The Event is subject to the Patient Safety Act and Reporting Requirement**

- **A root cause analysis (RCA) must be completed by the facility and submitted to PSRS**

- **An email is sent to the FacAdmins**
  - The RCA Due Date will be provided in an email to the FacAdmins and can also be located in the Communication Log
    - Note: PSRS must be added as a safe sender so PSRS emails do not go to your spam folder

2. Adverse Event Reporting Process

1. Reportable RCA Required *continued*

- **A Facility User must log into the PSRS to read the Determination, which will be located in the communication log for that event, and respond accordingly**

- **There are usually comments from the event reviewer that should be reviewed and addressed when the RCA is submitted**

2. Adverse Event Reporting Process

2. Reportable RCA not Required

- **The Event is subject to the Patient Safety Act and Reporting Requirements**
- **A root cause analysis (RCA) does <u>not</u> need to be completed by the facility**
  - Example: RFO discovered but retained at a different facility
- **An email is sent to the FacAdmins**
- **A Facility User must log into the PSRS to read the Determination, which will be located in the communication log for that event**
- **There may be comments from the event reviewer which should be reviewed**

2. Adverse Event Reporting Process

3. Not Reportable

- **PSRS recommends internal analysis**
- **A root cause analysis (RCA) does not need to be submitted to PSRS**
- **An email is sent to the FacAdmins**
- **A Facility User must log into the PSRS to read the Determination, which will be located in the communication log for that event**
- **There may be comments from the event reviewer which should be reviewed**

2. Adverse Event Reporting Process

4. Less Serious or Near Miss

- **PSRS recommends internal analysis**
- **A root cause analysis (RCA) does not need to be submitted to PSRS**
- **An email is sent to the FacAdmins**
- **A Facility User must log into the PSRS to read the Determination, which will be located in the communication log for that event**
- **There may be comments from the event reviewer which should be reviewed**

2. Adverse Event Reporting Process

5. Need More Information

- **PSRS makes comments to determine the status of the event**
- **An email is sent to the FacAdmins**
- **A Facility User must log into the PSRS and open the event to read the comments and respond accordingly**

2. Adverse Event Reporting Process

5. Need More Information *continued*

- **Respond to all comments *by editing* the event**
  - The description of the event is an unlimited text field
- **Resubmit the event to PSRS**
- **There may be more than 1 cycle of responding to comments**

2. Adverse Event Reporting Process

Other Communications <u>from</u> PSRS

1. General Comment or Email-Other

There is a new comment available from the Patient Safety Reporting System. Please log into the web based system and check the Communication Log to review the comment and respond accordingly

2. Access Communications by

- Communication Log--General Comment or E-mail Other

2. Adverse Event Reporting Process

Other Communications to PSRS

1. **General Comment or Respond to PSRS Comment**

2. **Send Communication through**
   - Communication Log--General Comment

2. Adverse Event Reporting Process

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**

3. Root Cause Analysis Reporting Process

Root Cause Analysis

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

3. Root Cause Analysis Reporting Process

Root Cause Analysis

- **The purpose of the RCA is to uncover the factor(s) that led to and caused a serious preventable adverse event.**
- **It is not intended to assign blame to individuals or to organizations.**
- **Only by determining the underlying systemic causes of an adverse event can an effective action plan be formulated to minimize the chances of reoccurrence.**
- **The goal and purpose of the Patient Safety Act is to improve system processes and implement best practices in order to prevent similar events from recurring.**

3. Root Cause Analysis Reporting Process

RCA Required Components

N.J.A.C. 8:43E-10.6(l)* requires the following RCA components:**

- **A description of the event and the adverse outcome**
- **An analysis of why the event happened**
  - Direct causes(s)
  - Potential underlying causes related to design/operation of facility systems
- **The corrective actions taken for the patient(s)**

* Link available on the NJ Patient Safety website
** List is not inclusive

3. Root Cause Analysis Reporting Process

RCA Required Components *continued*

- **The method to identify other patients having potential to be affected by the same event and corrective action(s)**
- **The measures to be put into place or the systematic changes needed to reduce the likelihood of similar events**
- **How the corrective action(s) will be monitored to assess their impact**

3. Root Cause Analysis Reporting Process

RCA Resources

- **RCA Report Questions**
- **Initial Event Reviewer's Comments**
- **Literature Review**
- **Information Consulted**
  - Literature cited in **ALL** RCAs
  - Information in this field is accessible to all facilities
- **RCA Form Definitions**

3. Root Cause Analysis Reporting Process

RCA: General Information
RCA Team

- **Ad hoc under Patient Safety Committee**
  - Distinct from QI activities
- **Multidisciplinary and diverse**
  - Leadership involvement
  - Subject matter experts
  - Front line staff
  - Staff involved in event?
- **Commitment to RCA Process**
  - Resources

3. Root Cause Analysis Reporting Process

RCA: General Information
Prior Similar Events

- **Review number and trend of similar events in the same Event Classification**
- **Review prior root causes and action plans**
- **Review effectiveness of prior action plans**
- **Review how serious preventable adverse events are identified**

3. Root Cause Analysis Reporting Process

RCA: Facts of the Event

- **Detailed chronological narrative**
- **Who, what, when, where and how**
- **Clear, complete and understandable**
- **Include the direct cause of the event**
- **Include any factors that may have contributed to the occurrence of the event.**

3. Root Cause Analysis Reporting Process

RCA: Facts of the Event *continued*

- **Do NOT copy and paste medical records or autopsy reports into the RCA**
  - Summarize the pertinent information that is related to the event (e.g., lab results, diagnostic studies, etc.)

- **Remember that the MyNJ Portal has a *two-hour time limit***

3. Root Cause Analysis Reporting Process

RCA: Facts of the Event *continued*

- **Answer all Reviewer comments/questions**
  - Helps provide a complete picture of the event and analysis
  - *Check for Event Reviewer comments which should be addressed in the RCA*

- **Some facilities will copy and paste the comments/questions into a word document**
  - Respond to each comment/question
  - Copy and paste this information into RCA: Facts of the Event item #2, which has an unlimited field of characters

3. Root Cause Analysis Reporting Process

RCA: Facts of the Event *continued*

- **Provide enough detail so that a person unfamiliar with the event can understand what happened**
  - Request other staff to review for clarity

- **The section "RCA: Facts of the Event item#2" is an unlimited text field**
  - Auto-populates information from the event report
  - VERIFY information is accurate
  - Include detailed facts of the entire event
  - *Add any additional pertinent information regarding the event.*

3. Root Cause Analysis Reporting Process

RCA: Facts of the Event *continued*

RCA Discussion

- **Provide a comprehensive description of the analysis process and findings**
  - What did the RCA Team review?
- **Document all systems/processes reviewed**
  - Explain how the RCA Team reached its conclusions
- **RCA Reviewer was not present at the time of the event or for the RCA Discussions**

3. Root Cause Analysis Reporting Process

Root Cause

- **Use the Facts of the Event to examine why the event occurred**
- **When choosing a root cause, fully explore all other options before choosing "Other"**
  - RCA Form Definitions on PSRS website
- **Start with a broad review of <u>all</u> systems/processes**
  - No process is above scrutiny
  - No preconceived beliefs
  - Honest and open discussion
- **Focus on prevention**

3. Root Cause Analysis Reporting Process

Root Cause

- **Look for modifiable risk factors**
- **Human error and violations of procedure must have a preceding cause**
- **Must continue to ask 'Why?'**
- **Often more than 1 root cause**
- **Evidence-based literature review**

3. Root Cause Analysis Reporting Process

Causality Statement

- **Connects the root causes with the event**
- **X (cause) increased the likelihood that Y (event) occurred**
- **The Five Rules of Causation***
  1 - Causal Statements must clearly show the "cause and effect" relationship.
  2 - Negative descriptors (e.g., poorly, inadequate) are not used in causal statements.
  3 - Each human error must have a preceding cause.
  4 - Each procedural deviation must have a preceding cause.
  5 - Failure to act is only causal when there was a pre-existing duty to act.

***Adapted for patient safety by the VA National Center for Patient Safety from David Marx.**

3. Root Cause Analysis Reporting Process

Obstacles on the road to the Root Cause

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

3. Root Cause Analysis Reporting Process

Root Causes Common Myths

- **A known complication**
  - Many complications can be prevented
  - What contributed to or caused the complication
- **Patient noncompliance/characteristics**
  - Focus should be on how facility decreases risk for patient
- **Policies and procedures were in place**
  - Adverse event still occurred

3. Root Cause Analysis Reporting Process

Root Causes Common Myths

- **The nurse/physician/technician did not follow…**
  - Human error and violations of procedure must have an preceding system cause—something in the system allowed these to occur
- **Occurrence rate lower than national average**
  - Adverse event still occurred
- **No Root Cause**

3. Root Cause Analysis Reporting Process

Action/Prevention Strategies

- **Specific, doable and measurable**
- **Should prevent or decrease future adverse events**
- **Address each root cause**
- **Stronger actions compared to weaker actions**

3. Root Cause Analysis Reporting Process

Action/Prevention Strategies

- **Permanent actions over temporary actions**
- **Each root cause may have multiple actions**
- **Should include time frame for implementation**
  - Within 45 day time frame for RCA
- **Someone who is not a member of the RCA Team should be able to understand what to do next**

3. Root Cause Analysis Reporting Process

Monitoring

- **Describes how the effectiveness of each action will be measured and monitored.**
  - What will be monitored, by whom, and for how long
- **Specific for each action**
- **How will the facility know that the action is being carried out?**
- **How will the effectiveness of each action be communicated?**

3. Root Cause Analysis Reporting Process

Common Pitfalls: Action Plans & 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

3. Root Cause Analysis Reporting Process

Common Pitfalls: Action Plans & Monitoring *continued*

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

3. Root Cause Analysis Reporting Process

RCA Review by PSRS

N.J.A.C. 8:43E-10.6(m)* requires the Department of Health to:

- **Review an RCA to determine whether it satisfies the criteria in (l) above**; and**
- **Return an RCA that does not meet the criteria in (l) above to the facility for revision and shall not consider the RCA complete until the Department determines that the RCA meets the criteria in (l) above**

* Link available on the NJ Patient Safety website
** Refer to slide #44

NJ Health New Jersey Department of Health

3. Root Cause Analysis Reporting Process

RCA Review by PSRS *continued*

- **Each RCA is reviewed by Clinical Reviewers (RN, MD)**
- **Reviewers must understand what occurred**
- **RCA must include required components**
- **RCA must be thorough and credible**

3. Root Cause Analysis Reporting Process

RCA Review by PSRS *continued*

Possible Review Outcomes:

1. **Email: RCA Comment Process**

2. **Email: RCA Complete**

3. Root Cause Analysis Reporting Process

RCA Review by PSRS *continued*

1. Email: RCA Comment process:

- **Additional information is needed**
- **PSRS makes comments to determine if the RCA contains the required components of an RCA**
- **Facility responds to comments *by editing* the RCA**
  - **The RCA: Facts of the Event section question #2 is an unlimited text field**
  - **Resubmit within 2 weeks; Extensions are available**

3. Root Cause Analysis Reporting Process

RCA Review by PSRS *continued*

1. Email: RCA Comment process *continued*:

- **Facility resubmits the RCA to PSRS**

- **There may be more than 1 cycle of responding to comments**

3. Root Cause Analysis Reporting Process

RCA Review by PSRS *continued*

2. Email: RCA Complete:

- **The RCA is closed**
- **Additional information or clarification may be requested to complete the RCA Review**
- **If requested, additional information may be sent to PSRS by**
  - **General Comment**
  - **Attachment (Upload Supporting Documentation)**

3. Root Cause Analysis Reporting Process

Communication

- **ALL communication should go through the confidential reporting system**
- **Do NOT use regular unsecured email**
- **General Comments should be limited to 2-3 sentences**
- **Most of the responses/information should be entered in the RCA**
- **The attachment function (Upload Supporting Documentation) is available if needed**

PSRS Contact Information

For General Questions about PSRS:

Contact Adan Olmeda, ***Administrative Support***
609-633-7759 or ***Adan.Olmeda@doh.nj.gov***

PSRS Website: ***https://www.nj.gov/health/healthcarequality/health-care-professionals/patient-safety-reporting-system/***

Presenters for the ESRD Training Webinar:

Mary Noble, MD, MPH, ***Clinical Director***
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