Preventable Adverse Event (PAE) Reporting--101

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2014
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Objectives:

- Review the background of Preventable Adverse Event reporting nationwide and in Texas.
- Introduce the legislative mandate for reporting of Preventable Adverse Events.
- Provide associated definitions related to PAE’s.
- List the reportable PAE’s and timeline.
- Explain the public reporting of facility PAE’s.
- Provide resources and references.
- Share planned follow-up training by DSHS.
Why Report?

- **1999 Institute of Medicine (IOM)**
  - Estimated 98,000 deaths/year
  - Most were systemic errors

- **2013 John T. James, PhD**
  - 2008-2011 four studies estimated a lower limit of 210,000 deaths/year
  - Newest estimate is 440,000 deaths/year
  - Serious harm 10-20 times higher than lethal harm (2-4 Million serious harm events/year)


Definitions

- **Medical Error:** The failure of a planned action to be completed as intended, the use of a wrong plan to achieve an aim, or the failure of an unplanned action that should have been completed, that results in an adverse event.

- **Incident/Variance:** A patient safety event that reached the patient, whether or not the patient was harmed.

- **Adverse Event:** An event that results in unintended harm to the patient by an act of commission or omission rather than by the underlying disease or condition of the patient.
Near Miss: Serious error or mishap that has the potential to cause an adverse event but fails to do so because of chance or because it is intercepted. Also called potential adverse event.

SRE—Serious Reportable Event or “never-event” (NQF): Clearly preventable, serious patient consequences, and indicative of a real problem in safety and credibility of a health care facility.

HAC—Hospital Acquired Condition (CMS): A reasonably preventable condition which was not present on admission (POA) but was present on discharge. Identified by CMS through claims.
World Health Organization*

- Healthcare prone to accidents—
  - Greatest contributor is human error
  - Most human errors induced by system failures
- One solution is reporting—
  - By doctor, nurse or other provider within an organization
  - By the organization to a broader audience
- Effective reporting—
  - Cornerstone of safe practice
  - Measure of progress toward a safety culture

"The most important function of a reporting system is to use the results of data analysis and investigation to formulate and disseminate recommendations for systems change."

National Quality Forum

- Institute of Medicine (IOM) 2000-2004 Reports
  - Most errors were systemic
  - Called for a nationwide, mandatory reporting system

- National Quality Forum developed list of 28 Serious Reportable Events 2002
  - Facilitate comparable public reporting
  - Enable systematic learning
  - Drive improvements in patient safety
  - Envisioned to be basis for national state-based reporting system.

Patient Safety and Quality Improvement Act of 2005

- Patient Safety and Quality Improvement Act of 2005 (PSQIA).
  - The goal of the Act was to improve patient safety by encouraging voluntary and confidential reporting of events that adversely affect patients.
  - Required AHRQ to develop definitions and reporting formats
  - Common Formats—AHRQ, NQF, PSWG, and the Public
AHRQ Common Formats

- Allows for identification and reporting of any adverse event from
  - Serious Reportable Events (rare) to
  - Falls/Medication Errors (common)
- Includes near misses and unsafe conditions
- Supports causal analysis
- Provides an assessment of harm (death, severe harm, moderate harm, mild harm, no harm)
- Facilitates the ability to aggregate the data and thus comparison of event information

Version 1.2 available at www.psoppc.org
Patient Safety Organizations

- Conduct activities to improve patient safety and health care quality that includes the collection and analysis of data (voluntary submission from facilities).

- Certified by HHS*

- May submit to the National Patient Safety Database (NPSD)

- Texas PSO’s as listed by AHRQ
  - Texas Center for Quality and Patient Safety (TCQPS)
  - PSO Services Group
  - Texas Patient Safety Organization, Inc.
  - Texas A&M Health Science Center Rural and Community Health Institute

* 42 CFR 3.102(b)(2)(i)(A) and 42 CFR 3.102(b)(2)(ii)
CMS Mandates

- CMS CoP for Quality Assessment and Performance (QAPI)* requires facilities to
  - Track adverse events
  - Analyze causes
  - Implement actions to prevent recurrence

- March 15, 2013 Memorandum to Hospitals and Surveyors
  - OIG reports that most adverse events are not identified
  - Recommended Common Format education

*42 CFR 482.21(a)(2)
Reasons for PAE Reporting

- Establish standards
- Transparency
- Consumer’s right to know
- Increase Patient Safety
- Systemic Learning
- Evidence-based Practices

Increase Patient Safety
Reporting in US States

- 28 states require PAE reporting systems*
  - At least 22 post public reports of aggregate data**
  - 6 states post facility specific data**

- Leapfrog has developed a composite safety score for acute care hospitals***

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*National Academy for State Health Policy Website

**2007 Guide to State Adverse Event Reporting Systems by Jill Rosenthal and Mary Takach

State Reporting Systems

Update on State Government Tracking of Health Care-Acquired Conditions and a Four-State In-Depth Review, June 2012
State of the Nation Overview

- Reporting of Preventable Adverse Events
  - Internal reporting, formal & informal
    - Facilities are required to track events*
    - Facilities are required to*
      - Monitor effectiveness/safety of services
      - Analyze causes
      - Implement actions to prevent recurrence
  - External reporting to CMS, PSO’s, States
  - Public reporting by time period by aggregate, by event type, by facility

*42 CFR 482.21(a)(2)
Positive Outcome of Reporting

“The biggest change is greater acceptance of transparency around adverse events, especially broadcasting our events and event patterns to the front-line. There is probably also a greater “pull” to learn from other facilities with the same challenges.”

Adverse Health Care Events Reporting System: What have we learned? 5-year Review, Minnesota Department of Health, January 2009
History of PAE Reporting in Texas

- **80th Legislative Session 2007** (SB 288)
  - HAI Reporting, Advisory Panel

- **81st Legislative Session 2009** (SB 203)
  - PAE Description and required Reporting,
  - Public Reporting of PAE data,
  - Advisory Panel Refinements

- **82nd Legislative Session 2011** (SB 7)
  - Public Reporting refinements
Advisory Panel on HAI and PAE

- Established by legislation in 2005 to guide the implementation, development, maintenance, and evaluation of the reporting system.

- 18 members, appointed by the Commissioner
  - Infection Preventionists, Physicians, QI/PI/RM Professionals, Hospital and ASC Administration, consumers, DSHS licensing and epidemiology department employees (non-voting)
  - 2 year terms
Texas Health and Safety Code

- Senate Bill 203 of the 81st Legislature (2009) amended the Health and Safety Code, Chapter 98.102.a.2,4,5, to require:

  Healthcare facilities to report certain preventable adverse events to the DSHS,

  **AND**

  DSHS to make this data available to the public by facility, by type, and by number.
Chapter 98 PAE Definition

- A health care-associated adverse condition or event for which the Medicare program will not provide additional payment to the facility under a policy adopted by the federal Centers for Medicare and Medicaid Services; and

- An event included in the list of adverse events identified by the National Quality Forum.

- The executive commissioner may exclude an adverse event from the reporting requirement if the executive commissioner, in consultation with the advisory panel, determines that the adverse event is not an appropriate indicator of a preventable adverse event.
Chapter 98 Requirements of DSHS

- Establish Healthcare-Associated Infection (HAI) and Preventable Adverse Event (PAE) reporting system
- Compile and make available to the public a data summary, by health care facility, at least annually
- Allow health care facilities to submit concise written comments
- Provide education and training
- Ensure confidentiality & legal protections
- Verify the accuracy and completeness of the data reported
- Receive reports from the public
- Enforcement--as part of your licensure you are required to comply with state reporting requirements
Who Must Report?

- *General Hospitals* licensed under Chapter 241 or operated by the State. It does not include a comprehensive medical rehabilitation hospital.

- *Ambulatory Surgery Centers* licensed under Chapter 243.
When to Report?

- 35 Total Preventable Adverse Events

- Phased in reporting over three years—
  - Tier I: January 1, 2015—16 events
  - Tier II: January 1, 2016—9 additional events
  - Tier III: January 1, 2017—10 additional events
What to Report?

- Reportable PAE’s comprise a combination of nearly all HACs, and all SRE’s.
- Texas will use modified AHRQ Common Formats
- Deaths and Severe Harm will be reported initially (the applicable SRE’s)
- Will not report or identify unsafe conditions or near misses—only actual events
- Will not be required to report causal information or contributing factors
- Will not report on anesthesia PAE’s
SURGICAL OR INVASIVE PROCEDURE EVENTS
1. Surgeries or invasive procedures involving a surgery on the wrong site, wrong patient, wrong procedure.
2. Foreign object retained after surgery.
3. Post-operative death of an ASA Class 1 Patient.

PATIENT PROTECTION EVENTS
1. Discharge or release of a patient of any age, who is unable to make decisions, to someone other than an authorized person.
ENVIROMENTAL EVENTS
1. Any incident in which systems designated for oxygen or other gas to be delivered to a patient contains no gas, wrong gas, or are contaminated by toxic substances.

2. Patient death or severe harm associated with use of physical restraints or bed rails while being cared for in a health care facility.

POTENTIAL CRIMINAL EVENTS

2. Sexual abuse or assault of a patient within or on the grounds of a health care facility.

3. Patient death or severe harm of resulting from a physical assault that occurs within or on the grounds of a health care facility.
First Tier PAE Reporting January 1, 2015

CARE MANAGEMENT EVENTS

1. Patient death or severe harm associated with unsafe administration of blood or blood products.
2. Patient death or severe harm due to a fall or trauma in a health care facility resulting in a fracture, dislocation, intracranial injury, crushing injury, burn or other injury.
3. Patient death or severe harm from the irretrievable loss of an irreplaceable biological specimen.
4. Perinatal death or severe harm (maternal or neonatal) associated with labor or delivery in a low-risk pregnancy while being cared for in a health care facility.
5. Patient death or severe harm due to failure to follow up or communicate laboratory, pathology or radiology test results.
How to Report?

- PAEs will be entered by the reporting facility into the Texas Healthcare Safety Network (TxHSN).
  - Manual entry online
  - XML Upload per TxHSN webservices

- PAE reporting deadlines, comment period and public posting of data will follow the established HAI schedule.
Public Reporting in Texas

- Consulted with the Texas Institute of Health Care Quality and Efficiency:
  - Available on the Department’s website [www.PAETexas.org](http://www.PAETexas.org)
  - May not disclose identities of patients, employees, contractors, volunteers, consultants, students, trainees or healthcare professionals in connection with an event.
  - Facilities can submit comments for posting.
  - Department must post an annual report.
## TxHSN PAE Reporting Schedule

<table>
<thead>
<tr>
<th>Reporting Quarter</th>
<th>Q1: Jan 1 – Mar 31</th>
<th>H1: Jan 1 – June 30</th>
<th>Q3: July 1 – Sept 30</th>
<th>H2: July 1 – Dec 31</th>
</tr>
</thead>
<tbody>
<tr>
<td>Facility data submission deadline</td>
<td>Within 60 days of end of reporting quarter</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>DSHS takes preliminary data snapshot</td>
<td>1-Jun</td>
<td>1-Sept</td>
<td>1-Dec</td>
<td>1-Mar</td>
</tr>
<tr>
<td>DSHS sends email to facility users review data</td>
<td>~15-Jun</td>
<td>~15-Sep</td>
<td>~15-Dec</td>
<td>~15-Mar</td>
</tr>
<tr>
<td>Facility data corrections due</td>
<td>30-Jun</td>
<td>30-Sep</td>
<td>31-Dec</td>
<td>31-Mar</td>
</tr>
<tr>
<td>DSHS takes final data snapshot</td>
<td>1-July</td>
<td>1-Oct</td>
<td>1-Jan</td>
<td>1-Apr</td>
</tr>
<tr>
<td>DSHS sends email to facility to review data summary and make comments</td>
<td>NA</td>
<td>15-Oct</td>
<td>NA</td>
<td>15-Apr</td>
</tr>
<tr>
<td>Facility comment period deadline</td>
<td>NA</td>
<td>30-Oct</td>
<td>NA</td>
<td>30-Apr</td>
</tr>
<tr>
<td>DSHS reviews comments</td>
<td>NA</td>
<td>15-Nov</td>
<td>NA</td>
<td>15-May</td>
</tr>
<tr>
<td>Public posting of data summary with approved comments</td>
<td>NA</td>
<td>1-Dec</td>
<td>NA</td>
<td>1-Jun</td>
</tr>
</tbody>
</table>
### Implementation Time Line

<table>
<thead>
<tr>
<th>Month</th>
<th>Event</th>
</tr>
</thead>
<tbody>
<tr>
<td>May - Aug 2014</td>
<td>PAE Reporting--101</td>
</tr>
<tr>
<td></td>
<td>Face to face and webinars</td>
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<tr>
<td>September 2014</td>
<td>Letter to Facility for TxHSN</td>
</tr>
<tr>
<td></td>
<td>Registration and Identification of Primary PAE Contacts</td>
</tr>
<tr>
<td>Sept - Nov 2014</td>
<td>Training for PAE Reporting via TxHSN</td>
</tr>
<tr>
<td></td>
<td>Face to face and webinars</td>
</tr>
<tr>
<td>January 2015</td>
<td>PAE Reporting by Facility begins</td>
</tr>
<tr>
<td>December 2015</td>
<td>First Public Display of PAE Data on PAETexas.org</td>
</tr>
</tbody>
</table>
Texas PAE Webinar Series

○ Texas Preventable Adverse Event Reporting—101
  • June 10, Tuesday and June 12, Thursday, 1:00 – 2:00 pm
  • July 8, Tuesday and July 10, Thursday, 2:00 – 3:00 pm

○ Texas Preventable Adverse Event Reporting—TxHSN Training
  • September  Dates TBD
  • October   Dates TBD
  • November  Dates TBD

○ Email PAETexas@dshs.state.tx.us for questions
○ Go to www.PAETexas.org COMING SOON for registration and call in information
Preventable Adverse Event (PAE) Reporting—101 Webinar Series

View the webinar at one of the following dates and times:
- 06/10/2014 1:00 PM - 2:00 PM (CST)
- 06/12/2014 1:00 PM - 2:00 PM (CST)
- 07/08/2014 2:00 PM - 3:00 PM (CST)
- 07/10/2014 2:00 PM - 3:00 PM (CST)

To join the webinar on any of the above dates/times:
- http://txdshs.adobeconnect.com/r1swyu9cc5l/
  Please sign in as guest with name and organization
  (e.g. Vickie Gillespie State Health Services)

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Organizations

- CMS—Centers for Medicare and Medicaid Services (HAC's)
- NQF—National Quality Forum (SRE's)
- AHRQ—Agency for Healthcare Research and Quality (Common Formats)
- PSOPPC—Patient Safety Organization Privacy Protection Center
- PSNET—AHRQ Patient Safety Network
- NHSN—National Healthcare Safety Network (HAI reporting)
- NPSF--National Patient Safety Foundation
- IHI--Institute for Healthcare Improvement
- THA--Texas Hospital Association (TCQPS—Texas Center for Quality & Patient Safety)
- TAHQ--Texas Association for Healthcare Quality
- TMF Health Quality Institute (was Texas Medical Foundation)
Resource Websites

- NQF  www.qualityforum.org
- AHRQ  www.ahrq.org
- PSO  www.pso.ahrq.org
- PSOPPC  https://psoppc.org/web/patientsafety/commonformats
- PSNET  http://www.psnet.ahrq.gov
- NHSN  www.cdc.gov/nhsn
- NPSF  www.nhsf.org
- IHI  www.ihi.org
- TCQPS  www.texashospitalquality.org
- TAHQ  www.txquality.org
- TMF  www.tmf.org
- TxChapter 98  www.statutes.legis.state.tx.us
- TxAdmCode  http://info.sos.state.tx.us/pls/pub/readtac$ext.viewtac
- PAETexas  www.PAETexas.org  COMING SOON
Texas Department of State Health Services

Health Care Safety Group

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Questions?

Thank you!
References

4. Update on State Government Tracking of Health Care-Acquired Conditions and a Four-State In-Depth Review, June 2012, Nathan West, MPA, Terry Eng, RN, PhD (c), Alexis Kirk, BA, RTI International, 3040 Cornwallis Road, Research Triangle Park, NC 27709
5. National Academy for State Health Policy Website
6. 2007 Guide to State Adverse Event Reporting Systems by Jill Rosenthal and Mary Takach