Patient Safety and Quality Improvement Act of 2005
Voluntary Confidential and Protected Reporting to PSOs
New Opportunities

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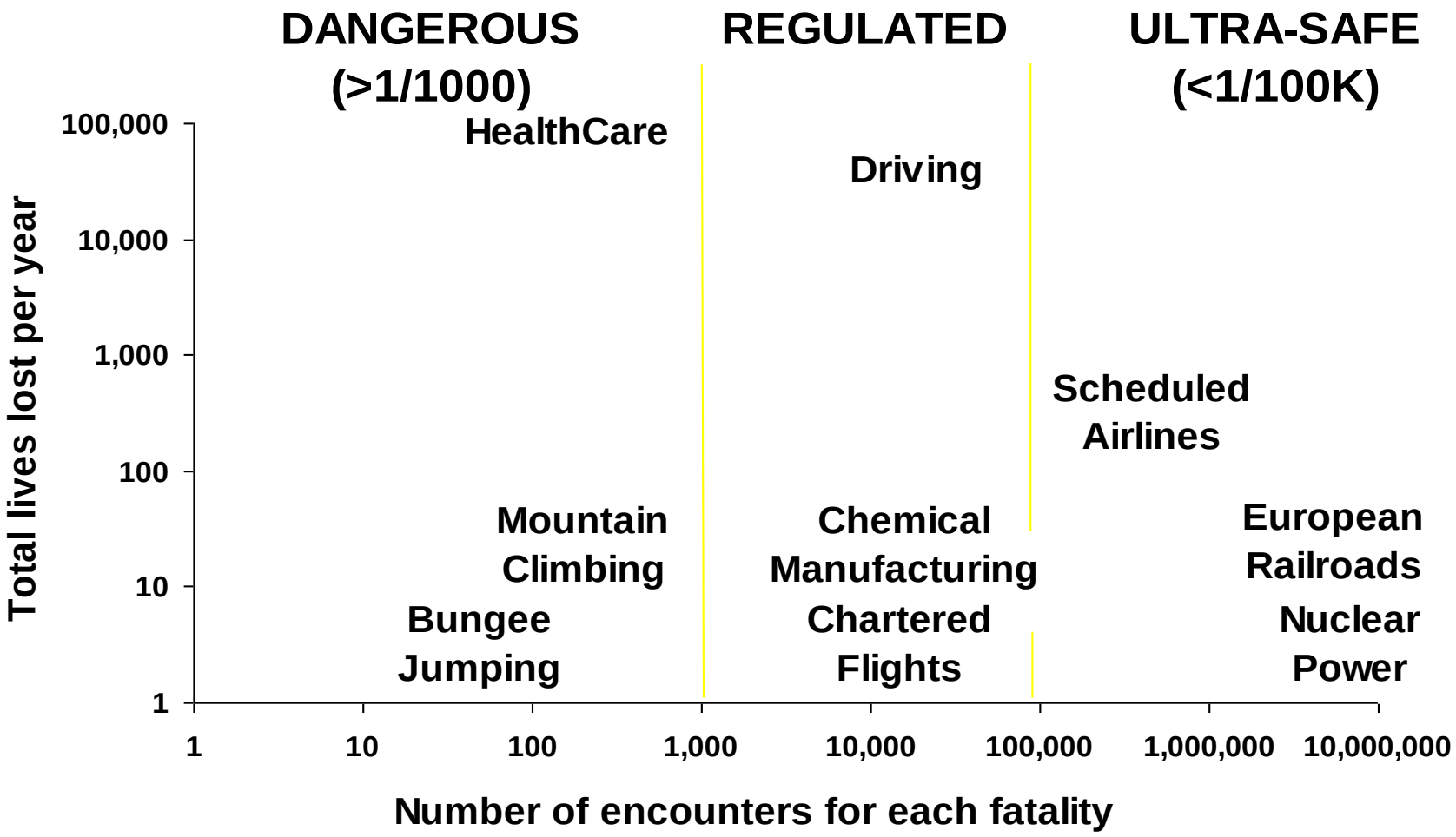
Agenda

- Introduction
- Patient Safety: Inpatient and Ambulatory
- PSQIA 2005
  - Provisions of the bill and AHRQ regulations
  - Patient Safety Organizations
  - Common Formats
- How can this help me and my organization?

How Hazardous Is Health Care?



To Err is Human
Building a Better Healthcare System

- 1999 IOM Report
- Between 44,000 and 98,000 die as a result of medical errors annually
  - Would be the 8th leading cause of death
  - Ranks higher than MVAs, breast CA, AIDS
- Total costs: $17-29 billion

Definitions

- Safety-freedom from accidental injury
- Error- failure of a planned action to be completed as intended (i.e. error of execution) or the use of a wrong plan to achieve an aim (i.e. error of planning)
- Adverse event- injury caused by medical management rather than the underlying condition of the patient

(to Err Is Human, IOM 1999)

Type of Errors

- Diagnostic- error or delay in diagnosis; failure to employ indicated tests; failure to act on results of tests or monitoring
- Treatment- error in the performance of an operation, procedure or test, administration of a treatment or drug; avoidable delay in treatment; inappropriate care
- Prevention – failure to provide prophylaxis, monitoring or follow-up
- Other- failure of communication, equipment or system functioning

(Leape et al. Qual Rev Bull 1993)

Why do Errors Occur?

Two schools of thought:

- Individuals make mistakes because they are forgetful, inattentive, slothful, evil, weak…
- Every system is perfectly designed to achieve the results that it gets; humans are fallible but systems create the conditions in which humans make mistakes and fails to prevent or mitigate them

Responses to Errors

- Name, blame and shame
  - Face validity, feels good, tradition, avoids institutional responsibility
  - Leads to a culture of secrecy, ineffective solutions
- Systems solutions:
  - All can learn from errors
  - Look for latent conditions, underlying factors, root causes
  - Change the system for sustainable results

Ambulatory care adverse events and preventable adverse events leading to a hospital admission

Donna M Woods, Eric J Thomas, Jane L Holl, Kevin B Weiss, Troyen A Brennan

Qual Saf Health Care 2007;**16**:127–131. doi: 10.1136/qshc.2006.021147

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Background: Most healthcare in the US is delivered in the ambulatory care setting, but the epidemiology of errors and adverse events in ambulatory care is understudied.

Methods: Using the population-based data from the Colorado and Utah Medical Practices Study, we identified adverse events that occurred in an ambulatory care setting and led to hospital admission. Proportions with 95% CIs are reported.

Results: We reviewed 14 700-hospital discharge records and found 587 adverse events of which 70 were ambulatory care adverse events (AAEs) and 31 were ambulatory care preventable adverse events (APAEs). When weighted to the general population, there were 2608 AAEs and 1296 (44.3%) APAEs in Colorado and Utah, USA, in 1992. APAEs occurred most commonly in physicians' offices (43.1%, range 46.8–27.8), the emergency department (32.3%, 46.1–18.5) and at home (13.1%, 23.1–3.1). APAEs in day surgery were less common (7.1%, 13.6–0.6) but caused the greatest harm to patients. The types of APAEs were broadly distributed among missed or delayed diagnoses (36%, 50.2–21.8), surgery (24.1%, 36.7–11.5), non-surgical procedures (14.6%, 25.0–4.2), medication (13.1%, 23.1–3.1) and therapeutic events (12.3%, 22.0–2.6). Overall, 10% of the APAEs resulted in serious permanent injury or death. The proportion of APAEs that resulted in death was 31.8% for general internal medicine, 22.5% for family practice and 16.7% for emergency medicine.

Conclusion: An estimated 75 000 hospitalisations per year are due to preventable adverse events that occur in outpatient settings in the US, resulting in 4839 serious permanent injuries and 2587 deaths.

Table 1 Estimates of ambulatory care adverse events and preventable adverse events that led to hospital admission by ambulatory care setting and level of harm

	Adverse events		Mean level of harm	Preventable adverse events		Mean level of harm
	n	% (95% CI)	Mean (95% CI)	n	% (95% CI)	Mean (95% CI)
Physician office	972	37.3 (46.8 to 27.8)	3.96 (4.13 to 3.79)	559	43.1 (57.7 to 28.5)	3.08 (3.33 to 2.83)
Emergency department	514	19.7 (27.5 to 11.9)	3.25 (3.42 to 3.08)	418	32.3 (46.1 to 18.5)	3.20 (3.45 to 2.95)
Home	611	23.4 (31.7 to 15.1)	2.90 (3.06 to 2.73)	170	13.1 (23.1 to 3.1)	3.20 (3.45 to 2.95)
Day surgery	248	9.5 (15.3 to 3.7)	2.57 (2.74 to 2.40)	92	7.1 (13.6 to 0.6)	4.50 (4.75 to 4.25)
Hospital clinic	263	10.1 (16.0 to 4.2)	2.67 (2.84 to 2.50)	57	4.4*	3.00 (3.25 to 2.75)
Ambulatory care	2608	100.0	3.01 (3.18 to 2.84)	1296	100.0	3.22 (3.47 to 2.97)

Table 2 Estimates of hospital-admission-related ambulatory care adverse events and preventable ambulatory adverse events by type and estimation of harm

	Adverse events		Mean level of harm	Preventable adverse events		Mean level of harm
Event type	n	% (95% CI)	Mean (95% CI)	n	% (95% CI)	Mean (95% CI)
Diagnostic	466	17.9 (25.4 to 10.4)	4.44 (4.61 to 4.27)	466	36.0 (50.2 to 21.8)	3.43 (3.68 to 3.18)
Surgical	737	28.3 (37.1 to 19.5)	3.16 (3.33 to 2.99)	312	24.1 (36.7 to 11.5)	4.03 (4.28 to 3.78)
Medication	827	31.7 (40.8 to 22.6)	3.00 (3.17 to 2.83)	170	13.1 (23.1 to 3.1)	2.57 (2.82 to 2.32)
Non-surgical procedures	222	8.5 (14.0 to 3.0)	3.33 (3.50 to 3.16)	189	14.6 (25.0 to 4.2)	2.59 (2.84 to 2.34)
Therapeutic	228	8.7 (14.2 to 3.2)	2.50 (2.67 to 2.33)	159	12.3 (22.0 to 2.6)	3.29 (3.54 to 3.04)
Fracture and falls	88	3.4 (6.4 to 0.2)	3.50 (3.67 to 3.33)	0	0.0	0.00
Anaesthesia	40	1.5*	3.00 (3.17 to 2.83)	0	0.0	0.00

Table 3 Estimates of hospital-admission-related ambulatory care preventable adverse events by type of service involved and estimation of harm

Service type	Total, n	% (95% CI)	Harm, n (95% CI)
Primary care	407	31.4 (33.5 to 29.3)	4.03 (4.28 to 3.78)
Medical specialty	282	21.8 (23.7 to 19.9)	2.51 (2.80 to 2.30)
Surgical specialty	293	22.6 (24.5 to 20.7)	2.90 (3.15 to 2.65)
Emergency medicine	239	18.5 (20.3 to 16.7)	3.08 (3.33 to 2.83)
Paediatrics	13	1.0 (1.5 to 0.05)	1.00 (1.25 to 0.75)
Radiology	58	4.5 (5.4 to 3.60)	3.00 (3.25 to 2.75)

Epidemiology or Ambulatory Errors

- A lot to learn!
- Incidence of 3.7 per 100,000 clinic visits (risk management data)
- Result in 5-36% of admissions to medical services and 11-13% on admissions to ICUs
- Majority are medication errors (51%); remainder are related to non-pharmacologic management (42%), diagnostic (34%) and equipment (5%). Contributing factors: poor communication (23%) and errors in judgment (22%) (Bhasale, MJA 1998)

Adverse Drug Events

- Occur in 25% of patients by their report
- 63% are associated with physician's failure to respond to medication-related symptoms
- 37% are associated with the patient's failure to inform the physician of symptoms
- ADEs were correlated with number of medical problems, failure to explain side effects and primary language other than Spanish or English

(Gandhi, NEJM 2003; JGIM 2000)

Outpatient Prescription Drug-Related Injuries in Elderly

- 50 ADEs per 1000 person years
- Etiology: 58% prescribing; 61% monitoring; 21% patient adherence
- Most common drugs: cardiovascular (24%), diuretics (22%), analgesics (15%), hypoglycemics (11%), anticoagulants (10%)
- Prevention of strategies: decision support for prescribing and monitoring; collaboration with pharmacists; improved patient education for adherence

(Gurwitz et al. JAMA 2003)

Study of Physicians' Information Needs

- 81% of return visits were plagued by missing information
- Mean number of data/case=3.7 (range 1-20)
- Coping strategies were generally ineffective

(Tang, AMIA 1994)

Early Lessons in Ambulatory Safety

- Less technologically complex than inpatient care but more complex logistically
- Infrastructure is highly variable
- Care in dependent on patients and families as well as providers and organizations
- Care must be coordinated over time and across settings, providers and transitions, highlighting the importance of communications and checks in the system

Definition of Patient Safety Practice

Systems Emphasis

Any health care process or structure whose presence or application reduces the probability of adverse events resulting from exposure to the health care system across a range of diseases and procedures.

Separates QI vs. Patient Safety

More Rigorous Standard than Errors

Safe Practices for Better Healthcare

- Matching healthcare needs with service delivery capabilities
- Facilitating information transfer and clear communication
- Increasing safe medication use
- Adopting specific safe processes of care
- Creating a culture of safety

(NQF, 2003)

Overarching Approaches

- Technology
- Interdisciplinary, collaborative approaches
- Adaptable system-level processes
- Communication amongst healthcare workers
- Partnership with patients
- Establishing behavioral norms

A Culture of Safety

- Non-punitive policies to address adverse events
- Organizational commitment to open communication about errors to encourage reporting and analysis
- Alignment between legal and clinical staffs to ensure openness without compromising the organization

Barriers and Motivators for Making Error Reports from Family Medicine Offices: A Report from the American Academy of Family Physicians National Research Network (AAFP NRN)

Nancy C. Elder, MD, MSPH, Deborah Graham, MSPH, Elias Brandt, and John Hickner, MD, MSc

Context: **Reporting of medical errors is a widely recognized mechanism for initiating patient safety improvement, yet we know little about the feasibility of error reporting in physician offices, where the majority of medical care in the United States is rendered.**

Objective: **To identify barriers and motivators for error reporting by family physicians and their office staff based on the experiences of those participating in a testing process error reporting study.**

Design: **Qualitative focus group study, analyzed using the editing method.**

Setting: **Eight volunteer practices of the American Academy of Family Physicians National Research Network.**

Participants: **139 physicians, nurse practitioners, physician assistants, nurses, and staff who took part in 18 focus groups.**

Instrument: **Interview questions asked about making reports, what prevents more reports from being made, and decisions about when to make reports.**

Results: **Four factors were seen as central to making error reports: the burden of effort to report, clarity regarding the information requested in an error report, the perceived benefit to the reporter, and properties of the error (eg, severity, responsibility). The most commonly mentioned barriers were related to the high burden of effort to report and lack of clarity regarding the requested information. The most commonly mentioned motivator was perceived benefit.**

Conclusion: **Successful error reporting systems for physicians' offices will need to have low reporting burden, have great clarity regarding the information requested, provide direct benefit through feedback useful to reporters, and take into account error severity and personal responsibility. (J Am Board Fam Med 2007;20:115–123.)**

The Patient Safety and Quality Improvement Act of 2005

- Creates "Patient Safety Organizations" (PSOs)
- Establishes "Network of Patient Safety Databases" (NPSD)
- Authorizes establishment of "Common Formats" for reporting patient safety events
- Requires reporting of findings annually in AHRQ's National Health Quality / Disparities Reports

The Patient Safety Act

- Aims to improve safety by addressing
  - Fear of malpractice litigation
  - Inadequate protection by state laws
  - Inability to aggregate data on a large scale
- Amends AHRQ's enabling legislation
  - AHRQ administers the program
  - Office for Civil Rights handles enforcement
  - Program is voluntary

Listing PSOs

- AHRQ began listing PSOs under Interim Guidance – Oct 2008
- Final rule published in the Nov 21st, 2008 Federal Register; effective Jan 19th, 2009
- 83 PSOs listed by AHRQ as February 9, 2015; complete list at http://www.pso.ahrq.gov

PSOs in 30 States and the District of Columbia

This map shows the physical location of each PSO. All PSOs can operate nationally regardless of their home state.

Alabama

P0123 Healthcare Improvement PSO, Inc. [HIPSO, Inc.]

Arkansas

P0051 American Data Network PSO

California

P0014 Quantros Patient Safety Center

P0002 California Hospital Patient Safety Organization (CHPSO)

Colorado

P0162 Catholic Health Initiatives Patient Safety Organization, LLC

Connecticut

P0091 QA to QI LLC

District Of Columbia

P0047 Pascal Metrics Inc

P0128 American College of Physicians Patient Safety Organization

P0132 Safe Pediatric Healthcare PSO

P0164 Patient Safety Leadership Council PSO

Florida

P0083 Baptist Health Patient Safety Partnership
P0148 Florida Academic Healthcare Patient Safety Organization
P0096 UM-JMH Center for Patient Safety PSO
P0052 Patient Safety Organization of Florida (PSOFlorida)
P0144 Strategic Radiology Patient Safety Organization LLC
P0034 MEDNAX PSO, LLC
P0039 Quality Circle for Healthcare, Inc.
P0154 Surgical Momentum PSO

Georgia

P0159 MAG Mutual Patient Safety Institute, LLC
P0084 Piedmont Clinic, Inc.

Illinois

P0163 Quality Alliance Patient Safety Organization
P0106 Society for Vascular Surgery Patient Safety Organization, LLC
P0152 Surgical Outcomes & Quality Improvement Center (SOQIC)
P0087 Midwest Alliance for Patient Safety
P0099 Anesthesia Quality Institute
P0074 Chicago Breast Cancer Quality Consortium
P0015 Clarity PSO
P0146 Symbria SAFE
P0043 The Patient Safety Research Foundation, Inc.
P0007 UHC Safety Intelligence

Indiana

P0168 Regenstrief Center for Healthcare Engineering at Purdue University
P0161 QAISys, Inc.

Kansas

P0119 Child Health Patient Safety Organization, Inc. (Child Health PSO)

Kentucky

P0022 Kentucky Institute for Patient Safety & Quality

Louisiana

P0115 Schumacher Group Patient Safety Organization, Inc.

Massachusetts

P0081 Fresenius Medical Care PSO, LLC

P0103 Academic Medical Center (AMC) PSO

Maryland

P0024 Mid-Atlantic Patient Safety Organization

P0032 AABB Center for Patient Safety

Maine

P0113 Specialty Benchmarks PSO

P0068 ABG Anesthesia Data Group, LLC

P0165 Quality Solutions

P0134 Fides, LLC

Michigan

P0038 MHA Patient Safety Organization

P0143 Michigan Surgical Quality Collaborative

P0069 Emergency Consultants PSO, LLC (d/b/a ECI PSO, LLC)

Minnesota

P0133 Emergency Medical Error Reduction Group

Missouri

P0011 Missouri Center for Patient Safety, dba Center for Patient Safety

P0111 Ascension Health Patient Safety Organization

North Carolina

P0094 Carolinas Rehabilitation - Patient Safety Organization

P0025 NC Quality Center PSO

P0097 Carolinas HealthCare System Patient Safety Organization

Nebraska

P0076 Nebraska Coalition for Patient Safety

New Jersey

P0082 New Jersey Hospital Association Health, Research & Educational Trust Institute for Quality & Patient Safety

New York

P0048 Medication Management Research Network
P0112 Somnia Patient Safety Organization, Inc.
P0095 MCIC Vermont, Inc. PSO

Ohio

P0124 EMP Patient Safety Organization
P0041 Ohio Patient Safety Institute

Pennsylvania

P0141 American Medical Foundation Patient Safety Organization
P0110 UHS Acute Care PSO
P0078 Chart Institute LLC
P0008 ECRI Institute PSO
P0136 Cassatt Patient Safety Organization
P0009 Institute for Safe Medication Practices (ISMP)
P0063 McGuckin Methods International, Inc.
P0145 Close Care Gap, PSO

Rhode Island

P0155 Enterprise Patient Safety Organization, L.L.C
P0089 The PSO Advisory, LLC

South Carolina

P0118 Verge Patient Safety Organization

Tennessee

P0075 PsychSafe (Component PSO of UHS of Delaware, Inc. Behavioral Health Division)
P0122 CHS PSO, LLC
P0066 Tennessee Center for Patient Safety
P0157 HCA Patient Safety Organization, LLC
P0067 TeamHealth Patient Safety Organization

Texas

P0079 The Texas A&M Health Science Center Rural and Community Health Institute (TAMHSC-RCHI)
P0135 Texas Center for Quality & Patient Safety (TCQPS) PSO
P0012 Texas Patient Safety Organization, Inc.

Virginia

P0151 Virginia PSO
P0030 Wake up Safe (a component of the Society for Pediatric Anesthesia)
P0153 Society of NeuroInterventional Surgery (SNIS) PSO
P0020 Alliance for Patient Medication Safety

Wisconsin

P0149 Center for the Assessment of Radiological Sciences PSO

Who Can be a PSO?

- Eligible organizations
  - Any public or private entity / component
  - Any for-profit or not-for-profit / component
- Ineligible organizations
  - Health insurance issuers or their components
  - Accrediting & licensing bodies
  - Entities that regulate providers, including their agents (e.g., QIOs)
  - Mandatory public reporting systems

PSOs: Becoming a PSO

- Entities seeking listing must complete a "Certification for Initial Listing" form
  - Available on AHRQ's PSO Web site http://www.pso.ahrq.gov/index.html
- Application: a simple process of attestation
  - Compliance with requirements ensured by spot checks
  - Entities subject to penalties for false statements
- Listing: for 3-year renewable periods
- Funding: no Federal funding from AHRQ, but technical assistance without charge
- Provider Choice of PSO: voluntary, marketplace assessment

Some of the First PSOs

- UHC Clinical Practice Advancement Center
- ECRI Institute PSO
- Florida Patient Safety Corporation
- Institute for Safe Medication Practices (ISMP)
- Kentucky Institute for Patient Safety and Quality
- California Hospital Patient Safety Organization

PSO Activities

- Collect, analyze patient safety (PS) data
- Assist providers to improve quality & safety
- Develop & disseminate PS information
- Encourage culture of safety & minimize patient risk
- Provide feedback to participants
- Maintain confidentiality & security of data

Potential Concerns with PSQIA 2005

- Relationship to other reporting requirements
  - Mandatory state reporting
  - CDC's NHSN for healthcare-associated infections
  - FDA reporting
  - Other systems
- Desire for one-time reporting & the elusive "interoperability"

Potential Concerns

- Challenges inherent in patient safety reporting
  - Uneven detection / surveillance
  - Lack of defined populations: denominators
  - Different cultures / styles of operation
  - Different definitions, scope, formats
- Challenges with PSO framework
  - Not discrete geographically
  - Voluntary, spontaneous reporting

How Do Providers Benefit From Working With A PSO?

- Receive uniform Federal confidentiality & privilege protections
- Gain protection for analysis beyond the initial report (e.g., root cause analysis)
  - In provider's patient safety evaluation system or the PSO's
  - Shared learning within the provider's system
- Benefit from aggregation
  - PSO level
  - PSO to PSO analysis & sharing
  - NPSD

Key Questions Providers Should Ask A PSO

- Does the PSO specialize or limit to a specific content area?
  - Topic specialization (e.g., medical devices, medications, pediatric anesthesia, etc.)
  - Geographical focus
- What types of analysis & service does the PSO provide?
- Does the PSO use consultants or services of another PSO?
  - Will I be consulted before the PSO shares my patient safety data with external consultants?

Key Questions Providers Should Ask A PSO

- Will the PSO help me set up a patient safety evaluation system?
- How will my patient safety work product be protected at the PSO?
- Does the PSO work with the NPSD?

Provider Notification of PSO Change in Status

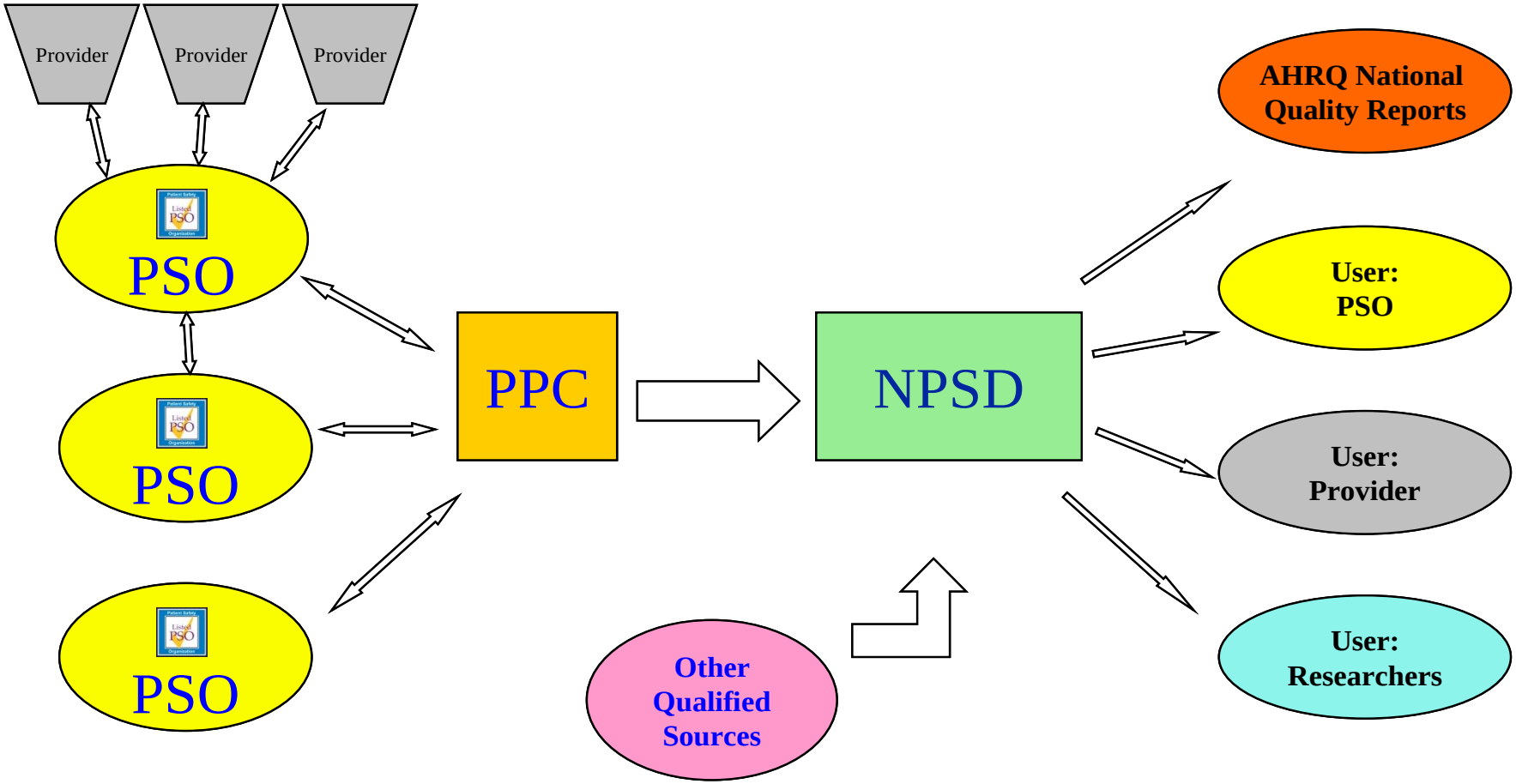
- AHRQ has established a process to notify health care providers when the status of a listed PSO changes (e.g., delisting)
- To request notification about a change in status of a specific PSO, please send an e-mail to ProviderNotification@ahrq.hhs.gov
  - Specify the PSO(s) about which you would like to be notified

AHRQ Common Formats

PSO Requirements

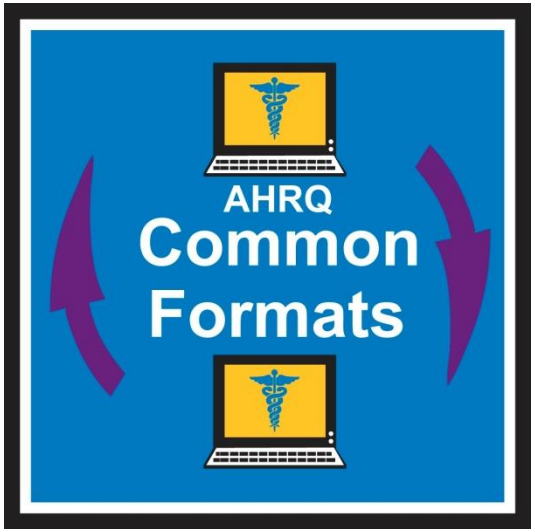
- PSOs & providers analyze patient safety data
  - PSOs are required to collect information that allows comparison of “similar events among similar providers”
  - “Common Formats” have been made available by AHRQ, acting for the Secretary of HHS, to assist PSOs to meet this requirement
  - At recertification, PSOs will be required to state how they meet the requirement

Data Flow: Provider to PSO to NPSD to User



AHRQ's Common Formats

- Standardize the patient safety event information collected
  - Common language & definitions
  - Standardized rules for data collection
- Allow aggregation of comparable data at local, PSO, regional, & national levels
- Facilitate exchange of information, learning



Design Goals

- Be driven by envisioned uses
  - First use at point-of-care
  - Roll up to PSO, regional, national levels
- Based on evidence; scientifically supportable
- Practical, intuitive, & useful
- As short & simple as possible
- Permit controlled expansion / revision
- Conform, where possible, with accepted wisdom (e.g., CDC for HAIs, WHO-ICPS)

Framework and Scope

- Limit initial scope to safety: preventing harm to patients from the delivery of health care
- Develop for specific delivery settings; begin with hospitals
- Start with first phase of improvement cycle – the initial report
- Construct in modules

Common Formats Scope

- Common Formats apply to all patient safety concerns
  - Incidents – patient safety events that reached the patient, whether or not there was harm
  - Near misses (or close calls) – patient safety events that did not reach the patient
  - Unsafe conditions – any circumstance that increases the probability of a patient safety event

Modularized Common Formats

Healthcare Event Reporting Form (HERF)
- Identity
- Date, Time
- Location
- Reporter
- Narrative
- Link to other forms

Patient information Form (PIF)
- Demographics
- Harm
- Interventions

Summary of Initial Report (SIR)
- Assessment of preventability
- Final narrative
- Contributing factors
- Encoding

Event-specific forms
- Eight types of events, e.g.,
- Fall
- HAI
- Medication

Hospital Common Formats - Version 1.2

General

- About Hospital Common Formats
- Clinical Release Notes
- ZIP File (All Event Descriptions, Sample Reports, and Forms)
- Users Guide & Glossary

Generic Formats

- HERF / PIF / SIR

Event-Specific Formats

- Blood or Blood Product
- Device or Medical/Surgical Supply, including HIT
- Fall
- Healthcare-associated Infection
- Medication or Other Substance
- Perinatal
- Pressure Ulcer
- Surgery or Anesthesia
- Venous Thromboembolism

Technical Specifications

- Overview
- Technical Release Notes
- Data Submission Specifications
- Appendix A: Resources Workbook
- Appendix B: Flow Charts
- Appendix C: CDA XML File Sample
- Data Dictionary
- Paper Forms Including Data Element Notations
- Local Specifications
- Report Specifications
- ZIP Files (All Tech Specs)

https://www.psoppc.org/web/patientsafety/commonformats

H DEVICE OR MEDICAL/SURGICAL SUPPLY, INCLUDING HEALTH INFORMATION TECHNOLOGY (HIT)

Use this form to report any patient safety event or unsafe condition involving a defect, failure, or incorrect use of a device, including an HIT device. A device includes an implant, medical equipment, or medical/surgical supply (including disposable product). An HIT device includes hardware or software that is used to electronically create, maintain, analyze, store, or receive information to aid in the diagnosis, cure, mitigation, treatment, or prevention of disease and that is not an integral part of (1) an implantable device or (2) an item of medical equipment.

For defects or events discovered prior to market approval or clinical deployment, do not use this form. If the event also involves a medication or other substance, please complete the Medication or Other Substance form in addition to this form. Narrative detail can be captured on the Healthcare Event Reporting Form (HERF). Highlighted fields are collected for local facility and Patient Safety Organization (PSO) use. This information will not be forwarded to the Network of Patient Safety Databases (NPSD).

1. Which of the following best describes the event or unsafe condition? CHECK ONE:

a. ☐ Device defect or failure, including HIT
b. ☐ Use error
c. ☐ Combination or interaction of device defect or failure and use error
d. ☐ Unknown

2. What type of device was involved in the event or unsafe condition? CHECK ONE:

a. ☐ Implantable device (i.e., device intended to be inserted into, and remain permanently in, tissue)

3. At the time of the event, was the device placed within the patient's tissue? CHECK ONE:

a. ☐ Yes

4. Did the event result in the device being removed? CHECK ONE:

a. ☐ Yes
b. ☐ No
c. ☐ Unknown

b. ☐ No
c. ☐ Unknown

b. ☐ Medical equipment (e.g., walker, hearing aid)
c. ☐ Medical/surgical supply, including disposable product (e.g., incontinence supply)
d. ☐ HIT device

5. **What is the name (brand or generic) of the device, product, software, or medical/surgical supply?**

_____

6. **What is the name of the manufacturer?**

_____

Initial Report Date (HERF Q1) _____

7. Which of the following identifiers are known? CHECK ALL THAT APPLY:

a. ☐ Model number → **8. What is the model number?** _____

b. ☐ Software version → **9. What is the software version?** _____

c. ☐ Firmware version → **10. What is the firmware version?** _____

d. ☐ Serial number → **11. What is the serial number?** _____

e. ☐ Lot or batch number → **12. What is the lot or batch number?** _____

f. ☐ Other unique product identifier → **13. What is the type of other unique product identifier?** _____

14. What is the other unique product identifier? _____

g. ☐ Date of expiration → **15. What is the expiration date?** ___ ___/ ___ ___/ ___ ___ ___ ___ (MM DD YYYY)

h. ☐ Unique Device Identifier → **16. What is the Unique Device Identifier (UDI)?** _____

i. ☐ Asset tag → **17. What is the asset tag number?** _____

j. ☐ No identifiers known

18. Was a device intended for single use involved in the event or unsafe condition (including use of a reprocessed single-use device)? CHECK ONE:

a. ☐ Yes
b. ☐ No
c. ☐ Unknown

19. Was a device intended for a single use reused in the event or unsafe condition? CHECK ONE:

a. ☐ Yes
b. ☐ No
c. ☐ Unknown

20. Did the event or unsafe condition involve a medication or other substance? CHECK ONE:

a. ☐ Yes → **ALSO COMPLETE THE MEDICATION OR OTHER SUBSTANCE FORM**
b. ☐ No
c. ☐ Unknown

IF THE EVENT OR UNSAFE CONDITION DID NOT INVOLVE AN HIT DEVICE

STOP This form is complete.

IF THE EVENT OR UNSAFE CONDITION INVOLVED AN HIT DEVICE, ANSWER QUESTIONS 21-26

21. Which of the following best characterizes the type of HIT device related to the event or unsafe condition?

CHECK ONE:

a. ☐ Administrative/billing or practice management system

b. ☐ Automated dispensing system

c. ☐ Electronic health record (EHR) or component of EHR

d. ☐ Human interface device (e.g., keyboard, mouse, touchscreen, speech recognition system, monitor/display, printer)

e. ☐ Laboratory information system (LIS), including microbiology and pathology systems

f. ☐ Radiology/diagnostic imaging system, including picture archiving and communications system (PACS)

g. ☐ Other: **PLEASE SPECIFY** _____

22. Which component of the administrative/billing system?

CHECK ONE:

a. ☐ Master patient index

b. ☐ Registration/appointment scheduling system

c. ☐ Coding/billing system

d. ☐ Unknown

e. ☐ Other: **PLEASE SPECIFY** _____

23. Which type or component of the EHR? CHECK ONE:

a. ☐ Computerized provider order entry (CPOE) system

b. ☐ Pharmacy system

c. ☐ Electronic medication administration record (e-MAR)

d. ☐ Clinical documentation system (e.g., progress notes)

e. ☐ Clinical decision support (CDS) system

f. ☐ Unknown

g. ☐ Other: **PLEASE SPECIFY** _____

24. Which of the following describes the circumstances involving the HIT device in the event or unsafe condition?
CHECK ALL THAT APPLY:

a. ☐ Incompatibility between devices
b. ☐ Equipment/device function
c. ☐ Equipment/device maintenance
d. ☐ Hardware failure or problem
e. ☐ Network failure or problem
f. ☐ Ergonomics, including human/device interface issue
g. ☐ Security, virus, or other malware issue
h. ☐ Unexpected software design issue
i. ☐ Unknown
j. ☐ Other: **PLEASE SPECIFY**

_____

25. Which problem(s) resulted from the equipment/device function problem? CHECK ALL THAT APPLY:

a. ☐ Loss or delay of data
b. ☐ System returns or stores data that does not match patient
c. ☐ Image measurement/corruption issue
d. ☐ Image orientation incorrect
e. ☐ Incorrect test results
f. ☐ Incorrect software programming calculation
g. ☐ Incorrect or inappropriate alert
h. ☐ Other: **PLEASE SPECIFY**

_____

26. Which ergonomics or human/device interface issue(s)?
CHECK ALL THAT APPLY:

a. ☐ Hardware location (e.g., awkward placement for use)
b. ☐ Data entry or selection (e.g., entry or selection of wrong patient, wrong provider, wrong drug, wrong dose)
c. ☐ Information display or interpretation (e.g., font size, color of font, location of information in display screen)
d. ☐ Alert fatigue/alarm fatigue
e. ☐ Other: **PLEASE SPECIFY**

_____

HEALTHCARE EVENT REPORTING FORM (HERF)

Use this form to report either a patient safety event or unsafe condition. The term event includes both an incident that reached the patient and a near miss (close call) that did not. Highlighted fields are collected for local facility and PSO use. This information will not be forwarded to the Network of Patient Safety Databases (NPSD).

1. Report Date: ___ ___ / ___ ___ / ___ ___ ___ ___
MM DD YYYY

2. What is being reported? CHECK ONE:

a. ☐ **Incident:** A patient safety event that reached the patient, whether or not the patient was harmed.

b. ☐ **Near Miss:** A patient safety event that did not reach the patient.

c. ☐ **Unsafe Condition:** Any circumstance that increases the probability of a patient safety event.

3. Event Discovery Date:
___ ___ / ___ ___ / ___ ___ ___ ___
MM DD YYYY

4. Event Discovery Time: ___ ___ ___ ___ HOURS
☐ Unknown
H H M M
(MILITARY TIME)

5. Briefly describe the event that occurred or unsafe condition:

6. Briefly describe the location where the event occurred or where the unsafe condition exists:

7. Which of the following categories are associated with the event or unsafe condition? CHECK ALL THAT APPLY:
FOR EACH CATEGORY SELECTED BELOW, EXCEPT "OTHER", PLEASE COMPLETE THE CORRESPONDING CATEGORY-SPECIFIC FORM. ALL CATEGORIES INCLUDE REPORTING OF INCIDENTS. ANY CATEGORY WITH + ALSO INCLUDES REPORTING OF NEAR MISSES. ANY CATEGORY WITH * ALSO INCLUDES REPORTING OF UNSAFE CONDITIONS.

a. ☐ Blood or Blood Product*+
b. ☐ Device or Medical/Surgical Supply, including Health Information Technology (HIT)*+
c. ☐ Fall
d. ☐ Healthcare-associated Infection
e. ☐ Medication or Other Substance*+
f. ☐ Perinatal
g. ☐ Pressure Ulcer
h. ☐ Surgery or Anesthesia (includes invasive procedure)+
i. ☐ Venous Thromboembolism
j. ☐ Other*+: PLEASE SPECIFY _____

PATIENT INFORMATION (COMPLETE ONLY IF INCIDENT):

Please complete the patient identifiers below. Additional patient information is captured on the Patient Information Form (PIF). (When reporting a perinatal incident that affected a mother and a neonate, please complete the patient identifiers below for the mother (Q8 – Q11) and the neonate (Q12 – Q15). Please also complete a separate PIF for the neonate involved.)

8. **Patient's Name:** _____ (FIRST) _____ (MIDDLE) _____ (LAST)

9. **Patient's Date of Birth:** __ __ / __ __ / __ __ __ __ (MM / DD / YYYY) 10. **Patient's Medical Record #:** _____

11. **Patient's Gender:** a. ☐ Male b. ☐ Female c. ☐ Unknown

NEONATAL PATIENT INFORMATION (COMPLETE ONLY FOR NEONATE AFFECTED BY PERINATAL INCIDENT):

12. **Neonate's Name:** _____ (FIRST) _____ (MIDDLE) _____ (LAST)

13. **Neonate's Date of Birth:** __ __ / __ __ / __ __ __ __ (MM / DD / YYYY) 14. **Neonate's Medical Record #:** _____

15. **Neonate's Gender:** a. ☐ Male b. ☐ Female c. ☐ Unknown

REPORT AND EVENT REPORTER INFORMATION

16. ☐ **Anonymous Reporter**

17. **Reporter's Name:** _____ (FIRST) _____ (MIDDLE) _____ (LAST)

18. **Telephone Number:** _____ 19. **Email Address:** _____

20. **Reporter's Job or Position:** _____

PATIENT INFORMATION FORM (PIF)

Use this form only if you are reporting an incident. (When reporting a perinatal incident that affected a mother and a neonate, complete a PIF for the mother and a separate PIF for the neonate.) Highlighted fields are collected for local facility and PSO use. This information will not be forwarded to the Network of Patient Safety Databases (NPSD).

1. At the time of the event what was the patient's age? CHECK ONE:

a. ☐ Neonate (0-28 days)
b. ☐ Infant (>28 days <1 year)
c. ☐ Child (1-12 years)
d. ☐ Adolescent (13-17 years)
e. ☐ Adult (18-64 years)
f. ☐ Mature adult (65-74 years)
g. ☐ Older adult (75-84 years)
h. ☐ Aged adult (85+ years)
i. ☐ Unknown

2. Is the patient's ethnicity Hispanic or Latino? CHECK ONE:

a. ☐ Hispanic or Latino
b. ☐ Not Hispanic or Latino
c. ☐ Unknown

3. What is the patient's race? CHECK ONE:

a. ☐ American Indian or Alaska Native
b. ☐ Asian
c. ☐ Black or African American
d. ☐ Native Hawaiian or Other Pacific Islander
e. ☐ White
f. ☐ More than one race
g. ☐ Unknown

4. Enter the patient's ICD-9-CM or ICD-10-CM principal diagnosis code at discharge (if available):

ICD-9-CM OR ICD-10-CM CODE

5. Was any intervention attempted in order to "rescue" the patient (i.e., to prevent, to minimize, or to reverse harm)?

CHECK ONE:

a. ☐ Yes
b. ☐ No
c. ☐ Unknown

6. Which of the following interventions (rescue) were documented?

CHECK ALL THAT APPLY:

a. ☐ Transfer, including transfer to a higher level care area within facility, transfer to another facility, or hospital admission (from outpatient)
b. ☐ Monitoring, including observation, physiological examination, laboratory testing, phlebotomy, and/or imaging studies
c. ☐ Medication therapy, including administration of antidote, change in pre-incident dose or route
d. ☐ Surgical/procedural intervention
e. ☐ Respiratory support (e.g., ventilation, tracheotomy)
f. ☐ Blood transfusion
g. ☐ Counseling or psychotherapy
h. ☐ Unknown
i. ☐ Other intervention: **PLEASE SPECIFY** _____

7. After any intervention to reduce harm, what was the degree of residual harm to the patient from the incident (and subsequent intervention)? CHECK FIRST APPLICABLE:

AHRQ Harm Scale

a. ☐ **Death:** Dead at time of assessment. → ANSWER QUESTION 9

b. ☐ **Severe harm:** Bodily or psychological injury (including pain or disfigurement) that interferes significantly with functional ability or quality of life.

c. ☐ **Moderate harm:** Bodily or psychological injury adversely affecting functional ability or quality of life, but not at the level of severe harm.

d. ☐ **Mild harm:** Bodily or psychological injury resulting in minimal symptoms or loss of function, or injury limited to additional treatment, monitoring, and/or increased length of stay.

e. ☐ **No harm:** Event reached patient, but no harm was evident. → ANSWER QUESTION 9

f. ☐ Unknown

8. What is the anticipated duration of the harm to the patient? CHECK ONE:

a. ☐ Permanent: not expected to revert to approximately normal (i.e., patient's baseline)

b. ☐ Temporary: expected to revert to approximately normal (i.e., patient's baseline)

c. ☐ Unknown

9. Approximately when after discovery of the incident was harm assessed? CHECK ONE:

a. ☐ Within 24 hours

b. ☐ After 24 hours but before 3 days

c. ☐ Three days or later

d. ☐ Unknown

10. Did, or will, the incident result in an increased length of stay? CHECK ONE:

a. ☐ Yes

b. ☐ No (or not anticipated)

c. ☐ Unknown

11. After the discovery of the incident, was the patient, patient's family, or guardian notified? CHECK ONE:

a. ☐ Yes

b. ☐ No

c. ☐ Unknown

H SUMMARY OF INITIAL REPORT (SIR)

Use this form after all other forms applicable to this event (incident or near miss [close call]) or unsafe condition reported on the Healthcare Event Reporting Form (HERF) have been reviewed. Highlighted fields are collected for local facility and PSO use. This information will not be forwarded to the Network of Patient Safety Databases (NPSD).

1. What is the date of the summary of the initial report?

__ __ / __ __ / __ __ __ __
MM DD YYYY

2. Where did the event occur, or, if an unsafe condition, where does it exist? (PLEASE REFER TO HERF QUESTION 6) CHECK ONE:

a. ☐ Inpatient general care area (e.g., medical/surgical unit)

l. ☐ Unknown
m. ☐ Other: **PLEASE SPECIFY** _____

3. Who reported the event or unsafe condition? (PLEASE REFER TO HERF QUESTION 20) CHECK ONE:

a. ☐ Healthcare professional
b. ☐ Healthcare worker, including nursing assistant, patient transport/retrieval personnel, assistant/orderly, clerical/administrative personnel, interpreter/translator, technical/laboratory personnel, pastoral care personnel, biomedical engineer, housekeeping, maintenance, patient care assistant, or administrator/manager
c. ☐ Emergency service personnel, including police officer, fire fighter, or other emergency service officer
d. ☐ Patient, family member, volunteer, caregiver, or home assistant
e. ☐ Unknown
f. ☐ Other: **PLEASE SPECIFY**
_____

4. What is the type of healthcare professional? CHECK ONE:

a. ☐ Doctor, dentist (including student)
b. ☐ Nurse, nurse practitioner, physician assistant (including student or trainee)
c. ☐ Pharmacist, pharmacy technician (including student)
d. ☐ Allied health professional (including paramedic, speech, physical and occupational therapist, dietician)

5. **Please describe any additional details about the event or unsafe condition discovered after completion of the HERF:**

_____

_____

IF UNSAFE CONDITION STOP **This form is complete.**

IF NEAR MISS, ANSWER QUESTIONS 6 - 11

IF INCIDENT, ANSWER QUESTIONS 7 - 12

6. **What prevented the near miss (close call) from reaching the patient?** CHECK ONE:
   - a. ☐ Fail-safe designed into the process and/or a safeguard worked effectively
   - b. ☐ Practitioner or staff member who made the error noticed and recovered from this error (avoiding any possibility of it reaching the patient)
   - c. ☐ Spontaneous action by a practitioner or staff member prevented the event from reaching the patient
   - d. ☐ Action by the patient's family member prevented the event from reaching the patient
   - e. ☐ Other: **PLEASE SPECIFY** _____
   - f. ☐ Unknown

7. **Was the event associated with a handover/handoff?** CHECK ONE:
   - a. ☐ Yes
   - b. ☐ No
   - c. ☐ Unknown

8. Are any contributing factors to the event known? CHECK ONE:

a. ☐ Yes
b. ☐ No
c. ☐ Unknown

9. What factor(s) contributed to the event? CHECK ALL THAT APPLY:

Environment

a. ☐ Culture of safety, management
b. ☐ Physical surroundings (e.g., lighting, noise)

Staff qualifications

c. ☐ Competence (e.g., qualifications, experience)
d. ☐ Training

Supervision/support

e. ☐ Clinical supervision
f. ☐ Managerial supervision

Policies and procedures, includes clinical protocols

g. ☐ Presence of policies
h. ☐ Clarity of policies

Data

i. ☐ Availability
j. ☐ Accuracy
k. ☐ Legibility

Communication

l. ☐ Supervisor to staff
m. ☐ Among staff or team members
n. ☐ Staff to patient (or family)

Human factors

o. ☐ Fatigue
p. ☐ Stress
q. ☐ Inattention
r. ☐ Cognitive factors
s. ☐ Health issues

Other

t. ☐ Other: **PLEASE SPECIFY** _____

10. Was the event a National Quality Forum (NQF) Serious Reportable Event? CHECK ONE:

a. ☐ Yes
b. ☐ No
c. ☐ Unknown

ANSWER QUESTION 12

11. What was the applicable Serious Reportable Event? CHECK ONE:

Surgical or Invasive Procedure Events

a. ☐ Surgery or other invasive procedure performed on the wrong site
b. ☐ Surgery or other invasive procedure performed on the wrong patient
c. ☐ Wrong surgical or other invasive procedure performed on a patient
d. ☐ Unintended retention of a foreign object in a patient after surgery or other invasive procedure
e. ☐ Intraoperative or immediately postoperative/postprocedure death in an ASA Class 1 patient

Product or Device Events

f. ☐ Patient death or serious injury associated with the use of contaminated drugs, devices, or biologics provided by the healthcare setting
g. ☐ Patient death or serious injury associated with the use or function of a device in patient care, in which the device is used or functions other than as intended
h. ☐ Patient death or serious injury associated with intravascular air embolism that occurs while being cared for in a healthcare setting

Patient Protection Events

i. ☐ D[illegible] of a [illegible] of anyone, who is unable to make decisions, to other than an

12. How preventable was the incident? CHECK ONE:

a. ☐ Almost certainly could have been prevented
b. ☐ Likely could have been prevented
c. ☐ Likely could not have been prevented
d. ☐ Almost certainly could not have been prevented
e. ☐ Provider does not make this determination by policy
f. ☐ Unknown

Thank you for completing these questions.

OMB No. 0935-0143 **Exp. Date10/31/2014**
Public reporting burden for the collection of information is estimated to average 15 minutes per response. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: AHRQ Reports Clearance Officer, Attention: PRA, Paperwork Reduction Project (0935-0143), AHRQ, 540 Gaither Road, Room #5036, Rockville, MD 20850.

H BLOOD OR BLOOD PRODUCT

Use this form to report any patient safety event or unsafe condition involving the processing and/or administration of blood or a blood product. This form is not intended for reporting blood or blood product collection and other processes prior to receipt of the product by the blood bank. If the event involves a device, please also complete the Device or Medical/Surgical Supply, including Health Information Technology (HIT) form. Narrative detail can be captured on the Healthcare Event Reporting Form (HERF). Highlighted fields are collected for local facility and PSO use. This information will not be forwarded to the Network of Patient Safety Databases (NPSD).

1. What type of blood product was involved in the event or unsafe condition? CHECK ONE:

- a. ☐ Whole blood
- b. ☐ Red blood cells
- c. ☐ Platelets
- d. ☐ Plasma
- e. ☐ Cryoprecipitate
- f. ☐ Granulocytes
- g. ☐ Lymphocytes
- h. ☐ Albumin
- i. ☐ Factors (e.g., VII, VIII, IX, AT III)
- j. ☐ IV immunoglobulin
- k. ☐ RhIg
- l. ☐ Other: **PLEASE SPECIFY** _____

2. What was the International Society of Blood Transfusion (ISBT) 8 digit product code for the product associated with this event or unsafe condition?

ISBT PRODUCT CODE

IF UNSAFE CONDITION → STOP This form is complete.

3. Which of the following best characterizes the event? CHECK ONE:

- a. ☐ Incorrect action (e.g., patient given blood of wrong ABO type)
- b. ☐ Adverse reaction during or following administration without any apparent incorrect action
- c. ☐ Unknown

→ STOP This form is complete.

4. What incorrect action was involved in administering the blood or blood product? CHECK ONE:

- a. ☐ Incorrect patient
- b. ☐ Incorrect ABO/Rh type
- c. ☐ Incorrect product (e.g., giving heterologous blood product when autologous blood product should have been given)
- d. ☐ Incorrect sequence of administration of products
- e. ☐ Incorrect use of expired or unacceptably stored products
- f. ☐ Incorrect volume (e.g., number of units or milliliters)
- g. ☐ Incorrect IV fluid (i.e., administered product with incorrect IV fluid)
- h. ☐ Incorrect timing (e.g., delay in administration)
- i. ☐ Incorrect rate
- j. ☐ Unknown
- k. ☐ Other: **PLEASE SPECIFY**

_____

5. Was a two-person, three-way check documented? CHECK ONE:

- a. ☐ Yes
- b. ☐ No
- c. ☐ Unknown

6. What was the volume? CHECK ONE:

- a. ☐ Too much/too many
- b. ☐ Too little/too few
- c. ☐ Unknown

7. Was the rate of administration: CHECK ONE:

- a. ☐ Too fast
- b. ☐ Too slow
- c. ☐ Unknown

8. During which stage was the event discovered (regardless of the stage when it originated)? CHECK ONE:

a. ☐ Product test or request
b. ☐ Sample collection
c. ☐ Sample handling
d. ☐ Sample receipt
e. ☐ Sample testing
f. ☐ Product storage
g. ☐ Available for issue
h. ☐ Product selection
i. ☐ Product manipulation
j. ☐ Request for pickup
k. ☐ Product issue
l. ☐ Product administration (transfusion or infusion)
m. ☐ Post-transfusion or administration
n. ☐ Unknown
o. ☐ Other: **PLEASE SPECIFY** _____

9. During which stage did the event originate (regardless of the stage when it was discovered)? CHECK ONE:

a. ☐ Product check-in
b. ☐ Product test or request
c. ☐ Sample collection
d. ☐ Sample handling
e. ☐ Sample receipt
f. ☐ Sample testing
g. ☐ Product storage
h. ☐ Available for issue
i. ☐ Product selection
j. ☐ Product manipulation
k. ☐ Request for pickup
l. ☐ Product issue
m. ☐ Product administration (transfusion or infusion)
n. ☐ Post-transfusion or administration
o. ☐ Unknown
p. ☐ Other: **PLEASE SPECIFY** _____

Thank you for completing these questions.

H FALL

Use this form to report details of a fall. For purposes of patient safety, a fall is a sudden, unintended, uncontrolled, downward displacement of a patient's body to the ground or other object (e.g., onto a bed, chair, or bedside mat). This definition includes unassisted falls and assisted falls (i.e., when a patient begins to fall and is assisted to the ground by another person). This definition excludes near falls (loss of balance that does not result in a fall) and falls resulting from a purposeful action or violent blow (e.g., a patient pushes another patient). Narrative detail can be captured on the Healthcare Event Reporting Form (HERF). Highlighted fields are collected for local facility and PSO use. This information will not be forwarded to the Network of Patient Safety Databases (NPSD).

1. Was the fall unassisted or assisted? CHECK ONE:

- a. ☐ Unassisted
- b. ☐ Assisted
- c. ☐ Unknown

2. Was the fall observed? CHECK ONE:

- a. ☐ Yes → **3. Who observed the fall?** CHECK FIRST APPLICABLE:
  - a. ☐ Staff
  - b. ☐ Visitor, family, or another patient, but not staff
- b. ☐ No
- c. ☐ Unknown

4. Did the patient sustain a physical injury as a result of the fall? CHECK ONE:

- a. ☐ Yes → **5. What type of injury was sustained?** CHECK ONE; IF MORE THAN ONE, CHECK MOST SEVERE:
  - a. ☐ Dislocation
  - b. ☐ Fracture
  - c. ☐ Intracranial injury
  - d. ☐ Laceration requiring sutures
  - e. ☐ Skin tear, avulsion, hematoma or significant bruising
  - f. ☐ Other: **PLEASE SPECIFY** _____
- b. ☐ No
- c. ☐ Unknown

6. Prior to the fall, what was the patient doing or trying to do? CHECK ONE:

a. ☐ Ambulating without assistance and without an assistive device or medical equipment
b. ☐ Ambulating with assistance and/or with an assistive device or medical equipment
c. ☐ Changing position (e.g., in bed, chair)
d. ☐ Dressing or undressing
e. ☐ Navigating bedrails
f. ☐ Reaching for an item
g. ☐ Showering or bathing
h. ☐ Toileting
i. ☐ Transferring to or from bed, chair, wheelchair, etc.
j. ☐ Undergoing a diagnostic or therapeutic procedure
k. ☐ Unknown
l. ☐ Other: **PLEASE SPECIFY** _____

7. Prior to the fall, was a fall risk assessment documented? CHECK ONE:

a. ☐ Yes
b. ☐ No
c. ☐ Unknown

8. Was the patient determined to be at increased risk for a fall? CHECK ONE:

a. ☐ Yes
b. ☐ No
c. ☐ Unknown

9. At the time of the fall, were any of the following risk factors present? CHECK ALL THAT APPLY:

a. ☐ History of previous fall
b. ☐ Prosthesis or specialty/prescription shoe
c. ☐ Sensory impairment (vision, hearing, balance, etc.)
d. ☐ None
e. ☐ Unknown
f. ☐ Other: **PLEASE SPECIFY** _____

10. Which of the following were in place and being used to prevent falls for this patient? CHECK ALL THAT APPLY:

a. ☐ Assistive device (e.g., wheelchair, commode, cane, crutches, scooter, walker)
b. ☐ Bed or chair alarm
c. ☐ Bed in low position
d. ☐ Call light/personal items within reach
e. ☐ Change in medication (e.g., timing or dosing of current medication)
f. ☐ Non-slip floor mats
g. ☐ Hip and/or joint protectors
h. ☐ Non-slip footwear
i. ☐ Patient and family education
j. ☐ Patient sitting close to the nurses' station
k. ☐ Physical/occupational therapy, includes exercise or mobility program
l. ☐ Sitter
m. ☐ Supplemental environmental or area lighting (when usual facility lighting is considered insufficient)
n. ☐ Toileting regimen
o. ☐ Visible identification of patient as being at risk for fall (e.g., Falling Star)
p. ☐ None
q. ☐ Unknown
r. ☐ Other: **PLEASE SPECIFY** _____

11. At time of the fall, was the patient on medication known to increase the risk of fall? CHECK ONE:

a. ☐ Yes
b. ☐ No
c. ☐ Unknown

12. Was the medication considered to have contributed to the fall? CHECK ONE:

a. ☐ Yes
b. ☐ No
c. ☐ Unknown

13. Did restraints, bedrails, or other physical device contribute to the fall (includes tripping over device electrical power cords)? CHECK ONE:

a. ☐ Yes
b. ☐ No
c. ☐ Unknown

HEALTHCARE-ASSOCIATED INFECTION

Use this form to report a healthcare-associated infection (HAI). An HAI is a localized or systemic condition resulting from an adverse reaction to the presence of an infectious agent(s) or its toxin(s). It is acquired during the course of receiving treatment for other conditions within a healthcare setting, with no evidence that the infection was present or incubating at the time of admission (except surgical site infection (SSI)). Narrative detail can be captured on the Healthcare Event Reporting Form (HERF). Highlighted fields are collected for local facility and PSO use. This information will not be forwarded to the Network of Patient Safety Databases (NPSD).

The Centers for Disease Control and Prevention's National Health Safety Network (NHSN) gathers surveillance data on four major types of healthcare-associated infections: surgical site infections (SSI), central line-associated bloodstream infections (CLABSI), ventilator-associated pneumonias (VAP), and catheter-associated urinary tract infections (CAUTI). Although the Common Formats capture information on additional types of HAIs, we limit capture of further detail on HAIs to those tracked in the NHSN. Specific NHSN definitions are provided below.

Central line-associated bloodstream infection (CLABSI):	Primary bloodstream infection (BSI) in a patient that had a central line within the 48-hour period before the development of the BSI and is not bloodstream related to an infection at another site. http://www.cdc.gov/nhsn/PDFs/pscManual/4PSC_CLABScurrent.pdf
Ventilator-associated pneumonia (VAP):	Pneumonia (PNEU) that occurs in a patient who was intubated and ventilated at the time of, or within 48 hours before, the onset of the PNEU. http://www.cdc.gov/nhsn/PDFs/pscManual/6pscVAPcurrent.pdf
Catheter-associated urinary tract infection (CAUTI):	Urinary tract infection (UTI) that occurs in a patient who had an indwelling urinary catheter in place within the 48-hour period before the onset of the UTI. http://www.cdc.gov/nhsn/PDFs/pscManual/7pscCAUTIcurrent.pdf
Surgical site infection (SSI):	For full details please refer to http://www.cdc.gov/nhsn/PDFs/pscManual/9pscSSIcurrent.pdf
Clostridium difficile infection (CDI):	For full details please refer to http://www.cdc.gov/nhsn/PDFs/pscManual/12pscMDRO_CDADcurrent.pdf

NOTE: There is no minimum period of time that the device must be in place in order for the infection to be considered device-associated.

1. Was the infection determined to be present or incubating on admission? CHECK ONE:

a. ☐ Yes – infection was determined to be present or incubating on admission → ANSWER QUESTION 2

b. ☐ No – infection developed during this admission → ANSWER QUESTION 3

c. ☐ Unknown → ANSWER QUESTION 3

2. Which of the following best describes the infection? CHECK ONE:

a. ☐ Surgical site infection (SSI) in a patient operated on at this facility in the previous 30 days or, if an implant, in the previous year → ANSWER QUESTION 3

b. ☐ Community acquired infection that was determined to be present or incubating on admission with no treatment at any facility → STOP This form is complete.

c. ☐ Presumed HAI (other than SSI) that developed following a discharge from this facility → STOP This form is complete.

d. ☐ Presumed HAI (other than SSI) that developed following treatment at an outpatient site, operated by this facility → STOP This form is complete.

e. ☐ Presumed HAI that developed following treatment at another inpatient or outpatient facility → STOP This form is complete.

3. Was the person who determined the infection to be a healthcare-associated infection (HAI) a healthcare professional with specific training in infectious disease and/or infection control? CHECK ONE:

a. ☐ Yes

b. ☐ No

c. ☐ Unknown

4. What type of HAI is being reported? CHECK ONE:

a. ☐ Primary bloodstream infection (BSI)

5. Was it central line-associated (CLABSI)? CHECK ONE:

a. ☐ Yes → ANSWER QUESTION 10

b. ☐ No → STOP This form is complete.

b. ☐ Pneumonia

6. Was it a ventilator-associated pneumonia (VAP - i.e., the patient had a device to assist or control respiration continuously through a tracheostomy or by endotracheal intubation)? CHECK ONE:

a. ☐ Yes → ANSWER QUESTION 11

b. ☐ No → STOP This form is complete.

c. ☐ Urinary tract infection

7. Was it catheter-associated (CAUTI)? CHECK ONE:

a. ☐ Yes → ANSWER QUESTION 12

b. ☐ No → STOP This form is complete.

d. ☐ Surgical site infection (SSI)

8. The SSI was classified as which of the following? CHECK FIRST APPLICABLE:

a. ☐ Organ/space
b. ☐ Deep incisional primary (DIP)
c. ☐ Deep incisional secondary (DIS)
d. ☐ Superficial incisional primary (SIP)
e. ☐ Superficial incisional secondary (SIS)
f. ☐ Unknown

→ STOP This form is complete.

PLEASE ALSO COMPLETE THE SURGERY OR ANESTHESIA FORM

e. ☐ Clostridium difficile infection (CDI) – gastrointestinal system infection → STOP This form is complete.

f. ☐ Other type of infection (not involving surgical site) that developed during admission → ANSWER QUESTION 9

9. Which other type of infection? CHECK ONE:

- a. ☐ Bone or joint infection
- b. ☐ Central nervous system infection
- c. ☐ Cardiovascular system infection
- d. ☐ Eye, ear, nose, throat, or mouth infection
- e. ☐ Gastrointestinal system infection – non CDI
- f. ☐ Lower respiratory tract infection (other than pneumonia)
- g. ☐ Reproductive tract infection
- h. ☐ Skin or soft tissue infection
- i. ☐ Systemic infection
- j. ☐ Other: **PLEASE SPECIFY** _____

→ STOP This form is complete.

ONLY IF EVENT INVOLVED A **CLABSI**, ANSWER QUESTION **10**

10. Which type of central line? CHECK ONE:

- a. ☐ Permanent (tunneled or implanted) central line
- b. ☐ Temporary (non-tunneled) central line
- c. ☐ Umbilical catheter

→ ANSWER QUESTION **14**

ONLY IF EVENT INVOLVED A **VAP**, ANSWER QUESTION **11**

11. The VAP was classified as which of the following? CHECK FIRST APPLICABLE:

- a. ☐ Clinically defined pneumonia (PNU1)
- b. ☐ Pneumonia with specific laboratory findings (PNU2)
- c. ☐ Pneumonia in an immunocompromised patient determined by both clinical and laboratory criteria (PNU3)
- d. ☐ Unknown

→ ANSWER QUESTION **14**

ONLY IF EVENT INVOLVED A **CAUTI**, ANSWER QUESTIONS **12 - 13**

12. What was the urinary catheter status at the time of specimen collection that was the basis for diagnosis of CAUTI? CHECK ONE:

- a. ☐ In place at the time of specimen collection
- b. ☐ Removed within 48 hours prior to specimen collection

13. The CAUTI was classified as which of the following? CHECK ONE:

- a. ☐ Symptomatic UTI
- b. ☐ Asymptomatic bacteremic UTI

ONLY IF EVENT INVOLVED A **CLABSI, VAP,** OR **CAUTI,** ANSWER QUESTION **14**

14. At which inpatient location was the patient assigned when the specimen that met the infection criteria was collected, or when the first clinical evidence of CLABSI, VAP, or CAUTI appeared? If the infection developed within 48 hours of transfer from one location to one or more other locations within this facility, select the patient's first such inpatient location within the 48 hour period where the central line, urinary catheter, or ventilator was used.

CHECK ONE:

a. ☐ Specialty care area (i.e., hematology/oncology ward, bone marrow transplant unit, solid organ transplant unit, inpatient dialysis unit, or long term acute care area)

b. ☐ Intensive care unit, including pediatric

c. ☐ Neonatal intensive care unit

d. ☐ Other location (e.g., surgical or medical ward)

e. ☐ Unknown

H MEDICATION OR OTHER SUBSTANCE

Use this form to report any patient safety event or unsafe condition involving a substance such as a medications, biological products, nutritional products, expressed human breast milk, medical gases, or contrast media. Do not complete this form if the event involves appropriateness of therapeutic choice or decision making (e.g., physician decision to prescribe medication despite known drug-drug interaction). If the event involves a device, please also complete the Device or Medical/Surgical Supply including Health Information Technology (HIT) form. Narrative detail can be captured on the Healthcare Event Reporting Form (HERF). Highlighted fields are collected for local facility and PSO use. This information will not be forwarded to the Network of Patient Safety Databases (NPSD).

1. What type of medication/substance was involved? CHECK ONE:

a. ☐ Medications

2. What type of medication? CHECK ONE:

a. ☐ Prescription or over-the-counter (including herbal supplements)
b. ☐ Compounded preparations
c. ☐ Investigational drugs
d. ☐ Unknown

3. Please list all ingredients:

_____

_____

_____

_____

b. ☐ Biological products

4. What type of biological product? CHECK ONE:

a. ☐ Vaccines
b. ☐ Other biological products (e.g., thrombolytic)

5. What was the lot number of the vaccine?

LOT NUMBER

c. ☐ Nutritional products

6. What type of nutritional product? CHECK ONE:

a. ☐ Dietary supplements (other than vitamins or minerals)
b. ☐ Vitamins or minerals
c. ☐ Enteral nutritional products, including infant formula
d. ☐ Parenteral nutritional products
e. ☐ Other: PLEASE SPECIFY _____

d. ☐ Expressed human breast milk

e. ☐ Medical gases (e.g., oxygen, nitrogen, nitrous oxide)

f. ☐ Contrast media

g. ☐ Radiopharmaceuticals
h. ☐ Patient food (not suspected in drug-food interactions)
i. ☐ Drug-drug, drug-food, or adverse drug reaction as a result of a prescription and/or administration of a drug and/or food prior to admission

STOP This form is complete.

j. ☐ Other substance: PLEASE SPECIFY _____

7. Which of the following best characterizes the event? CHECK ONE:

a. ☐ Incorrect action (process failure or error) (e.g., such as administering overdose or incorrect medication)

b. ☐ Unsafe condition

→ ANSWER QUESTIONS 17 - 25

c. ☐ Adverse reaction in patient to the administered substance without any apparent incorrect action

d. ☐ Unknown

→ STOP This form is complete.

8. What was the incorrect action? CHECK ALL THAT APPLY:

a. ☐ Incorrect patient

b. ☐ Incorrect medication/substance

c. ☐ Incorrect dose(s)

9. Which best describes the incorrect dose(s)? CHECK ONE:

a. ☐ Overdose
b. ☐ Underdose
c. ☐ Missed or omitted dose
d. ☐ Extra dose
e. ☐ Unknown

d. ☐ Incorrect route of administration

e. ☐ Incorrect timing

10. Which best describes the incorrect timing? CHECK ONE:

a. ☐ Too early
b. ☐ Too late
c. ☐ Unknown

f. ☐ Incorrect rate

11. Which best describes the incorrect rate? CHECK ONE:

a. ☐ Too quickly
b. ☐ Too slowly
c. ☐ Unknown

g. ☐ Incorrect duration of administration or course of therapy

h. ☐ Incorrect dosage form (e.g., sustained release instead of immediate release)

i. ☐ Incorrect strength or concentration

12. Which best describes the incorrect strength or concentration? CHECK ONE:

a. ☐ Too high
b. ☐ Too low
c. ☐ Unknown

j. ☐ Incorrect preparation, including inappropriate cutting of tablets, error in compounding, mixing, etc.

k. ☐ Expired or deteriorated medication/substance

13. What was the expiration date? __ __ / __ __ / __ __ __ __
MM DD YYYY

l. ☐ Medication/substance that is known to be an allergen to the patient

14. Was there a documented history of allergies or sensitivities to the medication/substance administered? CHECK ONE:

a. ☐ Yes
b. ☐ No
c. ☐ Unknown

m. ☐ Medication/substance that is known to be contraindicated for the patient

15. What was the contraindication (potential or actual interaction)? CHECK ONE:

a. ☐ Drug-drug
b. ☐ Drug-food
c. ☐ Drug-disease
d. ☐ Other: PLEASE SPECIFY _____

n. ☐ Incorrect patient/family action (e.g., self-administration error)

o. ☐ Other: PLEASE SPECIFY _____

16. At what stage in the process did the event originate, regardless of the stage at which it was discovered?

CHECK ONE:

a. ☐ Purchasing
b. ☐ Storing
c. ☐ Prescribing/ordering
d. ☐ Transcribing
e. ☐ Preparing
f. ☐ Dispensing
g. ☐ Administering
h. ☐ Monitoring
i. ☐ Unknown
j. ☐ Other: **PLEASE SPECIFY** _____

H PERINATAL

Use this form to report any patient safety event associated with the birthing process or intrauterine procedures that occur during the perinatal period to the mother, fetus(es), or neonate(s). The perinatal period extends from the 20th week of gestation through 4 weeks (28 days) postpartum. Narrative detail can be captured on the Healthcare Event Reporting Form (HERF). Highlighted fields are collected for local facility and PSO use. This information will not be forwarded to the Network of Patient Safety Databases (NPSD).

If a single event affected the mother, and/or fetus or neonate, use one perinatal event form. In the rare circumstance when a single event affects more than one neonate, fill out this form for the most severely affected neonate and note injury to other neonate(s) in the narrative.

1. Which of the following did the event involve? CHECK ONE:

a. ☐ Birthing process (labor and delivery)
b. ☐ Intrauterine procedure (prenatal)
c. ☐ Other
d. ☐ Unknown

→ STOP **This form is complete.**

2. Immediately prior to delivery, or at the time of the intrauterine procedure (prenatal), what was the best estimate of completed weeks of gestation? CHECK ONE:

a. ☐ 20-< 36 weeks
b. ☐ 36-< 38 weeks
c. ☐ 38-< 42 weeks
d. ☐ 42 weeks or more
e. ☐ Unknown

3. Was the mother a primipara? CHECK ONE:

a. ☐ Yes
b. ☐ No
c. ☐ Unknown

4. How many fetuses were in this pregnancy? ENTER NUMBER:

NUMBER

COUNT FETUSES WHETHER OR NOT BORN ALIVE. IF A FETAL REDUCTION WAS PERFORMED, COUNT THE NUMBER AFTER SUCH REDUCTION.

5. Who was affected by the event? CHECK ALL THAT APPLY:

a. ☐ Mother
b. ☐ Fetus(es)
c. ☐ Neonate(s)

ONLY IF EVENT AFFECTED THE MOTHER, ANSWER QUESTION 6 -8

6. Which adverse outcome(s) did the mother sustain? CHECK ALL THAT APPLY:

a. ☐ Hemorrhage requiring transfusion
b. ☐ Eclampsia
c. ☐ Magnesium toxicity
d. ☐ Infection
e. ☐ Injury to body part or organ
f. ☐ Death
g. ☐ Other: **PLEASE SPECIFY** _____

7. Which of the following maternal infections? CHECK ONE:

a. ☐ Chorioamnionitis
b. ☐ Endometritis
c. ☐ Other: **PLEASE SPECIFY** _____

8. Which body part(s) or organ(s)? CHECK ALL THAT APPLY:

a. ☐ Uterine rupture
b. ☐ Third- or fourth-degree perineal laceration
c. ☐ Ureter
d. ☐ Bladder
e. ☐ Bowel
f. ☐ Other: **PLEASE SPECIFY** _____

ONLY IF EVENT AFFECTED A FETUS, ANSWER QUESTION 9

9. Which adverse outcome did the fetus sustain? CHECK FIRST APPLICABLE:

a. ☐ Unexpected death
b. ☐ Injury

ONLY IF EVENT AFFECTED A NEONATE, ANSWER QUESTIONS 10- 12

10. What was the 5-minute Apgar score? ☐

APGAR SCORE

11. Which adverse outcome(s) did the neonate sustain? CHECK ALL THAT APPLY:

a. ☐ Birth trauma/injury as listed under ICD-9-CM 767 or ICD-10-CM P10-P15
b. ☐ Five-minute Apgar < 7 and birthweight > 2500 grams
c. ☐ Anoxic or hypoxic encephalopathy
d. ☐ Seizure(s)
e. ☐ Infection (e.g., group B strep)
f. ☐ Unexpected death
g. ☐ Other: **PLEASE SPECIFY** _____

12. Which birth trauma/injury? CHECK ONE:

a. ☐ Subdural or cerebral hemorrhage
b. ☐ Injury to brachial plexus, including Erb's or Klumpke's paralysis
c. ☐ Other: **PLEASE SPECIFY** _____

IF THIS EVENT INVOLVED THE BIRTHING PROCESS, ANSWER QUESTIONS 13 - 20

13. What was the date of delivery? ___ ___ / ___ ___ / ___ ___ ___ ___

MM DD YYYY

14. Number of live births: ☐

ENTER NUMBER

15. What was the neonate's birthweight (or weight of stillborn)?

ENTER IN GRAMS

16. Was labor induced or augmented? CHECK ONE:

a. ☐ Yes
b. ☐ No
c. ☐ Unknown

17. Which one? CHECK ONE:

a. ☐ Induced
b. ☐ Augmented

18. What was the mode of delivery? CHECK ONE:

a. ☐ Vaginal delivery
b. ☐ Attempted vaginal delivery followed by Cesarean section
c. ☐ Cesarean section
d. ☐ Unknown

19. Regardless of the final mode of delivery, was instrumentation used to assist vaginal (or attempted vaginal) delivery? CHECK ONE:

a. ☐ Yes
b. ☐ No
c. ☐ Unknown

20. What instrumentation was used? CHECK ONE:

a. ☐ Vacuum
b. ☐ Forceps
c. ☐ Vacuum followed by forceps

H PRESSURE ULCER

Use this form to report a pressure ulcer or suspected deep tissue injury that was 1) not present on admission (i.e., newly-developed) or 2) worsened during the patient's stay. Report only an event that occurred prior to patient discharge. Narrative detail can be captured on the Healthcare Event Reporting Form (HERF). Exclude mucosal, arterial, or venous ulcers, diabetic foot ulcers, and ulcers in patients receiving palliative care. If a pressure ulcer is reported at a certain stage and gets worse before improvement, please do not complete a new Pressure Ulcer Event Report. Instead, edit the existing event report to reflect the new stage and submit this report. Highlighted fields are collected for local facility and Patient Safety Organization (PSO) use. This information will not be forwarded to the Network of Patient Safety Databases (NPSD).

Note: For staging/category information refer to *National Pressure Ulcer Advisory Panel, Prevention and treatment of pressure ulcers: clinical practice guideline.* Washington DC: National Pressure Ulcer Advisory Panel; 2009. The NPUAP website is (http://www.npuap.org).

1. What was the most advanced stage of the pressure ulcer or suspected Deep Tissue Injury being reported? CHECK ONE:

- a. ☐ Stage/Category I
- b. ☐ Stage/Category II

→ STOP **This form is complete.**

- c. ☐ Suspected Deep Tissue Injury

→ GO TO QUESTION 2

- d. ☐ Stage/Category III
- e. ☐ Stage/Category IV
- f. ☐ Unstageable (any type)

→ GO TO QUESTION 3

- g. ☐ Mucosal, arterial, or venous ulcer or diabetic foot ulcer or pressure ulcer related to palliative care
- h. ☐ Unknown

→ STOP **This form is complete.**

2. What was the status of the suspected Deep Tissue Injury on admission? CHECK ONE:

- a. ☐ Present as suspected Deep Tissue Injury

→ STOP **This form is complete.**

- b. ☐ Present as a Stage/Category I pressure ulcer
- c. ☐ Not present
- d. ☐ Unknown

→ GO TO QUESTION 4

3. What was the status on admission of the Stage/Category III, IV, or unstageable pressure ulcer? CHECK ONE:

a. ☐ Not present
b. ☐ Stage/Category I
c. ☐ Stage/Category II

→ GO TO QUESTION 4

d. ☐ Suspected Deep Tissue Injury
e. ☐ Stage/Category III
f. ☐ Stage/Category IV
g. ☐ Unstageable

→ STOP This form is complete.

h. ☐ Unknown

→ GO TO QUESTION 4

4. On admission to this facility, was a skin inspection documented? CHECK ONE:

a. ☐ Yes
b. ☐ No
c. ☐ Unknown

5. When was the first pressure ulcer risk assessment documented? CHECK ONE:

a. ☐ On admission (within 24 hours)
b. ☐ Not on admission, but documented prior to the discovery of a newly-developed, or advancement of an existing, pressure ulcer
c. ☐ Not on admission, but documented after discovery of a newly-developed, or advancement of an existing, pressure ulcer
d. ☐ No risk assessment documented
e. ☐ Unknown

6. What type of risk assessment was documented? CHECK FIRST APPLICABLE:

a. ☐ Formal assessment (e.g., Braden, Braden Q (pediatric version), Norton, Waterlow)
b. ☐ Clinical assessment
c. ☐ Unknown

7. As a result of the assessment, was the patient documented to be at increased risk for pressure ulcer? CHECK ONE:

a. ☐ Yes
b. ☐ No
c. ☐ Unknown

8. Was any preventive intervention implemented? CHECK ONE:

a. ☐ Yes
b. ☐ No
c. ☐ Unknown

9. What intervention(s) was used?
CHECK ALL THAT APPLY:

a. ☐ Pressure redistribution device
b. ☐ Repositioning
c. ☐ Hydration and/or nutritional support
d. ☐ Skin care practices to prevent moisture and shearing
e. ☐ Other: **PLEASE SPECIFY**

_____

10. Was the use of a device or appliance involved in the development or advancement of the pressure ulcer? CHECK ONE:

a. ☐ Yes
b. ☐ No
c. ☐ Unknown

11. What was the type of device or appliance? CHECK ONE:

a. ☐ Anti-embolic device
b. ☐ Intraoperative positioning device
c. ☐ Orthopedic appliance (e.g., cast, splint, orthotic)
d. ☐ Oxygen delivery device (e.g., nasal prongs, oxygen mask)
e. ☐ Restraints
f. ☐ Tube
g. ☐ Other: **PLEASE SPECIFY**

_____

12. What type of tube?
CHECK ONE:

a. ☐ Endotracheal
b. ☐ Gastrostomy
c. ☐ Nasogastric
d. ☐ Tracheostomy
e. ☐ Indwelling urinary catheter
f. ☐ Other: **PLEASE SPECIFY**

_____

13. During the patient's stay at this facility, did the patient develop a secondary morbidity (e.g., osteomyelitis, sepsis, tunneling, or fissure)? CHECK ONE:

a. ☐ Yes
b. ☐ No
c. ☐ Unknown

14. Was the secondary morbidity attributed to the presence of the pressure ulcer? CHECK ONE:

a. ☐ Yes
b. ☐ No
c. ☐ Unknown

H SURGERY OR ANESTHESIA

Use this form to report an event involving a surgical or other invasive procedure (e.g., colonoscopy), or the administration of anesthesia. Do not complete this form if the event involved the removal of organs from brain-dead patients (ASA Class 6) or handling an organ after procurement. If the event involved an anesthetic device, please also complete the Device or Medical/Surgical Supply, including Health Information Technology (HIT) form. If the event involved an anesthetic, medical gas, medication, or other substance, please also complete the Medication or Other Substance form. If the event involved a healthcare-associated infection, please also complete the Healthcare-associated Infection form. Narrative detail can be captured on the Healthcare Event Reporting Form (HERF). Highlighted fields are collected for local facility and PSO use. This information will not be forwarded to the Network of Patient Safety Databases (NPSD).

1. Describe briefly the procedure associated with this event:

_____

2. Enter ICD-9-CM or ICD-10-CM procedure code associated with this event (if available):

ICD-9-CM OR ICD-10-CM CODE

3. What was the patient's documented American Society of Anesthesiologists (ASA) Physical Classification System class? CHECK ONE:

a. ☐ Class 1
b. ☐ Class 2
c. ☐ Class 3
d. ☐ Class 4
e. ☐ Class 5
f. ☐ ASA classification was not documented

4. Was the procedure performed as an emergency? CHECK ONE:

a. ☐ Yes
b. ☐ No
c. ☐ Unknown

5. Which combination of anesthesia and sedation was used? CHECK ONE:

a. ☐ Anesthesia only

6. What type of anesthesia? CHECK FIRST APPLICABLE:

a. ☐ General anesthesia → ANSWER QUESTION 10

b. ☐ Regional anesthesia (e.g., epidural, spinal, or peripheral nerve blocks)

c. ☐ Local or topical anesthesia

→ ANSWER QUESTION 11

b. ☐ Anesthesia and sedation

7. What type of anesthesia? CHECK FIRST APPLICABLE:

a. ☐ General anesthesia → ANSWER QUESTION 10

b. ☐ Regional anesthesia (e.g., epidural, spinal, or peripheral nerve blocks)

c. ☐ Local or topical anesthesia

→ ANSWER QUESTION 8

8. What was the level of sedation? CHECK ONE:

a. ☐ Deep sedation or analgesia

b. ☐ Moderate sedation or analgesia (conscious sedation)

c. ☐ Minimal sedation (anxiolysis)

d. ☐ Unknown

→ ANSWER QUESTION 11

c. ☐ Sedation only

9. What was the level of sedation? CHECK ONE:

a. ☐ Deep sedation or analgesia

b. ☐ Moderate sedation or analgesia (conscious sedation)

c. ☐ Minimal sedation (anxiolysis)

d. ☐ Unknown

→ ANSWER QUESTION 11

d. ☐ None

e. ☐ Unknown

→ ANSWER QUESTION 13

10. What was the length of time from induction of anesthesia to the end of anesthesia? CHECK ONE:

a. ☐ Less than 1 hour
b. ☐ Greater than or equal to 1 hour, but less than 3 hours
c. ☐ Greater than or equal to 3 hours, but less than 5 hours
d. ☐ Greater than or equal to 5 hours
e. ☐ Unknown

11. Who administered (or, if the event occurred prior to administration of anesthesia, person who was scheduled to administer) the anesthesia or sedation? CHECK ONE:

a. ☐ Anesthesiologist
b. ☐ Certified Registered Nurse Anesthetist
c. ☐ Other healthcare professional
d. ☐ Unknown

12. Was there supervision by an anesthesiologist? CHECK ONE:

a. ☐ Yes
b. ☐ No
c. ☐ Unknown

13. When was the event discovered? CHECK ONE:

a. ☐ Before anesthesia started or, if no anesthesia used, before procedure started
b. ☐ After anesthesia started, but before incision or start of procedure
c. ☐ After procedure started (incision), but before procedure ended (closure)
d. ☐ At closure, if surgical operation
e. ☐ After procedure ended, but before patient left operating room or other procedure area
f. ☐ During post-anesthesia care/recovery period
g. ☐ After post-anesthesia recovery, but before discharge
h. ☐ After patient was discharged
i. ☐ During anesthesia when no surgical operation or invasive procedure was performed
j. ☐ Unknown

14. What was the medical or surgical specialty of the provider or team who performed the procedure?

CHECK ONE: SELECT THE SPECIALTY OF THE PROVIDER OR TEAM THAT PERFORMED THE PROCEDURE. IF THE PROCEDURE WAS NOT STARTED, SELECT THE SPECIALTY OF THE PROVIDER WHO WAS SCHEDULED TO PERFORM THE PROCEDURE.

a. ☐ Anesthesiology
b. ☐ Cardiology
c. ☐ Colorectal surgery
d. ☐ Dentistry, including oral surgery
e. ☐ Dermatology
f. ☐ Emergency medicine
g. ☐ Family medicine
h. ☐ Gastroenterology
i. ☐ General surgery
j. ☐ Internal medicine
k. ☐ Neurological surgery
l. ☐ Obstetrics/Gynecology
m. ☐ Ophthalmology
n. ☐ Orthopedic surgery
o. ☐ Otolaryngology
p. ☐ Pediatrics
q. ☐ Pediatric surgery
r. ☐ Plastic surgery
s. ☐ Podiatry
t. ☐ Pulmonology
u. ☐ Radiology, including vascular and interventional
v. ☐ Thoracic surgery
w. ☐ Urology
x. ☐ Vascular surgery
y. ☐ Other: **PLEASE SPECIFY** _____

15. What best describes the event? CHECK ONE:

a. ☐ Surgical event → ANSWER QUESTION 18
b. ☐ Anesthesia event → ANSWER QUESTION 27
c. ☐ Major complication that could be associated with either surgery or anesthesia → ANSWER QUESTION 16

16. Which of the following major complications occurred? CHECK ONE:

a. ☐ Cardiac or circulatory event
b. ☐ Central nervous system event
c. ☐ Renal failure, impairment, or insufficiency
d. ☐ Respiratory failure, requiring unplanned respiratory support, within 24 hours after the procedure
e. ☐ Other: **PLEASE SPECIFY** _____

17. Which of the following best describes the respiratory support provided? CHECK ONE:

a. ☐ Prolonged ventilator support
b. ☐ Re-institution of ventilator following discontinuation
c. ☐ Other: **PLEASE SPECIFY** _____

IF MAJOR COMPLICATION → STOP **This form is complete.**

18. Was the surgical event a retained object? CHECK ONE:

a. ☐ Yes
b. ☐ No → **ANSWER QUESTION 24**

19. What type of object was retained? CHECK ONE:

a. ☐ Sponge
b. ☐ Needle (includes needle fragment or microneedle)
c. ☐ Towel
d. ☐ Whole instrument (e.g., clamp)
e. ☐ Instrument fragment
f. ☐ Other: **PLEASE SPECIFY** _____

20. Was a count performed for the type of object that was retained? CHECK ONE:

a. ☐ Yes

21. After counting, what was the reported count status? CHECK ONE:

a. ☐ Incorrect (unreconciled) count → ANSWER QUESTION 22

b. ☐ Correct (reconciled) count → STOP This form is complete.

b. ☐ No, object "countable"

c. ☐ No, object not "countable" (e.g., broken piece retained)

d. ☐ Unknown

→ STOP This form is complete.

22. Was an x-ray obtained before the end of the procedure to detect the retained object? CHECK ONE:

a. ☐ Yes

b. ☐ No

c. ☐ Unknown

23. Was the retained object radiopaque (i.e., detectable by x-ray)? CHECK ONE:

a. ☐ Yes

b. ☐ No

c. ☐ Unknown

IF RETAINED OBJECT → STOP This form is complete.

24. Which of the following best characterizes the surgical event? CHECK ONE:

- a. ☐ Surgical site infection
- b. ☐ Bleeding requiring return to the operating room
- c. ☐ Burn and/or operating room fire
- d. ☐ Incorrect surgical or invasive procedure
- e. ☐ Iatrogenic pneumothorax
- f. ☐ Unintended laceration or puncture
- g. ☐ Dehiscence, flap or wound failure or disruption, or graft failure
- h. ☐ Unintended blockage, obstruction, or ligation
- i. ☐ Unplanned removal of organ
- j. ☐ Air embolus
- k. ☐ Other: **PLEASE SPECIFY**

_____

ALSO COMPLETE THE HEALTHCARE-ASSOCIATED INFECTION FORM

25. Which of the following occurred? CHECK ONE:

- a. ☐ Burn
- b. ☐ Operating room fire
- c. ☐ Both

26. What was incorrect about the surgical or invasive procedure?
CHECK FIRST APPLICABLE:

- a. ☐ Incorrect patient
- b. ☐ Incorrect side
- c. ☐ Incorrect site
- d. ☐ Incorrect procedure
- e. ☐ Incorrect implant by mistake
- f. ☐ Incorrect implant because correct implant was not available
- g. ☐ Other: **PLEASE SPECIFY**

_____

IF SURGICAL EVENT STOP **This form is complete.**

27. If the event involved anesthesia, which of the following best characterizes the event? CHECK ONE:

a. ☐ Dental injury
b. ☐ Ocular injury
c. ☐ Peripheral nerve injury
d. ☐ Awareness (during anesthesia)
e. ☐ Malignant hyperthermia
f. ☐ Problem with anesthetic, medical gas, medication, or other substance administration

ALSO COMPLETE THE MEDICATION OR OTHER SUBSTANCE FORM

g. ☐ Problem with device used in the delivery of anesthesia

ALSO COMPLETE THE DEVICE OR SUPPLY, INCLUDING HEALTH INFORMATION TECHNOLOGY (HIT) FORM

h. ☐ Difficulty managing airway
i. ☐ Other: **PLEASE SPECIFY** _____

28. Which of the following best characterizes the airway management problem? CHECK ONE:

a. ☐ Difficulty during tracheal intubation
b. ☐ Difficulty maintaining airway during procedure
c. ☐ Esophageal intubation
d. ☐ Re-intubation, following extubation, in the operating or recovery room
e. ☐ Other: **PLEASE SPECIFY** _____

Event ID: _____

Initial Report Date (HERF Q1) _____

Patient Safety Event Report – Hospital:

VENOUS THROMBOEMBOLISM

Use this form to report a deep vein thrombosis (DVT) or a pulmonary embolism (PE) that (1) had onset during this stay; (2) was present on admission but that occurred or developed within 30 days of a prior discharge from this facility; or (3) had onset within 30 days of discharge from this facility.

DVT and PE are two presentations of the same disease: venous thromboembolism (VTE). DVT refers to partial or total thrombotic occlusion of a deep vein of the lower extremity or pelvis (e.g., inferior vena cava, iliac, femoral, popliteal, tibial, gastrocnemial, soleal, or peroneal vein) or a deep vein of the upper extremity or upper thorax (e.g., internal jugular, brachiocephalic, superior vena cava, axillary, brachial, or subclavian). Symptomatic DVT is an objectively confirmed DVT that results in symptoms including pain and/or swelling of the affected limb.

PE refers to a partial or total thromboembolic occlusion of one or more pulmonary arteries that causes symptoms or death. Symptomatic PE is an objectively confirmed PE that results in symptoms or signs such as shortness of breath, pleuritic chest pain, hemoptysis, oxygen desaturation, or death.

"Onset of the VTE incident" refers to the time of the first sign(s) or symptom(s) that leads to the eventual diagnosis and confirmation of the DVT or PE. A VTE that develops between two separate hospital stays at the same facility should only be reported once.

Do not use this form to report the following:

- Asymptomatic VTE (i.e., DVT and/or PE identified on screening exam or incidentally);
- VTE occurring in a patient receiving palliative or comfort care;
- Thrombosis involving another venous system such as intracranial veins or sinuses, or splanchnic, portal or renal veins;
- VTE that develops within 48 hours of admission, except if the patient had been discharged from the reporting facility within the prior 30 days;
- VTE in a patient admitted to the hospital with a diagnosis of, or suspected diagnosis of, acute DVT or PE, except if discharged from the reporting facility within 30 days of being readmitted to that same facility;
- VTE in a patient with prior or chronic VTE who has leg swelling and no documentation of acute changes on ultrasound report;
- VTE diagnosed more than 30 days after hospital discharge;
- VTE diagnosed based on any one, or any combination of, (1) clinical criteria, (2) D-dimer test results, or (3) imaging test results that are "inconclusive" or are of "low probability";
- Superficial vein thrombosis and/or phlebitis that does not extend into a deep vein;
- Non-thrombotic emboli (e.g., air, fat, amniotic fluid, or foreign body or material)

Narrative detail can be captured on the Healthcare Event Reporting Form (HERF). Highlighted fields are collected for local facility and PSO use. This information will not be forwarded to the Network of Patient Safety Databases (NPSD).

1. Which of the following occurred? CHECK ALL THAT APPLY:

a. ☐ Deep Vein Thrombosis (DVT)

b. ☐ Pulmonary Embolism (PE)

2. What was the location of the DVT? CHECK ONE:

a. ☐ Upper extremity/upper thorax

b. ☐ Lower extremity/pelvis

c. ☐ Both

IF DVT, WITH OR WITHOUT PE, WAS SELECTED IN QUESTION 1, ANSWER QUESTION 3
IF ONLY PE WAS SELECTED, ANSWER QUESTION 4

3. Which diagnostic test confirmed the DVT? CHECK ALL THAT APPLY:

a. ☐ Venous compression ultrasound or duplex ultrasound

b. ☐ Magnetic resonance imaging (MRI)

c. ☐ Computed tomography (CT)

d. ☐ Venography

e. ☐ None of the above

IF "E" WAS SELECTED IN QUESTION 3 AND IF ONLY DVT WAS SELECTED IN QUESTION 1 STOP This form is complete.

IF ANY OF "A", "B", "C", OR "D" WAS SELECTED IN QUESTION 3 AND IF ONLY DVT WAS SELECTED IN QUESTION 1, ANSWER QUESTION 5

4. Which diagnostic test confirmed the PE? CHECK ALL THAT APPLY:

a. ☐ Chest CT angiography with contrast
b. ☐ Nuclear medicine pulmonary scan (ventilation/perfusion lung scan, V/Q scan, pulmonary scintigraphy)
c. ☐ Magnetic resonance imaging (MRI)
d. ☐ Pulmonary angiography
e. ☐ Post-mortem examination finding that PE likely contributed to death of patient
f. ☐ None of the above

IF "F" WAS SELECTED IN QUESTION 4 AND IF ONLY PE WAS SELECTED IN QUESTION 1 → STOP This form is complete.

5. Prior to the onset of the VTE incident, was a formal VTE risk assessment documented? CHECK ONE:

a. ☐ Yes
b. ☐ No
c. ☐ Unknown

6. Was use of a VTE prophylaxis order set documented? CHECK ONE:

a. ☐ Yes
b. ☐ No
c. ☐ Unknown

7. What was the patient's documented risk of VTE? CHECK ONE:

a. ☐ Low risk of VTE
b. ☐ High risk of VTE
c. ☐ Unknown

8. Prior to the onset of the VTE incident, what was the documented risk of bleeding, if any? CHECK ONE:

a. ☐ At increased risk for bleeding
b. ☐ Not at increased risk for bleeding
c. ☐ Unknown

9. Prior to the onset of the VTE incident, was any physical or mechanical prophylaxis (e.g., graduated compression stockings, intermittent pneumatic compression device, venous foot pumps) applied? CHECK ONE:

a. ☐ Yes
b. ☐ No
c. ☐ Unknown

10. Prior to the onset of the VTE incident, was any pharmacological anticoagulant prophylaxis administered? CHECK ONE:

a. ☐ Yes → STOP This form is complete.
b. ☐ No
c. ☐ Unknown → STOP This form is complete.

11. Which of the following best describes why the pharmacologic anticoagulant prophylaxis was not given? CHECK ALL THAT APPLY:

a. ☐ Contraindicated
b. ☐ Patient determined to be at low risk
c. ☐ Risk/benefit did not warrant prophylaxis
d. ☐ Patient refused
e. ☐ Unknown
f. ☐ Other: **PLEASE SPECIFY** _____

Thank you for completing these questions.

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Feedback Process for Common Formats Evolution

- AHRQ seeing feedback to refine Common Formats
- The National Quality Forum
  - Online tool to gather comments – opens week of June 16th

    http://www.qualityforum.org
  - Expert panel to provide advice
- Process will be a continuing one, guiding periodic updates of the Common Formats

The Future

- Based on experience to date, Common Formats are likely to be widely adopted in the US (& in some other countries)
- Feedback to improve Formats will ensure that they are cutting-edge & provide both clinical & electronic interoperability
  - EHRs
  - Other reporting systems
- Data aggregation, analysis, & learning will be markedly accelerated, potentiating ability to make & measure progress in reducing risk

Next Steps

PSOs: Next Steps

- Continue to list new PSOs
- Provide technical assistance

Common Formats: Next Steps

- PSOs begin to gather data with electronic Common Formats – Fall 2010
- Future expansion to other settings (e.g., long term care)
- Future extension to other improvement cycle phases (e.g., root cause analysis)
- Continuing NQF assistance

Reporting: Next Steps

- First-level reports
  - Standard population reports; can be used at local, PSO, regional, & national level
- Second-level reports
  - Analysis of aggregated data
    - Standard reports
    - Ad hoc reports
  - Useful for safety experts, researchers

NPSD: Next Steps

NPSD
Network of
Patient Safety Databases

- Information will be submitted using the Common Formats (PSOs & other sources)
- Non-identifiable PSWP scheduled to be accepted in 2011
- Findings from NPSD will be published in AHRQ's annual National Healthcare Quality & Disparities Reports

Your Questions?

Common Formats 1.1 Highlights

- Components
  - Available now at: http://www.psoppc.org
    - Event Descriptions
    - Paper forms to allow immediate implementation
    - A Users Guide
    - Quick Guide
    - Patient safety population reports
    - Technical specifications

Common Formats 1.1 Highlights

- Event Descriptions
  - Outlines the precise information to be collected
  - Specifies the information desired for a particular event category
    - Definition, Scope, Risk Assessment / Preventive Actions, & Circumstances
    - Allows for easy location of content & comparison across different event specific categories
  - Facilitates the comment process for consideration of content for future versions
  - Supports multiple types of Common Formats implementations

Common Formats 1.0: Support Materials

- Users Guide
  - Common Formats background information & guidance on use of paper forms
- Quick Guide
  - Brief directions for completing the forms
  - Graphical demonstration of module assembly for complete report

Common Formats: Revising and Refining

- Common Formats 0.1 Beta released August 2008 (prior to listing of first PSOs)
- National Quality Forum (NQF) process established to solicit comments & provide advice
  - Over 900 comments on beta version received by NQF
  - NQF Expert Panel analyzed comments, provided advice to AHRQ during 2009

Common Formats: Revising and Refining

- AHRQ revised & refined Common Formats based upon advice from NQF & DHHS agencies; Version 1.0 released on September 2, 2009
  - NQF solicited comments; 135 comments received; expert panel met November 2009 to February 2010
  - AHRQ developed technical specifications and continued refinement process
- Version 1.1 published on March 31, 2010