

NATIONAL QUALITY FORUM

Serious Reportable Event Submission & Evaluation

The SRE Steering Committee with NQF member and public input has defined Serious Reportable Events (SREs) as preventable, serious, and unambiguous adverse events. The Committee further notes that some types of SREs are universally preventable and should never occur while other types of SREs are largely preventable and over time it may be possible to reduce these to zero as knowledge and safe practices evolve. Both types of SREs should be publicly reported.

Submitters: Complete all the non-shaded areas of this form. Please fill out a separate form for each event you are submitting to NQF for consideration. This form may be used to submit comments/changes to existing SREs or submit new SREs.

Reviewers: Complete all the yellow and pink highlighted areas of the form. Provide the rationale for your ratings.

(for NQF staff use) NQF Review #:		NQF Project:	
(for NQF staff use) Has all requested information been provided? No evidence of preventability provided.			
Staff Notes to Submitter (if submission returned):			
Staff Notes to Reviewers (issues or questions regarding any criteria):			
Staff Reviewer Name(s):			
1. CONTACT INFORMATION			
Submitter: <u>William R. Scharf, M.D.</u>			
Organization: <u>OSF Healthcare System</u>			
Street Address: <u>800 N.E. Glen Oak Avenue</u>			
City/State/Zip: <u>Peoria, IL 61603</u>			
Telephone Number: <u>309-665-4806</u>			
Fax Number:			
Email Address: <u>William.scharf@osfhealthcare.org</u>			
Date of Submission (MM/DD/YY): <u>06/10/10</u>			
Is this submission about a currently endorsed SRE or a proposed new SRE? <input type="checkbox"/> Currently Endorsed <input checked="" type="checkbox"/> New Submission (If new submission, skip to section 3a)			
2a. CURRENTLY ENDORSED SERIOUS REPORTABLE EVENT			
Name of Event:			
Suggested Change:			
<input type="checkbox"/> Specify the Applicable Care Setting(s) marked below			
<input type="checkbox"/> Remove Endorsement			
<input type="checkbox"/> Modify SRE Specifications			
Describe Suggested Modification(s) in specific detail:			
Rationale for removing endorsement or modifying the SRE (include pertinent evidence, data):			
If modifications are made, are the changes likely to result in a substantial change in the current count of SREs? <input type="checkbox"/> Yes <input type="checkbox"/> No If yes, please explain:			
(for NQF staff use) The proposed change is justified (Does the rationale justify the proposed change?)			Y <input type="checkbox"/> N <input type="checkbox"/>
Applicable Care Settings (Mark all to which event is relevant)			
<input type="checkbox"/> Hospital			
<input type="checkbox"/> Skilled Nursing Facility (SNF) / Nursing home			
<input type="checkbox"/> Outpatient or Office-based Surgery Center			
<input type="checkbox"/> Ambulatory Practice / Physician Offices			
<input type="checkbox"/> Other (Please specify):			

Reviewer Comments/Rationale:	
2b. ADDITIONAL INFORMATION for CURRENTLY ENDORSED SERIOUS REPORTABLE EVENT	
Provide any additional information that should be considered:	
Susceptibility to Inaccuracies, Errors, or Unintended Consequences <i>Identify susceptibility to inaccuracies, errors, or unintended consequences of the event and describe how these potential problems could be audited.</i>	
(for NQF staff use) Identify related endorsed measures	
Reviewer Comments:	
RECOMMENDATION	
Steering Committee: Do you recommend the proposed change? <input type="checkbox"/> Do you recommend the proposed change with modification? <input type="checkbox"/> Specify the modification	
Comments/Rationale:	Y <input type="checkbox"/> N <input type="checkbox"/> A <input type="checkbox"/>
3a. NEW SERIOUS REPORTABLE EVENT	
The Event is a discrete, auditable , and clearly defined occurrence Name of Proposed New Event: Patient death or disability as a consequence of MRI error, defined as magnetizable material inside the MRI room	Y <input type="checkbox"/> N <input type="checkbox"/>
3b. PREVENTABLE, SERIOUS, UNAMBIGUOUS	
Brief Description of Event: magnetizable material in the MRI that creates an incident resulting in harm to a patient. This could range from projectiles to burn injuries	
The event is Preventable (<i>Describes an event that could have been anticipated and prepared for, but that occurs because of an error or other system failure</i>)	Y <input type="checkbox"/> N <input type="checkbox"/>
Briefly summarize the Evidence Base that the event is preventable and provide citations: there are procedures and processes to screen and detect magnetizable material from entering an MRI room	
The event is Serious (<i>Describes an event that can result in death or loss of a body part, disability or loss of bodily function or risk thereof for harm</i>) <i>Please check the appropriate consequence and describe it</i> <input checked="" type="checkbox"/> Death or <input checked="" type="checkbox"/> risk of death <input checked="" type="checkbox"/> Loss of a body part or <input type="checkbox"/> risk of loss Describe: <input checked="" type="checkbox"/> Disability or <input type="checkbox"/> risk of disability Describe: there are a number of ways in which these incidents could cause harm, the most common due to a projectile <input checked="" type="checkbox"/> -Loss of bodily function or <input type="checkbox"/> risk of loss Describe:	Y <input type="checkbox"/> N <input type="checkbox"/>
The event is Unambiguous (<i>Refers to an event that is clearly defined and easily identified</i>) Definitions: Codes and descriptors (if used): Instructions for counting events, calculating rates, and providing context for low frequency: event counting is primarily through self reports	Y <input type="checkbox"/> N <input type="checkbox"/>
Reviewer Comments/Rationale:	
3c. ADVERSE, SAFETY SYSTEM PROBLEM, IMPORTANT FOR ACCOUNTABILITY	
Describe the outcome that demonstrates that the event is adverse (<i>Describes a negative consequence of care that results in unintended injury or illness</i>) in addition to harm, these events often cause an MRI to be taken out of service.	Y <input type="checkbox"/> N <input type="checkbox"/>
Describe how the event is indicative of a problem in a healthcare facility's safety systems: These events can be the reflection of leadership and a mindfulness of the safety culture	Y <input type="checkbox"/> N <input type="checkbox"/>

Describe why the event is important for public credibility or accountability: Pictures of projectiles can be spread via the electronic media such that the public can readily connect to the impact of the event	Y <input type="checkbox"/> N <input type="checkbox"/>
If the event is used in a public reporting initiative (disclosure of performance results to the public at large), provide name of initiative(s), locations, Web page URL(s):	

Reviewer Comments/Rationale:

3d. SETTINGS, DATA SOURCES

Applicable Care Settings (Mark all to which event is relevant) <input type="checkbox"/> X Hospital <input type="checkbox"/> Skilled Nursing Facility (SNF) / Nursing home <input type="checkbox"/> Outpatient or Office-based Surgery Center <input type="checkbox"/> Ambulatory Practice / Physician Offices <input type="checkbox"/> Other (Please describe): X outpatient centers offering services with MRI	
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Data Source Check the source(s) for the information on the SRE. <table style="width: 100%;"> <tr> <td style="width: 50%; vertical-align: top;"> <input type="checkbox"/> Electronic administrative data/ claims <input type="checkbox"/> Electronic Clinical Data (e.g., MDS) <input checked="" type="checkbox"/> X Incident Reports <input type="checkbox"/> Medical Record including Electronic <input type="checkbox"/> Pharmacy data <input type="checkbox"/> Public health data/vital statistics </td> <td style="width: 50%; vertical-align: top;"> <input checked="" type="checkbox"/> X Quality / Risk Management Databases <input type="checkbox"/> Registry data (or database) <input type="checkbox"/> Reports to External Bodies (states, federal) <input type="checkbox"/> Regulatory or Accreditation data (FDA, OSHA, etc.) <input type="checkbox"/> Special or unique data, specify: </td> </tr> </table>	<input type="checkbox"/> Electronic administrative data/ claims <input type="checkbox"/> Electronic Clinical Data (e.g., MDS) <input checked="" type="checkbox"/> X Incident Reports <input type="checkbox"/> Medical Record including Electronic <input type="checkbox"/> Pharmacy data <input type="checkbox"/> Public health data/vital statistics	<input checked="" type="checkbox"/> X Quality / Risk Management Databases <input type="checkbox"/> Registry data (or database) <input type="checkbox"/> Reports to External Bodies (states, federal) <input type="checkbox"/> Regulatory or Accreditation data (FDA, OSHA, etc.) <input type="checkbox"/> Special or unique data, specify:	
<input type="checkbox"/> Electronic administrative data/ claims <input type="checkbox"/> Electronic Clinical Data (e.g., MDS) <input checked="" type="checkbox"/> X Incident Reports <input type="checkbox"/> Medical Record including Electronic <input type="checkbox"/> Pharmacy data <input type="checkbox"/> Public health data/vital statistics	<input checked="" type="checkbox"/> X Quality / Risk Management Databases <input type="checkbox"/> Registry data (or database) <input type="checkbox"/> Reports to External Bodies (states, federal) <input type="checkbox"/> Regulatory or Accreditation data (FDA, OSHA, etc.) <input type="checkbox"/> Special or unique data, specify:		

Identify the specific data source/data collection instrument (e.g. name of database, clinical registry, collection instrument, etc.); include Web page URL where available:

Data dictionary/code table attached OR at web page URL:

Process(es) to Collect Data Provide additional information about how the data regarding the event are collected. Address verifiability, reliability, and validity, if possible. These events are readily verifiable and typically reliable. These events could be under-reported.	
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Reviewer Comments/Rationale:

3e. ADDITIONAL INFORMATION for NEW SERIOUS REPORTABLE EVENT

Provide any additional information that should be considered: [Safety in the MR Environment: MR Safety Screening Practices 2009 Pennsylvania Patient Safety Authority Vol 6, No 1](#)

Susceptibility to Inaccuracies, Errors, or Unintended Consequences
Identify susceptibility to inaccuracies, errors, or unintended consequences of the event and describe how these potential problems could be audited.

(for NQF staff use) Identify related endorsed measures —N/A

Reviewer Comments:

RECOMMENDATION

Steering Committee: Do you recommend for endorsement? Comments/Rationale:	Y <input type="checkbox"/> N <input type="checkbox"/> A <input type="checkbox"/>
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Steering Committee Reviewer Name:

4. PRIORITY AREAS

(for NQF staff use) Select the most relevant priority area(s), quality domain(s), and consumer need(s).

National Priority Partners Priority Area	<input type="checkbox"/> patient and family engagement <input type="checkbox"/> population health <input checked="" type="checkbox"/> safety	
<input type="checkbox"/> care coordination <input type="checkbox"/> palliative and end of life care <input type="checkbox"/> overuse		

IOM Quality Domain <input type="checkbox"/> effectiveness <input type="checkbox"/> efficiency <input type="checkbox"/> equity <input type="checkbox"/> patient-centered <input checked="" type="checkbox"/> safety <input type="checkbox"/> timeliness
Consumer Care Need <input type="checkbox"/> Getting Better <input type="checkbox"/> Living With Illness <input type="checkbox"/> Staying Healthy
(for NQF staff use) Notes on similar/related endorsed SREs and/or Safe Practices: —N/A
Steering Committee Reviewer Name:

NATIONAL QUALITY FORUM

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Submitters: Complete all the non-shaded areas of this form. Please fill out a separate form for each event you are submitting to NQF for consideration. This form may be used to submit comments/changes to existing SREs or submit new SREs.

Reviewers: Complete all the yellow and pink highlighted areas of the form. Provide the rationale for your ratings.

(for NQF staff use) NQF Review #:		NQF Project:	
(for NQF staff use) Has all requested information been provided? Staff Notes to Submitter <i>(if submission returned)</i> :			
Staff Notes to Reviewers <i>(issues or questions regarding any criteria)</i> :			
Staff Reviewer Name(s):			
1. CONTACT INFORMATION			
Submitter: Cynthia Lacker, RN, MS, LNCC, CPHRM Organization: Pennsylvania Patient Safety Authority Street Address: 5200 Butler Pike City/State/Zip: Plymouth Meeting, PA 19462 Telephone Number: 610-825-6000 x5040 Fax Number: 610-834-1275 Email Address: clacker@ecri.org			
Date of Submission (MM/DD/YY): 06/16/2010			
Is this submission about a currently endorsed SRE or a proposed new SRE? <input type="checkbox"/> Currently Endorsed <input checked="" type="checkbox"/> New Submission <i>(If new submission, skip to section 3a)</i>			
2a. CURRENTLY ENDORSED SERIOUS REPORTABLE EVENT			
Name of Event:			
Suggested Change:			
<input type="checkbox"/> Specify the Applicable Care Setting(s) marked below <input type="checkbox"/> Remove Endorsement <input type="checkbox"/> Modify SRE Specifications			
Describe Suggested Modification(s) in specific detail:			
Rationale for removing endorsement or modifying the SRE <i>(include pertinent evidence, data)</i> :			
If modifications are made, are the changes likely to result in a substantial change in the current count of SREs? <input type="checkbox"/> Yes <input type="checkbox"/> No If yes, please explain:			
(for NQF staff use) The proposed change is justified <i>(Does the rationale justify the proposed change?)</i>			
Applicable Care Settings (Mark all to which event is relevant)			
<input type="checkbox"/> Hospital <input type="checkbox"/> Skilled Nursing Facility (SNF) / Nursing home <input type="checkbox"/> Outpatient or Office-based Surgery Center <input type="checkbox"/> Ambulatory Practice / Physician Offices <input type="checkbox"/> Other <i>(Please specify)</i> :			

Y

N

Reviewer Comments/Rationale:	
2b. ADDITIONAL INFORMATION for CURRENTLY ENDORSED SERIOUS REPORTABLE EVENT	
Provide any additional information that should be considered:	
Susceptibility to Inaccuracies, Errors, or Unintended Consequences <i>Identify susceptibility to inaccuracies, errors, or unintended consequences of the event and describe how these potential problems could be audited.</i>	
<i>(for NQF staff use)</i> Identify related endorsed measures	
Reviewer Comments:	
RECOMMENDATION	
Steering Committee: Do you recommend the proposed change? <input type="checkbox"/> Do you recommend the proposed change with modification? <input type="checkbox"/> Specify the modification	Y <input type="checkbox"/> N <input type="checkbox"/> A <input type="checkbox"/>
Comments/Rationale:	
3a. NEW SERIOUS REPORTABLE EVENT	
The Event is a discrete, auditable , and clearly defined occurrence Name of Proposed New Event: Patient death or serious injury associated with prolonged fluoroscopy with cumulative dose> 1500 rads to a single field or any delivery of radiotherapy to the wrong body region, or 25 percent above or below the planned radiotherapy dose. —	Y <input type="checkbox"/> N <input type="checkbox"/>
3b. PREVENTABLE, SERIOUS, UNAMBIGUOUS	
Brief Description of Event: Overdose of fluoroscopy or radiation—	
The event is Preventable (<i>Describes an event that could have been anticipated and prepared for, but that occurs because of an error or other system failure</i>)	Y <input type="checkbox"/> N <input type="checkbox"/>
Briefly summarize the Evidence Base that the event is preventable and provide citations: Errors in Radiation Safety, Pa Patient Saf Advis 2009 Sep;6(3):87-92, at: http://www.patientsafetyauthority.org/ADVISORIES/AdvisoryLibrary/2009/Sep6(3)/Pages/87.aspx JC Sentinel Event at: http://www.jointcommission.org/NR/rdonlyres/10A599B4-832D-40C1-8A5B-5929E9E0B09D/0/Radiation_Overdose.pdf FDA Radiation Emitting Products Standards at: http://www.fda.gov/Radiation-EmittingProducts/ElectronicProductRadiationControlProgram/GettingaProducttoMarket/RecordsandReporting/default.htm An international review of patient safety measures in radiotherapy practice. Shafiq J, Barton M, Noble D, Lemer C, Donaldson LJ. The Collaboration for Cancer Outcomes Research and Evaluation, University of New South Wales, Sydney, Australia. Jesmin.Shafiq@sswahs.nsw.gov.au http://www.ncbi.nlm.nih.gov/pubmed/19395105 Quality assurance in radiotherapy: evaluation of errors and incidents recorded over a 10 year period. Yeung TK, Bortolotto K, Cosby S, Hoar M, Lederer E. Radiation Treatment Program, Northeastern Ontario Regional Cancer Centre, 41 Ramsey Lake Road, Sudbury, Ont., Canada, P3E 5J1. http://www.ncbi.nlm.nih.gov/pubmed/15763309	

<p>The event is Serious (<i>Describes an event that can result in death or loss of a body part, disability or loss of bodily function or risk thereof for harm</i>)</p> <p>Please check the appropriate consequence and describe it</p> <p><input checked="" type="checkbox"/> Death or <input checked="" type="checkbox"/> risk of death</p> <p><input checked="" type="checkbox"/> Loss of a body part or <input checked="" type="checkbox"/> risk of loss Describe:</p> <p><input checked="" type="checkbox"/> Disability or <input checked="" type="checkbox"/> risk of disability Describe:</p> <p><input checked="" type="checkbox"/> Loss of bodily function or <input checked="" type="checkbox"/> risk of loss Describe:</p> <p>Patient-specific illness, injury up to, and including death for over-exposure.</p>	<p>Y <input type="checkbox"/></p> <p>N <input type="checkbox"/></p>
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<p>The event is Unambiguous (<i>Refers to an event that is clearly defined and easily identified</i>)</p> <p>Definitions: As described, the event is a cumulative dose of over 1500 rads to a single field, radiation to the wrong body region or a dose of 25% above or below the planned radiotherapy dose.</p> <p>Codes and descriptors (if used):</p> <p>Instructions for counting events, calculating rates, and providing context for low frequency:</p>	<p>Y <input type="checkbox"/></p> <p>N <input type="checkbox"/></p>
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Reviewer Comments/Rationale:

3c. ADVERSE, SAFETY SYSTEM PROBLEM, IMPORTANT FOR ACCOUNTABILITY

<p>Describe the outcome that demonstrates that the event is adverse (<i>Describes a negative consequence of care that results in unintended injury or illness</i>)</p> <p>May result in death, organ damage, burns and spread of malignancy.</p>	<p>Y <input type="checkbox"/></p> <p>N <input type="checkbox"/></p>
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<p>Describe how the event is indicative of a problem in a healthcare facility's safety systems:</p> <p>Whether the failure is due to machinery or operator error, both indicate a lack of proper system safeguards that are required for the administration of radiotherapy and/or fluoroscopy. (Redundant design, double-checks, frequent calibration of machinery)</p>	<p>Y <input type="checkbox"/></p> <p>N <input type="checkbox"/></p>
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<p>Describe why the event is important for public credibility or accountability:</p> <p>Stories like the radiotherapy failure within the VA system undermine the public's confidence in medical therapy. Not only were the results adverse, there was evidence that the VA system did not comply with mandatory reporting.</p>	<p>Y <input type="checkbox"/></p> <p>N <input type="checkbox"/></p>
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If the event is used in a public reporting initiative (disclosure of performance results to the public at large), provide name of initiative(s), locations, Web page URL(s):

FDA at <http://www.fda.gov/Radiation-EmittingProducts/ElectronicProductRadiationControlProgram/GettingaProducttoMarket/RecordsandReporting/default.htm>

United States national Regulatory Commission at <http://www.nrc.gov/>

TJC Sentinel Event at http://www.jointcommission.org/NR/rdonlyres/10A599B4-832D-40C1-8A5B-5929E9E0B09D/0/Radiation_Overdose.pdf

Reviewer Comments/Rationale:

3d. SETTINGS, DATA SOURCES

<p>Applicable Care Settings (Mark all to which event is relevant)</p> <p><input checked="" type="checkbox"/> Hospital</p> <p><input type="checkbox"/> Skilled Nursing Facility (SNF) / Nursing home</p> <p><input type="checkbox"/> Outpatient or Office-based Surgery Center</p> <p><input checked="" type="checkbox"/> Ambulatory Practice / Physician Offices</p> <p><input type="checkbox"/> Other (<i>Please describe</i>):</p>	
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Data Source Check the source(s) for the information on the SRE.

- Electronic administrative data/ claims
- Electronic Clinical Data (e.g., MDS)
- Incident Reports
- Medical Record including Electronic
- Pharmacy data
- Public health data/vital statistics

- Quality / Risk Management Databases
- Registry data (or database)
- Reports to External Bodies (states, federal)
- Regulatory or Accreditation data (FDA, OSHA, etc.)
- Special or unique data, specify:

Identify the specific data source/data collection instrument (e.g. name of database, clinical registry, collection instrument, etc.); include Web page URL where available:

FDA Medwatch Medical device reports

<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm106737.htm>

TJC Sentinel event reports

Medical record abstraction

Incident Reports

Risk Management information

Data dictionary/code table attached OR at web page URL:

Process(es) to Collect Data

Provide additional information about how the data regarding the event are collected. Address verifiability, reliability, and validity, if possible.

Reviewer Comments/Rationale:

3e. ADDITIONAL INFORMATION for NEW SERIOUS REPORTABLE EVENT

Provide any additional information that should be considered:

Susceptibility to Inaccuracies, Errors, or Unintended Consequences

Identify susceptibility to inaccuracies, errors, or unintended consequences of the event and describe how these potential problems could be audited.

(for NQF staff use) Identify related endorsed measures N/A

Reviewer Comments:

RECOMMENDATION

Steering Committee: Do you recommend for endorsement?

Comments/Rationale:

- Y
- N
- A
-

Steering Committee Reviewer Name:

4. PRIORITY AREAS

(for NQF staff use) Select the most relevant priority area(s), quality domain(s), and consumer need(s).

National Priority Partners Priority Area patient and family engagement population health safety
 care coordination palliative and end of life care overuse

IOM Quality Domain effectiveness efficiency equity patient-centered safety timeliness

Consumer Care Need Getting Better Living With Illness Staying Healthy

(for NQF staff use) Notes on similar/related endorsed SREs and/or Safe Practices: N/A

Steering Committee Reviewer Name:

NATIONAL QUALITY FORUM

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Submitters: Complete all the non-shaded areas of this form. Please fill out a separate form for each event you are submitting to NQF for consideration. This form may be used to submit comments/changes to existing SREs or submit new SREs.

Reviewers: Complete all the **yellow** and **pink** highlighted areas of the form. Provide the rationale for your ratings.

(for NQF staff use) NQF Review #:		NQF Project:	
(for NQF staff use) Has all requested information been provided? Yes			
Staff Notes to Submitter <i>(if submission returned)</i> :			
Staff Notes to Reviewers <i>(issues or questions regarding any criteria)</i> :			
Staff Reviewer Name(s):			
1. CONTACT INFORMATION			
Submitter: Cynthia Lacker, RN, MS, LNCC, CPHRM Organization: Pennsylvania Patient Safety Authority Street Address: 5200 Butler Pike City/State/Zip: Plymouth Meeting, PA 19462 Telephone Number: 610-825-6000 x5040 Fax Number: 610-834-1275 Email Address: clacker@ecri.org			
Date of Submission (MM/DD/YY): 06/16/2010			
Is this submission about a currently endorsed SRE or a proposed new SRE? <input type="checkbox"/> Currently Endorsed <input checked="" type="checkbox"/> New Submission <i>(if new submission, skip to section 3a)</i>			
2a. CURRENTLY ENDORSED SERIOUS REPORTABLE EVENT			
Name of Event:			
Suggested Change: <input type="checkbox"/> Specify the Applicable Care Setting(s) marked below <input type="checkbox"/> Remove Endorsement <input type="checkbox"/> Modify SRE Specifications			Y <input type="checkbox"/> N <input type="checkbox"/>
Describe Suggested Modification(s) in specific detail:			
Rationale for removing endorsement or modifying the SRE <i>(include pertinent evidence, data)</i> :			
If modifications are made, are the changes likely to result in a substantial change in the current count of SREs? <input type="checkbox"/> Yes <input type="checkbox"/> No If yes, please explain:			
(for NQF staff use) The proposed change is justified <i>(Does the rationale justify the proposed change?)</i>			
Applicable Care Settings (Mark all to which event is relevant)			
<input type="checkbox"/> Hospital <input type="checkbox"/> Skilled Nursing Facility (SNF) / Nursing home <input type="checkbox"/> Outpatient or Office-based Surgery Center <input type="checkbox"/> Ambulatory Practice / Physician Offices <input type="checkbox"/> Other <i>(Please specify)</i> :			

Reviewer Comments/Rationale:	
2b. ADDITIONAL INFORMATION for CURRENTLY ENDORSED SERIOUS REPORTABLE EVENT	
Provide any additional information that should be considered:	
Susceptibility to Inaccuracies, Errors, or Unintended Consequences <i>Identify susceptibility to inaccuracies, errors, or unintended consequences of the event and describe how these potential problems could be audited.</i>	
<i>(for NQF staff use)</i> Identify related endorsed measures	
Reviewer Comments:	
RECOMMENDATION	
Steering Committee: Do you recommend the proposed change? <input type="checkbox"/> Do you recommend the proposed change with modification? <input type="checkbox"/> Specify the modification	Y <input type="checkbox"/> N <input type="checkbox"/> A <input type="checkbox"/>
Comments/Rationale:	
3a. NEW SERIOUS REPORTABLE EVENT	
The Event is a discrete, auditable , and clearly defined occurrence Name of Proposed New Event: Patient death or serious injury related to a central line associated blood stream infection (CLABSI).	Y <input type="checkbox"/> N <input type="checkbox"/>
3b. PREVENTABLE, SERIOUS, UNAMBIGUOUS	
Brief Description of Event: Development of a blood stream infection within 48 hours of central line insertion	
The event is Preventable (<i>Describes an event that could have been anticipated and prepared for, but that occurs because of an error or other system failure</i>) Current best practices identify ways to prevent nearly all CLABSI (central line bundle compliance).	Y <input type="checkbox"/> N <input type="checkbox"/>
Briefly summarize the Evidence Base that the event is preventable and provide citations: Four national 5-year prevention targets and metrics were proposed for central-line associated bloodstream infections (CLABSI). To be consistent with the targets and metrics currently outlined and/or adopted by other national organizations, including the NQF and the SHEA/IDSA Compendium of Strategies to Prevent Healthcare-Associated Infections in Acute Care Hospitals, the selected targets and metrics listed in Table 1 include one outcome [Metric 1] and one process [Metric 2] metric: [Metric1] CLABSI 1: CLABSIs per 1,000 device days by ICU and other locations. [Target1] CLABSIs per 1,000 device days by ICU and other locations below present NHSN 25th percentile by location type (75% reduction in Stratified Infection Ratio). [Metric 2] CLABSI 4: Central line bundle compliance (non-emergent insertions). [Target 2] 100% compliance with central line bundle (non-emergent insertions). At: http://www.hhs.gov/ophs/initiatives/hai/prevtargets.html NQF Endorsed Measures for Healthcare-Associated Infections (http://www.qualityforum.org/pdf/reports/HAI%20Report.pdf) SHEA/IDSA "Compendium of Strategies to Prevent Healthcare-Associated Infections in Acute Care Hospitals" (http://www.cdc.gov/ncidod/dhqp/HAI_shea_idsa.html)	
The event is Serious (<i>Describes an event that can result in death or loss of a body part, disability or loss of bodily function or risk thereof for harm</i>) <i>Please check the appropriate consequence and describe it</i> <input type="checkbox"/> Death or <input checked="" type="checkbox"/> risk of death	Y <input type="checkbox"/> N <input type="checkbox"/>

<input type="checkbox"/> Loss of a body part or <input type="checkbox"/> risk of loss Describe: <input type="checkbox"/> Disability or <input checked="" type="checkbox"/> risk of disability Describe: <input type="checkbox"/> Loss of bodily function or <input checked="" type="checkbox"/> risk of loss Describe:			
The event is Unambiguous (<i>Refers to an event that is clearly defined and easily identified</i>) Definitions: Codes and descriptors (if used): ICD9 999.31infection of central venous catheter Instructions for counting events, calculating rates, and providing context for low frequency:	Y <input type="checkbox"/> N <input type="checkbox"/>		
Reviewer Comments/Rationale:			
3c. ADVERSE, SAFETY SYSTEM PROBLEM, IMPORTANT FOR ACCOUNTABILITY			
Describe the outcome that demonstrates that the event is adverse (<i>Describes a negative consequence of care that results in unintended injury or illness</i>) Infection, sepsis and death are all possible complications of central line associated blood stream infections.	Y <input type="checkbox"/> N <input type="checkbox"/>		
Describe how the event is indicative of a problem in a healthcare facility's safety systems: Compliance with known best practice bundles required support of senior leadership, a culture of patient safety and commitment from all levels of staff.	Y <input type="checkbox"/> N <input type="checkbox"/>		
Describe why the event is important for public credibility or accountability: Public reporting of infection rates and recent press has helped to develop a baseline of understanding in the public that hospital acquired infections can be deadly and that they are largely preventable. If the event is used in a public reporting initiative (disclosure of performance results to the public at large), provide name of initiative(s), locations, Web page URL(s): CDC NHSN	Y <input type="checkbox"/> N <input type="checkbox"/>		
Reviewer Comments/Rationale:			
3d. SETTINGS, DATA SOURCES			
Applicable Care Settings (Mark all to which event is relevant) <input checked="" type="checkbox"/> Hospital <input checked="" type="checkbox"/> Skilled Nursing Facility (SNF) / Nursing home <input type="checkbox"/> Outpatient or Office-based Surgery Center <input checked="" type="checkbox"/> Ambulatory Practice / Physician Offices <input type="checkbox"/> Other (<i>Please describe</i>):			
Data Source Check the source(s) for the information on the SRE. <table border="0" style="width: 100%;"> <tr> <td style="vertical-align: top;"> <input type="checkbox"/> Electronic administrative data/ claims <input type="checkbox"/> Electronic Clinical Data (<i>e.g., MDS</i>) <input type="checkbox"/> Incident Reports <input type="checkbox"/> Medical Record including Electronic <input type="checkbox"/> Pharmacy data <input checked="" type="checkbox"/> Public health data/vital statistics ICD9 codes </td> <td style="vertical-align: top; border-left: 1px solid black; padding-left: 10px;"> <input type="checkbox"/> Quality / Risk Management Databases <input type="checkbox"/> Registry data (or database) <input checked="" type="checkbox"/> Reports to External Bodies (states, federal) <input type="checkbox"/> Regulatory or Accreditation data (FDA, OSHA, etc.) <input checked="" type="checkbox"/> Special or unique data, specify: CDC NHSN </td> </tr> </table>	<input type="checkbox"/> Electronic administrative data/ claims <input type="checkbox"/> Electronic Clinical Data (<i>e.g., MDS</i>) <input type="checkbox"/> Incident Reports <input type="checkbox"/> Medical Record including Electronic <input type="checkbox"/> Pharmacy data <input checked="" type="checkbox"/> Public health data/vital statistics ICD9 codes	<input type="checkbox"/> Quality / Risk Management Databases <input type="checkbox"/> Registry data (or database) <input checked="" type="checkbox"/> Reports to External Bodies (states, federal) <input type="checkbox"/> Regulatory or Accreditation data (FDA, OSHA, etc.) <input checked="" type="checkbox"/> Special or unique data, specify: CDC NHSN	
<input type="checkbox"/> Electronic administrative data/ claims <input type="checkbox"/> Electronic Clinical Data (<i>e.g., MDS</i>) <input type="checkbox"/> Incident Reports <input type="checkbox"/> Medical Record including Electronic <input type="checkbox"/> Pharmacy data <input checked="" type="checkbox"/> Public health data/vital statistics ICD9 codes	<input type="checkbox"/> Quality / Risk Management Databases <input type="checkbox"/> Registry data (or database) <input checked="" type="checkbox"/> Reports to External Bodies (states, federal) <input type="checkbox"/> Regulatory or Accreditation data (FDA, OSHA, etc.) <input checked="" type="checkbox"/> Special or unique data, specify: CDC NHSN		
Identify the specific data source/data collection instrument (e.g. name of database, clinical registry, collection instrument, etc.); include Web page URL where available: CDC NHSN Data dictionary/code table attached <input type="checkbox"/> OR at web page URL:			
Process(es) to Collect Data Provide additional information about how the data regarding the event are collected. Address verifiability, reliability, and validity, if possible.			
Reviewer Comments/Rationale:			
3e. ADDITIONAL INFORMATION for NEW SERIOUS REPORTABLE EVENT			
Provide any additional information that should be considered:			
Susceptibility to Inaccuracies, Errors, or Unintended Consequences <i>Identify susceptibility to inaccuracies, errors, or unintended consequences of the event and describe how</i>			

<i>these potential problems could be audited.</i>	
(for NQF staff use) Identify related endorsed measures PSM-001-10 (Under Review): NHSN CLABSI Outcome Measure; NQF 0139 (Endorsed): Central line catheter-associated blood stream infection rate for ICU and high-risk nursery (HRN) patients	
Reviewer Comments:	
RECOMMENDATION	
Steering Committee: Do you recommend for endorsement? Comments/Rationale:	Y <input type="checkbox"/> N <input type="checkbox"/> A <input type="checkbox"/>
Steering Committee Reviewer Name:	
4. PRIORITY AREAS	
(for NQF staff use) Select the most relevant priority area(s), quality domain(s), and consumer need(s).	
National Priority Partners Priority Area <input type="checkbox"/> patient and family engagement <input type="checkbox"/> population health <input checked="" type="checkbox"/> safety <input type="checkbox"/> care coordination <input type="checkbox"/> palliative and end of life care <input type="checkbox"/> overuse	
IOM Quality Domain <input type="checkbox"/> effectiveness <input type="checkbox"/> efficiency <input type="checkbox"/> equity <input type="checkbox"/> patient-centered <input checked="" type="checkbox"/> safety <input type="checkbox"/> timeliness	
Consumer Care Need <input checked="" type="checkbox"/> Getting Better <input type="checkbox"/> Living With Illness <input type="checkbox"/> Staying Healthy	
(for NQF staff use) Notes on similar/related endorsed SREs and/or Safe Practices: Safe Practice 21: CLABSI Prevention	
Steering Committee Reviewer Name:	

NATIONAL QUALITY FORUM

Serious Reportable Event Submission & Evaluation

The SRE Steering Committee with NQF member and public input has defined Serious Reportable Events (SREs) as preventable, serious, and unambiguous adverse events. The Committee further notes that some types of SREs are universally preventable and should never occur while other types of SREs are largely preventable and over time it may be possible to reduce these to zero as knowledge and safe practices evolve. Both types of SREs should be publicly reported.

Submitters: Complete all the non-shaded areas of this form. Please fill out a separate form for each event you are submitting to NQF for consideration. This form may be used to submit comments/changes to existing SREs or submit new SREs.

Reviewers: Complete all the **yellow** and **pink** highlighted areas of the form. Provide the rationale for your ratings.

(for NQF staff use) NQF Review #:	NQF Project:
(for NQF staff use) Has all requested information been provided? Yes	
Staff Notes to Submitter <i>(if submission returned)</i> :	
Staff Notes to Reviewers <i>(issues or questions regarding any criteria)</i> :	
Staff Reviewer Name(s):	
1. CONTACT INFORMATION	
Submitter: Cynthia Lacker, RN, MS, LNCC, CPHRM Organization: Pennsylvania Patient Safety Authority Street Address: 5200 Butler Pike City/State/Zip: Plymouth Meeting, PA 19462 Telephone Number: 610-825-6000 x5040 Fax Number: 610-834-1275 Email Address: clacker@ecri.org	
Date of Submission <i>(MM/DD/YY)</i> : 06/16/2010	
Is this submission about a currently endorsed SRE or a proposed new SRE? <input type="checkbox"/> Currently Endorsed <input checked="" type="checkbox"/> New Submission <i>(if new submission, skip to section 3a)</i>	
2a. CURRENTLY ENDORSED SERIOUS REPORTABLE EVENT	
Name of Event:	
Suggested Change:	
<input type="checkbox"/> Specify the Applicable Care Setting(s) marked below <input type="checkbox"/> Remove Endorsement <input type="checkbox"/> Modify SRE Specifications	
Describe Suggested Modification(s) in specific detail:	
Rationale for removing endorsement or modifying the SRE <i>(include pertinent evidence, data)</i> :	
If modifications are made, are the changes likely to result in a substantial change in the current count of SREs? <input type="checkbox"/> Yes <input type="checkbox"/> No If yes, please explain:	
(for NQF staff use) The proposed change is justified <i>(Does the rationale justify the proposed change?)</i>	
Applicable Care Settings (Mark all to which event is relevant)	
<input type="checkbox"/> Hospital <input type="checkbox"/> Skilled Nursing Facility (SNF) / Nursing home <input type="checkbox"/> Outpatient or Office-based Surgery Center <input type="checkbox"/> Ambulatory Practice / Physician Offices <input type="checkbox"/> Other <i>(Please specify)</i> :	

Reviewer Comments/Rationale:	
2b. ADDITIONAL INFORMATION for CURRENTLY ENDORSED SERIOUS REPORTABLE EVENT	
Provide any additional information that should be considered:	
Susceptibility to Inaccuracies, Errors, or Unintended Consequences <i>Identify susceptibility to inaccuracies, errors, or unintended consequences of the event and describe how these potential problems could be audited.</i>	
(for NQF staff use) Identify related endorsed measures	
Reviewer Comments:	
RECOMMENDATION	
Steering Committee: Do you recommend the proposed change? <input type="checkbox"/> Do you recommend the proposed change with modification? <input type="checkbox"/> Specify the modification	Y <input type="checkbox"/> N <input type="checkbox"/> A <input type="checkbox"/>
Comments/Rationale:	
3a. NEW SERIOUS REPORTABLE EVENT	
The Event is a discrete, auditable , and clearly defined occurrence Name of Proposed New Event: Death among surgical patients with serious, treatable complications (failure to rescue).	Y <input type="checkbox"/> N <input type="checkbox"/>
3b. PREVENTABLE, SERIOUS, UNAMBIGUOUS	
Brief Description of Event: Patient death within 2 days of admission for a surgical procedure.	
The event is Preventable (<i>Describes an event that could have been anticipated and prepared for, but that occurs because of an error or other system failure</i>)	Y <input type="checkbox"/> N <input type="checkbox"/>
Briefly summarize the Evidence Base that the event is preventable and provide citations: Failure to rescue (PSI 4) Tier 1 Evidence AHRQ sponsored a study in June 2009 to evaluate how to best use the quality indicators for public reporting conducted by the National Quality Forum. The report contains a rating system which places indicators within a tier (1-4) based on the current evidence and identified gaps. Tier 1 a) Public Reporting - Very good for reporting and accountability b) Reliable - Strongly evidence based. Good for comparative reporting c) Endorsed - Endorsed by NQF At: http://qualityindicators.ahrq.gov/downloads/publications/AHRO%20QI%20Guide%20to%20Comparative%20Reporting%20v10.pdf Supporting Evidence • Face validity: Clinical panel rated the indicator as acceptable for quality improvement purposes. The panel was not asked to rate the PSI specifically on usefulness for comparative reporting. Review by an NQF technical advisory panel rated acceptable for comparative public reporting. • Criterion validity: Several studies have noted that the complications that define the denominator may be present on admission. However, the conceptual basis of the indicator applies whether the complication occurred during or prior to admission. • Construct validity: Staffing levels and teaching hospital status have been associated with decreased mortality rates in patients with complications. • Risk adjustment: Hierarchical model based on age, gender, modified DRG and co-morbidities defined using the AHRQ co-morbidity software.	

<p>The event is Serious (<i>Describes an event that can result in death or loss of a body part, disability or loss of bodily function or risk thereof for harm</i>)</p> <p>Please check the appropriate consequence and describe it</p> <p><input checked="" type="checkbox"/> Death or <input type="checkbox"/> risk of death</p> <p><input type="checkbox"/> Loss of a body part or <input type="checkbox"/> risk of loss Describe:</p> <p><input type="checkbox"/> Disability or <input type="checkbox"/> risk of disability Describe:</p> <p><input type="checkbox"/> Loss of bodily function or <input type="checkbox"/> risk of loss Describe:</p>	<p>Y <input type="checkbox"/></p> <p>N <input type="checkbox"/></p>
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<p>The event is Unambiguous (<i>Refers to an event that is clearly defined and easily identified</i>)</p> <p>Definitions: Deaths per 1,000 patients having developed specified complications of care during hospitalization. Excludes patients age 75 and older, neonates in MDC 15, patients admitted from long-term care facility and patients transferred to or from other acute care facility.</p> <p>Rate of in-hospital death among surgical discharges, defined by specific DRG codes and an ICD-9-CM code of major operating room procedure in any procedure field, age 18 years and older and with a principal procedure within 2 days of admission OR admission type of elective and with an ICD-9-CM code of potential complications of care (e.g., pneumonia, DVT/PE, sepsis, shock/cardiac arrest, or GI hemorrhage/acute ulcer) in any secondary diagnosis field.</p> <p>Codes and descriptors (if used):</p> <p>Instructions for counting events, calculating rates, and providing context for low frequency:</p>	<p>Y <input type="checkbox"/></p> <p>N <input type="checkbox"/></p>
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Reviewer Comments/Rationale:

3c. ADVERSE, SAFETY SYSTEM PROBLEM, IMPORTANT FOR ACCOUNTABILITY

<p>Describe the outcome that demonstrates that the event is adverse (<i>Describes a negative consequence of care that results in unintended injury or illness</i>)</p> <p>Patient Death</p>	<p>Y <input type="checkbox"/></p> <p>N <input type="checkbox"/></p>
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<p>Describe how the event is indicative of a problem in a healthcare facility's safety systems:</p> <p>Ability to respond to a patient's deteriorating condition is a system-level process with many potential failure points.</p>	<p>Y <input type="checkbox"/></p> <p>N <input type="checkbox"/></p>
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<p>Describe why the event is important for public credibility or accountability:</p> <p>Mortality rates for many conditions are already in the public domain. The public has come to rely on these data.</p>	<p>Y <input type="checkbox"/></p> <p>N <input type="checkbox"/></p>
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If the event is used in a public reporting initiative (disclosure of performance results to the public at large), provide name of initiative(s), locations, Web page URL(s):

Hospital Compare at <http://www.hospitalcompare.hhs.gov/Hospital/Search/Welcome.asp?version=default&browser=IE%7C7%7CWinNT&language=English&defaultstatus=0&MBPProviderID=&TargetPage=&ComingFromMBP=&CookiesEnabledStatus=&TID=&StateAbbr=&ZIP=&State=&pagelist=Home>

AHRQ PSI 04

Reviewer Comments/Rationale:

3d. SETTINGS, DATA SOURCES

<p>Applicable Care Settings (Mark all to which event is relevant)</p> <p><input checked="" type="checkbox"/> Hospital</p> <p><input type="checkbox"/> Skilled Nursing Facility (SNF) / Nursing home</p> <p><input checked="" type="checkbox"/> Outpatient or Office-based Surgery Center</p> <p><input type="checkbox"/> Ambulatory Practice / Physician Offices</p> <p><input type="checkbox"/> Other (<i>Please describe</i>):</p>
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<p>Data Source Check the source(s) for the information on the SRE.</p> <p><input type="checkbox"/> Electronic administrative data/ claims</p> <p><input checked="" type="checkbox"/> Electronic Clinical Data (<i>e.g., MDS</i>)</p> <p><input type="checkbox"/> Quality / Risk Management Databases</p> <p><input type="checkbox"/> Registry data (or database)</p>
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- Incident Reports
- Medical Record including Electronic
- Pharmacy data
- Public health data/vital statistics

- Reports to External Bodies (states, federal)
- Regulatory or Accreditation data (FDA, OSHA, etc.)
- Special or unique data, specify: [AHRQ PSI 04](#)

Identify the specific data source/data collection instrument (e.g. name of database, clinical registry, collection instrument, etc.); include Web page URL where available:

ARHQ PSI 04

Data dictionary/code table attached OR at web page URL:

Process(es) to Collect Data

Provide additional information about how the data regarding the event are collected. [As above.](#)
Address verifiability, reliability, and validity, if possible.

Reviewer Comments/Rationale:

3e. ADDITIONAL INFORMATION for NEW SERIOUS REPORTABLE EVENT

Provide any additional information that should be considered:

Susceptibility to Inaccuracies, Errors, or Unintended Consequences

Identify susceptibility to inaccuracies, errors, or unintended consequences of the event and describe how these potential problems could be audited.

(for NQF staff use) Identify related endorsed measures

Reviewer Comments:

RECOMMENDATION

Steering Committee: Do you recommend for endorsement?

Comments/Rationale:

- Y
- N
- A
-

Steering Committee Reviewer Name:

4. PRIORITY AREAS

(for NQF staff use) Select the most relevant priority area(s), quality domain(s), and consumer need(s).

National Priority Partners Priority Area patient and family engagement population health safety
 care coordination palliative and end of life care overuse

IOM Quality Domain effectiveness efficiency equity patient-centered safety timeliness

Consumer Care Need Getting Better Living With Illness Staying Healthy

(for NQF staff use) Notes on similar/related endorsed SREs and/or Safe Practices: N/A

Steering Committee Reviewer Name:

NATIONAL QUALITY FORUM

Serious Reportable Event Submission & Evaluation

The SRE Steering Committee with NQF member and public input has defined Serious Reportable Events (SREs) as preventable, serious, and unambiguous adverse events. The Committee further notes that some types of SREs are universally preventable and should never occur while other types of SREs are largely preventable and over time it may be possible to reduce these to zero as knowledge and safe practices evolve. Both types of SREs should be publicly reported.

Submitters: Complete all the non-shaded areas of this form. Please fill out a separate form for each event you are submitting to NQF for consideration. This form may be used to submit comments/changes to existing SREs or submit new SREs.

Reviewers: Complete all the **yellow** and **pink** highlighted areas of the form. Provide the rationale for your ratings.

(for NQF staff use) NQF Review #:		NQF Project:	
(for NQF staff use) Has all requested information been provided? Staff Notes to Submitter <i>(if submission returned)</i> :			
Staff Notes to Reviewers <i>(issues or questions regarding any criteria)</i> : No information provided on event being adverse, indicative of a system failure or important for accountability.			
Staff Reviewer Name(s):			
1. CONTACT INFORMATION			
Submitter: Julie Apold Organization: Minnesota Alliance for Patient Safety (includes Minnesota Hospital Association, Minnesota Department of Health, Minnesota Medical Association and over 50 other public-private healthcare organizations). Street Address: 2550 University avenue W. Suite 350S City/State/Zip: saint Paul, MN 55114 Telephone Number: 651-641-1121 Fax Number: 651-659-1477 Email Address: japold@mnhospitals.org			
Date of Submission (MM/DD/YY): 6/16/10 Is this submission about a currently endorsed SRE or a proposed new SRE? <input type="checkbox"/> Currently Endorsed <input checked="" type="checkbox"/> New Submission <i>(If new submission, skip to section 3a)</i>			
2a. CURRENTLY ENDORSED SERIOUS REPORTABLE EVENT			
Name of Event:			
Suggested Change: <input type="checkbox"/> Specify the Applicable Care Setting(s) marked below <input type="checkbox"/> Remove Endorsement <input type="checkbox"/> Modify SRE Specifications Describe Suggested Modification(s) in specific detail: Rationale for removing endorsement or modifying the SRE <i>(include pertinent evidence, data)</i> : If modifications are made, are the changes likely to result in a substantial change in the current count of SREs? <input type="checkbox"/> Yes <input type="checkbox"/> No If yes, please explain: (for NQF staff use) The proposed change is justified <i>(Does the rationale justify the proposed change?)</i>			Y <input type="checkbox"/> N <input type="checkbox"/>
Applicable Care Settings (Mark all to which event is relevant) <input type="checkbox"/> Hospital <input type="checkbox"/> Skilled Nursing Facility (SNF) / Nursing home <input type="checkbox"/> Outpatient or Office-based Surgery Center			

<input type="checkbox"/> Ambulatory Practice / Physician Offices <input type="checkbox"/> Other (Please specify):		
Reviewer Comments/Rationale:		
2b. ADDITIONAL INFORMATION for CURRENTLY ENDORSED SERIOUS REPORTABLE EVENT		
Provide any additional information that should be considered:		
Susceptibility to Inaccuracies, Errors, or Unintended Consequences <i>Identify susceptibility to inaccuracies, errors, or unintended consequences of the event and describe how these potential problems could be audited.</i>		
(for NQF staff use) Identify related endorsed measures		
Reviewer Comments:		
RECOMMENDATION		
Steering Committee: Do you recommend the proposed change? <input type="checkbox"/> Do you recommend the proposed change with modification? <input type="checkbox"/> Specify the modification		Y <input type="checkbox"/> N <input type="checkbox"/> A <input type="checkbox"/>
Comments/Rationale:		
3a. NEW SERIOUS REPORTABLE EVENT		
The Event is a discrete, auditable, and clearly defined occurrence Name of Proposed New Event: Death of a neonate while being cared for in a healthcare facility following low-risk pregnancy and delivery and the absence of congenital abnormalities.		Y <input type="checkbox"/> N <input type="checkbox"/>
3b. PREVENTABLE, SERIOUS, UNAMBIGUOUS		
Brief Description of Event: This event is similar to the maternal death category involving the unexpected death of a neonate following a low-risk pregnancy and in the absence of obvious congenital abnormalities.		
The event is Preventable (<i>Describes an event that could have been anticipated and prepared for, but that occurs because of an error or other system failure</i>)		Y <input type="checkbox"/> N <input type="checkbox"/>
Briefly summarize the Evidence Base that the event is preventable and provide citations: Because deaths in otherwise healthy neonates are rare (similar to maternal deaths), capturing the learnings from these events when they do occur will provide an important knowledge base.		
The event is Serious (<i>Describes an event that can result in death or loss of a body part, disability or loss of bodily function or risk thereof for harm</i>) <i>Please check the appropriate consequence and describe it</i> <input checked="" type="checkbox"/> Death or <input checked="" type="checkbox"/> risk of death <input type="checkbox"/> Loss of a body part or <input type="checkbox"/> risk of loss Describe: <input type="checkbox"/> Disability or <input type="checkbox"/> risk of disability Describe: <input type="checkbox"/> Loss of bodily function or <input type="checkbox"/> risk of loss Describe:		Y <input type="checkbox"/> N <input type="checkbox"/>
The event is Unambiguous (<i>Refers to an event that is clearly defined and easily identified</i>) Definitions: Codes and descriptors (if used): Instructions for counting events, calculating rates, and providing context for low frequency:		Y <input type="checkbox"/> N <input type="checkbox"/>
Reviewer Comments/Rationale:		
3c. ADVERSE, SAFETY SYSTEM PROBLEM, IMPORTANT FOR ACCOUNTABILITY		
Describe the outcome that demonstrates that the event is adverse (<i>Describes a negative consequence of care that results in unintended injury or illness</i>)		Y <input type="checkbox"/> N <input type="checkbox"/>
Describe how the event is indicative of a problem in a healthcare facility's safety systems:		Y <input type="checkbox"/>

	N <input type="checkbox"/>
Describe why the event is important for public credibility or accountability:	Y <input type="checkbox"/> N <input type="checkbox"/>
If the event is used in a public reporting initiative (disclosure of performance results to the public at large), provide name of initiative(s), locations, Web page URL(s):	
Reviewer Comments/Rationale:	
3d. SETTINGS, DATA SOURCES	
Applicable Care Settings (Mark all to which event is relevant)	
<input checked="" type="checkbox"/> Hospital <input checked="" type="checkbox"/> Skilled Nursing Facility (SNF) / Nursing home <input checked="" type="checkbox"/> Outpatient or Office-based Surgery Center <input checked="" type="checkbox"/> Ambulatory Practice / Physician Offices <input type="checkbox"/> Other (Please describe):	
Data Source Check the source(s) for the information on the SRE.	
<input type="checkbox"/> Electronic administrative data/ claims <input type="checkbox"/> Electronic Clinical Data (e.g., MDS) <input type="checkbox"/> Incident Reports <input type="checkbox"/> Medical Record including Electronic <input type="checkbox"/> Pharmacy data <input type="checkbox"/> Public health data/vital statistics	
<input type="checkbox"/> Quality / Risk Management Databases <input type="checkbox"/> Registry data (or database) <input type="checkbox"/> Reports to External Bodies (states, federal) <input type="checkbox"/> Regulatory or Accreditation data (FDA, OSHA, etc.) <input type="checkbox"/> Special or unique data, specify:	
Identify the specific data source/data collection instrument (e.g. name of database, clinical registry, collection instrument, etc.); include Web page URL where available:	
Data dictionary/code table attached <input type="checkbox"/> OR at web page URL:	
Process(es) to Collect Data Provide additional information about how the data regarding the event are collected. Address verifiability, reliability, and validity, if possible.	
Reviewer Comments/Rationale:	
3e. ADDITIONAL INFORMATION for NEW SERIOUS REPORTABLE EVENT	
Provide any additional information that should be considered:	
Susceptibility to Inaccuracies, Errors, or Unintended Consequences <i>Identify susceptibility to inaccuracies, errors, or unintended consequences of the event and describe how these potential problems could be audited.</i>	
(for NQF staff use) Identify related endorsed measures N/A	
Reviewer Comments:	
RECOMMENDATION	
Steering Committee: Do you recommend for endorsement? Comments/Rationale:	Y <input type="checkbox"/> N <input type="checkbox"/> A <input type="checkbox"/>
Steering Committee Reviewer Name:	
4. PRIORITY AREAS	
(for NQF staff use) Select the most relevant priority area(s), quality domain(s), and consumer need(s).	
National Priority Partners Priority Area <input type="checkbox"/> patient and family engagement <input type="checkbox"/> population health <input checked="" type="checkbox"/> safety <input type="checkbox"/> care coordination <input type="checkbox"/> palliative and end of life care <input type="checkbox"/> overuse	
IOM Quality Domain <input type="checkbox"/> effectiveness <input type="checkbox"/> efficiency <input type="checkbox"/> equity <input type="checkbox"/> patient-centered <input checked="" type="checkbox"/> safety <input type="checkbox"/> timeliness	

Consumer Care Need <input type="checkbox"/> Getting Better <input type="checkbox"/> Living With Illness <input checked="" type="checkbox"/> Staying Healthy	
(for NQF staff use) Notes on similar/related endorsed SREs and/or Safe Practices: Related to SRE 4C: Maternal death or serious disability associated with labor or delivery in a low-risk pregnancy while being cared for in a healthcare facility	
Steering Committee Reviewer Name:	

NATIONAL QUALITY FORUM

Serious Reportable Event Submission & Evaluation

The SRE Steering Committee with NQF member and public input has defined Serious Reportable Events (SREs) as preventable, serious, and unambiguous adverse events. The Committee further notes that some types of SREs are universally preventable and should never occur while other types of SREs are largely preventable and over time it may be possible to reduce these to zero as knowledge and safe practices evolve. Both types of SREs should be publicly reported.

Submitters: Complete all the non-shaded areas of this form. Please fill out a separate form for each event you are submitting to NQF for consideration. This form may be used to submit comments/changes to existing SREs or submit new SREs.

Reviewers: Complete all the **yellow** and **pink** highlighted areas of the form. Provide the rationale for your ratings.

(for NQF staff use) NQF Review #: NQF Project:	
(for NQF staff use) Has all requested information been provided? Staff Notes to Submitter (if submission returned):	
Staff Notes to Reviewers (issues or questions regarding any criteria):	
Staff Reviewer Name(s):	
1. CONTACT INFORMATION	
Submitter: Allen Kachalia Organization: Brigham and Women's Hospital Street Address: 75 Francis St. City/State/Zip: Boston, MA 02115 Telephone Number: 617-732-8937 Fax Number: 617-738-6732 Email Address: AKACHALIA@PARTNERS.ORG	
Date of Submission (MM/DD/YY): 6-15-2010	
Is this submission about a currently endorsed SRE or a proposed new SRE? <input type="checkbox"/> Currently Endorsed <input checked="" type="checkbox"/> New Submission (If new submission, skip to section 3a)	
2a. CURRENTLY ENDORSED SERIOUS REPORTABLE EVENT	
Name of Event:	
Suggested Change: <input type="checkbox"/> Specify the Applicable Care Setting(s) marked below <input type="checkbox"/> Remove Endorsement <input type="checkbox"/> Modify SRE Specifications	
Describe Suggested Modification(s) in specific detail:	
Rationale for removing endorsement or modifying the SRE (include pertinent evidence, data):	
If modifications are made, are the changes likely to result in a substantial change in the current count of SREs? <input type="checkbox"/> Yes <input type="checkbox"/> No If yes, please explain:	
(for NQF staff use) The proposed change is justified (Does the rationale justify the proposed change?)	
Applicable Care Settings (Mark all to which event is relevant) <input type="checkbox"/> Hospital <input type="checkbox"/> Skilled Nursing Facility (SNF) / Nursing home <input type="checkbox"/> Outpatient or Office-based Surgery Center <input type="checkbox"/> Ambulatory Practice / Physician Offices	

Y <input type="checkbox"/>
N <input type="checkbox"/>

<input type="checkbox"/> Other (<i>Please specify</i>):		
Reviewer Comments/Rationale:		
2b. ADDITIONAL INFORMATION for CURRENTLY ENDORSED SERIOUS REPORTABLE EVENT		
Provide any additional information that should be considered:		
Susceptibility to Inaccuracies, Errors, or Unintended Consequences <i>Identify susceptibility to inaccuracies, errors, or unintended consequences of the event and describe how these potential problems could be audited.</i>		
<i>(for NQF staff use)</i> Identify related endorsed measures		
Reviewer Comments:		
RECOMMENDATION		
Steering Committee: Do you recommend the proposed change? <input type="checkbox"/> Do you recommend the proposed change with modification? <input type="checkbox"/> Specify the modification		Y <input type="checkbox"/> N <input type="checkbox"/> A <input type="checkbox"/>
Comments/Rationale:		
3a. NEW SERIOUS REPORTABLE EVENT		
The Event is a discrete, auditable, and clearly defined occurrence Name of Proposed New Event: Arterial Misplacement and Use of a Central Venous Catheter		Y <input type="checkbox"/> N <input type="checkbox"/>
3b. PREVENTABLE, SERIOUS, UNAMBIGUOUS		
Brief Description of Event: "Arterial Misplacement and Use of a Central Venous Catheter" occurs when a central venous catheter is misplaced in an artery and subsequently used for injection or infusion of medications, fluids or other therapeutic substances, not including routine fluid flushes to establish location or maintain patency. Central venous catheters placed during cardiopulmonary resuscitation are excluded from this measure.		
The event is Preventable (<i>Describes an event that could have been anticipated and prepared for, but that occurs because of an error or other system failure</i>)		Y <input type="checkbox"/> N <input type="checkbox"/>
Briefly summarize the Evidence Base that the event is preventable and provide citations:		
<p>Central venous catheter (CVC) placement is one of the most commonly performed surgical procedures in U.S. hospitals. The indications, clinical environments and operators involved in CVC placements vary from emergent indications in non-procedural areas to planned procedures occurring in operating rooms and from junior residents to board certified specialists placing lines. Historically, CVCs were placed "blindly" based on the operator's assessment of the patient's external anatomy and assessment of the nature of blood flow from needle puncture of the vessel. (1) Traditionally, serious complications, including arterial misplacement, accompany CVC placement procedures in about 15% of attempts (ranging widely from under 2% to over 25%) and the failure rate ranges up to 20%. (2) Malpractice claims are relatively uncommon, accounting for less than 2% of all claims against anesthesiologists. (3) The most common liability closed claims are, in order, wire/catheter embolization, hemopneumothorax, cardiac tamponade, and carotid artery puncture. (3)</p> <p>Technologies that allow operators to visualize the vessels in real time, including ultrasound or fluoroscopy have been shown to reliably reduce misplacement of CVCs, in some series down to zero. Multiple studies have shown that use of ultrasound to guide placement of CVCs increases first-attempt success, overall success and reduces complications. (4) Routine US guidance for placement of CVCs has been recommended by systematic evidence reports—a 2001 Agency for Healthcare Research and Quality Evidence Report rates use of real-time ultrasound guidance during</p>		

central line insertion to prevent complications among 11 of the most highly rated patient safety practices in terms of strength of the evidence supporting more widespread implementation.(4-7) Routine US guidance for placement of CVCs has also been deemed cost effective by Britain's NHS.(6) Despite increasing use of new technologies, CVC misplacements are still a significant problem, as the technology is not universally available, staff are not all trained in its use, and even when present it is not always used.

References:

1. Roberts J.R., Hedges, J.R. *Roberts: Clinical Procedures in Emergency Medicine, 5th ed.* 2009 Saunders, An Imprint of Elsevier.
2. McGee DC, Gould MK: Preventing complications of central venous catheterization. *N Engl J Med* 2003; 348:1123.
3. Domino KB, Bowdle TA, Posner KL, et al: Injuries and liability related to central vascular catheters: A closed claims analysis. *Anesthesiology* 2004; 100:1411.
4. Agency for Health Care Research and Quality (AHRQ). Evidence Report/Technology Assessment: Number 43. Making Health Care Safer. A Critical Analysis of Patient Safety Practices: Summary 2001. 2007.
5. Wigmore TJ, Smythe JF, Hacking MB, Raobaikady R, MacCallum NS. Effect of the implementation of NICE guidelines for ultrasound guidance on the complication rates associated with central venous catheter placement in patients presenting for routine surgery in a tertiary referral centre. *Br J Anaesth.* 2007 Nov;99(5):662-5. Epub 2007 Sep 14.
6. Calvert N. Hind D. McWilliams R. Davidson A. Beverley CA. Thomas SM. Ultrasound for central venous cannulation: economic evaluation of cost-effectiveness. *Anaesthesia.* 59(11):1116-20, 2004 Nov.
7. Milling TJ Jr. Rose J. Briggs WM. Birkhahn R. Gaeta TJ. Bove JJ. Melniker LA. Randomized, controlled clinical trial of point-of-care limited ultrasonography assistance of central venous cannulation: the Third Sonography Outcomes Assessment Program (SOAP-3) Trial. *Critical Care Medicine.* 33(8):1764-9, 2005 Aug.

The event is Serious (*Describes an event that can result in death or loss of a body part, disability or loss of bodily function or risk thereof for harm*)

Y
N

Please check the appropriate consequence and describe it

Death or risk of death

Loss of a body part or risk of loss Describe:

Disability or risk of disability Describe: All central lines can be associated with artery puncture with thromboembolism and resulting stroke, and air embolism. Serious complications accompany this procedure in about 15% of attempts (ranging widely from under 2% to over 25%) and the failure rate ranges up to 20%.(1-2) Even if there is no adverse outcome of arterial placement, surgery can be required to fix the misplacement. Malpractice claims are relatively uncommon accounting for less than 2% of all claims against anesthesiologists.(3) The most common liability closed claims are, in order, wire/catheter embolization, hemopneumothorax, cardiac tamponade, and carotid artery puncture.(3)

References:

1. Roberts J.R., Hedges, J.R. *Roberts: Clinical Procedures in Emergency Medicine, 5th ed.* 2009 Saunders, An Imprint of Elsevier.
2. McGee DC, Gould MK: Preventing complications of central venous catheterization. *N Engl J Med* 2003; 348:1123.
3. Domino KB, Bowdle TA, Posner KL, et al: Injuries and liability related to central vascular catheters: A closed claims analysis. *Anesthesiology* 2004; 100:1411.

Loss of bodily function or risk of loss Describe:

The event is Unambiguous (*Refers to an event that is clearly defined and easily identified*)

Y
N

Definitions:

- Central venous catheter - A tube surgically placed into a blood vessel for the purpose of giving intravenous fluid and drugs. It also can be used to obtain blood samples. This device avoids the need for separate needle insertions for each infusion or blood test. Examples of these devices include Hickman catheters, which require clamps to make sure the valve is closed, and Groshong catheters, which have a valve that opens as fluid is withdrawn or infused and remains closed when not in use. (1)
- Misplaced - refers to the location of the CVC in a central artery rather than a central vein.

1- National Cancer Institute website, dictionary of cancer terms.
<http://www.cancer.gov/dictionary/?Cdrid=45962> Accessed June 1, 2010.

Codes and descriptors (if used): This SRE does not require the use of administrative codes. Cases will be identified through incident reports or patient safety reviews. There is no ICD- code for "Arterial Misplacement of a Central Venous Catheter."

Instructions for counting events, calculating rates, and providing context for low frequency:
 Calculation of rates is not required as each occurrence of this SRE is significant.

Reviewer Comments/Rationale:

3c. ADVERSE, SAFETY SYSTEM PROBLEM, IMPORTANT FOR ACCOUNTABILITY

Describe the outcome that demonstrates that the event is adverse (*Describes a negative consequence of care that results in unintended injury or illness*)

Y
 N

All CVCs can be associated with artery puncture with thromboembolism and resulting stroke, and air embolism.(1) Serious complications accompany this procedure in about 15% of attempts (ranging widely from under 2% to over 25%) and the failure rate ranges up to 20%.(1-2)) Even if there is no adverse outcome of arterial placement, surgery can be required to fix the misplacement. The most common liability closed claims are, in order, wire/catheter embolization, hemopneumothorax, cardiac tamponade, and carotid artery puncture.(3)

References:

1. Roberts J.R., Hedges, J.R. Roberts: Clinical Procedures in Emergency Medicine, 5th ed. 2009 Saunders, An Imprint of Elsevier.
2. McGee DC, Gould MK: Preventing complications of central venous catheterization. N Engl J Med 2003; 348:1123.
3. Domino KB, Bowdle TA, Posner KL, et al: Injuries and liability related to central vascular catheters: A closed claims analysis. Anesthesiology 2004; 100:1411.

Describe how the event is indicative of a problem in a healthcare facility's safety systems:

As described above and below, "Arterial Misplacement and Use of a Central Venous Catheter" is almost completely preventable with use of real-time US guidance and post procedure radiography. Both of these technologies are widely available. Although real-time ultrasound is a newer technology, it has been highly recommended by the Agency for Healthcare Research and Quality for nearly 10 years. "Arterial Misplacement and Use of a Central Venous Catheter" is indicative of a problem in a facility's safety systems because it indicates that they have not implemented a real-time ultrasound program and/or have a practice of using CVCs prior to confirming their correct location by US or chest radiography.

Y
 N

Describe why the event is important for public credibility or accountability:

As "Arterial Misplacement of a Central Venous Catheter" is indicative of a problem in a healthcare facility's safety systems it is important for public accountability. The average patient would not understand why a central line had been placed in the artery if there was widely available technology that could largely prevent such an occurrence.

Y
 N

If the event is used in a public reporting initiative (disclosure of performance results to the public at large), provide name of initiative(s), locations, Web page URL(s):

Reviewer Comments/Rationale:

3d. SETTINGS, DATA SOURCES

Applicable Care Settings (Mark all to which event is relevant)
 Hospital
 Skilled Nursing Facility (SNF) / Nursing home
 Outpatient or Office-based Surgery Center
 Ambulatory Practice / Physician Offices
 Other (Please describe): **Emergency Department**

Data Source Check the source(s) for the information on the SRE.

<input type="checkbox"/> Electronic administrative data/ claims	<input checked="" type="checkbox"/> Quality / Risk Management Databases
<input type="checkbox"/> Electronic Clinical Data (e.g., MDS)	<input type="checkbox"/> Registry data (or database)
<input checked="" type="checkbox"/> Incident Reports	<input type="checkbox"/> Reports to External Bodies (states, federal)
<input checked="" type="checkbox"/> Medical Record including Electronic	<input type="checkbox"/> Regulatory or Accreditation data (FDA, OSHA, etc.)
<input type="checkbox"/> Pharmacy data	<input type="checkbox"/> Special or unique data, specify:
<input type="checkbox"/> Public health data/vital statistics	

Identify the specific data source/data collection instrument (e.g. name of database, clinical registry, collection instrument, etc.); include Web page URL where available:

Data dictionary/code table attached OR at web page URL:

Process(es) to Collect Data
 Provide additional information about how the data regarding the event are collected. Address verifiability, reliability, and validity, if possible.

Reviewer Comments/Rationale:

3e. ADDITIONAL INFORMATION for NEW SERIOUS REPORTABLE EVENT

Provide any additional information that should be considered:

In order to specify a reasonable definition of when CVC misplacement should be a SRE, two clinical questions need to be considered. At what point in CVC misplacement does the harm to the patient rise to the level of seriousness? At what point in the procedure is misplacement preventable? There are four points in CVC placement that could be interpreted as serious: incorrect vessel puncture, dilation of the incorrect vessel, placement of the catheter in the incorrect vessel and use of a catheter in the incorrect vessel. Although there is some risk of bleeding with puncture of a central artery, this is small in comparison to the risk associated with dilatation of a central artery, which is associated with significant hemorrhage and can require emergent vascular surgery.(1) Compared to vessel dilatation, placement of a catheter in the vessel carries little additional risk. Use of a catheter in the incorrect vessel can carry significant associated risk such including thrombosis, infection and adverse effects of medications, such as a vasopressor (e.g. epinephrine) is given through the carotid artery.

Preventability increases at each of these four points. Use of real-time ultrasound (US) guidance allows the operator to visualize the vein and artery while performing vessel puncture and has been shown to reduce the number of sticks and incorrect arterial punctures.(1) Even in experienced hands US cannot eliminate arterial punctures as the artery and vein are in close proximity and the artery may lie directly behind the vein, and is punctured inadvertently as the vein is compressed. Dilation of an artery is preventable with appropriate use of US. After needle puncture, when the guide wire is placed in the vessel, it is possible to directly visualize the guide wire and confirm the vessel type with ultrasound techniques such as Doppler waveform analysis. In the absence of real-time US the point of preventability is after completion of the CVC placement and prior to use of an inappropriately placed catheter, by X-ray of the line to assess placement. Radiography, when appropriately performed and interpreted, is sensitive for identifying inappropriate placement of subclavian and internal jugular lines but not for femoral lines. Additionally, transducing vascular pressure of central lines with waveform analysis is highly sensitive for

arterial versus venous placement, and can be done prior to use of the line.

When viewed in context of patient risk, preventability and feasibility of case ascertainment, the SRE definition should be “Arterial Misplacement and Use of a Central Venous Catheter”. This definition carries several benefits over other points in the misplacement process. First, it maximizes preventability. Although real-time US can almost completely prevent arterial dilation and misplacement of CVCs, it is not currently universally available and may never be available for all line placements, such as patients who need emergent lines in remote areas of a healthcare facility. Setting the definition at “misplacement and use” allows for the use of radiography, and vascular pressure analysis to judge line placement, thus increasing preventability. Second, as the definition based on “misplacement and use” straddles time between CVC placement, an operator led event (physician/PA/APRN), and injection or infusion through a CVC, a nursing event, it will empower nurses to be vigilant towards misplacement by performing a safety check. Third, the definition based on “use of a misplaced CVC” offers the clearest bright line standard, facilitating standardization and feasibility of reporting. If the SRE was defined based on dilatation of an artery during CVC placement, there could be ambiguity in interpreting what constituted dilatation and it would be easier for operators not to report a case if there was no immediate adverse event. It would be difficult to not report use of a misplaced CVC, as that involves both nursing and the operator (generally a physician) Finally, setting the standard for an SRE at the point of use will still provide a strong incentive for adoption of best practices, such as implementation of real-time ultrasound for CVC placement.

References:

1. Roberts J.R., Hedges, J.R. *Roberts: Clinical Procedures in Emergency Medicine, 5th ed.* 2009 Saunders, An Imprint of Elsevier.

Susceptibility to Inaccuracies, Errors, or Unintended Consequences

Identify susceptibility to inaccuracies, errors, or unintended consequences of the event and describe how these potential problems could be audited.

Defining CVC misplacement as an SRE would have important implications for providers, hospitals and payers. Immediately, there would be increased identification, investigation, and reporting of cases of CVC misplacement. Hospitals would adopt protocols and procedures that have been shown to minimize misplacement. These could include adoption of real-time ultrasound for CVC placement, reduction in the use of central venous catheters, substitution with other devices such as PICCs, and limitation of CVC placement to specific individuals with more training and/or expertise (e.g. line team). All of these could improve the climate of patient safety and lead to fewer adverse events. They could also have unintended consequences. Teaching trainees to insert CVCs may become more difficult as fear of complications increased. Although possible, appropriately trained supervising physicians could feel more comfortable supervising trainees with the benefit of real-time ultrasound guidance, which allows the supervisor to visualize the procedure and potentially intervene prior to serious errors, such as arterial dilatation. Alternative devices, such as intraosseous lines, may have adverse effects that as of yet are unknown (e.g. infections).

It is important that the specifications of an SRE be precise and meaningful. If grouped with “surgery on the wrong body part,” the unique causes and opportunities for prevention of CVC misplacement may not be fully implemented. For example, the universal protocol is designed to prevent wrong site surgery, but would have no impact on CVC misplacement. Furthermore, the number of CVC misplacements would likely dwarf the number of wrong site surgeries, and if grouped together under the heading of wrong site surgeries, could lead to very misleading summary statistics and public reporting. An overly broad definition, for example arterial puncture, could lead to underreporting, as reporting SREs involves significant negative risk and press.

A new SRE for central line of misplacement would raise questions about reimbursement for such events. As wrong site surgery is seen by payers as a “never” event, they have adopted policies to not reimburse for WSS events. Nonpayment would provide a strong incentive for hospitals and providers to use best practices to avoid this placement of CVCs. Unfortunately, it could also punish the facilities that can least afford it, as under-resourced and safety net hospitals are likely to have been slow to adopt real-time ultrasound, as it is costly to obtain the technology and train staff. We believe that the link

between this proposed SRE and reimbursement would best be approached by re-addressing nonpayment in several years, after national data are available on the frequency of CVC misplacements and the direct associated harms. Initially, misplacement of CVCs should not affect reimbursement for the procedure. After a several years, when hospitals could fully implement real-time ultrasound and other safety systems, payers should not reimburse for CVCs that were misplaced. Further discussion will be needed to determine whether the cost of complications from a misplaced CVC, such as vascular surgery on a punctured carotid artery, should be reimbursed.

(for NQF staff use) Identify related endorsed measures N/A

Reviewer Comments:

RECOMMENDATION

Steering Committee: Do you recommend for endorsement?
 Comments/Rationale: Y
 N
 A

Steering Committee Reviewer Name:

4. PRIORITY AREAS

(for NQF staff use) Select the most relevant priority area(s), quality domain(s), and consumer need(s).

National Priority Partners Priority Area patient and family engagement population health safety
 care coordination palliative and end of life care overuse

IOM Quality Domain effectiveness efficiency equity patient-centered safety timeliness

Consumer Care Need Getting Better Living With Illness Staying Healthy

(for NQF staff use) Notes on similar/related endorsed SREs and/or Safe Practices: N/A

Steering Committee Reviewer Name:

NATIONAL QUALITY FORUM

Serious Reportable Event Submission & Evaluation

The SRE Steering Committee with NQF member and public input has defined Serious Reportable Events (SREs) as preventable, serious, and unambiguous adverse events. The Committee further notes that some types of SREs are universally preventable and should never occur while other types of SREs are largely preventable and over time it may be possible to reduce these to zero as knowledge and safe practices evolve. Both types of SREs should be publicly reported.

Submitters: Complete all the non-shaded areas of this form. Please fill out a separate form for each event you are submitting to NQF for consideration. This form may be used to submit comments/changes to existing SREs or submit new SREs.

Reviewers: Complete all the **yellow** and **pink** highlighted areas of the form. Provide the rationale for your ratings.

(for NQF staff use) NQF Review #: NQF Project:	
(for NQF staff use) Has all requested information been provided? Staff Notes to Submitter (if submission returned):	
Staff Notes to Reviewers (issues or questions regarding any criteria):	
Staff Reviewer Name(s):	
1. CONTACT INFORMATION	
Submitter: Cynthia Lacker, RN, MS, LNCC, CPHRM Organization: Pennsylvania Patient Safety Authority Street Address: 5200 Butler Pike City/State/Zip: Plymouth Meeting, PA 19462 Telephone Number: 610-825-6000 x5040 Fax Number: 610-834-1275 Email Address: clacker@ecri.org	
Date of Submission (MM/DD/YY): 06/16/2010 Is this submission about a currently endorsed SRE or a proposed new SRE? <input type="checkbox"/> Currently Endorsed <input checked="" type="checkbox"/> New Submission (if new submission, skip to section 3a)	
2a. CURRENTLY ENDORSED SERIOUS REPORTABLE EVENT	
Name of Event:	
Suggested Change: <input type="checkbox"/> Specify the Applicable Care Setting(s) marked below <input type="checkbox"/> Remove Endorsement <input type="checkbox"/> Modify SRE Specifications Describe Suggested Modification(s) in specific detail: Rationale for removing endorsement or modifying the SRE (include pertinent evidence, data): If modifications are made, are the changes likely to result in a substantial change in the current count of SREs? <input type="checkbox"/> Yes <input type="checkbox"/> No If yes, please explain:	Y <input type="checkbox"/> N <input type="checkbox"/>
(for NQF staff use) The proposed change is justified (Does the rationale justify the proposed change?)	
Applicable Care Settings (Mark all to which event is relevant) <input type="checkbox"/> Hospital <input type="checkbox"/> Skilled Nursing Facility (SNF) / Nursing home <input type="checkbox"/> Outpatient or Office-based Surgery Center <input type="checkbox"/> Ambulatory Practice / Physician Offices <input type="checkbox"/> Other (Please specify):	Y <input type="checkbox"/> N <input type="checkbox"/>

Reviewer Comments/Rationale:	
2b. ADDITIONAL INFORMATION for CURRENTLY ENDORSED SERIOUS REPORTABLE EVENT	
Provide any additional information that should be considered:	
Susceptibility to Inaccuracies, Errors, or Unintended Consequences <i>Identify susceptibility to inaccuracies, errors, or unintended consequences of the event and describe how these potential problems could be audited.</i>	
(for NQF staff use) Identify related endorsed measures	
Reviewer Comments:	
RECOMMENDATION	
Steering Committee: Do you recommend the proposed change? <input type="checkbox"/> Do you recommend the proposed change with modification? <input type="checkbox"/> Specify the modification	
Comments/Rationale:	Y <input type="checkbox"/> N <input type="checkbox"/> A <input type="checkbox"/>
3a. NEW SERIOUS REPORTABLE EVENT	
The Event is a discrete, auditable, and clearly defined occurrence	Y <input type="checkbox"/>
Name of Proposed New Event: <u>Death or serious injury related to irretrievable, lost surgical specimens</u>	N <input type="checkbox"/>
3b. PREVENTABLE, SERIOUS, UNAMBIGUOUS	
Brief Description of Event: <u>The loss of a surgical specimen that is irretrievable (complete excision of organ or site).</u>	
The event is Preventable (<i>Describes an event that could have been anticipated and prepared for, but that occurs because of an error or other system failure</i>)	Y <input type="checkbox"/> N <input type="checkbox"/>
Briefly summarize the Evidence Base that the event is preventable and provide citations:	
<p>Association of Perioperative Registered Nurses. AORN Recommended Practices for the care and handling of specimens in the perioperative environment. AORN J 2006 March;83(3):688-99. [cited 2010 Jun 14] Available from Internet: http://download.journals.elsevierhealth.com/pdfs/journals/0001-2092/PIIS000120920660197X.pdf</p> <p>Pennsylvania Patient Safety Authority. Lost surgical specimens, lost opportunities. Patient Safety Advisory 2005 Sept; 2(3): 1-4. At: http://www.patientsafetyauthority.org/ADVISORIES/AdvisoryLibrary/2005/sep2(3)/Pages/01b.aspx</p> <p>Association of Surgical Technologists. AST recommended standards of practice for handling and care of surgical specimens. [cited 2010 Jun 14] Available from Internet at: http://www.ast.org/pdf/Standards_of_Practice/RSOP_%20Handling_Care_Surgical_Specimens.pdf</p> <p>OR Manager. Taking steps to protect patients from specimen-handling errors. OR Manager 2008 Dec;24(12):1-4.</p>	
The event is Serious (<i>Describes an event that can result in death or loss of a body part, disability or loss of bodily function or risk thereof for harm</i>) <i>Please check the appropriate consequence and describe it</i>	Y <input type="checkbox"/> N <input type="checkbox"/>
<input type="checkbox"/> Death or <input checked="" type="checkbox"/> risk of death <input type="checkbox"/> Loss of a body part or <input checked="" type="checkbox"/> risk of loss Describe: <input type="checkbox"/> Disability or <input checked="" type="checkbox"/> risk of disability Describe: <input type="checkbox"/> Loss of bodily function or <input checked="" type="checkbox"/> risk of loss Describe: <u>When an irretrievable specimen is lost, in addition to the risk of misdiagnosis or delayed diagnosis, or delayed or inappropriate treatment, the patient may have to undergo additional treatment as a safety measure, even though it may not have been needed, or</u>	

<p>undergo treatment of the wrong area of the body. A patient may also undergo anxiety, mental stress and loss of income.</p>			
<p>The event is Unambiguous (<i>Refers to an event that is clearly defined and easily identified</i>) Definitions: Whether or not a surgical specimen can be found is easily identifiable. Whether a surgical specimen can be replaced, such as an excised tumor or an organ, is also unambiguous. In addition, a specimen may be irreplaceable because the patient is unable to tolerate a repeat operation. Codes and descriptors (if used): Instructions for counting events, calculating rates, and providing context for low frequency:</p>	<p>Y <input type="checkbox"/> N <input type="checkbox"/></p>		
<p>Reviewer Comments/Rationale:</p>			
<p style="text-align: center;">3c. ADVERSE, SAFETY SYSTEM PROBLEM, IMPORTANT FOR ACCOUNTABILITY</p>			
<p>Describe the outcome that demonstrates that the event is adverse (<i>Describes a negative consequence of care that results in unintended injury or illness</i>)</p>	<p>Y <input type="checkbox"/> N <input type="checkbox"/></p>		
<p>Describe how the event is indicative of a problem in a healthcare facility's safety systems: Delivering a specimen to the pathology department involves a number of steps and handling by multiple healthcare workers. The handling of specimens before reaching the pathology lab is referred to as the preanalytic phase and includes: (1) Correctly identifying the patient; (2) correctly identifying and confirming the specimen by the surgical team; (3) placing the specimen in the correct container and preservative; (4) correctly labeling the specimen; (5) completing the pathology requisition slip/data entry; (6) transporting the specimen to the pathology department. The steps involved in managing surgical specimens also involve handoffs that are vulnerable to error.</p>	<p>Y <input type="checkbox"/> N <input type="checkbox"/></p>		
<p>Describe why the event is important for public credibility or accountability: The loss of an irretrievable surgical specimen can be identified and understood by a layperson as something that can be controlled and should never happen. The harm associated with such an event can similarly be understood by a layperson (e.g. a longer stay in the hospital, the possibility that their diagnosis and/or treatment may not be correct). As a matter of public policy, the loss of an irretrievable surgical specimen can be readily justified as not eligible for third party reimbursement because it is preventable through implementation and adherence to effective systemic processes.</p> <p>If the event is used in a public reporting initiative (disclosure of performance results to the public at large), provide name of initiative(s), locations, Web page URL(s):</p>	<p>Y <input type="checkbox"/> N <input type="checkbox"/></p>		
<p>Reviewer Comments/Rationale:</p>			
<p style="text-align: center;">3d. SETTINGS, DATA SOURCES</p>			
<p>Applicable Care Settings (Mark all to which event is relevant) <input checked="" type="checkbox"/> Hospital <input type="checkbox"/> Skilled Nursing Facility (SNF) / Nursing home <input checked="" type="checkbox"/> Outpatient or Office-based Surgery Center <input type="checkbox"/> Ambulatory Practice / Physician Offices <input type="checkbox"/> Other (<i>Please describe</i>):</p>			
<p>Data Source Check the source(s) for the information on the SRE.</p> <table border="0" style="width: 100%;"> <tr> <td style="width: 50%; vertical-align: top;"> <input type="checkbox"/> Electronic administrative data/ claims <input type="checkbox"/> Electronic Clinical Data (<i>e.g., MDS</i>) <input checked="" type="checkbox"/> Incident Reports <input checked="" type="checkbox"/> Medical Record including Electronic <input type="checkbox"/> Pharmacy data <input type="checkbox"/> Public health data/vital statistics </td> <td style="width: 50%; vertical-align: top;"> <input checked="" type="checkbox"/> Quality / Risk Management Databases <input type="checkbox"/> Registry data (or database) <input type="checkbox"/> Reports to External Bodies (states, federal) <input type="checkbox"/> Regulatory or Accreditation data (FDA, OSHA, etc.) <input type="checkbox"/> Special or unique data, specify: </td> </tr> </table> <p>Identify the specific data source/data collection instrument (e.g. name of database, clinical registry, collection instrument, etc.); include Web page URL where available: Lost surgical specimens can be identified and audited through adverse event reports, operative reports and surgical pathology records. Medical record abstraction</p>	<input type="checkbox"/> Electronic administrative data/ claims <input type="checkbox"/> Electronic Clinical Data (<i>e.g., MDS</i>) <input checked="" type="checkbox"/> Incident Reports <input checked="" type="checkbox"/> Medical Record including Electronic <input type="checkbox"/> Pharmacy data <input type="checkbox"/> Public health data/vital statistics	<input checked="" type="checkbox"/> Quality / Risk Management Databases <input type="checkbox"/> Registry data (or database) <input type="checkbox"/> Reports to External Bodies (states, federal) <input type="checkbox"/> Regulatory or Accreditation data (FDA, OSHA, etc.) <input type="checkbox"/> Special or unique data, specify:	
<input type="checkbox"/> Electronic administrative data/ claims <input type="checkbox"/> Electronic Clinical Data (<i>e.g., MDS</i>) <input checked="" type="checkbox"/> Incident Reports <input checked="" type="checkbox"/> Medical Record including Electronic <input type="checkbox"/> Pharmacy data <input type="checkbox"/> Public health data/vital statistics	<input checked="" type="checkbox"/> Quality / Risk Management Databases <input type="checkbox"/> Registry data (or database) <input type="checkbox"/> Reports to External Bodies (states, federal) <input type="checkbox"/> Regulatory or Accreditation data (FDA, OSHA, etc.) <input type="checkbox"/> Special or unique data, specify:		

Data dictionary/code table attached <input type="checkbox"/> OR at web page URL:	
Process(es) to Collect Data Provide additional information about how the data regarding the event are collected. Address verifiability, reliability, and validity, if possible.	
Reviewer Comments/Rationale:	
3e. ADDITIONAL INFORMATION for NEW SERIOUS REPORTABLE EVENT	
Provide any additional information that should be considered:	
Susceptibility to Inaccuracies, Errors, or Unintended Consequences <i>Identify susceptibility to inaccuracies, errors, or unintended consequences of the event and describe how these potential problems could be audited.</i>	
<i>(for NQF staff use) Identify related endorsed measures N/A</i>	
Reviewer Comments:	
RECOMMENDATION	
Steering Committee: Do you recommend for endorsement? Comments/Rationale:	Y <input type="checkbox"/> N <input type="checkbox"/> A <input type="checkbox"/>
Steering Committee Reviewer Name:	
4. PRIORITY AREAS	
<i>(for NQF staff use) Select the most relevant priority area(s), quality domain(s), and consumer need(s).</i>	
National Priority Partners Priority Area <input type="checkbox"/> patient and family engagement <input type="checkbox"/> population health <input checked="" type="checkbox"/> safety <input type="checkbox"/> care coordination <input type="checkbox"/> palliative and end of life care <input type="checkbox"/> overuse	
IOM Quality Domain <input type="checkbox"/> effectiveness <input type="checkbox"/> efficiency <input type="checkbox"/> equity <input type="checkbox"/> patient-centered <input checked="" type="checkbox"/> safety <input type="checkbox"/> timeliness	
Consumer Care Need <input type="checkbox"/> Getting Better <input type="checkbox"/> Living With Illness <input type="checkbox"/> Staying Healthy	
<i>(for NQF staff use) Notes on similar/related endorsed SREs and/or Safe Practices: N/A</i>	
Steering Committee Reviewer Name:	

NATIONAL QUALITY FORUM

Serious Reportable Event Submission & Evaluation

The SRE Steering Committee with NQF member and public input has defined Serious Reportable Events (SREs) as preventable, serious, and unambiguous adverse events. The Committee further notes that some types of SREs are universally preventable and should never occur while other types of SREs are largely preventable and over time it may be possible to reduce these to zero as knowledge and safe practices evolve. Both types of SREs should be publicly reported.

Submitters: Complete all the non-shaded areas of this form. Please fill out a separate form for each event you are submitting to NQF for consideration. This form may be used to submit comments/changes to existing SREs or submit new SREs.

Reviewers: Complete all the **yellow** and **pink** highlighted areas of the form. Provide the rationale for your ratings.

(for NQF staff use) NQF Review #:		NQF Project:	
(for NQF staff use) Has all requested information been provided? Staff Notes to Submitter <i>(if submission returned)</i> :			
Staff Notes to Reviewers <i>(issues or questions regarding any criteria)</i> :			
Staff Reviewer Name(s):			
1. CONTACT INFORMATION			
Submitter: Julie Apold Organization: Minnesota Alliance for Patient Safety (includes Minnesota Hospital Association, Minnesota Department of Health, Minnesota Medical Association and over 50 other public-private healthcare organizations). Street Address: 2550 University avenue W. Suite 350S City/State/Zip: saint Paul, MN 55114 Telephone Number: 651-641-1121 Fax Number: 651-659-1477 Email Address: japold@mnhospitals.org			
Date of Submission (MM/DD/YY): 6/16/10 Is this submission about a currently endorsed SRE or a proposed new SRE? <input type="checkbox"/> Currently Endorsed <input checked="" type="checkbox"/> New Submission <i>(If new submission, skip to section 3a)</i>			
2a. CURRENTLY ENDORSED SERIOUS REPORTABLE EVENT			
Name of Event:			
Suggested Change: <input type="checkbox"/> Specify the Applicable Care Setting(s) marked below <input type="checkbox"/> Remove Endorsement <input type="checkbox"/> Modify SRE Specifications Describe Suggested Modification(s) in specific detail: Rationale for removing endorsement or modifying the SRE <i>(include pertinent evidence, data)</i> : If modifications are made, are the changes likely to result in a substantial change in the current count of SREs? <input type="checkbox"/> Yes <input type="checkbox"/> No If yes, please explain:			Y <input type="checkbox"/> N <input type="checkbox"/>
(for NQF staff use) The proposed change is justified <i>(Does the rationale justify the proposed change?)</i>			
Applicable Care Settings (Mark all to which event is relevant) <input type="checkbox"/> Hospital <input type="checkbox"/> Skilled Nursing Facility (SNF) / Nursing home <input type="checkbox"/> Outpatient or Office-based Surgery Center <input type="checkbox"/> Ambulatory Practice / Physician Offices			

<input type="checkbox"/> Other (Please specify):	
Reviewer Comments/Rationale:	
2b. ADDITIONAL INFORMATION for CURRENTLY ENDORSED SERIOUS REPORTABLE EVENT	
Provide any additional information that should be considered:	
Susceptibility to Inaccuracies, Errors, or Unintended Consequences <i>Identify susceptibility to inaccuracies, errors, or unintended consequences of the event and describe how these potential problems could be audited.</i>	
(for NQF staff use) Identify related endorsed measures	
Reviewer Comments:	
RECOMMENDATION	
Steering Committee: Do you recommend the proposed change? <input type="checkbox"/> Do you recommend the proposed change with modification? <input type="checkbox"/> Specify the modification	Y <input type="checkbox"/> N <input type="checkbox"/> A <input type="checkbox"/>
Comments/Rationale:	
3a. NEW SERIOUS REPORTABLE EVENT	
The Event is a discrete, auditable, and clearly defined occurrence Name of Proposed New Event: Diagnostic testing error resulting in unnecessary invasive procedure, serious disability or death.	Y <input type="checkbox"/> N <input type="checkbox"/>
3b. PREVENTABLE, SERIOUS, UNAMBIGUOUS	
Brief Description of Event: Wrong procedure performed, or performed on the wrong patient, associated with a diagnostic testing error. (Eg. Mislabeling of specimens or films).	
The event is Preventable (<i>Describes an event that could have been anticipated and prepared for, but that occurs because of an error or other system failure</i>)	Y <input type="checkbox"/> N <input type="checkbox"/>
Briefly summarize the Evidence Base that the event is preventable and provide citations: Minnesota has experienced wrong patient or procedure events in which the procedure team did all verifications, site marking and time-out correctly but the information that they received for the procedure was incorrect due to diagnostic errors beyond their control. By creating a separate category for this type of event, the root cause analysis and corrective actions will be more targeted.	
The event is Serious (<i>Describes an event that can result in death or loss of a body part, disability or loss of bodily function or risk thereof for harm</i>) <i>Please check the appropriate consequence and describe it</i> <input checked="" type="checkbox"/> Death or <input checked="" type="checkbox"/> risk of death <input checked="" type="checkbox"/> Loss of a body part or <input checked="" type="checkbox"/> risk of loss Describe: <input checked="" type="checkbox"/> Disability or <input checked="" type="checkbox"/> risk of disability Describe: <input checked="" type="checkbox"/> Loss of bodily function or <input checked="" type="checkbox"/> risk of loss Describe:	Y <input type="checkbox"/> N <input type="checkbox"/>
The event is Unambiguous (<i>Refers to an event that is clearly defined and easily identified</i>) Definitions: Codes and descriptors (if used): Instructions for counting events, calculating rates, and providing context for low frequency:	Y <input type="checkbox"/> N <input type="checkbox"/>
Reviewer Comments/Rationale:	
3c. ADVERSE, SAFETY SYSTEM PROBLEM, IMPORTANT FOR ACCOUNTABILITY	
Describe the outcome that demonstrates that the event is adverse (<i>Describes a negative consequence of care that results in unintended injury or illness</i>) We have seen a number of events reported in which a diagnostic testing error, such as a mislabeling of specimens or reversing films leads to an incorrect or unnecessary procedure for the patient. These	Y <input type="checkbox"/> N <input type="checkbox"/>

procedure errors can have significant consequences to the patient.	
Describe how the event is indicative of a problem in a healthcare facility's safety systems: The types of events that we have seen typically have a system issue as the root cause, such as issues around the handling of specimen slides.	Y <input type="checkbox"/> N <input type="checkbox"/>
Describe why the event is important for public credibility or accountability: There have been a number of very high profile cases related to this issue, such as the wrong patient undergoing a mastectomy.	Y <input type="checkbox"/> N <input type="checkbox"/>
If the event is used in a public reporting initiative (disclosure of performance results to the public at large), provide name of initiative(s), locations, Web page URL(s):	

Reviewer Comments/Rationale:

3d. SETTINGS, DATA SOURCES

Applicable Care Settings (Mark all to which event is relevant)

- Hospital
- Skilled Nursing Facility (SNF) / Nursing home
- Outpatient or Office-based Surgery Center
- Ambulatory Practice / Physician Offices
- Other (*Please describe*):

Data Source Check the source(s) for the information on the SRE.

<input type="checkbox"/> Electronic administrative data/ claims	<input type="checkbox"/> Quality / Risk Management Databases
<input type="checkbox"/> Electronic Clinical Data (e.g., MDS)	<input type="checkbox"/> Registry data (or database)
<input type="checkbox"/> Incident Reports	<input type="checkbox"/> Reports to External Bodies (states, federal)
<input type="checkbox"/> Medical Record including Electronic	<input type="checkbox"/> Regulatory or Accreditation data (FDA, OSHA, etc.)
<input type="checkbox"/> Pharmacy data	<input type="checkbox"/> Special or unique data, specify:
<input type="checkbox"/> Public health data/vital statistics	

Identify the specific data source/data collection instrument (e.g. name of database, clinical registry, collection instrument, etc.); include Web page URL where available:

Data dictionary/code table attached OR at web page URL:

Process(es) to Collect Data
Provide additional information about how the data regarding the event are collected. Address verifiability, reliability, and validity, if possible.

Reviewer Comments/Rationale:

3e. ADDITIONAL INFORMATION for NEW SERIOUS REPORTABLE EVENT

Provide any additional information that should be considered:

Susceptibility to Inaccuracies, Errors, or Unintended Consequences
Identify susceptibility to inaccuracies, errors, or unintended consequences of the event and describe how these potential problems could be audited.

(for NQF staff use) Identify related endorsed measures N/A

Reviewer Comments:

RECOMMENDATION

Steering Committee: Do you recommend for endorsement?
Comments/Rationale:

Y
N
A

Steering Committee Reviewer Name:

4. PRIORITY AREAS

(for NQF staff use) Select the most relevant priority area(s), quality domain(s), and consumer need(s).

National Priority Partners Priority Area <input type="checkbox"/> patient and family engagement <input type="checkbox"/> population health <input checked="" type="checkbox"/> safety <input type="checkbox"/> care coordination <input type="checkbox"/> palliative and end of life care <input type="checkbox"/> overuse
IOM Quality Domain <input type="checkbox"/> effectiveness <input type="checkbox"/> efficiency <input type="checkbox"/> equity <input type="checkbox"/> patient-centered <input checked="" type="checkbox"/> safety <input type="checkbox"/> timeliness
Consumer Care Need <input type="checkbox"/> Getting Better <input type="checkbox"/> Living With Illness <input type="checkbox"/> Staying Healthy

(for NQF staff use) Notes on similar/related endorsed SREs and/or Safe Practices: N/A

Steering Committee Reviewer Name:

NATIONAL QUALITY FORUM

Serious Reportable Event Submission & Evaluation

The SRE Steering Committee with NQF member and public input has defined Serious Reportable Events (SREs) as preventable, serious, and unambiguous adverse events. The Committee further notes that some types of SREs are universally preventable and should never occur while other types of SREs are largely preventable and over time it may be possible to reduce these to zero as knowledge and safe practices evolve. Both types of SREs should be publicly reported.

Submitters: Complete all the non-shaded areas of this form. Please fill out a separate form for each event you are submitting to NQF for consideration. This form may be used to submit comments/changes to existing SREs or submit new SREs.

Reviewers: Complete all the **yellow** and **pink** highlighted areas of the form. Provide the rationale for your ratings.

(for NQF staff use) NQF Review #:		NQF Project:	
(for NQF staff use) Has all requested information been provided?			
Staff Notes to Submitter <i>(if submission returned)</i> :			
Staff Notes to Reviewers <i>(issues or questions regarding any criteria)</i> :			
Staff Reviewer Name(s):			
1. CONTACT INFORMATION			
Submitter: Julie Apold			
Organization: Minnesota Alliance for Patient Safety (includes Minnesota Hospital Association, Minnesota Department of Health, Minnesota Medical Association and over 50 other public-private healthcare organizations).			
Street Address: 2550 University avenue W. Suite 350S			
City/State/Zip: saint Paul, MN 55114			
Telephone Number: 651-641-1121			
Fax Number: 651-659-1477			
Email Address: japold@mnhospitals.org			
Date of Submission (MM/DD/YY): 6/16/10			
Is this submission about a currently endorsed SRE or a proposed new SRE? <input type="checkbox"/> Currently Endorsed <input checked="" type="checkbox"/> New Submission <i>(If new submission, skip to section 3a)</i>			
2a. CURRENTLY ENDORSED SERIOUS REPORTABLE EVENT			
Name of Event:			
Suggested Change:			Y <input type="checkbox"/> N <input type="checkbox"/>
<input type="checkbox"/> Specify the Applicable Care Setting(s) marked below			
<input type="checkbox"/> Remove Endorsement			
<input type="checkbox"/> Modify SRE Specifications			
Describe Suggested Modification(s) in specific detail:			
Rationale for removing endorsement or modifying the SRE <i>(include pertinent evidence, data)</i> :			
If modifications are made, are the changes likely to result in a substantial change in the current count of SREs? <input type="checkbox"/> Yes <input type="checkbox"/> No If yes, please explain:			
(for NQF staff use) The proposed change is justified <i>(Does the rationale justify the proposed change?)</i>			
Applicable Care Settings (Mark all to which event is relevant)			
<input type="checkbox"/> Hospital			
<input type="checkbox"/> Skilled Nursing Facility (SNF) / Nursing home			
<input type="checkbox"/> Outpatient or Office-based Surgery Center			
<input type="checkbox"/> Ambulatory Practice / Physician Offices			

<input type="checkbox"/> Other (<i>Please specify</i>):	
Reviewer Comments/Rationale:	
2b. ADDITIONAL INFORMATION for CURRENTLY ENDORSED SERIOUS REPORTABLE EVENT	
Provide any additional information that should be considered:	
Susceptibility to Inaccuracies, Errors, or Unintended Consequences <i>Identify susceptibility to inaccuracies, errors, or unintended consequences of the event and describe how these potential problems could be audited.</i>	
<i>(for NQF staff use)</i> Identify related endorsed measures	
Reviewer Comments:	
RECOMMENDATION	
Steering Committee: Do you recommend the proposed change? <input type="checkbox"/> Do you recommend the proposed change with modification? <input type="checkbox"/> Specify the modification	Y <input type="checkbox"/> N <input type="checkbox"/> A <input type="checkbox"/>
Comments/Rationale:	
3a. NEW SERIOUS REPORTABLE EVENT	
The Event is a discrete, auditable, and clearly defined occurrence Name of Proposed New Event: Patient death or serious disability associated with failure to communicate or follow-up on test results.	Y <input type="checkbox"/> N <input type="checkbox"/>
3b. PREVENTABLE, SERIOUS, UNAMBIGUOUS	
Brief Description of Event: Patient death or serious disability associated with failure to communicate or follow-up on test results.	
The event is Preventable (<i>Describes an event that could have been anticipated and prepared for, but that occurs because of an error or other system failure</i>)	Y <input type="checkbox"/> N <input type="checkbox"/>
Briefly summarize the Evidence Base that the event is preventable and provide citations: Patient harm due to failure to communicate or follow-up on test results has been shown to be related to system errors. Systems can be put into place to prevent these system issue from occurring.	
The event is Serious (<i>Describes an event that can result in death or loss of a body part, disability or loss of bodily function or risk thereof for harm</i>) <i>Please check the appropriate consequence and describe it</i> <input checked="" type="checkbox"/> Death or <input checked="" type="checkbox"/> risk of death <input checked="" type="checkbox"/> Loss of a body part or <input checked="" type="checkbox"/> risk of loss Describe: <input checked="" type="checkbox"/> Disability or <input checked="" type="checkbox"/> risk of disability Describe: <input checked="" type="checkbox"/> Loss of bodily function or <input checked="" type="checkbox"/> risk of loss Describe:	Y <input type="checkbox"/> N <input type="checkbox"/>
The event is Unambiguous (<i>Refers to an event that is clearly defined and easily identified</i>) Definitions: Codes and descriptors (if used): Instructions for counting events, calculating rates, and providing context for low frequency:	Y <input type="checkbox"/> N <input type="checkbox"/>
Reviewer Comments/Rationale:	
3c. ADVERSE, SAFETY SYSTEM PROBLEM, IMPORTANT FOR ACCOUNTABILITY	
Describe the outcome that demonstrates that the event is adverse (<i>Describes a negative consequence of care that results in unintended injury or illness</i>) Test results that are not communicated or followed-up on can lead to delays in diagnosis and proper treatment to the patient, such as the diagnosis of cancer.	Y <input type="checkbox"/> N <input type="checkbox"/>
Describe how the event is indicative of a problem in a healthcare facility's safety systems:	Y <input type="checkbox"/>

These types of events can typically be traced back to system issues related to communication between departments, facilities, provider to patient or information systems such as EHRs. N

Describe why the event is important for public credibility or accountability:
 This is an event category that resonates with the public. This topic becomes even more important when expanding to other settings such as ambulatory care. Y
N

If the event is used in a public reporting initiative (disclosure of performance results to the public at large), provide name of initiative(s), locations, Web page URL(s):

Reviewer Comments/Rationale:

3d. SETTINGS, DATA SOURCES

Applicable Care Settings (Mark all to which event is relevant)

- Hospital
- Skilled Nursing Facility (SNF) / Nursing home
- Outpatient or Office-based Surgery Center
- Ambulatory Practice / Physician Offices
- Other (Please describe):

Data Source Check the source(s) for the information on the SRE.

<ul style="list-style-type: none"> <input type="checkbox"/> Electronic administrative data/ claims <input type="checkbox"/> Electronic Clinical Data (e.g., MDS) <input checked="" type="checkbox"/> Incident Reports <input checked="" type="checkbox"/> Medical Record including Electronic <input type="checkbox"/> Pharmacy data <input type="checkbox"/> Public health data/vital statistics 	<ul style="list-style-type: none"> <input checked="" type="checkbox"/> Quality / Risk Management Databases <input checked="" type="checkbox"/> Registry data (or database) <input type="checkbox"/> Reports to External Bodies (states, federal) <input type="checkbox"/> Regulatory or Accreditation data (FDA, OSHA, etc.) <input type="checkbox"/> Special or unique data, specify:
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Identify the specific data source/data collection instrument (e.g. name of database, clinical registry, collection instrument, etc.); include Web page URL where available:

Data dictionary/code table attached OR at web page URL:

Process(es) to Collect Data
 Provide additional information about how the data regarding the event are collected. Address verifiability, reliability, and validity, if possible.

Reviewer Comments/Rationale:

3e. ADDITIONAL INFORMATION for NEW SERIOUS REPORTABLE EVENT

Provide any additional information that should be considered:

Susceptibility to Inaccuracies, Errors, or Unintended Consequences
Identify susceptibility to inaccuracies, errors, or unintended consequences of the event and describe how these potential problems could be audited.

(for NQF staff use) Identify related endorsed measures [NQF 0491: Tracking of Clinical Results Between Visits](#)

Reviewer Comments:

RECOMMENDATION

Steering Committee: Do you recommend for endorsement? Y
N
A
 Comments/Rationale:

Steering Committee Reviewer Name:

4. PRIORITY AREAS

(for NQF staff use) Select the most relevant priority area(s), quality domain(s), and consumer need(s).
 National Priority Partners Priority Area patient and family engagement population health safety

<input type="checkbox"/> care coordination <input type="checkbox"/> palliative and end of life care <input type="checkbox"/> overuse
IOM Quality Domain <input type="checkbox"/> effectiveness <input type="checkbox"/> efficiency <input type="checkbox"/> equity <input type="checkbox"/> patient-centered <input checked="" type="checkbox"/> safety <input type="checkbox"/> timeliness
Consumer Care Need <input type="checkbox"/> Getting Better <input type="checkbox"/> Living With Illness <input checked="" type="checkbox"/> Staying Healthy

(for NQF staff use) Notes on similar/related endorsed SREs and/or Safe Practices: Safe Practice 12: Patient Care Information

Steering Committee Reviewer Name:	
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NATIONAL QUALITY FORUM

Serious Reportable Event Submission & Evaluation

The SRE Steering Committee with NQF member and public input has defined Serious Reportable Events (SREs) as preventable, serious, and unambiguous adverse events. The Committee further notes that some types of SREs are universally preventable and should never occur while other types of SREs are largely preventable and over time it may be possible to reduce these to zero as knowledge and safe practices evolve. Both types of SREs should be publicly reported.

Submitters: Complete all the non-shaded areas of this form. Please fill out a separate form for each event you are submitting to NQF for consideration. This form may be used to submit comments/changes to existing SREs or submit new SREs.

Reviewers: Complete all the **yellow** and **pink** highlighted areas of the form. Provide the rationale for your ratings.

(for NQF staff use) NQF Review #: NQF Project:	
(for NQF staff use) Has all requested information been provided? Staff Notes to Submitter <i>(if submission returned)</i> :	
Staff Notes to Reviewers <i>(issues or questions regarding any criteria)</i> :	
Staff Reviewer Name(s):	
1. CONTACT INFORMATION	
Submitter: Cynthia Lacker, RN, MS, LNCC, CPHRM Organization: Pennsylvania Patient Safety Authority Street Address: 5200 Butler Pike City/State/Zip: Plymouth Meeting, PA 19462 Telephone Number: 610-825-6000 x5040 Fax Number: 610-834-1275 Email Address: clacker@ecri.org	
Date of Submission (MM/DD/YY): 06/16/2010	
Is this submission about a currently endorsed SRE or a proposed new SRE? <input type="checkbox"/> Currently Endorsed <input checked="" type="checkbox"/> New Submission <i>(If new submission, skip to section 3a)</i>	
2a. CURRENTLY ENDORSED SERIOUS REPORTABLE EVENT	
Name of Event:	
Suggested Change: <input type="checkbox"/> Specify the Applicable Care Setting(s) marked below <input type="checkbox"/> Remove Endorsement <input type="checkbox"/> Modify SRE Specifications	
Describe Suggested Modification(s) in specific detail:	
Rationale for removing endorsement or modifying the SRE <i>(include pertinent evidence, data)</i> :	
If modifications are made, <i>are the changes likely to result in a substantial change in the current count of SREs?</i> <input type="checkbox"/> Yes <input type="checkbox"/> No If yes, please explain:	
(for NQF staff use) The proposed change is justified <i>(Does the rationale justify the proposed change?)</i>	
Applicable Care Settings (Mark all to which event is relevant)	
<input type="checkbox"/> Hospital <input type="checkbox"/> Skilled Nursing Facility (SNF) / Nursing home <input type="checkbox"/> Outpatient or Office-based Surgery Center <input type="checkbox"/> Ambulatory Practice / Physician Offices <input type="checkbox"/> Other <i>(Please specify)</i> :	
Y <input type="checkbox"/> N <input type="checkbox"/>	

Reviewer Comments/Rationale:	
2b. ADDITIONAL INFORMATION for CURRENTLY ENDORSED SERIOUS REPORTABLE EVENT	
Provide any additional information that should be considered:	
Susceptibility to Inaccuracies, Errors, or Unintended Consequences <i>Identify susceptibility to inaccuracies, errors, or unintended consequences of the event and describe how these potential problems could be audited.</i>	
<i>(for NQF staff use)</i> Identify related endorsed measures	
Reviewer Comments:	
RECOMMENDATION	
Steering Committee: Do you recommend the proposed change? <input type="checkbox"/> Do you recommend the proposed change with modification? <input type="checkbox"/> Specify the modification	Y <input type="checkbox"/> N <input type="checkbox"/> A <input type="checkbox"/>
Comments/Rationale:	
3a. NEW SERIOUS REPORTABLE EVENT	
The Event is a discrete, auditable , and clearly defined occurrence Name of Proposed New Event: Death or serious injury resulting from care provided by an impaired healthcare worker	Y <input type="checkbox"/> N <input type="checkbox"/>
3b. PREVENTABLE, SERIOUS, UNAMBIGUOUS	
Brief Description of Event: Death or serious injury resulting from care provided by an impaired healthcare worker	
The event is Preventable (<i>Describes an event that could have been anticipated and prepared for, but that occurs because of an error or other system failure</i>) Briefly summarize the Evidence Base that the event is preventable and provide citations: Although the AMA Code of Medical Ethics requires physicians to report impaired and incompetent colleagues, only 45% actually report observation or suspicion of impairment to state licensing boards. Ann Int Med. 2007; 147: 795 -802. Alcohol is the most commonly abused substance among physicians. Compared with the general population, physicians have higher rates of prescription drug abuse, particularly benzodiazepines and opioids. This is because of the common practice of self-treatment and the ease of access to many drugs. JAMA. 1992; 267(17):2333-2339. Professional impairment: a history and one state's response. Pooler D, Sheheen F, Davidson J. J Addict Dis. 2009;28(2):113-23. Review.PMID: 19340673 [PubMed - indexed for MEDLINE] Fletcher CE. Michigan's unique approach to treating impaired health care professionals. J Addict Dis. 2001;20(4):97-111. Review. PubMed PMID: 11760930.	Y <input type="checkbox"/> N <input type="checkbox"/>
The event is Serious (<i>Describes an event that can result in death or loss of a body part, disability or loss of bodily function or risk thereof for harm</i>) <i>Please check the appropriate consequence and describe it</i> <input checked="" type="checkbox"/> Death or <input checked="" type="checkbox"/> risk of death <input checked="" type="checkbox"/> Loss of a body part or <input checked="" type="checkbox"/> risk of loss Describe: The risk of any event is patient and provider specific. <input checked="" type="checkbox"/> Disability or <input checked="" type="checkbox"/> risk of disability Describe: <input checked="" type="checkbox"/> Loss of bodily function or <input checked="" type="checkbox"/> risk of loss Describe:	Y <input type="checkbox"/> N <input type="checkbox"/>

The event is Unambiguous (<i>Refers to an event that is clearly defined and easily identified</i>) Definitions: Codes and descriptors (if used): Instructions for counting events, calculating rates, and providing context for low frequency:	Y <input type="checkbox"/> N <input type="checkbox"/>
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Reviewer Comments/Rationale:

3c. ADVERSE, SAFETY SYSTEM PROBLEM, IMPORTANT FOR ACCOUNTABILITY

Describe the outcome that demonstrates that the event is adverse (<i>Describes a negative consequence of care that results in unintended injury or illness</i>) Healthcare worker impairment inhibits physicians and others from rendering competent services due to serious flaws in medical judgment. Patients seeking medical treatment by an impaired physician may become victim to the adverse consequences including, but not limited to: improper performance of a procedure, misdiagnosis, or delayed or improper treatment. Treatment by other impaired healthcare workers can lead to medication errors and treatment errors leading to consequences up to and including patient death.	Y <input type="checkbox"/> N <input type="checkbox"/>
---	--

Describe how the event is indicative of a problem in a healthcare facility's safety systems: Robust credentialing programs, and strong system-wide education, supervision, and oversight can help to identify healthcare worker impairment so that proper steps can be taken to protect the public and assist the impaired worker. Lack of these systems can result in inability to identify and treat workers with impairment problems.	Y <input type="checkbox"/> N <input type="checkbox"/>
---	--

Describe why the event is important for public credibility or accountability: Adverse patient outcome related to healthcare worker impairment has a profound effect on the public's trust of the healthcare system. If the event is used in a public reporting initiative (disclosure of performance results to the public at large), provide name of initiative(s), locations, Web page URL(s): National Practitioner Database; state specific medical, nursing and other professional licensing boards.	Y <input type="checkbox"/> N <input type="checkbox"/>
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Reviewer Comments/Rationale:

3d. SETTINGS, DATA SOURCES

Applicable Care Settings (Mark all to which event is relevant) <input checked="" type="checkbox"/> Hospital <input checked="" type="checkbox"/> Skilled Nursing Facility (SNF) / Nursing home <input checked="" type="checkbox"/> Outpatient or Office-based Surgery Center <input checked="" type="checkbox"/> Ambulatory Practice / Physician Offices <input type="checkbox"/> Other (<i>Please describe</i>):	
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Data Source Check the source(s) for the information on the SRE. <table style="width: 100%; border: none;"> <tr> <td style="width: 50%; border: none; vertical-align: top;"> <input type="checkbox"/> Electronic administrative data/ claims <input type="checkbox"/> Electronic Clinical Data (<i>e.g., MDS</i>) <input checked="" type="checkbox"/> Incident Reports <input checked="" type="checkbox"/> Medical Record including Electronic <input checked="" type="checkbox"/> Pharmacy data <input type="checkbox"/> Public health data/vital statistics </td> <td style="width: 50%; border: none; vertical-align: top;"> <input checked="" type="checkbox"/> Quality / Risk Management Databases <input type="checkbox"/> Registry data (or database) <input checked="" type="checkbox"/> Reports to External Bodies (states, federal) <input type="checkbox"/> Regulatory or Accreditation data (FDA, OSHA, etc.) <input checked="" type="checkbox"/> Special or unique data, specify: NPDB; state licensing boards </td> </tr> </table>	<input type="checkbox"/> Electronic administrative data/ claims <input type="checkbox"/> Electronic Clinical Data (<i>e.g., MDS</i>) <input checked="" type="checkbox"/> Incident Reports <input checked="" type="checkbox"/> Medical Record including Electronic <input checked="" type="checkbox"/> Pharmacy data <input type="checkbox"/> Public health data/vital statistics	<input checked="" type="checkbox"/> Quality / Risk Management Databases <input type="checkbox"/> Registry data (or database) <input checked="" type="checkbox"/> Reports to External Bodies (states, federal) <input type="checkbox"/> Regulatory or Accreditation data (FDA, OSHA, etc.) <input checked="" type="checkbox"/> Special or unique data, specify: NPDB; state licensing boards	
<input type="checkbox"/> Electronic administrative data/ claims <input type="checkbox"/> Electronic Clinical Data (<i>e.g., MDS</i>) <input checked="" type="checkbox"/> Incident Reports <input checked="" type="checkbox"/> Medical Record including Electronic <input checked="" type="checkbox"/> Pharmacy data <input type="checkbox"/> Public health data/vital statistics	<input checked="" type="checkbox"/> Quality / Risk Management Databases <input type="checkbox"/> Registry data (or database) <input checked="" type="checkbox"/> Reports to External Bodies (states, federal) <input type="checkbox"/> Regulatory or Accreditation data (FDA, OSHA, etc.) <input checked="" type="checkbox"/> Special or unique data, specify: NPDB; state licensing boards		

Identify the specific data source/data collection instrument (e.g. name of database, clinical registry, collection instrument, etc.); include Web page URL where available: Data dictionary/code table attached <input type="checkbox"/> OR at web page URL:	
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Process(es) to Collect Data Provide additional information about how the data regarding the event are collected. When information regarding impairment is known, correlation between impairment and patient outcome can be analyzed. Address verifiability, reliability, and validity, if possible.	
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Reviewer Comments/Rationale:

3e. ADDITIONAL INFORMATION for NEW SERIOUS REPORTABLE EVENT

Provide any additional information that should be considered:	
Susceptibility to Inaccuracies, Errors, or Unintended Consequences <i>Identify susceptibility to inaccuracies, errors, or unintended consequences of the event and describe how these potential problems could be audited.</i>	
<i>(for NQF staff use)</i> Identify related endorsed measures N/A	
Reviewer Comments:	
RECOMMENDATION	
Steering Committee: Do you recommend for endorsement? Comments/Rationale:	Y <input type="checkbox"/> N <input type="checkbox"/> A <input type="checkbox"/>
Steering Committee Reviewer Name:	
4. PRIORITY AREAS	
<i>(for NQF staff use)</i> Select the most relevant priority area(s), quality domain(s), and consumer need(s).	
National Priority Partners Priority Area <input type="checkbox"/> patient and family engagement <input type="checkbox"/> population health <input checked="" type="checkbox"/> safety <input type="checkbox"/> care coordination <input type="checkbox"/> palliative and end of life care <input type="checkbox"/> overuse	
IOM Quality Domain <input type="checkbox"/> effectiveness <input type="checkbox"/> efficiency <input type="checkbox"/> equity <input type="checkbox"/> patient-centered <input checked="" type="checkbox"/> safety <input type="checkbox"/> timeliness	
Consumer Care Need <input type="checkbox"/> Getting Better <input type="checkbox"/> Living With Illness <input type="checkbox"/> Staying Healthy	
<i>(for NQF staff use)</i> Notes on similar/related endorsed SREs and/or Safe Practices: N/A	
Steering Committee Reviewer Name:	

NATIONAL QUALITY FORUM

Serious Reportable Event Submission & Evaluation

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Submitters: Complete all the non-shaded areas of this form. Please fill out a separate form for each event you are submitting to NQF for consideration. This form may be used to submit comments/changes to existing SREs or submit new SREs.

Reviewers: Complete all the yellow and pink highlighted areas of the form. Provide the rationale for your ratings.

(for NQF staff use) NQF Review #: NQF Project:	
(for NQF staff use) Has all requested information been provided? <u>No evidence of preventability provided; however this event is clearly preventable if healthcare workers are not intoxicated or under any influences.</u>	
Staff Notes to Submitter (if submission returned):	
Staff Notes to Reviewers (issues or questions regarding any criteria):	
Staff Reviewer Name(s):	
1. CONTACT INFORMATION	
Submitter: <u>William R. Scharf, M.D. —</u> Organization: <u>—OSF Healthcare System</u> Street Address: <u>800 NE Glen Oak Avenue</u> City/State/Zip: <u>Peoria, IL 61603</u> Telephone Number: <u>309-229-3719</u> Fax Number: Email Address: <u>william.scharf@osfhealthcare.org</u>	
Date of Submission (MM/DD/YY): <u>06/10/10</u> Is this submission about a currently endorsed SRE or a proposed new SRE? <input type="checkbox"/> -Currently Endorsed <input checked="" type="checkbox"/> XNew Submission (If new submission, skip to section 3a)	
2a. CURRENTLY ENDORSED SERIOUS REPORTABLE EVENT	
Name of Event:	
Suggested Change: <input type="checkbox"/> Specify the Applicable Care Setting(s) marked below <input type="checkbox"/> Remove Endorsement <input type="checkbox"/> Modify SRE Specifications Describe Suggested Modification(s) in specific detail: Rationale for removing endorsement or modifying the SRE (include pertinent evidence, data): If modifications are made, are the changes likely to result in a substantial change in the current count of SREs? <input type="checkbox"/> Yes <input type="checkbox"/> No If yes, please explain:	
(for NQF staff use) The proposed change is justified (Does the rationale justify the proposed change?)	
Applicable Care Settings (Mark all to which event is relevant) <input type="checkbox"/> Hospital <input type="checkbox"/> Skilled Nursing Facility (SNF) / Nursing home <input type="checkbox"/> Outpatient or Office-based Surgery Center <input type="checkbox"/> Ambulatory Practice / Physician Offices	
Y <input type="checkbox"/>	N <input type="checkbox"/>

<input type="checkbox"/> Other (Please specify):	
Reviewer Comments/Rationale:	
2b. ADDITIONAL INFORMATION for CURRENTLY ENDORSED SERIOUS REPORTABLE EVENT	
Provide any additional information that should be considered:	
Susceptibility to Inaccuracies, Errors, or Unintended Consequences <i>Identify susceptibility to inaccuracies, errors, or unintended consequences of the event and describe how these potential problems could be audited.</i>	
(for NQF staff use) Identify related endorsed measures	
Reviewer Comments:	
RECOMMENDATION	
Steering Committee: Do you recommend the proposed change? <input type="checkbox"/> Do you recommend the proposed change with modification? <input type="checkbox"/> Specify the modification	Y <input type="checkbox"/> N <input type="checkbox"/> A <input type="checkbox"/>
Comments/Rationale:	
3a. NEW SERIOUS REPORTABLE EVENT	
The Event is a discrete, auditable, and clearly defined occurrence Name of Proposed New Event: <u>Death or significant injury of a patient as a consequence of staff impaired by recreational drugs or alcohol use</u>	Y <input type="checkbox"/> N <input type="checkbox"/>
3b. PREVENTABLE, SERIOUS, UNAMBIGUOUS	
Brief Description of Event:	
The event is Preventable (Describes an event that could have been anticipated and prepared for, but that occurs because of an error or other system failure)	Y <input type="checkbox"/> N <input type="checkbox"/>
Briefly summarize the Evidence Base that the event is preventable and provide citations:	
The event is Serious (Describes an event that can result in death or loss of a body part, disability or loss of bodily function or risk thereof for harm) <i>Please check the appropriate consequence and describe it</i> <input checked="" type="checkbox"/> X Death or <input type="checkbox"/> risk of death <input checked="" type="checkbox"/> X Loss of a body part or <input type="checkbox"/> risk of loss Describe: <input checked="" type="checkbox"/> X Disability or <input type="checkbox"/> risk of disability Describe: <input checked="" type="checkbox"/> X Loss of bodily function or <input type="checkbox"/> risk of loss Describe:	Y <input type="checkbox"/> N <input type="checkbox"/>
The event is Unambiguous (Refers to an event that is clearly defined and easily identified) Definitions: <u>The event could only be detected by drug/alcohol testing of staff members. There would need to be thresholds for intoxication. For example, alcohol testing about the accepted legal limit.</u> Codes and descriptors (if used): Instructions for counting events, calculating rates, and providing context for low frequency:	Y <input type="checkbox"/> N <input type="checkbox"/>
Reviewer Comments/Rationale:	
3c. ADVERSE, SAFETY SYSTEM PROBLEM, IMPORTANT FOR ACCOUNTABILITY	
Describe the outcome that demonstrates that the event is adverse (Describes a negative consequence of care that results in unintended injury or illness) <u>Possible death or injury</u>	Y <input type="checkbox"/> N <input type="checkbox"/>
Describe how the event is indicative of a problem in a healthcare facility's safety systems: <u>This could be a marker of poor hiring policies. It may signal complacency towards evaluating and helping staff with alcohol or drug-related problems.</u>	Y <input type="checkbox"/> N <input type="checkbox"/>
Describe why the event is important for public credibility or accountability:	Y <input type="checkbox"/>

[The public has demanded mandatory drug testing in other positions for roughly 25 years, notably the transportation industry. Mandatory drug testing is a common and accepted practice in many organizations. The public's trust in the NQF Serious Adverse Event process could be undermined by failing to identify a condition that could infuriate its citizens. In other words, the public could be exasperated that physicians and nurses do not undergo testing after a serious event, yet a truckdriver undergoes annual random tests.](#)

If the event is used in a public reporting initiative (disclosure of performance results to the public at large), provide name of initiative(s), locations, Web page URL(s):

N

Reviewer Comments/Rationale:

3d. SETTINGS, DATA SOURCES

Applicable Care Settings (Mark all to which event is relevant)

Hospital
 Skilled Nursing Facility (SNF) / Nursing home
 Outpatient or Office-based Surgery Center
 Ambulatory Practice / Physician Offices
 Other (Please describe):

Data Source Check the source(s) for the information on the SRE.

<input type="checkbox"/> Electronic administrative data/ claims	<input checked="" type="checkbox"/> Quality / Risk Management Databases
<input type="checkbox"/> Electronic Clinical Data (e.g., MDS)	<input type="checkbox"/> Registry data (or database)
<input checked="" type="checkbox"/> Incident Reports	<input checked="" type="checkbox"/> Reports to External Bodies (states, federal)
<input type="checkbox"/> Medical Record including Electronic	<input checked="" type="checkbox"/> Regulatory or Accreditation data (FDA, OSHA, etc.)
<input type="checkbox"/> Pharmacy data	<input type="checkbox"/> Special or unique data, specify:
<input type="checkbox"/> Public health data/vital statistics	

Identify the specific data source/data collection instrument (e.g. name of database, clinical registry, collection instrument, etc.); include Web page URL where available:

Data dictionary/code table attached OR at web page URL:

Process(es) to Collect Data
 Provide additional information about how the data regarding the event are collected. [The data would likely be from self reporting organizations, although other sites could be identified](#)
 Address verifiability, reliability, and validity, if possible. [The data could be verifiable through drug/alcohol testing. The reliability would be the same as that currently used in other industries. The validity of the data would likely reflect under-reporting.](#)

Reviewer Comments/Rationale:

3e. ADDITIONAL INFORMATION for NEW SERIOUS REPORTABLE EVENT

Provide any additional information that should be considered:

Susceptibility to Inaccuracies, Errors, or Unintended Consequences
Identify susceptibility to inaccuracies, errors, or unintended consequences of the event and describe how these potential problems could be audited. [The intent of the serious reportable event would be to identify healthcare providers whose decision making capabilities or judgments have been altered as a consequence of recreational drug or alcohol use. This reportable event could be misconstrued to mandate drug testing on all staff members involved in the care of an individual incurring a poor outcome. This would be untenable in situations where patients are treated by large teams or when individuals exposed to a patient did not have a direct or contributory role in an adverse outcome.](#)

(for NQF staff use) Identify related endorsed measures —N/A

Reviewer Comments:

RECOMMENDATION

Steering Committee: Do you recommend for endorsement?
 Comments/Rationale:

Y
 N
 A

Steering Committee Reviewer Name:	
4. PRIORITY AREAS	
<i>(for NQF staff use)</i> Select the most relevant priority area(s), quality domain(s), and consumer need(s).	
National Priority Partners Priority Area <input type="checkbox"/> patient and family engagement <input type="checkbox"/> population health <input checked="" type="checkbox"/> safety <input type="checkbox"/> care coordination <input type="checkbox"/> palliative and end of life care <input type="checkbox"/> overuse	
IOM Quality Domain <input type="checkbox"/> effectiveness <input type="checkbox"/> efficiency <input type="checkbox"/> equity <input type="checkbox"/> patient-centered <input checked="" type="checkbox"/> safety <input type="checkbox"/> timeliness	
Consumer Care Need <input type="checkbox"/> Getting Better <input type="checkbox"/> Living With Illness <input type="checkbox"/> Staying Healthy	
<i>(for NQF staff use)</i> Notes on similar/related endorsed SREs and/or Safe Practices: —N/A	
Steering Committee Reviewer Name:	

NATIONAL QUALITY FORUM

Serious Reportable Event Submission & Evaluation

The SRE Steering Committee with NQF member and public input has defined Serious Reportable Events (SREs) as preventable, serious, and unambiguous adverse events. The Committee further notes that some types of SREs are universally preventable and should never occur while other types of SREs are largely preventable and over time it may be possible to reduce these to zero as knowledge and safe practices evolve. Both types of SREs should be publicly reported.

Submitters: Complete all the non-shaded areas of this form. Please fill out a separate form for each event you are submitting to NQF for consideration. This form may be used to submit comments/changes to existing SREs or submit new SREs.

Reviewers: Complete all the yellow and pink highlighted areas of the form. Provide the rationale for your ratings.

(for NQF staff use) NQF Review #: NQF Project:	
(for NQF staff use) Has all requested information been provided?	
Staff Notes to Submitter <i>(if submission returned):</i>	
Staff Notes to Reviewers <i>(issues or questions regarding any criteria):</i>	
Staff Reviewer Name(s):	
1. CONTACT INFORMATION	
Submitter: — Kevin T Kavanagh, MD, MS Organization: — Health Watch USA Street Address: — 3396 Woodhaven Dr City/State/Zip: — Somerset, KY 42503 Telephone Number: 606-875-3642 Fax Number: 606-679-7745 Email Address: kavanagh.ent@gmail.com	
Date of Submission (MM/DD/YY): — 09/17/10 Is this submission about a currently endorsed SRE or a proposed new SRE? <input type="checkbox"/> Currently Endorsed <input checked="" type="checkbox"/> New Submission <i>(If new submission, skip to section 3a)</i>	
2a. CURRENTLY ENDORSED SERIOUS REPORTABLE EVENT	
Name of Event:	
Suggested Change: <input type="checkbox"/> Specify the Applicable Care Setting(s) marked below <input type="checkbox"/> Remove Endorsement <input type="checkbox"/> Modify SRE Specifications Describe Suggested Modification(s) in specific detail: Rationale for removing endorsement or modifying the SRE <i>(include pertinent evidence, data):</i> If modifications are made, are the changes likely to result in a substantial change in the current count of SREs? <input type="checkbox"/> Yes <input type="checkbox"/> No If yes, please explain:	
(for NQF staff use) The proposed change is justified <i>(Does the rationale justify the proposed change?)</i>	
Applicable Care Settings (Mark all to which event is relevant) <input checked="" type="checkbox"/> Hospital <input checked="" type="checkbox"/> Skilled Nursing Facility (SNF) / Nursing home <input checked="" type="checkbox"/> Outpatient or Office-based Surgery Center <input checked="" type="checkbox"/> Ambulatory Practice / Physician Offices <input type="checkbox"/> Other <i>(Please specify):</i>	

Y
N

Reviewer Comments/Rationale:	
2b. ADDITIONAL INFORMATION for CURRENTLY ENDORSED SERIOUS REPORTABLE EVENT	
Provide any additional information that should be considered: _____	
Susceptibility to Inaccuracies, Errors, or Unintended Consequences <i>Identify susceptibility to inaccuracies, errors, or unintended consequences of the event and describe how these potential problems could be audited.</i> _____	
(for NQF staff use) Identify related endorsed measures	
Reviewer Comments:	
RECOMMENDATION	
Steering Committee: Do you recommend the proposed change? <input type="checkbox"/> Do you recommend the proposed change with modification? <input type="checkbox"/> Specify the modification	Y <input type="checkbox"/> N <input type="checkbox"/> A <input type="checkbox"/>
Comments/Rationale:	
3a. NEW SERIOUS REPORTABLE EVENT	
The Event is a discrete, auditable, and clearly defined occurrence	Y <input type="checkbox"/> N <input type="checkbox"/>
Name of Proposed New Event: <u>Incorrect Placement of a Feeding (Gastrointestinal) or Ventilation Tube Which Results in Patient Harm</u>	Y <input type="checkbox"/> N <input type="checkbox"/>
3b. PREVENTABLE, SERIOUS, UNAMBIGUOUS	
Brief Description of Event: <u>) The intent of this reportable event is to report incidents of placement of feeding tubes into the lungs and breathing tubes into the esophagus which go undetected and result in patient harm.</u>	
The event is Preventable (<i>Describes an event that could have been anticipated and prepared for, but that occurs because of an error or other system failure</i>) <u>A feeding tube placed into the lungs can happen in unresponsive patients. Proper protocols need to be in place to verify the position of the tube before food, water or medications are given. Placement should be verified by X-Ray, or return of gastric secretions.</u> <u>This event would also include passage of a gastric tube into the abdominal cavity with feeding as opposed to proper placement into the stomach.</u> <u>A ventilation tube passed into the esophagus and goes undetected will not be able to ventilate the patient properly. Even if the patient is spontaneously breathing, gastric distension from air will occur which also will compress the lungs.</u> <u>Rarely, proper placement of a ventilation tube may be hindered by diseases (cancer) in the oral cavity or larynx. In these cases passage of a tube should not be attempted but a tracheotomy under local anesthesia should be performed.</u>	Y <input type="checkbox"/> N <input type="checkbox"/>
Briefly summarize the Evidence Base that the event is preventable and provide citations:	
The event is Serious (<i>Describes an event that can result in death or loss of a body part, disability or loss of bodily function or risk thereof for harm</i>) <i>Please check the appropriate consequence and describe it</i> <input checked="" type="checkbox"/> Death or <input type="checkbox"/> risk of death	Y <input type="checkbox"/> N <input type="checkbox"/>

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<input type="checkbox"/> Loss of a body part or <input type="checkbox"/> risk of loss Describe: <input type="checkbox"/> Disability or <input type="checkbox"/> risk of disability Describe: <input type="checkbox"/> Loss of bodily function or <input type="checkbox"/> risk of loss Describe:	
The event is Unambiguous (<i>Refers to an event that is clearly defined and easily identified</i>) Definitions: Codes and descriptors (if used): Instructions for counting events, calculating rates, and providing context for low frequency:	Y <input type="checkbox"/> N <input type="checkbox"/>
Reviewer Comments/Rationale:	
3c. ADVERSE, SAFETY SYSTEM PROBLEM, IMPORTANT FOR ACCOUNTABILITY	
Describe the outcome that demonstrates that the event is adverse (<i>Describes a negative consequence of care that results in unintended injury or illness</i>) <u>An example was my wife's father that had an NG tube passed into his lungs and feed. He developed pneumonia. This event contributed to the death. This is clearly indefinable preventable and reflects poorly on the healthcare delivery system.</u>	Y <input type="checkbox"/> N <input type="checkbox"/>
Describe how the event is indicative of a problem in a healthcare facility's safety systems: <u>Protocols not in place to verify location of feeding or ventilation tubes before usage.</u>	Y <input type="checkbox"/> N <input type="checkbox"/>
Describe why the event is important for public credibility or accountability: <u>This speaks for itself.</u>	Y <input type="checkbox"/> N <input type="checkbox"/>
If the event is used in a public reporting initiative (disclosure of performance results to the public at large), provide name of initiative(s), locations, Web page URL(s):	
Reviewer Comments/Rationale:	
3d. SETTINGS, DATA SOURCES	
Applicable Care Settings (Mark all to which event is relevant) <input checked="" type="checkbox"/> Hospital <input checked="" type="checkbox"/> Skilled Nursing Facility (SNF) / Nursing home <input checked="" type="checkbox"/> Outpatient or Office-based Surgery Center <input checked="" type="checkbox"/> Ambulatory Practice / Physician Offices <input type="checkbox"/> Other (<i>Please describe</i>):	
Data Source Check the source(s) for the information on the SRE. <input type="checkbox"/> Electronic administrative data/ claims <input type="checkbox"/> Electronic Clinical Data (<i>e.g., MDS</i>) <input checked="" type="checkbox"/> Incident Reports <input checked="" type="checkbox"/> Medical Record including Electronic <input type="checkbox"/> Pharmacy data <input type="checkbox"/> Public health data/vital statistics <input checked="" type="checkbox"/> Quality / Risk Management Databases <input type="checkbox"/> Registry data (or database) <input type="checkbox"/> Reports to External Bodies (states, federal) <input type="checkbox"/> Regulatory or Accreditation data (FDA, OSHA, etc.) <input type="checkbox"/> Special or unique data, specify:	
Identify the specific data source/data collection instrument (e.g. name of database, clinical registry, collection instrument, etc.); include Web page URL where available:	
Data dictionary/code table attached <input type="checkbox"/> OR at web page URL:	
Process(es) to Collect Data Provide additional information about how the data regarding the event are collected. Address verifiability, reliability, and validity, if possible.	
Reviewer Comments/Rationale:	
3e. ADDITIONAL INFORMATION for NEW SERIOUS REPORTABLE EVENT	
Provide any additional information that should be considered:	
Susceptibility to Inaccuracies, Errors, or Unintended Consequences <i>Identify susceptibility to inaccuracies, errors, or unintended consequences of the event and describe how</i>	

these potential problems could be audited.
Auditing should take into account both placement and verification. For Example:
Patients with unexpected pathology of the upper airway or oral cavity which hindered tube placement two items should be audited. Placement and Verification.
In these cases, if improper tube placement and improper verification occurs then the event should be considered preventable. In other words, if a patient has an oral cancer and an endotracheal tube is passed, and the tube is incorrectly felt to be in the trachea, then an event occurred.
If attempts to pass the tube are unsuccessful and the healthcare professional verified improper placement, then an event did not occur, provided other treatment options were not feasible and pathology which inhibits tube placement was present.
Auditing should take to account if other treatment options were available.
In the example of oral and laryngeal pathology being present a question of whether a tracheotomy under local anesthesia should have been performed instead of attempting oral intubation. In a child or morbidly obese patient this may not be possible.

(for NQF staff use) Identify related endorsed measures

Reviewer Comments:

RECOMMENDATION

Steering Committee: Do you recommend for endorsement?
 Comments/Rationale:

Y
 N
 A

4. PRIORITY AREAS

(for NQF staff use) Select the most relevant priority area(s), quality domain(s), and consumer need(s).

- National Priority Partners Priority Area patient and family engagement population health safety
 care coordination palliative and end of life care overuse
- IOM Quality Domain effectiveness efficiency equity patient-centered safety timeliness
- Consumer Care Need Getting Better Living With Illness Staying Healthy

(for NQF staff use) Notes on similar/related endorsed SREs and/or Safe Practices:

Steering Committee Reviewer Name: