

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 (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 checked="" type="checkbox"/> Currently Endorsed <input type="checkbox"/> New Submission (If new submission, skip to section 3a)			
2a. CURRENTLY ENDORSED SERIOUS REPORTABLE EVENT			
Name of Event: Surgery performed on the wrong body part			
Suggested Change: <input checked="" 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 checked="" type="checkbox"/> Outpatient or Office-based Surgery Center <input checked="" 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 NQF 0267 Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant	
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"/>
Name of Proposed New Event:	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) Please check the appropriate consequence and describe it <input type="checkbox"/> Death or <input 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 (Refers to an event that is clearly defined and easily identified) 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 (Describes a negative consequence of care that results in unintended injury or illness)	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)

- ☐ 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

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:

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 (if submission returned):			
Staff Notes to Reviewers (issues or questions regarding any criteria):			
Staff Reviewer Name(s):			
1. CONTACT INFORMATION			
Submitter: Erin Graydon Baker Organization: Partners Healthcare Street Address: 115 4th Ave City/State/Zip: Needham/MA/02494 Telephone Number: 781-433-3776 Fax Number: 781-433-3667 Email Address: egraydonbaker@partners.org			
Date of Submission (MM/DD/YY): 06/16/10			
Is this submission about a currently endorsed SRE or a proposed new SRE? x <input type="checkbox"/> Currently Endorsed <input type="checkbox"/> New Submission (If new submission, skip to section 3a)			
2a. CURRENTLY ENDORSED SERIOUS REPORTABLE EVENT			
Name of Event: Surgery Performed on the Wrong Body Part			
Suggested Change: <input type="checkbox"/> Specify the Applicable Care Setting(s) marked below <input type="checkbox"/> Remove Endorsement x <input checked="" type="checkbox"/> Modify SRE Specifications			
Describe Suggested Modification(s) in specific detail: Separate surgical versus invasive procedures. Invasive procedures are defined as procedures where the UP/WHO checklists apply. Add the phrase " based on informed consent and or documented plan variation"			
Rationale for removing endorsement or modifying the SRE (include pertinent evidence, data): At PHS, as in the literature (J. Neily, RN, J. Bagian, MD, Arch/surg/Vol 144(NO.11), Nov 2009) roughly 50% of surgical/procedural events occur outside of the OR . If the public sees a large number of surgical SREs, they may determine the hospital to have flawed OR practices.			
If modifications are made, are the changes likely to result in a substantial change in the current count of SREs? <input type="checkbox"/> Yes x <input checked="" type="checkbox"/> No If yes, please explain:			
(for NQF staff use) The proposed change is justified (Does the rationale justify the proposed change?) Yes			Y <input type="checkbox"/> N <input type="checkbox"/>

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>):		
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. More accurate representation of SRE</i>		
(for NQF staff use) Identify related endorsed measures NQF 0267 Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant		
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:		Y <input type="checkbox"/> N <input type="checkbox"/>
3b. PREVENTABLE, SERIOUS, UNAMBIGUOUS		
Brief Description of Event:		
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:		
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 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 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 describe):	
Data Source Check the source(s) for the information on the SRE. <div style="display: flex; justify-content: space-between;"> <div> <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 </div> <div> <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: </div> </div>	
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	
Reviewer Comments:	
RECOMMENDATION	
Steering Committee: Do you recommend for endorsement?	Y <input type="checkbox"/> N <input type="checkbox"/> A <input type="checkbox"/>
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 <input type="checkbox"/> patient and family engagement <input type="checkbox"/> population health <input 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 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:	
Steering Committee Reviewer Name:	

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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>Yes</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 N.E. Glen Oak Avenue</u> City/State/Zip: <u>Peoria, IL 61603</u> Telephone Number: <u>309-655-4806</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: <u>Surgery performed on the wrong body part</u> <u>Surgery performed on the wrong patient</u>			
Suggested Change: <u>Surgery performed on the wrong patient or wrong body part</u> <input type="checkbox"/> Specify the Applicable Care Setting(s) marked below <input type="checkbox"/> Remove Endorsement <input checked="" type="checkbox"/> Modify SRE Specifications Describe Suggested Modification(s) in specific detail: Rationale for removing endorsement or modifying the SRE (include pertinent evidence, data): <u>This would streamline the Serious Reportable Event list without affecting its clarity</u> 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 checked="" 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 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 (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> <u>not likely</u>		
(for NQF staff use) Identify related endorsed measures — <u>NQF 0267 Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant</u>		
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:		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) Please check the appropriate consequence and describe it <input type="checkbox"/> Death or <input 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 (Refers to an event that is clearly defined and easily identified) 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 (Describes a negative consequence of care that results in unintended injury or illness)		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)

- ☐ 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

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:

Steering Committee Reviewer Name:	
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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 (if submission returned):			
Staff Notes to Reviewers (issues or questions regarding any criteria):			
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 Ave W. Suit 350 S City/State/Zip: saint Paul, MN 55114 Telephone Number: 651-641-1121 Fax Number: 651-659-1477 Email Addr: japold@mnhospitals.org			
Date of Submission (MM/DD/YY): 06/16/10 Is this submission about a currently endorsed SRE or a proposed new SRE? <input checked="" type="checkbox"/> Currently Endorsed <input type="checkbox"/> New Submission (If new submission, skip to section 3a)			
2a. CURRENTLY ENDORSED SERIOUS REPORTABLE EVENT			
Name of Event: Surgery performed on a wrong body part			
Suggested Change: <input checked="" type="checkbox"/> Specify the Applicable Care Setting(s) marked below <input type="checkbox"/> Remove Endorsement <input checked="" type="checkbox"/> Modify SRE Specifications			Y <input type="checkbox"/> N <input type="checkbox"/>
Describe Suggested Modification(s) in specific detail: 1) Recommend change wording to "Invasive procedure performed....." 2) Recommend changing "body part" to "site" 3) Recommend changing the overall category to "Surgical and Other Invasive Procedures" rather than "Surgery" to reflect the inclusion of all invasive procedures.			
Rationale for removing endorsement or modifying the SRE (include pertinent evidence, data): 1) In Minnesota, we have found that a significant number of our wrong body part procedures happen outside the operating room. Changing the wording to "invasive procedure" is more reflective of the types of events that occur under this category. 2) We often have events reported in which the procedure is performed on the correct body part but in the wrong location. The term "wrong site" is more inclusive of these types of events. 3) As mentioned in #1, the term "surgery" is too narrow and doesn't capture all of the events that are			

<p>captured under this category.</p> <p>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 checked="" type="checkbox"/> No If yes, please explain:</p> <p>(for NQF staff use) The proposed change is justified <i>(Does the rationale justify the proposed change?)</i></p>		
<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 checked="" type="checkbox"/> Ambulatory Practice / Physician Offices</p> <p><input type="checkbox"/> Other <i>(Please specify)</i>:</p>		
Reviewer Comments/Rationale:		
2b. ADDITIONAL INFORMATION for CURRENTLY ENDORSED SERIOUS REPORTABLE EVENT		
Provide any additional information that should be considered:		
<p>Susceptibility to Inaccuracies, Errors, or Unintended Consequences</p> <p><i>Identify susceptibility to inaccuracies, errors, or unintended consequences of the event and describe how these potential problems could be audited. There remains some confusion over the category "wrong body part" vs. "wrong procedure".</i></p>		
<p>(for NQF staff use) Identify related endorsed measures NQF 0267 Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant</p>		
Reviewer Comments:		
RECOMMENDATION		
<p>Steering Committee:</p> <p>Do you recommend the proposed change? <input type="checkbox"/></p> <p>Do you recommend the proposed change with modification? <input type="checkbox"/> Specify the modification</p> <p>Comments/Rationale:</p>		<p>Y <input type="checkbox"/></p> <p>N <input type="checkbox"/></p> <p>A <input type="checkbox"/></p>
3a. NEW SERIOUS REPORTABLE EVENT		
<p>The Event is a discrete, auditable, and clearly defined occurrence</p> <p>Name of Proposed New Event:</p>		<p>Y <input type="checkbox"/></p> <p>N <input type="checkbox"/></p>
3b. PREVENTABLE, SERIOUS, UNAMBIGUOUS		
Brief Description of Event:		
<p>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></p>		<p>Y <input type="checkbox"/></p> <p>N <input type="checkbox"/></p>
Briefly summarize the Evidence Base that the event is preventable and provide citations:		
<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><i>Please check the appropriate consequence and describe it</i></p> <p><input 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>
<p>The event is Unambiguous <i>(Refers to an event that is clearly defined and easily identified)</i></p> <p>Definitions:</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>

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 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 describe</i>):	
Data Source <i>Check the source(s) for the information on the SRE.</i> <div style="display: flex; justify-content: space-between;"> <div> <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 type="checkbox"/> Public health data/vital statistics </div> <div> <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: </div> </div>	
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	
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 ☐ 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:

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 (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 checked="" type="checkbox"/> Currently Endorsed <input type="checkbox"/> New Submission (If new submission, skip to section 3a)			
2a. CURRENTLY ENDORSED SERIOUS REPORTABLE EVENT			
Name of Event: Surgery performed on the wrong patient			
Suggested Change: <input checked="" 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 checked="" 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 checked="" type="checkbox"/> Outpatient or Office-based Surgery Center <input checked="" 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 NQF 0267 Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant	
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"/>
Name of Proposed New Event:	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) Please check the appropriate consequence and describe it <input type="checkbox"/> Death or <input 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 (Refers to an event that is clearly defined and easily identified) 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 (Describes a negative consequence of care that results in unintended injury or illness)	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)

- ☐ 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

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:

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 (if submission returned):			
Staff Notes to Reviewers (issues or questions regarding any criteria):			
Staff Reviewer Name(s):			
1. CONTACT INFORMATION			
Submitter: Erin Graydon Baker Organization: Partners Healthcare Street Address: 115 4th Ave City/State/Zip: Needham/MA/02494 Telephone Number: 781-433-3776 Fax Number: 781-433-3667 Email Address: egraydonbaker@partners.org			
Date of Submission (MM/DD/YY): 06/16/10			
Is this submission about a currently endorsed SRE or a proposed new SRE? <input checked="" type="checkbox"/> Currently Endorsed <input type="checkbox"/> New Submission (If new submission, skip to section 3a)			
2a. CURRENTLY ENDORSED SERIOUS REPORTABLE EVENT			
Name of Event: Surgery Performed on the Wrong Patient			
Suggested Change: <input type="checkbox"/> Specify the Applicable Care Setting(s) marked below <input type="checkbox"/> Remove Endorsement <input checked="" type="checkbox"/> Modify SRE Specifications			Y <input type="checkbox"/> N <input type="checkbox"/>
Describe Suggested Modification(s) in specific detail: Separate surgical versus invasive procedures. Invasive procedures are defined as procedures where the UP/WHO checklists apply.			
Rationale for removing endorsement or modifying the SRE (include pertinent evidence, data): At PHS, as in the literature (J. Neily, RN, J. Bagian, MD, Arch/surg/Vol 144(NO.11), Nov 2009) roughly 50% of surgical/procedural events occur outside of the OR. If the public sees a large number of surgical SREs they may determine the hospital to have flawed OR practices.			
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 checked="" 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 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>):	
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. More accurate representation of SRE</i>	
(for NQF staff use) Identify related endorsed measures NQF 0267 Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant	
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"/>
Name of Proposed New Event:	N <input type="checkbox"/>
3b. PREVENTABLE, SERIOUS, UNAMBIGUOUS	
Brief Description of Event:	
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:	
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 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 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 describe):	
Data Source Check the source(s) for the information on the SRE. <div style="display: flex; justify-content: space-between;"> <div> <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 </div> <div> <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: </div> </div>	
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	
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 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 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:	
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 (if submission returned):			
Staff Notes to Reviewers (issues or questions regarding any criteria):			
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 350 S 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 checked="" type="checkbox"/> Currently Endorsed <input type="checkbox"/> New Submission (If new submission, skip to section 3a)			
2a. CURRENTLY ENDORSED SERIOUS REPORTABLE EVENT			
Name of Event: Surgery performed on the wrong patient			
Suggested Change: <input checked="" type="checkbox"/> Specify the Applicable Care Setting(s) marked below <input type="checkbox"/> Remove Endorsement <input checked="" type="checkbox"/> Modify SRE Specifications			Y <input type="checkbox"/> N <input type="checkbox"/>
Describe Suggested Modification(s) in specific detail:			
1) Recommend modifying to "invasive procedure performed on...." 2) Recommend changing the overall category to "Surgical and Other Invasive Procedures" rather than "Surgery" to reflect the inclusion of all invasive procedures.			
Rationale for removing endorsement or modifying the SRE (include pertinent evidence, data): 1) In Minnesota, we have found that the majority of our wrong body part procedures happen outside the operating room. Changing the wording to "invasive procedure" is more reflective of the type of events that occur under this category. 2) As mentioned in #1, the term "surgery" is too narrow and doesn't capture all of the events that are captured under this category.			

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 checked="" 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>) Yes		
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 checked="" 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 NQF 0267: Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant		
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:		Y <input type="checkbox"/> N <input type="checkbox"/>
3b. PREVENTABLE, SERIOUS, UNAMBIGUOUS		
Brief Description of Event:		
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:		
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 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 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 describe</i>):	
Data Source <i>Check the source(s) for the information on the SRE.</i>	
<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 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	
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 ☐ 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:

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 (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 checked="" type="checkbox"/> Currently Endorsed <input type="checkbox"/> New Submission (If new submission, skip to section 3a)			
2a. CURRENTLY ENDORSED SERIOUS REPORTABLE EVENT			
Name of Event: Wrong surgical procedure performed on a patient			
Suggested Change: <input checked="" 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 checked="" 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 checked="" type="checkbox"/> Outpatient or Office-based Surgery Center <input checked="" 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 NQF 0267 Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant	
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"/>
Name of Proposed New Event:	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) Please check the appropriate consequence and describe it <input type="checkbox"/> Death or <input 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 (Refers to an event that is clearly defined and easily identified) 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 (Describes a negative consequence of care that results in unintended injury or illness)	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)

- ☐ 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

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:

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 (if submission returned):			
Staff Notes to Reviewers (issues or questions regarding any criteria):			
Staff Reviewer Name(s):			
1. CONTACT INFORMATION			
Submitter: Erin Graydon Baker Organization: Partners Healthcare Street Address: 115 4th Ave City/State/Zip: Needham/MA/02494 Telephone Number: 781-433-3776 Fax Number: 781-433-3667 Email Address: egraydonbaker@partners.org			
Date of Submission (MM/DD/YY): 06/16/10			
Is this submission about a currently endorsed SRE or a proposed new SRE? <input checked="" type="checkbox"/> Currently Endorsed <input type="checkbox"/> New Submission (If new submission, skip to section 3a)			
2a. CURRENTLY ENDORSED SERIOUS REPORTABLE EVENT			
Name of Event: Wrong Surgical Procedure			
Suggested Change: <input type="checkbox"/> Specify the Applicable Care Setting(s) marked below <input type="checkbox"/> Remove Endorsement <input checked="" type="checkbox"/> Modify SRE Specifications			Y <input type="checkbox"/> N <input type="checkbox"/>
Describe Suggested Modification(s) in specific detail: Separate surgical versus invasive procedures. Invasive procedures are defined as procedures where the UP/WHO checklists apply.			
Rationale for removing endorsement or modifying the SRE (include pertinent evidence, data): At PHS, as in the literature (J. Neily, RN, J. Bagian, MD, Arch/surg/Vol 144(NO.11), Nov 2009) roughly 50% of surgical/procedural events occur outside of the OR. If the public sees a large number of surgical SREs they may determine the hospital to have flawed OR practices.			
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 checked="" type="checkbox"/> No If yes, please explain:			
(for NQF staff use) The proposed change is justified (Does the rationale justify the proposed change?)			
Yes			
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 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. More accurate representation of SRE</i>	
(for NQF staff use) Identify related endorsed measures NQF 0267 Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant	
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"/>
Name of Proposed New Event:	N <input type="checkbox"/>
3b. PREVENTABLE, SERIOUS, UNAMBIGUOUS	
Brief Description of Event:	
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:	
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>) Please check the appropriate consequence and describe it <input type="checkbox"/> Death or <input 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 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 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 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?	Y <input type="checkbox"/> N <input type="checkbox"/> A <input type="checkbox"/>
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 <input type="checkbox"/> patient and family engagement <input type="checkbox"/> population health <input 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 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:	
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? Yes			
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: 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): 06/16/10 Is this submission about a currently endorsed SRE or a proposed new SRE? <input checked="" type="checkbox"/> Currently Endorsed <input type="checkbox"/> New Submission (If new submission, skip to section 3a)			
2a. CURRENTLY ENDORSED SERIOUS REPORTABLE EVENT			
Name of Event: Wrong surgical procedure performed on a patient			
Suggested Change: <input checked="" type="checkbox"/> Specify the Applicable Care Setting(s) marked below <input type="checkbox"/> Remove Endorsement <input checked="" type="checkbox"/> Modify SRE Specifications			
Describe Suggested Modification(s) in specific detail: 1) Recommend modifying to "wrong invasive procedure performed...." 2) Recommend changing the overall category to "Surgical and Other Invasive Procedures" rather than "Surgery" to reflect the inclusion of all invasive procedures.			
Rationale for removing endorsement or modifying the SRE (include pertinent evidence, data): 1) In Minnesota, we have found that a high percentage of our wrong procedures happen outside the operating room. Changing the wording to "invasive procedure" is more reflective of the type of events that occur under this category. 2) As mentioned in #1, the term "surgery" is too narrow and doesn't capture all of the events that are captured under this category.			Y <input type="checkbox"/> N <input type="checkbox"/>

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 checked="" 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>) Yes		
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 checked="" 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 NQF 0267 Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant		
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:		Y <input type="checkbox"/> N <input type="checkbox"/>
3b. PREVENTABLE, SERIOUS, UNAMBIGUOUS		
Brief Description of Event:		
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:		
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 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 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 describe</i>):	
Data Source <i>Check the source(s) for the information on the SRE.</i>	
<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 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	
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 ☐ 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:

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? Yes			
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 checked="" type="checkbox"/> Currently Endorsed <input type="checkbox"/> New Submission (If new submission, skip to section 3a)			
2a. CURRENTLY ENDORSED SERIOUS REPORTABLE EVENT			
Name of Event: Unintended retention of a foreign object in a patient after surgery or other procedure			
Suggested Change: <input checked="" 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 checked="" 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 checked="" 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 N/A	
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"/>
Name of Proposed New Event:	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 type="checkbox"/> Death or <input 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 (Refers to an event that is clearly defined and easily identified) 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 (Describes a negative consequence of care that results in unintended injury or illness)	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 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 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		
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 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 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:		
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 (if submission returned):			
Staff Notes to Reviewers (issues or questions regarding any criteria):			
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 350 S 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): 06/16/10			
Is this submission about a currently endorsed SRE or a proposed new SRE? <input checked="" type="checkbox"/> Currently Endorsed <input type="checkbox"/> New Submission (If new submission, skip to section 3a)			
2a. CURRENTLY ENDORSED SERIOUS REPORTABLE EVENT			
Name of Event: Retention of a foreign object in a patient after surgery or other procedure			
Suggested Change: <input checked="" type="checkbox"/> Specify the Applicable Care Setting(s) marked below <input type="checkbox"/> Remove Endorsement <input checked="" type="checkbox"/> Modify SRE Specifications			Y <input type="checkbox"/> N <input type="checkbox"/>
Describe Suggested Modification(s) in specific detail:			
1) Modify to "unintentional retention" 2) Modify to "surgery or other invasive procedure" instead of "surgery or other procedure" 3) Recommend specifically including vaginal births as an invasive procedure.			
Rationale for removing endorsement or modifying the SRE (include pertinent evidence, data):			
1) Adding "unintentional" to the category clarifies that these do not include items that are intentionally retained such as implants/orthopedic screws. 2) One of the most significant findings in this category in Minnesota has been that the retention of a sponge following a vaginal birth was initially the item retained most often. This finding has lead to statewide efforts to prevent this type of retained object. Including vaginal births in the specifications will help provide consistency in including this type of procedure.			

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 checked="" 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 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>):		
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 N/A		
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:		Y <input type="checkbox"/> N <input type="checkbox"/>
3b. PREVENTABLE, SERIOUS, UNAMBIGUOUS		
Brief Description of Event:		
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:		
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 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</i>		Y <input type="checkbox"/>

care that results in unintended injury or illness)	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 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 describe):	
Data Source Check the source(s) for the information on the SRE. <div style="display: flex; justify-content: space-between;"> <div> <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 </div> <div> <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: </div> </div>	
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	
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 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 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:	
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 (if submission returned):			
Staff Notes to Reviewers (issues or questions regarding any criteria):			
Staff Reviewer Name(s):			
1. CONTACT INFORMATION			
Submitter: Erin Graydon Baker Organization: Partners Healthcare Street Address: 115 4th Ave City/State/Zip: Needham/MA/02494 Telephone Number: 781-433-3776 Fax Number: 781-433-3667 Email Address: egraydonbaker@partners.org			
Date of Submission (MM/DD/YY): 06/16/10			
Is this submission about a currently endorsed SRE or a proposed new SRE? <input checked="" type="checkbox"/> Currently Endorsed <input type="checkbox"/> New Submission (If new submission, skip to section 3a)			
2a. CURRENTLY ENDORSED SERIOUS REPORTABLE EVENT			
Name of Event: Unintended Retention of Foreign Object			
Suggested Change: <input type="checkbox"/> Specify the Applicable Care Setting(s) marked below <input type="checkbox"/> Remove Endorsement <input checked="" type="checkbox"/> Modify SRE Specifications			Y <input type="checkbox"/> N <input type="checkbox"/>
Describe Suggested Modification(s) in specific detail: Consider retained fragments of equipment to fall under device events			
Rationale for removing endorsement or modifying the SRE (include pertinent evidence, data): In 2009, 67% of PHS retained foreign objects were "bits" of equipment and non preventable. Although we agree that we need to report these retained fragments, the best category for these events might be Product/Device related.			
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 checked="" type="checkbox"/> No If yes, please explain:			
(for NQF staff use) The proposed change is justified (Does the rationale justify the proposed change?)			
Yes			
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>):	
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. More accurate representation of SRE</i>	
(for NQF staff use) Identify related endorsed measures N/A	
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:	Y <input type="checkbox"/> N <input type="checkbox"/>
3b. PREVENTABLE, SERIOUS, UNAMBIGUOUS	
Brief Description of Event:	
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:	
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 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 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 describe):	
Data Source Check the source(s) for the information on the SRE. <div style="display: flex; justify-content: space-between;"> <div> <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 </div> <div> <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: </div> </div>	
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	
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 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 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:	
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?			
Staff Notes to Submitter (if submission returned): <u>Yes</u>			
Staff Notes to Reviewers (issues or questions regarding any criteria):			
Staff Reviewer Name(s):			
1. CONTACT INFORMATION			
Submitter: <u>Verna C. Gibbs M.D.</u> Organization: <u>NoThing Left Behind</u> Street Address: <u>270 Collingwood Street</u> City/State/Zip: <u>San Francisco, CA 94114</u> Telephone Number: <u>415-260-4025</u> Fax Number: <u>none</u> Email Address: <u>drgibbs@nothingsleftbehind.org</u>			
Date of Submission (MM/DD/YY): <u>6/15/10</u>			
Is this submission about a currently endorsed SRE or a proposed new SRE? <input checked="" type="checkbox"/> Currently Endorsed <input type="checkbox"/> New Submission (If new submission, skip to section 3a)			
2a. CURRENTLY ENDORSED SERIOUS REPORTABLE EVENT			
Name of Event: <u>Unintended retention of a foreign object in patient after surgery or other procedure</u>			
Suggested Change: <input type="checkbox"/> Specify the Applicable Care Setting(s) marked below <input type="checkbox"/> Remove Endorsement <input checked="" type="checkbox"/> Modify SRE Specifications			
Describe Suggested Modification(s) in specific detail: <u>1) Change the SRE to Unintended retention of a medical or surgical item. Use the term "medical or surgical item" rather than "foreign object". Foreign objects include bullets, pins, coins and ingested objects. This error reduction strategy is directed towards medical and surgical items that are used during the course of work that are inadvertently left inside of patients. 2) The wording "after surgery" and definition of when surgery ends is confusing. Some entities (Joint Commissions for example) interpret this guideline (or regulation when transferred to state laws) to mean that the operation is over when the surgical incision has been closed and use this as the defining element of determining when a retained surgical item event occurs, incorrectly excluding the other actions mentioned in the same sentence. The closure of an incision isn't the defining element of a completed operation and hospitals are reporting cases as having retained items when in fact it is not "after surgery". Under implementation guidelines the definition for when Surgery ends should be replaced to read:</u>			Y <input type="checkbox"/> N <input type="checkbox"/>

The operation ends after all incisions have been closed in their entirety; if conducted, the final surgical count(s) have concluded and the patient has been taken from the operating room. Or use: The operation ends at the recorded out of room time.

A procedure or delivery ends after all procedural materiel (e.g. supplies, devices, equipment) have been removed from the patient or area regardless of setting (e.g. postanesthesia recovery unit, labor and delivery room, surgical suite, endoscopy unit).

Rationale for removing endorsement or modifying the SRE (include pertinent evidence, data): An item is considered to have been retained in a patient "after surgery" or after a procedure has taken place. As worded this means at anytime after surgery and the ambiguity is; when is it after surgery versus during surgery? When is the procedure still going on versus when is it over. For cases that take place in a procedure room, operating room or designated space the operation or procedure can be considered over by many different variables. It can be case end time (when the wound is completely closed, dressing has been applied and drapes removed), the anesthesia end time or the out of the room time. All of these are valid definitions but I think the out of the room time is the best for determination of when an item is considered to have been retained.

If there is an incision or surgical wound many have interpreted after surgery to mean the surgery is over when the wound is closed. But many procedures don't have incisions or wounds to close - e.g. normal vaginal deliveries and we know that sponges have been retained in the vagina so using wound closure as the defining element is inadequate as is removal of probes or devices. Many incisions have multiple layers to close so is the wound closed when all the layers are closed or only the fascia or first structural layer or when the skin is closed? If the operation is over when the skin of the incision is closed, then surgeons only partially close the wound waiting for an xray if there has been an incorrect count and if an item is found inside the patient they remove the sutures and retrieve the item. Well, that isn't a closed wound and that isn't a retained item and therefore it's not reportable yet according to some entities this is coded as a retained foreign body case. Finally, suppose you have a wound where you don't close the skin but only the first structural layer e.g. fascia or sternum and put dressings in the subcutaneous space and leave the wound open. If there is an incorrect count and a sponge is found inside the patient while they are still in the OR and the fascia or sternum is reopened that isn't a retained sponge either because technically the wound wasn't "closed".

With regards to surgical counts: Usually there are three main surgical counts: The initial count and when items are added to the field, the closing count and the final count. The closing count is performed BEFORE the wound closure begins and the final count is executed AFTER the skin has been closed and should be performed after the sponges or items are no longer in use. So with the NQF definition of surgery END as stated above it implies that the counts are completed before the incision is closed and is determinative of surgery ending. Actually, the operation isn't over until the final count is taken which should happen AFTER the wound has been closed. You can't use the final count as the definition of when surgery is over anyway because in all operations or procedures surgical counts aren't performed.

Therefore, wound closure is a poor definition of when a case is over because it has limited application (there has to be a wound) and it's easy to game whether or not the wound is closed and you can't use surgical counts as the defining element because all cases or procedures don't have counts performed.

You could use end anesthesia time, but all procedures don't have anesthesia support or involvement so that isn't something that is recorded and often the anesthesia end time is actually after the patient has been taken from the OR perhaps to the ICU.
So..... To be a retained item, it has to be in the patient after the operation is over not while the

operation is still going on and the determination that the operation is over is that the patient has moved out of the operating room. Procedures are different. They may only have a puncture site so there is nothing to close, but the procedure is over when all materiel used during the procedure has been removed. This would include devices and probes but expands the definition to include equipment and supplies so the conditions present during normal vaginal deliveries would be covered.

Let's look at this for known situations of retention.

Sponges have been retained in pacemaker pockets. Usually surgical counts have not been performed for these cases (but they should be!). Pacemaker insertions could be considered an operation or a procedure. As an operation or as a procedure the sponge would be captured as retained under the new proposed definition.

Catheter insertions are performed in a wide variety of places and guidewires can be lost during insertion. Sometimes it's the whole wire, sometimes a fragment but the operator doesn't always immediately know if something has been lost. The way the guidewire is discovered to be retained is through taking of an xray. That doesn't happen in the procedure room and the discovery of the retained object has not taken place during the performance of the procedure but is found to be in the patient's body after the patient is someplace else. The procedure is usually over, as the insertion devices have been removed and the material used to perform the procedure gone. In endoscopy suites and procedure areas actually the room where the procedure is performed is not usually where the patient recovers. It may be in the same suite or area but it is not usually in the exact room where the procedure is performed. If it is the exact room where the procedure was performed usually the materiel used for the procedure has been removed and would define that the procedure is over. I would argue that if the item is lost, recognized to be present at the time of the procedure and retrieved in the same setting the item is not retained. For example, if in the placement of an IR catheter in radiology the guidewire is seen to be within the vessel and retrieved by the radiologist right there, its analogous to the surgeon removing the sponge that is seen on an intraoperative xray while the patient is still in the OR or the endoscopist who sees the tip of the coagulator fall off and retrieves the object during the same procedure.... It's NOT a retained item.

In cases such as retained vaginal sponges after normal deliveries, these sponges are usually not intended to remain in the patient and the patient often discovers them hours to weeks after the delivery. Even if they are found in the postpartum area the delivery is over and the delivery room is no longer a delivery room as it's now a bed room or a recovery room. The materiel (sponges, drapes) used during the delivery has been removed. If the sponge is found in the vagina very soon after the delivery, when the delivery room is still functioning as a delivery room then I would argue it's not a retained sponge. It's a near miss event.

The other vaginal situation is when the physician intentionally places a vaginal pack after all the sponges used in the delivery have been used and then usually because of poor communication the patient is discharged and the pack has not been removed. While in this circumstance at the end of the delivery the item was intended to remain in the vagina the item was found to be in the patient's body after leaving the hospital. In this case the team actually has the whole hospitalization to get the pack out and if they fail, it's a reportable retained surgical item event.

So I submit the above definition which captures most (I think) situations whether considered an operation or a procedure. There is less room for gaming.... Is the wound really closed? Is a normal vaginal delivery an operation or a procedure? With this definition, it doesn't matter. If you leave a surgical item inside any part of a person's body, that you didn't intend to leave there, if the patient leaves to procedure room or OR with the item in them, it's a reportable retained surgical item. If you do the right thing and take all necessary measures to find a missing item, find it and remove it before the patient leaves the OR or procedure area it's a close call but it's not a NQF defined serious reportable event.

If modifications are made, *are the changes likely to result in a substantial change in the current count of SREs?* ☒ Yes ☐ No If yes, please explain: Cases now are reported as a retained item if wound closure has occurred but the item has been successfully removed. It's not really retained in the patient and falsely elevates the number of events. I think we should look to the intent of the regulation. The reporting requirement is widely construed to act as a behavior modulator such that the threat of reporting and subsequent possible fines will induce practitioners to adopt safer practices to prevent retention. Alternatively, reporting may be to collect epidemiological data about event frequency without any punitive intent. I think for either reason we would want to only report or collect data on true retained item cases and not near miss events. We should encourage the providers to act and take all necessary means to prevent retention. By having the right definition of when reporting is required we reward their efforts to find and remove objects rather than penalize them and learn the true frequency of these events.

(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)

- ☒ Hospital
☐ Skilled Nursing Facility (SNF) / Nursing home
☒ Outpatient or Office-based Surgery Center
☐ Ambulatory Practice / Physician Offices
☒ Other (Please specify): Labor and Delivery, Procedure areas

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

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 the proposed change? ☐

Do you recommend the proposed change with modification? ☐ Specify the modification

Comments/Rationale:

Y ☐
N ☐
A ☐

3a. NEW SERIOUS REPORTABLE EVENT

The Event is a discrete, auditable, and clearly defined occurrence

Name of Proposed New Event:

Y ☐
N ☐

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 ☐
N ☐

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*)

Y ☐

bodily function or risk thereof for harm) Please check the appropriate consequence and describe it <input type="checkbox"/> Death or <input 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:		N <input type="checkbox"/>
The event is Unambiguous (Refers to an event that is clearly defined and easily identified) 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 (Describes a negative consequence of care that results in unintended injury or illness)		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 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 describe):		
Data Source Check the source(s) for the information on the SRE. <div style="display: flex; justify-content: space-between;"> <div> <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 </div> <div> <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: </div> </div>		
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 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:

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 (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 checked="" type="checkbox"/> Currently Endorsed <input type="checkbox"/> New Submission (If new submission, skip to section 3a)			
2a. CURRENTLY ENDORSED SERIOUS REPORTABLE EVENT			
Name of Event: Intraoperative or immediately postoperative death in an American Society of Anesthesiologists Class I patient			
Suggested Change: <input checked="" 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 checked="" 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 checked="" 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 N/A		
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:		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) Please check the appropriate consequence and describe it <input type="checkbox"/> Death or <input 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 (Refers to an event that is clearly defined and easily identified) 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 (Describes a negative consequence of care that results in unintended injury or illness)		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)

- ☐ 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

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:

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 (if submission returned):			
Staff Notes to Reviewers (issues or questions regarding any criteria):			
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): Is this submission about a currently endorsed SRE or a proposed new SRE? <input checked="" type="checkbox"/> Currently Endorsed <input type="checkbox"/> New Submission (If new submission, skip to section 3a)			
2a. CURRENTLY ENDORSED SERIOUS REPORTABLE EVENT			
Name of Event: Death during or immediately post-operatively in an ASA Class I patient			
Suggested Change: <input checked="" 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 checked="" type="checkbox"/> Hospital <input 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 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	Y <input type="checkbox"/>
Name of Proposed New Event:	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 type="checkbox"/> Death or <input 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 (Refers to an event that is clearly defined and easily identified) 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 (Describes a negative consequence of care that results in unintended injury or illness)	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 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 describe</i>):		
Data Source Check the source(s) for the information on the SRE. <div style="display: flex; justify-content: space-between;"> <div> <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 type="checkbox"/> Public health data/vital statistics </div> <div> <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: </div> </div>		
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		
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 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 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:		
Steering Committee Reviewer Name:		