**NATIONAL QUALITY FORUM**

# CONFERENCE CALL OF THE SERIOUS REPORTABLE EVENTS IN HEALTHCARE STEERING COMMITTEE

## September 8, 2010

*Steering Committee Members Present*: Gregg Meyer, MD, MSc (Co-Chair); Sally Tyler, MPA (Co-Chair); Tejal Gandhi, MD, MPH; Christine Goeschel, RN, MPA; Cynthia Hoen, Esq., MPH, FACHE; Helen Lau, RN, MHROD, BSN, BMus; Kathryn McDonagh, PhD; John Morley, MD, FACP; Deborah Nadzam, PhD, RN, FAAN; Martha Radford, MD, FACC, FAHA; Stancel Riley, Jr., MD, MPA, MPH; Diane Rydrych, MA; Doron Schneider, MD, FACP; Eric Tangalos, MD, FACP, AGSF, CMD; Michael Victoroff, MD

*Steering Committee Members Absent:* Leah Binder; Patrick Brennan, MD; Philip Schneider, FASHP, MS

*NQF Staff*: Peter Angood, MD; Helen Burstin, MD, MPH; Melinda Murphy, RN, MS; Lindsey Tighe, MS

### WELCOME AND INTRODUCTIONS

Dr. Angood welcomed the Committee members and thanked them for their participation on the call. Dr. Meyer and Ms. Tyler informed the Committee members that the purpose of this call would be to review the submitted modifications and Technical Advisory Panel (TAP) recommendations for the existing Serious Reportable Events (SREs) in the prioritized healthcare environments for expansion of the SREs. Those environments are Skilled Nursing Facilities (SNFs), Ambulatory Outpatient Practices, and Ambulatory and Office-based Surgery Centers.

### REVIEW OF THE EXISTING SREs

The TAP chairs reviewed the TAP recommendations for the existing SREs event by event. Recommendations from the TAPs are found in a separate spreadsheet that summarizes the TAP discussions.

Committee members reviewed the existing events, the submitted modifications to the events, and the TAP recommendations. Committee recommendations with respect to the material reviewed as well as the rationale for any modifications are found in the table below.

| Existing Serious Reportable Event | SC Recommendation for Event Modification | SC Rationale for Modification | Applicable Settings | Additional Comments |
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| Surgery performed on the wrong body part | Surgery or other procedure performed on the wrong site | • SC stated that the process or system errors that result in the provider performing a procedure on the wrong site are likely the same as those that occur when a surgery is performed on the wrong site. Inclusion of procedures in this event will increase reporting for learning with respect to this event.<br>• SC recommended use of the term "site" rather than "body part" because site clarifies the event, particularly with regard to procedures performed at the wrong level of the spine or on the wrong digit. | • Hospital,<br>• Outpatient/Office-based Surgery Centers<br>• Ambulatory Practice Settings/Physician Offices<br>• Long-Term Care/Skilled Nursing Facilities | • SC noted that informed consent is documented less stringently outside of the hospital. This should be stated in the implementation guidance for the event. |
| Surgery performed on the wrong patient | Surgery or other procedure performed on the wrong patient | • SC stated that the process or system error that result in the provider performing a procedure on the wrong patient are likely the same as those that occur when a surgery is performed on the wrong patient. Inclusion of procedures in this event will increase reporting for learning with respect to this event. | • Hospital,<br>• Outpatient/Office-based Surgery Centers<br>• Ambulatory Practice Settings/Physician Offices<br>• Long-Term Care/Skilled Nursing Facilities | • SC noted that informed consent is documented less stringently outside of the hospital. This should be stated in the implementation guidance for the event. |
| Wrong surgical procedure performed on a patient | Wrong surgical or other procedure performed on a patient | • SC stated that the process or system errors that result in the provider performing a procedure on the wrong patient are likely the same as those that occur when a surgery is performed on the wrong patient. Inclusion of procedures in this event will increase reporting for learning with respect to this event. | • Hospital,<br>• Outpatient/Office-based Surgery Centers<br>• Ambulatory Practice Settings/Physician Offices<br>• Long-Term Care/Skilled Nursing Facilities | • SC noted that informed consent is documented less stringently outside of the hospital. This should be stated in the implementation guidance for the event. |

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| Unintended retention of a foreign object in a patient after surgery or other procedure | *No changes* | | • Hospital,<br>• Outpatient/Office-based Surgery Centers<br>• Ambulatory Practice Settings/Physician Offices<br>• Long-Term Care/Skilled Nursing Facilities | • SC clarified that this event is not intended to capture objects that were retained that were **not** placed by the provider (event should not capture products of conception, parts of organs, bullets, etc.). |
| Intraoperative or immediately post-operative death in an ASA Class I patient | *No changes* | | • Hospital | • SC considered expanding the event to be relevant in other settings; however, the SC stated that ambiguity as to classification of the patient would make this too difficult to implement presently. |
| Patient death or serious disability associated with the use of contaminated drugs, devices, or biologics provided by the healthcare facility | Patient death or serious injury associated with the use of contaminated drugs, devices, or biologics provided by the healthcare setting | • SC recommended use of the term "serious injury" rather than "serious disability" because the adverse outcome to the patient may not result in disability or additional disability (for example, a patient exposed to HIV or hepatitis, or an already disabled patient enduring additional harm).<br>• SC recommended use of the term "healthcare setting" rather than "healthcare facility" to be more encompassing of healthcare environments other than the inpatient hospital. | • Hospital,<br>• Outpatient/Office-based Surgery Centers<br>• Ambulatory Practice Settings/Physician Offices<br>• Long-Term Care/Skilled Nursing Facilities | • SC recommended that the definition of serious injury be inclusive of iatrogenic infectious processes. SC stated that an example of this should be included in the implementation guidance (exposure to HIV or hepatitis resulting in additional care or monitoring). |
| Patient death or serious disability associated with the use or function of a device in patient care in which the device is used or functions other than | Patient death or serious injury associated with the use or function of a device in patient care in which the device is used or functions other than as intended | • SC recommended use of the term "serious injury" rather than "serious disability" because the adverse outcome to the patient may not result in disability or additional disability. | • Hospital,<br>• Outpatient/Office-based Surgery Centers<br>• Ambulatory Practice Settings/Physician Offices | • SC stated that this event is intended to capture device malfunctions, not provider errors. The clinician should make the judgment call as to how to use the device, permitting for off-label |

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| as intended | | | | use. |
| Patient death or serious disability associated with intravascular air embolism that occurs while being cared for in a healthcare facility | Patient death or serious injury associated with intravascular air embolism that occurs while being cared for in a healthcare setting | • SC recommended use of the term "serious injury" rather than "serious disability" because the adverse outcome to the patient may not result in disability or additional disability.<br>• SC recommended use of the term "healthcare setting" rather than "healthcare facility" to be more encompassing of healthcare environments other than the inpatient hospital. | • Hospital,<br>• Outpatient/Office-based Surgery Centers<br>• Long-Term Care/Skilled Nursing Facilities | • SC requested input from neurosurgical experts with regard to whether the exclusion of neurosurgical procedures is warranted. |
| Infant discharged to the wrong person | Discharge or release of a patient/resident of any age, who is unable to make decisions, to the wrong person | • SC recommended inclusion of all patients who are unable to make decisions because the system or process in place for discharge is likely the same and occurrence of the event for a patient of any age would signify a failure in the system or process. | • Hospital,<br>• Outpatient/Office-based Surgery Centers<br>• Ambulatory Practice Settings/Physician Offices<br>• Long-Term Care/Skilled Nursing Facilities | |
| Patient death or serious disability associated with patient elopement (disappearance) | Patient death or serious injury associated with patient elopement (disappearance) | • SC recommended use of the term "serious injury" rather than "serious disability" because the adverse outcome to the patient may not result in disability or additional disability. | • Hospital,<br>• Outpatient/Office-based Surgery Centers<br>• Ambulatory Practice Settings/Physician Offices<br>• Long-Term Care/Skilled Nursing Facilities | • SC recommended exclusion of patients leaving against medical advice (AMA).<br>• SC recommended defining at what point the individual is considered a patient. The individual needs to have received care from a member of the medical team. |

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| | | | | • SC discussed inclusion of a time limit for this event; however, because the driver of event reporting is death or serious injury and not solely occurrence of the event, the SC did not recommend inclusion of a time limit. |
| Patient suicide, or attempted suicide, resulting in serious disability while being cared for in a healthcare setting | Patient suicide, or attempted suicide, resulting in serious injury while being cared for in a healthcare setting. | • SC recommended use of the term "serious injury" rather than "serious disability" because the adverse outcome to the patient may not result in disability or additional disability.<br>• SC recommended use of the term "healthcare setting" rather than "healthcare facility" to be more encompassing of healthcare environments other than the inpatient hospital. | • Hospital,<br>• Outpatient/Office-based Surgery Centers<br>• Ambulatory Practice Settings/Physician Offices<br>• Long-Term Care/Skilled Nursing Facilities | • SC recommended defining at what point the individual is considered a patient. The individual needs to have received care from a member of the medical team. |
| Patient death or serious disability associated with a medication error (e.g., errors involving the wrong drug, wrong dose, wrong patient, wrong time, wrong rate, wrong preparation, or wrong route of administration) | Patient death or serious injury associated with a medication error (e.g., errors involving the wrong drug, wrong dose, wrong patient, wrong time, wrong rate, wrong preparation, or wrong route of administration) | • SC recommended use of the term "serious injury" rather than "serious disability" as the adverse outcome to the patient may not result in disability or additional disability. | • Hospital,<br>• Outpatient/Office-based Surgery Centers<br>• Ambulatory Practice Settings/Physician Offices<br>• Long-Term Care/Skilled Nursing Facilities | • SC recommended that SRE 4E, "Patient death or serious disability associated with hypoglycemia, the onset of which occurs while the patient is being cared for in a healthcare facility," be included in the implementation guidance of this event. SRE 4E is intended to capture insulin errors, which are examples of a medication error. |

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| Patient death or serious disability associated with a hemolytic reaction due to the administration of ABO/HLA incompatible blood or blood products | Patient death or serious injury associated with a hemolytic reaction due to the administration of ABO/HLA incompatible blood or blood products | • SC recommended use of the term "serious injury" rather than "serious disability" as the adverse outcome to the patient may not result in disability or additional disability. | • Hospital,<br>• Outpatient/Office-based Surgery Centers<br>• Ambulatory Practice Settings/Physician Offices | |
| Maternal death or serious disability associated with labor or delivery in a low-risk pregnancy while being cared for in a healthcare facility | Maternal death or serious injury associated with labor or delivery in a low-risk pregnancy while being cared for in a healthcare facility | • SC recommended use of the term "serious injury" rather than "serious disability" because the adverse outcome to the patient may not result in disability or additional disability. | • Hospital,<br>• Outpatient/Office-based Surgery Centers | |
| Death or serious disability of a neonate while being cared for in a healthcare facility following low-risk pregnancy and delivery | Death or serious injury of a neonate while being cared for in a healthcare facility following low-risk pregnancy and delivery | • SC recommended use of the term "serious injury" rather than "serious disability" because the adverse outcome to the patient may not result in disability or additional disability. | • Hospital,<br>• Outpatient/Office-based Surgery Centers | |

## PUBLIC COMMENT

There were no public comments.

## NEXT STEPS

A summary of this call will be e-mailed to Committee members within the next few weeks.

**The Steering Committee will next meet by conference call on Tuesday, September 14, 2010, at 11:00 am ET to continue evaluation of the existing Serious Reportable Events.**

The meeting was adjourned.