NATIONAL QUALITY FORUM

CONFERENCE CALL OF THE SERIOUS REPORTABLE EVENTS IN HEALTHCARE STEERING COMMITTEE

August 31, 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; Eric Colchamiro, MPA; Melinda Murphy, RN, MS; Lindsey Tighe, MS

Others Present: Rita Munley Gallagher, PhD, RN; Robert Raggi; Tom Scholomiti

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 Technical Advisory Panel (TAP) recommendations for the existing and newly submitted Serious Reportable Events (SREs) in the healthcare environments that are the first priority for expansion of the SREs. Those environments are Skilled Nursing Facilities (SNFs), Ambulatory Outpatient Practices, and Ambulatory and Office-based Surgery Centers. The chairs acknowledged that the agenda for the call was ambitious, but that any items not reviewed would be moved to the agenda for the September 8, 2010, call.

REVIEW OF THE NEWLY SUBMITTED SREs

The TAP chairs reviewed the TAP recommendations for the newly proposed SREs event by event. Recommendations from the TAPs are found in a separate spreadsheet capturing a summary of the TAP discussions.

The Committee, in addition to reviewing the TAP recommendations, also evaluated the events for applicability in the inpatient hospital setting. A summary of the recommendations, which supports the recommendations of the TAPs except where explicitly addressed, is below.

Newly Submitted SRE	SC Recommendation for SNFs	SC Recommendation for Ambulatory Outpatient Practices	SC Recommendation for Ambulatory and Office-based Surgery Centers	SC Recommendation for Inpatient Hospital setting	Additional Comments
Patient death or disability as a consequence of MRI error, defined as magnetizable material inside the MRI room	Event is not relevant for SNFs.	Event should be included on an SRE listing for Ambulatory Outpatient Practices.	Event should be included on an SRE listing for Ambulatory and Office-based Surgery Centers.	Event should be included on an SRE listing for Inpatient Hospitals.	• SC would like input from radiologists on how to best phrase this event to capture injury caused by magnetizable material inside the MRI room.
Patient death or serious injury associated with prolonged fluoroscopy with cumulative dose > 1500 rads to a single field or any delivery of radiotherapy to the wrong body region, or 25 percent above or below the planned radiotherapy dose	Event is not relevant for SNFs.	Event should be included on an SRE listing for Ambulatory Outpatient Practices.	Event should be included on an SRE listing for Ambulatory and Office-based Surgery Centers.	Event should be included on an SRE listing for Inpatient Hospitals.	• SC would like input from radiologists on how to best phrase this event as either one or two events to capture injury caused by radiation doses and delivery of radiotherapy to wrong area of body. SC states concerns about the auditability and feasibility of this event. • SC acknowledged that reporting of this event may create a disincentive for looking for the outcome.
Patient death or serious injury related to a central line associated blood stream infection (CLABSI)	SC would like input from topic experts to review wording due to feasibility concerns; event will be reconsidered during next call.	SC would like input from topic experts to review wording due to feasibility concerns; event will be reconsidered during next call.	SC would like input from topic experts to review wording because of feasibility concerns; event will be reconsidered during next call.	SC would like input from topic experts to review wording because of feasibility concerns; event will be reconsidered during next call.	• SC would like input from topic experts to review wording because of feasibility concerns; event will be reconsidered during 9/8/10 call. • SC suggested rewording event to something like “Insertion-related central line associated blood stream infection (CLABSI) diagnosed within 48 hours of central line insertion.” This will provide for all insertion infection events to be captured, although it

					would likely lead to errors in attribution. • SC does not want to pursue an event related to infection associated with maintenance of the line at this time because of tracking and attribution difficulty.
Death among surgical patient with serious, treatable complications (failure to rescue)	Event is not relevant for SNFs.	Event is not relevant for Ambulatory Outpatient Practices.	Event is not relevant for Ambulatory and Office-based Surgery Centers.	Event is applicable for Inpatient Hospitals; however, there are concerns about the feasibility of reporting.	• The difficulty in ascertaining the failure makes the feasibility of reporting too great a challenge at present. This event should not be included on the SRE listing.
Death of a neonate while being cared for in a healthcare facility following low-risk pregnancy and delivery and the absence of congenital abnormalities	Event is not relevant for SNFs.	Event is not relevant for Ambulatory Outpatient Practices.	Event should be included on an SRE listing for Ambulatory and Office-based Surgery Centers.	Event should be included on an SRE listing for Inpatient Hospitals.	• SC suggested rewording event to "Death or serious disability of a neonate while being cared for in a healthcare facility following low-risk pregnancy and delivery." • SC recommended inclusion of the definition of neonate with this event.
Arterial misplacement and use of a central venous catheter	Event should be included on an SRE listing for SNFs.	Event is not relevant for Ambulatory Outpatient Practices.	Event should be included on an SRE listing for Ambulatory and Office-based Surgery Centers.	Event should be included on an SRE listing for Inpatient Hospitals.	• SC recommended inclusion of this issue in the implementation guidance for a wrong site procedure event rather than as a new standalone event. • SC recommended that the example in the implementation guidance state that use of the incorrectly placed central venous catheter is the key factor that would lead to reporting of the event.
Death or serious injury related to irretrievable, lost surgical specimens	Event should be included on an SRE listing for SNFs.	Event should be included on an SRE listing for Ambulatory Outpatient Practices.	Event should be included on an SRE listing for Ambulatory and Office-based Surgery Centers.	Event should be included on an SRE listing for Inpatient Hospitals.	• SC recommended defining "irretrievable" to include that the lost specimen cannot be replicated through a repeat procedure or other means. • SC recommended combining this

					event with two testing event submissions below related to 1) unnecessary procedure and 2) failure to communicate or follow up on results; this will then be considered during the 9/8/10 call.
Diagnostic testing error resulting in unnecessary invasive procedure, serious disability, or death	Event should be included on an SRE listing for SNFs.	Event should be included on an SRE listing for Ambulatory Outpatient Practices.	Event should be included on an SRE listing for Ambulatory and Office-based Surgery Centers.	Event should be included on an SRE listing for Inpatient Hospitals.	• SC recommended combining this event with the preceding and next event submissions; this will then be considered during the 9/8/10 call.
Patient death or serious disability associated with failure to communicate or follow up on test results	Event should be included on an SRE listing for SNFs.	Event should be included on an SRE listing for Ambulatory Outpatient Practices.	Event should be included on an SRE listing for Ambulatory and Office-based Surgery Centers.	Event should be included on an SRE listing for Inpatient Hospitals.	• SC recommended combining this event with the previous 2 event submissions; this will then be considered during the 9/8/10 call.
Death or serious injury resulting from care provided by an impaired healthcare worker	Event is not relevant for SNFs.	Event is not relevant for Ambulatory Outpatient Practices.	Event is not relevant for Ambulatory and Office-based Surgery Centers.	Event is not relevant for Inpatient Hospitals.	• SC acknowledged that implementation of this event and feasibility of reporting would be difficult in terms of establishing evidence and demonstrating a causal relationship in a timely manner. • SC noted that reporting of impaired healthcare workers is already required in most jurisdictions; reporting of this event could be complicated by the differences between what this event contemplates and what a criminal investigation would consider. • SC noted that this event focuses on the acts of an individual provider and his/her behavior rather than a system or process error. This is qualitatively different from the other events, and capturing this event may not lead to improved system processes and

					safety.
Death or significant injury of a patient as a consequence of staff impaired by recreational drugs or alcohol use.	See notes above.	See notes above.	See notes above.	See notes above.	See notes above.

In addition to the formally submitted SRE proposals, a submission for Safe Injection Practices was received from a Committee member. The member will complete a submission form, and this event will be evaluated during the next Committee call on September 8, 2010.

DEFINITIONS USED IN THE SERIOUS REPORTABLE EVENTS

The Committee reviewed submissions for changes to several definitions used in the Serious Reportable Events. Suggested modifications were received formally during the Call for Events as well as informally through Committee and Technical Advisory Panel discussions.

End of Surgery

Committee members stated that a "wheels out" approach should form the basis of the definition of "end of surgery." However, the members agreed that the definition should allow for completion of all established processes to find retained foreign objects before the end of surgery is declared. For example, processes to image the surgical site to check for suspected retained foreign objects outside the procedure room would not be subject to reporting. Similarly, exigencies of safe patient care such as removing a patient from the surgical suite for stabilization with the plan to return to the procedure room, as needed to remove a retained foreign object, once the patient is stable should not trigger a report.

The Steering Committee recommended that the following definition be utilized:
Surgery 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/procedure room (the out of room time). All procedural material (e.g., supplies, devices, equipment) have been removed from the patient or area regardless of setting (e.g., labor and delivery room, surgical suite, endoscopy unit). This definition will be reviewed during a future Committee conference call.

Serious Disability

Steering Committee members stated that there was a need to either modify the definition of serious disability or to modify the term itself as used in the report.

It may be the case, particularly with regards to the Skilled Nursing Facility environment, that a patient is already disabled when an event occurs. As such, use of the term "serious disability" as the outcome of the event occurrence may lead to underreporting in the case when the patient is already disabled.

Use of the term "serious injury" was proposed as an alternative to "serious disability." The Committee agreed to review the definition used by Minnesota for its potential use.

Key elements of that definition are substantially similar to that of "serious" in the 2006 SRE report and include:

- Physical or mental impairment that substantially limited one or more major life activities for the individual that lasted more than seven days or was still present at the time of discharge; and/or,
- Loss of bodily function that lasted more than seven days or was still present at the time of discharge; and/or,
- Loss of a body part.

Committee members acknowledged that a caveat to use of the term "serious injury" may be that a toxic or contaminant exposure with unknown harm may not be captured, as this exposure leads to an increased risk of injury or disability but not necessarily to an immediate injury or disability.

Healthcare Facility

Steering Committee members recognized that boundaries of a facility are likely defined differently from state to state; as such, reporting entities may need to define facility perimeters independent of NQF. For example, some states use licensure to determine facility boundaries. Also, they wanted to be certain that birthing centers are appropriately included in any definition.

Use of the term "healthcare setting" rather than "healthcare facility" was suggested in order to avoid the ambiguities of multiple definitions across states. The 2002 and 2006 SRE reports define healthcare facility as "any licensed facility that is organized, maintained, and operated for the diagnosis, prevention, treatment, rehabilitation, convalescence, or other care of human illess or injury, physical or mental, including care during and after pregnancy. Healthcare facilities include, but are not limited to, hospitals, nursing homes, rehabilitation centers, medical centers or offices, outpatient dialysis centers, reproductive health centers, independent clinical laboratories, hospices, and ambulatory surgical centers."

PUBLIC COMMENT

Dr. Gallagher offered to provide the Steering Committee with the National Coordinating Council for Medication Error Reporting and Prevention's index and algorithm for categorizing medication errors to assist in the Committee consideration of the definition of harm and injury.

NEXT STEPS

Definitions for "end of surgery" and "serious disability" utilized by the State of Minnesota have or will be distributed to the Committee, as will the index and algorithm provided by Dr. Gallagher.

A summary of this call will be emailed to Steering Committee members within the next few weeks.

The Steering Committee will next meet by conference call on Wednesday, September 8, 2010, at 11:00 am ET.

The meeting was adjourned.