CONFERENCE CALL OF THE SERIOUS REPORTABLE EVENTS IN HEALTHCARE STEERING COMMITTEE

September 29, 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; 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 remaining modifications and new submissions for the 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 NEWLY SUBMITTED SREs

The Committee members reviewed submissions and expert opinion on the candidate SREs listed in the following table.

Serious Reportable Event Submission	SC Recommendation for Event	SC Rationale and Comments	Applicable Settings
Patient death or disability as a consequence of MRI error, defined as magnetizable material inside the MRI room	**Death or serious injury of a patient or staff associated with the unintentional introduction of a metallic object into the MRI area**	• The event should be part of the SRE listing because it is indicative of a failure in an MRI facility's safety program. • SC recommended that staff members should be included in this event.	• Hospital, • Outpatient/Office-based Surgery Centers • Ambulatory Practice Settings/Physician Offices
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	**Do not endorse as a standalone event.** **SC recommended that radiotherapy delivery to the wrong body region be included in the implementation guidance for "Surgery or other invasive procedure performed on the wrong site."**	• SC acknowledged that implementation of this event may be difficult, because the specifications need to be further developed. Death or injury likely would not occur for a significant time interval, leading to difficulties in attribution. • SC stated that not many patients are injured as a result of this event. • SC stated that this is an important area of consideration, and it would like to review this event in the future once specifications are further developed. • SC also stated that pediatric dosing of radiotherapy is an important topic, and it would like to see event specifications developed with respect to this as well.	
Death or serious injury resulting from the loss of critical information expected to be gained from a biological specimen whose loss is irretrievable; or the risk of death or serious injury because such a biological specimen must be replaced. **Event description was based on a previously reviewed new event*	**Patient death or serious injury resulting from the irretrievable loss of a biological specimen**	• SC acknowledged the importance of including this event on the SRE listing. • SC discussed capturing "risk of death or serious injury" with this event; however, SC stated that implementation of would be difficult as it would require a listing of procedures that would lead to a risk of death or serious injury. • SC recommended exclusion of procedures for which the specimen was properly handled, but the specimen proved to be non-diagnostic. • SC recommended that this event capture death or serious injury from any repeat procedures performed.	• Hospital, • Outpatient/Office-based Surgery Centers • Ambulatory Practice Settings/Physician Offices • Long-Term Care/Skilled Nursing Facility

submission modified by a Steering Committee subgroup.			
Death or serious injury; or immediate and substantial increase in the risk of death or serious injury resulting from failure to follow up, communicate or manage the care plan or clinical information **Event description was based on a previously reviewed new event submission modified by a Steering Committee subgroup.*	**"Death or serious injury resulting from failure to follow up or communicate clinical information."**	• SC acknowledged the importance of including this event on the SRE listing. • SC stated that inclusion of an "immediate and substantial increase of risk of death or serious injury" would make implementation of this event too difficult, because this is difficult to clearly define. • SC stated that because the event is capturing a failure to follow up with a patient, the event should not include anything about managing a care plan. • SC recommended inclusion of examples in the implementation guidance to clearly define this event and what is meant to be captured under serious injury, including progression in the stage of cancer and development of kernicterus in an infant.	• Hospital, • Outpatient/Office-based Surgery Centers • Ambulatory Practice Settings/Physician Offices • Long-Term Care/Skilled Nursing Facility
Incorrect placement of a feeding (gastrointestinal) or ventilation tube which results in patient harm	**Do not endorse as a standalone event.**	• SC stated that occurrence of this event may be an instance of provider error rather than a system or safety error. • SC recommended that use of the wrong tube during a procedure (e.g., a feeding tube being used to ventilate a patient) be included under the implementation guidance for "Surgery or other invasive procedure performed on the wrong site."	

During the course of the conference call, Committee members discussed off-label use of devices. The Committee wants to ensure that off-label use is not captured in any of the SREs, because the provider should have final judgment. This position is consistent with the stance of the Food and Drug Administration (FDA).

REVIEW OF SUBMITTED MODIFICATIONS TO THE EXISTING SRES

Committee members also reviewed a submitted modification to the following existing Serious Reportable Event:

"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)."

Submitted Modification	SC Recommendation	SC Rationale and Comments
Event 4A should include the following language in the "Additional Specifications" section: "Includes, but is not limited to, administration of a medication to which a patient has a known allergy and drug-drug interactions for which there is known potential for death or serious disability and the misuse of single dose/single use and multi-dose medication vials and containers."	SC recommended that the following language be included in the event's additional specifications (new language is italicized): "Includes, but is not limited to a) administration of a medication to which a patient has a known allergy, b) drug-drug interactions for which there is known potential for death or serious injury, *c) improper use of single dose/single use and multi-dose medication vials and containers leading to contamination or dose adjustment problems."*	• SC acknowledged that this is an instance of the wrong preparation of a medication. SC stated that this incident is serious and important enough to be included in the additional specifications for the event.

PUBLIC COMMENT

There were no public comments.

NEXT STEPS

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

The Steering Committee will next meet by conference call on Wednesday, October 20, 2010, at 4 pm ET to continue evaluation of the Serious Reportable Events.

The meeting was adjourned.