NATIONAL QUALITY FORUM

CONFERENCE CALL OF THE SERIOUS REPORTABLE EVENTS IN HEALTHCARE STEERING COMMITTEE

February 8, 2010

Steering Committee members present: Gregg Meyer, MD, MSc (Co-Chair); Sally Tyler, MPA (Co-Chair); Patrick Brennan, MD; 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; Stancel Riley, Jr., MD, MPA, MPH; Diane Rydrych, MA; Doron Schneider, MD, FACP; Philip Schneider, FASHP, MS; Eric Tangalos, MD, FACP, AGSF, CMD; Michael Victoroff, MD

Steering Committee members absent: Leah Binder; Martha Radford, MD, FACC, FAHA

NQF Staff: Janet Corrigan, PhD, MBA; Helen Burstin, MD, MPH; Peter Angood, MD; Jennifer Hurst, MHS; Lindsey Tighe, MS

Others Present: Erin Graydon-Baker, MS, RRT

WELCOME AND INTRODUCTIONS

Dr. Meyer and Ms. Tyler welcomed the Steering Committee members and thanked them for their participation. They reminded the Steering Committee members of the importance, and widespread interest, for the update and modification of the Serious Reportable Events (SRE) listing, as evidenced by the variety of comments received on the proposed modifications to the SRE definition. Committee members were encouraged to keep the focus of improving safety in healthcare at the forefront and to be careful not to let semantics impede the Committee from achieving this goal. Dr. Angood explained to the Committee that once the definition has been agreed upon, a call for revisions to the existing SREs and for new SREs will be opened. There is also the expectation that the proposed expanded environments of care discussed at the prior Steering Committee meeting (i.e. physician offices, ambulatory surgery centers, skilled nursing facilities) will have Technical Advisory Panels nominated and approved in order to also review the SREs in the context of expanded environments. Dr. Burstin reminded the Committee members that the posting of the proposed modifications to the SRE definition was a necessary step to ensure that all input was considered; however, the remainder of the project will adhere to the NQF Consensus Development Process.

UPDATE ON PROJECT STATUS AND GROUP DISCUSSION

Dr. Angood reminded the Committee that the overarching goal for the project is to facilitate improved public reporting with the use of Serious Reportable Events and to generate increased opportunity for organizational learning and public knowledge from reporting. He summarized conclusions reached by the Steering Committee during the November in-person meeting—as well as comments made during the recent Reporting Framework Steering Committee meeting—noting that adverse patient safety events may differ considerably in terms of their severity of harm and with their frequency of occurrence.

The Committee members were presented a potential classification system (Frequency vs. Severity) for adverse patient safety events; which was also a strategy discussed during the

Framework for Reporting Patient Safety Events Steering Committee. The initial classification terms proposed, based on severity and frequency of events, were:

- Serious Reportable Events (Rare & severe; should never happen 100 percent of the time)
- Patient Safety Events (common & less severe; should not occur with proper care but will still occur due to various circumstances. These events have the potential to eventually become SREs as the evidence base improves)
- High Frequency – Low Severity Events (not typically reported but mature HCOs may choose to report for QI/PI purposes)
- Low Frequency – Low Severity Events (no reporting anticipated)
- Near Miss Events – No Harm to Patient (important and will occur at various levels of severity and frequency).

Steering Committee members agreed that the most important events for public reporting are the events that fall under Serious Reportable Events, which should be considered a subset of Patient Safety Events rather than as a separate entity or grouping of events. Steering Committee members discussed strategies for distinguishing these events, including events that are considered universally preventable and events that are usually preventable, but can still occur under certain conditions. Steering Committee members agreed that the evidence base exists to demonstrate that some events should never occur and are 100 percent preventable, whereas other events should not occur but may occur due to uncontrollable circumstances and a lack of evidence regarding prevention. The Committee members discussed the concept that preventability would allow for the events to be tiered though not precisely categorized, since preventability is ultimately subjective and will change over time. In essence, the degree of preventability of occurrence could be considered as a third dimension for stratification of events.

Discussion of the use of the term "Near Miss Events" ensued, with Steering Committee members acknowledging that the definition of the term is confusing to the field. In order to increase understanding, and consequently increase reporting of these events, the Committee members favor the expression "Close Calls" because it more accurately reflects events that have the potential for occurrence of harm.

REVIEW OF PROPOSED MODIFICATIONS TO THE SRE DEFINITION

Steering Committee members next reviewed the proposed modifications to the definition of SREs, most notably the change to Serious Reportable Events as "preventable, serious, and unambiguous adverse events that should not occur." Committee members first acknowledged that use of the term "never events" has become widespread, both by consumers as well as in relation to payment and reimbursement issues. The Steering Committee members also recognized that the use of this term would continue regardless of a definition change and that the Committee is not in a position of authority to express opposition to the continued use of the term "never events." There was agreement that the term "never events" has been widely adapted to reflect a subset of SREs that pertains to reimbursement issues and not the SRE listing as a whole. The Steering Committee members also agreed that their primary task is to expand and encourage reporting of adverse patient safety events, not to try and stipulate how private entities utilize the SRE listing.

Discussion of the intent for modifying the definition of SREs ensued, with Committee members continuing to review the issues of whether the change from "never" to "not" would be the optimal strategy to facilitate increased reporting of adverse patient safety events. The Committee also agreed that all types of SREs should be reported in order to facilitate healthcare organizations becoming more accountable for results and to increase consumer knowledge. The Committee expects that with an SRE definition change an increase in reporting should occur, and thus improvements in patient safety knowledge, by creating a platform for learning from the events rather than encouraging a punitive response. Further, the Committee recognized that events which are publicly reported most frequently are often those events which are not necessarily 100 percent preventable. With the expectation that private organizations will continue to utilize the term "never events," Committee members stated that moving forward with a revised SRE definition should align with the committee's top priorities of increasing reporting and encouraging reporting for learning.

However, the point was again raised that there are several existing SREs which are considered 100 percent preventable and that they should "never" occur. Committee members discussed how to reconcile the revised definition of SREs given that true "never events" are still a segment of the SRE list; while other SREs are on the list for which an evidence base of preventability does not yet exist. The notion of removing those SREs which are not always preventable from the list was raised; however, Committee members felt that these events are still important for public reporting and thus should remain on the SRE list. The Committee members discussed how a system of tiering the SREs in terms of whether the SREs are 100 percent preventable or usually preventable would recognize that within the SRE list there are true "never events" as well as events that are usually preventable and should not occur. Creating this type of SRE stratification should allow for meaningful public reporting on the occurrence of all types of serious events, while still recognizing that occurrence of the events is not always indicative of a preventable error.

Again acknowledging that the ultimate goal is to increase reporting, the suggestion to entirely remove the phrase "that should not occur" from the SRE definition was raised, revising the definition of an SRE to "preventable, serious, and unambiguous adverse events." Eliminating the stipulation that the SREs either "should never" or "should not" occur would allow for tiering of the listing of SREs into events that truly should never happen (given the evidence base for prevention) as well as events that are usually preventable and should not occur but require more evidence before being considered true "never events." The Committee members recognized that this action might result in increased reporting. The Committee agreed that further attempts to revise the SRE definition so that it accommodates all aspects of the discussion should be attempted rather than trying to force the issue into a polarizing situation—which is what the discussion on the terms "never" vs. "not" creates.

PUBLIC COMMENT

An NQF member commented that the ambiguity of the term "or risk thereof" would result in increased reporting of events that may have little to no impact on reporting for learning. She acknowledged that events occur, such as falls, where there is a risk for serious harm but serious harm does not occur. These events would be reported if the definition of "Serious" included "or risk thereof." Similar comments had been noted in the submitted Public Comment period. The Steering Committee accepted this point and after discussion agreed that reporting of all

such events would not necessarily be beneficial for improving patient safety. The Committee decided to remove the phrase "or risk thereof" from the definition of "Serious". The definition of "Serious" is now "***describes an event that can result in death or loss of a body part, disability, or loss of bodily function*".**

With regards to the issue of reporting other SREs with "a risk thereof of bodily harm or serious disability", the Steering Committee will review during future meetings each SRE individually and attempt a determination of whether it is important for organizations participating with public reporting to report the "risk thereof" for those types of SREs.

In summary:

1) There was consensus on the call that Serious Reportable Events be defined as "***preventable, serious, and unambiguous adverse events. Some types of SREs are universally preventable and should never occur. 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."***
2) NQF staff and the Steering Committee co-chairs will continue to revise the SRE definition to accommodate the tiering for preventability (i.e., a subset of SREs may be 100 percent preventable and a subset of SREs are usually preventable but not 100 percent of the time).
3) The so-called "Never Events" should be considered a set of events that are rare and severe; should never happen 100 percent of the time; and are preventable 100 percent of the time.
4) A stratification of SREs will be considered during future Steering Committee meetings that is based upon "Preventability" (i.e. universally preventable vs. usually preventable).
5) With a stratification of SREs, it was recognized that as the evidence base accrues for prevention of SREs over time, those SREs might eventually move toward a universally preventable tier.
6) A review of the SRE list during future meetings will also consider determination of the SRE list according to "a risk thereof for bodily harm or serious disability."
7) The definition of Serious will be: "***describes an event that can result in death or loss of a body part, disability or loss of bodily function."***
8) "Close Calls" is a term that should be used instead of "Near Misses" because "Close Call" more accurately reflects events that have the potential for occurrence of harm.
9) The Call for Serious Reportable Events and Call for Nominations to three (3) Technical Advisory Panels will occur in the near future.

DISCUSSION OF COMMENTS RECEIVED REGARDING PROPOSED MODIFICATIONS TO THE SRE DEFINITION

	Commenter Information	General Comments on the Draft Definitions	Steering Committee Response
Comments Pertaining to Specific Serious Reportable Events			
1	**Name:** Patty Skolnik **Organization:** Citizens for Patient Safety **Date Entered:** 1/12/2010 3:40:31 PM	**Comments:** On behalf of all the members of Citizens for Patient Safety we understand that you are considering including ALL maternal deaths. We are in total agreement this should be adopted as the standard.	Comments pertaining to specific SREs will be evaluated during the next meeting of the SRE Steering Committee when modifications and newly submitted SREs will also be reviewed.
2	**Name:** Lori Nerbonne **Organization:** NH Patient Voices **Date Entered:** 1/12/2010 3:53:45 PM	**Comments:** Regarding the reporting of maternal deaths: Considering that the current definition of a reportable maternal death is excluding a disproportionate number of women, I am writing to ask that you include ALL MATERNAL DEATHS under your list of reportable adverse events. I would hedge that your definition of "low risk" eliminates at least 50% of woman.... Having been a maternal-child health nurse for 16 years, it is apparent that we are using (over using) medical technology in even low risk women--which in my opinion is contributing to poorer outcomes, not better. The more you do surgery, the more complications and deaths you have in any setting. The Cesarean birth rate in many metropolitan areas is approaching 50%.This is in part due to induction rates approaching 80% in some areas. Both carry great risks; as well as the anesthesia that follows. Considering the clinical and financial resources available to us in American healthcare, I would think that most if not all maternal deaths are preventable, so each one should be reported and then dissected, not only for clinical causes but also healthcare delivery/system & community breakdowns (i.e.; failure to rescue, lack of mental health resources, breakdowns in communication, fragmentation of care; especially when new mom's visit emergency rooms, etc, etc.). And we need to determine if excessive uses of medical interventions during labor contributed to the death. Thank you for considering this input.	Comments pertaining to specific SREs will be evaluated during the next meeting of the SRE Steering Committee when modifications and newly submitted SREs will also be reviewed.

3	**Name:** Lori Nerbonne **Organization:** NH Patient Voices **Date Entered:** 1/12/2010 11:06:15 PM	**Comments:** Re: SRE for serious medication errors: Is it possible to include anyone who suffers a brain hemorrhage (or other hemorrhage) who is on an anticoagulant? Or another way of handling this SRE is to require that they report anyone who requires the administration of an antidote for a medication i.e.; Protamine/Vit. K for anticoagulants I feel strongly that we need a SRE that includes anticoagulants because there is so much devastation (brain hemorrhage) and/or death and they involve one of the most common serious errors either in dosing or lack of appropriate monitoring. Anticoagulants are being used without enough caution in hospitalized patients; especially in the elderly. Women > 60 are at higher risk of these devastating bleeds but this is not something that many docs are taking seriously enough with close monitoring or safer alternatives (ambulation) Also, many pregnant women are put on aspirin if they have a history of miscarriage.. I believe there is emerging research showing that we are seeing more bleeds in pregnant women.	Comments pertaining to specific SREs will be evaluated during the next meeting of the SRE Steering Committee when modifications and newly submitted SREs will also be reviewed.
4	**Name:** Robert Gold **Organization:** DCBA, Inc. **Date Entered:** 1/25/2010 8:39:13 AM	**Comments:** 998.4, foreign body accidentally left in wound, overlooks national quality standards for operating room procedures in its definition of "end of the procedure." Although most procedures performed outside the OR are defined by completion of closure or patient leaving the suite or reversal of anesthesia, operating room procedures in which there is an incision are guided by standards of sponge, needle and instrument count. An operation is not considered "over" until the counts are resolved one way or another. If, during a count, a foreign body (sponge or needle or other instrument) is identified as being unaccounted for, national standards of AORN (Association of Operating Room Nurses) requires a second count, the possibility of an x-ray and retrieval of that foreign body. If it can be found and removed during the same episode in the OR suite without reinstituting anesthesia, the case should not be identified as "foreign body accidentally left in the wound" as the patient will have left without a foreign body. If it cannot be found, then a conscious decision must be made by the OR team to leave it there, which deserves identification of some sort. If it is consciously left in the wound, then it may be identified as a "foreign body left in the wound" without the term "accidentally" and there is an E code for that event. If the counts were erroneous and a foreign body was	Comments pertaining to specific SREs will be evaluated during the next meeting of the SRE Steering Committee when modifications and newly submitted SREs will also be reviewed.

		left in the wound, identified subsequently, then that's a 998.4.	
5	**Name:** Helen Lau **Organization:** Kaiser Permanente **Date Entered:** 1/26/2010 5:59:32 PM	**Comments:** Consider adding a qualifier of monitoring to SRE 4A regarding "Occurrences in which a patient dies or suffers serious disability as a result of the wrong administration technique." is useful. An example of this would be a patient that suffered a devastating bleed after anticoagulation that was not properly monitored by lab studies where a clear standard exists for monitoring. The monitoring piece is difficult to define, since it could be follow up lab studies or physical assessment (such as with sedation after analgesia.) **Comments:** For SRE 5B: Any incident in which a line designated for oxygen or other gas to be delivered to a patient contains the wrong gas or is contaminated by toxic substances. This definition should be broadened to include events that involve connecting a wrong line. The example used of connecting an enteral feeding to an IV line is a perfect example. This sort of event seems to happen when there is a transfer of care from one facility or provider to another, and perhaps there is different equipment at the receiving facility.	Comments pertaining to specific SREs will be evaluated during the next meeting of the SRE Steering Committee when modifications and newly submitted SREs will also be reviewed.
	General Definition Comments		
6	**Name:** Michael Rapp **Organization:** Centers for Medicare and Medicaid Services **Date Entered:** 1/26/2010 4:51:45 PM	**Comments:** It is clear how these definitions are applicable to facilities of any shape, size or form including nursing homes, hospitals, dialysis facilities, etc., however do they also apply to organizations/practices?	Comments pertaining to specific SREs will be evaluated during the next meeting of the SRE Steering Committee when modifications and newly submitted SREs will also be reviewed.
7	**Name:** Barbara Corn **Organization:** NAHQ **Date Entered:** 1/29/2010 9:22:16 AM	**Comments:** Will the revised definitions align with the Common Format definitions of harm? Death and 2 levels of permanent harm. The proposed term definition for serious: or risk thereof, does this add value? Does this imply that near misses without serious harm should be reported? By removing the 7 day time frame, does this allow for more underreporting vs. increased reporting? Example from PA on how to classify-A-D being incidents and E-I Serious Events to provide. Thanks for the opportunity to comment.	Steering Committee members agreed upon the need to align the SREs with the Common Formats and the FDA standards; research as to how to do this will be further explored by NQF.

8	**Name:** Steven J. Brotman, M.D., J.D. **Organization:** AdvaMed **Date Entered:** 2/2/2010 4:39:30 PM	**Comments:** The Advanced Medical Technology Association (AdvaMed) is pleased to submit the following comments on revisions to NQF's definition and criteria concerning serious reportable events ("SRE") in healthcare. AdvaMed member companies produce the medical devices, diagnostic products, and health information systems that are transforming health care through earlier disease detection, less invasive procedures, and more effective treatments. Our member companies produce nearly 90 percent of the health care technology purchased annually in the United States and more than 50 percent purchased annually around the world. AdvaMed members range from the largest to the smallest medical technology innovators and companies. I. Serious Reportable Events (SRE) Definitions and Criteria Involving Medical Devices Should be Aligned with those Required by FDA AdvaMed understands that the intent of the steering committee is to broaden the SRE definitions so as to encompass a wider range of potential adverse events across a variety of healthcare settings. However, AdvaMed would like to emphasize to the committee that the medical device manufacturers, importers and user facilities have been under a statutory responsibility to report serious medical device adverse events to the Food and Drug Administration ("FDA") since 1984. These include all device-related deaths, serious injuries, and certain malfunctions. **Comments:** (continued from previous comments) This legislation was designed to increase the amount of information FDA (and device manufacturers) receives about problems with medical devices. However, early after enactment of this legislation, numerous reports still revealed widespread underreporting. This underreporting of events was subsequently addressed by The Safe Medical Devices Act of 1990 ("SMDA"). Under SMDA, device user facilities must report device-related deaths and device-related serious injuries to the FDA and the manufacturer, if known. Subsequently, the Medical Devices Amendments of 1992 amended certain provisions (section 519 of the Food, Drug, and Cosmetic Act) relating to reporting of adverse events. The major impact of these Amendments was to clarify certain terms and to establish a single reporting standard for device user facilities, manufacturers, importers, and distributors. The final rule was published in 1995 and subsequent refinements were made in FDAMA, enacted in 1998. These rules for Medical Device Reporting ("MDR") are codified under 21 CFR Part 803, and	Steering Committee members agreed upon the need to align the SREs with the Common Formats and the FDA standards; research as to how to do this will occur and discussion will continue at future Steering Committee meeting.

		relevant definitions, including "serious injury," are discussed in 21 CFR 803.3. **Comments:** (continued from previous comments) Specifically, under 21 CFR 803.3: "MDR reportable event" (or reportable event) means: (1) An event that user facilities become aware of that reasonably suggests that a device has or may have caused or contributed to a death or serious injury; or (2) An event that manufacturers or importers become aware of that reasonably suggests that one of their marketed devices: (i) May have caused or contributed to a death or serious injury, or (ii) Has malfunctioned and that the device or a similar device marketed by the manufacturer or importer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur. "Serious injury" means an injury or illness that: (1) Is life-threatening, (2) Results in permanent impairment of a body function or permanent damage to a body structure, or (3) Necessitates medical or surgical interventions to preclude permanent impairment of a body function or permanent damage to a body structure. (Permanent means irreversible impairment or damage to a body structure or function, excluding trivial impairment or damage.) This history of the progression of MDR reporting is significant, as it provides perspective as to the development and evolution of standard definitions and reporting tools concerning adverse events, specifically as it relates to the device industry. **Comments:** (continued from previous comments) AdvaMed strongly believes that subjecting medical device adverse event reporting to a different set of standards than already established and implemented by statute would lead to confusion among those preparing to report. AdvaMed strongly believes that this resulting dichotomy of definitions and reporting requirements would have the unintended consequence of increasing the burden on the reporting parties and may subsequently have an overall effect of decreasing reporting of medical device adverse events. Therefore, AdvaMed urges NQF to harmonize the definitions and criteria concerning SREs with those that have been successfully developed and implemented by FDA over many years. II. Steering Committee Representation	

		AdvaMed applauds NQF for assembling a steering committee to examine the issue of serious adverse events related to various healthcare settings. AdvaMed wishes to emphasize that notably absent in the documentation provided — including the steering committee meeting transcripts on November 18-19, 2009, as well as the "NQF Serious Reportable Events in Healthcare 2006 Update" — was any lengthy discussion of SRE definitions and criteria as they may relate to the FDA MDR process. AdvaMed strongly recommends that the steering committee consider the addition of device industry representation (and other members of industry) to their membership in order to fully address significant issues from an industry perspective. **Comments:** (continued from previous comments) III. Unintended Consequences of Reporting AdvaMed commends NQF for its intention to create and implement a system of uniform reporting to broadly capture serious reportable events in healthcare. We recognize that the resulting SRE reporting list has the unintended potential consequence of causing various states to issue policies denying coverage and payment for cases associated with SREs. We do not believe that this was the intention contemplated by NQF. Therefore, AdvaMed strongly recommends that NQF clearly delineates the purpose of SRE reporting in all its associated documents and provides a disclaimer statement that indicates "it is not intended that SRE results be used for denial of payments to providers." AdvaMed appreciates NQF's responsiveness for the need to provide standardized event reporting and encourage widespread adoption of patient reporting systems.	
9	**Name:** Joyce Bruno Reitzner **Organization:** American College of Chest Physicians **Date Entered:** 1/26/2010 9:39:35 AM	**Comments:** Approve with comments. On behalf of the American College of Chest Physicians (ACCP) the ACCP Quality Improvement Committee (QIC) appreciates the opportunity to comment on this definition. The QIC approves this revised definition with the following comments. The QIC appreciates that the revised definition is aligning itself closer with patient safety initiatives. The QIC noted that there are many different definitions for "Serious Reportable Events," including at the state level and within the Food and Drug Administration (FDA). The QIC recommends harmonizing this definition with other definitions of "serious reportable events", most notably the FDA's definition. Furthermore, while the QIC understands the rationale for changing the word "never" to "not" they note that "never" and "not" have the same meaning and recommend using the word "rarely."	No action necessary

Against Changing Definition from "Never" to "Not"			
10	**Name:** Debra Ness **Organization:** National Partnership for Women & Families **Date Entered:** 2/2/2010 4:50:27 PM	**Comments:** The National Partnership for Women & Families appreciates the work being conducted by NQF's steering committee on Serious Reportable Events (SREs) in evaluating and considering improvements to the SRE definition. Currently, SREs are defined as "preventable, serious, and unambiguous adverse events that should never occur." As a consumer advocacy organization, the National Partnership is mindful of the weight and power that this definition – and its shorthand of "never events" – has for consumers. We therefore will continue to use this term in our advocacy work when discussing SREs with consumers, providers, the general public, and the media. We believe it is important to reinforce the goal of ensuring that such events never occur in a health care setting. At the same time, we respect the committee's thoughtful deliberation and decision to modify the definition in order to cast a wider net for measures to be labeled as SREs. We also applaud several of the other changes made by the Steering Committee, as they relate to the words "serious" and "adverse," and feel these too will broaden the definition in a positive way. In the end, we share with NQF the goal of increasing the universe of SRE measures and holding hospitals accountable via public reporting.	Steering Committee response can be found in the Steering Committee conference call summary under the "Proposed Modifications to the SRE Definition."
11	**Name:** Leah Binder **Organization:** The Leapfrog Group **Date Entered:** 1/12/2010 7:01:28 PM	**Comments:** I served on the SRE Steering Committee as the only purchaser representative, and was one of two Committee members voting in opposition to changing the SRE definition. I objected to removal of the word "never" from the definition. The word "never" in the Serious Reportable Adverse Events definition sparked a new word in the lexicon of American healthcare: "never events". Purchasers and patient advocates tend to be passionate about "never events", because removal of the wrong limb in surgery, for example, goes beyond physical harm; it is a profound violation of the trust we must place in the institutions that care for us in our most vulnerable moments of life. Some argue that in rare cases SREs occur that were not preventable, and so the term "never" is unfair to providers. But when we think about killing a patient through transfusion of the wrong blood, "never" should be the goal, if sadly not always the reality. Setting a standard of "never" does not mean we expect providers to achieve perfection, it means we expect them to aim for it. The word "never" is simply a more emphatic version of "not", and emphatic is a proper posture when describing how the health system should approach these	Steering Committee response can be found in the Steering Committee conference call summary under the "Proposed Modifications to the SRE Definition."

		disturbing tragedies. Perhaps that's just semantics, but downgrading the emphasis from "never" to "not" send a powerful and disheartening message to the public and purchasers, and words do matter.	
12	**Name:** Lisa Kaiser **Organization:** Health Action Council Ohio **Date Entered:** 1/21/2010 5:02:31 PM	**Comments:** My organization represents appx. 200 employers and 2 Million lives. These purchasers of health care are concerned about care quality, and a spark leaps across our coalition anytime we discuss *Never* events. The language is clear, and moves the dialogue about commitments to quality. "Never events" and nonpayment for never events has had significant impact on policies and payment reform for health plans, hospitals, and purchasers (like our members). The term "never events" captures the seriousness of a health system's commitment to preventing certain horrific events from happening in their delivery of health care. Indeed, purchasers and patient advocates tend to be passionate about "never events" because wrong side or wrong site surgery, for example, goes beyond physical harm; it is a profound violation of the trust we must place in the institutions that care for us in our most vulnerable moments. If a patient dies or is seriously injured, "never" to repeat the mistake should be the goal, if, sadly, not always the reality. Downgrading the definition from "events that should never happen" to "events that should not happen" sends the wrong message. During this time of so much confusion and angst surrounding our national health care system, why alter something that is meaningful and moving? We request that you leave the "Never events" definition intact..	Steering Committee response can be found in the Steering Committee conference call summary under the "Proposed Modifications to the SRE Definition."
13	**Name:** Mary McWilliams **Organization:** Puget Sound Health Alliance **Date Entered:** 1/21/2010 5:54:55 PM	**Comments:** I share the minority view that abandoning the term "never events" would lose the galvanizing interest of the industry and the public in the need to eradicate serious preventable events. The never events term has been very useful in focusing attention on the problem and on finding remedies, and I don't think we're so far along that we can dilute the needed impact of the words.	Steering Committee response can be found in the Steering Committee conference call summary under the "Proposed Modifications to the SRE Definition."
14	**Name:** John Miller **Organization:**	**Comments:** I understand that NQF is considering a change from "never" to "not" in "never events". Never Events is an already "branded" phrase, which is gaining	Steering Committee response can be found

	MidAtlantic Business Group on Health **Date Entered:** 1/21/2010 7:36:28 PM	recognition with purchasers, and even knowledgeable consumers. Changing the name will reduce the effectiveness of the previous communications. Furthermore, Never Events connotes the extreme nature of these mistakes. I ask that you retain "never events" for ease of understanding, and for meaning.	in the Steering Committee conference call summary under the "Proposed Modifications to the SRE Definition."
15	**Name:** Nancy Fisher MD **Organization:** WA State Health Care Authority **Date Entered:** 1/21/2010 2:48:11 PM	**Comments:** We are at a time when the respect and trust in the medical health care system and its practitioners is at all time low. It takes courage to face the reality and then to admit there is a problem and then have the strength to be part of the solution. When it comes to an individual's health care, anything less than 100% is not good enough. We may not achieve 100%, but we need to strive for it. IF we do not, we are part of the problem. There should never be plane crashes. There are plane crashes, but the industry strives for never a plane crash. There should never be construction accidents, but there are; however the companies strive for never. The steering committee believes the use of the word "not" rather than "never" reflects what is happening. Why do we want to reflect what is happening when what is happening in health care is not good? IF we keep doing the same thing, we get the same results. We in health care are to "do no harm". That is a positive, proactive, high standard statement. Let's keep our standards high. We need to do better than the airplane industry. Right now we cannot even match their standards. The public knows that mistakes happen, that sometimes events cannot be prevented. But they want the assurance the health system has high standards to keep them safe, processes to review adverse events, and strive not to make the same mistakes again. We have a long way to go and all the reasons for using the word "not" are backward steps.	Steering Committee response can be found in the Steering Committee conference call summary under the "Proposed Modifications to the SRE Definition."
16	**Name:** Louise Probst **Organization:** St. Louis Area Business Health Coalition **Date Entered:** 1/25/2010 6:07:13 PM	**Comments:** I am writing to strongly encourage you to not change the National Quality Forum definition of Serious Reportable Adverse Events (SREs), known to so many health care providers and patients as "never events." The proposed change would remove the word "never" from the definition. As you know, the word "never" in the Serious Reportable Events definition sparked a new word in the lexicon of American healthcare: "never events"; and had	Steering Committee response can be found in the Steering Committee conference call summary under the "Proposed Modifications to the

		significant impact on policies and payment reform for health plans, hospitals, and purchasers. The term "never events" captured, as nothing else has, the seriousness of a health system's commitment to preventing certain horrific events from happening in their delivery of health care. Indeed, purchasers and patient advocates tend to be passionate about "never events" because removal of the wrong limb in surgery, for example, goes beyond physical harm; it is a profound violation of the trust we must place in the institutions that care for us in our most vulnerable moments. Acknowledging this, health care providers are taught from their earliest education that some things are never done and some adverse events never need to occur.	SRE Definition."
17	**Name:** Julia Hallisy **Organization:** The Empowered Patient Coalition **Date Entered:** 1/26/2010 9:27:31 PM	**Comments:** Dear Quality Forum, I am writing to express my concern about the use of the word "not" to replace "never" when identifying adverse events. The term "never events" is very powerful in its meaning and it has become synonymous with the goal of zero preventable medical errors. We are asking that you leave the "Never Events" wording intact. We are also concerned about using the term "Serious Reportable Events" and leaving a large gray area for interpretation about what constitutes a serious event. We need all the data we can collect, not only the facts about serious situations. Patients may be confused about the term "serious reportable events" and it may not provide them with a point of reference that is clear and meaningful. Julia Hallisy The Empowered Patient Coalition	Steering Committee response can be found in the Steering Committee conference call summary under the "Proposed Modifications to the SRE Definition."
18	**Name:** Rebecca Zimmermann **Organization:** AHIP **Date Entered:** 2/2/2010 10:19:30 AM	**Comments:** Part 1 AHIP appreciates the opportunity to provided comments on the proposed revision to "serious reportable events" definition. As stated by NQF, the intention of this revision is to encompass a wider range of potential adverse events across a variety of healthcare settings. AHIP supports evaluating serious reportable events in new healthcare settings and broadening the definition to encompass these settings. For that reason, we support the revision to the current definition. We have several concerns, however, regarding this change and suggest that NQF directly address these issues when publicizing the new definition. In developing our position, we reviewed comments submitted by many purchasers	Steering Committee response can be found in the Steering Committee conference call summary under the "Proposed Modifications to the SRE Definition."

		and patient safety advocacy organizations against the definition change. Those groups support "never" as it is implies a stronger narrative than "not." Other comments note, and we concur, that "never events" is the standard lexicon and changing this language should be carefully considered as it may confuse consumers and may have unintended effects on efforts galvanized around "never events" terminology. Further, we disagree with the NQF's panel suggestion that "never" is punitive to providers. While we understand that not all events are preventable, AHIP believes that "never" should be a goal. **Comments:** Part 2 NQF should also explore and report on the impact of this change to other entities that measure and assess serious reportable events, including the effect on the Leapfrog Group Hospital Survey, CMS' nonpayment for healthcare acquired conditions, and other state-based patient safety initiatives.	
19	**Name:** Steven Findlay **Organization:** Consumers Union **Date Entered:** 2/2/2010 2:12:04 PM	**Comments:** Consumers Union is opposed to the change of language and phrasing from "never" to "not." We favor retaining the word never in the formal definition. We have emailed a PDF with our comments on that and other suggested changes the committee and NQF put out for public comment. Thanks for the opportunity to comment. Consumers Union appreciates the opportunity to comment on the proposed changes to the National Quality Forum's definition of "serious reportable events." We have reviewed the rationale for the suggested changes and believe they will significantly set back the focus on public reporting and prevention of serious harm to patients. ***"Adverse events that should never occur" vs. "…should not occur"*** We strongly object to the change of "never" to "not." While there is little apparent difference in meaning between saying an event should never occur or that it should not occur, in this context this change represents a not-so-subtle shift in policy. And, rather profoundly in this context, words matter. Moreover, the proposal clearly indicates that the committee is recommending the change to create a new meaning of "serious reportable events." Specifically, the proposal states: "There was concern with the concept that all SREs are entirely preventable when it is recognized some SREs are not always preventable in certain circumstances." The fact that SREs will occur is irrelevant to whether they should never occur. To change this language based on the belief that these events can never, in fact, be eradicated takes us back to the days of complacency and inevitability. We challenge	Steering Committee response can be found in the Steering Committee conference call summary under the "Proposed Modifications to the SRE Definition."

		the concept that there are no solutions to preventing serious reportable events as claimed by the proposal: "The use of the word "never" may imply that a solution exists for preventing SREs from ever occurring, which is not always the case." These are not randomly occurring events, they happen when errors are made or patients are neglected or some other action was not taken. Only when every proven prevention practice is used with every patient, should we begin talking about what is and is not preventable. This change in language and ultimately the change in the meaning of SRE sends the wrong message to the public and medical professionals at a time when more attention is focused on prevention and reaching for a goal of zero for these harmful events. ***Reporting common vs. rare events*** The proposal further states that the change would allow reporting of routine events rather than rare events "that many institutions may not ever see or, at best, see only sporadically." We believe that calling events that harm millions of patients and kill over 100,000 each year "rare" demonstrates a lack of perspective on the scope of this problem. We challenge the accuracy of this and believe this perception has contributed to a lack of urgency in preventing medical errors. Any other preventable problem existing in our culture that caused this volume of deaths and injuries would "never" be acceptable. Most recently, witness the concern around the Toyota accelerator problems and Toyota's response---suspension of sales and recall of millions of cars – all due to a problem that by all accounts has led to fewer than 50 deaths. The proposal also recommends keeping the term "serious" (thus, not necessarily "routine" events) but to change its meaning from events that result in "death or loss of a body part, disability or loss of bodily function …" to events that "can result in death or loss of a body part, disability or loss of bodily function or risk thereof"). This strikes us as a diversion that could confuse the public and medical professionals – is the event serious or potentially serious? The proposal claims this is to broaden SREs to "encourage reporting of close calls or near miss events." But there is absolutely no movement to publicly report those kinds of events and there's a great deal of skepticism about the ability to accurately account for near misses. Our concern is that these changes are being made to focus attention away from public reporting and toward "internal" (non-public, secret) reporting through such entities as "Patient Safety Organizations." This sort of confidential reporting has been the norm for decades and has not led us to a safer health care system. If there is a desire to broaden public reporting of other events, not only SREs, it	

		should be done by creating a new definition of those types of events and not attempting to substitute them for the truly serious events. We agree reporting of less serious events could provide a clearer picture of a hospital's safety record – e.g. the reporting of all falls, not just those that cause serious harm. However, we question whether this is a realistic goal in a world where reporting of significant harm continues to be minimal. Although reporting only falls that cause disability or death may fail to capture the complete picture of a hospital's safety, realistically the falls that cause harm are the ones that will come to the attention of caregivers for documentation, whereas falls that have no harmful consequences might not even be noticed and would be difficult to document in a verifiable manner. Another example of this is with hospital-acquired infections. We advocate reporting all hospital infections, not just those causing serious harm, but realistically, those are going to be the ones identified by hospitals. Many patients with hospital infections will get a treatment of antibiotics after discharge and the problem is resolved. As much as we would like to know about all infections for surveillance and prevention purposes, the hospital is unlikely to ever know or report these. Thank you again for the opportunity to comment.	
20	**Name:** Marcia Lysaght **Organization:** Las Vegas Health Services Coalition **Date Entered:** 1/21/2010 2:53:32 PM	**Comments:** It is my belief that changing the word "never" to "not" takes away from the gravity of the occurrence. These events should never occur and substituting the word "not" for "never" may be construed as events that if occur, under certain conditions may be acceptable. I believe that it also sends a wrong message to hospitals and healthcare providers and may lead to a slippery slope whereby attempts might be made to justify these events when they occurred.	Steering Committee response can be found in the Steering Committee conference call summary under the "Proposed Modifications to the SRE Definition."
21	**Name:** Bobbette Bond **Organization:** Nevada Healthcare Policy Group **Date Entered:** 1/21/2010 6:27:39 PM	**Comments:** Oppose changing never to not. Changing the wording exacerbates a problem that currently exists in some other definitions - ambiguity. First, neither patients nor health care providers benefit from gray area. Second, this specific change after so many years of work which is just now becoming more publically understood, would suggest that, in fact, these things might somehow not always be unacceptable. These things should NOT EVER happen - as in NEVER. Changing the wording to NOT EVER would be acceptable, changing the wording to NOT is an unacceptable and unwarranted retreat.	Steering Committee response can be found in the Steering Committee conference call summary under the "Proposed Modifications to the SRE Definition."
22	**Name:** Gaye Fortner **Organization:** HC21 Business Coalition	**Comments:** Thank you for the opportunity to comment on the revised Serious Reportable Events (SRE) definition, also known as "never events".	Steering Committee response can be found in the Steering

	Date Entered: 1/25/2010 3:03:10 PM	HealthCare 21 Business Coalition is a member driven organization committed to improving the quality of health care and supporting the drive for more informed health care consumers. Choosing quality care is important and we believe that our commitment to the public is to re-emphasize quality. I am always pleased to be a part of the National Quality Forum's voting process and have had the opportunity to be on steering committees in the past. It is our understanding that NQF has proposed a change that would remove the word "never" from the SRE definition. As an original member of the Leapfrog Group, we believe the policy of nonpayment for never events has had significant impact on policies and payment reform for health plans, hospitals, and purchasers. The term "never events" captures the seriousness of a health system's commitment to preventing these events from happening in the delivery of health care. Adverse events in health care are one of the leading causes of death and injury in the U.S. today. We oppose changing "events that should never happen" to "events that should not happen". Using the word never sends a strong message to purchasers, consumers and health care providers across the country that these serious events can and should never take place. Again, thank you for the opportunity to provide feedback on this change.	Committee conference call summary under the "Proposed Modifications to the SRE Definition."
23	**Name:** Louise Probst **Organization:** St. Louis Area Business Health Coalition **Date Entered:** 1/25/2010 6:07:13 PM	**Comments:** Downgrading the definition from "events that should never happen" to "events that should not happen" sends the wrong message to purchasers and consumers. Too often, wrong treatment decisions, incorrect diagnoses, unnecessary infections and other medical mistakes happen. These errors are often, but perhaps not always, preventable. However, as the existing definition makes clear, some health care errors should never occur and are always preventable. As purchasers and consumers of health care, we should always expect that those we trust with our care, and the care of our loved ones, will aim for the highest level of safety—which means demonstrating a commitment to ensuring that certain, serious events never happen. At a time when our health care system is working so hard to improve its quality and safety, we must not move backward.	Steering Committee response can be found in the Steering Committee conference call summary under the "Proposed Modifications to the SRE Definition."
24	**Name:** David Knowlton **Organization:** New	**Comments:** The New Jersey Health Care Quality Institute firmly believes that the definition of SREs should maintain the term "never." By taking away "never"	Steering Committee response can be found

	Jersey Health Care Quality Institute **Date Entered:** 1/27/2010 3:42:16 PM	and replacing with "not" there then is a diminished impact on the meaning of these events to purchasers and consumers. The term "never events" captured, as nothing else has, the seriousness of a health system's commitment to preventing certain horrific events from happening in their delivery of health care. In the aviation industry, sometimes airplane crashes are said to not have been preventable, but still we expect airlines to commit themselves to never allowing even one to happen. When we think about killing a patient through the transfusion of the wrong blood, "never" should be the goal, sadly though this is not always the reality. The health care industry, like the aviation industry should have a zero tolerance policy. Events such as these should NEVER occur!	in the Steering Committee conference call summary under the "Proposed Modifications to the SRE Definition."
25	**Name:** Peter Lee **Organization:** Pacific Business Group on Health **Date Entered:** 2/2/2010 5:04:09 PM	**Comments:** The Pacific Business Group on Health appreciates the opportunity to comment on the potential change in definition being considered by the NQF steering committee on Serious Reportable Events (SREs). We understand the practicality of broadening the SRE definition to increase the types of events labeled as SREs, and can envision the impact that this may have on public reporting and quality improvement in the future. At the same time, however, we cannot deny the power of the word "never," and the weight and resonance that the term "never events," – which has become common shorthand for SREs—has for the "buyer side" of healthcare, namely patients and purchasers. While we do not want to stand in the way of progress related to public reporting, and in fact applaud some of the other changes made by the steering committee to the SRE definition as it relates to the words "serious" and "adverse," we will continue to use the term "never events" when communicating to purchasers, providers, and consumers on sentinel events. We strongly believe that words matter, and the word "never" conveys an aspiration that our health care system achieve the goal of making sure that certain sentinel events never occur in a health care setting. This is a goal that has garnered broad consensus across the provider, payer, purchaser, and consumer communities.	Steering Committee response can be found in the Steering Committee conference call summary under the "Proposed Modifications to the SRE Definition."

26	**Name:** Frank Johnson **Organization:** State Of Maine **Date Entered:** 1/27/2010 3:42:44 PM	**Comments:** The Maine State Employee Health Commission believes that the term "never" has a universal application that is understood by all parties, particularly consumers. Never establishes a clear intolerance for these events. While we acknowledge that "never" may be unattainable, we find that goal to be far more powerful and persuasive than the "not". The issue is not practicality but a strong message to consumers and provider. We would strongly urge the NQF to reconsider the proposal to substitute "never" events for events that should not occur.	Steering Committee response can be found in the Steering Committee conference call summary under the "Proposed Modifications to the SRE Definition."
27	**Name:** Becky Cheney **Organization:** Florida Health Care Coalition **Date Entered:** 2/2/2010	**Comments:** The Florida Health Care Coalition is and has been a member of NQF since its founding. I have had the privilege of serving on the initial "never events" workgroup as well as the five year review group. That we called the incidents "never events" was no accident. In fact, it followed many long discussions about the message we truly wanted to convey. "Never" was selected over "not" because never is really what we meant. I believe Dr. Ken Kizer or Dr. Lucian Leape, who worked on the first report, could give you more details about those discussions. I do not recall any discussion about using "never" when we reviewed the work after five years. It had already become an acceptable term. We support expanding the Serious Reportable Events. However, we have created language many of our employer members are including in their contracts to communicate that they will not pay for "never events". Rebranding to "not"events? I hope not! NQF was founded to promote quality. Actions such as those of our members are key to advancing quality initiatives. If we change or dilute the message, it won't gather the momentum it needs for all stakeholders in health care to get behind one message. *Quality first, always!*	Steering Committee response can be found in the Steering Committee conference call summary under the "Proposed Modifications to the SRE Definition."
Stratification or Tiering of SREs into "Never" and "Not"			

28	**Name:** Roberta Fismer **Organization:** Mariners Hospital **Date Entered:** 1/28/2010 1:59:20 PM	**Comments:** Do not completely drop "Never". Stratify events into "never" and "not". An example: we should NEVER remove the wrong limb but it is not always possible to prevent a pressure ulcer in very debilitated critically ill patient	Steering Committee response can be found in the Steering Committee conference call summary under the "Proposed Modifications to the SRE Definition."
29	**Name:** Timothy Stockdale **Organization:** Dept. of Defense, Health Affairs **Date Entered:** 2/2/2010 10:40:12 AM	**Comments:** On behalf of the Office of the Assistant Secretary of Defense for Health Affairs, we believe that there is value in preserving the identification of "never" events within the taxonomy of Serious Reportable Events (SREs) in Healthcare. Serious events resulting in death, loss of a body part, or other events that, when evaluated, are deemed to have been preventable should be reported as "never" events. Examples would include removal of the wrong limb in surgery, or patient death associated with a hemolytic reaction due to the administration of ABO/HLA-incompatible blood or blood products, to name just a couple. However, we also see value in broadening the definition of SREs beyond the capture of just those rare and uncommon events that some institutions may not ever see. We certainly agree with modifying the definition to include less serious harm events and "near miss" events. We suggest a tiered approach to the classification of SREs that maintains a top-tier class or group of the most serious events defined as "never" events which, when evaluated, were determined to be preventable. These events are truly events that should "never" occur.	Steering Committee response can be found in the Steering Committee conference call summary under the "Proposed Modifications to the SRE Definition."
In Agreement with Changing "Never" to "Not"			
30	**Name:** Lea Anne Gardner RN, PhD (on behalf of the Performance Measurement Subcommittee) **Organization:** American College of Physicians **Date Entered:** 1/21/2010 3:11:44 PM	**Comments:** The Performance Measurement Subcommittee would like to acknowledge the improvements in the SRE definition and changes in the terminology, particularly the changes for "serious" that now include need to capture "near miss" events.	.Steering Committee response can be found in the Steering Committee conference call summary under the "Proposed Modifications to the SRE Definition."

31	**Name:** Helen Lau **Organization:** Kaiser Permanente **Date Entered:** 1/26/2010 5:59:32 PM	**Comments:** The change from "should never occur" to "should not occur" is a step in the right direction, but only a step. The term "SRE" - "serious reportable event" - is itself problematic as well. What defines these events is that they are serious - generally in terms of the harm that ensued; adverse (in terms of harm); and probably or certainly preventable (the term "unambiguous" does not describe the probability of occurrence or preventability.) These attributes make the event "reportable" - so the word "reportable" should not be part of the term, but rather make reference to the NQF list of types of events. The definition should make reference to the possible contribution of performance problems and/or systems problems (i.e., human factors and their interaction with potentially or actually flawed systems) - which may enhance reporting of such events, as that would not necessarily imply a performance problem.	Steering Committee response can be found in the Steering Committee conference call summary under the "Proposed Modifications to the SRE Definition."
32	**Name:** Karen Conti **Organization:** NSMC **Date Entered:** 1/27/2010 9:51:55 AM	**Comments:** I agree with the plan to remove the "never" from the definition because of the punitive nature. In addition, as a Clinician the goal is to strive to prevent an adverse outcome for someone in my care. Evaluation of preventability provides the thought process to evaluate adverse outcomes for those we care for to aide in optimizing improvement strategies to promote other adverse outcomes. The language in the SRE definition needs to be clear so clinicians, payors and lay people can understand its meaning. Thank you, Karen Conti BSN,RN,LNC	Steering Committee response can be found in the Steering Committee conference call summary under the "Proposed Modifications to the SRE Definition."
33	**Name:** Marcie Williams **Organization:** Texas Health Resources **Date Entered:** 1/28/2010 6:49:20 PM	**Comments:** I support the consideration of removing the word "never" from this list of events. As we have discussed with our payers, many of these events do happen and they are not preventable. In looking at some of the comments, I don't agree with those that say removing the word "never" will make the hospitals less likely to pay attention to these areas of concerns as these are major areas of care that are considered high risk and healthcare providers will not lessen their attention to the importance of preventing such medical errors.	Steering Committee response can be found in the Steering Committee conference call summary under the "Proposed Modifications to the SRE Definition."
34	**Name:** Kelle Jones **Organization:** Texas Health Resources Harris	**Comments:** There are too many nuances in providing care to an individual to have an ever expanding list of so-called 'never' events for which an organization will or may not be compensated for should they occur. Yes I agree that there are some	Steering Committee response can be found in the Steering

	Methodist Hurst Euless Bedford Hospital **Date Entered:** 1/29/2010 11:59:30 AM	discrete events/conditions that we can say should 'never' occur in the healthcare setting, but the problem is that payors are holding hospitals hostage financially for them, decreasing funds available to devote to quality efforts. Removing 'never' will in NO WAY reduce our efforts in this regard, we will not magically let down our guard on this front just because of the removal of a term! What it will do is allow us to focus our efforts more by not having to spend time at the table vying for healthcare dollars that are shrinking on many fronts.	Committee conference call summary under the "Proposed Modifications to the SRE Definition."
35	**Name:** Rita Munley Gallagher, PhD, RN **Organization:** American Nurses Association **Date Entered:** 2/1/2010 9:33:16 AM	**Comments:** The change in verbiage allows the opportunity for quality improvement. NQF's leadership in this regard is laudable.	Steering Committee response can be found in the Steering Committee conference call summary under the "Proposed Modifications to the SRE Definition."
36	**Name:** Elizabeth Bossley **Organization:** St. Mary's Medical Center **Date Entered:** 2/1/2010 1:32:15 PM	**Comments:** I completely support changing the wording from never to not. Some of the things listed on the "never" list are going to happen in spite of all of your best efforts to not let them happen. To say never sends the wrong message out to the public. You are inviting unnecessary litigation that will tie up hospitals for years in frivolous lawsuits. Hospitals have to spend enormous amounts of money on lawyers instead of other things that benefit the patients	Steering Committee response can be found in the Steering Committee conference call summary under the "Proposed Modifications to the SRE Definition."
37	**Name:** David Edwards **Organization:** Banner Health **Date Entered:** 2/2/2010 12:15:48 PM	**Comments:** I would support the use of the word "not". What has been missing from the discussion is the damage to the healing relationship between a clinician and a patient should a patient mistakenly believe that a "never event" is completely preventable.	Steering Committee response can be found in the Steering Committee conference call summary under the "Proposed Modifications to the SRE Definition."
38	**Name:** Erin Graydon-Baker **Organization:** Partners Healthcare **Date Entered:** 2/2/2010 1:05:45 PM	**Comments:** Founded by Brigham and Women's Hospital(BWH)and Massachusetts General Hospital(MGH)in 1994, Partners Healthcare is one of the largest healthcare systems in the United States, providing care for more than one million patients each year. With approximately 50,000 full and part time physicians, nurses, other care givers, researchers and staff, Partners is the largest employer in the Boston area. With a combined research budget of more than $1 billion, MGH and BWH are the largest	Steering Committee response can be found in the Steering Committee conference call summary under the "Proposed

		private hospital recipients of National Institute of Health funding in the nation. At the same time, Partners has maintained its strong commitment to the community; it remains among the state's largest providers of care to children and adults in poverty. On behalf of Partners Healthcare hospitals including Brigham and Women's, Massachusetts General, Faulkner, Newton Wellesley, Spaulding Rehabilitation, McLean and North Shore Medical Center, we respectfully submit the following comments regarding the revised SRE definition. **Comments:** While it is important that organizations are transparent and address safety concerns, a majority of the effort should be directed at mitigating risk and improving safety culture. Organizations are expected to do this by internally analyzing trends and contributing factors and following the Joint Commission standards related to sentinel events. Massachusetts, like many other states, already has reporting requirements which would make the proposed reporting duplicative. If the current definitions are not resulting in the desired level of reporting, we encourage the NQF Task Force on Serious Reportable Events to use their influence to ensure that other regulatory and accrediting bodies incorporate this goal into their standards and state medical boards include the requirement that all Serious Reportable Events as defined by the NQF are reported accordingly. Those organizations have mechanisms to hold entities accountable for adherence to their standards. In summary, we support the enforcement of the current reporting requirements but do not support reporting near misses as SREs. We strongly support removing the word "never" from the definition and removing the words " can" and "risk thereof" from the term definition for serious.	Modifications to the SRE Definition."
39	**Name:** Debbie Fritz **Organization:** GlaxoSmithKline **Date Entered:** 2/2/2010 4:32:31 PM	**Comments:** GSK supports the proposed revisions to the definition of serious reportable events. We agree that the proposed new definition is a better reflection of current clinical practice and of commonly occurring events. We recommend that the Committee add a clarification that this revised definition does not apply to medications. Adverse experiences with medications – and the reporting of such experiences – are regulated separately by the Food and Drug Administration.	Steering Committee response can be found in the Steering Committee conference call summary under the "Proposed Modifications to the SRE Definition."
40	**Name:** Catherine MacLean **Organization:** WellPoint, Inc. **Date Entered:** 2/2/2010 5:11:36 PM	**Comments:** In general, we supported the changes made to the SRE definition.	Steering Committee response can be found in the Steering Committee conference call summary under the "Proposed

			Modifications to the SRE Definition."
41	**Name:** Michael Rapp **Organization:** Centers for Medicare and Medicaid Services **Date Entered:** 1/26/2010 4:51:45 PM	**Comments:** we support the use of the term "not" over "never" as it seeks to increase the rate and types of events reported. Furthermore, the term "not" may be in interpreted as being less punitive in nature, which further increases reporting rates.	Steering Committee response can be found in the Steering Committee conference call summary under the "Proposed Modifications to the SRE Definition."
42	**Name:** Lela Holden **Organization:** Massachusetts General Hospital **Date Entered:** 1/26/2010 5:36:38 PM	**Comments:** I completely concur with the recommendation to eliminate the use of the term "never" and replace with "should not occur". The term never is not consistent with clinical or biological reality. Secondly, reporting is inhibited by such an extreme conceptualization, and implies that punishment is appropriate. Finally, it is unjust to infer from the concept "never" that healthcare professionals and organizations should not be paid.	Steering Committee response can be found in the Steering Committee conference call summary under the "Proposed Modifications to the SRE Definition."
43	**Name:** Elizabeth Mort **Organization:** MGH **Date Entered:** 1/27/2010 12:50:51 PM	**Comments:** Agree 100% with substituting not for never.	Steering Committee response can be found in the Steering Committee conference call summary under the "Proposed Modifications to the SRE Definition."
44	**Name:** Tim Hough **Organization:** NSMC **Date Entered:** 1/27/2010 1:56:14 PM	**Comments:** I do support changing the language from "never" to "not". I think this will actually increase reporting and awareness of adverse events--exactly what we should be striving for..	Steering Committee response can be found in the Steering Committee conference call summary under the "Proposed Modifications to the SRE Definition."
45	**Name:** Rita Munley Gallagher, PhD, RN	**Comments:** ANA concurs that the definition should reflect current clinical realities and that the choice of events for reporting should capture what is actually happening in the clinical environment on a routine basis. ANA applauds the change of the term	Steering Committee response can be found in the Steering

	Organization: American Nurses Association **Date Entered:** 2/1/2010 9:33:16 AM	"never" to one that demonstrates the seriousness of the problem without holding clinicians to a standard that is not attainable.	Committee conference call summary under the "Proposed Modifications to the SRE Definition."
46	**Name:** Erin Graydon-Baker **Organization:** Partners Healthcare **Date Entered:** 2/2/2010 1:05:45 PM	**Comments:** Partners Healthcare strongly supports the removal of the word "never" from the SRE definition.	Steering Committee response can be found in the Steering Committee conference call summary under the "Proposed Modifications to the SRE Definition."
Commenter Information		**Criteria for SRE classification**	**Steering Committee Response**
47	**Name:** Joyce Bruno Reitzner **Organization:** American College of Chest Physicians **Date Entered:** 1/26/2010 9:39:35 AM	**Comments:** Approve without comments. On behalf of the American College of Chest Physicians (ACCP) the ACCP Quality Improvement Committee (QIC) commends the National Quality Forum for clarifying the wording of this definition.	No action necessary
48	**Name:** Erin Graydon-Baker **Organization:** Partners Healthcare **Date Entered:** 2/2/2010 1:05:45 PM	**Comments:** We support the proposed criteria describing an SRE as an event that must be preventable, unambiguous and any of the following: adverse and or indicative of a problem in a healthcare facility's safety system and important for public credibility or public accountability. However, we strongly object to the definition of "serious". See comment 3 for details.	No action necessary
Commenter Information		**Term definition - Adverse**	**Steering Committee Response**
49	**Name:** Joyce Bruno Reitzner **Organization:** American College of Chest Physicians **Date Entered:** 1/26/2010 9:39:35 AM	**Comments:** Approve without comments.	No action necessary

50	**Name:** Michael Rapp **Organization:** Centers for Medicare and Medicaid Services **Date Entered:** 1/26/2010 4:51:46 PM	**Comments:** Removing the phrase "which may or may not have been preventable" from the definition of "adverse" seems to narrow the scope of events that could be reported as adverse, which goes against the rationale of the committee used to justify its removal.	The committee agreed the phrase "which may or may not have been preventable" was not inclusive of all the potential causes for error to occur.
51	**Name:** Lela Holden **Organization:** Massachusetts General Hospital **Date Entered:** 1/26/2010 5:36:39 PM	**Comments:** Agree and support the change in the definition---linking to preventability does inhibit reporting and wastes time discussing fine nuances and variations that do not contribute to identifying quality improvements.	No action necessary
52	**Name:** Catherine MacLean **Organization:** WellPoint, Inc. **Date Entered:** 2/2/2010 5:11:36 PM	**Comments:** The comments we have are about the definitions of serious and adverse. Are serious events a subset of adverse events? Please clarify the difference between serious and adverse. Is the main difference that adverse events result in unintended injury or illness, while serious events could be unintended or intended?	Steering Committee response can be found in the Steering Committee conference call summary under the "Proposed Modifications to the SRE Definition."
Commenter Information		**Term definition - Event**	**Steering Committee Response**
53	**Name:** Joyce Bruno Reitzner **Organization:** American College of Chest Physicians **Date Entered:** 1/26/2010 9:39:35 AM	**Comments:** Approve without comments.	No action necessary
Commenter Information		**Term definition – Preventable**	**Steering Committee Response**
54	**Name: J**ohn James **Organization:** PatientSafetyAmerica **Date Entered:** 1/12/2010 8:50:43 PM	**Comments:** Please clarify that a preventable event may be one due to an error of commission, an error of omission, or an error of communication. Errors of omission, although they may often be overlooked, are probably more common than errors of commission. For example, millions with heart failure died early because they did not get beta blockers during the years after the definitive 1982 study was published in	Important point; No action necessary

		the JAMA showing the life-saving ability of beta blockers. Errors of communication, for example failure in duty to warn, are also common and easily recognized. I lost a son because his doctors did not warn him not to run even though they had placed this warning in his medical record. He died soon afterward while running.	
55	**Name:** Joyce Bruno Reitzner **Organization:** American College of Chest Physicians **Date Entered:** 1/26/2010 9:39:35 AM	**Comments:** Approve without comments.	No action necessary
Commenter Information		**Term definition - Serious**	**Steering Committee Response**
56	**Name:** Joyce Bruno Reitzner **Organization:** American College of Chest Physicians **Date Entered:** 1/26/2010 9:40:21 AM	**Comments:** Approve with comments. On behalf of the American College of Chest Physicians (ACCP) the ACCP Quality Improvement Committee (QIC) appreciates the opportunity to comment on this definition. The QIC approves this revised definition with the following comments. The QIC felt that this definition lacked specificity, leaving room for ambiguity of interpretation. For example, would a patient who had a hematoma, as a result of a blood draw, which later got infected causing sepsis, be considered "serious?" Using the definition as written does not provide a clear answer. The QIC, therefore, recommends adding the word "significant" as a qualifier (…disability or loss of bodily function or "significant" risk thereof).	Important point; No action necessary due to subjective nature of term "significant"
57	**Name:** Michael Rapp **Organization:** Centers for Medicare and Medicaid Services **Date Entered:** 1/26/2010 4:51:46 PM	**Comments:** "Serious" as it is defined doesn't seem to include events such as leaving an instrument in a patient at the time of surgery as patients rarely die or lose a limb when they have to be re-operated on to remove a foreign body. Can the definition be changed to include the previous language "or, when referring to other than an adverse event, an event the occurrence of which is not trivial" to ensure that such events are remain included in the SRE list.	Important point; No action necessary due to subjective nature of terms – refer to other actions taken by committee
58	**Name:** Lela Holden **Organization:** Massachusetts General Hospital **Date Entered:** 1/26/2010 5:36:39 PM	**Comments:** Agree with the recommended change to eliminate the time frame and add "or risk thereof."	No action necessary

59	**Name:** Doug Bonacum **Organization:** Kaiser Permanente **Date Entered:** 1/27/2010 4:54:19 PM	**Comments:** The introduction of "can" and "or risk thereof" (1) introduces significant ambiguity in a definition that aims to be "unambiguous", (2) does not adequately recognize system attributes and team performance that stopped close calls from becoming an actual event, and (3) makes it more difficult for an organization to benchmark itself against others.	Steering Committee members agreed that each event would have to be carefully reviewed to determine whether "or risk thereof" is applicable to the specific event. The determination as to whether reporting of the "risk thereof" of an event is beneficial will be determined for each individual safety event. The definition of the term serious will be "*describes an event that can result in death or loss of a body part, disability or loss of bodily function.*"
60	**Name:** Erin Graydon-Baker **Organization:** Partners Healthcare **Date Entered:** 2/2/2010 1:05:45 PM	**Comments:** We approve of the terms "adverse", "event", "preventable" and "unambiguous" but strongly object to the definition of "serious". The proposed definition of serious as "describes an event that can result in death or loss of a body part, disability or loss of bodily function or risk thereof" implies that we report any near miss and all safety events that pose a "risk" of serious harm as an SRE. The term " risk thereof" lacks clarity and definition. If following this definition, we would have to report all falls for example, since any fall 'can' pose a risk for injury. We feel that this level of reporting does not add value in improving the conditions that have caused harm. We propose changing the work "can" to "did" and removing the reference to "risk thereof".	
61	**Name:** Linda Furkay **Organization:** WA State Department of Health **Date Entered:** 2/2/2010 5:50:29 PM	**Comments:** In order to broaden the SRE definition and encourage reporting of close calls or near miss events, the committee recommends to strike the time qualifiers from the definition and to include the term "or risk thereof". I agree with the plan to encourage reporting close calls or near misses, but striking the time qualifier from the definition will make it difficult to apply. We use the time qualifier frequently to decide if an event is serious enough to be reportable.	The definition of the term serious will be "*describes an event that can result in death or loss of a body part, disability or loss of bodily function.*"
Commenter Information		**Term definition - Unambiguous**	**Steering Committee Response**
62	**Name:** Joyce Bruno Reitzner **Organization:** American College of Chest Physicians **Date Entered:** 1/26/2010 9:40:22 AM	**Comments:** Approve without comments.	No action necessary

NEXT STEPS AND ADJOURN

The Steering Committee will next meet on May 3-4, 2010. At this point, existing SREs will be reviewed and proposed SREs received during the upcoming Call for Events will be evaluated.

ADJOURN.