Comments Received on the Serious Reportable Events in Healthcare-2011 Update Draft Report

Date of Comment	Comment Submitter Name	Comment Submitter Organization	On Behalf of Name	On Behalf of Organization	Question	Comment	Action
Dec 30 2010 4:55PM	Angela Franklin	American College of Emergency Physicians			1A. Surgery or other invasive procedure performed on the wrong site	ACEP believes the events related to incorrectly placed lines and tubes should include exclusions, or at least modifiers for "code" lines. In "codes" there is benefit from using a line or tube prior to using all techniques to check placement, and the risk / benefit ratio is different.'	The exclusion of emergent situations covers this circumstance.
Dec 22 2010 11:44AM	Rachel Groman	American Association of Neurological Surgeons			1A. Surgery or other invasive procedure performed on the wrong site	The AANS appreciates that this measure accounts for appropriate surgery at an adjacent level due to anatomic variability.	No action necessary.
Dec 29 2010 5:10PM	Carmella Bocchino	America's Health Insurance Plans			1A. Surgery or other invasive procedure performed on the wrong site	'AHIP supports the addition of four new SREs, as they monitor adverse patient outcomes, resulting from lack of appropriate care coordination and address new populations.'	No action necessary.

Dec 23 2010 5:19PM	Marie Kokol	Risk Management & Patient Safety Program			1C. Wrong surgical procedure or other invasive procedure performed on a patient	1C. This is the correct patient but the incorrect surgery, and this would be clearer if reworded "' performed on the correct patient."'	Believe language is clear and has been correctly interpreted over time as written.
Dec 29 2010 5:12PM	Carmella Bocchino	America's Health Insurance Plans			1C. Wrong surgical procedure or other invasive procedure performed on a patient	'To ensure safety of patients, it would be important to prevent wrong site and wrong procedure events even in emergent situations and suggest that at a minimum, these events should be tracked and reported to assess opportunities for improvement.'	Agree that such events would be useful to track internally for opportunity for improvement; do not believe stratification for public reporting is appropriate at this time.
Dec 23 2010 1:04PM	Cindy Barnard	Northwestern Memorial HealthCare			1D. Unintended retention of a foreign object in a patient after surgery or other invasive procedure	Changes are appropriate. Definition of "end of surgery" is extremely helpful. Note that sometimes surgical wound is left open for a period of time. It would seem that "end of surgery" is still the departure from the O.R., correct?'	Surgical wounds intentionally left open are not addressed by this event. The comment addresses definition of when surgery ends, for which no change is needed to allow for the intentional action described.

Dec 30 2010 12:58PM	Rabia Khan	Centers for Medicare and Medicaid Services	Michael Rapp	CMS	1D. Unintended retention of a foreign object in a patient after surgery or other invasive procedure	In regard to the definition of "End of Surgery," the CMS SCIP measures changed this element to "Anesthesia End Time," as it was determined this element was more readily available in the medical record (both electronic and paper based). Please consider using the same data element as current measures.'	The definition used in the SREs provides time for continued effort to locate foreign bodies including x-ray and encompasses procedures where anesthesia may not be used. Changing to anesthesia end time could have unintended consequences.
Dec 2 2010 3:14PM	Robert Gold	DCBA, Inc.			1D. Unintended retention of a foreign object in a patient after surgery or other invasive procedure	I appreciate the variation in the titleand the definition of foreign object to distinguish from (a) purposefully leaving an object and (b) objects that had not been introduced with the surgical procedure. The clarification of the intent of changing the definition of end of surgery and the new definition are delightful. Thank you all for understanding and getting it right.	No action necessary.

Dec 17 2010 10:42PM	VERNA GIBBS	NoThing Left Behind			1D. Unintended retention of a foreign object in a patient after surgery or other invasive procedure	Please reconsider changing the wording of this event to "unintended retention of a surgical item in a patient" instead of "foreign object". Retained foreign objects (RFO) include non-medical or surgical items that can be left in a patient after an operation. A retained surgical item (RSI) is a surgical patient safety event. A retained surgical item is less ambiguous than "foreign object" and provides clarity for the operation or procedure report and coding. The 2010 AORN recommended practices now refer to "retained surgical items". It is important for the NQF to change to "retained surgical item" so there will be a common language used in the medical and surgical literature which will aid in reporting, communication and case finding. It is very confusing to sort through articles reporting on retained foreign object cases which combine all types of objects left or found after or during operations. Currently 998.4 (foreign body accidentally left during a procedure) and E871.0 (foreign object left in body during procedure, surgical operation) do not clarify what kind of foreign object is being reported, when or in what case it was retained. Separate coding should be developed to distinguish between an RFO and an RSI.'	Steering Committee discussion centered around this event capturing any item introduced into the patient during surgery, regardless of whether it was a surgical item or a foreign object from the medical team since outcome of such retention could have deleterious effect regardless of type.

Dec 22 2010 1:17PM	Beth Honkomp	St. Cloud Hospital			1D. Unintended retention of a foreign object in a patient after surgery or other invasive procedure	'St. Cloud Hospital, St. Cloud, MN agrees with the definition of surgery or invasive procedure end presented within the definitions section (patient has been taken from the operating/procedure room).'	No action necessary.

Dec 23 2010 3:26PM	Nancy Levine	CDC			2A. Patient death or serious injury associated with the use of contaminated drugs, devices, or biologics provided by the healthcare setting	-under “event” -a. Patient death or, serious injury, or infection associated with the use of contaminated drugs, devices, or biologics provided by the healthcare setting - under “implementation guidance” suggest rewording as follows: Contaminants may be physical, chemical, or biological in nature. Not all contaminations can be seen with the naked eye or readily detected using generally available or more specialized testing mechanisms (e.g., cultures, nucleic acid testing, mass spectrometry, and tests that signal changes in pH or glucose levels). In some cases, contamination may simply be inferred (e.g., consider a syringe or needle contaminated once it has been used to administer medication to a patient by injection or via connection to a patient's intravenous infusion bag or administration set). - under implementation guidance, second bullet: “serious infection from contaminated drug or device used in surgery or an invasive procedure (e.g., a vial, needle, syringe, or scalpel).”	Infection meets the definition of "injury" if it leads to physical or mental damage that substantially limits one or more of the major life activities of an individual in the short term. It also includes if the infection results in a substantial change in the patient's long-term risk status. Implementation guidance has been modified to address comments.
Dec 23 2010 1:03PM	Cindy Barnard	Northwestern Memorial HealthCare			2A. Patient death or serious injury associated with	Changes are appropriate if event was detectable by the organization. Should explicitly exclude nondetectable contamination introduced prior to organization acquisition (eg contaminated implants or tissue).	The event is specific to use of contaminated items "provided by the healthcare setting." While a change in risk status for a period of 6 months is

					the use of contaminated drugs, devices, or biologics provided by the healthcare setting	The phrase "threat of disease that changes patient's risk status for life requiring monitoring not needed before the event" is unclear. Patient exposure to improperly cleaned instruments, for example, requires monitoring for several months but not for life. Is this included? Suggest clarification to something like "changes patient's risk status for six months or more." What does "serious" infection mean in the implementation guidance? Same criteria as "serious" injury? If the patient does not acquire an infection (ie not "death or serious injury"), it appears that the exposure is not considered a Serious Reportable Adverse Event. Unclear how events A and B are different with regard to a contaminated device, because implementation guidance for B includes "occurrences related to improper cleaning or maintenance of the device" - suggest this be clarified.'	significant, a change for life has been determined to be the appropriate starting point for introducing the concept of risk status change. "Serious" is defined in the glossary. Per Steering Committee discussion, the event is reportable when the potential changes risk status for life. Implementation guidance specific to cleaning relocated to 2A.

Dec 29 2010 5:51PM	Erin Graydon Baker	Partners HealthCare System, Inc.	Erin Graydon Baker	Partners Healthcare	2A. Patient death or serious injury associated with the use of contaminated drugs, devices, or biologics provided by the healthcare	Can you give examples that represent substantial change in the patient's long-term risk status? This seems vague.	Specification speaks to change that requires monitoring for life. Have clarified monitoring with addition of "medical".
Dec 29 2010 12:05PM	Margaret Reagan	Premier, Inc.			2A. Patient death or serious injury associated with the use of contaminated drugs, devices, or biologics provided by the healthcare setting	We would certainly agree that this is an important patient safety issue. However, as written, it does not appear to meet the NQF SRE criterion of being "clearly identifiable and measurable." It is rare to clearly link a patient's acquisition of viral infection to a specific contaminated drug, device, or biologic provided by the healthcare setting in an endemic situation. (This is quite different from large outbreak/clusters related to a common source). This approach requires first identifying the serious injury or death and then associating it with identifiable contamination. SREs should be rare, but investigation of single cases involving acquisition of disease are necessarily ill-defined-not able to be confirmed or refuted-given long incubation periods for viral infection. They are not easily associated with identifiable contamination. This may need to be reconsidered more definitively for an endemic situation	Event captures contaminations detected by the organization, or widespread contaminations upon recognition. Per Steering Committee discussion, this includes contaminated drugs, devices, and biologics, including those eventually recalled by the manufacturer. Addressed in previous comment.

						reconsidered more definitively for an endemic situation. Reporting of "the threat of disease that changes the patient's risk status for life" is fairly ill-defined. It is not clear whether this applies only to potential contamination within the healthcare institution or also if througha manufacturer or distributor (e.g., a recall of allograft tissue). This needs clarification. Unintended consequence - may discourage hospitals from aggressive follow-up of possible contamination events not clearly associated with subsequent infections.'	Appreciate the comment; would not expect that healthcare institutions would fail to follow up such events.

Dec 23 2010 1:00PM	Melanie Young	Society for Healthcare Epidemiology of America	Melanie Young	SHEA	2A. Patient death or serious injury associated with the use of contaminated drugs, devices, or biologics provided by the healthcare setting	SHEA agrees that this is an important patient safety issue. The Society is concerned as to whether this meets the NQF SRE criterion of being "clearly identifiable and measurable". It is a rare situation where a patient's acquisition of hepatitis, HIV or other infections can be clearly linked to a specific contaminated drug, device, or biologic provided by the healthcare setting except for very unusual large outbreaks that can be traced to a common source. Reporting of "the threat of disease that changes the patient's risk status for life" is ill-defined. Will this apply to possible contamination occurring within the healthcare institution as well as through a manufacturer or distributor (e.g., a recall of allograft tissue)? An unintended consequence might be that the requirement to report these events will discourage hospitals from aggressive follow-up of possible contamination events not clearly associated with subsequent infections.'	Addressed in previous comment.
Dec 30 2010 5:19PM	Denise Graham	Association for Professionals in Infection Control and Epidemiology	Denise Graham	APIC	2A. Patient death or serious injury associated with the use of contaminated drugs, devices, or biologics provided by the healthcare setting	APIC agrees that this is an important patient safety issue. However, as written, does it meet the NQF SRE criterion of being "clearly identifiable and measurable"? It is rare to clearly link a patient's acquisition of hepatitis, HIV, HCV etc. to a specific contaminated drug, device, or biologic provided by the healthcare setting in an endemic situation. This is quite different from large outbreaks such as reported by Perz et al. related to a cluster/large common source. This requires first identifying the serious injury/death and associating it with identifiable contamination. SREs should be rare and this certainly is, but investigation of single cases involving acquisition of disease are necessarily ill-defined given long incubation periods for viral infection. They are not easily associated with identifiable contamination. This may need to be reconsidered more definitively for an "endemic situation". Reporting of "the threat of disease that changes the patient's risk status for life" is fairly ill-defined. Does this apply to potential contamination with	Addressed in previous comment.

						fairly ill-defined. Does this apply to potential contamination with the healthcare institution as well as through a manufacturer or distributor (e.g., a recall of allograft tissue)? An unintended consequence might be that the requirement to report these events may be to discourage hospitals from aggressive follow-up of possible contamination events not clearly associated with subsequent infections.'	
Dec 30 2010 12:59PM	Rabia Khan	Centers for Medicare and Medicaid Services	Michael Rapp	CMS	2A. Patient death or serious injury associated with the use of contaminated drugs, devices, or biologics provided by the healthcare setting	'Patient death or serious injury associated with the use of contaminated drugs, devices, or biologics provided by the healthcare setting (Lines 330-331) may pose difficulty for abstraction, as many of these instances may not be evident for days or even months after the event takes place. For instance, patients undergoing a procedure in an ambulatory surgical center may show up at a hospital emergency department several months later with complaints of flu-like symptoms and jaundice. This may or may not be readily linked to the procedure. Also, patient behavior outside of the facility must also be taken into consideration.'	The language of the event is specific to provision of the contaminated item by the reporting institution. The significance of such events keeps it on the list. Attribution because of the potential abstraction difficulty, missed reporting due to distant discovery, and patient behavior concerns are real. The implied need to continue to refine events going forward is accepted.

Dec 23 2010 9:51AM	Jennifer Faerberg	Association of American Medical Colleges			2A. Patient death or serious injury associated with the use of contaminated drugs, devices, or biologics provided by the healthcare setting	The AAMC supports the definition for this event for those situations where the contamination can be detected by the instituiton. There should be an exclusion for those events where the contaminiation occurred outside of the institution and is not detectable.	The language of the event is specific to provision of the contaminated item by the reporting institution. If not detected, the event could not be reported.
Dec 29 2010 5:12PM	Carmella Bocchino	America's Health Insurance Plans			2A. Patient death or serious injury associated with the use of contaminated drugs, devices, or biologics provided by the healthcare setting	Patient death or serious injury associated with the use of contaminated drugs, devices, or biologics provided by the healthcare setting - Since the contamination could occur during manufacturing, packaging, transport, storage, or in the health care facility tracking the site of contamination would be important so that processes can be rectified at the right location to prevent future occurrences.'	Agreed. No action necessary.

Dec 23 2010 3:26PM	Nancy Levine	CDC			2B. Patient death or serious injury associated with the use or function of a device in patient care, in which the device is used or functions other than as intended	- under “additional specifications” – “Includes, but is not limited to, catheters, drains and other specialized tubes, infusion pumps, and ventilators.” Suggest rewording as “Includes, but is not limited to surgical equipment, ventilators, catheters, drains, intravenous tubing and other specialized tubes, infusion pumps, medication vials, syringes, and fingerstick lancing devices.’ - under “implementation guidance” – Add second bullet to read “instances in which harm results as a consequence of reuse of single use medications (i.e., single dose vials) or equipment that is intended for use only on individual patients (e.g., syringes)”	Additional Specifications modified to address non-medication related comments. Other SREs, 2A and 4A, address medication-related events.
Dec 3 2010 12:40PM	Kevin Kavanagh	Health Watch USA			2B. Patient death or serious injury associated with the use or function of a device in patient care, in which the device is used or functions other than as intended	First what a devise is needs to be defined. Is it a complex mechanical item or a simple tube such as an NG (Nasogastric) or ET (Endotracheal) Tube. It depends who defines it FDA vs Webster. Second, the example for subcategory B (misuse), just repeats the first subcategory A (Patient death or serious injury associated with the use of contaminated drugs, devices, or biologics provided by the healthcare setting.). Patient death or serious injury associated with the use or function of a device in patient care, in which the device is used or functions other than as intended. As in the previous event, failure to properly clean and maintain a device or misuse of a device that exposes a	Definition of device added to glossary. Suggested addition significantly expands the event and will be considered at next update. Addressed in previous comment.

						patient to disease or injury imposes a "serious injury" when it changes his or her risk status for life, requiring previously unneeded monitoring or treatment. This should be changed to Patient death or serious injury associated with the use or function of a device in patient care, in which the device is used or functions other than as intended. Improper placement, maintenance, or use of treatment tubes, catheters, devices or products that exposes a patient to disease or injury imposes a "serious injury" when it changes his or her risk status for life, requiring previously unneeded monitoring or treatment.'	

Dec 22 2010 11:48AM	Rachel Groman	American Association of Neurological Surgeons			2B. Patient death or serious injury associated with the use or function of a device in patient care, in which the device is used or functions other than as intended	We request clarification on appropriate device use. Is this meant to target devices used other than intended by implanting physician, other than directions specify, other than what the FDA has approved, or other than has been published in the literature? This measure may inapproriately target devices used for a patient's unique needs. For example, literature on lateral mass screws prepared by the manufacturer specify that they are to be used in the thoracic spine only and not in the cervical spine. The FDA hasn't approved screws in the cervical spine. Still, these screws are often effective/necessary in certain cervical spine cases. Many other spinal implants are used off label. As a result, nearly any complication in a posterior cervical fusion or any problem in a spine procedure where devices are used off label becomes a SRE based on use other than as intended. Furthermore, physicians should not be cited if a device is properly implanted, but later malfunctions and causes injury (e.g., baclifen pumps or vagus nerve stimulators). Also, many devices are implanted in children that have not been specifically trialed in that group because of difficulty testing in that population. This measure seems overly broad, and we request clarification.'	Per SC discussion, event is not intended to capture off label use of devices. The implementation guidance is intended to provide the clarification. The critical distinction that addresses the comment is that the outcome that triggers reporting is death or serious injury assocatied with the use or function of the device.

Dec 29 2010 5:54PM	Erin Graydon Baker	Partners HealthCare System, Inc.	Erin Graydon Baker	Partners Healthcare	2B. Patient death or serious injury associated with the use or function of a device in patient care, in which the device is used or functions other than as intended	Can you give examples that represent substantial change in the patient's long-term risk status? This seems vague.	The referenced event does not include a specification regarding change in risk status. Response to inclusion of risk status is addressed elsewhere.

Dec 23 2010 1:01PM	Melanie Young	Society for Healthcare Epidemiology of America			2B. Patient death or serious injury associated with the use or function of a device in patient care, in which the device is used or functions other than as intended	SHEA's major concern is whether this meets the NQF SRE criterion of being "clearly identifiable and measurable". It is a rare situation where a patient's acquisition of hepatitis, HIV or other infections can be clearly linked to failure to properly clean and maintain a device except for very unusual large outbreaks that can be traced to a common source. Reporting of "the threat of disease that changes the patient's risk status for life" is ill-defined. An unintended consequence might be that the requirement to report these events will discourage hospitals from aggressive follow-up of possible inadequate cleaning/disinfection practices not clearly associated with subsequent infections.'	Addressed in previous comment.

Dec 29 2010 9:33PM	Thomas James	Humana Inc.			2B. Patient death or serious injury associated with the use or function of a device in patient care, in which the device is used or functions other than as intended	'Humana appreciates the opportunity to comment on the Serious Reportable Events. We fully support the intention of this measure of patient death or serious injury associated with the us of a device other than as intended. We look forward t the enlargement of this concept to pharmaceuticals, therapies or services used in fashions other than as intended which lead to death or serious injury.'	No action necessary.

Dec 29 2010 12:11PM	Margaret Reagan	Premier, Inc.			2B. Patient death or serious injury associated with the use or function of a device in patient care, in which the device is used or functions other than as intended	Similarly, this language does not seem to meet the NQF SRE criterion of being "clearly identifiable and measurable." This is the same problem, linking a patient's acquisition of viral infection to failure to properly clean and maintain a device. That is, serious infection from a contaminated device used in surgery or an invasive procedure (eg, scalpel) would be very difficult to identify, as well as a contaminated vaccine or medication. This requires extensive investigation after multiple events-and to date such events were identified only as part of a cluster or large outbreak. Once again, endemic cases would be rare situations in which a patient's acquisition of viral hepatitis, HIV or other infections could not easily be linked to failure to properly clean and maintain a device. A RCA would be done if such an infection is acquired by a patient while in a given facility, but long incubation periods make just detectability difficult -much less definitively linked to a contaminated device. These cases are only identified as part of common source outbreaks. b) Again, reporting of "the threat of disease that changes the patient's risk status for life" is similarly ill-defined in this circumstance. Unintended consequence - may discourage hospitals from aggressive follow-up of possibleinadequate cleaning/disinfection practices not clearly associated with subsequent infections.'	Comments addressed in previous comment.

Dec 30 2010 5:22PM	Denise Graham	Association for Professionals in Infection Control and Epidemiology	Denise Graham	APIC	2B. Patient death or serious injury associated with the use or function of a device in patient care, in which the device is used or functions other than as intended	Does this meet the NQF SRE criterion of being "clearly identifiable and measurable"? This is the same problem of linking a patient's acquisition of hepatitis, HIV, HCV etc. to failure to properly clean and maintain a device unless part of a large outbreak. Reporting of "the threat of disease that changes the patient's risk status for life" is similarly ill-defined. An unintended consequence in this case may be that the requirement to report these events will discourage hospitals from aggressive follow-up of possible inadequate cleaning/disinfection practices not clearly associated with subsequent infections.'	Addressed in previous comment.
Dec 29 2010 5:13PM	Carmella Bocchino	America's Health Insurance Plans			2C. Patient death or serious injury associated with intravascular air embolism that occurs while being cared for in a healthcare setting	Patient death or serious injury associated with intravascular air embolism that occurs while being cared for in a healthcare setting - Embolism through an undetected patent foramen ovale (PFO) could only be eliminated by screening everyone having a procedure which could create excessive delays in other treatments and in cost. NQF should consider the presence of an unknown PFO as an exclusion.	The Steering Committee has recommended that an unknown PFO not be excluded since, while a rare occurrence, reporting could provide important learning opportunity.

Dec 29 2010 5:53PM	Erin Graydon Baker	Partners HealthCare System, Inc.	Erin Graydon Baker	Partners Healthcare	2C. Patient death or serious injury associated with intravascular air embolism that occurs while being cared for in a healthcare setting	Can you give examples that represent substantial change in the patient's long-term risk status? This seems vague.	Addressed in previous comment.
Dec 29 2010 10:57PM	Michael Phelan	Cleveland Clinic	Cleveland Clinic	Cleveland Clinic	3A. Discharge or release of a patient/resident of any age, who is unable to make decisions, to other than an authorized person	The specs include the examples of minors, newborns, adults with Alzheimer's and the measures was originally intended to apply just to minors. has the early definition been formally implemented and do we know the issues surrounding those events? Shouldn't we know that before broadening the scope? We would argue that the above examples have superior decision capacity compared to many other patients especially some geriatric, psychiatric and some emergency department(ED) patients. Most outpatients' visits and ED patients are discharged, the criteria/definitions used in making these determinations are important. More discrete criteria are needed for these definitions (measure) or there needs to be wide flexibility in making the determination and consideration of what level of documentation is acceptable to reflect this. Currently these issues (competency and authorized) are not documented in many medical records. Will there be some mandatory requirement to include this type of documentation. What will this competency documentation include? If these were a reportable event are we	Decision making capacity has been added to the glossary. For clarification, it is important to note that Implementation Guidance is not part of the specifications of events and is not endorsed. It is offered to assist potential reporters understanding of the events.

						documentation include? If these were a reportable event are we now going to have to do some sort of overall capacity determination at each patient visit? How will this apply for patients who have chronic functional psychoses? Is there any information or data about how large of a patient safety issue is this type of event?'	
Dec 20 2010 2:57PM	Rebecca Swain-Eng	American Academy of Neurology	Barney Stern	American Academy of Neurolgoy	3A. Discharge or release of a patient/resident of any age, who is unable to make decisions, to other than an authorized person	I have one comment. Regarding item 3A, how is the degree of cognitive incapacity defined? Is this an impression, a diagnosis, a score on the MMSE or MoCA, etc? Barney J. Stern, MD.'	A specific test is not recommended. Implementation guidance has been added to note the possibility of institution or other jurisdictional requirements.

Dec 29 2010 5:59PM	Erin Graydon Baker	Partners HealthCare System, Inc.	Erin Graydon Baker	Partners Healthcare	3A. Discharge or release of a patient/resident of any age, who is unable to make decisions, to other than an authorized person	Would the definition of authorized be more clear if stated as authorized means the guardian or other individual(s) (surrogate) having the generally recognized ability to consent on behalf of a minor or incapacitated individual, or person designated by the surrogate to release or consent for the patient? We think that operationalizing the legal recognition will be difficult.'	The definition was arrived at after considerable discussion. Replacing "legal" with "generally" is viewed as less clear.
Dec 31 2010 1:56PM	James Taylor, MD	Cleveland Clinic			3A. Discharge or release of a patient/resident of any age, who is unable to make decisions, to other than an authorized person	Request for further implementation guidance, as this event places an onerous burden on front office/reception staff, who are not equipped to conduct a rigorous discharge process in a very busy office seeing 50 or more patients daily. These burdens would be potentially greater in solo and small private practice settings.	Addressed in previous comment.

Dec 21 2010 11:51AM	Caitlin Connolly	American Geriatrics Society	Susie Sherman	The American Geriatrics Society (AGS)	3A. Discharge or release of a patient/resident of any age, who is unable to make decisions, to other than an authorized person	We would like this to be clearer. There are many people with impaired decision making capacity who have not yet been "measured," but who can and will continue to leave long term care facilities at their own will; this may result with injury.'	Addressed in previous comment.
Dec 23 2010 1:21PM	Linda Harvey	UPMC	Linda Harvey	UPMC	3A. Discharge or release of a patient/resident of any age, who is unable to make decisions, to other than an authorized person	Recommend not including at this time. Requesting additional specifications to clarify "unable to make decisions" (temporary/ permanent) vs competency of the patient along with definition of "authorized person". Requesting clarification on how each definition would be uniformly applied in each case.	Addressed in previous comment.

Dec 29 2010 5:13PM	Carmella Bocchino	America's Health Insurance Plans			3A. Discharge or release of a patient/resident of any age, who is unable to make decisions, to other than an authorized person	Discharge or release of a patient/resident of any age, who is unable to make decisions, to other than an authorized person - The definition of who is unable to make decisions is provided only through clear examples. There are those patients with early dementia, those who are not medically literate but capable of activities of daily living, and others for whom the determination of "unable to make decisions" needs to be clarified.'	Addressed in previous comment.
Dec 29 2010 10:57PM	Michael Phelan	Cleveland Clinic	Cleveland Clinic	Cleveland Clinic	3A. Discharge or release of a patient/resident of any age, who is unable to make decisions, to other than an authorized person	We strongly suggest clearly defining what one means by unable to make decisions (or lack of decision making ability) and authorized person. The definitions may need to include context and some better examples or even exclusions. These terms can change depending on the circumstances and what the patient is being asked to decide. Decision making capacity can possibly fluctuate in many medical conditions. This SRE category has been broaden and may have unintended consequences. How is "unable to make decisions" going to be actually defined and documented?	Addressed in previous comment.

Dec 30 2010 4:21PM	Patty Calver	Harborview Medical Center			3A. Discharge or release of a patient/resident of any age, who is unable to make decisions, to other than an authorized person	There is no "gold standard" for assessing decision-making capacity. Available decision-making assessment tools lack generalizability across context and patient populations; therefore, at this time, one standardized assessment tool is not available to fit all patients and all situations. Applying the local legal standard for competency would require assessments skills that are beyond the abilities of most medical personnel, since it requires that they be able to determine whether or not the patient's mental competence is "commensurate with the gravity of the decision (s)he may wish to make". In addition, decision-making capacity and competence are not static situations and can change over time (i.e. with appropriate medical treatment). How often and which patients should be assessed? Given the lack of any standardized approach for assessing decision-making capacity, and the complexity and heterogeneity of healthcare settings and patients, decision-making capacity in these situations would be extremely difficult to measure or prove.'	Addressed in previous comment.

Dec 30 2010 4:58PM	Angela Franklin	American College of Emergency Physicians			3A. Discharge or release of a patient/resident of any age, who is unable to make decisions, to other than an authorized person	ACEP recommends clarification of the term "unable to make decisions". For application in the ED setting, either more discrete criteria around this term, or flexibility in making the determination and the acceptable level of documentation may be needed. ACEP also urges clarification relating to the following questions: In practice, must decision making capacity be assessed for all patients? Must providers document decision making capacity for all discharged patients? How will the SRE apply for patients who have chronic functional psychoses, for example?'	Addressed in previous comment.

Dec 30 2010 4:58PM	Angela Franklin	American College of Emergency Physicians			3A. Discharge or release of a patient/resident of any age, who is unable to make decisions, to other than an authorized person	ACEP recommends clarification of the term "unable to make decisions". For application in the ED setting, either more discrete criteria around this term, or flexibility in making the determination and the acceptable level of documentation may be needed. ACEP also urges clarification relating to the following questions: In practice, must decision making capacity be assessed for all patients? Must providers document decision making capacity for all discharged patients? How will the SRE apply for patients who have chronic functional psychoses, for example?'	Addressed in previous comment.
Dec 2 2010 3:27PM	Robert Gold	DCBA, Inc.			3B. Patient death or serious injury associated with patient elopement (disappearance)	The definition of elopement is clear, however that is not the way personnel use that term. They will refer to patients/residents with clear mental capacity who disappear unannounced. Either the title should be specific about identifying elopement in patients with reduced mental capacity or some specification be placed to clarify that this is only reportable in patients with reduced mental capacity.'	Competent adults are explicitly excluded in the specifications for the event.

Dec 30 2010 4:52PM	Angela Franklin	American College of Emergency Physicians			3B. Patient death or serious injury associated with patient elopement (disappearance)	ACEP recommends an additional exclusion: patients with decision-making capacity who refuse to sign AMA forms, or otherwise elope'. ACEP also recommends clarification of the SRE so that elopement is reportable if: 1) an 'appropriate' evaluation was not done that showed the patient was at 'risk' (this needs to be defined) of elopement and 2) the patient had a chief complaint and findings on initial assessment consistent with 'risk of elopement and 3) 'appropriate' measures were not taken when identified as at risk of elopement'	Addressed in previous comment. How the event is operationalized is largely determined by the reporting institution. Implementation guidance has been added.
Dec 29 2010 11:04PM	Michael Phelan	Cleveland Clinic	Cleveland Clinic	Cleveland Clinic	3B. Patient death or serious injury associated with patient elopement (disappearance)	Perhaps use of the medical term adult with decison making capciaty rather than utilziztion of the legal term competnecy would be appropriate. Also while this measure is supposed to exclude patients who leave AMA or LWBS but does not exclude patients with decision-making capacity who refuse to sign AMA forms, or otherwise just elope, or walk out. These patients should be excluded as well.'	The exclusion covers the circumstances referenced.

Dec 21 2010 11:53AM	Caitlin Connolly	American Geriatrics Society	Susie Sherman	The American Geriatrics Society (AGS)	3B. Patient death or serious injury associated with patient elopement (disappearance)	Again, there needs to me more clarification around the definition of "competent," as the Draft Report states that this excludes competent adults who voluntarily leave. To reiterate the AGS's stance on 3A, there are many people with impaired decision making capacity who have not yet been "measured," but who can and will continue to leave long term care facilities at their own will; and this may result with injury.'	Addressed in previous comment.
Dec 23 2010 1:01PM	Cindy Barnard	Northwestern Memorial HealthCare			3B. Patient death or serious injury associated with patient elopement (disappearance)	Item B -suggest the word "competent" not be used (legal term). Instead, use "adult with decision-making capacity" (medical term). Possibly define such capacity or offer sources of guidance for definition.'	Addressed in previous comment.
Dec 29 2010 6:02PM	Erin Graydon Baker	Partners HealthCare System, Inc.	Erin Graydon Baker	Partners Healthcare	3B. Patient death or serious injury associated with patient elopement (disappearance)	Should we use the term adults with decision making capacity instead of competent?	Addressed in previous comment.

Dec 30 2010 1:16PM	Rabia Khan	Centers for Medicare and Medicaid Services	Michael Rapp	CMS	3B. Patient death or serious injury associated with patient elopement (disappearance)	In regard to Patient death or serious injury associated with patient elopement(Lines 374-376), consistent definitions of "elopement" or "disappearance" should be required in the specifications before any public reporting of this incident should take place.'	Addressed in previous comment. As noted in Appendix A introduction, definitions are part of the specifications of the events. Clarifying language has been added to the report.
Dec 23 2010 1:00PM	Cindy Barnard	Northwestern Memorial HealthCare			3C. Patient suicide, or attempted suicide, while being cared for in a healthcare setting	Suicide - (1) sometimes difficult to clarify a suicidal gesture vs. attempt. Suggest eliminating this loosening of the definition. (2) Note Joint Commission includes suicides within 72 hours after discharge from the organization. Recommend alignment.	Clarifying language has been added to the event.

Dec 29 2010 6:04PM	Erin Graydon Baker	Partners HealthCare System, Inc.	Erin Graydon Baker	Partners Healthcare	3C. Patient suicide, or attempted suicide, while being cared for in a healthcare setting	We agree with reporting any attempted suicide but would suggest that Psychiatry determine attempt.	Such a change could set an expectation that cannot be met in many institutions.
Dec 29 2010 11:08PM	Michael Phelan	Cleveland Clinic			3C. Patient suicide, or attempted suicide, while being cared for in a healthcare setting	Again the clarity of the defined elements of this metric and their appropriate exclusions will be critical. How is attempted suicide is going to be defined? How do we manage patients who have Axis II issues who allege suicide attempts when they learn they are going to be discharged? If not defined properly with some type of serious or significant injury associated with would this really be reportable as an attempted suicide? The same issue goes for borderline patients or patients slef harm themsleves ie who swallow sharp objects over and over again some time 2-3 times on the same visit. Often times there is really no indication to admit, there is no treatment. They are discharged but return some time later having repeated there behaviors. For a serious event these patients category should be explored further and categories and types of excluion outlined.'	Addressed in previous comment.

Dec 31 2010 1:56PM	James Taylor, MD	Cleveland Clinic			3C. Patient suicide, or attempted suicide, while being cared for in a healthcare setting	Request for further implementation guidance, as this event places an onerous burden on front office/reception staff, who are not equipped to conduct a rigorous discharge process in a very busy office seeing 50 or more patients daily. These burdens would be potentially greater in solo and small private practice settings.	Addressed in previous comment.
Dec 23 2010 5:26PM	Loriann DeMartini	department of Public Health			4A. 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	I would ask that the NQF reconsider the definition of a medication error to broaden its scope to capture events that occur through out the medication management continuum. A definition that achieves such a broad perspective is the one presented by the NCCMERP. Additionally I would ask for consideration of hypoglycemic events be added back into the NQF events. If this is not possible then consideration of the definition of medication error to be inclusive of those type of events. The implementation guidelines may address some of these issues. California statutorily adopted NQF SRE, the implementation guidelines are not included in the legislative language. As a public reporting requirement only the language of the SRE would apply and not the implementation guidelines. This in essence would fail to capture errors noted in the implementation guidelines (e.g. presence of contraindications, drug-drug interactions) and result in under reporting. I would encourage that this public reporting implementation issue be given consideration in the final adoption of the SRE language.'	NCCMERP definition is used. As noted in report, determination was made that individual examples of event types should be captured within SREs that capture the broader type. Implementation Guidance is intended to assist organizations in their implementation.

Dec 23 2010 1:00PM	Cindy Barnard	Northwestern Memorial HealthCare			4A. 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	Item A refers to contamination of medication containers - how is this separate from the product/device category above, which explicitly also refers to contaminated drugs? Includes safe injection practices - again, this is potentially confusing in connection with the "contamination" definitions noted above. Implementation guidance specifically notes high alert medications. Why? If the patient experiences death or serious injury the type of medication does not matter. Does the guidance imply that any incorrect dose administrations of high alert medications should be considered SRE even if there is not death or serious injury?'	Contamination deleted. Such events will be captured by 2A. Implementation guidance includes high alert medications as errors involving those meds are more likely to result in an adverse outcome. The guidance does not imply that other meds should be ignored or that any event involving the high alert meds should be reported, regardless of adverse outcome.

Dec 29 2010 12:14PM	Margaret Reagan	Premier, Inc.			4A. 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	'Item (d) is the same issue addressed above in the Product or Device Events. It too raises the same concern of endemic occurrences--the rare chance of detecting a viral infection event while clearly associating the event with improper use of single-dose/single-use and/or multi-dose medication vials. To date, these events have been detected only as part of large cluster or outbreak investigations.'	Addressed in previous comment. 2A. Specifically relates to use of comtaminated items. That element has been removed from 4A. Events for which an association is made should be reported.

Dec 17 2010 8:20AM	Steven Meisel	Fairview Health Services			4A. 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	'Clarify the definition of medication error. For example,does this include errors ofd omission? wrong administration technique? Prescribing errors?'	The definition, event description and additional specifications encompass the items questioned.

Dec 23 2010 5:24PM	Loriann DeMartini	department of Public Health			4A. 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	The definition of a medication error focuses on the administration phase of medication use continuum. Unfortunately this definition doesn't address the two most frequently cited phases of medication use that results in preventable harm; prescribing and monitoring. For example the prescribing of fentanyl transdermal patch to a patient without documented tolerance to opiates is frequently cited as a cause of preventable adverse outcomes resulting in, respiratory depression and death. In California, the identification of such a practice had contributed to preventable deaths and issuance of administrative penalties. Application of the NQF definition may not capture this type of event as the definition doesn't address the inappropriate prescribing of medications.'	The definition specifically includes prescribing and monitoring.

Dec 22 2010 11:50AM	Rachel Groman	American Association of Neurological Surgeons			4A. 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	'Medication errors are a serious problem and reporting such events is totally appropriate, but how this will be done and who will be responsible for reporting these events is not well delineated. Would an on-call neurosurgeon be held responsible for a Coumadin-associated sub-dural hematoma or other bleeds or for a seizure that results from fluctuating AED (antiepileptic drug) levels?'	Beyond the scope of the SRE listing. How events are reported is determined at the facility, state, or national level.

Dec 22 2010 12:42PM	Beth Honkomp	St. Cloud Hospital			4A. 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	'St. Cloud Hospital, St. Cloud, MN is wondering if this should include inappropriate monitoring of a patient after receiving a correct medication dose (insulin and sedation).'	The definition of medication error includes events related to monitoring.

Dec 23 2010 1:12PM	Melanie Young	Society for Healthcare Epidemiology of America	Melanie Young	SHEA	4A. 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	The last item d) improper use of single-dose/single-use and multi-dose medication vials and containers leading to death or serious injury as a result of contamination or dose adjustment problems under Table Appendix A pg A-9 is the same issue as addressed above in the Product or Device Events. It too raises the same concern of endemic occurrences--the rare chance of detecting a viral infection event and while clearly associating the event with improper use of single-dose/single-use and multi-dose medication vials. To date these events are detected as cluster or outbreaks.	Addressed in previous comment.

Dec 23 2010 5:25PM	Loriann DeMartini	department of Public Health			4A. 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	The deletion of the hypoglycemic event is one that NQF may consider reinstituting. Understandably, it can be viewed as a medication error and frequently is but a hypoglycemic event can occur that may not fit the NQF medication error definition. Administration of insulin to an individual whose dietary intake has changed. The medication may have been appropriate based on previous nutritional status but now precipitates a hypoglycemic event. Clearly medication related adverse events are significant cause of preventable morbidity and mortality. This was highlighted in the recently released OIG report on Adverse Events in Hospitals (November 2010). The executive summary extrapolated 15,000 deaths secondary to adverse events in a month. Approximately 44% are preventable. The most commonly cited cause for serious harm and temporary harm was medications with an occurrence rate of 31% and 42% respectively and 50% of these events were preventable. It should be noted that hypoglycemic events were noted as the second (temporary harm) and third (serious harm) most frequently cited outcome.'	Reinstatement of the hypoglycemia event is addressed in previous comment.

Dec 29 2010 9:48PM	Thomas James	Humana Inc.			4A. 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	Humana appreciates the opportunity to present comment. The definiton of reasonable differences in clinical judgment as describe in the measure (page 33) is realistic but makes the measure more difficult to score. Implicit in this measure is the need to ensure adequate capture of medications the patient is currently taking and drug allergies so as to avoid drug interactions or allergic reactions to medications. Without such information, the error is one of inadequate assessment by history of drugs used or drug allergies. However, there will not always be a competent patient to provide such information. Redundant electronic solutions are not yet universal but will be necessary to fully satisfy this measure.'	The need to capture medications the patient is currently taken is captured in the implementation guidance for this event. It is acknowledged that this is a complex issue.
Dec 30 2010 1:18PM	Rabia Khan	Centers for Medicare and Medicaid Services	Michael Rapp	CMS	4A. Patient death or serious injury associated with a medication error (e.g., errors involving the wrong drug, wrong dose,	Strongly support Patient death or serious injury associated with a medication error (Line 389) .	No action necessary.

Dec 30 2010 5:28PM	Denise Graham	Association for Professionals in Infection Control and Epidemiology	Denise Graham	APIC	4A. 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	The high rate of medication errors resulting in injury and death makes this event important to endorse again. With this update, two significant additions to the additional specifications have been made. One is the administration of a medication for which there is serious contraindication. The other relates to failure to observe safe injection practices (e.g., the improper use of single dose/single use and multi-dose containers leading to injury or death as a result of contamination or dosages). Table Appendix A page A-9 "injury associated with d) improper use of single-dose/single-use and contamination or dose adjustment problems." Item d is the same issue as addressed in the Product or Device Events. It raises the same concern of endemic occurrences - the rare chance of detecting a viral infection event and while clearly associating the even with improper use of single-dose/single -use and multi-dose medication vials. To date these events are detected as clusters or outbreaks.'	Addressed in previous comment.
Dec 21 2010 1:55PM	Bridget Griffin	Mayo Clinic	Timothy Morgenthaler, MD	Mayo Clinic	4B. Patient death or serious injury associated with unsafe administration of blood products	Mayo Clinic recommends: "Unsafe" is ambiguous. Either add the definition from the "Implementation Guidance" to additional specifications or add to the event category itself the specification that "unsafe administration includes, but is not limited to hemolytic reactions and administering a blood or blood types to wrong patient, wrong type of blood, or blood or blood products that have been improperly stored or handled."'	Statement moved from Implementation Guidance to Additional Specifications

Dec 23 2010 3:26PM	Nancy Levine	CDC			4B. Patient death or serious injury associated with unsafe administration of blood products	- under “event” -- a. Patient death or, serious injury, or infection associated with the use of contaminated drugs, devices, or biologics provided by the healthcare setting - Consider adding or expanding “event” to include “Patient death, serious injury, or infection associated with unsafe screening, harvesting, or implantation of an organ or tissue transplant” -This event should be broadened to include transfusion-associated adverse events beyond hemolytic reactions. Specifically, transfusion-transmitted infections should be included. This would not be included under a cause “not detectable by ABO/HLA matching”. There also are obvious gaps in organ and tissue safety, which do not appear to be addressed at all.	Transfusion-associated infections added to specifications. Organ and tissue safety will be included on list of potential events for the next update.
Dec 22 2010 12:49PM	Beth Honkomp	St. Cloud Hospital			4B. Patient death or serious injury associated with unsafe administration of blood products	'St. Cloud Hospital, St. Cloud, MN agrees with the comment made by Mayo Clinic. More specificity is needed.'	Addressed in previous comment.

Dec 23 2010 5:22PM	Marie Kokol	Risk Management & Patient Safety Program			4B. Patient death or serious injury associated with unsafe administration of blood products	I agree with Mayo on this.	Addressed in previous comment.
Dec 29 2010 4:47PM	Erin Graydon Baker	Partners HealthCare System, Inc.	Erin Graydon Baker	Partners Healthcare	4B. Patient death or serious injury associated with unsafe administration of blood products	Add the description in the implementation guidelines to the SRE definition. This would make the SRE definition clear without going to the implementation guide.	Addressed in previous comment.
Dec 29 2010 4:50PM	Erin Graydon Baker	Partners HealthCare System, Inc.	Erin Graydon Baker	Partners Healthcare	4C. Maternal death or serious injury associated with labor or delivery in a low-risk pregnancy while being cared for in a healthcare setting	'In cases where the patient is admitted to a different facility other than the birth facility, the death or serious injury should be verified by both facilities'	Language has been added to the report to encourage communication between facilities across the events, where relevant.

Dec 23 2010 4:19PM	Alyssa Keefe	California Hospital Association			4C. Maternal death or serious injury associated with labor or delivery in a low-risk pregnancy while being cared for in a healthcare setting	Further, CHA recommends that NQF define a 'low-risk' pregnancy. In reviewing the literature CHA suggests a low risk pregnancy may be defined as any pregnancy that is a single birth, with the infant in the vertex position, of a mother who received regular prenatal care beginning in the first trimester. Low risk pregnancies exclude women who have medical conditions, have had multiple births, caesarean sections delivery, previous pregnancy complications, previous small birth weight infats or large birth weight infants, the mother has had a problem delivery or a problem pregnancy, the mother uses recreational drugs, smokes, uses alcohol, is malnourished or is obese.	Low-risk is included in glossary.
Dec 15 2010 2:43PM	Janet Leiker	American Academy of Family Physicians			4C. Maternal death or serious injury associated with labor or delivery in a low-risk pregnancy while being cared for in a healthcare setting	Please provide guidance or an example of how low risk is determined.	Addressed in previous comment.

Dec 17 2010 8:35AM	Steven Meisel	Fairview Health Services			4C. Maternal death or serious injury associated with labor or delivery in a low-risk pregnancy while being cared for in a healthcare setting	Define the term low risk pregnancy	Addressed in previous comment.
Dec 21 2010 1:57PM	Bridget Griffin	Mayo Clinic	Timothy Morgenthaler, MD	Mayo Clinic	4C. Maternal death or serious injury associated with labor or delivery in a low-risk pregnancy while being cared for in a healthcare setting	Mayo Clinic recommends providing a cross reference to a standard definition of low-risk pregnancy.	Addressed in previous comment.

Dec 23 2010 5:23PM	Marie Kokol	Risk Management & Patient Safety Program			4C. Maternal death or serious injury associated with labor or delivery in a low-risk pregnancy while being cared for in a healthcare setting	Agree with comments about the definition of what a low-risk pregnancy is.	Addressed in previous comment.
Dec 29 2010 9:53PM	Thomas James	Humana Inc.			4C. Maternal death or serious injury associated with labor or delivery in a low-risk pregnancy while being cared for in a healthcare setting	Humana supports the recommendations of the Minnesota Hospital Association. A low risk pregnancy does not preclude a high risk infant because of lethal congenital anomalies	Addressed in previous comment.

Dec 30 2010 4:53PM	Angela Franklin	American College of Emergency Physicians			4C. Maternal death or serious injury associated with labor or delivery in a low-risk pregnancy while being cared for in a healthcare setting	ACEP urges the 'healthcare setting' should be clearly defined to exclude locations/settings that present additional risks for unfavorable outcomes, e.g. hospital waiting room, or hallway of the Emergency Department.'	Healthcare setting is defined. Event description includes the expectation of being under care.
Dec 13 2010 10:06AM	Julie Apold	Minnesota Hospital Association	Julie Apold	Minnesota Hospital Association	4D. Death or serious injury of a neonate associated with labor or delivery in a low-risk pregnancy while being cared for in a healthcare setting	Recommendation: 1) Include "full-term" neonate; 2) Exclude neonates with "congenital birth defects"; and 3) clarify "low-risk pregnancy".	The reportable event is death or serious injury associated with labor and delivery thus gestational age and presence of birth defects are unrelated.

Dec 29 2010 4:55PM	Erin Graydon Baker	Partners HealthCare System, Inc.	Erin Graydon Baker	Partners Healthcare	4D. Death or serious injury of a neonate associated with labor or delivery in a low-risk pregnancy while being cared for in a healthcare setting	Would this also apply to the midwife delivery of an infant that needs an unplanned admission within 24 hours of delivery?	While the setting in which the SRE applies has been specifically identified, the report notes that they may be relevant in other settings. This event and additional specifications have been modified to provide for reporting of death or serious injury associated with labor or delivery outside the healthcare setting.

Dec 15 2010 2:44PM	Janet Leiker	American Academy of Family Physicians	Janet Leiker	American Academy of Family Physicians	4D. Death or serious injury of a neonate associated with labor or delivery in a low-risk pregnancy while being cared for in a healthcare setting	Please provide guidance or an example of how low risk is determined.	Addressed in previous comment.
Dec 17 2010 8:33AM	Steven Meisel	Fairview Health Services			4D. Death or serious injury of a neonate associated with labor or delivery in a low-risk pregnancy while being cared for in a healthcare setting	1)This should only include "full-term" neonates; 2) Exclude neonates with "congenital birth defects"; and 3) define"low-risk pregnancy".	Addressed in previous comment.

Dec 21 2010 2:03PM	Bridget Griffin	Mayo Clinic	Timothy Morgenthaler, MD	Mayo Clinic	4D. Death or serious injury of a neonate associated with labor or delivery in a low-risk pregnancy while being cared for in a healthcare setting	The Minnesota Hospital Association recommends: 1) Include "full-term" neonate; 2) Exclude neonates with "congenital birth defects"; and 3) clarify "low-risk pregnancy". Mayo Clnic supports this recommendation.	Addressed in previous comment.
Dec 22 2010 12:33PM	Beth Honkomp	St. Cloud Hospital			4D. Death or serious injury of a neonate associated with labor or delivery in a low-risk pregnancy while being cared for in a healthcare setting	The Minnesota Hospital Association recommends: 1) Include "full-term" neonate; 2) Exclude neonates with "congenital birth defects"; and 3) clarify "low-risk pregnancy". St. Cloud Hospital, St. Cloud, MN supports these clarifications.'	Addressed in previous comment.

Dec 23 2010 4:08PM	Tanya Alteras	National Partnership for Women & Families	Tanya Alteras	Consumer-Purchaser Disclosure Project	4D. Death or serious injury of a neonate associated with labor or delivery in a low-risk pregnancy while being cared for in a healthcare setting	The Consumer-Purchaser Disclosure Project is very supportive of this new measure. Maternity and perinatal care makes up a significant percentage of spending in the health care system. We believe that more attention must be paid to the preventable, adverse, serious reportable events that occur in this segment of the patient population, in order to provide adequate accountability and patient safety protections to maternity patients'	No action necessary.
Dec 23 2010 5:24PM	Marie Kokol	Risk Management & Patient Safety Program			4D. Death or serious injury of a neonate associated with labor or delivery in a low-risk pregnancy while being cared for in a healthcare setting	Agree with the comments by Minesota Hospital Association.	No action necessary.

Dec 30 2010 4:53PM	Angela Franklin	American College of Emergency Physicians			4D. Death or serious injury of a neonate associated with labor or delivery in a low-risk pregnancy while being cared for in a healthcare setting	As above, ACEP urges the 'healthcare setting' should be clearly defined to exclude locations/settings that present additional risks for unfavorable outcomes, e.g. hospital waiting room, or hallway of the Emergency Department.'	Addressed in previous comment.

Dec 23 2010 4:10PM	Maureen Dailey	American Nurses Association	Maureen Dailey	American Nurses Association	4E. Patient death or serious injury associated with a fall during or after being cared for and prior to leaving the grounds of a healthcare setting	The American Nurses Association (ANA) respectfully suggests revision to Item E., line 412, to include a "special consideration" clause for assessment and management of falls and injury in the elderly (i.e., 65 years old) that adopts the assumption that all falls in the elderly are potentially serious and injury may be delayed (e.g., subdural hematomas). Background: Falls are the number one cause of unintentional death in the elderly 85 years and older. There is sufficient evidence indicating that mild injuries associated with falls among the elderly have grave consequences. In and of itself, the acceleration force on the brain when an older person falls, can result in a delayed-onset subdural hemorrhage, even when an older person does not actually strike his/her head (Quigley, 2009). Reference: Quigley P. (2009). Prevention of fall-related injuries: a clinical research agenda 2009-2014. J Rehabil Res Dev, 46(8),vii-xii.'	The comment is appreciated; however, the event deals specifically with the outcome of death or serious injury regardless of age or time lapse from event to outcome.

Dec 13 2010 10:09AM	Julie Apold	Minnesota Hospital Association	Julie Apold	Minnesota Hospital Association	4E. Patient death or serious injury associated with a fall during or after being cared for and prior to leaving the grounds of a healthcare setting	Recommendation: Delete "prior to leaving the grounds of a healthcare setting." Rationale: We do not believe that this event is intended to capture environmental incidents outside of the hospital itself. We have spent considerable time, through the review of reported cases, defining when someone becomes a patient and is no longer a patient and have developed the following definition which has worked well: *A person becomes a patient at the point that they are being "cared for" in the facility. Being "cared for" begins when they are first engaged by a member of the care team, e.g. assessment by the triage nurse in the E.D., walking with the phlebotomist to the lab for a lab draw. *A patient is no longer considered a patient at the point that they are no longer under the care of a member of the care team, e.g. the nursing assistant has safely assisted the patient to the car from an inpatient stay; the ambulating patient that does not need assistance leaves the radiology department following an outpatient test.'	Event has been modified to exclude reference to falls after care mirroring language of the 2006 update. Coupled with the clarifying language added to definition of patient, the intent should be clear.

Dec 30 2010 4:54PM	Angela Franklin	American College of Emergency Physicians			4E. Patient death or serious injury associated with a fall during or after being cared for and prior to leaving the grounds of a healthcare setting	ACEP recommends that the SRE more clearly define "patient" e.g, if a patient's visitor falls, hits his head and ultimately dies on the grounds while being treated, is this event reportable? He is a patient cared for at the hospital and he did have a fall and serious injury, but when he fell he was a visitor. Currently the Glossary defines "patient" as "a person who is a recipient of healthcare." ACEP also recommends clarification of the SRE so that fall is reportable if: 1) an 'appropriate' assessment was not done to determine whether patient or visitors were 'at risk of fall' (also defined) and 2) the patient or visitors had a chief complaint and findings on initial assessment that were consistent with a 'risk of fall' and 3) 'appropriate' measures were not taken when patient/visitors were identified as 'at risk of fall'.'	Clarification made in glossary and with implementation guidance for the SRE.

Dec 23 2010 12:59PM	Cindy Barnard	Northwestern Memorial HealthCare			4E. Patient death or serious injury associated with a fall during or after being cared for and prior to leaving the grounds of a healthcare setting	'Expansion of fall definition will be challenging. If the patient decides to linger on campus, the organization may not be aware and certainly does not have control of protecting the patient from a fall. Recommend returning to the prior definition, in which the relevant period concludes at discharge.'	Addressed in previous comment.

Dec 20 2010 9:40AM	Steven Meisel	Fairview Health Services			4E. Patient death or serious injury associated with a fall during or after being cared for and prior to leaving the grounds of a healthcare setting	This goes beyond the scope of what should be included as a serious reportable event. Such events should apply to the process of medical care delivery. The new scope sets up some preposterous scenarios, such as the otherwise healthy patient getting into or out of his car in the parking ramp and while doing so, trips. Or someone gets bumped by a baby stroller. Such falls do not count for NDNQI so should not be added here. It is preferable to narrow the scope to the end of care, which can be defined as when she is no longer under the care of a member of the care team.'	Addressed in previous comment.
Dec 21 2010 2:13PM	Bridget Griffin	Mayo Clinic	Timothy Morgenthaler, MD	Mayo Clinic	4E. Patient death or serious injury associated with a fall during or after being cared for and prior to leaving the grounds of a healthcare setting	Mayo Clinic supports the recommendation of the American and Minnesota Hospital Associations.	Addressed in previous comment.

Dec 21 2010 11:06AM	Beth Feldpush	American Hospital Association	Nancy Foster	American Hospital Association	4E. Patient death or serious injury associated with a fall during or after being cared for and prior to leaving the grounds of a healthcare setting	We suggest that the Steering Committee narrow the time period included in this event to the time that a patient is receiving care from the hospital or provider. This would appropriately remove from the definition events that are unrelated to the care process, such as if a patient were to trip and fall while walking to or from the hospital parking lot. We suggest that the Steering Committee use the following definitions. These have been developed and implemented in the state of Minnesota, a leader in the reporting of serious adverse events: "A person becomes a patient at the point that they are being "cared for" in the facility. Being "cared for" begins when they are first engaged by a member of the care team, e.g. assessment by the triage nurse in the E.D., walking with the phlebotomist to the lab for a lab draw. A patient is no longer considered a patient at the point that they	Addressed in previous comment.

Dec 22 2010 12:53PM	Beth Honkomp	St. Cloud Hospital			4E. Patient death or serious injury associated with a fall during or after being cared for and prior to leaving the grounds of a healthcare setting	St. Cloud Hospital, St. Cloud, MN agrees with the position of the Minnesota Hospital Association. Delete "prior to leaving the grounds of a healthcare setting." *A person becomes a patient at the point that they are being "cared for" in the facility. Being "cared for" begins when they are first engaged by a member of the care team, e.g. assessment by the triage nurse in the E.D., walking with the phlebotomist to the lab for a lab draw. *A patient is no longer considered a patient at the point that they are no longer under the care of a member of the care team, e.g. the nursing assistant has safely assisted the patient to the car from an inpatient stay; the ambulating patient that does not need assistance leaves the radiology department following an outpatient test.'	Addressed in previous comment.

Dec 21 2010 11:54AM	Caitlin Connolly	American Geriatrics Society			4E. Patient death or serious injury associated with a fall during or after being cared for and prior to leaving the grounds of a healthcare setting	We are concerned that making death as a result of a fall, a never event, may put the focus on keeping patients at risk from ever getting out of bed unless they are with a physical therapist, and thus, counterproductive. On the other hand, evidence suggests that falls and death from falls are likely to actually increase as a result of restraint use and this will result in poor quality of care. However, by the time the data tell us this, fall outcomes may actually have worsened. However, at this time, AGS supports this measure but strongly suggests a re-evaluation in one to two years to increase our understanding of falls and their consequences in acute care.'	Event will be re-evaluated at the next update of the SRE listing.

Dec 23 2010 5:49PM	Marie Kokol	Risk Management & Patient Safety Program			4E. Patient death or serious injury associated with a fall during or after being cared for and prior to leaving the grounds of a healthcare setting	If a patient in a hospital or a resident in a nursing home, has been assessed with the fall assessment tool the facility chose, and was not at risk, then there must be an assumption the patient/resident is independent. It is necessary for the facility staff to reevaluate the patient/resident at certain time intervals, if vital signs change, if new medication is added , or if the patient/resident has said he/she is dizzy. If none of these have occurred and the patient/resident is out of bed and falls, it should be reportable only if there was something the facility did that resulted in the patient/resident's fall or if there was something the facility staff should have done that would have prevented patient/resident's fall. Reporting a fall should be based on the issue of control or prevention, not just that a fall occurred - with a bad outcome so the facility is at fault. If there is a plan of care for a patient/resident assessed as a risk for falling, then it is a question of documentation. If the plan of care is followed and documented, the fall might not be reportable, depending on the documentation in the medical record. I think the emphasis should be placed on what was being done to prevent falls for the patient, if everything was being done, then maybe the fall was an unpreventable fall.'	In spite of the available processes identified in the comment, falls with serious injury and death continue to occur; reporting is intended to focus attention on the events for learning and improvement.

Dec 23 2010 9:36AM	Jennifer Faerberg	Association of American Medical Colleges			4E. Patient death or serious injury associated with a fall during or after being cared for and prior to leaving the grounds of a healthcare setting	The AAMC agrees with the previous commenters that the definition of falls needs to be revised to ensure only those events related to the delivery of care services are included.	Addressed in previous comment.
Dec 29 2010 5:05PM	Erin Graydon Baker	Partners HealthCare System, Inc.	Erin Graydon Baker	Partners Healthcare	4E. Patient death or serious injury associated with a fall during or after being cared for and prior to leaving the grounds of a healthcare setting	Good Clarification- We agree with the recategorization of Falls to Care Management	No action necessary.

Dec 21 2010 2:28PM	Bridget Griffin	Mayo Clinic	Timothy Morgenthaler, MD	Mayo Clinic	4F. Any Stage 3, Stage 4, and unstageable pressure ulcers acquired after admission/presentation to a healthcare setting	Mayo Clinic recommends removing unstageable pressure ulcers from the list.	Based on the NPUAP definition of "unstageable pressure ulcer" as either Stage 3 or Stage 4, it is appropriate that they remain.
Dec 23 2010 4:16PM	Maureen Dailey	American Nurses Association	Maureen Dailey	American Nurses Association	4F. Any Stage 3, Stage 4, and unstageable pressure ulcers acquired after admission/presentation to a healthcare setting	'The American Nurses Association (ANA) respectfully recommends the definition of unstageable pressure ulcer (page 47) be revised to align with the exact wording of the National Pressure Ulcer Advisory Panel and the European Pressure Ulcer Advisory Panel (NPUAP-EPUAP, 2009). Reference: National Pressure Ulcer Advisory Panel and European Pressure Ulcer Advisory Panel (NPUAP-EPUAP). (2009). Prevention and treatment of pressure ulcers: Clinical practice guideline. Washington DC: National Pressure Ulcer Advisory Panel. Accessed at www.npuap.org.'	Definition is aligned.

Dec 29 2010 5:02PM	Erin Graydon Baker	Partners HealthCare System, Inc.	Erin Graydon Baker	Partners Healthcare	4F. Any Stage 3, Stage 4, and unstageable pressure ulcers acquired after admission/presentation to a healthcare setting	We recommend that the definition of unstageable pressure ulcer should be revised to align with the National Pressure Ulcer Advisory Panel (NPUAP)definition. We would also delete the end phrase as present on admission/presentation as described on the exclusion criteria	Addressed in previous comment.
Dec 21 2010 11:54AM	Caitlin Connolly	American Geriatrics Society			4F. Any Stage 3, Stage 4, and unstageable pressure ulcers acquired after admission/presentation to a healthcare setting	The AGS supports this measure.	No action necessary.

Dec 22 2010 12:58PM	Beth Honkomp	St. Cloud Hospital			4F. Any Stage 3, Stage 4, and unstageable pressure ulcers acquired after admission/presentation to a healthcare setting	'St. Cloud Hospital, St. Cloud, MN suggests eliminating those ulcers that are a result of trauma prior to hospitalization and the skin breaks after admission. We recognize this may be difficult to determine, however, believe a skin care specialist would be able to evaluate and assess this.'	As written in the additional specifications, Stage 2 pressure ulcers and areas of deep tissue injury that are documented upon admission are excluded from this event.
Dec 29 2010 11:21PM	Michael Phelan	Cleveland Clinic			4F. Any Stage 3, Stage 4, and unstageable pressure ulcers acquired after admission/presentation to a healthcare setting	Outside of the hospital setting is this truly a serious event that is occurring with such frequency that we have to broaden it scope and definition to capture and report it? How often is it occurring in setting outside the hospital/nursing home/home care setting? Many patients don't undress completely for outpatient visits. Could it be better defined to be more specific to identify at risk patient populations. The issue is that vast majority of outpatient surgery is short in duration and should this really apply to every patient in that setting?	This event likely would be rare in the outpatient/office-based surgery centers. However, when it occurs, it should be reported.

Dec 31 2010 1:56PM	James Taylor, MD	Cleveland Clinic			4F. Any Stage 3, Stage 4, and unstageable pressure ulcers acquired after admission/presentation to a healthcare setting	This event should not apply to physician offices because of the short duration of visits. Clearly it should apply to outpatient surgery centers and to nursing homes. In considering this recommendation I spoke with a member of the NPUAP, a plastic surgeon and wound care nurses.	The event is not specified as applicable in ambulatory practice settings/office-based practices. No action necessary.

Dec 20 2010 9:44AM	Steven Meisel	Fairview Health Services			4H. Death or serious injury resulting from the irretrievable loss of a biological specimen	The term irretrievable should be changed to irreplaceable; if a 2nd specimen can be obtained, the patient's needs are met and the consequences will be minor. However, the consequences of an irreplaceable loss will be difficult to determine and will be subject to speculation. Further, such consequences may not be known for years in the future.'	Event modified to include "irreplaceable".

Dec 13 2010 10:14AM	Julie Apold	Minnesota Hospital Association	Julie Apold	Minnesota Hospital Association	4H. Death or serious injury resulting from the irretrievable loss of a biological specimen	Recommendation: Change to "Irretrievable loss of a biological specimen that significantly alters the patient's course of treatment". Rationale: It would be very difficult to determine death or serious disability resulting from the specimen loss.	Additional Specifications include this concept.
Dec 17 2010 10:04AM	Julie Apold	Minnesota Hospital Association	Rebecca Schierman	Minnesota Alliance for Patient Safety	4H. Death or serious injury resulting from the irretrievable loss of a biological specimen	Recommendation: Change to: 1) "Irreplaceable loss of a biological specimen" or; 2) "Irreplaceable loss of a biological specimen that significantly affects the patient's course of treatment". Rationale: A patient outcome after the loss of a specimen that cannot be replaced may be difficult to associate with the loss of the specimen and the effect may not be determined for months or years. If the loss of the specimen that cannot be replaced in itself is a rare event than adding the outcome qualifier may not be necessary.	Addressed in previous comment.

Dec 17 2010 10:17AM	Julie Apold	Minnesota Hospital Association			4H. Death or serious injury resulting from the irretrievable loss of a biological specimen	Revised Comment: Recommend changing to: 1) "Irreplaceable loss of a biological specimen" or; 2) "Irreplaceable loss of a biological specimen that significantly affects the patient's course of treatment".	Addressed in previous comment.
Dec 22 2010 12:21PM	Beth Honkomp	St. Cloud Hospital			4H. Death or serious injury resulting from the irretrievable loss of a biological specimen	'A group of three of us from the St. Cloud Hospital, St. Cloud, MN agree with the comments made by Julie Apold and Steve Meisel. Replace irretrievable with irreplaceable.'	Addressed in previous comment.
Dec 23 2010 9:27AM	Jennifer Faerberg	Association of American Medical Colleges			4H. Death or serious injury resulting from the irretrievable loss of a biological specimen	'The Association of American Medical Colleges fully supports the prior comments to add irreplaceable to the definition. If a specimen could be obtained a second time, this becomes a non-event.'	Addressed in previous comment.

Dec 23 2010 12:58PM	Cindy Barnard	Northwestern Memorial HealthCare			4H. Death or serious injury resulting from the irretrievable loss of a biological specimen	Specimen event: This is not worded properly. Should be "irretrievable loss of an irreplaceable biological specimen." The additional specifications imply this but it should be explicit. Note that it can be difficult to associate progression of disease, death, or serious injury with such loss. Also note comments above regarding lack of clarity in "changes the patient's risk status for life, requiring monitoring not needed before the event."'	Addressed in previous comment.
Dec 29 2010 10:00PM	Thomas James	Humana Inc.			4H. Death or serious injury resulting from the irretrievable loss of a biological specimen	Humana fully supports the comments on use of the word irreplaceable The accountability for ensuring no loss of specimen becomes less clear when non-medical delivery systems transfer specimens from one institution to another.	Addressed in previous comment.
Dec 30 2010 9:32AM	Erin Graydon Baker	Partners HealthCare System, Inc.	Erin Graydon Baker	Partners Healthcare	4H. Death or serious injury resulting from the irretrievable loss of a biological specimen	This should also include events where the specimen as lost and the patient refused a second procedure to obtain a new sample. We understand that death or injury may not be apparent for years. It may be difficult to connect the death or injury to the event in some cases.	Change addresses the concept of irreplaceable.

Dec 13 2010 10:15AM	Julie Apold	Minnesota Hospital Association	Julie Apold	Minnesota Hospital Association	4I. Death or serious injury resulting from failure to follow up or communicate clinical information	Recommendation: Do not add this event. Rationale: This event would be extremely difficult to operationalize - what constitutes "failure to follow up or communicate"; what is included as "clinical information", e.g. is the intent to capture communication of lab tests, pathology results, abnormal vitals reports, patient allergies, etc.? If this event is retained, significant additional guidance will need to be provided for consistent application and would recommend limiting it to "test results" rather than "clinical information".'	Such events occur with high frequency and should be reported in order to facilitate enterprise-wide learning and improvement. Based on the comments received, the event has been modified to narrow the scope with the expectation that it will be reexamined for broadening in future updates.

Dec 22 2010 11:52AM	Rachel Groman	American Association of Neurological Surgeons			4I. Death or serious injury resulting from failure to follow up or communicate clinical information	This metric also requires clarification, including a specific definition as to what constitutes a serious injury and a time frame that corresponds to a failure to communicate/follow-up. Operationalizing this measure will be challenging. Whose final responsibility is it to report? The primary care physician who initially sees the patient? Or the surgical subspecialist? Many times a surgeon orders a routine follow-up or non-urgent scan that ends up being done at an undetermined time. The surgeon does not know that the scan has been done until he receives the report it the patient calls. An example is a routine follow-up scan on a shunt patient that shows early shunt malfunction, and the patient shows up later very ill or injured. It's critical that the radiologist or discovering physician be held responsible for contacting the treating physician/surgeon urgently.'	Addressed in previous comment
Dec 30 2010 1:21PM	Rabia Khan	Centers for Medicare and Medicaid Services	Michael Rapp	CMS	4I. Death or serious injury resulting from failure to follow up or communicate clinical information	'Death or serious injury resulting from failure to follow up or communicate clinical information (Line 442) is a good SRE, but how will this type of information be abstracted? How can failure to follow up and inadequate communication of clinical information be distinguished from one another?'	Addressed in previous comment

Dec 23 2010 12:57PM	Cindy Barnard	Northwestern Memorial HealthCare			4I. Death or serious injury resulting from failure to follow up or communicate clinical information	Handoff / Communication Event: It is appreciated that this is the new home of the kernicterus serious adverse event. This is a problematic SRE definition. In many cases, breakdown in communication of serious (critical) results may be difficult to associate with a specific outcome. Also see comments in glossary - need to clarify serious injury. The implementation guidance should be worded differently. Instead of "examples of serious injury are a new diagnosis, or an advancing stage of an existing diagnosis," suggest wording it as "examples of serious injury are meaningful delay in reaching and communicating a new diagnosis, or an advancing stage of an existing diagnosis," etc. You would have to define meaningful delay as one that influenced long-term outcome, increased level of care required, etc. Or you could establish a time frame such as delay more than x days or weeks. Need to clarify boundaries. The "ownership" of these events will be difficult - hospital, licensed independent professional, etc. Problem may cross multiple settings (doctor's office, one or more hospitals, laboratory) and the definition needs to clarify whose SRE this is.'	Addressed in previous comment.

Dec 23 2010 1:13PM	Melanie Young	Society for Healthcare Epidemiology of America	Melanie Young	SHEA	4I. Death or serious injury resulting from failure to follow up or communicate clinical information	SHEA is concerned regarding the global nature and inherent ambiguity associated with this language. It is very broad and it would be difficult to determine when reporting would be necessary. In many cases co-morbidities and the critical illness of the patient make it difficult to determine a causal relationship between delay in communication and death. It is notable that this constitutes an enormous expansion from its original concept as failure to follow up on kernicterus, which had an easily definable population, condition, failure, and consequence.'	Addressed in previous comment.

Dec 17 2010 10:10AM	Julie Apold	Minnesota Hospital Association	Rebecca Schierman	Minnesota Alliance for Patient Safety	4I. Death or serious injury resulting from failure to follow up or communicate clinical information	Recommendation: We strongly recommend that this event not be added. Rationale: We do not feel that this meets the criteria for inclusion: 1) clearly identifiable and measurable; and 2) unambiguous. It would be difficult to consistently evaluate: 1) failure to follow up or commuicate; 2) clinical information; and 3) whether a patient death or serious injury was the result of a failure to follow up or communicate.	Addressed in previous comment.

Dec 20 2010 9:55AM	Steven Meisel	Fairview Health Services			4I. Death or serious injury resulting from failure to follow up or communicate clinical information	This recommended addition is well-intended but too vague for practical implementation. What constitutes failure to communicate? 2 doctors not talking with each other? A report not going to the primary care clinic? Communication occurring but the receiving party did not mentally process the conversation?? What is clinical information? Lab value? Imaging results? Surgical report? Blood pressure reading? A clinician's clinical impression? What if a patient underwent a CT scan of the abdomen for an acute process. During the course of reading the image, the radiologist notes something abnormal on the kidney, but nobody focuses on that due to the acute abdominal issue; that may be intentional or may be oversight. When or does this become failure to follow-up? I think the intent is to conver the bilirubin issue and other abnormal or critical lab test results. If the scope of the proposal were so narrowed, this would be an acceptable addition.'	Addressed in previous comment.

Dec 21 2010 2:48PM	Bridget Griffin	Mayo Clinic	Timothy Morgenthaler, MD	Mayo Clinic	4I. Death or serious injury resulting from failure to follow up or communicate clinical information	Mayo Clinic supports the recommendations from the American and Minnesota Hospital Associations. This is the most problematic proposal and contrary to NQF's own criteria that "to qualify for the list of SREs, an event must be unambiguous...". This new category is highly ambiguous. What is and is not communicated, and what was or was not followed up on can be highly subjective, difficult to determine, particularly in the era of electronic records. What if the clinical information was buried in outside records? The information that might in retrospect be clinically significant might only be in retrospect after other medical conditions, allergies, etc. are detected.'	Addressed in previous comment.
Dec 21 2010 11:07AM	Beth Feldpush	American Hospital Association	Nancy Foster	American Hospital Association	4I. Death or serious injury resulting from failure to follow up or communicate clinical information	We agree that the accurate and timely communication is critical for providing patient care. However, the definition of this event needs additional detail to make it actionable. "Failure to follow-up and communicate" must be better defined, and the relevant "clinical information" must be made more explicit in order for reporting of this event to be operationalized.'	Addressed in previous comment.
Dec 23 2010 1:23PM	Linda Harvey	UPMC	Linda Harvey	UPMC	4I. Death or serious injury resulting from failure to follow up or communicate clinical information	Recommend not including at this time. Requesting clarification on the specifics for "failure" in follow-up and also the parameters/definitions of "clinical information". This would be essential for standardization of review and reporting.	Addressed in previous comment.

Dec 23 2010 4:19PM	Alyssa Keefe	California Hospital Association			4I. Death or serious injury resulting from failure to follow up or communicate clinical information	Death or serious injury resulting from failure to follow up or communicate clinical information is an important event to identify and measure; however, for the following reasons CHA does not support the inclusion of this event at this time. First, unless greater explanation or clarity is provided with appropriate details that would enable consistent data collection and reporting, it would be difficult, if not impossible, to consistently evaluate and report "failure to follow up or communicate." How is this defined? Further, the committee does not clearly define "clinical information." What does this entail? Finally, attributing causality of whether a patient death or serious injury was the direct result of such an events is of great concern for public reporting. It is feasible to imagine an instance when one provider discovers	Addressed in previous comment.
Dec 23 2010 5:06PM	heather cook		(committee) RCA Review Committee	Swedish Medical Center	4I. Death or serious injury resulting from failure to follow up or communicate clinical information	We strongly recommend not adding this event to the list. It is not clearly defined & it could include changes in vital signs, abnormal lab values, allergies, or hand-off communication.'	Addressed in previous comment.

Dec 23 2010 5:51PM	Marie Kokol	Risk Management & Patient Safety Program			4I. Death or serious injury resulting from failure to follow up or communicate clinical information	I agree that while hand-off is the hot words of the year, this needs more defining and work. There are too many holes or grey areas that would make the comparisons of the data impossible due to the variety of ways states would choose to define and report.'	Addressed in previous comment.
Dec 23 2010 9:32AM	Jennifer Faerberg	Association of American Medical Colleges			4I. Death or serious injury resulting from failure to follow up or communicate clinical information	'While this event highlights a critical need for communication of clinical information, given the lack of clarity on the definition for this event, the attribution as well as the difficulty operationalizing all of the variations and combinations that could arise, the AAMC recommends this event not be added at this time.'	Addressed in previous comment.
Dec 30 2010 4:26PM	Patty Calver	Harborview Medical Center	Patty Calver	Harborview Medical Center	4I. Death or serious injury resulting from failure to follow up or communicate clinical information	We agree that communication and follow up are important components of patient safety. However, failure to follow up or failure to communicate are nebulous concepts that are not easily defined or measured. A more reasonable expectation for this event would be "Death or serious injury resulting from failure to communicate the abnormal/unexpected finding to the referring physician (or patient) in a manner that ensured receipt."'	Addressed in previous comment.

Dec 23 2010 4:13PM	Tanya Alteras	National Partnership for Women & Families	Tanya Alteras	Consumer-Purchaser Disclosure Project	4I. Death or serious injury resulting from failure to follow up or communicate clinical information	The Consumer-Purchaser Disclosure Project fully supports not only this measure, but the categorization of this set of SREs as "Care Management" measures. The consumer and purchaser communities have long argued that the lack of coordination and communication in health care results in significant costs to patients and the system as a whole. Making it clear that these SREs are directly linked to gaps in care coordination and communication will drive improvement in this area. As far as this specific measure, it is a long-overdue recognition of the enormous importance of communication to overall patient well-being, which includes not only avoiding death or serious injury, but to the establishment of a patient-centered health care system in general.'	No action necessary.
Dec 29 2010 10:11PM	Thomas James	Humana Inc.			4I. Death or serious injury resulting from failure to follow up or communicate clinical information	'The concepts in this measure get to the heart of much of the issues with quality and patient safety. In other industries, the abiity to learn from communication failures signal changes in processes. Our pleuralistic health care processes can institutionalize communication breakdowns. This measure may not be established in a way that allows for easy measurement, but that does not mitigate the real importance of the concept. Humana would urge NQF to make formulation of this measure in a	No action necessary.

Dec 13 2010 10:16AM	Julie Apold	Minnesota Hospital Association	Julie Apold	Minnesota Hospital Association	5A. Patient or staff death or serious injury associated with an electric shock in the course of a patient care process in a healthcare setting	Recommendation: Do not include staff members Rationale: There are other avenues, such as OSHA, to report employee incidences.'	Such events, whether shock as in this instance, burn, projectiles, assaults have the potential to facilitate enterprise wide learning and improvement to the benefit of patients and staff that is less likely to be forthcoming through organizations with fundamentally different goals.
Dec 29 2010 5:13PM	Erin Graydon Baker	Partners HealthCare System, Inc.	Erin Graydon Baker	Partners Healthcare	5A. Patient or staff death or serious injury associated with an electric shock in the course of a patient care process in a healthcare setting	The implementation guide excludes staff not involved in a patient care process. Can your further define patient care process?	Implementation guidance related to what the event is intended to capture has been modifed to improve clarity.

Dec 20 2010 10:06AM	Steven Meisel	Fairview Health Services			5A. Patient or staff death or serious injury associated with an electric shock in the course of a patient care process in a healthcare setting	'SRE should reflect issues/deficiencies in patient care. They should not include employee injuries, which have other avenues for reporting, such as OSHA.'	Addressed in previous comment.
Dec 29 2010 5:15PM	Carmella Bocchino	America's Health Insurance Plans			5A. Patient or staff death or serious injury associated with an electric shock in the course of a patient care process in a healthcare setting	Patient or staff death or serious injury associated with an electric shock in the course of a patient care process in a healthcare setting - The measure could be expanded to include electrical burns such as in the operating room.	Electrical burns in the operating room would be reportable under event 5C.

Dec 29 2010 5:16PM	Erin Graydon Baker	Partners HealthCare System, Inc.	Erin Graydon Baker	Partners Healthcare	5B. Any incident in which systems designated for oxygen or other gas to be delivered to a patient contains no gas, the wrong gas, or is contaminated by toxic substances	Would this apply to a gas cylinder that runs dry but is discovered and replaced before causing harm?	As stated, the event would capture the event listed in the comments. There is no qualifier of a degree of harm such as serious injury or death.
Dec 29 2010 5:15PM	Carmella Bocchino	America's Health Insurance Plans			5B. Any incident in which systems designated for oxygen or other gas to be delivered to a patient contains no gas, the wrong gas, or is contaminated by toxic substances	Any incident in which systems designated for oxygen or other gas to be delivered to a patient contains no gas, the wrong gas, or is contaminated by toxic substances - This measure could be expanded to include gases administered at the wrong concentration such as those that could contribute to Retinopathy of Prematurity or Adult Respiratory Distress Syndrome.'	This will be included as a consideration in the next update of the SREs. Comment relates to a care strategy which is beyond the scope of the SRE.

Dec 13 2010 10:17AM	Julie Apold	Minnesota Hospital Association	Julie Apold	Minnesota Hospital Association	5C. Patient or staff death or serious injury associated with a burn incurred from any source in the course of a patient care process in a healthcare setting	'Recommendation: Do not include staff members Rationale: There are other avenues, such as OSHA, to report employee incidences.'	Addressed in previous comment.
Dec 20 2010 9:56AM	Steven Meisel	Fairview Health Services			5C. Patient or staff death or serious injury associated with a burn incurred from any source in the course of a patient care process in a healthcare setting	SRE is not intended to cover employee injuries; such matters are covered by OSHA. Limit SRE to patient-care events.	Addressed in previous comment.

Dec 22 2010 1:00PM	Beth Honkomp	St. Cloud Hospital			5C. Patient or staff death or serious injury associated with a burn incurred from any source in the course of a patient care process in a healthcare setting	'St. Cloud Hospital, St. Cloud, MN agrees with the comments by Fairview Health System - eliminate any reference to staff.'	Addressed in previous comment.
Dec 23 2010 5:53PM	Marie Kokol	Risk Management & Patient Safety Program			5C. Patient or staff death or serious injury associated with a burn incurred from any source in the course of a patient care process in a healthcare setting	Agree with the comments that staff should not be included. Their information is reported through worker's comp, osha, etc. With Patient Safety needs to remain Patient.'	Addressed in previous comment.

Dec 23 2010 12:54PM	Cindy Barnard	Northwestern Memorial HealthCare			5D. Patient death or serious injury associated with the use of physical restraints or bedrails while being cared for in a healthcare setting	Appropriate changes. Helpful to clarify "physical" restraints. It is perhaps a small item, but recommend deletion of the sentence, Death/injury resulting from falls caused by lack of restraints would be captured under "falls." This may wrongly suggest that restraints are a useful strategy to prevent falls.'	Modification made.
Dec 29 2010 5:17PM	Carmella Bocchino	America's Health Insurance Plans			5D. Patient death or serious injury associated with the use of physical restraints or bedrails while being cared for in a healthcare setting	Patient death or serious injury associated with the use of physical restraints or bedrails while being cared for in a healthcare setting - NQF should clarify if aspiration pneumonia would be included in this measure.	The determination should be made on the basis of the event and related definitions.

Dec 29 2010 5:18PM	Erin Graydon Baker	Partners HealthCare System, Inc.	Erin Graydon Baker	Partners Healthcare	5D. Patient death or serious injury associated with the use of physical restraints or bedrails while being cared for in a healthcare setting	The SRe definition is clear but the glossary definition of restraints does not include the word physical.	The broader definition of restraints in the glossary is delimited by the modifer in the event.
Dec 22 2010 1:08PM	Beth Honkomp	St. Cloud Hospital			5D. Patient death or serious injury associated with the use of physical restraints or bedrails while being cared for in a healthcare setting	'St. Cloud Hospital, St. Cloud, MN agrees to the addition of physical restraints.'	No action necessary.

Dec 22 2010 11:53AM	Rachel Groman	American Association of Neurological Surgeons			6A. Death or serious injury of a patient or staff associated with the introduction of a metallic object into the MRI area	It is critical that a surgeon who orders a scan, but is not present when the scan is done is not held responsible for this event.'	The SREs are intended for organizational quality improvement and public reporting. They do not address individual responsibility.
Dec 13 2010 10:18AM	Julie Apold	Minnesota Hospital Association	Julie Apold	Minnesota Hospital Association	6A. Death or serious injury of a patient or staff associated with the introduction of a metallic object into the MRI area	'Recommendation: Do not include staff members Rationale: There are other avenues, such as OSHA, to report employee incidences.'	Addressed in previous comment at line 138 .
Dec 20 2010 10:08AM	Steven Meisel	Fairview Health Services			6A. Death or serious injury of a patient or staff associated with the introduction of a metallic object into the MRI area	'Excellent addition. However, SRE should be focused on patient care issues/deficiencies and not employee injuries. There are other avenues, such as OSHA, to report and follow-up on employee injuries.'	Addressed in previous comment.

Dec 22 2010 12:29PM	Beth Honkomp	St. Cloud Hospital			6A. Death or serious injury of a patient or staff associated with the introduction of a metallic object into the MRI area	'St. Cloud Hospital, St. Cloud, MN agree this should be a reportable event but limited to patients only.'	Addressed in previous comment.
Dec 20 2010 10:10AM	Steven Meisel	Fairview Health Services			7A. Any instance of care ordered by or provided by someone impersonating a physician, nurse, pharmacist, or other licensed healthcare provider	'SRE should be focused on patient care issues and not criminal acts. While criminal acts should never occur anyplace, they can and do happen everywhere. Health care settings are not immune. There are other places to report and follow-up on such issues. I think they are inappropriate to be included as a SRE.'	This event is a patient care issue. The Steering Committee has opined that the objective of judicial systems does not include learning or improvement of patient care processes and that the potential criminal events should be retained in the SREs.

Dec 23 2010 5:54PM	Marie Kokol	Risk Management & Patient Safety Program			7A. Any instance of care ordered by or provided by someone impersonating a physician, nurse, pharmacist, or other licensed healthcare provider	Agree with the comments that staff should not be included. Their information is reported through worker's comp, osha, etc. With Patient Safety needs to remain Patient.'	Addressed in previous comment.
Dec 29 2010 5:22PM	Erin Graydon Baker	Partners HealthCare System, Inc.	Erin Graydon Baker	Partners Healthcare	7A. Any instance of care ordered by or provided by someone impersonating a physician, nurse, pharmacist, or other licensed healthcare provider	Criminal events should be handled by state and local authorities and not be reported as an SRE	Addressed in previous comment.
Dec 20 2010 10:10AM	Steven Meisel	Fairview Health Services			7B. Abduction of a patient/resident of any age	'SRE should be focused on patient care issues and not criminal acts. While criminal acts should never occur anyplace, they can and do happen everywhere. Health care settings are not immune. There are other places to report and follow-up on such issues. I think they are inappropriate to be included as a SRE.'	Addressed in previous comment. The potential criminal event included in the SREs is patient care related.

Dec 29 2010 10:17PM	Thomas James	Humana Inc.			7B. Abduction of a patient/resident of any age	The definition of abduction does not get to the gray areas where there is joint custody of a child in a pediatric hospital, since both parents may have responsibility for the child'	Implementation guidance provides clarification. The event includes removal of a patient/resident, who does not have decision-making capacity, without specific notification and approval by staff even when the person is otherwise authorized to be away from the setting
Dec 31 2010 1:56PM	James Taylor, MD	Cleveland Clinic			7B. Abduction of a patient/resident of any age	Request for further implementation guidance, as this event places an onerous burden on front office/reception staff, who are not equipped to conduct a rigorous discharge process in a very busy office seeing 50 or more patients daily. These burdens would be potentially greater in solo and small private practice settings.	The event should be reportable as this is indicative in a failure of a facility's safety systems.
Dec 13 2010 10:20AM	Julie Apold	Minnesota Hospital Association	Julie Apold	Minnesota Hospital Association	7C. Sexual abuse/assault on a patient or staff member within or on the grounds of a healthcare setting	Recommendation 1: Do not include staff members Rationale: There are other avenues, such as OSHA, to report employee incidences. Recommendation 2: Do not include "sexual abuse" in the event. Rationale: The term sexual assault has worked well and is well defined in state statutes.'	Addressed in previous comment.

Dec 20 2010 10:00AM	Steven Meisel	Fairview Health Services			7C. Sexual abuse/assault on a patient or staff member within or on the grounds of a healthcare setting	Do not include staff members; SRE should be limited to patient care issues. Staff issues are reportable in other venues. Sexual abuse can be interpreted to cover sexual harrassment; this is too broad. On a larger view, I think this entire element is inappropriate as a SRE. SRE should be focused on clinical care; while criminal acts should never occur, they are funamentally different than deficiencies in patient care. These same criminal acts can occur at the grocery store and are not unique to health care. Therefore, I would delete this one.'	Addressed in previous comment. Sexual abuse is defined in the glossary.
Dec 21 2010 2:51PM	Bridget Griffin	Mayo Clinic	Timothy Morgenthaler, MD	Mayo Clinic	7C. Sexual abuse/assault on a patient or staff member within or on the grounds of a healthcare setting	Mayo Clinic supports the recommendations of the Minnesota Hospital Association.	Addressed in previous comment.
Dec 22 2010 1:03PM	Beth Honkomp	St. Cloud Hospital			7C. Sexual abuse/assault on a patient or staff member within or on the grounds of a healthcare setting	'St. Cloud Hospital, St. Cloud, MN agrees with the comments of the Minnesota Hospital Association and Fairview Health System.'	Addressed in previous comment.

Dec 23 2010 5:55PM	Marie Kokol	Risk Management & Patient Safety Program			7C. Sexual abuse/assault on a patient or staff member within or on the grounds of a healthcare setting	Staff should not be included. Their information is reported through worker's comp, osha, etc. and in this case through the local law enforcement. With Patient Safety needs to remain Patient.'	Addressed in previous comment.
Dec 23 2010 12:53PM	Cindy Barnard	Northwestern Memorial HealthCare			7C. Sexual abuse/assault on a patient or staff member within or on the grounds of a healthcare setting	'Agree with prior comments; do not include staff; in addition, see comment on glossary regarding sexual abuse. Align definition with TJC sentinel event definition..'	Addressed in previous comment.
Dec 29 2010 5:25PM	Erin Graydon Baker	Partners HealthCare System, Inc.	Erin Graydon Baker	Partners Healthcare	7C. Sexual abuse/assault on a patient or staff member within or on the grounds of a healthcare setting	We recommend removing staff member. Would harrassment be considered abuse? Criminal events should be handled by state and local authorities	Addressed in previous comment.

Dec 6 2010 12:00PM	Linda Gerbig	Texas Health Resources	marcie Williams	Texas Health Resources	7C. Sexual abuse/assault on a patient or staff member within or on the grounds of a healthcare setting	Even with good security the event is not always preventable.	The criteria for SREs acknowledge that events are either wholly preventable or largely preventable.
Dec 29 2010 5:28PM	Erin Graydon Baker	Partners HealthCare System, Inc.	Erin Graydon Baker	Partners Healthcare	7D. Death or significant injury of a patient or staff member resulting from a physical assault (i.e., battery) that occurs within or on the grounds of a healthcare setting	All other SREs use serious injury yet this SRE uses significant injury. Is there a difference? Criminal events should be handled by state and local authorities.	Change from "significant" to "serious" made. Otherwise addressed in previous comment at line 138.

Dec 13 2010 10:21AM	Julie Apold	Minnesota Hospital Association	Julie Apold	Minnesota Hospital Association	7D. Death or significant injury of a patient or staff member resulting from a physical assault (i.e., battery) that occurs within or on the grounds of a healthcare setting	'Recommendation: Do not include staff members Rationale: There are other avenues, such as OSHA, to report employee incidences.'	Addressed in previous comment.
Dec 20 2010 10:01AM	Steven Meisel	Fairview Health Services			7D. Death or significant injury of a patient or staff member resulting from a physical assault (i.e., battery) that occurs within or on the grounds of a healthcare setting	'Omit staff issues; these are reportable in other venues such as OSHA. SRE should be focused on patient care issues and deficiencies. I think this entire element is inappropriate as a SRE. SRE should be focused on clinical care; while criminal acts should never occur, they are funamentally different than deficiencies in patient care. These same criminal acts can occur at the grocery store and are not unique to health care. Therefore, I would delete this one.'	Addressed in previous comment.

Dec 23 2010 5:55PM	Marie Kokol	Risk Management & Patient Safety Program			7D. Death or significant injury of a patient or staff member resulting from a physical assault (i.e., battery) that occurs within or on the grounds of a healthcare setting	Staff should not be included. Their information is reported through worker's comp, osha, etc. and in this case through the local law enforcement. With Patient Safety needs to remain Patient.'	Addressed in previous comment.
Dec 6 2010 12:01PM	Linda Gerbig	Texas Health Resources			7D. Death or significant injury of a patient or staff member resulting from a physical assault (i.e., battery) that occurs within or on the grounds of a healthcare setting	Even with very good security this event may not always be preventable	Addressed in previous comment.

Dec 21 2010 12:35PM	Caitlin Connolly	American Geriatrics Society			General comments on Serious Reportable Events additional recommendations	POST PROCEDURE MEASURE The AGS supports this measure. We are aware that last February, there was discussion around a 30 day post-procedure mortality rate, but this was excluding those aged over 75 and admission from a skilled nursing facility (SNF); all mention of this has disappeared entirely from the SRE draft report. From a geriatric point of view, measuring mortality for a period longer than the immediate post-procedure period tends to bring out issues related to risks of procedures specific to frail elderly that are potentially informative. We would like to see a broadening of the 'event' and to keep older individuals included when it is expanded and for appropriate procedures. Such measurement may give empirical evidence about procedures with high risk/benefit ratios in the older person.'	This was not submitted as a candidate SRE.
Dec 23 2010 9:57AM	Jennifer Faerberg	Association of American Medical Colleges			General comments on Serious Reportable Events additional recommendations	The AAMC agrees with the additional recommendations listed in the report. We would strongly recommend that further action be taken in support of the need to develop effective ways to communicate with the public on these very serious but infrequent events. The work of the Patient Safety Reporting Committee started that work but more needs to be done. As this data is being reported on a national basis we need to figure this out.	The comment has been provided to NQF leadership for consideration.

Dec 29 2010 12:28PM	Margaret Reagan	Premier, Inc.			General comments on Serious Reportable Events additional recommendations	General comments related to both SRE Product or Device Events and Category Care Management Premier suggests that the issues raised could be resolved by first considering the SRE to be the discovery of exposure to contamination or discovery of an exposure due to a pattern of unacceptable practice and not the infectious outcome, since the contamination or unacceptable practice is more likely a detectable event. Discovery of a potential exposure requires action to investigate for potential infectious outcomes even if a patient does not present immediately with an infection. Given lengthy viral incubation periods, patients then become subject to much testing over time, testing that would be unnecessary without the risk of serious or life-threatening injury due toexposure. As currently worded, the infectious outcome being detected as related to the device or event would rarely be identified as an SRE.'	The issue is captured by the "change in risk status of a patient" as noted in the additional specifications of several SREs. The event described in the comment would thus be captured for a patient exposed to a contaminated drug, device, medication, etc.

Dec 21 2010 11:08AM	Beth Feldpush	American Hospital Association	Nancy Foster	American Hospital Association	General comments on Serious Reportable Events not recommended for endorsement	The Steering Committee decided not to put forward central line-associated blood stream infections (CLABSI) as a new serious reportable event. While we respect the Steering Committee's decision, we strongly urge the NQF to consider this event for the next update of the serious reportable events list. The AHA has engaged in a major initiative to reduce the incidence of CLABSI in America's hospitals. Because there are effective, focused tools that hospitals can use to prevent CLABSIs from occurring, we believe we can make tremendous progress in driving the rate of these infections toward zero. CLABSIs truly are becoming preventable events. Currently, hospitals collect information on CLABSIs on a regular, ongoing basis and will begin reporting on them as a quality measure under Medicare's pay-for-reporting program. However, as CLABSIs are reduced over time, we may see the appropriate reporting frequency shift from ongoing data collection for performance measurement to periodic reporting when a CLABSI event occurs. The question of when to move from ongoing data collection to event reporting is unanswered. We suggest that the NQF consider this question and use CLABSIs as an example for discussion during the next update of the serious reportable events list.'	This event will be revisited in the next SRE update.
Dec 13 2010 10:23AM	Julie Apold	Minnesota Hospital Association	Julie Apold	Minnesota Hospital Association	General comments on Serious Reportable Events not recommended for endorsement	We recommend the addition of an event "diagnostic testing error resulting in unnecessary invasive procedure, serious injury or death"'	An event related to this concept was not recommended as the event would capture provider error rather than preventable system or safety errors. Suggest that a system-focused event be submitted at next call for event submissions.

Dec 20 2010 10:04AM	Steven Meisel	Fairview Health Services			General comments on Serious Reportable Events not recommended for endorsement	We have had instances of wrong procedure performed when the procedural staff did everything right but acted secondary to a lab or pathology mix-up. This unfairly counts the event as if it were a problem with, say, the Universal Protocol. I would prefer adding an event focused on death/serious injury resulting from diagnostic testing errors.'	The event reported would be the wrong procedure. Institutional review should identify contributing factors to be addressed. Suggest a system-focused event of the type mentioned at the next call for event submissions.
Dec 21 2010 3:03PM	Bridget Griffin	Mayo Clinic	Timothy Morgenthaler, MD	Mayo Clinic	General comments on Serious Reportable Events not recommended for endorsement	MHA recommends the addition of an event Mayo does not support the recommendation to add the following event: "Diagnostic testing error resulting in unnecessary invasive procedure, serious injury or death". It is ambiguous and needs more definition and clarification.'	No action necessary.
Dec 23 2010 1:14PM	Melanie Young	Society for Healthcare Epidemiology of America	Melanie Young	SHEA	General comments on Serious Reportable Events not recommended for endorsement	Patient death or serious injury related to a central line associated blood stream infection (CLABSI) Comment: SHEA agrees with the decision not to recommend this event for endorsement because of issues related to attributing causality as well as relative lack of measurement experience and reporting.	No action necessary.

Dec 23 2010 12:51PM	Cindy Barnard	Northwestern Memorial HealthCare			General comments on Serious Reportable Events not recommended for endorsement	Events Deferred Wrong dose fluoro or radiation tx - this is a Joint Commission sentinel event and should be considered as a SRE Death/serious injury related to a central line associated bloodstream infection - agree with deferring this for now since CMS is tracking the performance measure Failure to rescue - Agree with deferring this, the performance measure is more appropriate Agree with remaining recommendations'	The fluoroscopy event was deferred to the next SRE update based on advice from the radiology community that a number of important parameters are changing.

Dec 23 2010 4:19PM	Alyssa Keefe	California Hospital Association			General comments on Serious Reportable Events not recommended for endorsement	CHA is grateful for the committee's careful consideration of several standards for endorsement, and agrees with the recommendations to not endorse these measures at this time. Additional deliberation at a future date by the committee regarding measures such as the CLABSI infection should be considered. Currently, this is an NQF-endorsed measure under the patient safety report framework. The current specifications are detailed for continued monitoring of performance and reporting over time. At some point in the future, it is anticipated that this infection, in most settings, will be a rare event. At the point this should occur is worthy of a full discussion that accounts for some of the unique patient populations that we care for in our hospitals. We support the committee's recommendation to not move the measure forward at this time, as it would duplicate reporting already ongoing.	The SC has recommended that this event be revisited in the next SRE update.

Dec 29 2010 5:23PM	Carmella Bocchino	America's Health Insurance Plans			General comments on Serious Reportable Events not recommended for endorsement	It is important to underscore that CLABSI continues to be a significant public health challenge[1], and while we note that the Committee has raised issues pertaining to attributing causality, we would encourage the Committee to come up with a plan to address the issues raised prior to the next SRE Update. A number of states have been working on ways to reduce CLABSI infections, and many in fact, have demonstrated progress, suggesting that there is an opportunity today for NQF to issue a recommendation for an NQF-endorsed CLABSI event. A report from the Michigan Health & Hospital Association (MHA) revealed a dramatic reduction in the occurrence of CLABSI for the time period between 2004 and 2009, resulting in the saving of more than 1,800 lives, and $271 million in health care costs. We support the Committee's recommendation to not endorse the remaining events listed as they have been incorporated into implementation guidance of other SREs for which endorsement is recommended; are addressed by existing measures that are NQF endorsed, e.g. failure to rescue; or will be included in future updates as experience and the evidence become more substantiated'	The SC has recommended that this event be revisited in the next SRE update.

Dec 29 2010 10:30PM	Thomas James	Humana Inc.			General comments on Serious Reportable Events not recommended for endorsement	Humana appreciates the opportunity to comment. We support the recommendations by others below to bring the Central Line associated Blood Stream Infections (CLABSI) back to NQF for reconsideration. This is a significant issue for both morbidity and for cost. It is high volume and Dr. Provost has demonstrated in Michigan and elsewhere that it is preventable. Humana also recommends that two measures not recommended for endorsement be combined into one. These are the two measures related to impaired healthcare workers. This is a systems issues that industries such as the airlines have addressed successfully. So can healthcare. Measurement of the effectiveness of credentialling and monitoring can help energize this part of the process for patient safety	The SC has recommended that the CLABSI event be revisited in the next SRE update. The SC recommended that the events related to impaired healthcare workders not be advanced due to issues with feasibility in determining the impairment of healthcare workers and attributing causation of an adverse outcome to the impairment of the healthcare worker.
Dec 29 2010 12:30PM	Margaret Reagan	Premier, Inc.			General comments on Serious Reportable Events not recommended for endorsement	General category of events not endorsed: Among the eight events that were not endorsed is "Patient death or serious injury related to a central line associated blood stream infection (CLABSI)" The key issue for not accepting this as a SRE was causality and attribution. Premier would agree with this assessment and also supports the non-acceptance of all events in this category.	No action necessary.

Dec 30 2010 5:31PM	Denise Graham	Association for Professionals in Infection Control and Epidemiology			General comments on Serious Reportable Events not recommended for endorsement	Among the eight events that were not endorsed is "Patient death or serious injury related to a central line associated blood stream infection (CLABSI)". The key issue was causality and attribution. APIC would agree with this assessment.	No action necessary.
Dec 23 2010 5:57PM	Marie Kokol	Risk Management & Patient Safety Program			General comments on Serious Reportable Events not recommended for endorsement	Where is 1E? Beginning on line 323 of the SRE Draft for Comment you have listed the following: 1E. Intraoperative or immediately postoperative/postprocedure death in an ASA Class 1 patient. In going through the public comment section, there is not a corresponding 1E found. The addition of this SRE would have given a valuable window to at least open discussions as to these type deaths and I was disappointed to see it left out without comment. I would like to see the rational used in the decision making process to exclude this from the 2011 SREs.I feel the death of an ASA Class 1 patient, while some will argue there are times when death maybe due to nondisclosure on the part of the patient or other unknown physical condition, to disregard to entire SRE.'	Omission of the event in the commenting tool was inadvertent and has been addressed.

Dec 13 2010 10:22AM	Julie Apold	Minnesota Hospital Association	Julie Apold	Minnesota Hosiptal Association	General comments on Serious Reportable Events recommended for retirement	Supportive of retirement of spinal manipulative therapy event.	No action necessary.
Dec 15 2010 3:33PM	Kara Webb	American Chiropractic Association	Rick McMichael	American Chiropractic Association	General comments on Serious Reportable Events recommended for retirement	The American Chiropractic Association strongly supports the recommendation to retire the Care Management Event 4.G. "Patient death or serious disability due to spinal manipulative therapy" from the Serious Reportable Events (SRE) list. The ACA supports this action because, unlike other events on the SRE list, such as performing surgery on the wrong patient, incidents occurring after spinal manipulation are not related to a preventable provider behavior. The most recent study shows that patients are no more likely to experience strokefollowing a chiropractic visit than they are following a visit to a family physician.The study goes on to say that any observed association between a vertebrobasilar artery (VBA) stroke and manipulation, as well as its apparent association with family physician visits, is likely due to patients with an undiagnosed vertebral artery dissection seeking care for neck pain and headache prior to their stroke.[1] In the draft version of the Consensus Report the incongruous nature of including death or serious disability due to spinal manipulation on the SRE list is noted and the ACA appreciates NQF's recognition of this distinct difference.	No action necessary.

Dec 21 2010 2:58PM	Bridget Griffin	Mayo Clinic	Timothy Morgenthaler, MD	Mayo Clinic	General comments on Serious Reportable Events recommended for retirement	Mayo Clinic supports the retirement of the event relative to spinal manipulative therapy.	No action necessary.
Dec 23 2010 4:19PM	Alyssa Keefe	California Hospital Association			General comments on Serious Reportable Events recommended for retirement	Generally, CHA supports the committee's recommendation to retire three events (4D, 4E, 4G) and appreciates the detailed justification for retirement provided. Despite our support for the retirement of 4E-death or serious disability (kernicterus) associated with failure to identify and treat hyperbilirubinemia in neonates-we have concerns about the more broadly envisioned event under which this would be captured. Those concerns are noted below.	No action necessary.
Dec 29 2010 5:30PM	Erin Graydon Baker	Partners HealthCare System, Inc.	Erin Graydon Baker	Partners Healthcare	General comments on Serious Reportable Events recommended for retirement	We agree with the events being retired.	No action necessary.

Dec 21 2010 11:03AM	Beth Feldpush	American Hospital Association	Nancy Foster	American Hospital Association	General Comments on the Draft Report	'While we agree with the proposed changes in scope and definition of the Serious Reportable Events and believe that the proposed additions are appropriate, we also believe that these changes are likely to increase the number of reports that are filed. Because members of the public who do not track these definitional changes and additions to the list as closely as we who are immersed in this process, we also urge the Steering Committee to consider affirmatively stating that these changes may result in an increase in the number of reported events that should not be confused with a decrement in safety. Rather, one would have to look to see if the increase in number of events reported is merely a result of the expansion of what is reportable or whether it represents a real change in the safety of care provided.'	Report language modified to address this possibility.

Dec 21 2010 11:04AM	Beth Feldpush	American Hospital Association	Nancy Foster	American Hospital Association	General Comments on the Draft Report	The Steering Committee has expanded the scope of several of the serious reportable events to also include death or injury sustained by staff. Adverse events that harm a hospital staff member are just as serious as events that harm patients and should be given equal attention. However, we believe such events should be reported through other mechanisms. Employee safety is regulated through other channels, including the Occupational Safety & Health Administration (OSHA) and various state and local laws. Data repositories on the serious reportable events should remain focused on patient safety, and staff events should be fully investigated and reported through the appropriate employee safety mechanisms. The AHA would like to express our appreciation for the clarity and detail of the Steering Committee's discussions presented in the report. The report is very well written and provides sufficient detail of the Steering Committee's deliberations while keeping brevity in mind. The NQF should use this report as a model for reports written for other NQF projects.'	Addressed in previous comment.

Dec 23 2010 12:46PM	Melanie Young	Society for Healthcare Epidemiology of America	Melanie Young	Society for Healthcare Epidemiology of America	General Comments on the Draft Report	Congratulations on a much improved and readable document. SHEA is pleased that a fair amount of current ambiguity was addressed, and appreciates the care taken with definitions/glossary. SHEA is pleased with the removal of the term "never events". We would caution that with clearer definitions, it is fair to expect the numbers of reports to increase. As these definitions are published and typically used for public reporting in states and by CMS for healthcare-associated conditions, it could appear that healthcare is worse-not better. We strongly recommend that the NQF Committee comment on that point when these definitions are finalized-and that the Committee should be very clear on that point to CMS when setting thresholds for performance on HACs. SHEA does have a few areas of concern as noted below. The Society is happy to provide input on these infection related issues raised, as these move forward for the next level of review.'	NQF appreciates the comment and offer of input. Language to address potential increase in reports has been added to report language.
Dec 2 2010 3:20PM	Robert Gold	DCBA, Inc.			General Comments on the Draft Report	I am concerned about the use of the term associated with rather than attributable to. Current Official Coding Guidelines lead some professional coders to interpret with as a temporal relationship and not a causative one. Inappropriate identification of cases will take place without a definition of associated with that explains this relationship.	The term is defined in the glossary.

Dec 2 2010 5:05PM	Charlotte Weaver	Gentiva Health Services			General Comments on the Draft Report	Recommend expanding healthcare settings to include Home Health, Hospice and Hospice Inpatient Units where appropriate. Specifically, recommend including them in: 1) #4 Care Management under A. Medication Errors. Home Health and Hospice have regulatory responsibility for meds review, reconciliation, drug interaction and allergy checking. 2.) Care Management under E - falls. Home Health added to settings for incidents that occur while clinician is working directly with the patient. 3.) Care Management under F. Stage 3 & 4 pressure ulcer developed during the Home Health or Hospice care episode. 4.) Under Environmental: B - Oxgyen systems -- include DME companies who deliver and administer O2 in the Home 5.) Under Environmental: C- Burns -- for those that occur while clinician or paraprofessional is working directly with the patient.'	At this time, the SRE listings have not been evaluated for relevance in the Home Health, Hospice, and Hospice Inpatient Units. The Steering Committee has recommended that the applicability of the SRE listing for other environments be considered in future updates. Of note, the report specifies focus on the 4 settings but does not preclude use of the events in other care settings.
Dec 6 2010 10:15AM	Jon Olson	Connecticut Dept of Public Health			General Comments on the Draft Report	It can be confusing to revise the SRE list so that a previous category 6 (criminal) is now category 7 with a new type of event becoming category 6. It is better to re-order the list a little as possible.	Comment appreciated and was considered in placement of the new category.

Dec 20 2010 2:58PM	Rebecca Swain-Eng	American Academy of Neurology	Samuel Frank	American Academy of Neurology	General Comments on the Draft Report	I think the document is interesting, complete and outlines some important steps forward in reporting. I would suggest the document clarify that the reporting is for clinical events, not research-related events and point the reader to specific policies for SRE's in the research realm. Also, there should be guidance for reporting for international companies and for patients that have experienced a reportable event outside the US. Thank you, Sam Frank'	The events as specified would apply to all patients, including those enrolled in research protocols. Additional requirements for reporting events that are specific to research activities should be outlined in the procedures and protocols for such research. At present, the SREs have not addressed events outside the US.
Dec 21 2010 1:43PM	Bridget Griffin	Mayo Clinic	Timothy Morgenthaler, MD	Mayo Clinic	General Comments on the Draft Report	Mayo Clinic concurs with recommendations from both the American Hospital Association and the Minnesota Hospital Association regarding expanding the scope of several of the serious reportable events to also include death or serious injury sustained by staff. Events that harm staff are serious and require equal attention. However, there are other avenues for reporting such events, including the Occupational Safety & Health Administration and various state and local laws.'	Addressed in previous comment.

Dec 21 2010 2:00PM	Paul Conlon	Trinity Health			General Comments on the Draft Report	It is our opinion that the changes will improve reporting and make the reports received more comparable. The definitions are much clearer in this version although broader in scope. The new SREs will capture a number of events that we have been including in our own 'catch all' category. The discussion group on 12/15/2010 raised some very specific issues . We did not find these to be serious caveats, and these were the only concerns raised during the call. As with all voluntary reporting, there will be some discrimination done by staff on which reports rise to the level of SREs and these will vary by site. We see that with our own SRE reporting already. All and all, the changes recommended will help clarify a number of issues that we see from our own experience with SRE reporting.'	No action necessary.

Dec 21 2010 11:02AM	Beth Feldpush	American Hospital Association	Nancy Foster	American Hospital Association	General Comments on the Draft Report	The American Hospital Association (AHA) appreciates the opportunity to comment on the draft report Serious Reportable Events in Healthcare-2011 Update: A Consensus Report. The report updates the NQF's list of serious reportable events and expands the applicable settings of care to include ambulatory and post-acute care settings. In general, we believe the events included on the list are appropriate for systematic reporting to drive national improvements in patient safety. We agree that those events remaining on the list since the 2006 update remain relevant, and the four newly added events are important patient safety topics. We are pleased to see the applicable settings of care expanded to include the ambulatory and post-acute care settings in the update of the serious reportable events list. It is critical to call attention to patient safety issues across the care continuum. The use of a common set of reportable events across care settings will help connect and expand our lessons learned when serious adverse events occur.'	No action necessary.

Dec 21 2010 11:10AM	Beth Feldpush	American Hospital Association	Nancy Foster	American Hospital Association	General Comments on the Draft Report	'The AHA believes that the potential criminal events, while certainly events that should not occur in a healthcare setting, should be treated differently by regulatory agencies because of their criminal nature. The types of system changes that one would put in place to reduce medical errors are very different from the security precautions that would be put in place to protect against criminal activities. Thus, we believe these events should be acted upon differently. While hospitals and other providers should certainly report an occurrence of these events, it is most appropriate that such reporting be done to a legal authority such as the local police department. While payment reductions may be an appropriate policy lever to drive down the incidence of medical errors, we urge against any action by payers to reduce hospital payments because of the occurrence of a criminal event at the hospital.'	Addressed in previous comment.
Dec 21 2010 11:50AM	Caitlin Connolly	American Geriatrics Society			General Comments on the Draft Report	The American Geriatrics Society (AGS) supports this step in increasing transparency for our systems as our organization was part of the movement that initiated this work.	No action necessary.

Dec 21 2010 12:38PM	Clem McGinley	Blue Mountain Health System			General Comments on the Draft Report	Spinal manipulation and Serious Reportable Events I opine that the above should be eliminated from the list. While any serious event is reportable - whether ir occurs from Surgical complications, adverse drug reaction, Physical/Occupational Therapy treatments, etc - singling out spinal manipulation seems somewhat prejudicial the Doctors of Chiropractic. Any way it is a moot point, since by definition any serious event is reportable. Clem McGinley, MD *VP of Medical Af* fairs Blue Mountain Health System'	No action necessary.

Dec 23 2010 1:37PM	Erin O'Malley	Safe Injection Practices Policy Task Force			General Comments on the Draft Report	The Safe Injection Practices (SIP) Policy Task Force (PTF) appreciates the opportunity to comment in support of the draft report on Serious Reportable Events (SREs). We are especially pleased that this draft addresses unsafe injection practices in two events (2A and 4A). In the last decade, more than 150,000 patients in the United States were notified of potential exposure to hepatitis B virus, hepatitis C virus, and HIV due to unsafe injection practices in healthcare settings. Members of the SIP PTF, which includes patients, providers and industry partners, are committed to eliminating unsafe injection practices across the healthcare system. We strongly encourage the National Quality Forum (NQF) and its members to preserve language on injection safety intact in the final version of the SRE report. We applaud NQF for recognizing unsafe injection practices as a SRE in its next iteration of the NQF SRE guidelines. Safe Injection Practices Policy Task Force members: American Association of Nurse Anesthetists (AANA) Association for Professionals in Infection Control and Epidemiology, Inc. (APIC) BD Healthcare Accreditation Resources, LLC Hepatitis Outbreaks National Organization for Reform (HONOReform) Hospira National Association of County and City Health Officials (NACCHO)'	No action necessary.

Dec 23 2010 4:03PM	Tanya Alteras	National Partnership for Women & Families	Tanya Alteras	Consumer-Purchaser Disclosure Project	General Comments on the Draft Report	The Consumer-Purchaser Disclosure Project appreciates the opportunity to comment on the measures being recommended for endorsement by the steering committee on Serious Reportable Events. The importance of identifying, categorizing, and reporting of SREs for accountability and improvement in patient safety and outcomes is a given; however, the circumstances and understanding of how and where SREs may occur have evolved. Thus, we are very pleased that the National Quality Forum has convened this steering committee to reconsider existing SREs, as well as evaluate potential new events for SRE designation. In terms of specific changes, we fully support the expansion of the surgery-related SREs to now also apply to procedures, and we fully support the expansion of the population to whom SREs may apply to include residents in long-term care facilities.'	No action necessary.
Dec 23 2010 4:07PM	Maureen Dailey	American Nurses Association	Maureen Dailey	American Nurses Association	General Comments on the Draft Report	'The American Nurses Association (ANA) believes death related to healthcare acquired infections (HAI) should be considered a serious reportable event, regardless of the issue of causality. The American Nurses Association (ANA) has concerns regarding the potential consequences of cuts in funding at the state level for support of analysis of reportable events. Data are being reported, however, key positions are being eliminated within the State Departments of Health that support the analysis and synthesis of data identified in organizational root cause analysis processes.'	No action necessary.

Dec 23 2010 4:57PM	heather cook		(committee) RCA Review Committee	Swedish Medical Center	General Comments on the Draft Report	We appreciate the opportunity to provide comments regarding the 2011 update. We are concerned about extending the reporting of the Serious Reportable Events to include office-based practices, ambulatory surgery centers, & skilled nursing facilities because the work load potentially will escalate, requiring more staff at additional cost to meet unfunded mandates. Also, we believe that the Environmental Events, Radiologic Events, & Potential Criminal Events should exclude staff since they are covered by OSHA.'	Addressed in previous comment.
Dec 23 2010 5:21PM	Marie Kokol	Risk Management & Patient Safety Program			General Comments on the Draft Report	'Where is 1E? Beginning on line 323 of the SRE Draft for Comment you have listed the following: 1E. Intraoperative or immediately postoperative/postprocedure death in an ASA Class 1 patient. In going through the public comment section, there is not a corresponding 1E found. The addition of this SRE would have given a valuable window to at least open discussions as to these type deaths and I was disappointed to see it left out without comment. I would like to see the rational used in the decision making process to exclude this from the 2011 SREs.I feel the death of an ASA Class 1 patient, while some will argue there are times when death maybe due to nondisclosure on the part of the patient or other unknown physical condition, to disregard to entire SRE.'	Addressed in previous comment

Dec 23 2010 5:56PM	Paul Drucker	Association of Critical Care Transport	Paul Drucker	Association of Critical Care Transport (ACCT)	General Comments on the Draft Report	ACCT thanks the NQF for the opportunity to comment on this project. ACCT is a patient advocacy organization committed to ensuring that critically ill and injured patients have access to the safest and highest quality critical care transport system. Our member organizations provide the entire spectrum of out of hospital services. ACCT applauds the NQF for the continued evolution of SRE by broadening them outside the inpatient hospital setting. ACCT appreciates as well that NQF acknowledges a focus on the four settings of care identified for this project does not preclude use of the events in other settings. Emergency medical care/transport is provided in a variety of environments, a variety of vehicles and all levels of acuity. ACCT believes emergency medical care/transport uniquely qualifies as a healthcare setting as defined in Appendix B of the draft. The medical transport environment is fraught with risks similar to and some absolutely not encountered in other settings, yet these risks have an impact on care, unfortunately, at times, to the patient's detriment. ACCT appreciates any opportunity to dialogue with NQF for this or future projects regarding serious reportable event updates. Collaboration between NQF, ACCT and any additionally interested stakeholders is encouraged to build necessary accountability.'	No action necessary at this time. For consideration in planning for future updates.

Dec 29 2010 5:09PM	Carmella Bocchino	America's Health Insurance Plans			General Comments on the Draft Report	AHIP appreciates the opportunity to provide comments on the NQF 2011 Update for Serious Reportable Events (SREs). As stated by NQF, the intention of this update is to encompass a wider range of potential adverse events across a variety of healthcare settings, as well as to ensure that existing SRE events remain timely and actionable in today's health care system. AHIP supports the updates to the 2006 SRE list, as well as the list of events recommended for endorsement. We would also note that many of the changes provide clarifying language that will better enable care givers to identify triggers of SRE situations. We also encourage NQF to ensure that there is a feedback loop that assists with updating of the SRE events based on field testing and experience. Finally we encourage NQF to harmonize the SRE list with the list of CMS hospital-acquired conditions in the near future. We ask that the NQF clarify the following terms included in the Glossary: serious Injury, competent individual, low risk pregnancy - describes the maternal condition but does not include fetal status. This more limited definition restricted to the mother's status can affect the interpretation of several maternal measures.'	Addressed in previous comment.

Dec 29 2010 5:48PM	Erin Graydon Baker	Partners HealthCare System, Inc.	Erin Graydon Baker	Partners Healthcare	General Comments on the Draft Report	Partners Healthcare appreciated the opportunity to provide feedback on the new and existing SRE definitions. We applaud the NQF SRE Committee for clarifying the existing definitions with considering their applicability to other settings including ambulatory care. We strongly support the removal of the term never events. In general, we find that the revised existing and new SREs make sense and are clear. However, some of the new terms could be explained further such the definition for serious injury. The term substantial change in the patient's long-term risk status remains vague. We also think that Criminal Events should be handled by state and local authorities and question whether these should be reported additionally as SREs.'	Addressed in previous comment.

Dec 29 2010 10:28PM	Michael Phelan	Cleveland Clinic	Cleveland Clinic	Cleveland Clinic	General Comments on the Draft Report	The incidents describe Serious Reportable Events whose reporting are important relevant to improving care and patient safety. We could support these but would insist on attention to definition clarity for many of the events. The guidance provided is insufficient. Overall the intent of including the events are good, however implementation and identification of the events will require high level analysis by qualified personnel. Operationalizing this list to being reportable will be a challenge mainly because these are not event/measures that are readily or easily tracked. For the most part there needs for clearer definitions for many of the events listed as well as defined inclusion and exclusions events listed. It may have been better to have listed a smaller set of discreet(specific defined) type events first then broaden the definitions once a set of event were deemed acceptable as SRE's.'	Reporting of these events is expected to occur after organizational review processes are satisfied, including those of review by appropriate individuals charged with oversight of safety, quality, risk management, medication management, and similar departments. The initial set of 27 events was first released in 2002. Subsequent updates have been informed by input from users and experts from the disciplines and care areas touched by the events. As noted, they should continue to be improved and be supplemented by measurement tools.

Dec 29 2010 11:52AM	Margaret Reagan	Premier, Inc.			General Comments on the Draft Report	General remarks The Premier healthcare alliance congratulates NQF on a much improved and clearer document over the existing list of Serious Reportable Events (SRE). We are pleased at the effort to resolve ambiguities and we appreciate the care taken with the definitions, including the removal of the term "never event". We would caution that with clearer definitions, it is fair to expect thenumbers of reported SREs to increase. As these definitions are published and continue to be used for public reporting in states and by CMS for healthcare-associated conditions (HACs), hospitals are likely to report more SREs, which might lead to a perception that there is a lack of improvement in reducing serious injuries and death. This could also impact CMS when setting future thresholds for performance on selected HACs. We strongly recommend that the NQF Committee address the potential for an artificial increase when these revised SREs are finalized and published. Please find below, a few areas of concern that we think should be addressed in order to strengthen the 2011 Update of the NQF Serious Reportable Events (SREs).'	Addressed in previous comment.

Dec 30 2010 4:50PM	Angela Franklin	American College of Emergency Physicians			General Comments on the Draft Report	'The American College of Emergency Physicians (ACEP) applauds the NQF for its work on the 2011 Update for Serious Reportable Events (SREs) , and appreciates the opportunity to comment. ACEP is the oldest and largest national medical specialty organization representing physicians who practice emergency medicine. With more than 28,000 members, ACEP is the leading continuing education source for emergency physicians and the primary information resource on developments in the specialty.'	No action necessary.
Dec 30 2010 5:23PM	Denise Graham	Association for Professionals in Infection Control and Epidemiology			General Comments on the Draft Report	'APIC suggests the intent of SRE Product or Device Events: 2A and 2B should be on discovery of the contamination or discovery of a pattern of unacceptable practice and not the outcome, since the contamination/poor practice is more likely a detectable event. Discovery would require action to investigate potential infections even if a patient did not develop an infection as the result of testing. Not knowing for sure, given lengthy incubation periods, patients are subject to much testing over time, unnecessary without the potential exposure. As currently worded, the infectious outcome being detected as related to the device or event would rarely be identified as an SRE.'	Addressed in previous comment.

Dec 30 2010 12:56PM	Rabia Khan	Centers for Medicare and Medicaid Services	Michael Rapp	CMS	General Comments on the Draft Report	These 29 SREs are important, and are useable for measure development and data analysis if implementation specifications are defined. Operational definitions will lead to clarity of SREs, which would otherwise be subject to interpretation. For instance, "serious" injury has multiple interpretations unless "serious" is defined. SRE specifications will result in implementable reporting. Also, reportable data and pertinent information used for the NQF SREs update should be included in the report, as this would benefit members and the public reading the report. Specifications of the SRE's need more fleshing out. As they are written, it would be difficult to incorporate SRE's into national pay for reporting or pay for performance programs. Strongly support expanding coverage to include ambulatory surgical centers, office-based practices, and skilled nursing facilities. SREs should broaden to include elective surgeries and elective procedures, as they are also serious procedures that can result in possible death or disability.'	Glossary includes definition of serious. Fleshing out of SREs can likely be best accomplished through identification, development and endorsement of performance measures. NQF continues to explore this strategy. Events involving surgery and procedures apply to those that are elective and non-elective.

Dec 23 2010 12:49PM	Cindy Barnard	Northwestern Memorial HealthCare			General comments on the Serious Reportable Events glossary	High alert meds - references "a" high alert medication list. Does NQF mean this to be an authoritative list, or merely one to consider? Recommend making ISMP the gold standard if you do reference such a list. But it is not clear what relevance "high alert" has to the SRE. Surely any medication event leading to death or serious injury is a SRE, so why highlight this list? See comments on medication events, above. Informed consent - clarify "discussion between a person with decisional capacity" etc; also, should explain "benefits and risks and alternatives" Injury - This is too vague. In the past the focus for a "serious" injury was on "disability lasting 7 or more days" which was helpful. What is short term? Recommend returning to the seven-day framework. Medication error - this appears to be the NCCMERP definition. Should be footnoted. Preventable- should say"because of an error or othersystem failure." Serious - See Injury, above. (1) needs a time frame, eg harm lasting 7+ days. (2) should not say "can result" but rather "results." Sexual abuse - recommend adopting the Joint Commission definition.'	The ISMP high alert medication list is the recommended list. This has been noted in the glossary. "Alternatives" has been added to informed consent. The definition of serious is unchanged to avoid limiting reporting based on time.

Dec 23 2010 4:19PM	Alyssa Keefe	California Hospital Association			General comments on the Serious Reportable Events glossary	Generally, a glossary is a much-needed addition to this report; however, further clarity is necessary. As noted in a number of comments, there are some instances where the definition could be wide open to interpretation, and we would ask the committee to consider the requests for refinements to accurately reflect the intention of the committee in developing the definitions. We concur with many of the definitional questions raised in the comments, including comments by the Minnesota Hospital Association, and offer two additional for your review and consideration. NQF proposes two separate definitions for "serious" and "injury". Further clarification is needed to better understand the committee;s intention developing two separate definitions. Are we to assume that if we combined the two, we will have a definition for "serious injury."	Addressed in previous comment.

Dec 23 2010 4:19PM	Alyssa Keefe	California Hospital Association			General comments on the Serious Reportable Events glossary	The definition for "end of surgery" should be reconsidered to remove ambiguity, and we offer an alternative definition below. Removing the "ands" and noting that some surgeries do require wounds to be left open is appropriate. Original: Surgery ends after all incisions or procedural access routes have been closed in their entirety, device(s) such as probes or instruments have been removed, and, if relevant, final surgical counts confirming accuracy of counts and resolving any discrepancies have concluded and the patient has been taken from the operating/procedure room. Revised for consideration: Surgery ends after all the following: incisions or procedural access routes have been closed in their entirety (to the extent that closure is intended), device(s) such as probes or instruments have been removed, processes to confirm accuracy of counts and resolve any discrepancies have concluded (when relevant), and the patient has been taken from the operating/procedure room (when relevant).	Addressed in previous comment.
Dec 29 2010 5:25PM	Carmella Bocchino	America's Health Insurance Plans			General comments on the Serious Reportable Events glossary	We ask that the NQF clarify the following terms included in the Glossary: serious Injury, competent individual, low risk pregnancy - describes the maternal condition but does not include fetal status. This more limited definition restricted to the mother's status can affect the interpretation of several maternal measures.'	Addressed in previous comment.