American Hospital Association

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Dear Dr. Corrigan:

On behalf of the American Hospital Association (AHA) and our 4,800 member hospitals, health care systems and other health care organizations, and our 35,000 individual members, we are pleased to provide comments to the National Quality Forum (NQF) and the steering committee charged with updating the report on serious reportable events. The original list of serious reportable events has been a helpful tool to a few states in which state agencies were given the responsibility to intercede when an individual has been seriously harmed or died during the course of medical treatment, and where it appeared the outcome was unexpected and likely preventable. These events were dubbed the "never events" because the assumption was that they should never be allowed to happen.

It is important to the states that have adopted this approach, as well as to other states that may consider tasking a state agency with this role, that they have a standardized list of serious reportable events to use. We offer the following comments to assist the NQF's efforts to update its current list.

General Comments

Usefulness of the List. In reviewing the list of serious reportable events, the steering committee must have addressed the basic question of whether or not the list continues to be useful – essentially reaffirming the need for such a list. Yet, there is no mention of this in the report. We urge the NQF to affirmatively include a recommendation from the steering committee for the maintenance of this list as a means of identifying those rare events that warrant further investigation. By making such a recommendation, NQF members can affirmatively vote on its continued usefulness. It also sets precedence for the question being asked in review of all NQF-endorsed measures and products.

Framework for the List. Currently, the list of serious reportable events is a mix – many events relate to serious harm, but some do not require that any real harm to the patient be documented; others describe occurrences that are difficult to identify and may be rarely, if ever, reported because the facilities and health care professionals have no way of knowing they occurred. As the patient safety movement advances, we need a more consistent list of serious reportable events. For example, bringing together a group of individuals that run patient safety reporting systems and having them identify the kinds of rare but significant events that are appearing in their databases may generate a more useful set of serious reportable events for the future.

National vs. Local Action. The report suggests that independent actions by states to address serious reportable events are less desirable than coordinated national action to collect data. But, the first steering committee's work was based on the importance of facilitating patient safety work at a variety of levels, and that the list of serious reportable events was most likely a resource for state agency actions. If the current steering committee believes that national action is better, it should be articulated in the report. If not, this should be deleted from the report. (Specific places for editing include page 1, lines 10–12 and lines 21–23.)

Lessons Learned from Implementation of Original List. The current report mentions that the first report became the basis for work in Minnesota and Connecticut. It would be helpful to have a summary of the lessons learned from the implementation of the list in these states and how these lessons helped to shape modifications to the list. We suggest the NQF include such a summary near the front of the report so that others can learn from Minnesota's and Connecticut's experiences and to have a better context for understanding modifications to the original list.

Call for Standardized "Reporting." The report references in several places the standardized "reporting" of serious reportable events. But "reporting" means different things to different people – public display of information, collection and submission of data to a single source, collecting data and sharing an analysis of the results. In the case of the serious reportable events, the NQF is assisting organizations in *standardized case finding*, not standardized reporting. That is, cases that meet the criteria on the list should be subject to whatever actions are deemed appropriate by the organizations implementing the list. The report does not attempt to standardize the elements of information that would be collected, how it would be analyzed, or how information might be shared publicly – all of which are common elements for public reporting. This report is appropriately different in that it only addresses what kinds of cases should go into a collection of serious reportable events, but leaves open the question of exactly what information needs to be collected. Some of the most helpful safety reporting systems from other industries have very successfully used this method of standardized case identification. Health care should, as well, but we should not confuse that with standardized reporting.

Relationship to the Patient Safety Organizations. This NQF report calls for the list of serious reportable events to be used as a guide for the work of patient safety organizations (PSOs). However, the PSOs are to collect confidential, non-disclosed data to illuminate opportunities to improve safety. The Patient Safety and Quality Improvement Act of 2005 gives the Department of Health and Human Services the authority to certify PSOs to collect and analyze confidential information from health care providers and professionals about safety risks, near misses and events that caused harm to patients. These PSOs are intended to help providers learn how to prevent tragedies. State agencies using the list of serious reportable events have a different purpose: public accountability. It may be desirable for the event analysis information also to be captured in the PSOs' databases to further understanding of risks and opportunities. But the list of serious reportable events should not be used in implementing the PSO legislation. It confuses the confidential analysis and learning purposes of the PSOs with the public accountability functions of the state agencies. Current references to the Patient Safety and Quality Improvement Act should be dropped from this report.

Specific Suggestions

Page 1, lines 15–19. This text references the dichotomy between excellent skill and biomedical research and fragmentation of the health care delivery system. This should be tied to supporting evidence, including the work of Elizabeth McGlynn of Rand, Jack Wennberg, M.D., of Dartmouth, the Institute of Medicine reports and other reliable sources.

Page 2, line 56. The language states that a recommendation is being made, but it is not written in a way that can be discussed and voted upon by the NQF membership. In general, if a recommendation is being made, it should be offered for a vote. If not, it should be dropped. In this instance, we believe the report delves too far into how those implementing the list should perform their tasks, and suggest this language should be dropped. There are many ways in which state agencies or other authorities can use this list to act in the public's interest. Without evidence determining which is best, it would be unwise to suggest specific approaches.

Page 4, Table. The second criterion says that the events identified in this report are meant to be "identifiable and measurable." By design, these events are included because they are rare. The list is to be used to identify that which, when it occurs, ought to be examined closely to learn how it could have happened; it is not a measurement system. The word "measurable" should be replaced by "unambiguous." Further, the fourth bullet states that the events are intended to be "of a nature that the risk is significantly influenced by the policies and procedures of the *health care facility*." Yet, event 4E (kernicterous), 4G (spinal manipulative therapy), and 4H (artificial insemination) are usually adverse events that occur in individual clinician offices, not health care facilities.

We suggest altering the criteria to state that the events are "influenced by the policies and procedures of *health care professionals* and facilities."

Pages 6–7, Table. The implementation guidance for surgery on the wrong body part includes a sentence noting that an incorrect mark can result in wrong site surgery, but surgery does not begin "at time surgical mark is made on the patient." Greater clarity may be provided by saying, "Placing a mark on the wrong body part does not, in itself, constitute wrong site surgery."

Page 8, Table item C. The event says "surgical procedures," but the specifications say "procedures." There are many non-surgical procedures. Is the event "surgical procedures only," or is the broader array of procedures intended by the committee?

Page 10, Event 2.A. The implementation guidance includes the definition of "detectable." This should be in the specifications, not guidance.

Page 11, Event 2.B. This event calls for the reporting of instances when the use of a device for functions other than the one(s) for which it was intended was associated with a patient death or serious disability. We suggest the steering committee consider creating an exception in those instances when a natural disaster (e.g., Hurricane Katrina) or other extraordinary situation interrupts normal supply lines and creates situations in which health care professionals have to improvise because normal equipment is unavailable.

Page 11, Event 2.C. This event is defined as death or serious disability associated with an air embolism, and the additional specifications indicate that deaths associated with neurosurgical procedures should be excluded. It is unclear why the additional specifications limit the exclusion to deaths associated with neurosurgery but does not exclude serious disabilities associated with neurosurgery. Further, the implementation guidance lists other procedures that, like neurosurgery, are known to put patients at high risk of air embolism. It is unclear whether the steering committee intended for these other procedures also to be excluded, which would make clinical sense, or whether the committee had determined that these other procedures should be left in because there was some substantive difference between neurosurgery and the other procedures. Until there is good science that can be applied to reduce the risk, these other procedures also should be excluded from the description of what constitutes a serious reportable event. Like neurosurgery, the risk of air embolism is not within the control of the facility and the health care professionals.

Page 12, Event 3.A. The "implementation guidance" provided for this event – infant discharged to a wrong patient – is not guidance, but an affirmative statement about organizational responsibilities not specifically apropos to this event. We believe the discussion at the beginning of this report establishes the rationale for such a list and suggest dropping this statement.

Page 13, Event 4.A. The event description was either truncated or needs to be edited because it seems to cut off in mid–sentence ("… wrong preparation, or wrong route of administration or").

Page 14, Event 4.C. This event covering maternal death or serious disability associated with labor and delivery in a low-risk pregnancy has the additional specification that it includes occurrences within 42 days post-delivery. This unusual time frame needs to be justified with clinical evidence or expert opinion.

If you have questions about our comments, please contact the AHA's Nancy Foster, vice president for quality and patient safety policy, at (202) 626-2337.

Sincerely,

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