College of American Pathologists

Comments to the
National Quality Forum on
The List of Serious Reportable Events

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The College of American Pathologists (CAP) appreciates the opportunity to respond to National Qualify Forum (NQF) on the updated endorsed list of serious reportable events (SREs). CAP is a national medical specialty society representing 17,000 board-certified pathologists who practice pathology and laboratory medicine. The College's Commission on Laboratory Accreditation is responsible for accrediting more than 6,000 clinical laboratories worldwide. Our members have extensive expertise in providing and directing laboratory services and also serve as inspectors in the CMS-deemed CAP accreditation program. CAP also provides laboratories with a wide variety of proficiency testing programs and has the responsibility to evaluate the accuracy of test performance and interpretation in more than 20,000 laboratories worldwide.

The NQF endorsed list of SREs reflects a list of serious, preventable adverse events that should be used for the basis of a national reporting system and lead to substantial improvements in patient safety. CAP believes that patient safety is promoted by processes, procedures, and innovations that may be applied at any number of levels, including the individual professional, the clinical laboratory, a health care system, a professional society, or a governmental entity. Moreover, the College supports a comprehensive, nationwide health systems approach to reducing and preventing medical errors but believes that two of the new SRE additions regarding irretrievable loss of an irreplaceable biological specimen and failure to follow up or communicate laboratory, pathology, or radiology test results are not adequately defined and thus will adversely impact the practice of pathology and laboratory medicine.

Impact of SREs on Pathologists and Clinical laboratories

The Clinical Laboratory Improvement Amendments of 1988 (CLIA) holds the clinical laboratory and the laboratory directors, who are predominately pathologists, responsible for monitoring all steps of the total testing process (TTP)[1]. The SREs listed below are encompassed within the total testing process and therefore may be attributed as sentinel events caused by the clinical laboratory, which would actually mask the true cause of such patient safety issues. Moreover, the link between SRE's and causation has not been readily documented in medical literature.

Threats to patient safety are manifold and resist any single classification. In the practice of pathology and laboratory medicine, patient safety can be imperiled by a myriad of factors such as human error, patient or specimen misidentification, ineffective reporting of test results, failure to correct reporting errors, or an organizational culture that fails to emphasize the importance of quality, safety, motivation, responsiveness to customers, or quality standards.

While errors can occur in every step of the TTP, the frequency of errors is low. An extensive review of reported errors in laboratory medicine published from 1992 to 2001 found the distribution of errors was 32-75% in the pre-analytic phase, 13-32% in the analytic phase, and 9-31% in the post-analytic (administration) phase.[2] CAP promotes patient safety by requiring specific laboratory practices as part of the CAP Laboratory Accreditation Program, through professional education and ongoing professional training, support of an anonymous quality and safety reporting system, the development of Cancer Checklists and other reporting standards, support of research related to quality and patient safety, and advocacy for standards that further safety and high quality care. In addition, CAP introduced a system of terminology for the electronic health records (*SNOMED*), and supported programs to define frequency of errors throughout all facets of laboratory testing. Given that the College has been working to improve

[1] The total testing process (TTP) is the total process from the ordering of a test to the interpretation of a test result. The TTP starts and ends with the patient, and can be subdivided into three distinctive phases: the pre-analytical step (before the analysis), the analytical step (the actual analysis) and the post-analytical step (after the analysis)

[2] Goodman, Cliff, etc, Laboratory Medicine: National Status Report 2007, https://www.futurelabmedicine.org/pdfs/2007%20status%20report%20laboratory_medicine_-_a_national_status_report_from_the_lewin_group.pdf, May 2008 p 149

patient safety within the laboratories for over a decade, we believe that the SRE's selected, in their current formulation, are not ALWAYS easily identifiable, not ALWAYS serious, and not ALWAYS preventable.

1. *Patient death or serious injury resulting from the irretrievable loss of an irreplaceable biological specimen*

   The concept of "specimen loss" should apply to misplacement or willful destruction of a specimen. The loss of biological specimens can preclude necessary studies, current and or future, on specimens that are then essentially "lost". The incidence of specimen loss is low but may have severe consequences for patients. In a study conducted by SANDBANK et al, it found that in an outpatient clinic between October 2001 and April 2005 the incidence of specimen loss was 1 in 1,466 (0.068%) in biopsy specimens. Five specimens were reported as lost during the period. Two were retrieved, two were lost probably because of failure to insert the pathology specimen into the container, and one was lost in the pathology laboratory during processing.[3]

   Specimen loss is an unacceptable, but inevitable, occurrence without a universal solution. Poor outcomes and harm may results for lost of patients' specimens. Often, patients can undergo additional unnecessary surgical or diagnostic procedures. In other cases, patients will experience significant delays in the treatment of medical conditions they never knew they had. Specimen loss can lead to unnecessary hospitalizations or failure to treat unreported conditions. If a patient suffers no physical harm from the loss, the prospect of being subjected to additional procedures is not without risk. Such additional procedures, such as prostate biopsy, colonoscopy, fine-needle aspiration of the lung, phlebotomy, or other diagnostic testing, are not without risks that have associated opportunity costs to patients, families, the health care system, and society. [4]

   The College believes that the SRE list should be better defined, and focused on one specific aspect of the irretrievable loss of an irreplaceable biological specimen (e.g. loss of surgical specimen due to misplacement or willful destruction of the primary specimen).

2. *Patient death or serious injury resulting from failure to follow up or communicate laboratory, pathology, or radiology test results*

   Poor communication between laboratory professionals and clinicians is generally cited as the chief issue affecting quality of laboratory services during the pre-analytic and post-analytic phases. Throughout the health care continuum, communication failures are a leading cause of shortfalls in quality, particularly of preventable errors that harm patients. Widely overlooked in training of health care providers are that few clinicians or laboratory professionals receive formal training in effective communications.[5] Communicating results, critical or not, is an everyday challenge in any hospital laboratory. Critical values and critical results are communicated to designated health care providers and others. In pathology, all tests results are communicated through

[3] Sandbank MD, Sharon, Klein, MD, Doron, Westreich MD, Melvyn, Shalom MD, Avshalom. The Loss of Pathological Specimens: Incidence and Causes. Dermatologic Surgery .July 2010, Vol. 36, Issue 7, pp. 1084–1086,
[4] Edward J. Dunn and Paul J. Moga (*2010*) Patient Misidentification in Laboratory Medicine: A Qualitative Analysis of 227 Root Cause Analysis Reports in the Veterans Health Administration. Archives of Pathology & Laboratory Medicine: February 2010, Vol. 134, No. 2, pp. 244-255.
[5] Goodman, Cliff, etc, Laboratory Medicine: National Status Report 2007, https://www.futurelabmedicine.org/pdfs/2007%20status%20report%20laboratory_medicine_-_a_national_status_report_from_the_lewin_group.pdf, May 2008 p 149

written or electronic reports crossing several layers in order to get to patients. The communication is indirect and often beyond the laboratory's reasonable control. For instance, electronic health record (EHR) systems while designed to improve health care, may in some instances, particularly when first implemented, create further patient safety risks. Significant risk for misinterpretation by the health care provider may occur due to inadequate or poorly designed display of laboratory results.

The College believes that the SRE list is amended to better define the elements that constitutes "successful" communication of critical results and whether the test results involved in these communications should be of a critical nature or not.

Conclusion

The College believes that the focus on these SREs should have the objective of improving the patient test management processes, including patient identification, and critical results reporting and interpretation. The goal of the SREs should be to ensure better care coordination among clinicians with regard to patient safety with the objective of improving identification, and communication of medical errors. Moreover, using a system approach rather than a personal approach is the best way to reduce error and improve patient safety.

CAP appreciates this opportunity to comment on this vital scientific issue and would welcome the opportunity in the near future to discuss our views on this issue. If you have any questions, please do not hesitate to contact, Helena Duncan, Assistant Director, Public Health Policy (202.354.7131/hduncan@cap.org.)

Thank you for allowing the opportunity to request reconsideration of any of the 29 Serious Reportable Events (SREs) in healthcare as outlined in the forthcoming report "Serious Reportable Events in Healthcare - 2011 Update: A Consensus Report." This communication is being sent with the input of Kaiser Permanente Patient Safety, Clinical Risk Management, and Quality staff. Kaiser Permanente cares for nearly 9 million members in the United States and therefore has interests that are directly and materially affected by the NQF-endorsed recommendations.

We do believe the newly added items all offer an opportunity to improve the safety and quality of care for our members and patients. That being said, we have several recommendations for your consideration concerning both the existing and new items:

- *We very much appreciate the use of the term "resulting from" in the newly added events related to loss of an irreplaceable specimen and failure to follow up or communicate test results. The term "associated with" is used in the other two newly added items, and in numerous existing items. "Resulting from" is more objective than "associated with" and we believe its use would add clarity to event investigation and classification. We recommend NQF review the use of these two terms throughout its report.*
- *While the full report, "Serious Reportable Events in Healthcare," contains a glossary of definitions, several of our internal reviewers felt that the wording or definition of some of the 29 SREs lacked specificity. The result of ambiguity is inconsistent identification and reporting across differing health care systems. The question we would like NQF to entertain is "do you feel that you have clear and consistent operational definitions of these events in a way that assures a high degree of "inter-rater reliability" across various health care systems? If yes, how do you know?" Some systems may be under- or over-reporting as a result of this issue which is good for no one.*
- *We are concerned that as more items are added, the level of analysis required to prove causation increases. This might result in unwarranted variation in reporting events across various health care systems, as well as the redirection of existing resources to proving or disproving causality for the primary purpose of knowing whether an event is reportable or not.*
- *We are learning that not all Stage 3, Stage 4, and unstageable pressure ulcers acquired after admission/presentation to one of our healthcare settings is preventable. To that end, we request the NQF consider language that makes certain exceptions to this type of event being classified as an SRE (such as HAPUs acquired in the end stage of a terminal disease).*

Thank you for consideration of these comments.

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Dear NQF Board,

On behalf of The Council of Women and Infants Specialty Hospitals (CWISH) and the National Perinatal Information Center/Quality Analytic Services (NPIC/QAS) we are writing to request reconsideration of the following Serious Reportable Events presently under review by the NQF:

- Maternal death or serious injury associated with labor or delivery in a low risk pregnancy while being cared for in a health care setting, and
- Death or serious injury of a neonate associated with labor or delivery in a low-risk pregnancy

NPIC/QAS is a 26 year old non-profit company that provides quality, volume, and utilization benchmarking services to over 150 member and non-member hospitals including 49 Military Treatment Facilities throughout the world.

The Council of Women and Infants Specialty Hospitals (CWISH) is a subgroup of NPIC/QAS member hospitals which are identifiable women's hospitals, with most of their activity focused on women's and infant's services. Present CWISH membership is comprised of twelve, Level 3 perinatal care hospitals with large obstetrical and neonatal volumes. On average, more than 8800 women are delivered at each hospital every year. In CY 2010 over 105,000 babies were born at the CWISH hospitals collectively. CWISH members make up ten of the top 25 hospitals in birth volume as listed in the 2009 American Hospital Association Data Base. CWISH is dedicated to facilitating excellence in providing healthcare services to women and infants nationally through collaboration and through support of programs, practices and national policy. Through sharing of quality, operational and financial data, CWISH members are driven by and represent the highest standards of perinatal care and hospital operation in the nation.

The overall concern with these two Serious Reportable Events (SRE) is weaknesses in the definitions/specifications such that an event could be labeled as seriously reportable when that is not the case. In the current and growing climate of public reporting of quality measures, and pay for performance/ denial of payment initiatives by payers, "endorsing" a weak or untested measure will encourage regulatory and other organizations to "adopt" these events for such actions.

Our specific concerns regarding the SRE " Maternal death or Serious injury in a low-risk pregnancy" are the following:

a) The low-risk definition allows for certain appropriate exclusions of previously documented high risk conditions but does not include obesity or diabetes nor women transferred to a higher level of care without appropriate documentation.
b) The definition also includes the phrase "or other *previously documented* conditions", a catch-all phrase that misses an all too frequent experience in our hospitals. Many hospitals, especially regional perinatal centers providing subspecialty care, care for women presenting for imminent delivery with no or little prenatal care and/or no documentation of prior pregnancy history. This sets up a situation where a woman may appear to be full term and low risk when in fact she has a high risk condition that was not previously documented and is unknown.
c) An additional specification is "death within 42 days post-delivery". Post-delivery discharges occur usually within 1.5-5 days of delivery; if the delivered mom dies outside the hospital or at another facility other than hospital at which she delivered, it is very difficult for hospital to know of the death, or be held accountable for the death.

NPIC and CWISH are requesting this measure not be endorsed by NQF. Short of that we request modifications to the exceptions list to include women who are: obese, diabetic, present with little or no prenatal care, present with no medical records, and are discharged to home and die outside a hospital or at a non-delivery hospital. (The last exclusion will allow for the inclusion of women who are discharged to home, readmitted to the hospital where she delivered for a postpartum condition and die within the 42 day window.)

Regarding the SRE "Death or serious injury of a neonate associated with labor or delivery in a low-risk pregnancy", the same issues regarding the definition of "low risk" pregnancy apply. Additionally:

a) The measure developer states that they are piloting this measure beginning in August, 2011 and will know "what types of definitional issues arise and will develop additional guidance as needed based on the pilot". Clearly this indicates the specifications are in development and the definition of "serious injury", which currently uses one developed for the adult population, has not been refined for the neonate.
b) There are instances when the mother has a low risk pregnancy and the infant has an undetected congenital anomaly or other condition that merits an exclusion above and beyond "serious injury".
c) The above comments regarding women who are discharged home and die within 48 days also apply to infants discharged to home who die within 28 days outside a hospital or at a non-birth hospital.

NPIC and CWISH request that the SRE " Death or serious injury of a neonate associated with labor or delivery in a low-risk pregnancy" not be endorsed at the present time.

We are available for further consultation if that will assist the Board in its deliberations.

Thank you in advance for your consideration of our requests.

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