THE NATIONAL QUALITY FORUM

CONFERENCE CALL OF THE COMMON FORMATS EXPERT PANEL

August 17, 2009

Panel members present: Henry Johnson, MD, MPH (Co-Chair); David C. Classen, MD, MS (Co-Chair); Matthew Grissinger, RPh, MS; Mark Keroack, MD, MPH; David Knowlton, MA; Mary Krugman, PhD, RN; Helen Lau, MHROD, BSN; Lori Paine, RN, BSN; Shannon Phillips, MD, MPH; Nancy Ridley, MS; Heather Sherman, PhD; Liaison Member: William Munier, MD

Others present: Diane Cousins, RPh; Peter Goldschmidt, MD; John Moquin, and Ira Yanowitz, AHRQ; Rhonda Davis, Iowa Foundation for Medical Care

NQF Staff: Peter Angood, MD, FCCM; Eric Colchamiro, MPA; Melinda Murphy, RN, MS, NE-BC.

WELCOME, INTRODUCTIONS, AND APPROVAL OF JULY MINUTES

Following Dr. Johnson's welcome, the Panel approved the minutes of its July conference call without change. Dr. Johnson then introduced Drs. Munier and Helwig, from the Agency for Healthcare Research and Quality (AHRQ), to provide an update on revisions to AHRQ's Common Formats for event reporting

UPDATE ON REVISIONS TO COMMON FORMATS

GENERAL COMMENTS

Dr. Munier first noted that the Panel had previously seen examples of Event Descriptions, which outline specifics of what is important to collect about each patient safety event. The Event Descriptions use a set of four common categories (Definition of Events, Scope of Reporting, Risk Assessments and Preventive Actions, and Circumstances of Events), that ensure a standardized approach and collection of appropriate information.

AHRQ staff has continued to add Event Descriptions. Event descriptions allow for paper or electronic implementation. These revisions are critical to ensure the necessary information to produce reports is included prior to writing code.

The Healthcare Associated Infections (HAI) forms and event descriptions have not been completed. Staffs from AHRQ and Centers for Disease Control and Prevention (CDC) continue to work together; however, AHRQ is unlikely to be able to release HAI forms with the August release of the Common Formats. Any version released now would not be automated or compatible with the National Health Safety Network (NHSN) database. One panel member reiterated the suggestion to AHRQ staff members that they include the 21 states that mandate NHSN in CDC/AHRQ discussion if at all possible and/or work with the lead states and the group's listserv. Dr. Munier noted that they do not have a forum for the 21 states at this time. He also noted that some state requirements are very labor intensive.

Panel members responded that, overall, the reporting forms are significantly improved over Version 0.1 Beta, are laid out logically resulting in an improved, more straightforward final

product. It was noted that that the forms are still in early stages of development and will be refined as users provide feedback about need for refinement, including additional items. That process will be informed by what the Expert Panel and AHRQ understand will occur as Patient Safety Organizations (PSOs) amplify reporting requirements to meet what they and their users determine is needed. Dr. Munier said that AHRQ should be asking questions that collect data fundamental to the safety events with the understanding that users may elaborate to collect information for use at organizational and other levels below that of those deemed important to national understanding and learning. If, over time, other content is needed, it can be added to these forms. He also added that AHRQ staff had recently visited with PSOs that had automated the Beta version of the Common Formats, and that additional questions had been suggested. They also communicated with a PSO from a specialty group, which has need for very few of the forms but intends to add multiple additional questions to satisfy its purposes.

AHRQ plans to release technical specifications for the reporting forms in late December or early January. The specifications will allow for additional questions, allow for reports to AHRQ and the Network of Patient Safety Databases (NPSD), and facilitate creating local reports which can further improve the process. In response, a Panel member asked about forms methodology in terms of the number of questions asked and the language/definitions used within the forms, addition of questions, and mapping concerns. Dr. Munier responded that the Common Formats are a work-in-progress, and that they can be adapted if unnecessary or additional questions negatively impact the process.

Regarding the Release of Version 1.0 of the Common Formats, Dr. Munier said that aside from the HAI forms, AHRQ staff appears to be close to meeting its August deadline for release. AHRQ plans to pair the Event Descriptions and the Paper Forms upon release but will not initially provide paper reports. This would allow AHRQ to delay reports until the technical specifications came out. AHRQ is planning for release of the specifications in the first quarter of 2010. In the meantime, if individual Panelists have suggestions, these should be submitted to Dr. Helwig with a copy to Dr. Munier.

EVENT-SPECIFIC COMMENTS
Dr. Helwig discussed changes to the paper reporting forms noting that there were minor changes in wording across all of these documents. Within each type of event type, there were sometimes also more significant changes.

For the Blood or Blood Product form, the scope has now been limited to blood or blood products dropping organs, tissue, and gene therapy . Organ transplant events are now captured on the Surgery and Anesthesia form. AHRQ staff also worked with the AABB (formerly American Association of Blood Banks) and the CDC to use appropriate language and questions. Dr. Munier added that this form only gathers information that the AABB deems necessary to collect.

Dr. Helwig said that there were very few changes to the **HERF** form. The **PIF** form now includes the AHRQ Harm Scale, which was presented to the Panel in February. Questions were also streamlined on this form to simplify the process. The **SIR** form (previously Final

Assessment Form (FAF)) also has undergone some changes. The form name was changed to resolve questions as to when it is to be completed. Other major revisions to SIR include: a notation of whether a Serious Reportable Event (SRE) occurred, and if so, which one; a section on Contributing Factors, which are generic and can be filled out across many different events.

A Panel member asked whether a person completing the SIR form would be able to amplify, modify, or complete questions from earlier forms noting that, as an example, it was unlikely that the initial reporter would be able to answer questions 8 or 9 on the Blood form. Dr. Helwig said that one purpose of the SIR form is to allow the person completing the form to confirm the findings of the initial reporter. AHRQ staff and the Panel member agreed that as long as the individual with more specialized knowledge has continued access to the form, that reporting should be valid.

A Panel member asked about the HERF form and the notation that information is collected for PSO or facility use only, while the PIF says that information is collected solely for facility use. Dr. Helwig said that this was a typographical error and would be corrected.

A Panel member asked about question 6 in the SIR noting that it is the same as question 1 in the HERF; is AHRQ simply asking the individual with more specialized knowledge to confirm the results. Dr. Helwig responded that AHRQ is looking for confirmation from the patient safety manager at a facility, as to whether the event was correctly identified. This Panel member asked why "Location" and "Who Reported the Event" are in the SIR rather than the HERF. Dr. Helwig said that these two items in the HERF are considered free text narrative, and that many institutions already have coding developed for individuals doing reports. On the SIR, the forms require the quality manager to look at the narrative information, and map it to the appropriate category, to allow for standard codes. This Panel member also asked about "Contributory Factors", and whether this was based on an existing system, or if it was something developed by AHRQ staff. Dr. Helwig responded that it was developed based on analysis of many different systems. In addition, AHRQ staff worked with a specialist in contributing factors from the Canadian patient safety system.

A Panel member noted that SIR question 11 permit one response contributing factors response where there may be multiple. Other Panel members agreed. Dr. Munier responded that AHRQ was divided on this point but considering the Panel's arguments, AHRQ will revise the form to allow users to check all that apply.

A Panel member asked about Question 13 on HERF, and the rationale for including criminal activity. This member said that the World Health Organization's International Classification for Patient Safety (WHO-ICPS) work group have taken the position that criminal activity should be kept out of reporting systems. She also noted that the Veterans Health Administration has a separate component to their reporting system for criminal activity. This Panel member suggested that AHRQ may get public criticism because of its inclusion. Dr. Helwig responded that, information about the NQF Serious Reportable Events is being captured on the forms based on suggestions from the Expert Panel and the intent in including criminal events is simply to reflect the NQF's complete list. There is not a focus on criminal activity. If a user

wanted to report a criminal event, they would have to do it through narrative, as this is the only area that references it. Dr. Munier added that many states have gone to considerable effort to define criminal events, and that AHRQ is including it as a resource for states that require tracking of these incidents.

A Panel member asked about limits to describing an event in general terms and whether there would be character or space limits within their database. Dr. Helwig responded that the NPSD currently will not be able to handle non-coded, narrative information. Narrative information will remain at the local level where local limits will be applied.

Dr. Helwig next spoke about the **Medication and Other Substances** form. AHRQ staff, using feedback from the Panel, now asks about both the intended medication and the medication administered. In addition, breast milk was included on this form.

A Panel member commented on question 7 suggesting that the form contain the standard language used by pharmacists – "medication error for incorrect action" and "adverse drug reaction" for two of the response options. Other Panel members agreed with this comment.

A Panel member asked about question 8, and about unsafe conditions that could occur before medication reaches the patient. Two options on the form (K and L) imply that medication has reached the patient (by the "administration of expired drugs" and "administration of a known allergen"). In option L, it is unclear whether a nurse error can be captured. Another member added that if a nurse recognizes an error before it is administered, it should be classified as a "near miss". AHRQ staff said that they will review and try to better distinguish between a near miss and an administration error.

Dr. Cousins said that the generic language in the form reflects the fact that not all incidents are adverse drug reactions, and since this encompasses more than medication incidents, it could be an adverse reaction. One Panel member said that the term "medication error" or "incorrect medication, etc." could be added to the "e.g." on the form to better clarify what should be included, and would then be using standard, accepted language. Further discussion on this form centered on appropriate title, and wording of the questions.

Dr. Helwig spoke next on the **Perinatal** form. The instructions to this form now include a clearer definition of a perinatal event, which specifically refers to a patient safety event associated with the birthing process. The form has been shortened and simplified to capture only events related to outcomes. Panel members note the changes have been done well.

Discussion continued with a review of the **Pressure Ulcer form**. This form has not been significantly changed since the July meeting and AHRQ staff did confirm that the definitions used are aligned with those of the National Pressure Ulcer Advisory Panel.

Dr. Helwig spoke next about the **Surgery and Anesthesia** documents. . The main change is that two of the Version 0.1 Beta forms (Surgery and Other Invasive Procedure, and Anesthesia) are now combined into a single form. A Panel member asked if this form will capture

invasive procedures, such as cauterizations. Dr. Helwig responded that this would be captured within the definition of surgery which includes "other invasive procedures". A Panel member asked whether the title of the form clearly conveys what is to be captured. Dr. Munier responded that the definitions, language of the event descriptions and questions within the form itself convey the scope and that, overall, the titles are intended to be simple general headers.

Discussion next moved to the **Fall** documents. Dr. Helwig noted that AHRQ has added a question as to whether medication played a role with the fall, along with notations about specific falls injuries. A Panel member asked about question 8, and whether it was a worthwhile inclusion to ask "whether the patient was documented to be at risk for a fall", as this is similar to a previous question. Dr. Helwig responded that AHRQ staff is trying to learn whether a falls risk assessment was done.

The final items reviewed were the **Device or Medical/Surgical Supply** documents. Dr. Helwig said that only minor changes to the answer options were made on this form. There were no Panel member comments.

NQF MEMBER COMMENT

The meeting was opened to NQF member comments or questions; none were received.

TIMELINE FOR COMMENTS

Dr. Munier spoke about the timeline for comments, following the release of the Common Formats Version 1.0. He noted that if errors are noticed as AHRQ staff is writing the technical specifications, they will be able to correct these mistakes. He asked whether the Panel should stick with its current schedule, and meeting in February, despite comments having already been received and incorporated into the technical specifications. An alternative would be for the Panel to meet earlier to consider the comments received. Ms. Murphy noted that comment period can be closed at any point. The driver for the commenting period should be what is expected in terms of comments and the potential impact of comments the forms, therefore the technical specifications.. Dr. Helwig said that AHRQ staff will look for comments from the Panel specifically on Event Descriptions. Ms. Murphy said that, if the Panel is accepting of the possibility of closing the commenting period earlier than the planned December 31 closing, she and the Panel co-chairs could meet with AHRQ staff to determine a timeline. The Panel agreed to having the Panel co-chairs discuss this with AHRQ staff prior to its September meeting in order to resolve the issue.

SEPTEMBER IN-PERSON MEETING OF THE EXPERT PANEL

The tentative agenda for the September meeting includes parts of three separate meetings:

- The Expert Panel will first gather in the Bethesda North Marriott on Wednesday, September 16 for the 10 to 11:30 a.m. presentation on PSOs during the AHRQ annual meeting.
- The Panel will then convene separately for a two-hour meeting which will include a working lunch.

- Following the Expert Panel luncheon meeting, transportation will be provided to move the Panel to the AHRQ headquarters in Rockville, MD, for a PSO demonstrations and networking on Wednesday night followed by the PSO meeting on Thursday. The Panel will adjourn at the end of the meeting on Thursday.

PLANS FOR FUTURE EXPERT PANEL MEETINGS

Mr. Colchamiro noted that, after polling the Panel, Monday at 4 p.m. ET remains the time preferred for regular monthly teleconferences by the majority of members. Since this schedule precludes participation of some panelists, the Panel asked to poll for availability late on Friday mornings. This would permit a rotating Monday/Friday meeting schedule.

REMINDERS

The next Common Formats Expert Panel conference call will be Monday, October 12, 2009 from 4:00-5:30 p.m. ET. Materials and dial-in information for the call will be sent via email prior to the call.