NATIONAL QUALITY FORUM

CONFERENCE CALL OF THE COMMON FORMATS EXPERT PANEL

February 8, 2010

Panel members present: Henry Johnson, MD, MPH (Co-Chair); David C. Classen, MD, MS; John R. Clarke, MD; Peter L. Elkin, MD; Karen S. Frush, BSN, MD; Matthew Grissinger, RPh, MS; Mark A. Keroack, MD, MPH; Mary Krugman, PhD, RN; Helen Lau, MHROD, BSN; Arthur Levin, MPH; Lori Paine, RN, BSN; Shannon Phillips, MD, MPH; Nancy Ridley, MS; Heather Sherman, PhD; Liaison Member: William Munier, MD

Others present: Amy Helwig, MD; John Moquin; Debbie Perfetto; and Ira Yanowitz, AHRQ; Lauren Richie, The Joint Commission; Victoria Polich, Iowa Foundation for Medical Care.

NQF Staff: Peter Angood, MD; Melinda Murphy, RN, MS, NE-BC

WELCOME AND INTRODUCTIONS
Dr. Classen welcomed the group and described the process and agenda for the meeting.

OVERVIEW OF COMMENTS RECEIVED
Ms. Murphy stated that 188 comments were received over the entire comment period. Thirty comments are pending the Expert Panel's deliberation. Of these, 12 were submitted through AHRQ and acted upon by AHRQ staff. Those 12 were submitted for the groups' comment and any further recommendation they might have.

AHRQ UPDATE ON VERSION 1.1
Dr. Munier thanked the Expert Panel for its work and noted that, though AHRQ staff expected they might not be able to address all comments in Version 1.1, the relatively low number of comments coupled with the Expert Panel's flexibility in addressing them quickly has resulted in virtually all recommendations being considered in Version 1.1 and, where relevant, the technical specifications. Dr. Helwig then thanked the Expert Panel members and reiterated Dr. Munier's comments. She advised that technical specifications are being finalized and that Version 1.1 will include revised paper forms and event descriptions reflecting guidance received from the Expert Panel, a data dictionary, metadata which will be placed in USHIK, a Clinical Document Architecture (CDA) implementation guide that specifies the file format for data transfer from Patient Safety Organizations (PSOs) to the PSO Privacy Protection Center (PPC) and a "validation rules and errors" document. Once the specifications are released, they will be ready for vendors to start incorporating into electronic reporting systems; AHRQ staff project that it will take about six months for this to be accomplished. AHRQ is targeting September 2010 for first receipt of data at the PPC. Since it will take some time for accumulation of date, February 2011 has been targeted for the first transmission of data files to the Network of Patient Safety Databases (NPSD) where the information will be used in preparation of the AHRQ quality report and disparities report.

Dr. Helwig mentioned the recent release of the GAO report related to the Common Formats. Also, she noted AHRQ has begun work on the next set of common formats – for skilled nursing facilities. At present, it has been determined that the perinatal and blood sets do not apply. Some new event types have been identified. It will likely take several months for AHRQ to work through content with its work group and then several additional months for AHRQ staff

to prepare the necessary materials. In response to a question from the Expert Panel, Dr. Helwig noted that the Federal Advisory Committee Act (FACA) and Office of Management and Budget rules have resulted in the work group including only federal agencies. A panel member suggested that state agencies, which have contracts with the Centers for Medicare and Medicaid Services for long term care, might not be subject to the FACA limitations. Dr. Helwig noted that there is long term care expertise represented on the work group. For example, the Veterans Health Administration operates a large number of long term care/skilled nursing facilities.

Dr. Munier clarified that the Common Formats process for long term care will follow the process used for the hospital set, which is development with the federal work group followed by public comment and Expert Panel consideration. This process may not be as efficient as it might if all parties were involved from the beginning but it has worked well with the hospital set. Well over half of the Common Formats content for skilled nursing facilities will be the same as those for hospitals.

Version 1.1 of the hospital-focused Common Formats will likely be the only set that will be available in 2010.

RECOMMENDATIONS AND PANEL ACTION RELATED TO HERF/PIF/SIR

Ms. Ridley led the presentation of Group A recommendations related to the Healthcare Event Reporting Form (HERF), Patient Information Form (PIF) and Summary of Initial Report (SIR). She noted that Group A had three comments, all related to the PIF, were addressed after AHRQ action. Discussion related to PIF items is included in the Group A minutes of January 6, 2010. Two of the comments were related to the harm scale in PIF question 10. The last one was related to "rescue", addressed in PIF question 12. One of the comments regarding harm related to potential escalation of the perception of harm based on the response choices available. The comment related to rescue is similar to comments that were received in response to the earlier versions. At that time Group A and the Expert Panel had suggested revising the reporting form item, PIF question 12, to place the term later in the question. This was done though Group A recognizes the term is emotionally charged. In both instances, Group A concurred with AHRQ that change is not needed until the forms have been put into use and that use informs future iterations.

Ms. Ridley suggested that the harm and rescue issues should go into the AHRQ "tickler file" and asked AHRQ how it plans to use this file. Dr. Helwig stated that all items that have been identified for review and possible revision after the forms have been in use in the field are flagged in the AHRQ databases. Each time a form set is reviewed for update, those items are reviewed. Ms. Ridley suggested that AHRQ might want to probe the PSOs on the more controversial or emotional issues.

No additional recommendations were made by Group A. The Expert Panel endorsed the comments and suggestions of Group A as submitted.

RECOMMENDATIONS AND PANEL ACTION RELATED TO BLOOD, FALLS, PRESSURE ULCERS

Ms Krugman led the presentation of Group C recommendations related to a total of 13 comments – six related to Blood or Blood Product, 3 related to Fall, and 4 related to Pressure Ulcer.

She noted that a number of pediatric-sensitive comments were made and that the group had the expertise of a pediatrician on the group. The group noted its appreciation for the interest of pediatric groups and the comments related to type of bed and to diapers. Since both can be

captured with existing items, the group recommended no change at this time but does recommend evaluation of comments that are received after the forms are in use to determine if refinement is needed. One Expert Panel member commented on Event Description Item 4.2.1 (Question 13) related to Pressure Ulcers noting that in his state, eight events related to pressure ulcer associated with pulse oximetry, had occurred in eight months. Ms. Krugman noted it had considered this matter and recommended that pulse oximetry be captured in the "Other" response option in Version 1.1 and reevaluated after forms are in use. Based on his experience, the member believes that pulse oximetry should be added as a response option at this time. Both AHRQ and Expert Panel members appreciate the issue and agree that AHRQ should monitor reports using this form to determine if change should be made though the panel did not recommend a change at this time.

With respect to Blood or Blood Product, Ms. Krugman noted that Dr. Barbee Whitaker, American Association of Blood Banks, consulted with Group C on the Blood elements. The group recommended one change on the blood reporting form. It recommended that response option 4.f. be changed from "Incorrect number of units (i.e., wrong volume)" to "Incorrect volume (i.e., number of units or mL)" and to revise Question 6 reporting form response options to read: "a. Too much; b. Too little; c. Unknown" to properly capture pediatric volume events.

Discussion and recommendations related to the comments are included in the Group C minutes of January 19, 2010. All recommendations of Group C were approved as submitted.

RECOMMENDATIONS AND PANEL ACTION RELATED TO HEALTHCARE-ASSOCIATED INFECTIONS, MEDICATION AND OTHER SUBSTANCES, PERINATAL

Dr. Keroack lead the discussion of Group D recommendations related to a total of nine comments – eight related to Healthcare-Associated Infection (HAI) and one related to Medication and Other Substance.

In response to the comment related to the Medication form, Group D had discussed whether to break vaccines out of biologics as a distinct response option on Question 1. The group suggested that AHRQ staff contact FDA to harmonize with that organization and report back to the Expert Panel. Dr. Helwig noted this had been done and that Version 1.1 of the Common Formats will retain vaccines within biologics and determine how to proceed in later versions based on field user feedback.

Of the eight comments related to HAI, the group determined no action is needed at this time in six of the eight. The group did recommend that AHRQ it work with CDC's National Healthcare Safety Network (NHSN) to incorporate user guidance outside limits for linking infection to period of hospitalization. Dr. Helwig reported that AHRQ will use the NHSN definition for each infection (catheter-associate urinary tract infection, central line infection, ventilator-associated pneumonia, surgical site infection) in Common Format user materials. She noted this is 48 hours for each infection other than surgical site infection, which is 30 days. Dr. Keroack noted that it had been suggested that this information be incorporated into Question 2 to ensure that responses are selected based on knowledge of the definitions. Dr. Helwig said that, because the definitions are lengthy and response options b. – d. at present do not specify type of infection, AHRQ had planned to include the information in the User Guide in Version 1.1 and make further revisions in later versions. Based on concern of the Panel that lack of explicit information about time intervals will have dubious cases submitted, AHRQ will revisit the matter with the goal of pointing users to definitions when they are responding to the question.

Dr. Keroack noted that NHSN assumes personnel entering NHSN data is a trained infection control professional and that, if useful, the group would be willing to share their observations and concerns with CDC. Dr. Munier agreed that this could be useful.

Dr. Helwig asked the Expert Panel to revisit a recommendation made at the November 13 meeting related to inclusion of "amniotic fluid embolism" noting that AHRQ staff subsequently reviewed research indicating it is not clear that amniotic fluid embolism is preventable. After considerable discussion that touched on the scope of safety initiatives generally, the question of including any event that could be considered a naturally occurring event (act of God) without clear cause, limitations to improving safety if limit review to those events that are considered preventable, the Panel accepted a motion and second and voted to exclude amniotic fluid embolism as a response option in Question 11 on the Perinatal form at this time. The Panel asked AHRQ staff to further consult with Dr. Gluck, panelist unable to join the meeting today, in light of its new information and to readdress the matter in future iterations of the forms based on his consultation.

All other recommendations of Group D were approved as submitted.

GENERAL COMMENTS

Dr. Johnson lead the discussion related to five general comments received over the course of the comment period.

Two of the comments suggested inclusion of a new health information technology (HIT) form to capture events that occur because of the technology. The Panel agreed that HIT does has a pervasive effect but also agreed that it is a contributing factor in events rather than cause. In discussing how the issue could be addressed in Version 1.1, the possibility of adding it as a response option in Question 11 on the Summary of Initial Report (SIR) was proposed as one option. There was a suggestion that it be broken into two components – computerized prescriber order entry and "other" HIT to try to quantify where major issues arise. In order to carefully consider how best to capture the information in Version 1.1, given where it is in production, AHRQ staff will discuss this with relevant staff and contractors to determine what it can do. It was further suggested that PSOs might be asked to look for HIT-related issues in reports they received and to report such in order to begin to understand the prevalence of these issues.

The Panel recommended that, as a first option, AHRQ add response options to Question 11 in SIR to capture HIT as a potential contributing factor. If the first option is not feasible, given the current state of development of Version 1.1, the Panel proposed a second option that information be added to the Users Guide and the HERF/PIF/SIR Event Description pointing the user to SIR Question 11, response options i., j., k., or l. under "Equipment/Device" as the location to record HIT as a contributing factor.

Ms. Ridley asked that if the first option is not feasible that AHRQ provide Group A with information about how it proposes to handle this matter so that the group can provide consultation in advance of change. Dr. Munier said that it will do so when time permits. The Panel accepted a motion, second and approved the recommendation that AHRQ develop detail and potential solutions to the issue of HIT as a contributing factor and bring that to the Expert Panel through Group A.

A third comment provided general observations about the forms in terms of usability. After some discussion of the elements of usability testing or experiments, the Panel heard from AHRQ staff regarding the approach taken to address usability issues and noted their continuing focus on ensure that the forms are crisp and as brief as possible while capturing essential core

content. The Panel also discussed the opportunities for user feedback and solicitation of PSOs for detail about what is or is not useful, what they like and do not like about the forms, and what should be retained, added or deleted. The Expert Panel recommended no specific action other than continued consideration of the concerns of usability and capture of credible, comparable data.

Two comments received from AHIMA stressed importance of transitioning the Common Formats to electronic data capture methods as soon as possible. General recommendations regarding improving the Event Descriptions and clarifying skip logic were included as well as request for feedback regarding comments. To ensure that the comments are properly understood and attended, the Expert Panel suggested that AHRQ staff contact AHIMA directly. An Expert Panel member observed that the public may not understand the full process of the Common Formats development or the fact that they are undertaken based on the Patient Safety and Quality Improvement Act of 2005 and as such have specific input and review requirements and limitations. Additionally, the Panel discussed the methods by which the comments are reviewed as well as how commenters are advised of group and full panel meetings, how they may participate and how they may learn of action taken through the NQF website.

NQF MEMBER COMMENT

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

NEXT STEPS

The next Expert Panel call is scheduled for March 12, 10:00 a.m. ET. The agenda will include items from this meeting that were to be carried forward for action.

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