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CONFERENCE CALL FOR THE COMMON FORMATS EXPERT PANEL

September 17, 2010

Panel Members Present: David Classen, MD, MS (co-chair); Henry Johnson, Jr., MD, MPH (co-chair); Matthew Grissinger, RPh, MS; Mark Keroack, MD, MPH; Shannon Phillips, MD, MPH; Nancy Ridley, MS; Heather Sherman, PhD; Liaison Member: William Munier, MD, MBA

NQF Staff Present: Peter Angood, MD; Melinda Murphy, RN, MS; Lindsey Tighe, MS

Others Present: Peter Goldschmidt, MD; Amy Helwig, MD, MS; John Moquin (AHRQ)

WELCOME AND INTRODUCTIONS

Dr. Johnson welcomed the panel members to the call and thanked them for their continued participation on the Common Formats Expert Panel. Dr. Johnson then asked Drs. Munier and Helwig to provide an update on the status of Common Formats.

UPDATE ON COMMON FORMATS

Dr. Munier informed the panel members that the development of Common Formats for health information technology (HIT) has been a high priority in the past several months as the Office of the National Coordinator for Health Information Technology (ONC) begins to implement meaningful use. Dr. Munier noted that Dr. Helwig would provide more detail later regarding progress with development of HIT Common Formats.

Dr. Munier next provided an update on Common Formats for hospital acquired infections (HAI). He noted the decision of the Centers for Medicare & Medicaid Services (CMS) to tie payment to submission of central line associated blood stream infections (CLABSI) events in ICUs and NICUs. It is anticipated that hospitals will be reporting these events to get an annual payment update, likely leading to more hospitals enrolling with the National Healthcare Safety Network (NHSN) prior to August 15, 2011 when the program will be enforced.

In light of this new development, the Agency for Healthcare Research and Quality (AHRQ) has been evaluating options regarding its HAI Common Formats and the goal to have Common Formats align with the Centers for Disease Control and Prevention's (CDC) NHSN. As the Common Formats are efficient in collecting patient safety event data, the Common Formats may be a useful alternative for hospitals to meet the CLABSI reporting requirements. [AHRQ subsequently sought input from developers creating software for Common Formats as to whether development of a collection database mimicking the NHSN database would be useful. The developers stated that Common Formats were more efficient in collecting clinical data than NHSN, but they did not see added value to mimicking the NHSN database. As such, Common Formats for HAI will remain unchanged, and AHRQ will continue to pursue interface options so that HAI reports entered into NHSN can be downloaded into Common Formats. This procedure will minimize redundant data entry.]

Dr. Angood noted that the CDC's CLABSI measures are undergoing the National Quality Forum (NQF) consensus development process. This process should be complete by the end of the year.

Dr. Helwig stated that the Patient Safety Organization (PSO) Privacy Protection Center (PPC) is currently on schedule to complete building of the input processor so that PSOs will be able to input data at the end of November 2010; however, it is not yet clear when data will begin coming into the PSO PPC. An important function of the PSO PPC is to make the data non-identifiable so that it can be transferred to the Network of Patient Safety Databases (NPSD). The process will take several months, as a large enough

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volume of data must be received before transfer of data can occur. February 2011 is the target date for the first transfer of data from the PSO PPC to the NPSD.

A Panel member asked what happens if the PPC receives an incomplete Common Formats submission. Dr. Helwig responded that each event needs all required fields to be filled out, depending on the skip logic for that event. The PPC will notify the PSO about which items need to be completed or have errors in them so that the PSO can obtain the necessary information and resubmit.

A Panel member noted that since reports are voluntary in nature, the requirement that every question be answered may lead to fewer reports being received. Dr. Munier explained that there likely will be questions where the reporter does not know the answer and a response option indicating this is provided; however, the skip logic requires questions to be answered before the respondent may move to the next question. The Common Formats were developed with the aim of asking only questions deemed essential for event reporting, so the questions are required. Panel members agreed that in principle, this makes sense; however, from a practical standpoint it could be difficult for a PSO to follow up with the reporting facilities on every incomplete submission. Dr. Munier explained that ultimately the questions all must be answered, because allowing users to select which questions to answer would result in inconsistent and potentially unreliable data calculated from the aggregate of the reports. Further, there is pressure from consumer groups and payers to standardize data collection. If there are questions in the Common Formats which the Expert Panel believes should be optional, in all likelihood these questions should be dropped from future versions of the Common Formats.

COMMON FORMATS VERSION 1.1

Dr. Helwig informed the Expert Panel that comments are still being received on Version 1.1. The commenting tool will stay open through the end of the year, closing around December 31, 2010. After that, the Expert Panel will consider all comments received and make recommendations to revise Common Formats Version 1.1. The next release will be Version 1.2, which is scheduled to be released by March 31, 2011. The technical specifications will be released in late summer, 2011.

AHRQ is currently working to revise the device form to incorporate HIT patient safety events. They have been working with the Food and Drug Administration (FDA) and ONC to capture information on HIT-related events. The draft revised device form which captures HIT events was presented to the federal work group the week of September 6. Final revisions are now being made to the form, and it should be released for comment in beta form by the end of October 2010. The Expert Panel will review comments received on this modified form. It will then be updated and released as part of the Version 1.2 release in March 2011.

Due to all the other Common Formats activity, the Common Formats for Skilled Nursing Facilities (SNFs) has been pushed back. As soon as the device form with HIT is released at the end of October, work will resume on the Common Formats for SNF. It is anticipated that the Common Formats for SNF will be released by the end of the year. They will go out for comment as a beta version with event descriptions, forms, and sample reports. In the SNF set of Common Formats, blood, perinatal and surgery events were eliminated. Falls, pressure ulcers, HAI, medication as well as device events will be included but revised specific to the setting.

AHRQ will continue to follow the development of the NQF listing of Serious Reportable Events (SREs); since they anticipate that items of interest to the Common Formats for SNF such as elopement will be contained within the SREs for SNFs. NQF expects the SRE report to be finalized in 2011.

A panel member was concerned that it may not be intuitive that HIT events involving software errors are to be reported in the Common Formats as device events. Dr. Helwig stated that reporters will be asked

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whether HIT was a contributing factor to the event; if the reporter indicates that it was, they will be cued to complete the device event form. Dr. Munier added that judgment of the etiology of the event is not the task of the reporter, but likely will be determined through root cause analysis. As such, the reporter should not have to determine whether the software or hardware contributed to the event.

NEXT STEPS

The Expert Panel will be providing recommendations on the HIT-related events elements and two separate sets of Common Formats—hospitals and SNFs.

The first of these will be the HIT-related events form, which will be released as a single form for comment in mid to late-October. AHRQ has asked that the commenting period close after 30 days to allow revisions to be made in time to incorporate them into the next versions of Common Formats for hospitals and SNFs. Assuming a mid- to late-October release, the Expert Panel should expect the December teleconference agenda to be devoted to review of comments and form recommendations about that single HIT device form.

With release of Common Formats for SNFs pending, it is not yet possible to predict when they will be open for comment or when the commenting period will close. Thus, NQF cannot yet tell the Expert Panel in what order Common Formats for hospitals or SNFs will be considered.

Common Formats for Hospitals Version 1.1 is currently open for comment with a December 31 closing date anticipated. Of the comments received, 18 have been triaged to the panel as of September 17. A low number of comments at this point in the process was anticipated. With release of technical specifications with Version 1.1, AHRQ anticipated that institutions would wait for software to begin using an electronic version of Common Formats. Software development was expected to take six months. Commenting should resume once organizations actually gain experience using the software. The Expert Panel is scheduled to have an in-person meeting to review comments and form recommendations. This schedule could change depending on the volume of comments to be considered. As in past versions, AHRQ will make revisions and update the Common Formats to Version 1.2, after receiving the Panel's recommendations. This new version is anticipated to be released at the end of March, 2011.

NQF has planned for the Common Formats Expert Panel to convene for two in-person meetings during 2011. The second one is scheduled for consideration of the Common Formats for SNFs. In addition the Expert Panel is invited to, and NQF has planned for its attendance at, the AHRQ annual PSO meeting in early May 2011.

Minutes of the July 2010 meeting were approved.

The group determined it should continue to meet monthly by teleconference, alternating Monday afternoon and Friday morning meetings so the greatest number of members can attend.

The next call will take place on Monday, October 18 at 4:00 pm ET.