THE NATIONAL QUALITY FORUM

CONFERENCE CALL OF THE COMMON FORMATS EXPERT PANEL

November 10, 2008

Panel members present: Henry Johnson, MD, MPH (Co-Chair); David C. Classen, MD, MS (Co-Chair); John R. Clarke, MD, FACS; Karen Frush, BSN, MD; Paul A. Gluck, MD; Mark Keroack, MD, MPH; Mary Krugman, PhD, RN; Helen Lau, RN, MHROD, BSN; Arthur Levin, MPH; Bryan A. Liang, JD, MD, PhD; Lori Paine, RN, MS; Shannon Phillips, MD, MPH; Nancy Ridley, MS; Prof. William Runciman; Heather B. Sherman, PhD; Liaison Member: William Munier, MD

Others present: Amy Helwig, MD, John Moquin, AHRQ

NQF Staff: Melinda Murphy, RN, MS, CNA; Alexis Forman, MPH

APPROVAL OF MINUTES OF OCTOBER 13, 2008 CONFERENCE CALL

Following Dr. Johnson's welcome and encouragement to the Expert Panel to make comments on the Common Formats using the NQF commenting tool, the minutes from the October 13, 2008 conference call were approved unanimously.

As presenter regarding AIMS, Professor Runciman provided disclosure that he travels on behalf of the Australian Patient Safety Foundation (APSF) which pays his expenses. Also, he is President of the Governing Council of the APSF and is a minor shareholder of Patient Safety International (PSI) as well as a member of PSI's board.

UPDATE ON PATIENT SAFETY ORGANIZATIONS (PSOs)

Dr. Munier stated that as of Wednesday, November 5, 2008, there were ten official Patient Safety Organizations (PSOs). Five more organizations will become official on Wednesday, November 19, 2008. Of note, these are the only organizations that have applied and submitted self-certifications to date. The official list of PSOs is located on the Agency for Healthcare Research and Quality (AHRQ) website. The final rule implementing the Patient Safety and Quality Improvement Act of 2005 will be published before end of year and may be published during November. It will be the regulation by which PSOs are to operate. The interim guidance, currently in effect, stipulates that PSOs must be in compliance and meet the conditions of the final rule at the time it becomes effective (60 days after publication). This will likely require PSOs to submit additional paperwork and there is no grace period. Of note, PSOs will be encouraged to provide feedback on the Common Formats through the NQF commenting tool.

APPROVAL OF REFINEMENT OF PROCESS AND CRITERIA FOR CONSIDERATION OF COMMON FORMATS COMMENTS

The revised process and criteria were approved unanimously. Based on agreement that the criteria should continue to be open to refinement, any additional Expert Panel member comments regarding the criteria should be sent by email to Dr. Johnson and Dr. Classen and copied to Ms. Murphy.

ADVANCED INCIDENT MANAGEMENT SYSTEM (AIMS)-SPECIFIC COMMENTS RELATED TO THE COMMON FORMATS AND DISCUSSION OF AIMS RELEVANCE-GENERAL AND COMMENT-SPECIFIC

Professor Runciman presented an overview of AIMS to give the Expert Panel a common understanding of AIMS and more clarity regarding his comments on the Common Formats. Professor Runciman suggested that it would be useful to look at the concepts used in the Common Formats and seek to form an international initiative/process that could result in harmonization of patient safety concepts. He noted that AIMS is an incident management software that includes a classification system to capture adverse events and near misses in the healthcare delivery system. The concepts and terms used in AIMS will be in the public/ international domain. The software product in which they are included is proprietary.

Ms. Ridley asked if AHRQ had evaluated or utilized AIMS as it developed the Common Formats. Dr. Munier stated that he and other AHRQ staff has seen the system but was not able to access complete information to assess the system, for the reasons Professor Runciman provided. Dr. Munier commented that AHRQ staff was impressed with the AIMS system and would have benefitted from greater access; he also noted that AHRQ was provided the most recent versions of the International Classification for Patient Safety (ICPS) as well as 64 other patient reporting systems, some down to the data dictionary level. ICPS, a World Health Organization product, was developed to harmonize patient safety concepts so that all healthcare providers would be speaking the same language; however, the ICPS is a classification system not a reporting system so AHRQ was able to use ICPS to a limited extent. Dr. Munier noted that AHRQ was required to address concerns of U.S. federal agencies that currently have healthcare-related reporting systems specific to their mandates (such as FDA, CDC). A Panel member noted that the Panel likely will not want the process of providing input to AHRQ for improvement of the Common Formats to be slowed.

Dr. Johnson asked if Professor Runciman could provide specifics regarding his more general /generic AIMS-related comments. To a significant degree, he cannot do so given the current work being done with AIMS and the proprietary nature thereof. However, in his comments, Professor Runciman noted that AIMS categorizes events by incident type and stressed the importance of what an event would be called. He defined incident as any event or circumstance that could have or did cause harm and further elaborated by noting that an event can be an unsafe condition, a near miss, a no-harm incident, or an incident resulting in patient harm. A

brief discussion followed about the potential that a circumstance could occur as a contributing factor to a patient safety event and the value of capturing this information.

Dr. Clarke explained that there are some incidents that do not get to the patient that are important to report because they constitute unsafe situations, such as something that is poorly labeled. He further indicated that the Pennsylvania reporting system requires that a patient be involved in an event for it to be reportable but suggested that there should be reports that are not directly connected to a specific patient in order to capture unsafe situations.

In response to a question from Dr. Johnson, Dr. Munier commented that the Common Formats forms contemplated all the categories discussed by Prof. Runciman noting that the forms are event-centered rather than patient-centered. In this way, the categories of events discussed can be captured by the existing forms. AHRQ staff did determine it would modularize the Common Formats forms to collect information in a consistent way depending on the type of incident; e.g., surgical events. Dr. Munier discussed the challenges of addressing the desires/preferences of the representatives/owners of the 64 systems that were evaluated noting it was not possible to fulfill all desires. Of note, the Common Formats exist on paper at present because there was no other option initially and the government has not been a software developer. An electronic format of the forms, when available, should be expected to have the capability to address many of the current challenges.

Prof. Runciman noted, in discussing type of incident, that concept harmonization is fundamental. He opined that the four concepts that should be addressed would include: 1) unsafe condition; 2) incident/event that does not reach a patient; 3) incident/event that reaches the patient but causes no harm; 4) incident/event that reaches the patient and causes harm. He noted that the APSF experience is that 15 incident types should be included and captured across all specialties and that information should not be reclassified under different categories but rather captured under the generic systems to avoid duplications and replications that make it difficult to analyze information. Dr. Munier noted that the Common Formats have addressed these matters.

Noting that the Expert Panel cannot now address most of the AIMS-related comments, Dr. Johnson asked if specifics to clarify/elaborate the information in Professor Runciman's comments can be provided to the Expert Panel. Professor Runciman stated that he is in the process of trying to get the information available so the Expert Panel will have access.

In response to a question regarding the expectation that Common Formats and AIMS harmonization would be one-way or involve adaptation in both, Professor Runciman indicated his view would be that adaptation would occur across all involved systems (the 64 AHRQ reviewed and others, including international) to achieve harmonization in what he envisions as an internationally democratic process. A concern that such a process would be lengthy and go beyond the timeline available to AHRQ and NQF was expressed. Dr. Runciman was asked if it is possible to get explicit comments with which the Panel could work in a relatively short timeline; e.g., 30-, 60-, 90 days. Dr. Johnson also noted that the suggestion for international harmonization, while laudable, exceeds the scope of this project. Dr. Runciman outlined the

steps still required to provide additional detail noting he hoped the steps could be completed within 90 days.

Dr. Munier stated that AHRQ expects to issue annual updates of the Common Formats. To meet the commitment made in the original Federal Register notice of proposed rulemaking, the first revision, in paper version (version 1.0) should be available for use by June 2009. Dr. Munier indicated that AHRQ needs as much feedback and guidance from the Expert Panel as quickly as they can get it prior to having to impose a design freeze to produce version 1.0. He noted that the richness in AIMS may not be able to be fully captured until the Common Formats are automated, if then.

A suggestion was made that a meeting be set up for the Expert Panel with the newly designated PSOs to glean information about what forms they will be using and to obtain feedback. Dr. Munier indicated that the requirements and guidance under which AHRQ is required to operate may preclude it arranging such a meeting. In any case, AHRQ staff and some Expert Panel members know that the beta version of the Common Formats will not be used by some PSOs, pending refinement and release of a later version. Dr. Munier did commit that PSOs will be asked to provide direct feedback regarding the Common Formats through the NQF commenting tool.

As of November 9, 2008 at 12 p.m., 447 total comments about the Common Formats had been submitted by 28 people.

- 252 comments were triaged to AHRQ based on the criteria refined by the Expert Panel in October and approved at this meeting
- 147 comments will go directly to the expert panel
- 35 comments are still pending (received during the weekend)

Ms. Murphy will provide the Expert Panel with all comments, noting how triaged, in the December meeting materials.

PLANS FOR EXPERT PANEL MEETINGS THROUGH FEBRUARY 2009

The tentative agenda for the December 8th meeting is AHRQ's discussion about how they will approach comments that have been triaged to them.

At the January 12th meeting, the Expert Panel will complete any final refinements to the criteria that will be used at the February in-person meeting. There will also be a discussion about the approach to handling comments triaged to the Expert Panel.

REMINDERS

The in-person 1 ½ day meeting in Washington, D.C. is tentatively scheduled for Wednesday, February 25, 2008 and Thursday, February 26, 2008. The Expert Panel will receive additional information regarding travel and lodging accommodations from NQF staff in the near future.

If you have not created an account and submitted comments on the Common Formats, please do so. The Co-chairs would like AHRQ to have the benefit of the expertise of each member of the Expert Panel.

The next Common Formats Expert Panel conference call will be Monday, December 8, 2008 from 4:00-5:30 p.m. EST. The materials and dial-in information for the call will be sent via email prior to the call.