Thursday, October 29, 2015
USP-US
Rockville, MD
Draft Meeting Summary

Goals and Anticipated Outcomes

- New and Old Business
- Council reports and activities
- 20th Anniversary
- Lessons learned and the Council's Future

Attendance

Present: Frank Federico, IHI (Chair); Ann Gaffey, ASHRM (Vice Chair); Leigh Purvis, AARP (via WebEx); James Burris, American Geriatrics Society (via WebEx); Diane Cousins, AHRQ; Barry Dickinson, AMA (via WebEx); Holly Carpenter, ANA (via WebEx); Bona Benjamin, ASHP; Ashok Ramalingam, Department of Defense; Michael Gaunt, ISMP; Ronald Wyatt, The Joint Commission (via WebEx); E. Robert Feroli, Medication Safety Officers Society (via WebEx); Tara Modisett, NASPA (via WebEx); Elizabeth (Scotti) Russell, NABP; Maureen Cahill, NCSBN (via WebEx); Deborah Davidson, NCPIE; Caitlin Lorincz, National Patient Safety Foundation; Rita Brueckner, VA (via WebEx); Shawn Becker, USP; Deborah Nadzam (via WebEx); Rita Munley Gallagher

Absent: APhA, ASCP, FDA, GPhA, Society of Hospital Medicine, PhRMA, Chrissie Blackburn

Alternates attending with Primary Delegates: Deborah Pasko, ASHP; Matt Grissinger, ISMP; N. Lee Rucker, NCPIE; Donna Bohannon, USP

Observers: Emily Ann Meyer, USP; Rick Schnatz, USP

1. **Opening, Procedural, and Administrative Matters**
   a. **Welcome, Call Meeting to Order**
   Mr. Frank Federico, Chair, called the meeting to order at 10:00 a.m.

   Ms. Emily Ann Meyer called roll and determined that a quorum was present.

   b. **Approval of the Summary of the Previous Meeting**
   Council Members reviewed the summary of the previous meeting and provided no changes.

   Motion: Dr. Rita Munley Gallagher moved to approve the summary of the previous meeting. The motion was seconded.

   The motion was adopted by unanimous voice vote with no abstentions.

   c. **Approval of the Agenda**
   The Council members reviewed the meeting agenda.

   Ms. Bona Benjamin asked for the addition of an item prior to the Subcommittee Updates to allow Ms. Debra Pasko to summarize a medication initiative by ASHP under an FDA grant.

Motion: Ms. Tara Modisett moved to approve the agenda with the addition of item described by Ms. Benjamin, and the motion was seconded.

The motion was adopted by unanimous voice vote with no abstentions.

2. Secretariat's Report

a. Update on Membership

Ms. Donna Bohannon provided the update on membership, noting the following:

- The Anesthesia Patient Safety Foundation has chosen to terminate their membership following the retirement of Dr. Donald Martin. They recognize the important work of the Council and wish it well.
- USP spoke with PhRMA last week. They have no delegate currently, but wish to remain members.

Mr. Federico recommended sending a thank you note to the Anesthesia Patient Safety Foundation if it has not already been sent.

b. Permissions

Ms. Bohannon informed participants there had been one request—a researcher from Brazil asked permission to adopt the taxonomy for a cross-cultural adaptation. Permission was granted.

c. Call for Nominations

Ms. Bohannon explained that the two year term of the Chair and Vice Chair had expired, and nominations are now open for a new Chair and Vice Chair. The Call for Candidates was sent to the delegates the week of October 19.

Mr. Federico explained that it is important for others to participate in the leadership of the Council in order to move it forward.

In a later discussion, the deadline for the call for nominations was extended to Friday, November 13, 2015.

3. ASHP Project on Standardization of IV and Oral Liquid Medications

Ms. Debra Pasko provided a summary of an ASHP project on the standardization of intravenous (IV) and oral liquid medications. She noted the following:

- ASHP received an FDA contract to develop the national standardization.
- Every time a patient is introduced to a different concentration, there is also room for an error to be introduced.
- The IV concentrations have been divided into those patients below 50 kg in weight and those above 50 kg in weight.
- The oral liquid part of the study is reviewing compounded oral liquids that are not commercially available.
    - The plan is to make this an expansion of work originally begun at the University of Michigan, following an error in the compounding of Baclofen Oral Suspension.
    - The final phase of the oral liquid medication study will review oral chemotherapy dosage forms.
- Council members were supportive of this initiative.

Discussion

In response to Council members' questions, Ms. Pasko clarified and noted the following:

- There is currently no component for solid oral dosage forms in the grant, but it is worth consideration.
- Creating the list of standardized concentrations is less complicated than implementing it. It will be important to ensure that there are resources such as a toolkit to allow people to review their operational plan thoroughly. It will be a multi-year implementation process.
- The focus will be on a list of 28 concentrations for adult patients used for continuous infusion, which she will share with the Council.
- Ms. Pasko has reached out to the patient safety organizations (PSOs).

Ms. Ann Gaffey, the Vice Chair, asked whether there was a specific request of the Council, and Ms. Pasko indicated she would appreciate the Council's general support of this effort, but did not have a specific request.

The Chair indicated that one way the council could support the efforts would be to draft a statement supporting standardized dosing.

Action Item: Ms. Pasko will share the list of 28 concentrations for adult patients with the Council.

4. Subcommittee Updates

a. Medication Safety for Older Adults

The Chair noted that he distributed a revised statement via email prior to the meeting. He requested that members' review and provide any feedback by Friday, November 13, 2015. The statement will then be redistributed and members will vote via electronic ballot.

b. Patient Representative

The Chair reopened the discussion regarding having an alternate to the patient representative. Participants raised the following points:

- A patient representative, unlike the organizational representative, represents an individual viewpoint. What if the alternate and the primary representative hold conflicting viewpoints?
- There are currently no alternates for individual members.
- This position should be called patient and family representative because pediatric patients cannot represent themselves.

Council members generally agreed that there should not be an alternate for this position.

5. History of the Council

Noting that it is the twentieth anniversary of the Council, Ms. Diane Cousins provided a history of its origins.

- USP and the Institute for Safe Medication Practices (ISMP), through their medication errors reporting programs began to see trends. It was evident that the problems were so pervasive that it was unlikely that any one organization could address them.
- USP had a model for bringing people together that had been effective for large volume parenterals, and it seemed logical that a similar model would work for a collaborative of various organization which defined the NCC MERP.

- The original member organizations had the authority, mechanisms, and resources to affect the complexities as well as the vision to see what solutions might prevent medication errors from recurring.
- There were many issues to consider at nearly every meeting, and the Council routinely scheduled presentations on specific topics.
- The first objective of the Council was to develop a definition of a medication error. The concept of "preventable event" was not in people's vocabulary at the time.
- The next step was to develop the taxonomy and severity index.
- The Council also convened two external meetings—around barcoding and drug name suffixes.

Ms. Cousins then described the original structure of the Council, noting the following:

- The Council was originally comprised of a Chair, the Secretariat, and member organizations.
- The originally-established rules have changed over the years in positive ways.
- Working groups were established to address topics the Council wanted to address. This was seen as a way to engage both the delegates and the alternates in the work of the council.
- A steering committee was established, comprised of founding members, that focused on rule changes and setting strategic direction. This activity was ultimately brought back to the full council, as a way to involve all members and be more inclusive.

Discussion

Dr. Rita Munley Gallagher added that one theme that ran through the early Council activity was that attention was focused on "stuff" (specific medication error related issues) rather than structure. The Council always worked best when it was working on "stuff."

Dr. Deb Nadzem noted the following:

- The Council has become more efficient over time.
- With the addition of WebEx meetings, there have been fewer participants attending in person.
- Continuity is lost when representatives change.

The Chair noted the following:

- The Council has tried different ways of maintaining or increasing momentum, and ensuring that its activities provide value to members.
- Some things, such as the algorithm, have been big steps forward, but there are still a lot of things putting pressure on healthcare workers, and the culture continues to change.

6. Anniversary Report

A copy of the draft anniversary report was circulated prior to the meeting. Dr. Gallagher asked that changes be submitted by Friday, November 13, 2015.

Discussion

Council members asked about a press release to announce the report, and Ms. Shawn Becker explained that the secretariat could draft a press release, but it would have to be approved by the Council as a whole.

7. Journal Article on Perioperative Medication Errors

Ms. Lee Rucker summarized the results of an ISMP study that was published in the journal *Anesthesiology.*

- One out of 20 perioperative medication administrations, and every second operation resulted in an error or adverse drug event.
- One third of those errors resulted in patient harm.
- The study acknowledged those errors may be under-reported.
- The study used its own definition of medication error event, and there should be some consideration of the article's taxonomy and NCC MERP's.
- The results suggest the need for heightened awareness and ways to identify risk beyond error reporting.

Discussion

Participants raised the following points:

- One reason we don't know more about perioperative errors and ICU errors is that in most patients the vital signs are being controlled.
- There is little knowledge of anesthesia errors unless the doctor self-reports.

8. Discussion of Council Survey and Next Steps

The Chair noted that all Council members had been interviewed and the next question is what to do with the results. Some of the relevant comments included the following:

- There needs to be a process for keeping the Council's activities at the forefront even when they're not meeting.
- Outside speakers could be brought in to the meetings.
- Consider one face-to-face meeting a year and more frequent WebExes.
- There is no formal orientation process to the Council: Is that the Council's responsibility, or the other delegate's responsibility?
- Members should be encouraged to discuss the relevance of the topics introduced to their organizations.

The Chair then asked participants to share their organization's mission and vision and to articulate why they participate on the Council.

The mission and visions articulated are as follows:

- **Institute for Healthcare Improvement**—The mission of IHI is to improve healthcare around the world. The vision is that everyone gets the care that they deserve and everyone has good health, and they try to bring joy into their work.
- **ASHRM**—The mission statement is to advance patient safety, reduce uncertainty, and maximize value.
- **ASHP—**The mission and vision is to represent pharmacists that work in hospitals and health systems.
- **ISMP—**The mission is to advance patient safety worldwide by empowering the healthcare community, including consumers, to prevent medication errors.
- **NABP**—The general mission is to assist member states in protecting the public through the regulation of the practice of pharmacy.
- **ANA—**The organization represents the nation's 3.5 million nurses and establishes high standards of nursing practice.
- **NCPIE—**The mission of this organization is closely aligned with that of the council.
- **USP—**The mission is to improve global health through public standards and related programs that help ensure the quality, safety, and benefit of medicines and foods. We feel

privileged to act as the secretariat and provide assistance to the Chair and Vice Chair along with the other duties of the secretariat which will be provided later in the meeting.

- **Medication Safety Officers Society—**The main mission is to eliminate preventable patient harm associated with medications.
- **NASPA and APMS—**The missions of these organizations are to enhance the success of state pharmacy organizations in their efforts to advance the profession of pharmacy, and to encourage a culture of safety by providing recommendations on best practices and workflow processes designed to reduce medication errors, improve medication use, and minimize patient risk respectively.
- **AHRQ**—The mission is to produce evidence to make healthcare safer, higher quality, more accessible, equitable, and affordable and to work with HHS and other services to ensure this is used.
- **DoD—**The recently-formed Defense Health Agency brings all services together to standardize policies and processes within one system. It is on a journey toward high reliability, transparency, metrics, and outcomes.
- **American Medical Association**—The mission is to promote the science of medicine and its betterment. It is an umbrella organization with 115 specialties in 50 states.
- **NPSF—**The mission is to create a world where people are free from harm, and the organization does this through collaboration.
- **VA**—The mission is to fulfill President Lincoln's promise “To care for him who shall have borne the battle, and for his widow, and his orphan” by serving and honoring the men and women who are America’s Veterans. The core values are integrity, commitment, advocacy, respect, and excellence.

Participants described their reasons for participating, including the following recurring themes:

- The council is an excellent environment for collaboration.
- The work the council does is important to bring back to individual members.
- It is exciting to tackle unresolved issues through the Council.
- There is value in the ability to hear and learn from colleagues in a wide variety of disciplines.
- There is power when a group of 20+ organizations stand behind its work.

The Chair then asked participants to consider what disciplines, or perspectives might be missing from the Council’s. Participants suggested the following:

- Long-term care and assisted living
- Compounding
- Technology and meaningful use
- Home health
- Case management
- Practicing physicians

Discussion

Participants suggested that it may be more effective to invite organization in an advisory capacity rather than to add a number of new organizations to the Council.

- It may be useful to do a scan of what topics the council might consider that have not already been addressed.
- It may be useful to get editorials into journals that are read by practicing physicians to continue to raise awareness of the Council’s work.

- It is necessary to understand the problem the Council wants to solve in order to understand who the players are.

9. Member Updates

NPSF

- There was a report on root cause analysis recently released; the report and the associated webcast are available on the NPSF website.
- There have been 200 abstracts submitted for the organizations upcoming congress; a number of them address medication safety.
- The schedule for 2016 webcasts is currently under development.

NCPIE

- October is "Talk about your Medicines Month," and the theme this year is safe use, safe storage, and safe disposal.
- There is a new program underway with the Boy Scouts. A Scout can complete a four-lesson program on responsible and safe medication use in order to earn a patch. The program can even be shared with other organizations.

ISMP

- A revamped community pharmacy self-assessment will soon be released.
- There was a summit on IV push medications that resulted in recommendations and guidelines.
- There was also a two-day summit on insulin administration that included aspects on prescribing, storing, and dispensing.
- Updated targeted safe medication practices have been released.
- HEN 2.0 will be an important topic in the near term.

AHRQ

- There will be an expert panel review of PSO public comments.
- The report is available on the NQF website and will fit with any ambulatory pharmacy reporting.
- The two types of reports through the PSOs are in the area of falls and medications; there is not enough information to publish non-identifiable data.

USP

- There are two relevant General Chapters that will be published in February
  - Revised General Chapter <17> *Prescription Container Labeling* focuses on patient centered labels and revisions related to best practice standardization.
  - New General Chapter <800> *Hazardous Drugs—Handling in Healthcare Settings*.
- General Chapter <797> *Pharmaceutical Compounding —Sterile Preparations* is out for public comment and we encourage all to review the Chapter and comment or make suggestions.
- There is a call for candidates up on USP's website looking for expertise for four Expert Panels for the USP Healthcare Quality Expert Committee.

10. Next Steps and Next Meeting Dates

Council members then discussed the next steps and raised the following points:

- The Council is willing to try scheduling shorter, more frequent WebExes.
- The Council will always look for ways to be more efficient.

- The Chair and Vice Chair will reflect on the points raised and schedule a WebEx in January to further discuss the path forward.

Ms. Meyer reviewed the action items.

The meeting adjourned at 3:30 p.m.