

**Thursday, November 3, 2016
ASHP Headquarters
Final Meeting Summary**

Goals and Anticipated Outcomes

- New and Old Business
- Council reports and activities

Attendance

Present: Frank Federico, IHI (Chair); Ashok Ramalingam, DoD (Vice Chair); Leigh Purvis, AARP (WebEx); Diane Cousins, AHRQ (WebEx); Barry Dickinson, AMA; Sharon Morgan, ANA; Ann Gaffey, ASHRM (WebEx); Bona Benjamin, ASHP; Todd Bridges, FDA; E. Robert Feroli, Medication Safety Officers Society; Tara Modisett, NASPA; Maureen Cahill, NCSBN (WebEx); Elizabeth (Scotti) Russell, NABP (WebEx); Caitlin Lorincz, National Patient Safety Foundation; Rita Brueckner, VA (WebEx); Rita Munley Gallagher (WebEx), Deborah Nadzam (WebEx)

Alternates Attending in Place of Primary Delegates: Matthew Grissinger, ISMP; N. Lee Rucker, NCPIC

Non-Voting Substitute: Jenna Ventresca, APhA

Absent: ASCP, GPhA, The Joint Commission, Society of Hospital Medicine, Chrissy Blackburn

Alternates Attending with Primary Delegates: Donna Bohannon, USP

Observers: Amy Cadwaller, AMA; Celeste Karpow, FDA; Judith Racoosin, FDA; Maximilian Straka, ISMP; 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: Tara Modisett 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.
Mr. Frank Federico proposed the addition of a discussion of re-implementing the steering committee.
Motion: Dr. Barry Dickinson moved to approve the revised meeting agenda.
The motion was seconded and adopted by unanimous voice vote with no abstentions.

Secretariat's Report

a. Update on Membership

Ms. Shawn Becker welcomed the American Nurses' Association (ANA) back to the table.
Ms. Sharon Morgan introduced herself and described ANA's interest in the Council.

Ms. Becker also noted that we had been unsuccessful in reaching The Joint Commission (TJC) representative, Dr. Ron Wyatt. Mr. Federico noted that Dr. Wyatt is no longer with TJC. He will reach out to them. Ms. Becker mentioned that there has been an increase in people requesting individual membership, and she replies providing the information on how to formally make the request to the council.

Action Item:

- Mr. Federico will contact TJC regarding their representative on the Council.

Ms. Becker then summarized the following requests:

- A fifth year pharmacy student in India is working on a project and would like to share the details with the Council.
 - Mr. Federico suggested that he and Ms. Becker review the details first, and Council members agreed to that approach.
- Another individual was looking for information on non-verbal orders, noting that electronic medical records (EMR) do not allow for remote entry.
 - Participants noted this was an interesting question, and raised the question of what to do with orders conveyed via text.
- There was also a request for the Council's interpretation of the word "analyze" in the context of their statements and recommendations.
 - Council members suggested that the definition should be self-evident, but could perhaps be strengthened by greater description of what is being analyzed.

Council members also expressed interest in seeing a breakdown of the popular areas within the NCC MERP Website.

Action Item

- USP staff will provide analytics of the NCC MERP Website at an upcoming meeting.

2. Follow-up on Opioid Discussion

a. Review of themes from Summer WebEx

Mr. Federico explained that at the last meeting the Council members discussed opioids, opioid safety, and the opioid epidemic. There was also some discussion about what the NCC MERP could do related to the issue, and members decided to do more information gathering before reaching a decision.

b. Update on FDA/CDER's Opioid-Related Activities

Dr. Judith Racoosin was invited to present information on the FDA's Opioid-Related activities. Her presentation included the following:

- Drug utilization data show that the total number of opioid prescriptions peaked in 2012 with 214 million and has since decreased to 198 million in 2014
- Immediate release formulations make up the majority of prescriptions.
- The FDA's Center for Drug Evaluation and Research (CDER) is taking a multi-pronged approach to ensuring that patients in pain have access to relief while reducing the misuse and abuse of prescription opioids. This includes the following:
 - Exploring new technologies and promoting the use of abuse deterrent formulations
 - Strengthening safety labeling including enhanced warnings on immediate-release opioids, and highlighting the danger of opioid-benzodiazepine interactions.

- Using post market authority to engage an advisory committee to discuss the risk evaluation and mitigation strategy (REMS) for extended-release, long-acting opioids.
- Developing guidances to foster development of both brand name and generic drugs with abuse-deterrent properties.

Discussion

Participants then engaged in a discussion with Dr. Racoosin. Their questions are in top-level bullets and her responses are in sub-bullets.

- What has helped push the decline in opioid prescriptions since 2012?
 - This has to be viewed holistically. There is no one thing.
- Are there data on the concomitant benzodiazepine/opioid prescriptions by year? There may be a relationship to the fact that Medicare Part D began covering benzodiazepines four or five years ago?
 - FDA has published two analyses based on INS data on concomitant prescribing. It is nationally representative rather than broken out and does not specifically look at Medicare.
 - There has been some excellent research collaborations published in the past two weeks, most recently on erythropoietin dosing and reimbursement policy. There may be another opportunity for collaboration particularly given the Part D policy change.
- Where does the box warning show up?
 - The FDA issued a safety labeling change notification letter at the end of August. With that, the agency also issued a drug safety communication. Sponsors have to submit a supplement to add the warning to their labeling. It is still in the processing stage, and should be completed by the end of the year.
- Would a “regular person” understand what “concomitant” means?
 - This is in the package, which is geared to the prescriber. Alternatively, drug safety communication is aimed at the eighth grade level
- At the most recent workshop on abuse deterrence it was clear that neither the Center for Medicare and Medicaid Services (CMS) nor the Veteran’s Administration (VA) are promoting the use or addition of abuse-deterrent medications to their formulary. Can you speak to collaboration with other government agencies?
 - We are aware that the VA has not endorsed adoption of abuse-deterrent products, but are not really certain what the agency’s perspective is. We are certain the conversations are continuing.
- Is there any collaboration with the Drug Enforcement Agency?
 - There is some interaction, but not part of usual activities. A lot of it is based on scheduling.
- Dentists are an important prescriber of opioids.
 - Yes, dentists are prescribers and are included in the work being done. We have seen the data and are trying to gauge metrics for determining whether the extended release REMS is accurate.
- Do extended-release, long-acting formulations have an indication allowing for opioid tolerant therapy in the label?
 - As drugs are developed for different indications in different realms, they may have lower starting doses. It is difficult to make one size fits all.
- Does the education piece include alternatives to opioid therapies?
 - One of the key points of discussion at the advisory committee is whether there should be a discussion about pain management more broadly.

- There are concerns about patients that have legitimate needs for opioids being threatened or humiliated at the counter. There is merit to the idea of a pharmacist being able to see that there are patients on a pain plan.

c. Additional Feedback from Members on Current Activities

Mr. Federico noted that this is clearly a multifactorial, multipronged problem that includes both starting at the origin (i.e., abuse-deterrent formulations) and also ensuring that prescribers are aware of the alternatives. Additionally there is a need to education patients regarding pain management and appropriate drug storage.

Discussion

Participants then raised the following points:

- Doctors need to understand the concepts of pain management. It is acceptable to try over-the-counter analgesics first.
- Anesthesiologists are very familiar with these issues; it would be useful to engage them in these discussions.
- The *Journal of the American Medical Association* recently published an article about broadening blueprint on opioids.
- Many people are often prescribed more opioids than needed because physicians do not want to get called back.
- The National Patient Safety Foundation has an opioid course available publicly.
- There is increased interest in patients trying marijuana to control pain.
 - In states where marijuana is legal, the use of opioids decreases and overdose deaths have gone down.
- Prescribers do not understand that despite the longstanding use of morphine, there remains an individualized patient response with regard to tolerance, dependence, and abuse.
- Massachusetts is trying to pursue the partial fill option, however there are complications with regard to DEA regulations
 - People opposed to partial fills generally do not understand how it would be operationalized
- Pennsylvania has implemented a prescription drug monitoring plan that makes it easier for pharmacists to make the decision of whether or not to fill.
- CMS is working to de-link the pain survey from reimbursement models. They have also provided notice that they are working on a measure on concomitant opioid/benzo prescribing.

d. Opportunity for the Council to Have an Impact?

Mr. Federico noted that there is a great deal of individual stuff going on and asked whether there was a place to ground it or if there is already so much going on that the Council's voice would be not be heard.

Participants raised the following points:

- Even if the Council is not heard, we should still speak up.
- There are simple steps that can be taken around safe use to reduce harm and avoid unintended consequences.
 - Register for PMP
 - Limit the amount of opioids for pain
 - Use non-opioid therapy
 - Reduce exposure for those that are already on high-dose opioids

- Reduce stigma
- Prescribe Naloxone
- Identify and assist patients that have use disorder.
- There are also efforts around the safe use of Naloxone.
- The American Medical Association is about to release a Continuing Medical Education unit on what every prescriber needs to know.
- The Council can come out with a recommendation without too much effort. Many members have already done something, and the Council can synthesize that.
- This could be organized as follows:
 - Patient Expectation
 - Prescribing
 - Filling
 - Using (which links back to the patient)
 - Removing (what do you do with it after you are finished)
- This falls within the purview of NCC's mission to advocate for the safe use of medication.
- It could be directed at all healthcare workers and also patients

Participants then developed the following process to develop the statement:

- Members will forward their association specific information to USP who will create a clearing house.
- Mr. Bob Feroli will create an outline and allow people to fill in the blanks where it belongs. This will allow participants to immediately spot where the lack of suggestions are and facilitate additional discussion.
- Simplicity is very important additional high level categories should only be added as appropriate.

3. Proposed Recommendation on Patient Weights and the Impact of Medication Safety

Mr. Matt Grissinger presented an overview of medication errors in weight based dosing. His presentation noted the following:

- Most weight-based medications are critical use medications in oncology, geriatrics, and pediatrics.
- If there is an error in weight in the emergency room, it is transferred with the patient throughout the hospital stay.
- Weights are frequently guessed incorrectly.
- A pound/kilogram mix-up can result in a 2.2 fold under- or over-dose.

He recommended that NCC MERP adopt the following recommendations:

1. Weigh each patient as soon as possible on admission and during each appropriate outpatient or emergency department encounter.
 - a. Avoid the use of a stated, estimated, or historical weight.
2. Measure and document patient weights in metric units only.

Discussion

Participants discussed whether it might be feasible to work weight-based dosing into an existing recommendation, and after consideration decided to develop a new recommendation specific to that topic, and then update other recommendations to reference it.

Participants then raised the following

- Most adult medications are not dosed by weight.

- It would be useful if prescriptions included the dose, the dose basis, and the weight; the pharmacist could then perform a double-check.
- If pounds and kilograms are entered into the wrong area of an EHR, it can introduce an error in conversion.
- Extreme obesity has similar problems, both in weighing the patient, and in calculating appropriate dosing.
- Veterinary medicine does weight-based dosing, and may be able to offer insight.
- There are also questions of what should be the dosing weight, for example in cases of fluid overload, should it be based on dry weight or actual weight.

Motion

Mr. Matt Grissinger moved to develop a special NCC MERP alert on weight based dosing, and the motion was seconded.

Participants discussed the motion, and then adopted it unanimously with no abstentions.

Participants then discussed the approach to the special recommendation, and noted the following:

- There should be recommendations based on setting, age, and other considerations.
- Including e-prescribing will help.
- Include some wording that indicates that vendors should consider only having a kilogram field in the EHR.

Action Item

Mr. Matt Grissinger and Mr. Maximilian Straka will draft a first copy of the weight-based dosing recommendation for Council consideration.

4. Discussion of Other Potential Council Topics

Dr. Ashok Ramalingam led a discussion of other potential topics for Council exploration.

a. Price Spikes

In discussion of price spikes, participants raised the following points:

- This should be price “hikes” as the prices never come back down.
- There may not be much the Council can say here as discussions of cost are out of scope.
- As people look for substitutes, there may be safety considerations.
 - Between drug shortages and price hikes, there is a lot of substitution. Maybe the angle is that.
 - A lot of time is spent researching alternative drugs none of this budgeted into the schedule.

There was general agreement that the council could make a recommendation that health care systems should be aware that price hikes and shortages are big issues with the potential to introduce errors. It may also be possible for the council to take a position on the grey market.

b. Drug Shortages

This was addressed above in conjunction with the discussion on price spikes.

c. CPOE/EHRs and Medication Errors

Council members noted that this is an increasing issue as it is part of what people use to deliver healthcare. However with the number of vendors and software versions any recommendations would have to be so generic as to be possibly meaningless.

d. Indications-based Prescribing

Participants noted the following:

- It may be worthwhile to invite Dr. Gordon Schiff to a meeting to discuss his research on the topic.
- Indications on prescriptions is recommended in some current statements but not in any great detail.
- USP General Chapter <17> Prescription Container Labeling also recommends this practice.
- The FDA is starting look at off-label communication.

e. HEN 2.0

Participants noted the following:

- Round three was just awarded, but the name of the acronym changed. There are fewer participants than in the first two rounds, but medication safety remains emphasis of their work.
- There is a requirement to measure ADEs, but it is not comparable because each network does something different.

f. Medical Marijuana

In general participants decided that this issue was too political to address at this time and may not be within scope of Council.

g. Liquid Medication Dosing Errors

Participants raised the following points:

- This is a significant issue.
- The CDC Protect initiative recommends using mL only as a liquid measurement.
- There was a recent study that reviewed the use of dosing cups and oral syringes, and concluded that doses under 10 mL should always be given in syringe.

h. Medication Overuse

Mr. Federico noted that he will be sending the draft polypharmacy recommendation for Council review. Although, medication overuse is not exactly the same, the issues are related.

A Council member suggested this topic could be called “Appropriate Medication Use” as both overuse and underuse are inappropriate.

i. How to Measure medication errors

Participants noted the following:

- This remains a problem; people want to believe that voluntarily reported errors can be rated.
- The Council may wish to come up with a statement that there is no global metric for medication errors.
- There are some good metrics if the numerator and denominator are crisply described, voluntary reporting is not part of it, and the methodology for collecting is robust.

j. Resurrecting the Steering Committee

Mr. Federico explained that as Chair he wants to make members' time on the NCC MERP worthwhile. He struggles at times to make the agenda meaningful and design sessions and topics that are of value to everyone.

To that end, he proposed resurrecting a steering committee in order to develop a plan for what would be accomplished over the year, oversee the management of the statements and recommendations, and work on agenda development.

The following five members and organizations volunteered to serve on the steering committee:

- Dr. Bob Feroli
- Mr. Matthew Grissinger
- Ms. Ann Gaffey
- Ms. Lee Rucker
- Dr. Rita Munley Gallagher
- Chair and Vice Chair
- Secretariat

5. Member Updates

AMA

Dr. Barry Dickinson noted that Dr. Amy Cadwaller would be the primary AMA representative, and he will be the alternate.

ASHP recently published pediatric concentrations for public comment and finalized the list of adult concentrations.

USP just completed the public comment period for the *Medicare Model Guidelines version 7.0*, which will be available to the public in February. USP is developing a new product that is currently out for public comment, the *USP Drug Classification System*, which is an independent drug classification including drugs beyond the Part D benefit. Ms. Bohannon will send the Website information to the membership.

NPSF is collaborating with the CDC and ASHP on a webcast about get smart about antibiotics. It will be accessible on November 14. They will send a link to the Council.

NCPIE just concluded talk about medicines month. The theme was polypharmacy. Administratively, NCPIE is in the process of consolidating the many websites under one primary domain. They also recently affiliated with healthline.com, and will be producing articles.

With the AMA, NCPIE has worked on an online training module related to promoting medication adherence. Additionally, the Boy Scouts can now get a badge on helping others use meds appropriately. This was met with considerable applause from the Council members.

Discussion

Participants raised the following points in wrap-up:

- It may be useful for Mr. Federico to present on what he has learned and observed with regard to medication errors internationally.
- National Health Service in England recently developed a patient weight safety toolbox.
- The *New England Journal of Medicine* published an article on the recent problems of the NIH clinical center to frame the broader perspective on creating a culture of safety.



6. Wrap-up and Next Steps

The next meeting will be a WebEx in January or February. USP will send a poll out to determine the date.

Prior to the meeting the steering committee will hold a meeting to discuss its process.

The meeting adjourned at 3:00 p.m.