



**NCC MERP Meeting
October 9, 2018
10:00 a.m.–2:00 p.m.
WebEx**

Attendees:

Matthew Grissinger (ISMP), Chair; Deborah Pasko (ASHP), Vice Chair; Shawn Becker (USP), Secretariat; Amy Cadwallader (AMA); Holly Carpenter (ANA); Lindsay Kunkle (APhA); Bob Feroli (MSOS); Frank Federico (IHI); Rita Brueckner (Department of Veterans Affairs); Elizabeth Scotti Russell (NABP); Rita Munley Gallagher; Deborah Melnyk; David Gaugh (AAM); Maureen Cahill (NCSBN); Leigh Purvis (AARP); Tara Modisett (NASPA)

USP Observers: Abbey Ammerman; Donna Bohannon; Valerie Jensen (FDA), Krista Levy (ACCP); Deborah Davidson (NeedyMeds);

Opening, Procedural, and Administrative Matters

Mr. Matthew Grissinger called the meeting to order at 10:00 a.m. and welcomed everybody to the meeting. Ms. Ammerman called roll and acknowledged a quorum. The summary of the previous meeting was reviewed and approved unanimously. Dr. Grissinger reviewed the agenda for the meeting and asked for approval of the agenda. The agenda was approved unanimously.

Drug Shortages

Captain Valerie Jensen (FDA) offered a presentation on the work that FDA is doing to monitor and prevent drug shortages. She explained that there is a program office that is designated by FDA to oversee and facilitate the resolution of all drug shortage situations. They work with suppliers and facilities to address many urgent and significant issues in solving drug shortages.

According to 506C of the FD&C Act, manufacturers are required to notify the FDA of “a change in production that is reasonably likely to lead to a reduction in the supply” of a covered drug in the United States. FDA has encouraged early reporting and had seen a decrease in shortages in 2015-16, until Hurricane Maria hit Puerto Rico and the southern US. FDA worked closely with IC fluid manufacturers to approve temporary imports to help resolve the shortages. Additionally FDA is working to expedite the approval of new applications.

Another current shortage is for injectable narcotics. FDA is working with the manufacturer and DEA to mitigate this shortage. ASHP is also involved in these discussions.

Council members discussed the need for more education and awareness around shortages, including at the executive level. It was noted that they don't necessarily have a complete

understanding of what is needed to provide appropriate backup plans when there are shortages. Similarly, many physicians may not understand how patients are affected by drug shortages. Ms. Pasko (ASHP) noted that ASHP produced patient communications videos that could be shared with council members.

Action Item: Ms. Pasko will share the videos with council members.

Secretariat's Report

Ms. Shawn Becker provided updates on the NCC MERP membership. She welcomed Ms. Krista Levy from The American College of Clinical Pharmacology (ACCP), our newest member organization who is sitting in for the new delegate. She also introduced Holly Carpenter who will serve as the representative from the American Nurses Association (ANA) and Lindsay Kunkle serving as the representative for APhA going forward. She provided information on two organizations that were not represented The Joint Commission and ASCP to establish new representatives. Ms. Becker addressed the issue of PhRMAs lack of participation and asked for assistance from council members. Ms. Becker introduced Ms. Davidson from NeedyMeds and explained that her former organization, NCPIE had formally dissolved, but is now under the NeedyMeds umbrella. Ms. Davidson provided information on this new organization and asked to have this organization become a member representing the patient and consumer needs of the Council.

Action Item: Ms. Becker will send a notice to council members requesting a reliable contact at PhRMA.

A motion to formally invite NeedyMeds to join the council was seconded and approved by unanimous consent.

Ms. Bohannon provided an update on the website analytics, noting that the NCC MERP website had more than 180,000 hits since January. Most often, visitors looked for the member organizations and the definition of medication errors. Traffic comes primarily from the US. The index and the taxonomy are still the most popular downloads. She also highlighted web analytics for the past three years showing a gradual increase in traffic year to year. Ms. Bohannon asked council members to please send any new or updated information for the Consumers page and for the Opioids resource page.

There was discussion about the possibility of expanding the Council social media presence, including a potential LinkedIn page. It was noted that an increased presence would also require significant time monitoring. It was agreed that the chair would investigate the possibility of a LinkedIn page, but no further efforts would be made at this time. It was noted that when the Council has statements or recommendation announcements, they should be further publicized by Council members through their organizational newsletters.

NCC MERP Recommendations and Statements



Mr. Grissinger noted that the Patient Weights statement was currently open for ballot. There were minor edits made during the meeting and Ms. Ammerman will distribute the new version to Council members. Members were reminded to cast their ballot by October 25, 2018.

It was suggested that going forward, suggestions for statements or recommendations should have a sponsor who will review and provide feedback and recommended changes to the advisory group prior to proposing to the entire council. This would help to streamline this process. Dr. Feroli noted that he had proposed language that could be used to formalize this process. He will forward to the chair and vice chair for consideration. Council members also discussed the need to develop a formal archiving process for statements and recommendations that are no longer current.

Action Item: Dr. Feroli will send the chair and vice chair language to consider for a formal policy on statement/recommendation updates.

The chair explained that the discussion of the polypharmacy statement had been tabled at the last meeting. Dr. Feroli provided an outline of the statement. Several Council members provided feedback and suggested updating some of the references. Ms. Davidson will assist in the final review of the statement. Once final revisions are made it will be sent to the Council for balloting.

NCC MERP Taxonomy

The taxonomy workgroup held several calls considering what will be most helpful moving forward. It was emphasized that the taxonomy still plays an important role, but there might be other ways to have more utility. It was suggested that a survey to gauge how it is utilized might be helpful. ASHRM and the advisory group will work on developing a survey to be distributed.

Potential Topics for Council Action

Drug Shortages – While Council members noted the importance of understanding drug shortages, it is clear that there is existing work being done and there are no clear pathways for Council action at this time.

Medication management and Patient Counseling – Council members questioned whether there were adequate resources for teaching medication management and counseling patients on their medications. It was noted that there are no current requirements for hospitals to document patient counseling and that would likely only happen if CMS or other payors start requiring it. Ms. Bohannon noted that USP is considering the development of a standard on patient counseling, but noted that some stakeholder groups felt it would impede on practice standards and could also raise liability issues. It was noted that some states have mandated counseling and a council member has seen this in practice.

Council members discussed other means to educate patients and encourage them to discuss their medications with their physicians and pharmacists. Dr. Deborah Nadzam Melnyk offered to put initial thoughts on paper to outline what steps the Council could potentially take in the future.

Measurement for Medication Safety – it was noted that there are some robust markers of harm, but not of safety. Council members discussed the need for institutions to identify the questions they're trying to solve before identifying measures. It was noted that depending on who's asking the question, there are very different measures/processes needed. Dr. Federico offered to take a first stab at identifying ways the Council could take action.

Indications-based Prescribing – it was noted that there has been a lot of work in this area and it was suggested that the Council invite Dr. Gordy Schiff to present at an upcoming council meeting. His presentation could assist the Council on any informal discussion around future work in this area.

The Role of Leadership in Medication Safety/Patient Safety – Dr. Federico noted that he had information from a presentation that he would share with the Council. It was agreed that he and Mr. Grissinger would develop a first draft of a statement to share with the council.

New Business/Member Updates

- NABP is focusing a work on the opioids epidemic.
- APhA has developed an opioids resource center and is advocating for naloxone distribution. They are also working on new resources for pharmacists to use an appointment based model for refills and medication reconciliation.
- ACCP is developing educational programs particularly aimed at providing better pharmacology curriculum to 4th year pharmacy students.
- MSOS is hosting a webinar on October 25 on best practices from the MARQUIS trials.
- ISMP recently launched a new website.
- USP recently posted general chapters <797> and <825> for public comment. Additionally, the USP Drug Classification will be posted for comment later this month.
- IHI is focusing on efforts to optimize medications in primary care who do not have access to a pharmacist consult. Additionally they have been very involved in the WHO's third challenge on reducing polypharmacy.
- AMA continues its work on the opioids taskforce including a focus on pain management.
- ANA is working with FDA Medwatch in promoting a Healthy Nurse Healthy Nation campaign.
- ASHP is hosting a webinar with NQF focused on opioids and is gearing up for the midyear meeting in December.

Closing



Ms. Ammerman announced that the next meeting would take place via webinar in January. The chair thanked Council members and adjourned the meeting at 2:00 p.m.

DRAFT