

Thursday, October 31, 2013
10:00 a.m. – 4:00 p.m.
Bache and Woods - USP Meeting Room
Draft Meeting Summary

Goals and Anticipated Outcomes

- Develop a statement on geriatric medication safety.
- Develop criteria for a patient delegate to NCC MERP
- Finalize the “Quick Fill” recommendation.

Attendance

Present: Frank Federico, IHI, (Chair); Ann Gaffey, ASHRM, (Vice-Chair); Barry Dickinson, AMA; James Owen, APhA; Robert Feroli, ASMSO; Deborah Myers, DoD; Matthew Grissinger, ISMP; Maureen Cahill, NCSBN; Scotti Russell, NABP; Tara Modisett, NASPA; Deborah Davidson, NCPIE; Shawn Becker, USP; Todd Bridges, FDA; Trisha Kurtz, TJC; Marsha Gilbreath, APhA; Deborah Nadzam

Via WebEx: James Burris, AGS; Darryl Roberts, ANA; Bona Benjamin, ASHP; Don Martin, APSF; David Gaugh, GPhA; Patricia McGaffigan, NPSF; Michael Garvin, PhRMA; Rita Brueckner, VA; Rita Munley Gallagher .

Alternate Delegates Attending with the Delegate: Donna Bohannon, USP; Lee Rucker, NCPIE

Absent: AAPA; AARP; ASCP; SHM; Manisha Shah, Diane Cousins

Observers: Emily Ann Meyer, USP; Rick Schnatz, USP; Marie Temple, USP; Linda Smith, ASHP; Mary Andrawis and Zandra Glenn, CMS.

1. Opening, Procedural, and Administrative Matters

Mr. Frank Federico, Chair, called the meeting to order at 10:10 a.m. and welcomed everyone to the 57th meeting of the National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP). Ms. Emily Ann Meyer called roll and determine that a quorum was established.

Since a quorum was not present for the last meeting, the Council reviewed the two previous meeting summaries and provided no edits.

Motion: Ms. Tara Modisett moved to approve the summary of the two previous meetings, and it was seconded. The Council adopted the motion unanimously.

The Council reviewed the meeting agenda. The Chair noted the following changes:

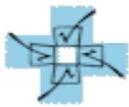
- Diane Cousins’ presentations may be postponed as she was unable to attend.

Motion: Ms. Shawn Becker moved to adopt the meeting agenda, and it was seconded. The Council adopted the motion unanimously.

2. Secretariat’s Report

a. Chair and Vice Chair Election

Ms. Becker announced that Frank Federico and Ann Gaffey were re-elected as Chair and Vice-Chair respectively. They will serve for the next two years.



b. Individual Membership Renewal for Deborah Nadzam

Ms. Becker reported that Dr. Deborah Nadzam requested that her individual membership be renewed.

Motion: Ms. Becker moved to renew Dr Nadzam's individual NCC MERP membership, and it was seconded. The Council members discussed the motion, and it was adopted unanimously.

Ms. Nadzam left the room while the Council voted.

c. AARP Representative Needed

Ms. Lee Rucker explained that she left her position at AARP and will no longer represent that association. She attended this Council meeting as a National Council on Patient Information and Education (NCPPIE) alternate and will continue to attend Council meetings in that capacity. The Council will contact AARP to seek another representative.

Action Item

- Ms. Becker will follow-up with AARP for representation.

d. New Representatives

The following new Council representatives introduced themselves:

- Dr. Kellie Taylor is the new delegate for U.S. Food and Drug Administration (FDA) replacing Carol Holquist and Mr. Todd Bridges is the new FDA alternate delegate.
- Ms. Trisha Kurtz is the new Joint Commission representative, replacing Crystal Riley.

e. Resignation of Manisha Shah

Ms. Becker read a resignation letter from Manisha Shah, who moved to England. She was serving on the Council as an individual member.

f. American Society of Medication Safety Officers

Matt Grissinger explained that the American Society of Medication Safety Officers (ASMSO) and the Institute for Safe Medication Practices (ISMP) are merging to form the Medication Safety Officer Society (MSOS). ASMSO will exist within ISMP.

Action Item

- NCC MERP will address the ASMSO membership eligibility on the Council when more information is made available.

g. New Governmental Relations Category

This topic was tabled until the next meeting.

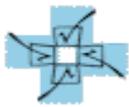
Action Items

- The Chair will circulate a document describing a proposed governmental relations category for NCC MERP.

h. Permissions

i. Xavier Gray Request

Ms. Becker explained that the Council received a communication from Mr. Xavier Gray requesting a link to his website Open Education Database (OEDb.org) be added on the NCC MERP website. The Council discussed this request and members indicated that doing so could imply endorsement.



Action Item

- Ms. Becker will decline Xavier Gray's request for a link to their website on the NCC MERP website.

ii. Permissions Granted

Ms. Becker detailed permissions granted since the last meeting.

3. Reports and Activities

a. Addition of a Patient Representative to NCC MERP

Ms. Chrissie Blackburn presented information on the possibility of NCC MERP partnering with a Patient and Family Advisor (PFA). She stressed that an effective partnership between the Council and a PFA would need a clearly defined PFA role and expectations, and clear Council goals. Ms. Blackburn indicated that to effectively engage with the PFA the Council would have to do the following:

- Learning how to communicate with the PFA,
- Set PFA expectations,
- Follow up with PFA on their suggestions
- Engage the PFA on projects
- Encourage PFA participation in meetings
- Assign a Council liaison/mentor to prepare the PFA for meetings
- Offer recognition to the PFA
- Avoid using acronyms and medical jargon in meetings.

The Council discussed the following topics:

PFA Title

- PFAs are referred to as "advocates" or "advisors." An alternative term could be "Consumer Representative."

Number of Representatives

- It may be difficult for one person to represent all groups of patients, e.g., pediatric, chronic inpatient, healthy patients. It would be helpful to have a few different consumer voices.

Term Limits

- It could take a few meetings for a representative to become familiar with the Council's activities and to strengthen relationships with other Council members.
- Continuity and historical perspective are important. A two year term minimum may be preferable, with the ability to extend beyond the two years.

Funding

- The Council should consider whether it can afford to fund a PFA's participation in face-to-face meetings, especially if the representative is not from this region.

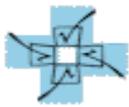
Criteria

- Selection criteria will help drive how the council picks a representative.
- The dedicated medication manager should be involved in these criteria.

Next Steps

The Council decided to form a Patient Representative Subcommittee to determine the criteria and purpose for the new patient representative. The following members volunteered to serve on the Subcommittee:

- Frank Federico
- Matthew Grissinger
- Tricia Kurtz



- Tara Modisett
- Donna Bohannon
- Patricia McGaffigan
- Chrissie Blackburn

Action Item

- The Patient Representative Subcommittee will
 - Develop criteria for the NCC MERP patient representative membership category, and
 - Develop a rationale for including the patient category.

b. Finalization of “Quick Refill” Recommendation

Mr. Matthew Grissinger, on behalf of Michael Gaunt, explained that pharmacies are promising rapid prescription filling, and may be bypassing safety for speed. Safety should be the focus, not speed and convenience. He suggested that Council members read an article, *A Day in the Life of a Corporate Retail Pharmacist*. He presented the following “Statement Advocating for the Elimination of Prescription Time Guarantees in Community Pharmacy:”

The National Coordinating Council for Medication Error Reporting and Prevention advocates the elimination of prescription time guarantees and a strengthened focus on the clinical and safety activities of pharmacists within the community pharmacy setting.

Mr. Grissinger noted that Council members have had time to review the statement and background information and asked the Council to vote on the statement.

Motion: Ms. Deborah Nadzam moved to accept the Statement Advocating for the Elimination of Prescription Time Guarantees in Community Pharmacy, and it was seconded.

The motion was discussed and a majority of Council members adopted the motion with one abstention: Veterans Administration (VA) and one no vote from the American Pharmacists’ Association (APhA)

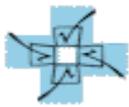
- Rita Brueckner, the VA representative, noted that as the VA has a metric in place that may not be congruent with the NCC MERP statement, it is important to emphasize that these metrics are used at a facility level as an operational tool to enable managers to assess, at a given period of time, the need for additional resources. The metric should never be used as a type of performance evaluation regarding the services performed by a professional. Ultimately, the VA goal is to maximize patient safety.
- The Chair clarified that the Council statement is not a policy statement. Pharmacies that still want to fill prescriptions quickly should have enough resources to maintain patient safety.

Council members discussed the importance of disseminating the statement and raising awareness among patients and consumers, including the following:

- The Council depends on its member organizations to disseminate information.
- As the NCC MERP Secretariat, USP staff could prepare and disseminate a press release announcing the statement.
- The Secretariat refers calls seeking interviews on Council statements/recommendations to the Council Chair and Vice Chair for response.

Wording on the statement will indicate that the recommendations and statements reflect the decisions of the Council as a whole and not that of an individual organization. **Action Items**

- NCC MERP members will publicize the NCC MERP “Statement Advocating for the Elimination of Prescription Time Guarantees in Community Pharmacy” (“Quick Refill Statement”).



- USP staff will develop a Quick Refill Statement press release and send it to all NCC MERP member organizations for approval.
- USP staff will post the statement on the NCC MERP website and send to all organizations for their newsletters.
- Ms. Becker will develop a cover letter to the *Annals of Internal Medicine* to accompany the Quick Refill Statement press release and send it to the Chair and Vice Chair for review. She will then send the letter, press release, and Quick Refill Statement to *Annals*.

c. Development of a Statement on Medication Safety for the Geriatric Population

The Chair explained that elderly patients are receiving many medications that may be contraindicated. A Council statement on medication safety for the geriatric population should do the following:

- Start with the Beers criteria,
- State that some chronic medications should be stopped, and
- State those medications should be reviewed to avoid adverse reactions, reconcile different medications, and increase medication adherence.

The Chair introduced a draft for the Council's review and noted that the audience should be everyone involved with a patient's care. Council members discussed the following topics:

- The Certified geriatric pharmacist credential is recognized in California.
- The recommendations should be broad in scope.
- In New York, "Next Steps in Care" has information for families and patients.
- NCIIE resources include a new report and the "Be Medicine Smart" campaign through the talkaboutrx.org website.

The following Council members volunteered to review and revise the first draft:

- Ann Gaffey
- Matthew Grissinger
- Donna Bohannon
- Deborah Nadzam
- Barry Dickinson
- Jim Burris
- Linda Smith an observer from ASHP

Action Item

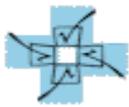
- The identified NCC MERP volunteers will review and revise the draft "Statement on Medication Safety for the Geriatric Population."

4. Subcommittee Updates

a. Taxonomy Survey

Ms. Ann Gaffey explained that the results of an informal poll taken by ASHRM indicated that the NCC MERP taxonomy is useful and does not require revision. She noted the following:

- Many organizations have adopted NCC MERP's taxonomy for their medication reporting systems.
- Respondents included 40 risk managers of 40 large reporting companies.
- 80% of the hospitals polled use an electronic event reporting system.
- All of the respondents indicated that the NCC MERP taxonomy meets their present needs.
- Data on electronic health record related errors are being collected, but not yet available.



Decision: The Council reviewed the taxonomy and determined that no changes were needed.

Action Items

- USP staff will add the following topic to the parking lot for future discussion:
 - NCC MERP will consider future taxonomy revisions pertaining to medication errors related to electronic health records.
- Ms. Becker will research web analytics on medication errors related to electronic health records.

b. Recommendations/Statements

Mr. Barry Dickinson reported that a Subcommittee reviewed all NCC MERP recommendations and statements and made suggestions for archiving, updating, or retaining with no changes. He noted the following:

- The subcommittee recommended updating eight of the 14 recommendations and statements.
- Most of the updates pertained to harmonizing USP General Chapters with the documents.
- Some statements may require a formal review by Council member organizations.

Mr. Dickinson proposed the following next steps:

- Determine Council member assignments for individual statements.
- Determine a revision schedule.
- Discuss the statements electronically via email and reserve the next face-to-face meeting for final discussion.

The Council discussed the following:

- The statements could be grouped by audience.
- USP staff can assist by scheduling teleconferences.

Council members volunteered to review specific statements and recommendations (see Appendix 1).

Action Items

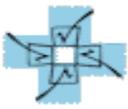
- USP staff will send to Council members the grid listing volunteers to review specific statements and recommendations determined at this meeting.
- NCC MERP members will inform Ms. Becker or Ms. Bohannon if they have additional interest in working on specific statements or recommendations.
- Volunteer groups will review the recommendations and statements and suggest revisions.
- NCC MERP members will review proposed revisions to recommendations and statements and finalize the statements at the April 2014 NCC MERP meeting.

c. Adverse Drug Events / Adverse Drug Reactions

Dr. Nadzam summarized the recommended changes to the draft “Differentiating Adverse Drug Reaction (ADR) from Medication Error” algorithm, including the following:

- Definitions were added.
- Decision loops were clarified.

The Council discussed revising the algorithm (see Appendix 2) and discussed the following topics:



Documented Allergy

- The algorithm should include the patient's voice, such as: "Have you had a negative or allergic reaction to this drug in the past?"
- The text could be revised to include "documented allergy."
- "Negative or allergic reaction" could be changed to "Known hypersensitivity." Council members decided not to make this change because it only applies to subsequent exposures, not initial reactions.
- Council members revised the text to the following:
 - "Did the patient report or is it otherwise documented that a negative reaction occurred to this drug in the past?"

Clinical Judgment

- If a patient reports a negative event, the practitioner may use clinical judgment to assess whether to prescribe the medication based on a risk/benefit analysis.
- Council members added the following text:
 - "Was this information appropriately considered or documented when developing a treatment plan?"
- Off-label use was incorporated to represent the clinician's viewpoint.

Adverse Drug Event and Adverse Drug Reaction

- The difference between an ADE and an ADR is unclear.
- The ADR definition could be removed.
 - "ADR" is still used in clinical trials, but NCC MERP could replace the term and discourage its use.
 - If a medication issue could have been prevented, it could be called an "avoidable ADE" instead of an ADR. If it could not have been prevented, it could be called an "unavoidable ADE."
- The World Health Organization defines an ADR as a reaction to a dose normally used in man. It does not specify if it is an error.
 - If the dose was used in man, it would be an ADR.
 - Definitions from literature and other organizations could be included as footnotes.
- "ADR" implies that harm occurred. Many medication errors do not result in harm.
- Council members decided to
 - Change the algorithm title to "Contemporary View of Medication-related Harm: A New Paradigm,"
 - Add an appendix listing historical terms and how they were used, and
 - Add "ADE" between the first and second diamond in the algorithm.

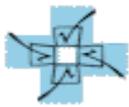
Other Suggestions

- Add an opening paragraph explaining the purpose of the tool and identifying the audience.
- Include case studies and scenarios.
- Publish the tool in journals such as *JAMA*.

Action Items

- Ms. Bohannon will revise the "Contemporary View of Medication-related Harm: A New Paradigm" to incorporate the changes determined at the meeting and send the revised draft to Council members for review.
- When the algorithm is completed the Subcommittee will develop an article for possible publication in *JAMA*.

5. Member Updates: Medication Safety Activities



a. Partnership for Patients

Dr. Mary Andrawis and Ms. Zandra Glenn from the Centers for Medicare and Medicaid Services described the Partnership for Patients campaign to improve the quality of patient care. They noted the following:

- Since launching in 2011, federal partners and private associations have formed Hospital Engagement Networks (HENs).
- Each HEN works with approximately 25 hospitals and focuses on ADEs.
- The HENs Affinity Group for Medication Safety is focusing on hypoglycemia, opioids, and anticoagulants.

b. Post-Discharge Medication Reconciliation Insights

Dr and Andrawis and Ms. Glenn introduced a draft “Post-Discharge Medication Reconciliation Insights” document for Council review. The document focused on the following areas:

- Target: How do hospitals target post discharge patients?
- Finance: How do hospitals pay for medication reconciliation services?
- Operationalization: How do hospitals provide medication reconciliation services?

They noted the following:

- National organizations can help ensure that more patients receive these types of services.
- Patients should be informed so that they can ask for these services.
- The goal of the service is to reduce hospital readmissions.

Council members involved with HENs noted the following:

- Awareness and use of the phrase “Post-Discharge Medication Reconciliation (PDMR)” is increasing.
- Hospitals need resources to implement the service.
- HEN activities can identify staff deficiencies (e.g., lack of knowledge of opioid use).
- Challenges include
 - Generating reports that aggregate data and reveal trends, and
 - Developing measures that account for disparities between large and small hospitals.

Council members discussed the following:

- Pharmacists should be included in the process.
- NCC MERP could join the Partnership for Patients and publish examples and results of successful implementation of PDMR.
- The term “post-discharge” could be changed to “transition” or “follow-up.”

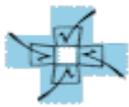
Action Items

- NCC MERP members were encouraged to send feedback on the “Post-Discharge Medication Reconciliation Insights” document to CMS representatives.
- NCC MERP members should consider joining the Partnership for Patients.
- NCC MERP members were encouraged to publicize PDMR activities to their organizations and consider publishing examples and results.

6. New Business: NCC MERP Communiqué

Council members provided the following feedback on the usefulness of the NCC MERP Communiqué:

- Council members use the communiqué to provide information to their organizations.
- USP is aiming to provide the summaries in a timelier manner.



- At this time, meeting summaries are not intended for public disbursement. Council members noted that summaries could be published publicly if opinions were not attributed to specific members.

Motion: Maureen moved that NCC MERP discontinue documenting and publishing the NCC MERP Communiqué and it was seconded. The motion was discussed and NCC MERP members adopted the motion unanimously.

Action Items

- Meeting summaries will not attribute comments to specific organizations in NCC MERP meeting summaries.
- NCC MERP Communiqué will be discontinued
- USP will produce meeting summaries in a timely manner.
- NCC MERP members will share summaries within their organizations.

7. Additional Member Updates

ISMP: Mr. Grissinger noted that ISMP aims to publish medication safety best practices in 2014.

PhRMA: Dr. Garvin described a recent study on adherence, prevention, and proper medication use for chronic disease states and how it can limit hospital stays. He offered to invite someone to speak to NCC MERP on this topic at a future meeting.

NASPA: Ms. Modisett noted that NASPA is working with other national pharmacy groups on pharmacy provider status. NASPA provides support and resources to state pharmacy associations. She works with the Alliance of Patient Medication Safety.

APhA: Dr. Gilbreath noted that APhA is updating care transition policies.

NCPIE: Ms. Rucker distributed an article from the *New England Journal of Medicine*, Sounding Board on talking with patients about errors from other clinicians. The article does not discuss NCC MERP or recognize the Council's work to define medication errors but it contains a format that may be useful for the paradigm article.

AMA: No additional updates.

NCSBN: Ms. Cahill noted that the Regulatory Action Pathway tool parallels the Just Culture Model. State boards are participating in a pilot study of this tool.

JCR: Dr. Nadzam noted Top-Off Prescriptions Month, an FDA grant, and a survey.

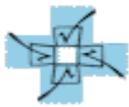
ASMSO: See item 2f on ASMSO's partnership with ISMP. Dr. Feroli noted that the Medication Safety Officers Society is international and multidisciplinary.

FDA: No additional updates.

AASHRM: Ms. Gaffey described a conference on falls and pressure ulcers.

IHI: Mr. Federico noted that the 25th international forum will be held soon. Many organizations are approaching IHI for help with population health management.

USP:



Ms. Bohannon reported the following:

- Proposed General Chapter <7>Labeling will be published in USP Pharmacopeial Forum, a free publication for public comment. November 1. It includes a revision that ratio expression should not be used with single entity epinephrine and a new naming convention for compounded preparations.
- USP and the National Council for Prescription Drug Programs are drafting a white paper on the use of mL instead of teaspoon.

Dr. Schnatz reported that the Compounding Expert Committee (EC) and General Chapters–Microbiology EC are revising General Chapter <797> *Pharmaceutical Compounding–Sterile Preparations*. He noted the following:

- The primary objective is to prevent harm.
- An Expert Panel is reviewing the General Chapter and will provide feedback to the ECs.
- The revised General Chapter will be published in Pharmacopeial Forum for comment.
- The General Chapter does not consider the cost of upgrading facilities to comply with the standard. National studies on the use of <797> in hospitals may provide some cost data.
- Hospitals should plan to comply with <797>.

NABP: Ms. Russell noted that NABP is:

- Working with states on their responses to adverse events associated with compounding.
- Training their inspectors to comply with USP standards.
- Developing uniform inspection programs, and

TJC: Ms. Kurtz noted that The Joint Commission is working with ASHP and FDA to develop webinars to explain new federal compounding legislation and TJC's expectations. Webinars focusing on surveyors and General Chapter <797> will also be developed. She noted that development of the <797> webinar could be postponed until USP revises <797>.

VA: Dr. Brueckner noted the implementation of a patient-centered prescription label. A study of the impact of culture and age on prescription labels confirmed that patients preferred the new standardized label.

APSF: Dr. Martin described an algorithm to increase safety in operating room environments.

Dr. Munley-Gallagher: No additional updates.

NPSF: Ms. McGaffigan reported that she attended a conference on identifying family caregivers in electronic health records. A dedicated medication manager can improve patient safety and quality of care.

8. Next Steps and Next Meeting Date

The Chair noted that USP will poll Council members to determine the best winter meeting date. He requested that members send future agenda topics to him, Ms. Gaffey or Ms. Becker.

Action Items

- USP will send a Doodle poll to Council members to determine the date of the January–February 2014 meeting.
- Council members will send ideas for future agenda topics to the Chair and Vice Chair or Secretary.

The meeting was adjourned at 2:50 p.m. by consensus.