June 2, 2005

Council delegates present:

Linda Hanold (JCAHO), Chair	Carol Holquist (FDA)
Diane Cousins (USP), Secretary	Sal Peritore (GPhA)
Lee Rucker (AARP)	Matt Grissinger (ISMP)
Janet Myder (AHCA)	Eleni Anagnostiadis (NABP)
Joseph Cranston (AMA)	Polly Johnson (NCSBN)
Rita Munley Gallagher (ANA)	Ray Bullman (NCPIE)
Veronika Oven (AONE)	David Kotzin
Ron Nosek (DoD)	Mick Murray (USP SMU EC)

Alternates attending as representatives of their organizations:

Mary Anne Hilliard (ASHRM)
Margaret Hogan (NPSF)
Rosemary Cook (PhRMA)
Lynn Sanders (VA)

Alternates attending with their delegates:

Mary Gross (FDA)
Kristin Hellquist (NCSBN)
Shawn Becker (USP)

Organizations/Members not represented:

AHA	ASHP
APhA	HDMA
ASCP	Deborah Nadzam

Observers:

Marcus LaChapelle (U of MD School of Pharmacy)
Linda Kim (FDA)
Susan Camp (USP)
Rick Schnatz (USP)
Shruti Shah (USP Summer Intern)

Linda Hanold (JCAHO), Chair, welcomed Council members and guests and called the meeting to order at 1:50 p.m. Introductions were made of new members and alternates. Ms. Hanold thanked the Council for its hard work in preparing for the 10th Anniversary publication and the planning for the Drug Suffixes Conference. She proposed requesting from Kasey Thompson (ASHP) a complimentary space at the ASHP 2005 Clinical Midyear Meeting that would promote the Council's mission, purpose, and products as part of the 10th anniversary celebration. Margaret Hogan (NPSF) indicated that the Council would be welcome to exhibit at the NPSF annual meeting and would only need booth coverage for during lunch and breaks. She indicated that a computer could be set up linking to the NCC MERP web site and Council documents could be copied to a CD ROM for presentation also.

Action Item: Linda Hanold will follow up with Kasey Thompson regarding a complimentary NCC MERP space at the 2005 Clinical Midyear Meeting in Las Vegas, NV and with Margaret Hogan on the NPSF meeting in May 2006, San Francisco, CA.

The next order of business was to establish a cancellation procedure for inclement weather conditions. Proposals were made to establish a procedure so that no confusion would occur due to bad weather including: (1) a calling tree with a target notification time of the evening before a meeting; (2) a phone recording; (3) e-mails; (4) refraining from holding meetings December-February; and (5) holding winter meetings outside the Washington, D.C. area. Diane Cousins reminded the Council that USP does not make the decision to close the building or remain open until 6:30 a.m. on the day of a meeting and a recording is put on the main phone at that time. Unfortunately, that may be too late for members who are traveling from out of town. Members were asked to provide cell phone numbers so that they could be contacted expeditiously.

Action Item: Linda Hanold will develop a meeting cancellation policy that includes specified timelines and a calling tree for review and approval at the October Council meeting.

The Chair noted that she had received solicitations from several companies wishing to make presentations to the Council and that she has created a list of these companies and their products. Anyone interested in more information should contact the Chair. If there are products that would be advantageous for Council review, the Council will initiate an offer to the company for a presentation.

Action Item: Linda will notify those companies soliciting presentations to the Council that their offers cannot be accommodated at this time but will be kept on file for future reference.

On behalf of the Council, Linda Hanold presented a floral arrangement to Diane Cousins (USP) in recognition of winning APhA's Pinnacle Award for lifetime achievement for her contribution to the improvement of product quality and the prevention of medication errors.

Secretary's Report: *Diane Cousins (USP)*
Diane Cousins announced the results of the Council elections for Chair and Vice Chair for 2005-2006. Linda Hanold was re-elected as Chair and Carla Saxton (ASCP) was elected as Vice Chair.

A letter was sent to UHC stating that the Category Index is the Council's intellectual property and therefore should be provided with appropriate attribution. Linda Hanold received a call from Scott Stanley (UHC) indicating that attribution will be added as requested.

Action Item: Linda Hanold will contact UHC requesting written confirmation that an attribution statement will be added and that a hard copy of the attribution verbiage be forwarded to the Council.

***Subcommittee Reports**:*

- **Taxonomy**— *Rita Munley Gallagher (ANA), Co-chair*

The Council agreed with comments submitted by Joe Cranston and Ray Bullman for the Taxonomy Use document. The title was changed to reflect "requirements", not principles. It was moved, and unanimously carried to accept the document and tool with the approved changes. A version that incorporates Council input will be forwarded to the Council for information only.

ACTION ITEMS:
Rita Munley Gallagher will incorporate the Council's input to the requirements document and tool and forward them to Diane Cousins for posting on the NCC MERP web site.

Ellen Quinn's follow up on the use of the Taxonomy with Stars and RiskMaster was postponed until the October meeting.

A poster on the findings and accuracy of the reliability of the NCC MERP Index for Categorizing Medication Errors by the Ohio State University was presented at the recent National Patient Safety Foundation meeting. Recommendations resulting from the study included: (1) examining those error categories that had lower levels of agreement, particularly Category E; (2) determining whether the lower Kappa statistics were due to ambiguity between some of the Index categories; and (3) modifying the Index to remove cost factors and focus on harm factors. This study was referred to the Taxonomy Subcommittee to explore how these findings affect the current Category Index, if there are ways to improve the reliability of the Index, or whether the Council is satisfied with the index as adopted. It was suggested that a study with non-MEDMARX facilities be conducted using the same criteria as in the OSU study. Rita Munley Gallagher (ANA) suggested that this be an on-going student project under the aegis of a Council member. Questions concerning how this would fit into a 5-year strategic plan and whether metrics and constant enhancements are necessary and/or desirable were referred to the Taxonomy Subcommittee for further consideration.

Action Item: The Taxonomy Subcommittee will review the recommendations of the Ohio State University study and devise a strategy for approaching the issue that would include non-MEDMARX users.

- **Practice Related Issues**

Recommendations
The revised recommendations to reduce errors in relation to (1) Accuracy of prescription writing, (2) Assuring accuracy of dispensing medications, and (3) Administration of drugs were all approved on the basis of written ballots. Member organizations can now disseminate these revised recommendations to their membership.

Action Item: USP will disseminate the final version of the recommendations to all Council members and will post the revised recommendations on the NCC MERP web site.

Action Item: Linda Hanold will bring the revised recommendations to the attention of JCAHO's "Benchmark" journal to explore the possibility of doing an article on these revisions.

At-Risk Behaviors – *Matthew Grissinger (ISMP)*
In August 2003, random reports from the USP/ISMP Medication Errors Reporting database were evaluated by members of the Council to assess the extent of shortcuts and those work-around behaviors condoned even though they are known to be risky. The investigation identified 10-12 behaviors that coalesced around the following areas: lack of double checks, intimidation, verbal orders not being read back, lack of knowledge, and multiple priorities. Next steps were proposed and include: (1) creation of a Council position identifying organizational at-risk behaviors with analysis of why people continue such behaviors, (2) development of Council recommendations regarding at-risk behaviors, (3) addition of at-risk behaviors to the Taxonomy, and (4)develop an article or statement about at-risk behaviors on the NCC MERP web site. Margaret Hogan (NPSF) suggested the *Journal of Patient Safety* as another possible vehicle for this type article.

Action Item: Matt Grissinger (ISMP), Rita Munley Gallagher (ANA), and Veronika Oven (AONE) will draft an article on at-risk behaviors to be reviewed at the October meeting. The article will take an organizational approach toward condoned at-risk behaviors and include discussion of the most frequent behaviors and suggestions to obviate such behaviors.

Action Item: Matt Grissinger (ISMP) will follow up with John Combes to establish the possibilities of a continued relationship with David Marx in an effort to undertake a collaborative project on risk modeling and associated predictive capabilities.

Sample Medications – *Diane Cousins, (USP)*
Errors resulting from the use of sample medications arise from a variety of situations: manufacturers' labels are designed for physician use, not patient use; storage issues; expired drugs; etc. However, patients favor sample medications to save money and to try new drugs to see if they are effective before investing in a full prescription. Although drug manufacturers have programs to assist indigent patients, it is not all-inclusive; and the AMA is opposed to eradicating the sample program because without it some patients may not have access to any medications. Suggestions to rectify the problem have included offering rebates, labeling that is clearly understood by patients, and bar coding. There is currently in use a software program that tracks inventory control by salespersons, but it is not universally used. This issue may be an opportunity for the Council to identify both the risks involved with sample medication use and the roles of manufacturers and physicians in the sample drug distribution process. Further exploration of how to approach the issue is needed.

Action Item: Diane Cousins, Dave Kotzin, Linda Hanold, and Mary Gross will begin to develop a set of recommendations regarding the use of sample medications. This effort will include an issue statement, including the Council's position, benefits of samples, the consumer role, and supporting data.

Action Items: Mary Gross will research FDA regulations regarding drug samples and forward information to Diane Cousins. Joseph Cranston will contact the Federation of State

Medical Boards (FSMB) for any regulations it has regarding drug samples and forward the information to Diane Cousins, and Eleni Anagnostiadis will contact the Boards of Pharmacy regarding any regulations about drug samples and forward the information to Diane Cousins.

- **Technology –** *Matt Grissinger (ISMP)*

Tubing Interchangeability

As of its January 22 meeting the American Association of Medical Informatics (AAMI) has been looking into the issue of tubing interchangeability and would appreciate the support of the Council in identifying the most serious issues and the potential for errors that would assist its activities in developing national standards for IV connectors.

Action Item: Matt Grissinger will contact AAMI for an update of its current position and then will work with Linda Hanold to draft a letter from the Council to AAMI to ascertain if there is a role for the Council in AAMI's development of national standards for IV connectors.

The meeting was adjourned at 5 p.m.

June 3, 2005

Council Delegates Present:

Linda Hanold, Chair
Joe Cranston, Vice Chair
Diane Cousins, Secretary
Lee Rucker (AARP)
Janet Myder (AHCA)
Rita Munley Gallagher (ANA)
Bill Ellis (APhA)
Kasey Thompson (ASHP)
Ron Nosek (DoD)
Sal Peritore (GPhA)
Matt Grissinger (ISMP)
Eleni Anagnostiadis (NABP)
Polly Johnson (NCSBN)
Ray Bullman (NCPIE)
Jeff Ramirez (VA)
David Kotzin
Mick Murray (Chair, USP Safe Medication Use Expert Committee)

Alternates attending as representatives of their organizations:

Mary Gross (FDA)
Margaret Hogan (NPSF)
Rosemary Cook (PhRMA)

Alternates attending with their delegates:

Shawn Becker (USP)

Organizations/Members not represented:

AONE
ASHRM
ASCP
HDMA
Deborah Nadzam

Observers:

Linda Kim (FDA)
Susan Camp (USP)
Elizabeth Cowley (USP)
Shruti Shah (USP Summer Intern)
Rick Schnatz (USP)
Sue Zmuda (USP)

The Chair resumed the meeting at 8:44 a.m. with discussion of the 10-year Anniversary Report. It was agreed to expand the title of the report to include recommendations. There are still some outstanding sections that should be forwarded to Deborah Nadzam for finalization as soon as possible. Member organizations should expand on their reasons for maintaining membership on the Council and the impact of the Council's work on these organizations. The Council concurred that an Executive Summary should be an integral part of the report and could also be included as part of a fact sheet to be developed by the PME subcommittee. It was suggested that a modified version of the report be prepared for national attention in consumer journals, such as the New Yorker. Other discussion was deferred until the Chair of the PME Subcommittee was available.

Action Item: Member organizations will forward all outstanding information for the 10 Year Report to Deborah Nadzam as soon as possible.

Review Process for Council Recommendations and Products – Joseph Cranston (AMA)

The Recommendation and Product Review Process should be framed as an on-going update of strategic plan deliverables to assure applicability. The Category Index and the Taxonomy are under continuous review by the Taxonomy Subcommittee and should not be considered as part of this process. The Council's definition of a medication error, although 10 years old, should not be modified, as it has been accepted by national organizations, such as CMS and FDA. A timetable was proposed that would result in all recommendations being reviewed and/or in the process of up-dating by mid-2006. The Council unanimously accepted Dr. Cranston's process suggestions to maintain the integrity of recommendations and other Council products.

Action Items: The Secretariat will incorporate the Council-approved process for routine recommendation and product review into official Council policies and procedures. In addition, the Secretariat will track review dates and recommend subsequent reviews every two years or sooner, if needed.
Joe Cranston, Sal Peritore, Rosemary Cook, Jeff Ramirez, and Carol Holquist will review the bar coding recommendations and the four sets of recommendations related to reducing errors due to packaging and labeling and report suggested revisions to the Council by the October 2005 meeting.
Matt Grissinger and Mick Murray will review the NCC MERP statement on medication error rates to ensure that it is in accord with current Medicare Part D wording and bring any suggested revisions before the Council at the October 2005 meeting.
Ray Bullman, Lee Rucker, and Margaret Hogan will review the NCC MERP web site for additions or deletions of links to other websites and an upgrade of consumer and Council information as appropriate. Suggested revisions will be reported at the October 2005 meeting.
Matt Grissinger will review the recommendations to reduce medication errors associated with verbal orders and report suggested revisions to the Council no later than the February 2006 meeting.
Polly Johnson and Ray Bullman will review the recommendations to reduce medication errors in non-healthcare settings and report suggested revisions to the Council no later than the February 2006 meeting.

Drug Suffix Conference

Location
Linda Hanold has tentatively booked JCAHO headquarters for mid-October. PhRMA's board room is available but can accommodate only 70 people. FDA expressed concerns about the appropriateness of industry hosting this event. Rosemary Cook stated that the offer was made in good faith by PhRMA, a founding member of the Council. DoD does have space but getting security clearances for everyone would be of extremely difficult.

Action Items: Mary Ann Hilliard (ASHRM) will explore the availability of meeting space at Children's Hospital for the conference. David Kotzin and Eleni Anagnostiadis will finalize the list of potential meeting locations and forward to the Council for review and approval.

Issue Statement

A question was raised as to whether or not the issue statement fully describes the magnitude of the problem of drug suffixes. It was suggested that the issue paper open with the explanation that USP and FDA are showing medication error trends and follow with the need for standardization as part of the rationale for the conference. A list of drugs involved in errors should be attached. It should be noted that the identification of drugs may not be inclusive of all drugs. If generic drugs are to be included, the title of the conference should be expanded. The issue statement should have consistent use of the word "suffixes" and not refer to modifiers or prefixes.

Action Items: Matt Grissinger will finalize the drug list (Attachment A) and forward to Mary Gross for inclusion as part of the issue statement.
By June 10, 2005, Mary Gross and Carol Holquist will revise the issue statement to incorporate the Council's input. It will then be sent to the Subcommittee and the Council for final review.

Agenda

The proposed draft agenda and the issue statement will be sent out to solicit funding. The fourth objective listed on the draft agenda– devising a strategy to disseminate proposed recommendations – was deleted as being beyond the scope of a one-day meeting. The main goals of the conference are to frame and debate the issue. There was much discussion as to which perspectives should be represented and the amount of time that should be apportioned for each. A 10-minute speaking timeframe would not allow for any depth of topic so it was agreed that speakers could provide additional information through handouts, cds, etc. Evaluation sheets should be included in meeting materials to determine if the conference goals were met or not. Dissemination of conference materials and recommendations/conclusions can be posted of the NCC MERP web site.

Action Item: Linda Hanold and Mary Gross will make suggested changes to the agenda and then forwarded to the Council for final review and approval.

Breakout Sessions

Breakout sessions should be homogeneous and the technology session (Session D) should be integrated into discussions in all sessions. Some questions should be pulled out of the breakouts and included as part of the speakers' invitation letters to focus the debate.

Action Item: Rosemary Cook and Sal Peritore will revise the breakout sessions questions per the Council's input and distribute to the full Council for final review and approval.

Budget

The Council reviewed the proposed conference budget, including in-kind contributions. The Chair reported the following results of funding solicitations: Robert Wood Johnson – no support, NPC – no promises but $1500 may be possible, APhA and ASHP will provide some support through their foundations. ISMP has graciously offered $2000. Eleni Anagnostiadis (NABP) knows someone at Glaxo that can be contacted. If not enough funding is raised, options include charging a registration fee and lunch.

Action Items: Linda Hanold will follow-up with Bill Ellis (APhA) and Kasey Thompson (ASHP) to fund a portion of the drug suffixes conference.

Eleni Anagnostiadis will explore contact with Glaxo for funding support.
Linda Hanold and Mary Gross will finalize the budget and distribute to the Council for information use only.

Speakers
It was suggested that speakers and participants could include, specific members from AAFP, AHRQ, NQF, IOM, USAN, HL7, etc. Once the list is approved invitation letters will be finalized.

Action Items: Matt Grissinger and Ron Nosek will finalize the list of speakers and invited participants per the Council's input and distribute for review and approval.
Shawn Becker and Marilyn Storch will take final list of speakers and invitees and personalize invitation letters.

Other Business
The meeting summary for the February meeting will be changed to reflect that Day 1 was cancelled due to the snow storm. Absences will be excused due to weather. It was moved, seconded and carried to accept the meeting summary of February 2005, as revised.

Linda Kim (FDA) distributed a spreadsheet of MedDRA-requested definitions and asked for Council comments. FDA has four weeks to determine final definitions and asked that Council comments be forwarded by June 24 to Linda Hanold, who will facilitate and forward to FDA by June 30.

Action Item: Council members will forward comments regarding MedDRA-requested definitions to Linda Hanold, who will consolidate and return to FDA by June 30.

Diane Cousins (USP) provided an historical perspective on the Council's 2-day meeting schedule. The summer meeting was originally scheduled to coincide with the founding of the Council; but with many people taking vacations in July, the meeting was moved to June. The spring and fall meetings were distributed throughout the year, taking into account weather and members' schedules. Travelers preferred being able to leave early on the second day to avoid traffic. A motion to test a one full-day meeting model was rejected by the Council.

Janet Myder offered AHCA's facilities for the October meeting if it were to be held in conjunction with the drug suffixes conference.

AHA has not designated a new Delegate or Alternate to the Council since John Combes resigned. The Secretariat will follow-up with AHA to obtain a new delegate.

Action Item: The Secretariat will contact AHA, requesting a new Delegate and Alternate be named to the Council.

Roundtable Updates:

- **ISMP** (Matthew Grissinger) – Mike Cohen and Judy Smetzer are currently updating the Medication Errors book. ISMP is holding a CPOE web cast.

- **SMU EC** (Mick Murray) – First meeting will be held on June 28-29, 2005. New committee has been formed with 18 health professionals. Ron Nosek and Matt Grissinger were elected as members for the 2005-2010 cycle. It is hoped that the work of the Committee will integrate with the NCC MERP's work and create significant impact.
- **VA** (Jeff Ramirez) – Bar coding has been a major project for the VA facilities. We have 36,000 beds using bar coding technology. We are printing and verifying bar codes but feel that minimum standards are not being met. Quality leads to variability. Wristbands have been an issue so VA is publishing standards for packaging and for wristbands. VA is also publishing an article on its experience with CPOE from its 2000 data where transcription errors were practically eliminated.
- **APhA** (Bill Ellis) – National Pharmacy Benchmarking may not necessarily be a safety issue but it may come out. As mentioned by Linda Hanold, Diane Cousins was a recipient of the Pinnacle Award this year. Pearls from the Pinnacle awards will be available in the fall 2005. Bill Ellis commented on the progress being made by the NCC MERP since its inception in1995. He was privileged to be the first Chair which he held for two consecutive years and was able to watch the growth of the Council. Bill is very encouraged with this growth and sees the willingness of the Council to explore new issues. Bill announced that this would be his last meeting with the Council as the delegate from APhA. Anne Burns will be taking his place as the delegate. Bill encouraged the group to not lose site of the Council's culture. Linda Hanold thanked Bill for his leadership and commitment to the Council. She also thanked the entire membership for the time and effort expended. She commented that if you looked at the amount of time each delegate expends in the activities of the Council it would amount to 315 equivalent Full Time days and 2500 hours in work effort. This is truly commendable.
- **ANA** (Rita Munley Gallagher) – ANA is involved in testimony for the Institute of Medicine where they used MEDMARX data and this was very much appreciated. Staffing issues are still being addressed on Capitol Hill.
- **AHCA** (Janet Myder) – CMS is revising surveyor advisement and focusing on Medical Director activity, unnecessary drugs, and pharmacy services. AHCA submits comments and works on these panels. Medicare Modernization Act has kept the AHCA very busy on keep constituents informed. Currently working on HL7, electronic health records, and e-prescribing by identifying gaps where long term care is excluded. Also working with CDC on vaccinations of influenza "Nick the Flu" collaboration.
- **NABP** (Eleni Anagnostiadis) – Working on task force on medication error reduction in community pharmacy and on counterfeiting issues.
- **GPhA** (Sal Peritore) – Nothing to report.
- **NCSBN** (Polly Johnson) – Working on utilization of unlicensed personnel and medication orders. One subcommittee is dealing with regulation of assisted personnel-root cause analysis of errors, and English proficiency for foreign nurses.
- **AARP** (Lee Rucker) – Launching on-line "Medicines and You." Suggestions for how to prepare for physicians visits, tutorial for seeking information. Will be looking at issues of samples. This web site should be added to NCC MERP web site and promote sign-up.

- **ASHP** (Kasey Thompson) – Looking into price gouging on vaccines. Currently working with the safe use of insulin (Diane Cousins, Allen Vaida, and Tim Lesar are also collaborating on this project). Assisting members with designing processes for JCAHO medication reconciliation. Minimum standards still need to apply to small rural hospitals.
- **PhRMA** (Rosemary Cook) – The PhRMA Paperless Task Force completed its Large Scale Field Trial (LSFT) with more than 170 pharmacies participating. The Task Force concluded that the LSFT had effectively demonstrated that the electronic delivery of package inserts for marketed non-emergency drug products could provide an alternative to the traditional paper mechanism for obtaining prescribing information. A formal summary will be available soon. Billy Tauzin is the new President and CEO of PhRMA. Mr. Tauzin is a cancer survivor and has directed that PhRMA be patient-focused. Detailed information about a rolled-out patient assistance program is available at ***www.phrma.org***.
- **FDA** (Mary Gross for Carol Holquist) – Guidance on risk management on FDA homepage. Drug Safety oversight board emerging.
- **AMA (**Joe Cranston) – AMA is partnering with the Institute for Healthcare Improvement on a campaign to prevent common in-hospital errors. AMA testified on color coding at FDA hearing in March. The AMA Annual meeting will be held in 2 weeks where a resolution on drugs will be considered (direct to consumer advertising, dietary supplements, patient information, internet sales, SSRI's, and suicidal ideation.
- **USP** (Diane Cousins) – Continuing concern of patient safety legislation. Supporting coalition letter to Congress urging passage of patient safety bill.
- **JCAHO** (Linda Hanold) – JCAHO has a new International patient safety center ***www.jcipatientsafety.org***

Council reviewed the action items resulting from the meeting and the key message is that work of the Council is moving forward.

The meeting adjourned at 2:10 PM.