

October 27, 2005

Council delegates present:

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|--------------------------------|------------------------|
| Linda Hanold (JCAHO), Chair | Ellen Quinn (ASHRM) |
| Diane Cousins (USP), Secretary | Sal Peritore (GPhA) |
| Lee Rucker (AARP) | Matt Grissinger (ISMP) |
| Joseph Cranston (AMA) | Polly Johnson (NCSBN) |
| Rita Munley Gallagher (ANA) | Ray Bullman (NCPIE) |
| Carla Saxton (ASCP) | Deborah Nadzam |

Alternates attending as representatives of their organizations:

Marcie Bough (APhA)
Mary Gross (FDA)
Jon May (NABP)
Rosemary Cook (PhRMA)

Alternates attending with their delegates:

Shawn Becker (USP)

Organizations/Members not represented:

| | |
|--|--------------|
| AHA | HDMA |
| AHCA | NPSF |
| ASHP | VA |
| DoD | David Kotzin |
| Michael Murray (Chair, USP Safe Medication Use Expert Committee) | |

Observers:

Carol Stocks (AHRQ, HCUP)
Scott Dallas (FDA)
Jill Garlich (APhA Student)

The Chair, Linda Hanold, welcomed Council members, alternates, and guests and called the meeting to order at 1:47 p.m. Introductions were made for all observers. The vote to approve the summary of the June meeting was deferred to Day 2 to allow review by the members.

Chair's Report

1. Ms. Hanold reported that plans for a complimentary booth at the ASHP MidYear Clinical Meeting are proceeding and verification should be received shortly. Coverage will be needed at appropriate times and several members indicated that they are planning to attend the meeting and would share that responsibility. Materials that will be on display include advance copies of the 10-Year Anniversary Report and Executive Summary, the Category Index and Algorithm, the Taxonomy, and NCC MERP Recommendations. Rita Munley Gallagher and Deborah Nadzam volunteered to assist Linda Hanold in producing the backboards for the exhibit. Any further suggestions for the booth should be forwarded to the Chair.

Action Item: Rita Munley Gallagher and Deborah Nadzam will assist Linda Hanold in producing backboards for the NCC MERP booth at the ASHP MidYear Clinical Meeting.

2. The discussions regarding the meeting cancellation notification and calling tree procedures were postponed and will be addressed via e-mail.

Action Item: Linda Hanold will finalize the meeting notification and calling tree procedures and e-mail them to the Council.

3. Subcommittee assignments were deferred to Day 2.
4. The Chair announced that the updated recommendations have been posted to the Council's web site.

Secretary's Report

1. Diane Cousins circulated a letter from the American Organizations of Nurse Executives declining to continue membership on the Council.
2. Despite previous attempts to contact AHA regarding representation on the Council, no response has been forthcoming. Ms. Cousins will contact Don Neilsen, SVP, directly.
3. George Van Komen, a member of the Federation of State Medical Boards and a participant in the Council's Suffix Roundtable in October, contacted the leaders of the Federation to encourage membership on the Council.

Action Item: The Secretary will contact Don Nielsen regarding the appointment of an AHA delegate to the Council.

Action Item: The Secretary will forward an invitation to apply for Council membership to the Federation of State Medical Boards.

Membership

Deborah Nadzam requested that her individual membership on the Council be renewed. Her membership renewal was unanimously approved for a 2-year extension.

Patient Safety Activity on Capitol Hill – Carla Saxton (ASCP)

Ms. Saxton reported on the passage of the Patient Safety and Quality Improvement Act of 2005, emphasizing that the bill protects information, not people. Ellen Quinn inquired whether the Council could become a PSO. Ms. Cousins explained the three aspects necessary for a PSO – collecting and analyzing data, and disseminating information – noting they were not within the purview of the Council. AHRQ will issue specific criteria for PSOs and then it will be up to organizations to apply for certification. AHRQ has much to do before the criteria can be released – preparing an inventory of existing systems to create a taxonomy and then issuing a RFI to the public. AHRQ is aware of the NCC MERP taxonomy so there is nothing for the Council to do at this time. It is expected that the criteria will not be issued before spring/summer of 2006. Jennifer Devine (USP) explained that certification will result from a review process by DHHS of how organizations meet the specified criteria. DHHS will then publish a list of certified bodies.

Subcommittee Reports:

➤ **Promoting, Monitoring & Evaluating Taxonomy — Deborah Nadzam**

The Vision Statement and Purpose were deferred for discussion under Strategic Planning on Day 2. Suggestions were made to improve the 10-Year Anniversary Report with emphasis on the Council's

willingness to address controversial issues and convene stakeholders to raise awareness of those issues. The Executive Summary will be available to everyone on-line. It was proposed that the PR group work with member organizations on how to promote the report in newsletters and web sites.

Action Item: Deborah Nadzam and Mary Gross will incorporate the suggested changes into the report and send it out for Council review.

Action Item: Deborah Nadzam will forward the new version of the report to Sherrie Borden (USP), who will convene the PR group to discuss promotional strategies.

➤ *Taxonomy –Rita Munley Gallagher and Ellen Quinn, Co-chairs*

Ms. Quinn reported on the use of the Council's Taxonomy by Stars and Riskmaster. Both provide customers with mapped fields, using the Council's Taxonomy without permission if the customer requests it. The Council's Taxonomy is available through the website so it is out there for anyone to use without the permission or knowledge of the Council. As far as can be determined, no organization uses the Taxonomy in its entirety, partly because it is not user-friendly. Riskmaster currently has an interface with the MEDMARX taxonomy. The Chair questioned whether the Council has approached the point where the Taxonomy should be updated. Rita Gallagher recommended waiting until the NQF taxonomy is finalized. The discussion to update the Taxonomy was tabled until the February meeting at which time the possibility of adding risk behaviors will be addressed.

Action Item: The Taxonomy Subcommittee will start development of a plan for updating the Taxonomy should the Council determine that the NQF taxonomy is insufficient for its purposes.

Polly Johnson reported how NCSBN has been trying to determine what contributes to practice breakdowns and developing its TERCAP program as a data collection instrument to study the experiences of nurses involved in practice breakdown by (1) addressing demographics and contributions to practice breakdowns, (2) tracking outcomes of involved patients and nurses, and (3) identifying eight major practice categories where errors can occur. NCSBN asked and received permission to incorporate the Taxonomy as the resource for the medication administration category. Several additions were made under the Personnel Involved element and the Causes element to further differentiate roles and actions. Outcomes from analyzing data have resulted in multiple versions of TERCAP, with the elements related to causes of error identified as most useful. The patient harm index has been kept intact and is recognized as one of the best portions of the instrument.

Council Recommendations

Lee Rucker and members of the consumer subcommittee reviewed the consumer section of the Council web site and presented the Council with the following observations and recommendations:

1. The recommendations are extremely technical and not user friendly.
2. The Council may want to make recommendations specific to consumers, such as maintaining a list of medications.
3. Emphasis should be placed on the preventability of adverse drug events with patients and caregivers acknowledging their role as members of the healthcare team.
4. Several members' web site links should be to their home pages, rather than to inside pages.
5. Several new web sites should be added.
6. The removal of "The" before each the member listing.

Action Item: Ms. Rucker will make the suggested changes for Council review before the Secretariat posts to the Consumer web page.

Matt Grissinger reviewed the Council's statement on medication error rates and reported that it is accurate as it stands and needs no revisions at this time.

The meeting adjourned at 4:52 p.m.

National Coordinating Council for Medication Error Reporting and Prevention

October 28, 2005

Council Delegates Present:

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|---------------------------------|------------------------|
| Linda Hanold, Chair (JCAHO) | Kasey Thompson (ASHP) |
| Carla Saxton, Vice Chair (ASCP) | Sal Peritore (GPhA) |
| Diane Cousins, Secretary (USP) | Matt Grissinger (ISMP) |
| Lee Rucker (AARP) | Jon May (NABP) |
| Joe Cranston (AMA) | Polly Johnson (NCSBN) |
| Rita Munley Gallagher (ANA) | Ray Bullman (NCPIE) |
| Marcie Bough (APhA) | Lynn Sanders (VA) |
| Ellen Quinn (ASHRM) | |

Alternates attending as representatives of their organizations:

Mary Gross (FDA)
Rosemary Cook (PhRMA)

Alternates attending with their delegates:

Shawn Becker (USP)

Organizations/Members not represented:

| | |
|--|----------------|
| AHA | HDMA |
| AHCA | NPSF |
| DoD | David Kotzin |
| | Deborah Nadzam |
| Michael Murray (Chair, USP Safe Medication Use Expert Committee) | |

Observers:

Scott Dallas (FDA)

Ms. Hanold reconvened the meeting at 9:00 a.m. It was moved, seconded, and approved to accept the summary of the June 2005 meeting. Members were reminded to complete calendars to aid scheduling for the spring 2006 meeting. Ms. Hanold circulated the UHC attribution for use of the Council's Taxonomy.

Recommendation Revisions

Joe Cranston reported that his subcommittee which was charged with reviewing Council recommendations for packaging and labeling and bar coding has completed a first draft of revisions and a final report will be presented at the February 2006 meeting.

Drug Suffix Workshop

Members' comments indicated that the Workshop was a success. It was a perfect example of how the Council is able to gather disparate groups and vet issues that are controversial. Everyone had a voice and discussions did not center on whether or not suffixes should be used, but rather that this issue affects every aspect of medication usage. According to the attendees, even when discussions veered from the agenda, Ms. Cousins, who facilitated the discussions, was able to keep the momentum going and all objectives were still met. Having the various perspectives represented was helpful for many stakeholders. Ms. Hanold indicated that she is in the process of reconciling

expenses to the budget and will provide copies to members when it has been completed. Letters of thanks will be sent to funders and speakers.

Action Item: The Secretary will send letters of thanks and appreciation to the speakers and the funders of the Workshop.

Members who attended the Roundtable proposed the following activities to promote the goals of the conference:

- Publish a list of current suffixes and determine how to disseminate to widest audience
- Minimize the complexity of the medication use process by developing a guidance document for providers, organizations, patients, and industry outlining what can be done to alleviate the problem, e.g., hospitals should have P & T committees to address the problem through their formulary
- Develop educational programs for healthcare professionals and give CE credits
- Forward recommendations to FDA for regulation of suffixes
- Define a suffix
- Determine how many of the suffix-related problems are actually systems problems
- Create a general consensus that each suffix has only one meaning
- Develop a strategy to keep the total number of suffixes to a minimum
- Provide data to pharmaceutical companies to educate them about the extent of the problem
- Have PhRMA's guidelines on good naming practices distributed to its members, when completed, with endorsement from the Council
- Participate in a PhRMA conference – have USP incorporated into the program
- Have standardized format for renaming drugs using RxNorm terminology
- Have the NCC MERP create a glossary for consumer drug inserts
- Have USP standardize the meaning of suffixes, particularly those for extended release, and create naming terminology that will have meaning to clinicians
- Solicit comments on suffixes via NCC MERP web site

The VA is in the process of standardizing drug names within its systems but would prefer national standards on nomenclature. Ms. Cousins volunteered to bring the issue of broadening the terminology of “extended release” before one of USP’s Expert Committees with the goal of standardizing definitions and perhaps include dosing frequency on labels. There was general agreement about the need to work with industry on short and long term goals. The industry is willing to address the issues but wants the issues approached in a systematic way.

A follow-up subcommittee consisting of meeting attendees should work with Sherrie Borden regarding a press release for multiple audiences (providers, practitioners, health care systems, industry, IT and drug information vendors, regulators, standards-setters, and consumers) and develop a white paper, using the bar coding white paper as a template, that summarizes the meeting and the preliminary findings, followed by specific recommendations. It was suggested that a survey to quantify what is causing errors be taken either at the NCC MERP booth at the ASHP MCM or by utilizing Survey Monkey. A question was raised as to whether it would be more productive to have the survey embedded in a newsletter, such as ISMP’s. Conference presentations should be posted on the web site, along with a standardized definition of “suffix”.

Action Item: Sherrie Borden (USP) will develop a press release on the conference that can be posted on the NCC MERP Web site.

Action Item: Matt Grissinger, Deborah Nadzam, and Kasey Thompson volunteered to develop a survey to determine the scope of the suffix issue and what current programs exist.

Action Item: Linda Hanold, Joe Cranston, Carla Saxton, and Shawn Becker will draft a white paper for Council review at the February 2006 meeting.

Action Item: Deborah Nadzam, Kasey Thompson, Matt Grissinger, and Rosemary Cook will draft recommendations pertaining to drug suffix use for Council review at the February 2006 meeting.

Action Item: Diane Cousins will bring the issue of broadening the terminology for suffixes before one of USP's Expert Committees with the goal of standardizing definitions and dosing on labels.

Roundtable Updates:

- **NABP (Jon May)** – NABP is currently engaged in two major programs that are having a positive impact on patient safety. The first is the VIPPS program (Verified Internet Pharmacy Practice Sites) which was developed and implemented in 1999 to bring “law and order” to the Internet pharmacy arena. It is intended to help consumers make informed choices regarding their use of Internet pharmacies. The VIPPS seal attests that an Internet pharmacy is properly licensed with the appropriate State boards of pharmacy and has met a rigorous criteria review that considers patient confidentiality, security of prescriptions, a quality assurance program, and patient-pharmacist consultation. Consumers can access the VIPPS list via NABP’s web site at www.nabp.net. The second program is called VAWD (Verified Accredited Wholesale Distributors), a program that has garnered much support from State Boards of pharmacy and the Food and Drug Administration. All of these entities recognize the additional safety VAWD can provide to the country’s drug supply and, subsequently, the patient safety benefits. NABP launched the VAWD program on February 28, 2005, in order to better assist the boards of pharmacy and other State agencies regulating wholesale drug distribution by accrediting wholesale distributors in accordance with standards set forth in NABP’s “Model Rules for the Licensure of Wholesale Distributors”. Currently, two states have incorporated VAWD into their wholesale distributor legislation: Indiana now required all wholesale distributors to obtain VAWD accreditation in order to operate within the State; also, Oklahoma’s governor signed into law House bill 1347 and the Senate bill 640, both of which recognizes VAWD as an authorized outside agency for accrediting wholesale drug distributors and repackagers. Both VIPPS and VAWD are aimed at combating counterfeit, adulterated and misbranded drugs, all of which pose serious health problems for consumers. Information regarding the VAWD program or the model rule can be obtained via the web at custserv@nabp.net.
- **ISMP (Matt Grissinger)** – ISMP is working with Joint Commission Resources on a program that will examine medication management, including reconciliation processes, and features best practices to enhance medication safety. This conference will take place on November 14 at JCR headquarters. ISMP will be giving two exhibitor’s theaters at the ASHP MCM in Las Vegas – one will be devoted to safety issues associated with patient-controlled analgesia (PCA) and the other will explore the current trends in insulin therapy, barriers to optimal therapy and safety, and common types of errors that occur with insulin. Additionally, ISMP is updating the “Medication Errors” book for publication next spring, as well as its current web site which will be ready this fall. The

- anti-coagulant self-assessment is still available for organizations to use with a deadline for submission of March 2006. The John D. and Catherine T. MacArthur Foundation named Mike Cohen as one of 25 new MacArthur Fellows for 2005.
- **PhRMA (Rosemary Cook)** – PhRMA has redesigned its web site to be more patient/consumer friendly. A Spanish version of web site is also available. The new leadership at PhRMA (Bill Tauzin, President) is more patient-focused and has instituted an Office of Accountability. The PPA program, which assists low income seniors with drug purchases, has served its 1 millionth person. Rosemary Cook offered a speaker on the program for a future Council meeting.
 - **ANA (Rita Munley Gallagher)** – ANA continues its work as a strategic partner with the Institute for Healthcare Improvement (IHI) in the Saving 100,000 Lives Campaign, which is educating nurses and others on ways to enhance patient safety in the hospital setting. In adding a component on “Near Misses” to ANA’s Effecting Positive Change in Patient Safety/Advocacy initiative, ANA is working to quantify nurses’ interventions in preventing errors by capturing information about their knowledge regarding near misses. The “Near Misses” questionnaire, which can be submitted anonymously, may be found at <http://www.nursingworld.org/patientsafety/misses.htm>. Comments are typed directly by respondents into the form. Responses are then forwarded electronically to ANA staff. There is no automatic e-mail address included for the respondent. All e-mails processed through the web site are forwarded without identification to ANA staff members from the Webmaster@ana.org address. Respondents that do choose to include their names should be cautioned that ANA cannot guarantee continuing anonymity if records are subpoenaed. Over time, nurses’ confidential responses will be synthesized, aggregated, and posted on a *Nurses Share Their Stories* section on NursingWorld.org.
 - **NCPIE (Ray Bullman)** – As part of its Consumer Medication Initiative NCPIE is serving as a convener for stakeholders and the FDA to discuss medication guides. As part of its 20th annual prescription month, NCPIE has been asked to work with the FDA to teach Hispanic patients how to order medications online.
 - **NCSBN (Polly Johnson)** – NCSBN was directed by delegates at this year’s annual meeting to develop a medication aide training curriculum and competency test for state boards. This is in response to the increase in state legislation to allow the use of this level of care provider, especially in long term care settings. NCSBN continues to use its TERCAP tool in its Practice Breakdown Research Project. There are now 18 states participating in the Nurse Licensure Compact with at least three more states to implement in 2006. Official congratulations were offered to Kristin Hellquist in her absence.
 - **FDA (Mary Gross)** – Drug Watch, which is scheduled for publication in May, is open for comments for only a very short time. FDA has appointed a new director of the Office of Drug Safety, Steven K. Galson, M.D., M.P.H.
 - **APhA (Marcie Bough)** – APhA has been focused on implementation of Medicare Modernization Act drug therapies and the education of pharmacists through its medication therapy management service.
 - **AARP (Lee Rucker)** – AARP has been expanding its educational outreach for enrollment for Medicare Part D. There is a new program available online to teach people about the medication use system. The first consumer drug reference book, Medicines and You, is due out next year.

- **AMA (Joe Cranston)** – AMA continues to collaborate with the Institute for Healthcare Improvement (IHI) on its 1000,000 Lives campaign. It is also beginning to look at the issue of medicine reconciliation within hospitals and, eventually, will have a hospital-ambulatory interface. Detailed comments were provided to the IOM Committee studying drug safety for FDA and to FDA on its Drug Watch web site that is intended to provide information about emerging drug safety problems with drugs. Next week AMA will testify at FDA's Part 15 Hearing on direct-to-consumer advertising and in December will testify at FDA's Part 15 Hearing on risk communication. The AMA was pleased that federal safety legislation finally was passed into law. Some drug issues that will be taken up at the 2006 AMA Interim meeting in November include: Schedule II narcotics in nursing homes, coverage of benzodiazepines under Medicare Part D, methamphetamine abuse, and coverage of drugs for off-label uses.
- **ASHP (Kasey Thompson)** – Dr. Thompson and Dr. Henri Manasse's book, Improving Medication Safety, has been released and can be ordered from the ASHP web site. ASHP has developed a broad framework for measuring the quality of Medicare Part D, and is about to release guidelines on handling hazardous substances for health professionals. ASHP has issued a statement against tablet splitting if done solely for cost containment but realizes that tablet splitting is currently being done in pharmacies and by patients. The question is how to appropriately and effectively split tablets maintaining uniformity. Tablet splitting is an area of focus for USP's Safe Medication Use Expert Committee, so as liaison to that committee, Shawn Becker will assist Mr. Thompson in this area.
- **ASCP (Carla Saxton)** – ASCP's 36th Annual Meeting in Boston, November 9-12, 2005, will focus on formulary issues and electronic prescribing and health records.
- **USP (Diane Cousins)** – A recent issue of *The Journal of Patient Safety and Quality* featured the Council's definition of medication error at the beginning of its lead story. The MEDMARX[®] Annual Report, scheduled for release in December, concentrates on medication errors in radiological services and in ICUs. A major finding was that most errors occurred during hand-offs. A presentation will be made for the benefit of the Council at the February meeting. The Safe Medication Use Expert Committee established its short-and long-term goals at its October meeting. Among them were: label standardization; tall man lettering; issuing a list of standardized drug concentrations for use in critical care settings, and pediatrics; creating standards for rules and alerts in CPOE systems; developing and/or modifying standards for safe work environments; and analyzing medication error data for incidents linked to patient harm.

National Coordinating Council for Medication Error Reporting and Prevention

The current subcommittee assignments are as follows:

| Strategic Planning | Taxonomy | Promoting/ Monitoring/ Evaluating | Technology | Practice-Related Issues |
|--------------------|------------------------|---|-----------------|----------------------------|
| Linda Hanold | *Rita Munley Gallagher | *Deborah Nadzam | Joe Cranston | *Carla Saxton |
| Carla Saxton | *Ellen Quinn | Sal Peritore | Rosemary Cook | Polly Johnson |
| Diane Cousins | Carol Holquist | Anne Burns | Lee Rucker | Eleni Anagnostiadis |
| | Janet Myder | Ray Bullman | Dave Kotzin | Kasey Thompson |
| | Louise Kodela | Kristin Hellquist | Tracy Casteuble | Jeff Ramirez |
| | | | Matt Grissinger | Mick Murray |
| | | | Mike Datena | |

* Indicates current subcommittee chairs and subchairs

This is an opportunity for members to change subcommittees for the coming year. Anyone interested in doing so should e-mail Linda Hanold. An agenda item for the February meeting will be to reflect on the relevance of the subcommittees and whether they should be renamed, or refocused.

Vision Statement

It was moved, seconded, and passed unanimously to accept Suggestion 4 as the new vision statement for the Council. The new vision statement now reads, “No patient will be harmed by a medication error.”

The meeting was adjourned at 1:55 p.m.