

National Coordinating Council for Medication Error Reporting and Prevention

June 26-27, 2001

Day One

Council delegates present:

Jerry Phillips (FDA), Chairperson	Sal Peritore (GPhA)
John Combes (AHA), Vice Chair	Lisa Clowers (HMDA)
Diane Cousins (USP), Secretary	Jon May (NABP)
Janet Myder (AHCA)	Barbara Newman (NCSBN)
Joseph Cranston (AMA)	Lisa Hanlon Wilhelm (NPSF)
Tom Clark (ASCP)	Alan Goldhammer (PhRMA)
Monica Berry (ASHRM)	Jeff Ramirez (VA)
Kasey Thompson (ASHP)	Deborah Nadzam (Cleveland Clinic)
William B. Kelly – (ex officio) USP Safe Medication Use Expert Committee	

Alternates present:

Judy Smetzer (ISMP)

Alternates attending with their delegate:

Mary Gross (FDA)
Judy Milford (GPhA)
Shawn Becker (USP)

Delegates absent:

Andrew Smith (AARP)
Rita Munley Gallagher (ANA) (participated via teleconference)
William Ellis (APhA)
Michael Cohen (ISMP)
Linda Hanold (JCAHO)

Observers:

Veronika Oven (AHA)	Sherrie Borden (USP)	Kathy Muenchow (USP)
Keran Heuriksen (AHRQ)	Rita Calnan (USP)	Marilyn Storch (USP)
Marge Keyes (AHRQ)	Elizabeth Cowley (USP)	Sue Zmuda (USP)
Duane Sylvia (FDA)	Judy McMeekin (USP)	

Jerry Phillips called the meeting to order and asked everyone present to introduce him/herself and identify the organization for which he/she works.

Diane Cousins reported on the ballot results of three proposals that were before the Council:

- NCC MERP endorsement of the ISMP Medication Safety Self-Assessment for Community/Ambulatory Pharmacy – The endorsement was passed with 13 approvals, 1 disapproval (ASHRM), and 2 abstentions (AMA & PhRMA).
- Bar Coding White Paper – Responses to balloting to accept Draft 6 of the bar coding paper resulted in comments expressing concern with some definitions. The suggested changes included “unit-of-use”, “unit-of-use-level”, and “unit dose”. “Unit-of-use-level” was changed to “unit-of-use-package”. There was discussion on the terms “medication” and “pharmaceutical product”, their differences and the intent of the document. The Council chose to refrain from making the document sound too regulatory by using such strict terminology and decided to retain the word “medication”. Further discussion focused on the placement of footnotes and definitions of terms according to USP usage. The text was reworked and presented to the Council with a 48-hour deadline for any comments.
- Practitioner Accountability Workshop – The Council approved holding the workshop as an invitational program. It will be held Wednesday, October 10, at the National Press Club in downtown D.C. Invitations will be sent to the Boards of Medicine, Nursing, and Pharmacy, as well as to selected guests.

Current Activities

Written reports were distributed by the following organizations:

- **JCAHO**
- **PhRMA**

Verbal updates provided by:

- **AHA** (John Combes) -- The AHA has shifted its focus from medication safety initiatives to the promotion of a medication safety culture in its hospitals. Two self-assessments were undertaken – one using Baldrige criteria and the second was written with assistance of the Dana Farber Institute for COO’s on developing a personal commitment to patient safety. In Pennsylvania the Bayer Institute held a seminar on error reporting that concentrated on the culture of safety. It focused on methods of building relationships with patients and their families as a result of error disclosure.
- **PhRMA** (Alan Goldhammer) –As soon as the standard is available PhRMA will undertake to pilot Reduced Space Symbology (RSS) 14 with ophthalmic drug companies and hopes to publish a paper reporting its results. It is encouraging the delivery of label information electronically, rather than as a package inset. There are vendors in the Washington area that are interested in pursuing this as a pilot project. The industry would like to build a single labeling database using Adobe Acrobat that each vendor can adapt to individual pharmacies. The highest priority is the input of data for the top 200 prescription drugs, followed by all new drugs since 1999. PhRMA is also encouraging the submission of label information to HHS in electronic form.

- **Cleveland Clinic** (Deborah Nadzam) – The Cleveland Clinic recently held a conference on technology and safety issues. The topic of discussion was, “Is technology the solution for patient safety problems?”
- **ASHRM** (Monica Berry) – ASHRM has been working on a white paper dealing with the disclosure of medical errors. It had its first satellite videoconference during which questions were transmitted by telephone and e-mail. A tape of this conference will be available at a later date. ASHRM has also been working with the Center for Disease Control and Prevention in a study addressing nursing staffing levels in regard to infection control and has been asked to endorse a number of programs and projects, including AHRQ proposals. The annual ASHRM conference is scheduled for the end of October and includes a keynote address by Jim Conway of the Dana Farber Institute.
- **ASCP** (Tom Clark) – ASCP is in the process of applying for an AHRQ grant that would focus on improving drug therapy and reporting adverse drug events on geriatric patients in nursing homes. Glaxo/Smith/Kline has developed a program, “Ask the Pharmacist”, to provide resource material for this program, such as sample letters for when a problem has been identified and monthly toolkits. ASCP also has a new web site at www.scoop.net.
- **NPSF** (Lisa Hanlon Wilhelm) – Lisa reported that there were over 600 attendees at the Annenberg III Conference held in St Paul, Minnesota. Success of the last three conferences has led it to be established as an end of year annual conference with 2 days of clinical trials and 3 days of communications. “Think It Through”, a program developed for the public, stresses the fundamental concept that all life, including medications, involves both risks and benefits.
- **AHCA** (Janet Myder) – Nothing to report.
- **AMA** (Joseph Cranston) – The AMA has been involved in various projects relating to medication safety including a major health literacy initiative. The AMA continues to address concerns about dietary supplements, particularly performance enhancing supplements. The AMA was part of the NPSF group working on the “Think It Through” brochure and is now working with Intel and Verisign to produce digital signatures for physicians to facilitate the ordering of prescription drugs on-line.
- **HDMA** (Lisa Clowers) – HDMA Barcode Guidelines are being revised to reflect distribution at unit-of-use levels. There is concern about a shortage of flu vaccine and drug development and supply again this year. Some drugs are becoming less and less available.
- **Veterans Affairs** (Jeff Ramirez) – Bar coding is an integral part of their hospital procedure. They are developing a second version of bar coding that is being expanded to include parenterals. VA hospitals are working to define nursing functions and procedures for dealing with medication errors. They are creating training videos to improve the methodology for reporting adverse events and are moving toward a web-based design to enter reports directly to a patient’s record and then to the FDA.
- **USP Council of Experts Safe Medication Use Committee** (Bill Kelly) – The Safe Medication Use Expert Committee has struggled to define its role and has decided to focus on four new major areas: (1) MedMARx – review and analyze data and work to improve the system as a meaningful reporting and research tool; (2) medication errors - work to substantiate suppositions surrounding their causes and possible interventions; (3) computerized prescriber order entry and other technology relating

to safe medication use; and (4) geriatric populations – research errors in ambulatory settings. The Committee will also continue its work on (1) neuromuscular blocking agents –work with the Nomenclature and Labeling Expert Committee and the Pharmaceutical Waters Expert Committee to make recommendations addressing the medication difficulties with these drugs; (2) standardizing imprint codes; (3) pediatric and neo-natal medication – completing analysis and preparing a statement; and (4) researching evidence-based practices that reduce medication errors.

- **GPhA** (Sal Peritore) – Nothing to report.
- **NCSBN** (Barbara Newman) -- The NCSBN continues in its Commitment to Excellence project that encompasses practices, discipline, and rehabilitation in response to complaints sent to Boards of Nursing. The emphasis is on multiple boards working together to develop professional accountability using alternative models of discipline. The annual meeting on August 6-11, 2001, will focus on models of responsibility for nursing personnel and will have Tim Porter O’Grady as the keynote speaker.
- **NABP** (Jon May) – Copies of the recent recommendations on bar coding were sent to the main office to be distributed to all Boards of Pharmacy. As pharmacy compounding has become more popular, difficulties have been arising concerning the quality of bulk substances, with contamination becoming a major problem.
- **ASHP** (Kasey Thompson) – Kasey Thompson, as the new ASHP delegate, reported that ASHP has been working in conjunction with the AHA to create a web-based system of health briefs, each of which will be comprised of information on and recommendations for a specific safety issue. In March the ASHP began an initiative seeking to define the qualities necessary for a Medical Safety Officer, an official who would oversee all aspects of safety in a hospital setting. A study will be conducted to determine whether or not having a Medical Safety Officer affects patient safety. If the results of the study prove the efficacy of having such a position, a residency program for medication safety will be developed. ASHP is also working on a general document of principles of computerized prescriber order entry, available on their web site; a computer database for new and emerging drug shortages; and machine-readable coding on medications.
- **USP** (Diane Cousins) – USP has recently published updated poster and laminated cards that mirror *Quality Review No. 76* “Use Caution, Avoid Confusion” similar drug names as reported to the USP Medication Errors Reporting Program. Names new to the list are highlighted in red. Demand has been exceptionally high and several reprints have already been ordered. The USP Nomenclature and Labeling Committee and the USAN Council will be asked to respond to the Council’s call to action regarding the recently approved white paper on bar coding. The State of Oklahoma is the first to offer legal protection to persons reporting adverse medication and medical events to medical databases, which include MedMARx and the Medication Errors Reporting (MER) program.
- **JCAHO** (Linda Hanold) – As reported in the May, 2001, *Sentinel Event Alert* not enough is being done in institutional settings to deal with look-alike, sound-alike drugs. This is now being addressed and included in new JCAHO accreditation standards.
- **FDA** (Jerry Phillips) -- The Council was provided with an overview of Tommy Thompson’s presentation to Congress outlining the HHS Patient Safety Initiatives, including (1) facilitating medical/medication error data collection and analysis; (2)

developing the NEDSS data system by the CDC; (3) continuing funding for AHRQ, CMS, and FDA regulatory work regarding adverse events reporting systems and improvement of packaging and labeling standards; (4) collaborating with government partners to reduce the burden for reporting adverse events; and (5) affirming the critical need for confidentiality of all parties involved in the collection and analysis of error data and the elimination of liability for those reporting errors.

Presentation:

David Horowitz, Acting Director, FDA Office of Compliance, Center for Drug Evaluation and Research (CDER) – Medical Gas Mix-ups

The recent FDA Public Health Advisory on medical gas mix-ups focused on incidents of serious injury and death of patients due to a gas other than oxygen being attached to oxygen lines. In almost all cases a staff person was not properly trained and bypassed a connection safeguard and/or did not examine the labels carefully. To prevent further such errors, the Office of Compliance has initiated a new program to identify the problem to healthcare facilities and a new Medical Gas Mix-up Working Group has been established to publish guidance and recommendations to insure adequate safeguards. Some ideas being considered are (1) working with JCAHO and the Center for Medicare and Medicaid Services (CMS) to require the purchase of medical gases be from a JCAHO-accredited supplier; (2) the permanent welding of unique oxygen connection fittings so that fittings cannot be removed; (3) improved gas tank wrap-around labeling and/or additional color coding; and (4) separate medical grade gas storage areas. The FDA has already published some guidelines in newsletters and on several web sites and a Public Health Advisory will be sent out soon.

The Council discussed other possible interventions and recommendations including

- bar coding on medical gas containers
- color coding of medical gas containers
- pre-fill inspections of tanks
- supervision of staff making connections
- creating a Sentinel Event
- alert special interest groups like the American Association of Respiratory Therapists, the American Society of Anesthesiologists and the American Society of Healthcare Engineers to the problem
- add a hyperlink to the FDA to the NCC MERP web site

ACTION ITEM: All Council members will ask their organizations to put information about medical gas mix-ups on their respective organization's web sites to inform their membership of the potential for harm.

The meeting was adjourned at 4:45 p.m.

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Day Two

Council delegates present:

Jerry Phillips (FDA), Chairperson	Kasey Thompson (ASCP)
John Combes (AHA), Vice Chairperson	Salvatore Peritore (GPhA)
Diane Cousins (USP), Secretary	Lisa Clowers (HDMA)
Andrew Smith (AARP)	Jon May (NABP)
Janet Myder (AHCA)	Barbara Newman (NCSBN)
Joseph Cranston (AMA)	Jeff Ramirez (VA)
William Ellis (APhA)	Deborah Nadzam (Cleveland Clinic)
Tom Clark (ASCP)	
William Kelly, USP Safe Medication Use Expert Committee	

Alternates present:

Judy Smetzer (ISMP)

Alternates that attended with their delegates:

Mary Gross (FDA)
Judy Milford (GPhA)
Shawn Becker (USP)

Delegates absent:

Rita Munley Gallagher (ANA)
Monica Berry (ASHRM)
Michael Cohen (ISMP)
Linda Hanold (JCAHO)
Alan Goldhammer (PhRMA)

Observers present:

Kerm Henrikson (AHRQ)	Judy McMeekin (USP)
Marge Keyes (AHRQ)	Kathy Muenchow (USP)
Rita Calnan (USP)	Marilyn Storch (USP)
Elizabeth Cowley (USP)	Sue Zmuda (USP)

Jerry Phillips, Chairperson, called the meeting to order and introduced the guest speaker, Marge Keyes, Project Officer for AHRQ.

Presentation:

Marge Keyes, Project Officer for the Agency for Healthcare Research and Quality (AHRQ) – A Patient Safety Network: DHHS Patient Safety Task Force

Information about current patient safety projects, on-going research and analysis, best practices and other patient safety information can be found on the web at www.ahrq.gov. The Department of Health and Human Services' Patient Safety Task Force is setting up a pilot program, the Patient Safety Network, in conjunction with the FDA, CMS, and the CDC, is

Meeting Summary - Final

working to create a knowledge system that will accumulate, exchange, and integrate information and resources from private and public stakeholders to support local efforts to protect patients and promote safety. Four goals have been proposed for the Network: (1) improve safety by creating and disseminating knowledge necessary to detect and respond to current healthcare safety threats; (2) protect confidentiality; (3) reduce the reporting burden and ensure local access to healthcare safety information; and (4) monitor progress toward achieving local, state, and federal patient safety goals. The Patient Safety Network will be based on some basic concepts:

- It is essential to have a knowledge system for patient safety and this system should be accessible to state and local safety programs.
- The system will be of optimal use if it is integrated with other government data systems. This will decrease the burden of multiple reporting.
- The system should be modular so that it can evolve over time.

The proposed information content in the Patient Safety Network will span three focal points: (1) information on prevention, lessons learned, and best practices; (2) data on incident reports on adverse events or near misses; and (3) tracking trends, performance measures, and continuous improvement. A stakeholder meeting is being planned to discuss and specify the actual content of the collection modules. Computer network development has begun to implement the Safety Network. The Task Force will create a single portal for data entry to negate the need for multiple repositories and reporting forms. All data will be captured at one time and made readily available to all appropriate agencies. AHRQ will act as the portal for other agencies, since it has extraordinarily strong research protection. However, it will not become the central database for medication errors.

In the discussion that followed the presentation Council members discussed the issues of voluntary versus mandatory reporting. It was agreed that any medical or medication error that results in death should fall under mandatory reporting requirements. Quality and quantity of data were also concerns. Quality may be low if the system is only voluntary and both quality and quantity will be low if the system is not anonymous and protected. Questions of access and privacy still need to be more precisely defined.

Medication Error Rates Subcommittee Update

Shawn Becker

The first draft of “NCC MERP Recommendations for Medication Error Rates” defined the problems associated with error rates and offered recommendations for practices used in determining and interpreting medication error rates. Council members offered a number of comments on the draft, including the inclusion of more information from medical literature on how to calculate error rates. Cited literature should be summarized and incorporated into the document. It was stressed that there is a need to distinguish between inpatient and outpatient errors and between actual and potential errors. Although there are numerous difficulties in creating medication error rates, it is vital that everyone be using the same basis of information on a consistent basis and realize that the error rate is actually an error-reporting rate. Error-reporting rates can be used to track and trend flawed processes but cannot be used to determine an exact error rate. The Council is not advocating any particular method of calculating error rates.

ACTION ITEM: The draft will be taken back to the subcommittee to clear up the definitions of inpatient and outpatient, actual and potential medication errors and whether the medication errors did or did not reach the patient.

A question was raised as to whether or not the Council should have an educational role to teach facilities how to do active surveillance. It was suggested that the recommendations should include what to do after facilities have computed an error rate. Janet Myder will join the subcommittee in its redrafting efforts and Bill Ellis will aid in evaluating.

Practitioner Accountability Workshop Subcommittee

Jerry Phillips/Judy Smetzer

The invitational workshop will consist of four panels composed of representatives of accrediting and regulating bodies, healthcare organizations, professional societies, and healthcare practitioners. Lucian Leape will be the luncheon keynote speaker and will also moderate the wrap-up session. The 100 available spaces at the National Press Club will be apportioned thusly: 25 from each board (75), 1 from each member organization (22), speakers (10), plus 4 invited guests (AHRQ, CMS, NASL, and NASHB).

ACTION ITEM: Judy Smetzer will get information about Panel 3 to be included in the packet that will be sent out.

ACTION ITEM: Jerry Phillips will call National Academy of State Health Policy (NASHP) and National Association of State Legislators (NASL) to invite them to the workshop.

The Council declined to assess each member organization to defray the costs of the workshop. Bill Ellis indicated that the APhA Foundation would commit to a \$2500 donation and he would contact other education foundations to see if they would be interested in contributing. Barbara Newman, Lisa Wilhelm and several other delegates indicated that they may be able to contribute also. It was decided that the registration fee would be \$100 and would include lunch.

ACTION ITEM: Workshop organizers will look into the production of a low-cost videotape of the proceedings that could be sold to attendees.

Index for Categorizing Medication Errors/Algorithm

The Council approved the Categorization Index and Algorithm as presented. The Council also decided that there is a need to look at potential errors more closely. A working group was formed to do this.

ACTION ITEM: Jerry Phillips, Deb Nadzam and Bill Kelly will look at the taxonomy and report to the Council at the October meeting.

Automation in the Medication Use Process

Deb Nadzam

A large number of organizations have prepared or are currently working to produce guidelines and recommendations for the design, purchase and/or use Computerized Prescriber Order Entry systems (CPOE). Each group has worked on a paper addressing some aspect of the system. With so much attention focused on the issue, the question is what unique role can the Council have? It was suggested that instead of starting from scratch, the Council collate the information already available to create a catalog of resources. It was suggested that the Council post references and information on its web site. It could also create a readiness assessment of what precursors have to be in place before a CPOE system could be effective.

ACTION ITEM: Deb Nadzam will draft a list of current resources pertaining to CPOE and report to the Council at the next meeting.

ACTION ITEM: Jeff Ramirez, Kasey Thompson, Judy Smetzer, John Combes, and Bill Ellis will create a compendium of resources on computerized or computer-aided prescription and medication assistance.

Future Directions

Jerry Phillips recounted the history of the Council and the scope of work that the Council has accomplished. He also mentioned several areas that he thought were important enough for the Council to consider pursuing in the future:

- Taxonomy – The taxonomy has not been revised since its inception. If AHRQ is going to function as a collection and collating body, then they should be urged to adopt the taxonomy. The real work of dissemination and universal acceptance of the taxonomy may be through the National Quality Forum's consensus process and risk managers of healthcare institutions.

ACTION ITEM: Each member of the Council should provide his/her organization information about the taxonomy.

- Medication administration by non-licensed personnel – There are no uniform procedures and very little data in the training of non-licensed personnel who function as medication aides. The NCSBN has a study project underway and so far it is validating the considerable need for more research. Research and recommendations for the use and training of aides would be applicable for assisted living facilities, school health programs, facilities for persons with developmental disabilities, correctional institutions, behavioral health clinics, adult day services, schools, and child care centers. Once the issues have been defined, the Council can look into existing databases to find what programs already exist and what training programs can be identified.

ACTION ITEM: Tom Clark, Barbara Newman, and Janet Myder will form an initial working group that will hold a brainstorming session to further define the topic and make recommendations for a training curriculum to the Council at the next meeting.

- Fostering a culture of safety – Several suggestions were made on how front line practitioners can affect change: (1) creation of training curricula and tools; (2) development of a check-list for the progress of safety training; (3) making recommendations to chief executive officers and risk managers; (4) address personnel on the behavioral and social levels; and (5) education.

ACTION ITEM: Judy Smetzer will arrange a teleconference on how industry is relating to the culture of safety.

- Labeling – It may be time to update labeling guidelines and recommendations, dealing with the issue of pharmacy labels versus industry labels.
- Access and storage of medications – Special procedure areas of hospitals (emergency rooms, recovery rooms, radiology, cardiac cath units, etc.) have drugs that are readily accessible and, therefore, may not be stored properly. Should the Council attempt to provide answers to the following questions:
 1. What is appropriate floor stock?
 2. What levels of access are necessary?
 3. What is the turnaround time for receiving stock from the pharmacy?
 4. Is this a question of poor process design?

ACTION ITEM: Invite process experts from various facilities and health systems (PRHI, etc) to speak to the Council about how they handle this process.

The Practitioner Accountability Workshop is scheduled for Wednesday, October 10, 2001, at the National Press Club. The next meeting of the Council will be Thursday, October 11, 2001, at the AHCA offices at 12th and L Streets NW, Washington, D.C. Proposed agenda items include:

- Taxonomy Revision
- Medication error reporting rates
- New membership issues
- Next steps resulting from the accountability workshop

The meeting adjourned at 2:55 p.m.