<u>February 6-7, 2003</u> <u>Day One</u>

Council delegates present:

John Combes (AHA), Chairperson Linda Hanold (JCAHO), Vice Chair Diane Cousins (USP), Secretary Janet Myder (AHCA) Joseph Cranston (AMA) Rita Munley Gallagher (ANA) Karen Drenkard (AONE) William Ellis (APhA) Ellen Quinn (ASHRM) Kasey Thompson (ASHP) Jerry Phillips (FDA) Sal Peritore (GPhA) Judy Smetzer (ISMP) Jon May (NABP) Ray Bullman (NCPIE) Rebecca DeVivo (NPSF) Jeff Ramirez (VA) Deborah Nadzam (Cleveland Clinic) (by phone)

Alternates attending with their delegate: Mary Gross (FDA) Shawn Becker (USP)

Kristin Hellquist (NCSBN) attended representing NCSBN

Delegates absent:

Andrew Smith (AARP) Tom Clark (ASCP) William Davies (DoD) Lisa Clowers (HMDA) Debra Brady (NCSBN) Alan Goldhammer (PhRMA) Bill Kelly (ex officio) USP Safe Medication Use Expert Committee

Observers:

Michele Douglas (Med-Touch)John Santell (USP)Michael Gaunt (FDA student)Marilyn Storch (USP)Sherrie Borden (USP)Albert Kinley (Temple School of Pharmacy & ISMP student)

Linda Hanold, Vice Chair, called the meeting to order at 1:25 p.m. She welcomed everyone and introduced Ray Bullman, Vice President, NCPIE, as the newest member of the Council. Mr. Bullman provided an overview of NCPIE for the members. Ms. Hanold asked that observers introduce themselves.

Announcements from the Chair

John Combes, Chair, resumed his role and announced that the Council experienced a surge of publicity since the last meeting. He circulated news items that mentioned the NCC MERP. The news release on the statement of medication error rates was picked up by PRHI and the Australian Patient Safety Foundation in its September newsletter. Both organizations said that it was very timely and tied in with what they were doing. A California group has requested use of

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the Taxonomy as a data collection form for its facilities. A request came in from India asking the Council's permission to use definitions in a dictionary on pharmacovigilance and drug safety. Dr. Combes was asked to speak at several engagements and was interviewed by Channel 5 in New York regarding the exploration of pharmacy errors. NPSF will be publishing an article in its newsletter in March or April that compares hospital performance by measuring medication error rates. McKesson is now using the NCC MERP Index for Categorizing Medication Errors for all medical errors.

Presentation: David Marx (Outcome Engineering) – Patient Safety and the "Just Culture"

Outcome Engineering deals primarily with risk assessment and risk modeling within the aviation industry. It focuses on how to look at errors and then establishes a framework to deal with risk. Three distinct cultures exist in our society: (1) blame-free, (2) just culture, and (3) punitive. In a "Just Culture" there is a balance between discipline and systems and people have to be taught the different levels of risk. Discipline is based on risk versus rule violations. The outcome is what drives disciplinary action. Mr. Marx emphasized that people do not "choose" to make mistakes (human error); therefore, why punish someone for something he/she does not regard as risky behavior? Within the corporate world mistakes are most commonly rule violations, which are not the same as reckless (intentional) conduct. Proper training will lead to a reduction of errors but within a Just Culture will never be 100% error free.

Once problems have been identified, Mr. Marx advocated that the Council (1) get the topic into the public dialog; (2) define the issues as a compromise between blame-free and punitive; (3) make recommendations to regulatory bodies, state boards, and government agencies; and (4) provide guidance in identifying other error prevention strategies.

Mr. Marx's presentation provided information and a thought-provoking discussion amongst the Council membership. His presentation was well received and he will be invited back for additional sessions.

The meeting resumed with discussion on the Practitioner Accountability conference and agreed that the presentation by Mr. Marx would broaden the scope of the conference to include at-risk behavior. It would be more conducive to board participation by finding an agenda that cuts across different levels of behavior and would allow boards to share information on their new educational programs. A conference on the issue and any subsequent Council recommendations may not have an immediate result but would start the process for changing how people look at errors. The Council will have to look at various options for subsidizing the conference, if it is held.

The question was raised as to whether the Council could work with AHRQ (Jim Battles) to review a document regarding just culture and add its own recommendations. It was suggested that the Council may want to pursue a grant for this purpose.

ACTION ITEM: Under the new structure, this activity is assigned to the Practice-Related Issues Subcommittee, Joe Cranston, Chair, for follow-up.

ACTION ITEM: All scheduled conference calls for the various subcommittees will be posted so the entire NCC MERP listserv will be aware of all activities and can work on any projects of interest.

Day Two February 7, 2003

Council delegates present:

John Combes (AHA), Chairperson Linda Hanold (JCAHO) Diane Cousins (USP), Secretary Janet Myder (AHCA)-by phone Joseph Cranston (AMA) Rita Munley Gallagher (ANA)-by phone William Ellis (APhA) Ellen Quinn (ASHRM)

Ron Nosek (DoD) Jerry Phillips (FDA) Salvatore Peritore (GPhA) Lisa Clowers (HDMA) Judy Smetzer (ISMP) Jon May (NABP) Ray Bullman (NCPIE) Rebecca DeVivo (NPSF) Jeff Ramirez (VA)

Alternates that attended for their delegates: Kristin Hellquist (NCSBN) attended representing NCSBN

Delegates absent:

Andrew Smith (AARP) Karen Drenkard (AONE) Tom Clark (ASCP) Kasey Thompson (ASHP) Debra Brady (NCSBN) Alan Goldhammer (PhRMA) Deborah Nadzam (Cleveland Clinic) Bill Kelly (ex officio) USP Safe Medication Use Expert Committee

Observers present:

Michele Douglas (Med-Touch) Albert Kinsky (ISMP Intern) Marilyn Storch (USP)

John Combes, Chairperson, called the meeting to order at 9:35 a.m.

Report on Executive Session of February 6, 2003

It was moved, seconded and approved to accept NACDS as a Regular Member of the Council for a two-year term under the category of Trade and Manufacturer Organizations.

Presentation: Diane Cousins & Rodney Hicks (USP) -- USP's Patient Safety Initiatives: MEDMARX 2001 Data Summary

Diane Cousins and Rodney Hicks presented summary results of the 2001 MEDMARX data. Diane encouraged the Council to do more to educate and train their constituents in the use

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of this data. The causes of medication errors in hospitals are known so the primary question is what the Council can do to provide guidance and suggestions for error reduction, while taking fiscal restraints into consideration. Practical solutions, like having an area where less distraction would occur or even a separate medication preparation room, can be simple yet effective. System changes have to affect risk associated behaviors but cannot be implemented without considering the benefits of the procedures.

Although MEDMARX and MER provide different aspects of medication errors, both are needed to compile a global perspective of the issue. The Council is familiar with MEDMARX but would like more information about MER, how it contrasts and compliments MEDMARX. It was suggested that presentations of other reporting systems, with attendant advantages and disadvantages, be encouraged for future meetings.

ACTION ITEM: Diane Cousins (USP) will present a report on the MER program at the June meeting.

Subcommittee Reports

> Practice-Related Issues – Joe Cranston, Chair

The subcommittee on Practice-Related Issues held a teleconference on January 16, 2003, and selected Joe Cranston as its permanent chair. Discussion led to several proposals for the Council's consideration:

- promotion of medication error reporting Judy Smetzer was asked to talk with Deb Nadzam to see if the PME Subcommittee was interested in taking this on,
- 2) system vs. accountability focus on systems improvement the Practice Related issues Subcommittee will investigate this issue further, and
- 3) tablet splitting -- The topic of tablet splitting was discussed by the membership and does not appear to rank as a high priority for the Council at this time; however, the issue may have significance for individual members. The Council discussed how best to address the issue. It was suggested that the Council provide pro and con information to the public and elaborate on the science associated with splitting and scoring tablets. A question arose as to whether the Council should reject splitting in all instances except under extremely rare circumstances. It was the opinion of the Council that manufacturers have never tested whether or not splitting delivers equal doses of medication. This practice has the potential to imperil patients whose medication doses must be precise. It was noted that the manufacturing process could not be changed for older medications, a situation that may become a problem should splitting become prevalent. According to Jeff Ramirez the VA has drafted a process for splitting non-scored tablets. Studies have been done by the VA and the results will be presented at the ASHP annual meeting. To date, no state has a policy on the books for tablet splitting. The Council decided not to pursue this issue.

Joe Cranston thanked Lisa Clowers for her work in finalizing the consumer education piece that is now posted on the Council's web site. It can be found under the link "For Consumers" in the upper left menu on the NCC MERP Home Page.

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Draft 6 of the unlicensed personnel recommendations was circulated to Council members for review. All commentary/suggestions should be forwarded to Joe Cranston, who will incorporate them and prepare a final draft for Council balloting.

ACTION ITEM: Joe Cranston, with the Practice-Related Issues Subcommittee will incorporate members' suggestions into a final draft of recommendations for the administration of medications by non-licensed personnel for official sanction by the membership.

> Taxonomy – Ellen Quinn & Rita Munley Gallagher, Co-chairs

The subcommittee on Taxonomy met via teleconference and selected Ellen Quinn and Rita Munley Gallagher as its co-chairs. The subcommittee proposed that the Council

- (1) solicit feedback about other organizations' taxonomies and their current usage in an attempt to determine what the users are gleaning from the data. The Council could then develop a reach-out program to educate health care professionals about the NCC MERP taxonomy and how it relates to reporting medication errors.
- (2) consider putting the Taxonomy in an Access database and posting it on the web as a Word document.

ACTION ITEM: Rebecca DeVivo offered to work with the subcommittee to develop a tool for soliciting feedback from current taxonomy users.

Promotion Subcommittee – Deborah Nadzam, Acting Chair

The Promotion subcommittee held a conference call and proposed that the following be incorporated into Council meetings on a regular basis:

- (1) standard agenda
- (2) cutting-edge speakers
- (3) MEDMARX updates
- (4) standing committee reports

It was also proposed that the Council create reporting papers to highlight programs that are already in existence. For example, how to easily report an error may benefit middle managers. The subcommittee was directed by Diane Cousins to feed all promotional items to Sherrie Borden for tracking.

ACTION ITEM: Sherrie Borden will contact AHA's public relations person to collaborate on tracking publicity on the subcommittees' and Council's work.

Roundtable Discussion

AMA (Joe Cranston) – The AMA has become the lead physician organization in developing physician performance measures. The goal is to compile common sets of performance measures for various diseases that are derived from evidence-based practice guidelines.

Meeting Summary – Final

NPSF (Rebecca DeVivo) – NPSF is in the midst of planning for a very busy March. The Patient Safety Awareness Week is scheduled for March 9-15 and will promote national educational programs on patient safety. Templates, tool kits, fliers, etc. are available on the NPSF web site. The 5th Annual Congress (formerly the Annenberg Conference) is scheduled for March 12-15, 2003, in DC. The theme is Let's Get Results-Improving the Safety of Patients. March 12 will also see the release of a national report on patients and families. The NPSF is promoting membership campaign that targets individual memberships.

NCPIE (Ray Bullman) – NCPIE distributed tool kits to raise awareness of the appropriate use of medications during an October "Talk About Prescriptions Month" campaign.

NABP (Jon May) – The Drug Addiction Act which was passed by Congress in 2000 allows for the prescribing of drugs and treatment for drug addiction in physicians' offices. Physicians would need training and a waiver from FDA to participate in this program and they would be supervised and inspected on a regular basis. This new approach for opiate-addicted individuals provides a confidential alternative to methadone clinics and apparently has no stigma attached. More than 1000 doctors have already applied to participate in the program.

ASHRM (Ellen Quinn) – ASHRM has produced a brochure for risk managers to distribute to hospital personnel. Along with the AHA, ASHRM is in support of patient safety legislation that supports voluntary and confidential reporting. ASHRM is also working with the AMA and AHRQ on patient safety quality measures.

FDA (Jerry Phillips) – Jerry noted that the new FDA Commissioner is a long-time supporter of patient safety initiatives and should be an asset in promoting issues that coincide with the Council's interests. FDA's bar coding recommendations are proceeding and are now in OMB, which is the last step before final implementation. FDA, PhRMA, and ISMP are sponsoring a joint workshop at the end of July 2003 that will address regulatory reforms. One such reform is that manufacturers must start testing for medication errors (i.e., sound-alike, look-alike drug names) before applications are submitted to the FDA. The workshop is closed but other interested organizations and individuals can be invited. Dr. Combes queried whether a representative of the Council should attend. There was no interest on the part of the Council to attend. Jerry also described a downloadable pamphlet and a15-minute video available on FDA's web site that have been expanded to include medication errors, new drug approvals, and other patient safety issues.

NCSBN (Kristin Hellquist) – The headquarters for NCSBN have moved to a new location on East Wacker Drive in Chicago. NCSBM jointly sponsored a patient safety conference regarding the collection of data on performance measures, during which the NCC MERP was a topic of discussion. There was optimal interest in the conference but poor attendance due to participants' budgeting concerns. Such results force the boards to focus only on licensing and not expand into other topics. NCSBN has noted that the influx of internationally educated nurses has resulted in problems related to the differences in knowledge of the technology, systems, and procedures. VA (Jeff Ramirez) – Veterans Administration performance measures are now shared with 21 VA hospital networks. VA's National Center for Patient Safety has established a reporting program for medical errors in conjunction with NASA. The VA pharmacy bar coding measures project is now in its third year. Hospital to hospital differences were huge when measuring the success of this project and issues were found in systems engineering that needed attention. It has been a constant learning process and the 3^{rd} version of these measures is being released in sections. Health e-Vet is a future VA program where each patient has his own web site and owns his own medical information. The first pilot program for Health E-Vet is now being tested in Florida and the VA hopes to roll out the full program by 2004.

GPhA (Sal Peritore) – GPhA is anxiously waiting for the bar coding guidelines and has nothing new to report.

DoD (Ron Nosek) – DoD has a new patient safety structure that is housed in Tricare Management in Falls Church, VA. The new program director, Deborah McKay of the Navy Nurse Corps, oversees three programs: (1) the Patient Safety Center in Silver Spring, MD, where all errors are registered and data is disseminated throughout the system, (2) education and training at the military medical school, and (3) continuous team training at military facilities by patient safety officers. DoD has partnered with USP to utilize MEDMARX at all its sites as the tool for reporting medication errors. Sites are linked through the MEDMARX multi facility module, which allows patient safety officers to review data online for all facilities. **AHA** (John Combes) – AHA has been working in conjunction with HRET and ISMP developing tools to assist hospitals in writing strategic plans for healthcare, getting teams proactively involved in hazard analysis, and determining bar coding readiness. It has also instituted a voluntary program with CMS and its member hospitals to develop a clinical evidence tool to enable the practice of evidence-based medicine. A collection of quality measures will be available for public disclosure. The goal is to issue results of evidence-based medicine on a public web site that will be updated every six months. A series of tool kits on leadership for safety will be released mid February to all AHA facilities. **USP** (Diane Cousins) – USP testified before the Patient Safety Data Standards Committee of the

IOM. The Committee is being funded by AHRQ to determine a structure of data for a new DHHS database that will eventually be integrated with other databases and is interested in MEDMARX for the medication section. During the ASHP midyear meeting in Atlanta, Diane Cousins moderated a panel entitled *Medication Error Rates: Can They Be Calculated?* John Combes was a member of the panel. At the ISMP Cheers Award dinner, the USP Center for the Advancement of Patient Safety (CAPS) received an award for its support of voluntary reporting of medication errors and its tireless work with US Congressional staff to shape healthcare policy relating to protection of error reports and other patient safety data. The MEDMARX Annual Report for 2001 was published in December 2002. MEDMARX subscribers can now view reports in real time. USP is evaluating various new ways to present the MEDMARX data for the year 2002. USP's Safe Medication Use Expert Committee and the Pediatric Expert Committee have issued recommendations on pediatric error avoidance. These recommendations can be found on USP's web site.

No new business was put forth and the meeting was adjourned at 12:54 p.m.

NCC MERP Meeting Summary Ballot

February 6-7, 2003 Meeting

I have reviewed the Meeting Summary:

I approve the Meeting Summary as it stands.

I approve the Meeting Summary with changes as marked on the enclosed pages.

Name _____

Organization _____

Date

Please return this ballot by COB Monday, April 7, 2003, by mail or fax to:

Diane Cousins USP 12601 Twinbrook Parkway Rockville, MD 20852

Fax: 301-816-8532