Day One
February 3, 2004

Council delegates present:

John Combes (AHA), Chair	Ron Nosek (DoD)
Diane Cousins (USP), Secretary	Jerry Phillips (FDA)
Rita Munley Gallagher (ANA)	Jon May (NABP)
Veronika Oven (AONE)	Ed Staffa (NACDS)
William Ellis (APhA)	Polly Johnson (NCSBN)
Carla Saxton (ASCP)	Ray Bullman (NCPIE)
Ellen Quinn (ASHRM)	

Individual Members present:

David Kotzin	Deborah Nadzam

Alternates attending as representatives of their organizations:

Teresa Rubio (ASHP)	Rosemary Cook (PhRMA)
Judy Milford (GPhA)	Virginia Torrise (VA)

Alternates attending with their delegates:

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

Organizations Not Represented:

AARP	ISMP
AHCA	JCAHO
AMA	NPSF
HMDA	SEFH

USP Safe Medication Use Expert Committee

Observers:

Frederick Razzaghi (CHPA)
Sherrie Borden (USP)

John Combes (AHA), Chair, welcomed the Council members and guests and called the meeting to order at 1:40 p.m. Dr. Combes reported that he had received a request from Linda Murphy, a registered nurse at Integris Baptist Hospital in Oklahoma, for individual membership on the Council. The matter was referred to the Steering Committee for deliberation. The Pennsylvania Patient Safety Authority has suggested the use of a decision tree to facilitate the application of the Council's Category Index that would be applied to all errors and near misses, not just medication errors. The Department of Defense and the Cleveland Clinic are also interested in expanding the use of the Index to include all errors. Any adaptations of the Index will be shared with the Taxonomy Committee and the Council. The Indian Health Services of Kansas were very appreciative of receiving the Category Index and the Algorithm from Dr. Combes.

Secretary's Report

Diane Cousins (USP) reported that

- The latest IOM report – "Patient Safety, Achieving a New Standard for Care"-- has several citations for NCC MERP. Recommendations from this report will become the agenda for future AHRQ projects.
- There have been five requests in the past three months for reprint permissions to the Taxonomy (1), the Medication Error Index (3), and the definition of error (1).
- The National Quality Forum has put out a call for recommendations for members of a new Steering Committee to establish and advance a national standardized taxonomy. Diane Cousins has been nominated for this position. With no objections from the Council, John Combes volunteered to send a letter to Dr. Kenneth Kizer supporting Diane.

ACTION ITEM: John Combes will send a letter to Dr. Kenneth Kizer on behalf of the Council supporting Diane Cousins' nomination to the NQF Steering Committee.

- The National Health Services of the United Kingdom has adopted the Council's definition of medication error. This was reported in the best practice guide entitled "Building a safer NHS for patients" that was issued in 2003.

Ellen Quinn reported that she received a letter from an ASHRM member inquiring about medication errors resulting from similar packaging. The Council has issued recommendations pertaining to packaging and labeling, but nothing in regard to color coding. The only project for current Council consideration pertains to at-risk behaviors. The Council should be looking to MEDMARX for ideas to drive Council projects.

***Presentation: MEDMARX^{SM} 2002 Data Report Highlights* – Rod Hicks, RN, MSN, MPA, Research Coordinator, USP**

Rod Hicks presented a PowerPoint presentation of MEDMARX data as summarized in the fourth annual MEDMARX data report. The report analysis covered the following criteria:

- type of facility
- categories of errors
- types of errors
- threshold of harmful vs. non-harmful types of errors
- causes of errors
- most commonly reported products involved in errors

The report focused on four of JCAHO's patient safety goals; patient identification, communication, high alert medications, and the errors involved with the use of infusion pumps. A special section highlighted seniors as a separate patient population with emphasis on the types of errors and products involved that are most harmful to seniors.

Currently, the MEDMARX database contains more than 580,000 records that are available for analysis and is growing by 20,000 records monthly. An ADR module is being developed and should be available for users in the summer of 2004. The next Annual Report will be a five year anniversary issue with a likely emphasis on technology. MEDMARX can provide the Council's subcommittees with opportunities to promote patient safety by providing

national leadership in error reporting and prevention and the issuance of recommendations. In the domain of the Taxonomy Subcommittee, the Taxonomy needs to be updated in regard to clarity and definition of Node, Types, and fields. It was suggested that the Subcommittee contact large users, such as DoD and PRHI, to discern whether or not they have discovered holes in the taxonomy. This would be a good time to add enhancements to the Taxonomy to make it more JCAHO-compliant and there is a need to establish a basis for the least amount of information needed for a minimum data set.

The Practice-Related Issues Subcommittee could utilize MEDMARX data to delve into tubing and interchangeability issues, product suffixes, and recurring products, types, and causes of errors. The Subcommittee may determine that the interchangeability of tubing may be of enough significance that it should be the next "big" topic (similar to bar coding) for the Council to pursue or it may decide to issue recommendations and/or letters that raise awareness of manufacturers, patients, caregivers, and the FDA.

ACTION ITEM: Jon May will communicate with his subcommittee to select a permanent chair and pick a project within two weeks. A report will be made at the June Council meeting.

There are opportunities for the Technology Subcommittee for setting minimum requirements for patient information systems, including CPOE.

Sherrie Borden, Director of Public Relations, USP

Since July 2003, USP's public relations department has released six press releases related to NCC MERP. Ms. Borden reported that a detailed analysis of activity by topic, demographics, etc. can be done on all press releases by using VOCUS, a public relations data management program. A template can be created to expand VOCUS to include NCC MERP. Most of the activity was centered on the General Principles, which had also been promoted in ASHRM's newsletter, with ninety media requests received at USP. Ms. Borden is in the process of updating PR contact lists and is planning a conference call by the beginning of March.

Subcommittee Reports:

Promoting/Monitoring/Evaluating – Deborah Nadzam, Chair

The Subcommittee held a conference call to determine what and how materials, including news releases, should be disseminated by the Council. Three suggestions included (1) regular submissions of the Council's work to trade journals and (2) a one page meeting synopsis that would include key messages and actions taken that could be used both internally and externally as a quick recap of meetings. This synopsis could later be used to draft a yearly report of the Council's activities. It was decided by the members that, for this meeting, the synopsis would be used only internally. For anything that is published externally, the Council prefers that PR people be involved for their expertise in using the external media. Dr. Nadzam created this meeting's issue throughout the meeting.

ACTION ITEM: USP will prepare a prototype for the synopsis of this meeting and e-mail it to Council members for comment and internal distribution.

ACTION ITEM: The newly resurrected PR group under the auspices of the Promoting/Monitoring/ Evaluating Subcommittee will prepare press releases publicizing topic(s) and major action(s) after each meeting of the Council.

The third suggestion was that the Council publish an annual report of its activities for 2004. An overriding question was whether there would be USP staff support to produce the report.

Taxonomy – Rita Munley Gallagher (ANA) & Ellen Quinn (ASHRM), Co-chairs

The Subcommittee would like a wish list from MEDMARX users and USP of what is necessary to update the Taxonomy. Information from JCAHO and IOM on the mandatory fields would enhance the credibility of the Taxonomy.

Practice-Related Issues – Joe Cranston (AMA), Chair

The Subcommittee has not met since the Council meeting in October. At this time members are searching for projects.

Technology

The Subcommittee has had no activity and nothing to report at this meeting.

Dr. Combes suggested that the subcommittees meet at 8:00 a.m. on Wednesday to discuss and prioritize three projects for future endeavors.

The meeting was adjourned at 4:54 p.m.

The Steering Committee moved in Executive Session at 5:00 p.m.

Day Two
February 4, 2004

Council delegates present:

John Combes (AHA), Chairperson	Jerry Phillips (FDA)
Diane Cousins (USP), Secretary	Lisa Clowers (HDMA)
Joseph Cranston (AMA)	Judy Smetzer (ISMP)
Rita Munley Gallagher (ANA)	Jon May (NABP)
Veronika Oven (AONE)	Ed Staffa (NACDS)
Ellen Quinn (ASHRM)	Ray Bullman (NCPIE)
Carla Saxton (ASCP)	
Ron Nosek (DoD)	

Individual Members present:

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ASHP	NPSF
GPhA	SEFH

USP Safe Medication Use Expert Committee

John Combes (AHA), Chair, called the meeting to order at 8:42 a.m. and presented a review of actions approved by the Steering Committee in Executive Session. ASHRM, DoD, and VA, whose memberships were due to expire in February 2004, were renewed for two year terms. Deborah Nadzam, whose individual membership also was due to expire in February, was renewed for a 13-month term to bring all Individual Memberships to a June 2005 renewal date. There was discussion as to whether the Council should be proactive and seek to recruit individual members or remain reactive to membership requests. It was decided that as the Council approaches its 10th year, it would be an appropriate time to review its structure.

***Presentation Virtual Tool Box for Quality Pharmacy Practice* – Ed Staffa, R.Ph., NACDS**

Development of the Tool Box was a joint endeavor by the Institute for the Advancement of Community Pharmacy (IACP), the National Association of Chain Drug Stores (NACDS), and the National Community Pharmacists Association (NCPA) to standardize written quality procedures. The free on-line program allows pharmacy managers to review

programs that are currently in use and to customize their own quality programs. Already 23 pharmacies have voluntarily contributed information to this shared resource. The Community Exchange feature allows users to communicate with each other, as well as provide a current listing of states' requirements in regard to quality assurance.

ACTION ITEM: Diane Cousins will send information to Ed Staffa to link the NCC MERP web site with the Tool Box.

At-Risk Behaviors -- Judy Smetzer (ISMP)

Using the answer sheets from the October 2003 meeting, Ms. Smetzer described her method for interpreting the results from the At-Risk Behavior exercise. Sixty nine behaviors were identified for the exercise and 137 random errors of Category C and higher from the MER Program were reviewed. Risky behavior is not necessarily bad medical practice, but healthcare professionals have to be cognizant of the risk and the potential of failure. The goal is to discover why risky behaviors occur and develop recommendations to help people avoid them. Recommendations may not cause permanent change but may focus attention on the constant prevalence of risk. Development of behavioral-bases responses are needed to counter system failures.

ACTION ITEM: John Combes will share this information with David Marx and invite him to the June meeting to form a strategy of where the Council should go with this data.

It was emphasized that the data came from random, voluntary reporting and should not be used to extrapolate conclusions relevant to the general population. However, it could lead to topics that should be explored, i.e., expanding the Taxonomy to include risk factors. NCSBN has similar data that focuses on a balance between accountability and system issues. Some of the behaviors described in the at-risk exercise are evident in NCSBN's data. It was suggested that further exploration of this issue may need to involve human behavioralists and human factors people. Even though the data is not researchable, it may be sufficient as "clinically observable and significant" to launch several levels of recommendations. Deborah Nadzam suggested that the Council's earlier recommendations be reviewed and updated. Rosemary Cook (PhRMA) stressed that the emphasis should be on recommendations that form the culture of safety. The issue was referred back to the Practice Related Issues Subcommittee.

Structure of the Council

As the Council approaches its 10-year anniversary, it has seen increased requests for memberships, national and international recognition, and dedicated commitment on the part of its members. Although not in favor of change just for the sake of change, it seemed appropriate at this time to open a discussion as to what the structure of the Council should be.

Mike Cohen, ISMP, (via telephone) opened the discussion by noting that all organizations should feel as though they are contributing to the Council on an equal level. Regular Members, who must petition to renew membership every two years, do not have the same standing as Steering Committee Members, who were the founding organizations and whose seats are permanent. Because the Steering Committee deals mainly with minor

by-law changes and membership, it would be more equitable to having an alternating membership on the Steering Committee. The system as it is now is neither democratic nor all-inclusive.

Diane Cousins, Secretary, noted that the Council was founded on a topic-focused model of membership organizations and that its rules developed as questions and issues arose. All "clinical" issues have always been open to all members for comment and voting. Members have always had the option of not renewing membership should their organization's priorities change.

Generally, comments could be classified as follows:

- not comfortable with life membership for some members and not all
- there should be some accountability by life members, for example, regarding attendance
- membership should be based on commitment, not pedigree
- some members see no problems with the current organization of the Council
- rotational membership for the Steering Committee – everyone should have the opportunity to serve
- Steering Committee has outlived its usefulness – everything should be brought before the whole Council
- there is probably a need for periodic review and revision of rules and regulations
- some members never felt "excluded" as Regular Members
- Steering Committee may be lacking in diversity
- there needs to be a leadership body to guide the membership
- mechanism should be in place to remove someone from the Council
- no multi-disciplinary category of membership
- characteristics of member organizations should be reviewed

Dr. Combes concluded the discussion by emphasizing that many good suggestions were proffered and that they would be considered during any reevaluation of the Council's structure.

ACTION ITEM: The Steering Committee will convene by conference call to develop a plan for restructuring the Council that will be presented to the membership at the June meeting.

Roundtable

AHA – AHA, HAP, HRET, AHRQ, and others sponsored a conference for 20 senior leading health care system executives to acquaint them with a series of performance skills designed to assist them in managing a high hazard industry. A National Quality Initiative provides an incentive for 2500 hospitals to report to a public reporting system. Hospitals receive no money if they do not participate. The Pennsylvania Patient Safety Authority (PAPSA) is piloting a reporting system that will incorporate the Council's Category Index. The goal is to have all hospitals participate. Within the past three months 22 facilities have filed 1800 reports. ECRI and ISMP will evaluate the data.

AMA – AMA continues to convene a consortium of medical specialty societies in developing disease-based physician performance measures. It has developed a "Drug Policy and Therapeutics" web site as part of its larger web site. It is waiting final approval

to go live. A "Medication Error" module will be added in 2004. Medication-related public policy issues that are being addressed by AMA include:

- Internet prescribing/dispensing
- drug shortages
- counterfeiting of drugs
- importation of drugs
- dietary supplements
- e-prescribing
- pain management

At its June meeting AMA will have a report from its Council on Scientific Affairs on the issue of color coding in reducing medication errors.

ANA – ANA is working with the National Quality Forum on nursing measures. It is also developing a series of audio conferences, the last one of which centered on medication use.

AONE – Pam Thompson, MS, RN, FAAN, Chief Executive Officer, continues to represent AONE on the Executive Board of the National Patient Safety Foundation. AONE hosted a program on patient safety entitled, Flawed Execution: The Patient Safety Mandate, on January 31, 2004, in Orlando, FL. The program was presented by Afterburner Healthcare, Inc. The Afterburner team of former and current fighter pilots presented a one-day experiential training event based on their combat experience, combines with extensive skills in aviation safety. The objectives of this program were:

- How to begin to change organizational effectiveness to reduce the incidents of patient safety-related errors
- How to combat task saturation
- How teamwork and crew management lead to flawless execution

AONE has posted the more recent NCC MERP press releases on its web site and included announcements in its weekly e-News Update that is distributed to all AONE members.

APhA – The Medicare drug benefit and importation issues have been the major areas of attention at APhA. The annual meeting is schedule for March in Seattle and will concentrate on medication safety in pediatrics and risk management. The Pinnacle Awards will be presented in June. The application deadline for the Pinnacle Awards is the end of February.

ASCP – The newly elected president of ASCP has formed a Quality Improvement Task Force to explore medication error prevention programs as they pertain to LTC pharmacies. ASCP is in the process of developing a framework for a future product that will serve as a basis for LTC pharmacies when implementing a QI or med error program. This toolkit will focus on the operational aspects of LTC pharmacies and internal error prevention. A draft version of this toolkit is scheduled to be completed by fall 2004. The Individual Nursing Facility Quality Measures have been revised and publicly released by CMS. ASCP, in conjunction with MedPass, is in the process of revising its reference these Measures. The second edition, due out in spring 2004, will summarize the changes in the quality measures and provide an overview of their impact on LTC pharmacies. ASCP's Annual Legislative Conference is scheduled for April 3-6 in D.C. Programming will include:

- Discussion of the new Medicare legislation

- Budget constraints and cost containment methods of various states, including mandatory tablet splitting, return-reuse of meds in LTC, and changes in special packaging allowances in LTC
- The value of pharmaceuticals and pharmacists' services
- Drug importation

Tom Scully, former CMS administrator is the keynote speaker at the Opening General Session of ASCP's Mid-Year Meeting in May in Scottsdale, AZ.

ASHP – ASHP is in the process of creating guidelines for the development, testing, and use of CPOE systems that are due for completion and publication by summer 2004. The ASHP Research & Education Foundation has several projects that are nearing completion:

- Development of an educational program and toolkit to assist pharmacists in preparing pharmacies to implement machine-readable coding technology - expected to be completed spring 2004
- Preparation to launch a major awards program in recognition of practitioner/organizational achievement for excellence in medication use safety
- Establishment of a $100,000 per year grant program designed to foster collaborative medication use safety research between nurses and pharmacists

ASHP has also developed a resource document to educate members on how to avoid counterfeit products. Information is available at www.ashp.org. In an effort to improve the practice of pharmacy in health systems and conceptualize how pharmacy practice should look in the future, ASHP launched its 2015 Initiative last September. The Initiative included 6 key goals and 31 objectives to make medication use more effective, scientific, and safe by the year 2015.

ASHRM –ASHRM's membership has expanded to 4400 members and risk management has been restructured to include patient safety. A National Advisory Council on Patient Safety has been established to assist risk managers before harm occurs.

DoD -- DoD has scheduled 8 MEDMARX training sessions through September 2004 and may expand training to include as many as 8 more as part of a series of advanced patient safety courses for facility patient safety officers. Approximately 120 people attended a Basic Patient Safety Course in San Antonio January 13-16, 2004. The DoD patient safety web site has been expanded to included Safety Alerts and Hot Topics in Patient Safety and soon will host a web-based organizational cultural assessment for hospitals. Patient safety questions have been included for the first time in TRICARE's beneficiary satisfaction survey. NCC MERP severity scale index and definition of harm have been incorporated in DoD's new Hospital Balanced Score Care Metric and DoD is looking to adopt the Index for all errors – medication and medical.

FDA – On December 3, 2003, an FDA Advisory Committee met to discuss the various methods that are used to determine whether a proprietary name sounds or looks alike to another marketed proprietary name. The Drug Safety & Risk Management Advisory Committee recommended that the Agency create a workgroup of FDA and industry experts to:

- identify current screening method deficiencies
- define validation techniques of new screening methods
- determine needed additional study methods
- propose what data are needed to most effectively screen proprietary drug names

FDA has developed a computerized screening tool named POCA (Phonetic and Orthographic Computer Analysis) that compares the phonetic and orthographic similarities of new proprietary names against known and marketed proprietary names. The Final Rule for Bar Coding of Pharmaceutical and Blood Products will be issued in the near future. Jerry Phillips announced that he is retiring from the FDA after 30 years and may not be at the next Council meeting.

HDMA – HDMA has concentrated its efforts in ensuring the safety of the drug supply chain by tagging individual products. EPC tags can be embedded in bar codes and HDMA hopes to have them in place by 2005. At the present time, HDMA is doing its end of year survey on drug availability.

ISMP – ISMP's 2004 hospital self-assessment tool should be in hospitals by April. At the NPSF Summit in May, ISMP will present its analysis of the preliminary data. Additionally, ISMP has been:

- working with ECRI on a statewide Pennsylvania survey on intimidation in the workforce with the intention of publishing the results
- updating its high alert drug list and dangerous abbreviation list
- working to establish an ISMP in France
- working on its fourth and final video on patient safety for physicians and boards

ISMP is celebrating its 10th anniversary as a nonprofit organization.

NABP – Despite warnings that imported drugs may be subpotent, super potent, contaminated, or counterfeit, and that neither Canadian nor American authorities can guarantee their safety, city and state governments in the US continue to show interest in establishing drug importation programs. NABP has been working to educate people about the dangers of imported drugs and buying drugs via the Internet. A National Planning Safety Initiative is in the planning stage that will air issues such as CPOE, that NABP feels should be implemented on the state level. Jon May announced that the Practice-Related Issues Subcommittee of which he was the temporary Chair, met and elected Carla Saxton as the permanent Chair.

NACDS – Ed Staffa was a member of the NQF panel to select the winners of the John Eisenberg Award. Since the October meetings, NACDS has been concentrating its efforts on:

- Sure Scripts – a program that is assisting pharmacies comply with requirements pertaining to electronic prescribing
- producing a newsletter instructing pharmacists how to detect counterfeit drugs
- hosting a conference that defined pharmacists' role in combating bioterrorism
- working with NCPIE on patient information

NCSBN – David Marx was the main speaker at NCSBN's Patient Safety Conference in November. Unfortunately only 25 people representing 6-7 states were able to attend. Major concerns for the boards include nursing shortages, with the subsequent infusion of foreign nurses, and unlicensed medication personnel. The big challenge is to write rules and regulations that cover these situations.

NCPIE – In October 2003 NCPIE posted an announcement/description of NCC MERP's recommendations to reduce medication errors in non-healthcare settings on its web site

www.talkaboutrx.org, with an embedded link to the NCC MERP press release. NCPIE continues to serve as a catalyst/convener for a multi-stakeholder Consumer Medicine Information (CMI) Initiative. The goal is to ensure that by 2006 the private sector meets federal targets for the distribution and content/quality of written consumer medicine information established in Public Law 104-180 and the *Keystone Action Plan for the Provision of Useful Prescription Medicine Information.* Current activities include broadening the base of stakeholder participation, organizing three work groups (Criteria, Education, and Implementation) and planning for an "All Hands" CMI Stakeholders' Meeting on March 8, 2004, in the D.C. metro area. Details about the CMI Initiative are available at www.talkaboutrx.org/cmi.html.

PhRMA – As part of a multi-stakeholder group led by HDMA, PhRMA is currently evaluating the business case for Electronic Track & Trace for packaging medications using Radio Frequency Identification (RFI) technology. PhRMA is also working on its Paperless Labeling Initiative to make electronic package inserts for non-emergency medications available to dispensing pharmacists. This multi-stakeholder task force will be conducting a nation-wide beta test of the electronic labeling systems in 2004.

USP – Diane Cousins announced that USP has been named in the new Medicare Bill to develop a national formulary. The 2002 MEDMARX Annual Report was successfully launched in two waves – the first aimed at seniors and the second at the JCAHO goals. The latest IOM book, Patient Safety, Achieving a New Standard for Care, mentioned both MEDMARX and the MER Program in discussion of four national reporting systems. USP conducted a series of briefing sessions entitled "Transforming data collection and analysis into useful information" in conjunction with Joint Commission Resources' Executive Briefing Sessions. One observation that came out of these sessions is that there is still a lot of confusion and people need more instruction in using the Category Index. In January USP held its first meeting of the Medication Errors Databases Research Advisory Panel (MEDRAP), a group that was established to develop a research agenda and explore ways of opening USP's databases to researchers.

VA – The Bar Code Administration Project has begun phase 2 with Chris Tucker as administrator. The VA is also looking at:

- making medical record prescribing safer
- enhanced reporting at the point of care
- increased reporting by nurses
- a mail order pharmacy program that would include medication error reporting

VA hospitals have received their second JCAHO accreditation and are looking to expand the Patient Safety Center.

David Kotzin – Since the October meeting, GBMC has embarked on several medication safety initiatives which included selection of Meditech® as the hospital's information system. Go-live for the Pharmacy-Lab-Radiology (integration) is scheduled for October 2004, with bedside medication verification and automated MARs in December. CPOE is scheduled for April 2005. Automated dispensing cabinets in pediatric ICU, pediatric ER, 4 new operating rooms and additional ER bays increased total cabinets to approximately 50. Maryland's MEDSAFE project just completed a 2003 assessment of medication safety for all 50 of Maryland's hospitals through an online survey developed by the Maryland

Hospital Association in collaboration with ISMP. Further medication safety projects included:

- adding profile dispensing cabinets for respiratory therapy blood gas rooms
- developing a policy for oral contrast media
- disseminating of an antibiogram of GBMC's Infoweb and MD Online for use by all personnel
- rewriting and enforcement of GBMC's new policy on abbreviations

Mr. Kotzin is actively participating in ISMP's 2004 self assessment advisory committee that was rewriting the self assessment survey.

***ACTION ITEMS*:**

- ***The Taxonomy Subcommittee will report on recommendations on how to proceed to update the Taxonomy in regard to definitions, types, and the use of high alert products.***
- ***The Practice-Related Issues Subcommittee will review current recommendations to discover if they need to be updated.***
- ***The Technology Subcommittee will develop an approach and set up a work group to explore accidents and errors caused by the interchangeability of IV tubes and the lack of color coding.***
- ***All Council members were to brainstorm for ideas on what can be done with at risk behaviors.***

Dr. Combes reminded everyone that elections were near and that ballots would be mailed in March. There being no new business, Dr. Combes adjourned the meeting at 1:34 p.m.