February 6-7, 2002
Day One

Council delegates present:

Jerry Phillips (FDA), Chairperson	Lisa Clowers (HMDA)
John Combes (AHA), Vice Chair	Linda Hanold (JCAHO)
Diane Cousins (USP), Secretary	Jon May (NABP)
Janet Myder (AHCA)	Barbara Newman (NCSBN)
Joseph Cranston (AMA)	Alan Goldhammer (PhRMA)
Rita Munley Gallagher (ANA)	Jeff Ramirez (VA)
Karen Drenkard (AONE)	Deborah Nadzam (Cleveland Clinic)
Ellen Quinn (ASHRM)	William B. Kelly – (ex officio) USP Safe Medication Use Expert Committee

Alternates present:
        Judy Smetzer (ISMP)
        Louis Diamond (NPSF)

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

Delegates absent:
        Andrew Smith (AARP)
        William Ellis (APhA)
        Kasey Thompson (ASHP)
        Sal Peritore (GPhA)
        Mike Cohen - ISMP
        Rebecca DeVivo (NPSF)

Observers:

LCDR David Hardy (DoD)	Sherrie Borden (USP)	Marsha Protzel (USP)
Joanne Peterson (ISMP)	Susan Camp (USP)	John Santell (USP)
David U (ISMP-Canada)	Elizabeth Cowley (USP)	Marilyn Storch (USP)
Ed Staffa (NACDS)	Angie Long (USP)	Sue Zmuda (USP)
	Judy McMeekin (USP)	

David McCulloch (Uhlmann Packaging Systems, LP)   Kathy Muenchow (USP) (Transcriber)

Jerry Phillips called the meeting to order at 1:15 p.m. and asked everyone present to introduce him/herself and identify the organization for which he/she works.

Guest Presentation:
Ed Harrison, Director, Patient Safety, Pittsburgh Regional Healthcare Initiative
(PRHI) *– Migrating CQI Concepts from Other Industries to Healthcare: The Toyota Production System*

With more than 34 hospitals, PRHI's main goal is to reinvent healthcare to help every patient in Western Pennsylvania when they need it by adhering to a medication administration process that cuts across all departments. Pharmacists, other clinicians, and state officials recognize that medication errors happen in all sectors of hospitals. PRHI member hospitals are using USP's MedMARx℠ program and the Toyota Production System (TPS) to effect improvements in their healthcare system. TPS is a system in which activities are extremely rigid but operations are flexible and adaptable. The system can be learned by observing, describing, and experimenting to discover the underlying scientific principles, which can then be transferred to other settings. By watching a short clip from the sitcom "I Love Lucy", the NCC Members observed Lucy & Ethel working the conveyor belt wrapping candy in a chocolate factory. The group was able to grasp how that system was failing and how labor and management could work together to fix it. The four basic rules that underlie TPS have built-in tests to automatically signal problems. The four rules are: (1) All work should be highly specified; (2) There must be an unambiguous method of communication; (3) Everyone connected to a product or service is necessary; and (4) Improvement follows the scientific method at the lowest possible level. It is the response to problems that makes the system flexible and adaptable. The system is applied to healthcare by having administrators develop a hospital "learning line" while keeping the welfare of the patient in mind. PRHI has divided each task into its component parts and assigned a person to be responsible for that segment. The results produced increased compliance and improvements in areas of the hospital where changes were not even anticipated.

Report of meeting with AHRQ concerning collaboration on Practitioner Accountability Workshop and progress toward rescheduling workshop in Rockville

Structure and Function of Boards of Nursing: NCC MERP Practitioner Accountability Workshop
Kristin Hellquist, Associate Director of Policy and External Relations for the National Council of State Boards of Nursing (NCSBN) presented information about the structure and functions of the 61 Boards of Nursing in the U.S. She noted that Boards have no regulatory oversight and less than half of them have the authority to issue advisory opinions, even when asked to do so. Nursing Boards have been working with individual state task forces (i.e., state Patient Safety Task Forces) to reduce errors and have forwarded feedback to nursing schools for curriculum changes. The NCSBN and individual boards are working to educate nurses about medication errors at the institutional level and are working to promote remediation rather than punitive actions when medication errors do occur.

Progress on rescheduling the meeting; experiences with AHRQ visit seeking funds and support
Diane Cousins, Jon May and Jerry Phillips met November 21, 2001, with Nancy Foster at AHRQ regarding the possible USP/AHRQ collaboration on a Practitioner Accountability Workshop and applying for a grant to fund this workshop. AHRQ collaboration with NCC MERP did not spark any specific interest and the time frame for applying for a small conference grant was too short to meet AHRQ's deadline. Tentative plans to reschedule the Conference to Rockville in October

2002 were presented. The proliferation of similar conferences by other health-related organizations resulted in a consensus of the Council was to forego the workshop and reframe the issue into another context. A survey of NABP and other licensing bodies would determine what issues are relevant and should be pursued by the Council.

> ***ACTION ITEM: Diane Cousins will act as lead for a subcommittee composed of Joe Cranston, Mary Gross, Linda Hanold, Jon May, Deb Nadzam, and Barbara Newman to prepare a questionnaire to determine the necessary topics for a possible accountability workshop.***

The meeting was adjourned at 5:15 p.m.

The Steering Committee met in Executive Session to discuss new memberships and renewals.

Council delegates present:

Jerry Phillips (FDA), Chairperson	Linda Hanold (JCAHO)
Diane Cousins (USP), Secretary	Jon May (NABP)
Joseph Cranston (AMA)	Barbara Newman (NCSBN)
Rita Munley Gallagher (ANA)	Alan Goldhammer (PhRMA)

The Steering Committee unanimously voted to approve the following organizations for membership:

New Member:

US Department of Defense in the category of Government Agencies for a period

of two years.

Membership Renewals:

Department of Veterans Affairs in the category of Government Agencies for a period of two years
American Society for HealthCare Risk Management in the category of Risk Management/Quality Assurance for a period of two years.

National Coordinating Council for Medication Error Reporting and Prevention

February 7, 2002
Day Two

Council delegates present:

Jerry Phillips (FDA), Chairperson	Lisa Clowers (HDMA)
Diane Cousins (USP), Secretary	Judy Smetzer (ISMP)
Andrew Smith (AARP)	Linda Hanold (JCAHO)
Janet Myder (AHCA)	Jon May (NABP)
Joseph Cranston (AMA)	Barbara Newman (NCSBN)
Rita Munley Gallagher (ANA)	Alan Goldhammer (PhRMA)
Karen Drenkard (AONE))	Jeff Ramirez (VA)
Tom Clark (ASCP)	Dave Hardy (DoD)
Ellen Quinn (ASHRM)	Deborah Nadzam (Cleveland Clinic)
Kasey Thompson (ASHP)	William Kelly, USP Safe Medication Use
	Expert Committee

Alternates that attended with their delegates:
Mary Gross (FDA)
Shawn Becker (USP)

Delegates absent:
John Combes (AHA)
William Ellis (APhA)
Salvatore Peritore (GPhA)

Observers present:

Joanne Peterson (ISMP)	Judy McMeekin (USP)
David U (ISMP-Canada)	Kathy Muenchow (USP) (Transcriber)
Sherrie Borden (USP)	Marsha Protzel (USP)
Elizabeth Cowley (USP)	John Santell (USP)
Jennifer Devine (USP)	Meagan Sleman (USP) (Intern)
Rodney Hicks (USP)	Marilyn Storch (USP)
Angie Long (USP)	Sue Zmuda (USP)
Jeff McCulloch (Uhlmann Packaging Systems)	

Jerry Phillips, Chairperson, called the meeting to order at 8:47 a.m. and announced the results of the Executive Session. The Steering Committee voted to renew the Regular Membership status of ASHRM and the Department of Veterans Affairs. Jerry also reported that the Department of Defense was voted in as a new member of the Council.

Discussion of the Acceptance and Adoption of the Council's Bar Coding Recommendations

Diane Cousins reported on the amount of exposure and excellent reception that the Council's bar coding recommendations were afforded. She provided a list of publications that carried the news regarding the release of the bar coding recommendations.

Jerry Phillips reported that the FDA announced in December 2001 that it was moving forward in adopting a regulation on bar coding. A meeting is planned for this spring to obtain public response before an agency rule is proposed. Alan Goldhammer noted that the pharmaceutical industry would prefer that FDA not specify what system of bar coding should be used. Coding primary information is not a concern; however, there is no equipment for high-speed reading of secondary identifiers. The Council may want to enlist the services of John Roberts at UCC, who is an expert in the field and can answer question about omni-directional and uni-directional scanners. Joe Cranston reported that at its December meeting the AMA House of Delegates issued a resolution supporting the use of bar coding. Jerry noted that Tommy Thompson, Secretary of HHS, has also publicly supported its use. It was moved, seconded, and carried to proceed with a second-generation white paper that would include recommendations for front line practitioners.

ACTION ITEM: Alan Goldhammer will lead a subgroup composed of Kasey Thompson, David Hardy, Lisa Clowers, Judy Smetzer, Jeff Ramirez, Ellen Quinn, John Combes, and Diane Cousins to draft a white paper to assist front-line practitioners in the use of bar codes. The draft will be presented at the next meeting of the Council.

Guest Presentation:
    David U, President & CEO, ISMP-Canada – Report on the use of the NCC MERP *Taxonomy in the computer software program, Analyze-ERR Reporting System*

ISMP-Canada is involved in the Canadian programs for reducing medication errors. It receives reports of errors, recommends prevention strategies, and publishes error prevention alerts. Analyze-ERR has five beta hospitals and 250 records to date. David U described Analyze-ERR and showed how parts of the NCC Taxonomy are used in the program. In the course of the presentation, it became obvious that the Taxonomy was not used in its entirety, as was the intention of the NCC MERP permission of use. This was an apparent misunderstanding by ISMP-Canada and led to a discussion of whether the Taxonomy should be approved for partial use.

The intention of the Council for establishing the Taxonomy was to establish a nationally recognized standard that would be used in its entirety. However, as ISMP-Canada indicated, there is increasing evidence in many instances that only partial use of the Taxonomy is needed or wanted. Questions affecting current practice arose that would alter the use of the Taxonomy, such as (1) what would be the process for determining partial use and (2) are there critical elements that must be included?

ACTION ITEM: Jerry Phillips will chair a subcommittee with members including Bill Ellis, Judy Smetzer, Diane Cousins and either Rebecca DeVivo or Lou Diamond from NPSF, to review the Taxonomy and consider the following: partial vs total use, commercial vs noncommercial use, identification of critical fields, and development of a copyright statement that clearly identifies what portions of the Taxonomy are being used and/or for what use permission is being given. The subcommittee will also work on updating the process requiring feedback from those who are allowed to use the Taxonomy.

Diane Cousins reported that there has been no response from Cardinal Health who requested and received permission to use the NCC MERP Taxonomy despite repeated inquiries as to when they could present their use of the Taxonomy to the Council. DoctorQuality.com, who also sought permission to use the Taxonomy chose not the use the Taxonomy after Council permission had been granted, preferring to develop its own version.

Discussion of the NCC MERP draft on Medication Error Rates

Shawn Becker distributed the 7th draft of the *NCC MERP Recommendations for Use of Medication Error Detection Rates by Health Care Organizations*. Comments were noted concerning the document's name, its method of calculation, etc. The subcommittee was opened to other Council members wishing to assist in refining the document's text. All Council members were encouraged to review the documents and render comments to the subcommittee as soon as possible.

ACTION ITEM: Kasey Thompson, Tom Clark, Joe Cranston, and Ellen Quinn will join the original members of the Medication Error Rates Subcommittee to revise Draft 7, which will be sent electronically to the Council for review and approval in the interim period before the next Council meeting.

Reports of other NCC MERP Activities:
1. Evaluation of the Algorithm for Determining Error Types

Deborah Nadzam presented the Council with an algorithm for determining error types. The algorithm is currently in use at the Cleveland Clinic in support of its use of the MedMARx program and has proven useful. Every medication error is categorized but only once, so the first error is the one selected for error type. Additional work needs to be done to align the algorithm with the NCC MERP Taxonomy.

ACTION ITEM: Deb Nadzam will work with Judy McMeekin (USP) to refine current algorithm for medication administrators and develop additional algorithms dealing with prescribing, dispensing, and monitoring.

2. Training Programs for Non-licensed Personnel

Tom Clark, that Barbara Newman and Janet Myder sent a survey AHCA state affiliates to gather information on training of non-licensed personnel and reporting of medication errors in alternative settings. The survey showed that very little data is currently being collected on medication errors and there is little or no literature available on non-licensed personnel. It is recognized that problems do exit within these settings; however, there are very few reporting requirements and practically no organized system of reporting. Everyone would like to have data, but there is no central repository for error reporting. Some states, like California and Utah, are working to initiate voluntary reporting programs on their own. Training requirements for non-licensed personnel, if any, vary from state to state. More research needs to be done to determine the scope of errors and data collection.

ACTION ITEM: Tom Clark will lead a group including Barbara Newman, Janet Myder, and Drew Smith to draft recommendations for the training unlicensed personnel on the administration of medicines in alternative settings

Strategic Planning

Jerry Phillips proposed the establishment of a Strategic Planning Subcommittee comprised of the current and previous Chairs of the Council, as well as other strategic members, to review where the Council has been and what its future goals and projects should be. This group would include John Combes, Joe Cranston, Bill Ellis, Linda Hanold, Deb Nadzam, Kasey Thompson, Diane Cousins, and Jerry Phillips. Suggested areas included issues such as imprint coding and computer order entry. Council Members should e-mail any suggestions or ideas to the Secretary.

ACTION ITEM: Jerry Phillips will initiate a conference call of the Strategic Planning Subcommittee to discuss and report concepts at the meeting in June.

Formation of a Workgroup to develop Consumer Recommendations for Error Avoidance

The Council has refrained in the past from proposing recommendations for consumers for fear of duplicating the efforts of other organizations such as the National Consumer League, American Association of Retired Persons, and National Council on Patient Information and Education. Jerry Phillips suggested that the Council rethink this position and look for places where Council recommendations can fill in gaps of consumer knowledge. Several Council members acknowledged that they were on boards of outside organizations with whom the Council may want to consider collaborating with in an effort to disseminate any recommendations put forth by the Council.

ACTION ITEM: Lisa Clowers will lead the subcommittee of Alan Goldhammer and Drew Smith in developing and drafting recommendations appropriate to consumers.

Roundtable Update

♦ **FDA** (Jerry Phillips) –In December 2001 the FDA issued bar code recommendations with a hearing for public comment scheduled in the spring. The Office of Drug Safety has been reorganized to include new divisions and now reports to the Deputy Center Director. A drug safety advisory committee has been established with expertise in clinical trials and risk management. The creation of a panel on risk management has been cleared to be a full advisory committee.

♦ **USP** (Diane Cousins) -- USP is finalizing the MedMARx℠ 2000 Annual Report and it should be released before the June meeting. Work has already begun on the 2001 Annual Report. The Strategic Research Partnership, a group of 15 MedMARx subscriber hospitals, has been working with USP on a project to establish a standardized protocol and better practices for the drug heparin. An advisory group has been established to work with imprint coding and the USP is moving forward

with FDA on bar coding standards. The Safe Medication Use Expert Committee has been asked to consider USP's role in providing standards for CPOE.

♦ **JCAHO** (Linda Hanold) – JCAHO will be an active participant at the Annenberg Conference beginning April 22 in Indianapolis. It has been involved in meetings and workshops dealing with the culture of safety within organizations. In May it will convene a roundtable to discuss the issue of nurse staffing. A committee of board members has been appointed to look at a taxonomy for medical errors.

♦ **AMA** (Joseph Cranston) – There have been staff changes at the AMA with Joanne Turnbull and Linda Bresolin leaving. A resolution supporting the NCC MERP's bar coding recommendations was passed and Connie Morella was voted to receive a lifetime service award. Tom Houston is now the AMA alternate to NCC MERP.

♦ **ASHRM** (Ellen Quinn) – ASHRM was a participant in the National Patient Safety Fellowship Program, a program to train executives in patient safety risk management. Scholarships are available. They are working to change the reputation of hospitals to emphasize faith and trust in today's healthcare system.

♦ **PhRMA** (Alan Goldhammer) – PhRMA has had a favorable response to the Council's bar coding recommendations. It is working with the FDA to develop tools for risk management and cosponsored last spring the first of three CERTs conferences on risk assessment.

♦ **HDMA** (Lisa Clowers) – The bar code recommendations have been circulated within HDMA and will be a topic at the annual meeting in Pittsburgh this May. Drug availability continues to be a problem because of year-end closures of some drug companies. A task force was started to counter the bad publicity resulting from the short supply of flu vaccines. HDMA has been working on bioterrorism and other emergency preparedness.

♦ **ASCP** (Tom Clark) – ASCP has established an Assisted Living Coalition that will develop standards and guidance on medication use risk. The January issue of the *Journal* has information on long term care.

♦ **AHCA** (Janet Myder) – CMS is working to develop a survey for guidance to determine if facilities are providing vaccines and immunizations to patients who need them.

♦ **AARP** (Drew Smith) – The AARP continues to support and promote safe medication use and is in the formative stage of determining what the best message is.

♦ **ISMP** (Judy Smetzer) – ISMP will be forwarding a newsletter with funding from the Commonwealth Fund stressing patient safety to commercial pharmacies by July. AHA, HRET, and the Advisory Board are working on three tools: a technology readiness assessment tool for bar coding, a strategic plan for medication safety, and a compendium of risk assessment for FMEAs and ADRs. A 12-credit program on clinical risk assessment is now in its second year at Temple University School of Pharmacy. Ultimately, ISMP would like to expand the core courses to other pharmacy schools. ISMP will be participating in the Annenberg Conference and the ASHP summer workshops. ISMP now has three fellowship programs in place: managed care, scholar in residence and a traditional fellowship. The Delaware Valley local council is moving forward on 16 strategic objectives and there is interest from other communities.

♦ **ANA** (Rita Munley Gallagher) – *Principles of Nurse Staffing* series is continuing with several sections being recently added: delegation/supervision, redundancy of

documentation, and working with the CDC on adult immunization. The House of Delegates will review bar coding recommendations.

◆ **VA** (Jeff Ramirez) – The VA in Ann Arbor has been working on root cause analysis and human factor analysis. Their root cause software (SPOT) program is based on the NASA system. The second version of bar coding software has added IV and other routes of administration. Since September 11 the VA has been spending a lot of time dealing with emergency preparedness, working with the Department of Defense Disaster Preparedness and the CDC.

◆ **ASHP** (Kasey Thompson) – Bioterrorism and counter-terrorism information is now available on the ASHP web site. Also on the web site is the ASHP/ISMP task analysis of the medication safety officer position. ASHP has been meeting with pharmaceutical supply chain representatives regarding drug and staff shortages. ASHP is participating in the Annenberg Conference and is sponsoring a conference on Measures for Medication Safety in Hospitals April 8-9 in Tucson, AZ.

◆ **DoD** (David Hardy) – Since September 11 DoD has been concentrating on disaster preparedness and responses. It has been working closely with USP in developing a multi-facility module for the MedMARx program, which is now being used in over 100 DoD facility worldwide. DoD has developed the second generation computerized patient record-keeping system and is working with the VA on a prescription drug refill by mail program to facilitate access to medical facilities when bases are locked down for security. It is attempting to enhance its computer order entry system and incorporate a full range of market functionality. DoD has co-signed a letter on bar coding and is working the supply chain angle.

◆ **NABP** (Jon May) -- NABP has been researching Internet and overseas pharmacies to investigate the proliferation of counterfeit drugs. Federal (HHS) assistance has been requested to control illegal, illegitimate web sites and sales and there is movement to require that all Internet pharmacies be licensed by the NABP. Pharamacist.com is a new web site recently launched jointly by NABP and APhA that provides community pharmacies with a one-stop portal offering information, education, and late-breaking news. It has links between pharmacist.com and the individual NABP and APhA web sites. The Missouri State Board of Pharmacy has initiated a non-punitive quality assurance program that addresses prescription discrepancies through a systems approach. Though the program has some limits, it has been successful in recognizing and decreasing error rates. As the last state not to recognize multi-state testing and license reciprocation (NAPLEX), California State Board of Pharmacy voted to begin using NAPLEX to satisfy its requirements for professional licensing. Before this can happen, the California legislature must enact legislation and a separate California jurisprudence exam put unto place. The earliest possible start date would be January 1, 2003.

◆ **NCSBN** (Barbara Newman) – Bar coding recommendations were shared with the Board on March 5. NCSBN will hold is mid-year conference in Chicago. It has been working with the Citizens' Advocacy Council on a joint study to gather national data on rising trends and to develop a best practice model for nursing boards.

Jerry Phillips wrapped up the meeting with a list of the eight subcommittees that came out of the meeting:

> Taxonomy
> Consumer Recommendation

   Medication Error Rates
   Strategic Planning
   Non-Licensing Personnel Training
   Practitioner Accountability
   Algorithm for Types of Errors
   Bar Coding
Each of these groups will teleconference and report back to the Council at the June meeting.

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