February 20, 2001
Day One

Council delegates present:

Jerry Phillips (FDA), Chairperson	John Santell (ASHP), Vice Chair
Diane Cousins (USP), Secretary	Linda Hanold (JCAHO)
John Combes (AHA)	Jon May (NABP)
Janet Myder (AHCA)	Barbara Newman (NCSBN)
Rita Munley Gallaghr (ANA)	Lisa Hanlon Wilhelm (NPSF)
Tom Clark (ASCP)	Jeff Ramirez (VA)
Monica Berry (ASHRM)	Deborah Nadzam (Cleveland Clinic)

Art Atkinson – (ex officio) USP Safe Medication Use Expert Committee

Alternates attending with their delegate:
Shawn Becker (USP)

Delegates absent:
Andrew Smith (AARP)
Joseph Cranston (AMA)
Michael Cohen (ISMP)
William Ellis (APhA)
Alan Goldhammer (PhRMA)
Tom Schafer (HDMA)

Observers:

Sal Peritore (GPhA)	Sherrie Borden (USP)
Kristin Hellquist (NCSBN)	Rita Calnan (USP)
Terry O'Brien (Meds-Alert USA)	Elizabeth Cowley (USP)
Burton Schultz (Meds-Alert USA)	Judy McMeekin (USP)
	Marilyn Storch (USP)
	Sue Zmuda (USP)

Jerry Phillips called the meeting to order and initiated a discussion of how the Council wished to deal with presentations by guest speakers at regular meetings. These presentations should be categorized as informational/educational for members and not as a method of obtaining Council endorsement of products. It was decided by the membership that prior to the scheduled meetings those associations/individuals wishing to present will be required to send materials relevant to the topic to the Secretariat for distribution to the Council members. The Council would then vote on whether to extend an invitation for a presentation at its next regularly scheduled meeting.

Current Activities

Written reports were distributed by the following organizations:
- HDMA
- NABP
- JCAHO
- AHA
- NPSF
- ASCP

Verbal updates follow:
- **NPSF** (Lisa Hanlon Wilhelm) **--** The Annenberg 3 Conference is scheduled for May 16-18 in St. Paul, Minnesota. The focus will be on communications regarding medication errors between patients and health care professionals.
- **ASHP (**John Santell) – ASHP is putting together a list of must-ask questions for computerized order entry systems.
- **Cleveland Clinic** (Deborah Nadzam) – Provided an update on the status of information available on automation. Products are available for automation, but the problem lies with integration within existing systems. There is information available on automation; however, no white paper exists that covers all aspects of the subject. Council should consider holding a conference on the issues surrounding automation. Discussions arose regarding the need for further investigation of the issues before the Council rushes to set up a nation-wide conference.

ACTION ITEM: Subcommittee needs to plan a conference on automation with a written document addressing the issues and work done to date. Plan needs Council approval before moving forward.

  Deborah also mentioned that The Cleveland Clinic will be hosting a program about automation to promote patient safety, with speakers including Ken Kizer, Jeff Ramirez, Jay Crowly, Ray Vanderbilt, and David Woods.
- **NABP** (Jon May) -- The NABP has a written document pertaining to patient safety that he will obtain for the Council's perusal. Pharmacy errors are exceeding acceptable rates and must come down. The NABP Model Pharmacy Act proposes minimal standards for pharm tech personnel. The California State Senate Bill (13-39) provides for a medication error system in every pharmacy by January 1, 2003 with a Quality Assurance Program that documents medication errors (not subject to discovery). The web site is www.leginfo.ca.gov.
- **NCSBN** (Barbara Newman) – NCSBN is working with the Citizens Advocacy Council exploring alternative disciplinary models. The pilot project started in November 2000, with test sites in Maryland and Colorado. Its focus will be on how complaints are handled. At its mid-year meeting March 6-7 in Chicago the NCSBN will be focusing on patient safety and the prevalent shortage of nurses. Speakers for the meeting include individuals from the George Mason Center for Health Policy and Ethics and from JCAHO. Following the mid-year meeting a summit on the use of unlicensed personnel will be held on March 8.

- **ASHRM** (Monica Berry) –Monica announced that she has changed jobs but will still represent ASHRM, since she is the president-elect for ASHRM. They are busy developing the agenda for their annual meeting in October 2001. There is a patient safety track and practitioner accountability track. Risk managers have shown concern over the HIPPA regulations.
- **AHCA** (Janet Myder) – AHCA has been focused on nursing hours. HCFA has drafted Quality Indicators for medications that will serve as manual guidance for nursing home inspectors and surveyors to make decisions that are in patients' best interests. Currently, HCFA gives surveyors the authority to second-guess medical decisions.
- **ANA** (Rita Munley Gallagher) – ANA is focusing on the shortage of nurses in healthcare institutions and the obvious involvement with medication errors. Shortage concerns are different from hostile environment issues and the need to protect whistle-blowers.
- **ASCP** (Tom Clark) –A series of articles on assisted living have highlighted the number of medication errors occurring in this type of facility. Causes include the lack of regulation and oversight for these facilities and the fact these facilities are supervised by unlicensed personnel. In nursing homes, medication administration is overseen by consultant pharmacists. Since assisted living has become a major concern, the ASCP has expanded its web site www.ascp.com to provide more information. They are working on the development of a medication safety alert system similar to the class recalls currently being used. Instead of the numerous reporting forums now available, Tom Clark proposed an independent, centralized web site with links to invested parties or an 800 line to report ADRs, medication errors, etc. Calls would be forwarded to the appropriate agency. Tom Clark distributed a summary of the February 7th meeting held at ASCP regarding medication safety and reporting of adverse drug events.
- **JCAHO** (Linda Hanold) – The upcoming Annenburg 3 Conference will be May 17-19 in St. Paul, MN. The Solutions 2000 Conference Compendium will be coming out very soon. In July 2001, JCAHO will be issuing patient safety standards that will impact all hospitals seeking to continue JCAHO accreditation.
- **VA** (Jeff Ramirez) – VA is in the throws of bar coding. Even though 92 % of wards have bar coding at bedsides, there have been some stumbling blocks. Regulations have been drafted for CPOE and VA is working with the DEA to expedite the use of electronic signatures.

Medication Error Rates Subcommittee Update
Shawn Becker

The subcommittee on medication error rates (Shawn Becker, Jerry Phillips, Joe Deffenbaugh, Monica Berry, and Deborah Nadzam) has drafted the background material on error rates and developed preliminary recommendations. The committee will reconvene via teleconference to finalize the first draft for presentation to the Council at the June meeting. More consideration must be given to gathering information about potential errors and establishing a correlation between potential errors and sentinel events. Any conclusions by the Council should be circulated to the USP Safe Medication Use Expert Committee for its input.

Request to modify the NCC MERP Recommendation to Reduce Errors Related to Administration of Drugs
Diane Cousins

A request was received from Ketan Premani to modify the Administration Recommendations to include the name and strength of a medication. Mr. Premani felt that this would ensure that the person administering the medicine could check the medicine at the last stage before ingestion. The Council did not agree with changing the Administration Recommendations and felt that this should be covered in the Labeling Recommendations.

ACTION ITEM: Check the labeling recommendations to make sure this topic is covered. Make as a minimum standard.

Requests for Permission to Use NCC MERP Medication Errors Taxonomy
Diane Cousins

The Council reviewed two requests for permission to use the Taxonomy. ISMP Canada requested permission to use the taxonomy in a revenue-generating product. Permission was granted. DoctorQuality.com requested to use only part of the Taxonomy for a fee based reporting system for medical errors and permission was denied as specified previously for this selective use. Dr. Quality.com will be informed that they can use the Category Index as adopted by the Council. A question was raised as to whether the Council should look at the Taxonomy with the prospect of broadening the scope to include adverse events (medical errors). Since this is outside the scope of the NCC MERP, a call or petition could be made to an outside entity, such as the NQF.

ACTION ITEM: Check to see whether or not groups that have been granted permission to use the Taxonomy have ever incorporated the Taxonomy into their projects as proposed.

It was moved, seconded, and carried that companies that have been granted permission to use the Taxonomy will provide a written report and a visual presentation to the Council within three months of marketing their product or at the next meeting of the Council following that period.

The Orlando Regional Healthcare System was granted permission to use the NCC MERP taxonomy section 30:Patient Outcome: NCC MERP Categorization Index.

Diane Cousins read an e-mail message from a VA hospital that adopted the Council's category index and has been using it for the past 3 years. They noted numerous improvements. While not seeing any national reporting benchmarks from the Council, their reporting increased 400%.

Verbal Orders Subcommittee, Report of Balloting for Approval
Shawn Becker

The balloting proved inconclusive for the finalizing the verbal order recommendations. Eleven members approved the recommendations as drafted, two members approved with changes, one member abstained, and two members sent questions and comments without a ballot. Each recommendation was reviewed with the entire Council and changes made accordingly. The recommendations were reworked, finalized and approved. The finalized version will be posted on the NCC MERP web site and a press release will be generated.

Invitation for Membership
John Santell

A suggestion was made regarding possibly increasing the size of the current Council. Slots are available for two nursing and two physician groups, as well as at large and individual members. It was decided that invitations would be sent to the American Organization of Nurse Executives (AONE), the American Academy of Family Physicians (AAFP), the American College of Physicians/American Society for Internal Medicine (ACP/ASIM), and the Nursing Organization Liaison Forum (NOLF) to join the NCC MERP.

The meeting was adjourned at 5:08 p.m. The Steering committee met in closed session immediately following the adjournment.

Council delegates present:

Jerry Phillips (FDA), Chairperson   Salvatore Peritore (GPhA)
John Santell (ASHP), Vice Chairperson   Linda Hanold (JCAHO)
Diane Cousins (USP), Secretary   Jon May (NABP)
John Combes (AHA)   Barbara Newman (NCSBN)
Janet Myder (AHCA)   Lisa Wilhelm (NPSF)
Rita Munley Gallagher (ANA)   Alan Goldhammer (PhRMA)
William Ellis (APhA)   Jeff Ramirez (VA)
Monica Berry (ASHRM)   Deborah Nadzam (Cleveland Clinic)
Tom Clark (ASCP)
Art Atkinson, USP Safe Medication Use Expert Committee

Alternates present:
Lisa Clowers (HDMA)

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

Delegates absent:
Andrew Smith (AARP)
Joseph Cranston (AMA)
Michael Cohen (ISMP)

Observers present:
Kristin Hellquist (NCSBN)
Terry O'Brien (Meds-Alert USA)
Burton Schultz (Meds-Alert USA)

Jerry Phillips, Chairperson, called the meeting to order. The first order of business was to announce the results of the Steering Committee's closed session deliberations. It was determined by the Steering Committee that the Founding Members would remain as originally constructed, and that an expansion of the Steering Committee would not occur at the present time. The Steering committee also voted to allow the Generic Pharmaceutical Association to replace the GPIA with founding membership status. Salvatore Peritore is the new GPhA delegate. Jerry welcomed Mr. Peritore and GPhA to the Council. Mr. Peritore was asked to provide background on his position in GPhA.

Unfinished business

Bill Ellis and Alan Goldhammer were absent on Day One and wished to report.

- **APhA** (Bill Ellis) – APhA has joined the APhA Foundation and NACDS in co-sponsoring work with ISMP to create a medication safety self-assessment for ambulatory and long-term care pharmacies. The goal is to have this available by May 2001. The Council's endorsement of such a self-assessment would support the concept of a safety self-assessment, not necessarily the actual language. ISMP would collect and analyze the data as it did for the hospital self-assessments. APhA is promoting the idea of reporting with an article in the February issue of *Pharmacy Today* and a column in the March/April issue of the *Journal*, which will include a history of the Council and list the various ways by which people can report medication errors.

- **PhRMA (Alan Goldhammer)** – PhRMA co-sponsored with the FDA and the American Association for the Study of Liver Diseases a two-day study on the improvement of lymphatic toxicity drugs. Additionally, they will be working with USP on solid oral dosage forms. The concentration will be primarily on new drugs entering the market, leaving the older drugs to be dealt with at a later time.

Bar Coding Subcommittee Report
Jerry Phillips

It was suggested by the Chairperson that the bar coding recommendations be separated from the complete paper and released separately as an executive summary in conjunction with a press release. The introduction could be pared down into a preamble for the executive summary and a reference could be made that the conference summary was available if requested. The summary should also be sent directly to major organizations alerting them of the finalized recommendations. The entire text of the white paper will be posted on the NCC MERP web site. Discussion ensued regarding the use of references to make the point that bar coding supports patient safety. References are part of the completed document and reference 5,6 and 7 appear to support the document. Jerry Phillips will verify the references associated with the background. It was discussed and agreed upon that the data elements of a bar code shall include the NDC number as the unique product identifier, the lot/ batch/control number, and the expiration date. The existence of both 10-and 11-digit NDC numbers needs to be addressed by key stakeholders (FDA and HCFA). However, a uniform NDC number must be part of the bar code and the elements of the bar code must be uniformly ordered. The UCC should determine the actual format of the bar code. Considerable discussion surrounded the terms unit-of-use, unit dose, immediate container, SKU, etc. Also open to discussion was the concern about what facilities the recommendation applied to. Is it for hospitals, outpatient pharmacies, or community pharmacies? It was moved, seconded, and carried to add a statement clarifying that the focus of the recommendations is on inpatient health systems. If a bar coding system is implemented there are several barriers to implementation that should be addressed, including work-arounds, culture changes, and costs. These issues were perceived as major concerns that would have to be overcome on a step-by-step basis if a bar coding system for medication administration were to ever be considered viable. It was moved, seconded, and carried to accept the bar coding recommendations as edited during the meeting.

ACTION ITEM: The Council will be balloted to release the entire document.

Meeting Summary - Draft

After lunch the three versions of the verbal orders were voted on. It was moved, seconded and carried to accept version 3 with added words "Confusion over the similarity of drug names accounts for approximately 25 percent of all reports of the USP medication errors reporting program. To reduce confusion pertaining to verbal orders and to further support the Council's mission to minimize medication errors, the following recommendations have been developed."

Practitioner Accountability Workshop Subcommittee
Jerry Phillips/Judy Smetzer

The subcommittee presented a draft format and agenda for a workshop in October 2001, to be held at the National Press Club in Washington, D.C. Judy Smetzer and Janet Myder joined discussions via teleconference. The focus of the workshop would be the debate between personal accountability and systems thinking in terms of error and where those two intersect and join. The issue at stake is to create a balance between accountability and creating a blame-free environment that encourages learning and professional growth. A question was raised as to whether the workshop should be limited to medication errors or broadened to include medical and healthcare errors. The subgroup felt that there was little difference in how the different errors were handled and, therefore, the Council could choose to make the title broader, keeping in mind that the Council's expertise is in medication errors. A proposed option was to have the workshop deal with medication errors and conclude by saying that the processes and models could be expanded to include medical and healthcare errors. It was voted to have the title and workshop limited to medication errors. The proposed topics of the workshop are:
- What should a system accountability model look like?
- How can accrediting and regulatory bodies best use information collected through reporting programs?
- Is practitioner involvement in errors a measure of competency?

Although costs for the workshop are considered to be relatively low, it was discussed whether or not to apply for an AHRQ grant if the parameters of the workshop are within the AHRQ research agenda.

It was moved, seconded, and carried that the workshop would take place and that the subcommittee would rework the document to include balance between individual practitioner accountability and system accountability. It was also moved, seconded, and carried that the name of the workshop would be "The NCC MERP Workshop on Medication Errors and Practitioner Accountability—Emerging Models and Approaches." The coordination of remaining work will be done through the Office of the Secretariat to provide balanced views in work product and to hasten programs

ACTION ITEM: **Diane Cousins will establish a process for written responses for reworking the draft in order to address concerns for balance within the background and workshop goals. The document will be balloted by the Council before the June meeting.**

Category Index Subcommittee
Linda Hanold

Discussion centered on whether or not the definition of harm assumed an intervention. In effect, this would revert to the Council's original definition of harm. Harm without an intervention would be difficult, if not impossible, to track in a healthcare system because without an intervention it would not be possible to tell if an error occurred. An assumption was made that the algorithm is not going to be able to deal with those errors that have harm but no intervention. It was moved, seconded, and carried to accept the algorithm as modified and presented. It was also moved, seconded, and carried to accept the circular index with the refined definition.

The revised bar coding recommendations were distributed to the members for review.

ACTION ITEM: **Diane Cousins will e-mail the bar-coding draft to the Council, incorporate any comments, and then ballot the Council for final approval.**

The meeting adjourned at 3:09 p.m.

NCC MERP Meeting Summary Ballot
February 20-21, 2001

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 August 3, 2001, by mail or fax to:

Diane Cousins
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12601 Twinbrook Parkway
Rockville, MD 20852

Fax: 301-816-8532