June 19-20, 2003
Day One

Council delegates present:

John Combes (AHA), Chairperson	Tom Clark (ASCP)
Linda Hanold (JCAHO), Vice Chair	Kasey Thompson (ASHP)
Diane Cousins (USP), Secretary	Sal Peritore (GPhA)
Joseph Cranston (AMA)	Jon May (NABP)
Rita Munley Gallagher (ANA)	Ray Bullman (NCPIE)
Ellen Quinn (ASHRM)	Alan Goldhammer (PhRMA)

Alternates attending as representatives of their organizations:
Kristin Hellquist (NCSBN)
Veronica Oven (AONE)

Delegates absent:

Andrew Smith (AARP)	Lisa Clowers (HMDA)
Janet Myder (AHCA)	Judy Smetzer (ISMP)
William Ellis (APhA)	Ed Staffa (NACDS)
Ron Nosek (DoD)	Robert Krawisz (NPSF)
Jerry Phillips (FDA)	Jeff Ramirez (VA)

Deborah Nadzam (Cleveland Clinic)
Bill Kelly (ex officio) USP Safe Medication Use Expert Committee

Observers:
Megan Mok (Peoplechart)
Susan Camp (USP)

John Combes (AHA), Chair, welcomed the Council members and called the meeting to order. He preceded with a brief overview of the day's agenda and the subcommittee reports that would be covered. Introductions were made around the room and the following announcements were made:

- Reports have been forwarded to the Chair, as well as ISMP, that unlike medication prep areas that have overhead lighting, NICU areas are not well lit and this could conceivably be leading to errors. Anyone with information about this issue should speak with the Chair. The Practice-Related Issues Subcommittee will address this issue.

ACTION ITEM: Diane Cousins will provide examples of reports of errors in medication prep areas with overhead lighting.

- The bar code recommendations were published in *Pharmacy Voice* and by a Japanese newspaper company.
- Deb Nadzam (Cleveland Clinic) did a Google search on the Council and found some interesting linkage. Word is getting out and references to the Council are becoming very frequent.

- Several requests have been received for Council membership – David Kotzin (GBMC) has applied for an individual membership and the Spanish Society of Hospital Pharmacy has applied as an "At-Large" member. Both applications will be considered during an Executive Session after the close of business today.
- Megan Mok gave a short explanation of Peoplechart, an independent service provider that offers an integrated patient-centric solution for the management of medical records and health information. Informational materials were available on the back tables.
- Diane Cousins (USP), Secretary, announced the results of the recent ballot for Chair and Vice Chair of the Council. John Combes was reelected as Chair and Linda Hanold was reelected as Vice Chair.

Subcommittee Reports:

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

The Practice-Related Issues Subcommittee held one conference call since the last Council meeting. Two items were on the agenda for the call – the Recommendations for Non-Healthcare Settings and "Just Culture"/Systems Improvement and Practitioner Accountability.

A final draft of the Recommendations for Non-Healthcare Settings was distributed for ballot by the Secretary with a resultant approval vote of 16-3. Technically, the recommendations were adopted and could be released to the public. However, comments on the balloting forms indicated that several editorial changes might enhance the document. The Council decided to review changes that were suggested on the ballots and multiple motions were made and subsequently withdrawn.

Action Item: Joe Cranston and Diane Cousins will redraft the Recommendations for a final vote on Friday. NCPIE will assist with distribution of the Recommendations. Any questions received by Council members or officers should be directed to the full Council for consideration. Tom Clark volunteered to field questions if needed.

The Subcommittee was asked for its recommendations regarding a Practitioner Accountability workshop based on amplified interest from David Marx's presentation on "Just Culture" at the February meeting. The Subcommittee agreed that the issue is important and worthy of the Council's attention. However, it would not consider the program viable unless travel funding was provided for all participants. At the present time, the group believes that a literature search with a follow-up discussion paper should be the next steps for the Council. Several members were not interested in pursuing the workshop and felt the Council was not the right forum for disciplinary issues. Their opinion was that the Council should focus on promoting reporting and recommendations.

Alan Goldhammer suggested that the guiding principles developed by the Patient Safety Coalition be put on the agenda for the next meeting for discussion of endorsement

by the Council. The principles will be sent to the Taxonomy Subcommittee for evaluation and recommendations.

Action Item: The Taxonomy Subcommittee will evaluate the guiding principles of the Patient Safety Coalition and make recommendations for endorsement at the next meeting.

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

The Subcommittee has not been able to successfully poll users of the Taxonomy. There is potential but the Subcommittee can't progress any further without communicating with users. It was suggested that something be posted on the web site and that MEDMARX users be contacted.

University HealthSystem Consortium requested permission to incorporate a modified version of the NCC MERP Category Index into its Patient Safety Net, an on-line incident reporting system. The modifications would involve dividing Category B errors into B1(error occurred because of chance) and B2 (error did not reach the patient because of active recovery efforts by caregivers). Additionally, a Category X would be added for errors for which harm could not be assessed at the time. The Council voted to allow the split of Category B errors with the stipulation that whenever Category B is mentioned, it will be noted that this is a deviation from the NCC category. The addition of Category X was denied because the Council felt that harm cannot be undetermined. UHC's definition for Category I did not include "may have" which alters the definition. It was suggested that a temporary code be used, such as Category D, which requires monitoring. The changes to Category B were approved and permission granted with the stipulation that the Council would receive feedback in six months on user applicability. Also, the Council requested a presentation after one year to evaluate the data collected. Modifications on other category definitions were denied.

Action Item: Ellen Quinn will work with Diane Cousins to obtain a list of Taxonomy users.

Technology – Sal Peritore (GPhA), Chair

There was a general consensus on the issue of bar coding, with GPhA and PhRMA somewhat concerned with how all required information would fit on small packaging. A waiver process was discussed as an alternative to having exemptions to the rule. OTC products could present a problem because there is limited space available on blister packs for bar coding. Bar coding is also cheaper than initiating a CPOE system and, therefore, may be more readily acceptable. Speaking for ASHP, Kasey Thompson indicated that ASHP was more than willing to take on added responsibility to promote bar coding.

The meeting was adjourned at 5:00 p.m.

Day Two
June 20, 2003

Council delegates present:

John Combes (AHA), Chairperson
Linda Hanold (JCAHO)
Diane Cousins (USP), Secretary
Joseph Cranston (AMA)
Ellen Quinn (ASHRM)
Tom Clark (ASCP)
Kasey Thompson (ASHP)
Ron Nosek (DoD)
Salvatore Peritore (GPhA)
Judy Smetzer (ISMP)
Jon May (NABP)
Ray Bullman (NCPIE)

Barbara Newman and Kristin Hellquist attended representing NCSBN

Delegates absent:

Andrew Smith (AARP)
Janet Myder (AHCA)
Rita Munley Gallagher (ANA)
Karen Drenkard (AONE)
William Ellis (APhA)
Jerry Phillips (FDA)
Lisa Clowers (HDMA)
Ed Staffa (NCPIE)
Debra Brady (NCSBN)
Robert Krawisz (NPSF)
Alan Goldhammer (PhRMA)
Jeff Ramirez (VA)
Deborah Nadzam (Cleveland Clinic)*
Bill Kelly (ex officio) USP Safe Medication Use Expert Committee*

Observers present:

Megan Mok (Peoplechart)
Susan Camp (USP)

*By phone for David Marx's presentation only

John Combes, Chairperson, called the meeting to order and welcomed everyone to the second session of the meeting.

Presentation:* David Marx, JD, President, Outcome Engineering, *Socio-Technical Probabilistic Assessment

Probabilistic Risk Assessment (PRA) is a process for prioritizing risk using probability. It helps build a visual map (fault tree) of risk by modeling the way in which risk occurs in a hospital, showing relative rankings of most likely to least likely estimates of individual errors and at-risk behaviors. Within a mechanical system, redundancy is built into the process to compensate should one component fail. However, equipment PRAs have not coped well with human error, as people breakdown redundancy, leading to a rise in error rates. The PRS model consists of dependent and independent variables. It identifies the top level risk and helps pinpoint key safety behaviors. Important to note is that the estimated percentage of error reductions is only a guestimate and the model is not a harm predictor. The scientific validity of the model is dependent on the confidence of

people in the model. Models can become very large very quickly. PRS enables hospitals to identify safety nets for errors and to evaluate complex systems without becoming overwhelmed by the process.

Recommendations to Reduce Medications in Non-Health Care Settings

A revised version of the recommendations was presented to the Council. Joe Cranston moved and Tom Clark seconded to accept this version as final for the recommendations. The Council approved the recommendations.

***Presentation: MER System & At-Risk Behavior,* Judy Smetzer (ISMP & Diane Cousins (USP)**

Judy Smetzer and Diane Cousins evaluated 100 random MER reports for instances of at-risk behavior. At-risk behavior was defined as intentional actions that could endanger a patient but were within tolerable and acceptable limits. The behavior is deemed acceptable based on a facility's culture and system. Behavior needs to be managed and can be utilized to promote best practices. It was suggested that the Council may want to produce a paper on the topic with the focus on safe behaviors instead of at-risk behaviors. Three groups (John Combes/Linda Hanold, Ron Nosek/Judy Smetzer, and Ellen Quinn/Diane Cousins) volunteered to divide 200 random electronic MER records and evaluate them for at-risk behavior. David Marx offered to work with the three groups to build a PRA around the data and apply it to a high risk level model. The Council should raise the bar on acceptable behaviors and provide facilities a template to assist them in addressing at-risk behavior within their organizations.

Action Item: John Combes and Diane Cousins will present the methodology for evaluating the MER records and building a PRA. They will report back to the Council at the October meeting.

Roundtable Discussion

ASHP (Kasey Thompson) – Kasey's title has changed to Director, Practice Standards & Quality Division, with a subtitle of Director, Patient Safety. ASHP is hosting a CPOE technology program in Dallas on October 27, 2003.
AMA (Joe Cranston) – AMA has been working with ASHP on the drug shortage problem; they have asked the FDA to convene a meeting to identify/implement solutions. AMA has evaluated and commented on the FDA's Risk Management Programs "concept paper". AMA has raised concerns with FDA's decision to allow "qualified health claims" on convention foods. The AMA's Council on Ethical and Judicial Affairs has issued a report on medical errors and the physician's ethical responsibilities. Among its recommendations, the report says that physicians have an ethical responsibility to prevent errors, physicians should be involved in the analysis of errors that occur, and physicians should explain to patients the nature of any errors and what measures have been taken to prevent the error from recurring.

NCPIE (Ray Bullman) – NCPIE, working with AHRQ, has developed a consumer brochure entitled "Your Medicine, Play It Safe". It is also providing comments on and taking part in the July 31 FDA meeting on pharmacy-generated information for patients leaflets. FDA is calling on stakeholders to establish criteria for useful information and to make improvements in the quality of information.
NCSBN - Barbara Newman announced that NCSBN will be celebrating its 25th anniversary at its annual meeting August 5-8 in Alexandria, VA. In July it will be issuing its "Steps to Ensure Continuing Competence…" NCSBN is a co-sponsor of the Citizens Advocacy Center Conference November 13-15 and will be presenting a session on patient safety.
NABP (Jon May) – NABP is participating in the July 31 FDA meeting on pharmacy-generated patient safety leaflets. The issue is of importance to NABP because if the criteria are not met, FDA may federally mandate what must be included in the leaflets.
JCAHO (Linda Hanold) – JCAHO has reorganized and has created a new center for patient safety under the Department of Health Policy Issues with Andrew Chang, an attorney by background, as director. Overcrowding in emergency departments has led JCAHO to issue a call to action. According to Marilyn Chow of the Nursing Advisory Council there are currently 126,000 unfilled nursing positions, which severely limit the ability to respond to critical situations. JCAHO is working on a new standard that will include the effective monitoring of patients, performance indicators, the use of temporary beds, and pre-hospital resources.

Action Item: At the October meeting JCAHO will present its medical error taxonomy and Jim Battles will be invited to present an update on AHRQ and the report of the IOM Patient Safety Data Standards Committee.

GPhA (Sal Peritore) – GPhA participated in the FDA bar coding meeting and supported complying with the exemption.
ASHRM (Ellen Quinn) – ASHRM's annual conference is scheduled for November 2-5. Shawn Becker (USP) will be presenting on medication error reporting.
ISMP (Judy Smetzer) – Judy updated the Council on ISMP-Canada's use of the Analyze-ERR program. Currently 15 Ontario hospitals are using the program with approximately 40 hospitals implementing it this year. Within a 9-month period 4500 medication error reports have been received. Using the built-in analytical tool, error data have been used to provide assistance in identifying improvement projects and relevant information for reporters and the Safety Bulletins.
DoD (Ron Nosek) – DoD has appointed Ron Nosek as Interim Director of the DoD Patient Safety Center until a new Director can be hired. 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. DoD has made extensive use of MEDMARX training and is developing an overall error database. The Navy is internally developing a dangerous abbreviation policy and is working to build a curriculum for the military medical school and pharmacy tech training that incorporates JCAHO standards.
AHA (John Combes) – AHA has released a quality initiative that has 800 hospitals reporting on 10 standard quality measures to a public website. Twenty states have already endorsed the program. AHA is also working on new indicators to be developed on 20 priority areas

singled out in the IOM report. Using its bar code readiness tool, AHA has been working been working in conjunction with HRET in implementation of CPOE. Writing strategic plans and getting teams proactively involved in hazard analysis is just a part of what is involved.

USP (Diane Cousins) – USP worked with eight other organizations to produce the "Think It Through" brochure and upon its release, USP conducted a radio media tour promoting the brochure. In March USP released recommendations for health professionals and consumers about leading medication errors in hospital emergency rooms. Currently, the USP-NF has two proposals out for comment – one dealing with neuromuscular blocking agents and the other restricting what can be printed on bottle caps and ferrules.

Report on the Executive Session of June 19, 2003

- It was moved, seconded and approved to accept David Kotzin as an Individual Member of the Council for a period of one year.
- AONE has indicated its interest in continuing its membership on the Council, but attendance has been poor. A letter will be sent asking for better support for the Council by increasing attendance for Council meetings.
- It was moved, seconded, and approved to renew the Individual Membership of Deb Nadzam. However, there are attendance issues and she will be asked to indicate her continued interest through improved attendance.
- The Spanish Society of Hospital Pharmacy, located in Madrid, Spain, requested at At-large Membership on the Council. The request was denied, since there are no international membership categories; however, the Society was invited to the October meeting to make a presentation.
- After perusing the Rules concerning attendance, the Council's opinion was that if the designated delegate and alternate are unable to attend a meeting, it would be better to send a third person than no one at all.

New Business

- Linda Hanold (JCAHO) announced that the John M. Eisenberg Safety Award will be given out at the NQF Annual Meeting. Applications are now being accepted.
- AHA and McKesson are accepting applications through August for the Request for Quality Award that will be given out at the Health Forum in San Francisco.
- The next meeting will be October 15-16, 2003. At that time Andrew Chang from JCAHO's Patient Safety Center will give a presentation. Also, Jerry Phillips (FDA) will update the Council on the bar coding rule and reports received from industry dealing with medication errors.

It was moved, seconded, and approved to adjourn the meeting.