

September 12-13, 2002

Day One

Council delegates present:

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|----------------------------------|---|
| John Combes (AHA), Chairperson | Jerry Phillips (FDA) |
| Linda Hanold (JCAHO), Vice Chair | Sal Peritore (GPhA) |
| Diane Cousins (USP), Secretary | Lisa Clowers (HMDA) |
| Andrew Smith (AARP) | Judy Smetzer (ISMP) |
| Joseph Cranston (AMA) | Jon May (NABP) |
| Karen Drenkard (AONE) | Barbara Newman (NCSBN) |
| Ellen Quinn (ASHRM) | Rebecca DeVivo (NPSF) |
| Tom Clark (ASCP) | Alan Goldhammer (PhRMA) |
| Kasey Thompson (ASHP) | Bill Kelly (ex officio) USP Safe Medication Use Expert Committee |

Alternates attending with their delegate:

Mary Gross (FDA)
Shawn Becker (USP)

Delegates absent:

Janet Myder (AHCA)
Rita Munley Gallagher (ANA)
William Ellis (APhA)
William Davies (DoD)
Jeff Ramirez (VA)
Deborah Nadzam (Cleveland Clinic)

Observers:

| | |
|----------------------------|----------------------|
| Jay Watkins, (ASHP Intern) | Joe Ciccarello (DoD) |
| Ron Nosek (DoD) | Marsha Protzel (USP) |
| Terry O'Brien (MedAlert) | Tangela Smith (USP) |
| Chris Walsh (ISMP) | Marilyn Storch (USP) |
| Michael Gaunt (ISMP) | |

John Combes called the meeting to order at 1:44 p.m. He welcomed everyone and asked that introductions be made around the room.

Report from the Secretary

Diane Cousins (USP) reported that permission requests for use of the Taxonomy are still being received and she distributed a list of organizations requesting such permission within the past six months. Interest in the Council's work has spread as far as India, with a request for the bar coding recommendations. The National Council on Patient Information and Education (NCPPIE) accepted the Council's invitation to apply for membership. The Steering Committee will vote on the application during an Executive Session after the close of today's meeting. A prototype of a new NCC MERP brochure was passed around; however, the opinion was that information on the web site seems to satisfy most people.

Presentation: Vickie Sheets (NCSBN) (by teleconference)

The NCSBN requested the Council's permission to incorporate the Taxonomy into its Taxonomy of Error, Root Cause Analysis and Practice Responsibility (TERCAP) project. This project is a coding instrument template that is non-commercial and would be used to promote uniform language in developing a pro-active approach to nursing practice breakdowns. The general consensus of the Council was that this was an appropriate use of the Taxonomy. NCSBN will be presenting an evaluation of the TERCAP project at its Annual Meeting in August 2003, and will share those results with the Council during its fall meeting. The Council requested that NCSBN share any suggestions for possible revision to the Taxonomy.

ACTION ITEM: A letter will be sent from the Secretariat to NCSBN confirming permission to incorporate the Taxonomy into the TERCAP project and requiring feedback to the Council.

Subcommittee Reports

Bar Coding – Alan Goldhammer (PhRMA), Chair

The PhRMA bar-coding white paper is being held up awaiting the FDA's final rule to be issued in 18-24 months. Judy Smetzer (ISMP) reported that USP, AHA and HRET are working with ISMP to develop a readiness assessment tool to help hospitals determine when they are geared up for a smooth and successful transition to bar coding at the point of care. The tool will be free of charge and should be available in December 2002. ASHP is developing guidelines for pharmacies that deal with human factors, work patterns, and communication. Other groups are also working on bar coding papers (HIMSS) that may provide additional technical information.

ACTION ITEM: The subgroup will develop an outline of current bar coding projects and who is sponsoring them.

Taxonomy – Jerry Phillips (FDA), Chair

There has been no response from Premier in regard to a Council letter. At the present time the Council has no idea what systems are using the whole Taxonomy. It may be necessary for a subgroup to investigate and determine who is using the Taxonomy both with and without permission.

Practitioner Accountability – Lisa Clowers (HDMA), Reporting

The questionnaire is completed and ready to go out to the members of the state boards of medicine, nursing and pharmacy. John Combes asked if this was something that the Council still wanted to pursue. The Council agreed that it should be pursued to promote a non-punitive approach to errors. The goal is to pull people together and open a dialog that will continue into the future. The Council may decide to develop a reaction paper if the conference is held. Response to the questionnaire will be the defining element as to whether or not a conference should be held. If there is sufficient interest, a planning group will be set up at the February meeting to determine the conference date. The program will probably not be scheduled before next fall. There may be other organizations, legislators, regulators, etc. within the states

that should be involved in the conference and the questionnaire will be expanded to cover this possibility.

Unlicensed Personnel – Tom Clark (ASCP), Chair

The subcommittee presented their latest draft, focusing on medication management in unlicensed settings. Although some facilities and national associations do provide training, very few states have the resources available to do so. Several handouts from the National Association of School Nurses indicate that other organizations, besides the Council, are seeing the need for more regulation or guidance in this area. Many facilities have policy manuals, but little training in implementing actual procedures. The Council agreed to keep the recommendations broadly worded so that they would act as a statement of the problem and explain the issues. The goals are to get the issue on the radar screen within these settings and encourage education and training where needed. It was suggested that some of the language (controlled substances, e.g.) be simplified and that there be a hyper-link to on-line resources. This initial step may not be addressing all the safety issues as perceived by the Council. A follow-up paper may be needed to provide specific direction and guidelines. If we suggest training, then where does the training occur? Should unlicensed personnel manage controlled drugs? The subcommittee was thanked for doing such a great job in pulling this all together.

ACTION ITEM: The subcommittee will rework Draft 5 and then field-test it with several kinds of institutions. It will then be finalized and presented at the next Council meeting for a final vote. A press release will be ready for review at the next meeting.

Medication Error Rates – Diane Cousins (USP), Chair

The release of the medication error rates statement did not produce an uproar within the healthcare community. Rather, USP has received positive feedback. The Council members heard various positive statements such as, “It was about time this was brought out into the open.” ASHP acknowledged that they were reviewing error rates within one of their safety groups. Ken Barker called to validate the meaning of the document.

Strategic Planning – John Combes (AHA), Chair

The strengths and weaknesses of the Council were discussed within the context of how the Council should structure itself and its meetings. The Council needs to prioritize its current scope of work. Doing so may necessitate restructuring the organization and/or its workflow. Two workgroups (Council structure and meeting structure) have already met and reported their suggestions to improve the workflow of the Council.

The meeting adjourned at 4:42 p.m.

National Coordinating Council for Medication Error Reporting and Prevention

Day Two

September 13, 2002

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)
Jerry Phillips (FDA)

Salvatore Peritore (GPhA)
Lisa Clowers (HDMA)
Judy Smetzer (ISMP)
Jon May (NABP)
Barbara Newman (NCSBN)
Rebecca DeVivo (NPSF)
Alan Goldhammer (PhRMA)
Bill Kelly (ex officio) USP Safe Medication
Use Expert Committee

Alternates that attended with their delegates:

Mary Gross (FDA)
Shawn Becker (USP)

Delegates absent:

Andrew Smith (AARP)
Janet Myder (AHCA)
Rita Munley Gallagher (ANA)
Karen Drenkard (AONE)
William Ellis (APhA)
William Davies (DoD)
Jeff Ramirez (VA)
Deborah Nadzam (Cleveland Clinic)

Observers present:

Ron Nosek (DOD)
Christopher Walsh (ISMP)
Marilyn Storch (USP)
Jay Watkins (ASHP Intern)
Michael Gaunt (ISMP)

John Combes, Chairperson, called the meeting to order at 8:42 a.m.

Report on Executive Session of September 12, 2002

During the Executive Session the Steering Committee voted to renew both ASCP and HDMA as Regular Members for two-year terms. At Large members ISMP and NPSF (Executive Committee shifted NPSF out of “Consumer Organizations” and into “At Large membership category) were also renewed for two-year terms. It was moved, seconded and approved to accept NCPIE as a Regular Member of the Council for a two-year term under the category of Consumer Organization.

In his tribute to Barbara Newman, who is stepping down as NCSBN Delegate to the Council, the Chair thanked her for her outstanding contributions and stated that she will be sorely missed.

Committee Reports

Linda Hanold (JCAHO) reported on a conference call of the Meeting Structure Subgroup, held on September 10. The subgroup recommended that four standing subcommittees (reporting, technology, taxonomy, and practice-related issues) be subordinated to a strategic planning committee, whose function would include acting as a feeder to identify issues appropriate for the Council's attention by reviewing, summarizing, and presenting issues and topics for consideration. The suggestion was made that each subcommittee be composed of 7-8 members with staggered one-year terms. It was also suggested that on the second day of the meeting there should be a working lunch (sans break) thus concluding the meeting one hour earlier.

Alan Goldhammer reported that the Council is lacking in representation of consumer and physician groups and has limited financial resources. However, the Structure Subgroup's recommendations included no major changes in the core membership of the Council, no dues structure, the establishment of a strategic planning committee, and a permanent taxonomy committee. The strategic planning committee would identify major issues for the Council's consideration and be responsible for developing and distributing meeting agendas prior to meetings.

Break Out Groups

The Break Out groups were then set up to discuss differing structure options. It was determined that the Council should have a Strategic Planning Committee that acts as a focal point for four standing subcommittees – Taxonomy, Promoting/Monitoring/Evaluation (PME), Technology, and Practice-Related Issues. The breakdown and specifics of each group is as follows:

Strategic Planning Committee

Comprises: 7 members-1 year term
Council Chair
Council Co-Chair
Secretary
Chair or designee of Taxonomy subcommittee
Chair or designee of PME Subcommittee
Chair or designee of Technology Subcommittee
Chair or designee of Practice-Related Issues Subcommittee

- 1) Establish priorities for Council activities and projects
- 2) Establish the annual work plan for the Council
- 3) Establish funding based on annual work plan and develop criteria for funding sources
- 4) Recommend topics for the agenda of each meeting including the educational needs for the Council
- 5) Assign projects to the Taxonomy Subcommittee, Promoting, Monitoring, and Evaluating (PME) Subcommittee, Technology Subcommittee, and the Practice-Related Issues Subcommittee
- 6) Define strategic direction and frame issues to bring before the Council

National Coordinating Council for Medication Error Reporting and Prevention

Establish the expectation that the leaders of these subcommittees are drivers and need to take responsibility for the activities and work products. Need to establish the appropriate funding and funding source for the work of the subcommittee, and also supply the support for the subcommittee regarding conference calls, copies, e-mails, etc.

Taxonomy Subcommittee

Comprises: 5 delegates-1 year term

- 1) Revise/Maintain/Evaluate/Improve medication errors Taxonomy
- 2) Consider requests for use of Taxonomy and make recommendations to Council
- 3) Solicit feedback on use of Taxonomy by organizations that received approval for use
- 4) Provide update to Council 2 x per year, at a minimum, on the use and suggested improvements of the Taxonomy
- 5) Consider policy issues regarding Taxonomy and make recommendations to Council

Promoting/Monitoring/Evaluating Subcommittee

Comprises: 5 delegates-1 year term

- 1) Identify key stakeholder groups for Council products. Develop a plan for promoting Council work products to these key stakeholder groups, defining capabilities of Council member organizations, and their identified public relations liaison to regularly publicize and promote the work of the Council
- 2) Disseminate Council Recommendations, Statements, and Information including meetings, agendas, work group assignments, etc., using the identified PR liaison. Develop a plan for appropriate and effective dissemination of work products
- 3) Review current work products to determine how they have been used. Evaluate usage and report impact on quality/patient safety back to the Council
- 4) Produce annual report of overall Council activities (for possible publication)

Technology Subcommittee

Comprises: 5 delegates-1year term

React and respond to Council's assignments to:

- 1) Turn priorities of Council into work products/action items
- 2) Identify outside experts to assist work of subcommittee
- 3) Establish time lines and deadlines for outside conferences, meetings, seminars, panels, etc.
- 4) Determine costs associated with work products/activities for presentation to Council
- 5) Report progress to the Council at each meeting

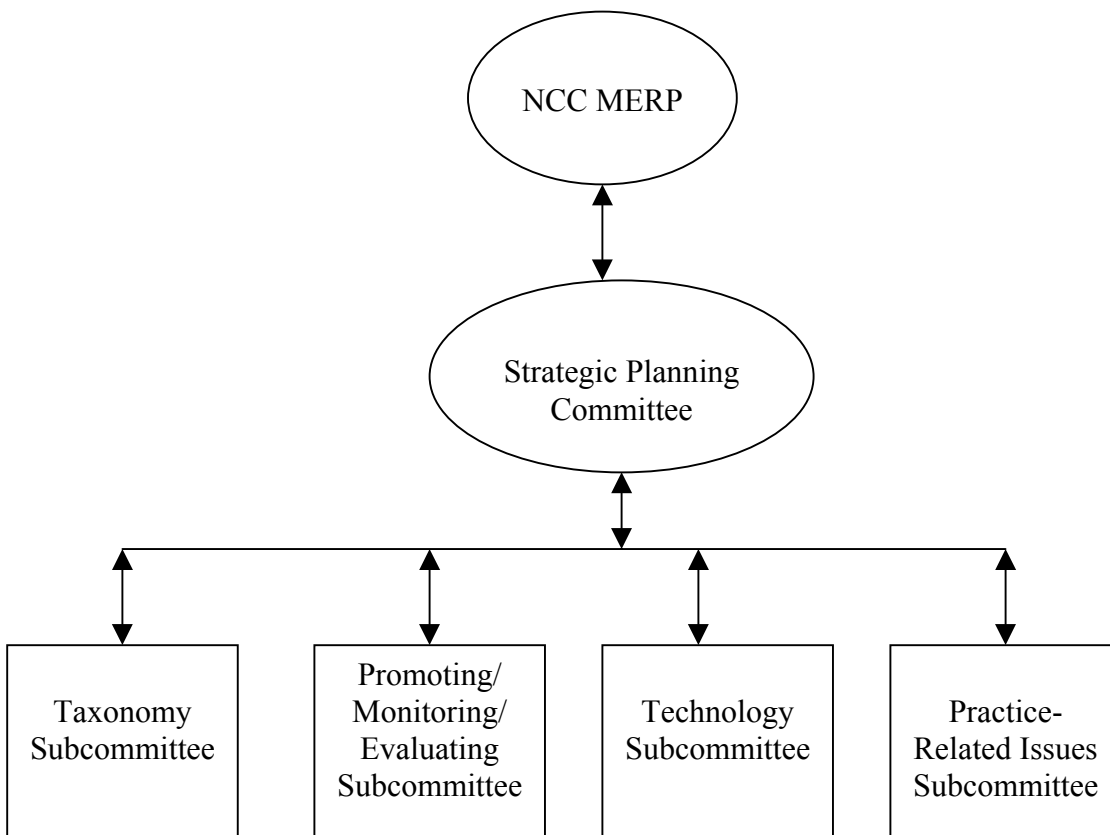
Practice-Related Issues Subcommittee

Comprises: 5 delegates-1year term

React and respond to Council's assignments to:

- 1) Turn priorities of Council into work products/action items
- 2) Identify outside experts to assist work of subcommittee
- 3) Establish time lines and deadlines for outside conferences, meetings, seminars, panels, etc.
- 4) Determine costs associated with work products/activities for presentation to Council
- 5) Report progress to the Council at each meeting

The final Council organization would be structured as follows:



The purpose of the restructuring would allow the Council to stay focused on specific projects. Members would rotate among subcommittees following one-year terms. Some members' terms would extend beyond one year in Year 1 to ensure a staggered rotation. Members involved with a specific subcommittee project will stay with that project until completion.

ACTION ITEM: Within the next few weeks members should select three subcommittees in order of preference and submit their choices to John Combes or Diane Cousins.

It was agreed that the Council should take advantage of press releases, issuing them when projects are identified and committee leaders are chosen, thus enhancing public exposure for the work and leadership of the NCC MERP.

Committee Reports (cont.)

Consumer Education

Lisa Clowers (HDMA) reported on the enhancement of the NCC's web site to include consumer-related information. Several changes were suggested. The Council agreed to include just the core NCC MERP group on the web site to avoid having to venture into an area of quality control. It was moved, seconded and approved to approve the web site material.

Roundtable Discussion

NABP (Jon May) – The NABP has been actively involved with two issues that have far-reaching effects: (1) the Narcotic Addiction Treatment Act – everything is ready to go but the drugs were not approved as quickly as expected. This act will be a major change in the way doctors treat drug addiction in the country and (2) S. 812, which passed July 31 with a vote of 78-21. This bill expands access to generic pharmaceuticals and insures that seniors have access to the drugs that they need.

ISMP (Judy Smetzer) – The new newsletter *Medication Safety Alert*, developed for the Community/Ambulatory Pharmacy, is still in the marketing and improvement phase. Comments are encouraged.

PhRMA (Alan Goldhammer) – PhRMA has been working with AMA, ASHP, GPhA, among others, to develop an Internet labeling system that produces labels, full prescribing information, product updates, and new product information in a PDF format with touchscreen access. It will have a great impact on medication errors, Dear Pharmacist letters, and product recalls. Updates are available within 24 hours. The system will be revenue neutral for pharmacies and will be totally paperless within two years. Five community pharmacies and five chain pharmacies are now involved in a three-month test of the system. The PDF standards for e-labels are 8-point type size or above. The FDA through the National Library of Medicine is developing a database so that labeling amendments can be handled quickly. Patient packets could be created using this approach. Labels in the system are stored by their NDC number and are accessible with an instantaneous search. Implementation of new software will lead to abandoning Adobe Acrobat and getting into a database that can be used and searched. The database will eventually include every prescription drug on the market. GPhA is working on this project also. Most PhRMA member companies are actively testing and submitting comments on the labeling project. They are fully committed to applying bar coding codes and predict 100% compliance on all products within three years. The majority will be done within the first year.

NPSF (Rebecca DeVivo) – Five new brochures have been released on their web site. The NPSF has released a report on surgery performed in office settings. The 5th Annual Congress (formerly the Annenberg Conference) is scheduled for March 12-15, 2003, in DC. The Patient Safety Awareness Week is the second week in March. More information will be sent out shortly.

AMA (Joe Cranston) – The AMA testified before the FDA in favor of bar codes and supported NCC MERP's recommendations as a starting point. AMA has expressed concerns about the

FDA's Risk Management Program (i.e., restricted distribution) because it appears the FDA may dictate which drugs physicians can and cannot prescribe.

NCSBN (Barbara Newman) – Nothing to add to TERCAP project.

ASHP (Kasey Thompson) -- Kasey introduced Jay Watkins, R.Ph., who is the first participant in the Army's patient safety project to measure medication safety. Within the month, ASHP will be publishing *"Making CPOE a Reality in Hospitals"* as part of its emphasis on education in conjunction with the AHA.

HDMA (Lisa Clowers) -- Pharmacia is funding a project for the HDMA Healthcare Foundation in response to the FDA's plan to propose bar coding on unit dose packages. The study will be completed by the spring of 2003. HDMA has joined a coalition including PhRMA and GPhA, to urge technological flexibility in any approach the FDA may take in developing regulations for bar codes. Due to the increase of counterfeit drugs in the US, HDMA is forming a taskforce to determine potential collaborations. The goals of a taskforce that HDMA formed last fall is to study the attributes of pharmaceutical products that make them susceptible to availability problems and to develop a decision matrix to determine which supply systems will most efficiently distribute these products. The taskforce will also develop an industry white paper regarding recommendations for communication of drug availability.

FDA (Jerry Phillips) –FDA held a conference on bar coding July 28, 2002, that went very well. They are now addressing public comment. By the beginning of the year FDA Commission will announce a reorganization of Biologics and CDER. FDA is planning to shift trade and generic naming of drugs to industry and put forth new recommendations for labeling and good packaging practices.

SMU EC (Bill Kelly) – The expansion of MedMARx has allowed the SMU to examine reports for trends and assess the reliability of the data. The Expert Committee is beginning to focus its attention on medication errors that are occurring in ambulatory settings and is setting up standards for CPOE. It will continue to act as a resource to the Council.

ASCP (Tom Clark) -- National attention has recently focused on the issue of tablet splitting and Medicaid has implemented a policy for splitting Zoloft tablets. ASCP, however, has been opposed to the practice for many years. Its membership serves the elderly and splitting tablets is an issue of grave concern. No research has been done that proves the practice is safe and whatever anecdotal evidence exists is not supportive of splitting. Tom has an article on ASCP's web site that emphasizes this position, stressing that rarely is splitting done uniformly. With some medications this may not pose a health risk, but with others it may be life threatening. Tom questioned whether or not the Council should consider issuing recommendations about tablet splitting.

ACTION ITEM: Tom Clark will e-mail ASCP's position paper to Council members.

ASHRM (Ellen Quinn) – The ASHRM Annual Meeting is scheduled for September 28-October 1 with an increased emphasis on patient safety. Currently there are 3500 members throughout the US.

GPhA (Sal Peritore) – GPhA is working very closely with PhRMA on bar coding issues.

JCAHO (Linda Hanold) – A new series of medication use standards that are now out for field review focus on the key processes of selections and procurements. JCAHO has been invited to be a member by the Leapfrog Group, which would formalize an informal relationship that already exists. The *Speak Up* campaign continues to encourage patients to be more actively involved in their own care. Dr. O'Leary testified before Congress about the private sector's efforts to improve patient safety. Six patient safety goals for 2003 go into effect on January 1

and FAQ's are currently on JCAHO's web site. JCAHO is beginning to proactively address the nursing shortage. Four John M. Eisenberg Safety Awards were announced – one lifetime achievement award and three project awards. Julie Morath and David Bates were among the awardees.

AHA (John Combes) – Four facilities, including Missouri Baptist, and Children's Hospital in Fairview, recently won awards for establishing a culture of safety. A Citation of Merit was awarded to Brigham and Women's Hospital. The award program is in its second year and an application is on AHA's web site. The National Alliance for Healthcare Information Technology (NAHIT) now has 72 members and is becoming very active. It recently testified on developing technology standards for the industry.

USP (Diane Cousins) – The MedMARx Annual Report 2001 will be published in December 2002. Its theme this year is human factors. USP has created the Center for the Advancement of Patient Safety (CAPS) to improve the quality of patient care by focusing on (1) the analysis and dissemination of information, data mining, etc; (2) research and grants; (3) education; and (4) standards development. CAPS has also initiated a monthly e-newsletter called CAPSLink. Council members should have already received the first issue.

No new business was put forth and the meeting was adjourned at 1:37 p.m.

NCC MERP Meeting Summary Ballot

June 12-13, 2002 Meeting

I have reviewed the Meeting Summary:

☐

I approve the Meeting Summary as it stands.

☐

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

Name _____

Organization _____

Date _____

Please return this ballot by COB Wednesday, November 27, 2002, by mail or fax to:

Diane Cousins
USP
12601 Twinbrook Parkway
Rockville, MD 20852

Fax: 301-816-8532