

**Day One**

**October 15, 2003**

Council delegates present:

Linda Hanold (JCAHO), Vice Chair	Jerry Phillips (FDA)
Diane Cousins (USP), Secretary	Sal Peritore (GPhA)
Joseph Cranston (AMA)	Judy Smetzer (ISMP)
Rita Munley Gallagher (ANA)	Jon May (NABP)
Veronica Oven (AONE)	Polly Johnson (NCSBN)
Ellen Quinn (ASHRM)	Deborah Nadzam (Cleveland Clinic)
Tom Clark (ASCP)	David Kotzin (Greater Baltimore Medical Center)
Kasey Thompson (ASHP)	
Ron Nosek (DoD)	

Alternates attending as representatives of their organizations:

Carl Armstrong (AHA)	Ronna Biggs (NACDS)
Anne Burns (APhA)	Lee Rucker (NCPIE)
Tracy Casteuble (HDMA)	Rosemary Cook (PhRMA)

Alternates attending with their delegates:

Carla Saxton (ASCP)	Kristin Hellquist (NCSBN)
Mary Gross (FDA)	Shawn Becker (USP)
Judy Milford (GPhA)	

Delegates absent:

John Combes (AHA)	Ray Bullman (NCPIE)
AARP – no designated delegate	Alan Goldhammer (PhRMA)
Janet Myder (AHCA)	Patricia Sokol (NPSF)
William Ellis (APhA)	Jeff Ramirez (VA)
Lisa Clowers (HMDA)	Bill Kelly (ex officio) USP Safe Medication Use Expert Committee Chair
Ed Staffa (NACDS)	

Observers:

Robyn Bragg (APhA student)	Elizabeth Cowley (USP)
Sherrie Borden (USP)	Jeff Silverstone (USP)
Rita Calnan (USP)	Marilyn Storch (USP)
Susan Camp (USP)	
Pilar Blasco (Spanish Society of Hospital Pharmacy)	
Eric Boomhower (Florida Department of Citrus)	

Linda Hanold (JCAHO), Vice Chair, welcomed the Council members and observers and called the meeting to order. Because there were numerous first time attendees, Ms. Hanold requested that all delegates, alternates, and observers introduced themselves and gave a brief background on their organizations' or individual efforts in medication safety.

**Subcommittee Reports:**

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

Rita Gallagher invited Sherrie Borden, USP's Director of Public Relations, to give a short historical background on the General Principles for Patient Safety Reporting Systems covering how and why the Principles were initiated. The question being introduced before the Council was whether or not the Council, as an independent entity, should endorse the Principles as written. Discussion ensued, including:

- 1) Differentiating NCC MERP as a standards-setter, rather than an endorser
- 2) The Council would be appear conspicuous by its absence from this list of supporters
- 3) The Council could support the Principles without actually endorsing them
- 4) The Council could pass its own set of recommendations on what is necessary for a reporting program
- 5) There should be uniformity – everyone should support the same document
- 6) NCC MERP could adopt the General Principles and put them on NCC MERP's web site

It was moved, seconded, and approved to adopt the General Principles as the basis for Council recommendations and display them on the NCC MERP web site. It was also moved, seconded, and approved to support the General Principles by adding the Council's name to the list of signatories.

**Action Item: USP will arrange for the display of the General Principles on the NCC MERP web site and will arrange to have the NCC MERP name included on the list of Principles supporters.**

***Promoting/Monitoring/Evaluating – Deborah Nadzam (The Cleveland Clinic), Chair***

According to Dr. Nadzam, the Council is becoming very influential. One Thousand One hundred and twelve (1112) references were found when performing general searches of the Internet (not MedLine) but few references were found in the professional literature sources. Dr. Nadzam proposed that a formal evaluation of how the Council's efforts in affecting patient safety would be appropriate. This would be a wonderful graduate student project. Dr. Nadzam is seeking volunteers in this effort. Dr. Nadzam suggested that a public relations group consisting of a PR person from each organization be resurrected to promote the dissemination of the Council's recommendations, suggestions, work products, information, etc. Kasey Thompson noted that for some organizations it may be more effective to go through the Council delegate, rather than a PR person. There was some agreement with this suggestion. The Council's PR group would report to the Promoting/Monitoring/Evaluating Subcommittee. Organization's actions in the area of patient safety should be reported to the Council, as well as how NCC MERP products are being used. This should be part of all reports during the meeting Roundtables. It was

stressed that there is not just one correct avenue for dissemination. Internet, classes, reports, and press releases are just a few of the many ways the Council can get its message out to the public. The subcommittee proposed the following recommendations for Council consideration:

- Key stakeholders for Council products should be identified and a plan for promoting Council work products should be developed
- All Council recommendations, statements and information should be disseminated using PR liaisons
- Current work products should be review to evaluate usage and impact on quality and patient safety
- An annual report of Council activities should be produced, possibly for publication

***Action Item: Sherrie Borden will work with her staff to contact PR representatives from member organizations in order to resurrect the Council's PR group.***

It was suggested that each subcommittee look at its annual objectives and be prepared to revisit the annual plans at the scheduled February meeting. The term of membership on a subcommittee was originally designated as one year, so Ms. Hanold asked members to indicate first and second choices for subcommittee service for the upcoming year. Alternates were also encouraged to sign up for subcommittee projects.

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

No new information to report at this time.

***Technology – Sal Peritore (GPhA), Chair***

No new information to report at this time.

***Clinical Exercise in At-Risk Behaviors***

At-risk behaviors are work habits stemming from flaws in the system processes that health care practitioners know not to act upon but carry out anyway. The exercise being conducted consisted of having Council members divide into groups to code actual error reports from the USP MER Program. The primary purpose was to assist the Council in articulating common at-risk behaviors and proposing Council recommendations for better practices. It would also serve notice as to whether the Taxonomy needed to be updated. Judy Smetzer volunteered to collect the completed cases and analyze the results.

***Action Item: Judy Smetzer will analyze the results of the clinical exercise and report at the scheduled February Council meeting.***

Impressions from Council members after performing the exercise:

- It was obvious that not enough information is being collected.

*National Coordinating Council for Medication Error Reporting and Prevention*

- The coding system focuses on a hospital environment.
- Coding done by an untrained analyst could be dangerous and misleading.
- No indication of patient counseling was indicated in the reports.
- Members would like to see a cross reference between behaviors and outcomes.
- Members were amazed by the number of errors caught by patients.
- There was no indication in the reports as to the patient's diagnosis.
- The Administration node should be added to case #7.
- Examples of coding may need to be added to the cases to provided instructions on how to code.
- Health care practitioners need to be educated about at-risk behaviors.

The meeting was adjourned at 4:51 p.m. and the Steering Committee moved into Executive Session.

**Day Two**  
**October 16, 2003**

Council delegates present:

Linda Hanold (JCAHO)	Salvatore Peritore (GPhA)
Diane Cousins (USP), Secretary	Judy Smetzer (ISMP)
Joseph Cranston (AMA)	Jon May (NABP)
Rita Munley Gallagher (ANA)	Polly Johnson (NCSBN)
Ellen Quinn (ASHRM)	Ray Bullman (NCPIE)
Tom Clark (ASCP)	Alan Goldhammer (PhRMA)
Kasey Thompson (ASHP)	Jeff Ramirez (VA)
Ron Nosek (DoD)	Deborah Nadzam (Cleveland Clinic)
Jerry Phillips (FDA)	David Kotzin (GBMC)

Alternates attending as representatives of their organizations:

Carl Armstrong (AHA)	Ronna Biggs, (NACDS)
Anne Burns (APhA)	Rosemary Cook (PhRMA)
Tracy Casteuble (HDMA)	

Alternates attending with their delegates:

Carla Saxton (ASCP)	Kristin Hellquist (NCSBN)
Mary Gross (FDA)	Shawn Becker (USP)
Judy Milford (GPhA)	

Delegates absent:

John Combes (AHA), Chairperson (AARP)	Lisa Clowers (HDMA)
Janet Myder (AHCA)	Ed Staffa (NACDS)
Veronika Oven (AONE)	Patricia Sokol (NPSF)
Bill Ellis (APhA)	Alan Goldhammer (PhRMA)
	Bill Kelly (ex officio) USP Safe Medication Use Expert Committee Chair

Observers present:

Pilar Blasco (Spanish Society of Hospital Pharmacy)  
Eric Boomhower (Florida Department of Citrus)  
Jim Battles (AHRQ)  
Robyn Bragg (APhA student)  
Marilyn Storch (USP)

USP staff present:

Susan Camp	John Fowler	Sue Zmuda
Elizabeth Cowley	Jeff Silverstone	

Linda Hanold, Vice Chairperson, called the meeting to order at 8:36 a.m. Ms. Hanold welcomed everyone to the second session of the meeting and requested that any member who had not turned in their choices for subcommittee service for the upcoming year should mail their requests to Marilyn Storch.

Ms. Hanold turned the meeting over to Judy Smetzer (ISMP) for an announcement regarding the death of a long-time patient safety researcher and cohort, Tony Grasha. Dr. Grasha had previously presented to the NCC MERP on Human Factors as related to medication errors.

***Presentation: Pilar Blasco, Ph.D., Spanish Society of Hospital Pharmacy (SEFH)***

The National Association of Civil Hospital Pharmacists (AEFH) was founded in Madrid in 1955 and was one of the precursors of the Spanish Society of Hospital Pharmacy. By 1967 every new social security hospital in Spain had to include a department of pharmacy. The first hospital pharmacy meeting was held in 1970 and was organized by the Board of Directors of the Ministry of Health and Social Security. By 1984 the National Committee of Hospital Pharmacy Specialty was founded to establish the requirements for training accreditation of the Departments of Pharmacy and by 1986 a Specialty in Hospital Pharmacy degree was recognized by law. SEFH was fully incorporated in the European Association of Hospital Pharmacists in 1987 and in 1988 it formally changed its name to the Spanish Society of Hospital Pharmacy. The Society's history in medication errors began with a study to improve the quality of drug use and distribution system at the Hospital of Barcelona in 1996. An overview publication on medication errors edited in collaboration with the Spanish Society of Quality Improvement in Health Care Organizations, *Errores de Medicación Prevención*, was published in 2001. A medication error prevention plan to improve the safety of drug use at the San Juan University General Hospital employed a voluntary reporting system with education support activities. The Medication Error Group was established in 2003 with the following objectives:

- Enhance awareness of medication errors throughout the healthcare system
- Develop a standard taxonomy of medication errors
- Encourage the development of voluntary reporting systems in hospitals
- Standardize data collection methods in hospitals and establish medication error rates as quality improvement indicators
- Implement strategies for assessing the causes of medication errors
- Provide information and institutional recommendations to prevent medication errors
- Support any research regarding medication errors, their causes, and prevention

Dr. Blasco completed her presentation and responded to questions from the membership.

***Presentation: AHRQ Patient Safety Activities: An Update, Jim Battles, Ph.D., Senior Service Fellow for Patient Safety, AHRQ***

AHRQ was formed by a Congressional mandate to conduct and support research by:

- Identifying the causes of preventable health care errors and patient injury during health care delivery

- Developing, demonstrating, and evaluating strategies for reducing errors and improving patient safety
- Disseminating effective strategies throughout the healthcare industry

Toward this end AHRQ was funded with \$50 million in FY 01 and has a proposed budget of \$84 million for FY 04. AHRQ's underlying principle is that safety is essential and has a higher priority than quality. Before a facility is concerned with quality, it must have a safe system of medical care. For the past three years AHRQ has been working to identify the risks and hazards that may harm patients and raise awareness that patients are at risk. It is now working to design, test, and implement practices and processes that will eliminate these risks and develop a positive patient safety culture. A Patient Safety Task Force, with membership from AHRQ, FDA, CDC, and CMS, has established Challenge Grants to (1) find out where the risks for patients are and (2) implement safe practices to eliminate those risks. The Task Force coordinates the data collection of medical errors and ADEs and research and analysis efforts, and promotes collaboration on reducing injuries resulting from medical errors. AHRQ asked the Institute of Medicine for guidance on Patient Safety Data Standards and charged the IOM to develop a detailed plan to facilitate the development of standards applicable to the collection and coding of safety information. This plan would encompass medical errors and adverse event data. The final report is scheduled for release November 20, 2003. Dr. Battles then described the different types of identification systems (event reporting, patient surveillance, triggers, direct observation, videotape, etc.) expounding on the pros and cons of each. The National Patient Safety Network is an IT effort to increase patient safety and reduce the severity of medical errors by improving existing reporting systems. This involves

- developing a common user interface for 6 different systems,
- developing a data warehouse,
- creating a user based software application,
- analyzing vocabulary, coding, and classification used by current systems, and
- providing training for 50 hospitals.

The biggest challenge will be how to get all this information disseminated in usable form.

Dr. Battles completed his presentation and entertained questions from the membership.

***Presentation: Medication Errors—A FDA Analysis, Jerry Phillips, R. Ph., FDA***

To identify and quantify the types and causes of errors resulting in death in ambulatory, inpatient, domestic and foreign settings for the period 1/1/93-12/31/98, each report to the FDA was reviewed to determine if the death was related or possibly related to an error. The results showed that 5366 medication error reports were identified of which 3660 were defined as serious and 528 resulted in death. California (29), Maryland (28), Florida (26), and Pennsylvania (23) ranked as the top four states in the US for errors resulting in death. More than 97% of errors involved a pharmaceutical product and almost ½ were injectable. Types of errors, listed in order of severity, were improper dose (40.9%), wrong drug (16%), and incorrect route (9.5%). Causes of errors included performance or knowledge deficit (65.2%), communication (16%), name confusion (9%), labeling and packaging (10.1%), and illegible handwriting. A review of 2002 data revealed that 3660 reports were received, of which 63% were from manufacturers and 37% were from MedWatch and

USP. 12% were fatal. 11% were potential errors (Category A), and 89% were actual errors (Categories B-I). The three leading types of errors were improper dose (31%), wrong drug (20%), and wrong technique (7.5%). Again, human factors (knowledge and performance deficit) accounted for 47% of errors and communication accounted for 25%.

### ***Roundtable Discussion***

**NABP** (Jon May) – NABP routinely forwards all NCC MERP recommendations and reports to the State Boards. The State Newsletters, which are sent to approximately 50,000 pharmacists, also publish articles relating to medication errors and patient safety. The biggest problem confronting pharmacy today and the one that relates most closely to patient safety is the rapidly-growing practice of importing drugs from Canada. Although blatantly illegal under federal and state law, it is flourishing and Canadian drugs are advertised on TV in most major US cities. Concern has been expressed by FDA, NABP, and other pharmacy organizations, plus individual state boards of pharmacy, concerning adulterated and counterfeit drugs and the possibility of terrorist acts involving medications.

CPT Phillips finished his presentation and answered questions posed by the Members.

**AMA** (Joe Cranston) – The NPSF is moving its headquarters to the DC area in the fall with a new acting director. The move is part of an effort to make the NPSF self sufficient. AMA has created a 20 minute video program to train doctors about the problem of health literacy.

**ISMP** (Judy Smetzer) – The Massachusetts Coalition on Patient Safety held a very successful meeting to discuss a series of sessions to educate management to the issues involved in changing culture. The new ISMP newsletter is doing quite well and has received additional funding for FY 04 for the nursing issue.

**GBMC** (Dave Kotzin) – GBMC conducts 50,000 out-patient surgeries per year and has increased the number of operating rooms from 40 to 52. It recently received \$2.5 million to upgrade the pharmacy department so that pharmacists can review all orders. Part of this money will be used to add 28 dispensing cabinets. The Board of Directors at GBMC made a commitment to improve patient safety with an emphasis on improving doctors' handwriting. GBMC has partnered with MEDMARX, using it as a tool to improve patient safety. The average error reporting after adopting a non-punitive strategy has increased dramatically to 300 ADEs per month. GBMC has signed a contract with MediTech for bar coding and CPOE, which they hope to have operational by next October.

**HDMA** (Tracy Casteuble) – HDMA is working with McKesson on several studies concerning patient safety:

- the Medication Errors in Patient Safety Bar Coding Connection is determining which drugs should have priority for bar coding and should be out by the end of the year
- a business case for discovering and dealing counterfeiting of drugs should be sending out a RFP soon

HDMA's Product Integrity Guidelines have been approved by its members and the Product Safety Task Force, a technology-focused group, should be delivering its report within 6 months.

**ANA** (Rita Munley Gallagher) – The ANA has been focusing on patient safety issues relating to nurse staffing and worked with the NQF on nursing performance measures. Dr. Gallagher is preparing a report about medical waste in long term care facilities and would appreciate receiving any data that members are willing to share.

**PhRMA** (Rosemary Cook) – PhRMA sent a letter in September to Mark McClellan (FDA) expressing its strong support for FDA's proposed regulation on bar coding hospital packaged pharmaceuticals and urging the FDA to finalize it as soon as possible.

**VA** (Jeff Ramirez) – The VA's bedside bar coding program has been in effect for the past four years in 162 VA centers and its development and use have created new issues. The VA is establishing a program manager's office in the support process. A conference is scheduled for San Francisco to explore the options for dealing with new issues that have arisen from newly introduced procedures. A National Center for Patient Safety is being established as a result of an internal request for medication safety initiatives. Discharge data will be used to capture trigger points.

**ASHP** (Kasey Thompson) – The Council's medication error rates statement has been formally endorsed by the Board of Directors of ASHP and the recommendations for non-healthcare settings has been publicized in ASHP newslink services and newsletters. ASHP is strongly opposed to the reimportation of drugs and is very concerned with the proliferation of counterfeit drugs. Pharmacists are being trained to look for counterfeit drugs by examining ADR reports. The website has been redesigned and is now searchable with up-to-date information about drug shortages. ASHP is participating with ISMP in a technology assessment program next weekend in Dallas, Texas. The summer program format has been designed around education programs such as evidence-based medication use and informatics beyond CPOE that will extend for 3 days, rather than the usual 2-3 hour programs. Research grant programs have been expanded to include pharmacy practice residents and pharmacy practitioners. The new big issue for ASHP is sterile compounding. Implementation of best practices in this area has been uneven and ASHP is revising its guidelines to be consistent with USP Chapter 797.

**ASHRM** (Ellen Quinn) – ASHRM's annual meeting will be held beginning November 1 in Nashville, Tennessee. Shawn Becker from USP and Ms. Quinn will be presenting on November 4. ASHRM has been involved with creating new educational programs dealing with the emerging trends in infection control and a manual on SARS for risk managers. The Patient Safety Task Force group has been providing education for patient safety risk managers using NCC MERP as a primary source.

**ASCP** (Tom Clark) – ASCP is also opposed to drug reimportation programs as a threat to patient safety and believes that it increases the possibility of drug counterfeiting. It believes that some state Medicaid pharmacy benefits programs have been promoting inappropriate

ideas, such as tablet splitting. Mr. Clark asked whether the Council should propose recommendations for pharmacy benefit design. ASCP has recently produced several resources including *Medication Management in Assisted Living*, *Medication Guide for the Home Health Nurse, 6<sup>th</sup> Edition*, and a daily medication calendar form in partnership with the National Association for Homecare and Hospice. Its new website [seniorcarepharmacist.com](http://seniorcarepharmacist.com) has links to consumer pages of Council members.

**NCPIE** (Ray Bullman) – October is NCPIE's 18<sup>th</sup> "Talk About Prescriptions" month and information for consumers is already available. On December 8-9 NCPIE will host its 14<sup>th</sup> National Conference at the Marriott at Metro Center, Washington, D.C. The theme is "Be Medwise". A new phase of the "Be Medwise" campaign began September 10 with radio service ads and a tool kit for outreach activities on how to use OTCs with prescriptions. On July 31, 2003, NCPIE presented a multi-stakeholder plan to meet quality and content for risk and safety medication use. Reconfiguring printed drug information was used as a catalyst. A day-long "Talk with your Pharmacist" day was held September 9 co-sponsored by the American Council on Aging. It was so successful that the AOA wants to create state-level programs.

**FDA** (Jerry Phillips) – FDA's 5-year strategic plan was released with the bar coding rule moving to high priority. On October 14 public comment was closed on the SADR rule. In June there will be a public meeting on drug naming. An advisory committee was set up; however, its first meeting was cancelled due to Hurricane Isabela. The meeting has been rescheduled for December 4. HealthCanada is hosting a look-alike drug meeting that CPT Phillips will be attending. The FDA is developing a MedDRA dictionary to classify ADEs by causes and types. Several member organizations of the Council (GPhA, ISMP, PhRMA, USP) will be involved. The NCC MERP taxonomy is the basis of discussion.

**NACDS** (Ed Staffa) – An online tool related to the outpatient setting was recently launched on NACDS' web site. Additions are being made on a regular basis to promote the sharing of information, communication, peer review, etc.

**DoD** (Ron Nosek) – DoD has appointed Dr. Geoffrey Rake as the new full-time Director of the DoD Patient Safety Center. DoD has established 3 patient safety awards for the 2004 Tricare Conference in the areas of team training, policy and procedure, and technology. It has contracted with ISMP for copies of all ISMP newsletters to be disseminated to all DoD facilities and has partnered with ISMP for 2004 to participate in the hospital assessment program. In September DoD renewed its MEDMARX contract with USP for MEDMARX subscriptions for 143 facilities worldwide, 25 multi facility modules, and 8 training sessions. A training session was held for patient safety officers in Orlando last month. The next conference, a hands-on curriculum-based workshop, is scheduled for January 2004 in San Antonio. A committee has been established to set the requirements for a DoD-wide bar coding program.

**APhA** (Anne Burns) – Drug counterfeiting is a major concern for APhA and compounding has been elevated as a patient safety strategic issue. Patient safety is profiled in all publications sponsored by APhA. A community pharmacy residency program has been

established in cooperation with ASHP. The annual Pinnacle Awards ceremony was held in June.

**GPhA** (Sal Peritore) – GPhA has appointed a new vice president for scientific affairs and organizational subcommittees for drug shortages and labeling have been established. Drug reimportation is a major concern and GPhA opposes Provision 5, which mandates certain technology for tracking and recalling drugs. GPhA has been very active on the state level testifying about mental health drugs and rationing medication.

**USP** (Diane Cousins) – USP's Safe Medication Use Expert Committee met September 30-October 1. Its 2004 review of MER and MEDMARX data will explore errors occurring in the home, insulins (establishing a standard sliding scale), common threads in distractions, product recommendations, and practical education recommendations for consumers. Neuromuscular blocking agents appeared in the *PF* with a warning label requirement. USP is conducting validity testing on the MEDMARX database, beginning with the NCC MERP Category Index. Working with Ohio State University, the study will be looking at three groups of MEDMARX users: (1) paper users, (2) algorithm users, and (3) users of an electronic interactive program. The results will be available in the spring. The Annual Report on information submitted to MEDMARX in 2002 will be released November 18. More than 192,000 records from 400 facilities provided information for this report. Three special areas of investigation include the top 25 products involved in errors, (2) geriatric errors, and 4 JCAHO patient safety goals. USP's Board approved the development of an ADR module for MEDMARX. USP is working to establish the best approach to interface with the FDA.

**JCAHO** (Linda Hanold) – Benchmark Journal will reproduce NCC MERP's rates paper. Dennis O'Leary has recently testified before the Senate about 6 crucial strategies for creating a culture of safety. JCAHO's June bulletin focused on surgical fires and urging awareness on the part of all healthcare professionals on how to prevent them. The 2004 patient safety goals are identical to those released for 2003 with the addition of reducing the risk of healthcare-induced infections. JCAHO is a cosponsor of the Eisenberg Awards.

**Action Item: Add to agenda for next meeting – Problems associated with agents of providers**

The meeting was adjourned at 1:45 p.m. and moved into closed session.

**NCC MERP Meeting Summary Ballot**

**October 15-16, 2003 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, December 3, 2003, by mail or fax to:

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