June 28, 1999
Day one

Council delegates present:

Deborah Nadzam, Chairperson, (Cleveland Clinic)	Diane Cousins, Secretary (USP)
	Bill Ellis (APhA)
Jerry Phillips (FDA)	Nancy Rapp Guilliom (ASHRM)
Barbara Newman (NCSBN)	Michael Cohen (ISMP)
Joseph Cranston (AMA)	Alice Till (GPIA)
Jon R. May (NABP)	Joseph Deffenbaugh (ASHP)
John R. Combes (AHA)	John Kessler (USP Advisory
Andrew Smith (AARP)	Panel on Medication Errors)

Alternates present:
David Keepnews (ANA)

Other alternates that attended along with their delegates:

Shawn Becker (USP)	Herbert Carlin (GPIA)

Delegates absent:

Janet A. Myder (AHCA)	Rita Gallagher (ANA)
Linda Hanold (JCAHO)	Michael Horan (PHRMA)

Observers present:

Marge Keyes (AHCPR)	Russell Jenkins (ISMP)
Jeff Ramirez (VA)	David Kvancz (Cleveland Clinic)
Molla Donaldson (APhA)	David Holmen (USP)
Fay Menacker (USP)	Elizabeth Cowley (USP)
Judy McMeekin (USP)	Sara Foer (USP)

Dr. Deborah Nadzam called the meeting to order at 1:40 P.M. Dr. Nadzam welcomed the members, introduced the invited guest, Ms. Marge Keyes, from the Agency for Health Care Policy and Research, and welcomed the observers, who were asked to introduce themselves and acknowledge their affiliations.

The Chairperson opened the floor for any added agenda items. Mike Cohen suggested that the Council address the issue of practitioner's names being released to the public after a specific medication error is reported through their state board newsletter. Mr. Cohen feels that this is harmful and that it sends a very strong signal to practitioners to not voluntarily report errors for fear that it may somehow wind up at the state board level and be reported out to the public. Mr. Cohen gave an example of this, where in a particular state, a nurse was placed on probation for two years for committing an error that the Council has seen reported on a fairly routine basis. When this appears in the state boards newsletters' it is already punitive and Mr. Cohen thinks it serves no purpose. It does not address the issues, which may have led to the error in the first place. He would like to see this placed on the agenda because there are people on the Council that represent the state boards for nursing and pharmacy, who are concerned with this very issue. It would do the Council well to have an open discussion on this issue. Dr. Nadzam suggested that, if time permits, this topic could be added to the current agenda or addressed at the next meeting.

Review of Rules Changes and Announcement of Results of Election for Chairperson and Vice Chairperson

Diane Cousin reported on the rules changes for those members who are not on the steering committee. She summarized the areas within the rules that were changed in April and have an effect on the Council. Two topics entertained by the steering committee via conference call were:

1) Creating a new office called Vice Chairperson to the Council. This Vice Chairperson will serve for a one-year term concurrent with the term of the Chairperson, so those positions are elected at the same time. The Vice Chairperson cannot be with the same organization or agency as the Chairperson, to reflect a better representation. In the event of the vacancy of the Chairperson's seat, the Vice Chairperson would become the Chairperson for the remainder of the term. A term limit was not specified for the Vice Chairperson. The steering committee preferred a Vice Chairperson to be more along the concept of a Chairperson Elect. There was some feeling that the commitment to fill the position of both Chairperson and Chairperson Elect might be too much to expect and this prolonged commitment might cause more problems in the long run.
2) Creation of a category of membership called an individual member. The current rules have 34 seats available on the Council. Organizations or agencies have occupied all of those seats and even in the at-large category it was intended to be an organization or agency. Because of Debbie Nadzam's affiliation with practice as opposed to with an organization and her interest in continuing to be involved with the Council, the steering committee looked at the creation of a new category called "Individual Member." The steering committee decided to create two seats for Individual Members. An Individual Member would be someone who has a significant interest in medication error reporting and prevention. This seat could be for one or two years. The steering committee will make that determination each time it considers the Individual Member slot. The Individual Member cannot hold the position of Vice Chairperson but they can hold the position of Chairperson. The steering committee wanted the Individual Member to be elected to the position of Chairperson and not merely to inherit it. This brings the membership category up to 36 seats. The Individual Member will be a new category under Regular Member and not part of the steering committee.

Ms. Cousins passed around the summary of the telephone conference and also a new set of rules that will reflect the changes that have been absorbed into the current rules.

The steering committee then voted to invite as the first Individual Member, Dr. Deborah Nadzam, to become a member for two years, which she has accepted, beginning July 1, 1999. This date coincides with the beginning of the Council's cycle. The new category of membership led to reissuing the call for candidates for Chairperson and Vice Chairperson. One nomination was received for the Chairperson and two for the Vice-Chairperson position. The election results were as follows:

Chairperson	-	Deborah Nadzam
Vice Chairperson	-	Jerry Phillips

Activities Update

USP (Diane Cousins) -As the Council Secretary, Ms. Cousins reported that the Council had received more mail than in any other previous time period. The amount of work that came out of the last Council meeting was incredible and reflects a lot of work on the part of the membership for the kinds of things we moved forward in doing. The four things that we balloted by mail were as follows:

1)Dispensing recommendations

2)Administration recommendations (copies available)
3)Meeting summary from the last meeting (copies available)
4)Rules changes

We have had significant interest in the taxonomy, much of which comes through the NCC MERP website. Ms. Cousins noted that when the members see the number of hits on the site and the number of downloads of the taxonomy they would really feel gratified that the Council has produced a very useful work product. The secretariat received one suggestion for a change to the taxonomy from Neil Davis of the Safe Medication Practices Group. That change is dealing with the use of abbreviations in naming drugs. This issue will be dealt with if time permits on tomorrow's agenda. Ms. Cousins handed out Dr. Davis' suggestion.

From USP's side, Ms. Cousins mentioned that USP has published an updated version of the similar drug names. This is available in a laminated reference and it is also available in a poster and a *USP Quality Review*. USP presented two posters at the ASHP Annual Meeting in Reno, NV. One on a one year summary of the MedMARx database, which will be presented later today, and one on a summary of a Neuromuscular Blocking Agent Survey, which was sent out to ASHP members, who might use these agents in their practice. They were surveyed as to certain proposals that were presented to them by the USP Advisory Panel on Medication Errors regarding how these products might be packaged or labeled, to be more obvious that they are neuromuscular blocking agents. Before the USP Standards group makes a change they want to make sure that practitioners generally feel that these methods would be effective in preventing errors. The results of this poster will be available for viewing. Ms. Cousins explained some of the proposed recommendations and how the reporting programs were used to gather this information.

A lot of work has been done by USP on the category index created by the Council. USP received numerous requests to look at this document and summarize what would make that index more effective. USP has a meeting scheduled with both the VA and the FDA, in August, to look at the possibility of developing an adverse drug reaction component into the MedMARx™ Program. This would allow hospitals that have been using a system for medication errors to use the structure of an anonymous reporting system in collecting their adverse drug reactions as well. USP is looking forward to the results of this meeting and Ms. Cousins will keep the Council posted as to the progress.

Finally, USP will be working with hospitals to find champions in medication error prevention. Through MedMARx, USP will be partnering with these institutions to develop and focus on QI Projects to progress to best practices in medication error prevention and reduction. It will define performance improvement strategies for hospitals through the identification of patterns and trends in the incidence of errors seen through MedMARx and through profile building, a system predicting these errors and hence their prevention. USP is working with the Center for Performance Sciences, part of the Maryland Hospital Association, which has been working with quality indicators for quite some time. USP is looking forward to collaborating with hospitals on that project. Ms. Cousins distributed a homework assignment for the Council members in preparation for the discussions on the categorization index. Rita Calnan and Elizabeth Cowley put together a set of case studies, for review by the Council members, that are examples of the kinds of medication error reports received by the USP/ISMP Medication Errors Reporting Program and MedMARx. These case studies were prepared in an effort to allow each Council member to choose a level of the category index that best apply the category of error. USP needs to get the members minds set for how they would apply the category index so that they can see how confusing it actually gets. This assignment will address where the areas for confusion lie. The cases will be talked through during the discussion of the category index tomorrow. Ms. Cousins explained what the exercise would look like.

Another issue which Ms. Cousins needed to address was the draft guidance for industry in placing the therapeutic equivalence codes on prescription drug labels and labeling. The members should all be aware of the response that the Council put together. Ms. Cousins indicated that this was one of the touchiest things she has had to do because there was so much concern as to whether this letter would be representing the opinions of individuals or organizations, or the Council as a whole. The Council came to the agreement that this would be presented as a general consensus of the Council as a whole and not individual members or

organizations represented. The comment period just closed June 21, 1999, so we do not have any response as yet. Dr. Combs commented that he thought this document was an excellent representation of the Council's position.

•**AARP** (Andrew Smith) - AARP is still working on two papers. One is being conducted by Dr. Lucian Leape and Dr. Rothchild at the Harvard School of Public Health, looking at the entire range of preventable medical error and injury, in the 65+ age group, and how they fair relative to others. It will also look at the problems peculiar to that patient group and the costs associated with preventable error. The second paper is by Dr. Eric Thomas and Troy Brennan of the University of Texas Houston Medical Center, looking at medical errors and the cost implications with older patients. Both of these papers are quite far along and just about ready to go out for external peer review. Mr. Smith is working on a paper looking at the tort system and how it serves or disserves primarily older patients and what kind of system should replace the current blame system. This should be completed by November. AARP is continuing its activities with NPSF.

•**NABP** (Jon May) - After the last meeting Mr. May was interested in finding out if NABP could provide any information on the rate of error, or number of errors being reported to the state boards of pharmacy. Unfortunately, that data cannot be given out because in the disciplinary database at NABP it cannot be determined how many medication errors are reported or what percentage is reported. Mr. May discussed the NABP annual meeting which was held in Albuquerque, NM about three or four weeks ago. NABP passed the following resolution:

> • NABP should encourage the FDA and USP to adopt standards whereby the product package, vial-label, and flip-top vial cap of all same ingredient vaccine products, irrespective of the manufacturer, will be similarly color coded making vaccine identification easier and reducing the probability of inadvertent or incorrect vaccine administration.

At the same time that resolution came through, there were many people on the Council who became aware of this independently. Mike Cohen put information together on the Internet that he was concerned about this resolution and that in his opinion it was not the way to go and I understand that Tom Clark sent a similar message. Mr. May wants the Council to understand that when organizations like NABP pass resolutions they come from the different districts of the organization and they come to a committee that looks at them and records whether the recommendation should pass, should not pass, or if it should receive no recommendation. This resolution came through with a should pass. Mr. May made the point that we all recognize that there is a problem and how we deal with that problem can lead to a difference of opinion. This resolution did pass and Mr. May does not believe there was any dissent. The real focus is to let those organizations that have responsibility for dealing with these problems know that NABP is concerned about it and what was passed as a resolution. NABP is not saying that this is the ultimate answer, its purpose is to get this moving so there will be a resolution for this vaccine-labeling problem. That is the real purpose it serves. It will be forwarded soon to the organizations named, for them to deal with. Mr. May does not know what will happen with this particular resolution but he hopes that it gets consideration and moves along. The second resolution was one that actually didn't pass. It says that:

> •NABP work with the FDA, PhRMA, and USP to implement the use of prescription labels that contain the physical description and identification code of non-unit dose prescription tablets and capsules.

If you have followed the workings of NABP over the last five years, this originated out of the state of Oregon, where they were very much sold on this as a means to prevent medication errors. Every prescription vial dispensed from a pharmacy would have a picture of the tablet or capsule that should be in the vial. They have been trying for many years to get this passed by NABP and it has never done so.

VIPPS is of interest because of the proliferation of pharmacy sites on the Internet. Congress does not appear to understand who regulates the practice of pharmacy, whether it is FDA or the states. A congressman from Virginia wants answers and he has put the agency on notice that within two weeks they will provide answers about the regulation of Internet pharmacies or be called to testify.

•**NCSBN** (Barbara Newman) - National Council is very interested in participating on this Council and they want to make sure that Ms. Newman represent them and that she reports back all activities and relevant information for future action.

•**AHA** - (John Combes) - In the past 3-months AHA and NPSF have had a joint news release on the problem of errors in hospitals and the recognition by hospitals that it is a problem and some steps that hospitals can take to ensure patient safety. AHA wants to take a leadership position on this issue with our members which is often a very sensitive issue for our members. PHA has attempted to get an IHI collaborative on medication errors together but it has been very difficult to get this off the ground because of some pricing issues. We are still trying to work something out with Dr. Berwick's organization. Additionally, PHA discussed the possibilities of using MedMARx and at present it appears that facilities are very short on human resources because of the balanced budget act. PHA has been working with Mike Cohen through the AHA on the national level to develop some type of tool for hospitals to access their ability to deal with medication errors or even sponsor some kind of conference on medication errors. Dr. Combs received a communication from Arthur McNeil about a campaign that they are taking nationally to inform consumers about the problems with prescription medication errors. They have actually put out a brochure, which Dr. Combs passed around to the members, and asked AHA to endorse it. AHA has made no decision on this issue as yet.

•**ANA** (David Keepnews) -In terms of activities particular to medication errors, most of ANA activities are in collaboration with other groups. Most notably earlier this month the NPSF meeting on pharmaceutical safety, at which ANA had many representatives. ANA will be participating in the July 15th Annenberg 2.5 meeting. Other activities on quality and safety issues that ANA has been involved with are testing and validating some of the work ANA has been doing on nursing sensitive quality indicators, which actually don't include medication errors, and some other related activities.

•**ASHRM** (Nancy Rapp Gulliom) - Like many of the other groups around the table ASHRM is a partner with the NPSF to look at medication errors. Ms. Gulliom passed around the recommendations to reduce the risk of medication errors that were posted on ASHRM's website as well. ASHRM is gearing up for their annual meeting in October. Lucian Leape and Dr. Nancy Dicky will be guest speakers. The agenda is available for anyone who is interested. This will be Ms. Gulliom's last meeting, which she regrets immensely. The alternate will be taking over for Ms. Gulliom because ASHRM wants to share the opportunity of sitting on the Council with other members of its organization. ASHRM has approximately 3,600 members and they share the ISMP newsletter with their membership and hope to continue to share pertinent medication error information with its membership.

•**ASHP** - (Joe Deffenbaugh) - As reported previously, ASHP is also participating in NPSF and was present at the June 10-11 meetings. One of ASHP's agenda items is to create or stimulate a fail safe medication use process and to look at ways to allow for funding of these projects. Mr. Deffenbaugh expressed his thanks to Mike Cohen and Diane Cousins for speaking out on the resolutions for mandatory reporting being passed at the ASHP convention in June. There was some ambiguity in the wording that appears to have been straightened out.

•**AMA** (Joseph Cranston) - House of Delegates meeting was held last week and a resolution supporting safe medical products was adopted. One of the resolves based on R-18, was the continued participation in the NPSF efforts to advance the science of safe medication use and likewise working with the NCC MERP. AMA will also be a part of the July 15 meeting of NPSF. A number of other reports and actions are out, including an Internet report dealing with direct-to-consumer advertising. More about these efforts can be seen at the AMA website (www.ama.assn.org). In the Internet report VIPPS was cited and it encouraged physicians and patients to use it.

•**FDA** - (Jerry Phillips) - FDA is also participating with the NPSF. Dr. Henney released a substantive drug safety report on the Internet. Part of that dealt with medication errors. The Commissioners office is reorganizing and MedWatch is moving to another office out of the commissioner's office and into the Center for Drug Evaluation and Testing. Mr. Phillips wants to reassure everyone that the functions of MedWatch

will continue on as they have in the past. Also in that reorganization, the Office of Health Affairs run by Dr. Nightingale and Tom McGinnis has been disbanded. These people will be placed back into the centers. At the last meeting it was mentioned that CRADA was collaborating to develop tools and computer analogies to look at drug names. That has been extended to December 1, 1999, for anyone interested. OPDRA will begin looking at drug names in the pre-approval stage. The nomenclature committee members will now all be full time. The therapeutic equivalence guidance comment period has closed. Mr. Phillips has not seen the comments received to date but he should be able to comment at the next meeting. John Kessler asked a question about the FDA authority in approving drug names. Mr. Phillips noted that the FDA hopes to increase the science in the analysis of names before they are approved. OPDRA acts as a consulting body to the rest of the center, so their job is to make the case for certain names.

•**USP Advisory Panel on Medication Errors** (John Kessler) - The Advisory Panel has not had a meeting since the Council last met so there is nothing new to report. A meeting is scheduled for July 19-20, 1999.

•**GPIA** - (Herb Carlin) - Nothing new to report. Mr. Carlin asked Diane Cousins to report on Amrinone/Amiodarone issues. Ms. Cousins reported on the present confusion with these two products and the fact that this issue was presented to the USAN Council. The USAN Council agreed to a name change for one or both of those product names. They also suggested that USP take the lead in this because the USP's official name can actually be different from that of the United States Adopted Name. The USAN Council wanted USP to generate practitioner comment to this issue. One of the things USP will be doing is developing a survey to address the issues of the name change. It has been suggested that Amrinone become Inamrinone and Amiodarone become Camiodarone. What it has done is pull the "C" and the "I" from the brand name products into generic names, which should help to distinguish them. This will go out for comment in the near future. It is not easy to change names of products but the USAN and USP nomenclature committee is trying to make the practitioners aware of the problem.

•**ISMP** (Mike Cohen) - Judy Smetzer will be representing ISMP tomorrow the 29th and she will participate in the discussion on the agenda about comparing medication error data from health system to health system. ISMP moved their offices to larger quarters and have added a nurse attorney to the staff. ISMP has recently completed a study on the use of automation, which will be presented later today and earlier this year completed a study on the use of hospital pharmacy computer systems. They looked at the computer systems ability to stop medication errors. That data will also be presented later.

JCAHO (Linda Hanold) – Working closely with the NPSF to put on programs in the relatively near future. A July 15th meeting is scheduled for the National Press Club in Washington, DC, that is an invitational conference with emphasis on policy issues. Another program will be a “Solutions Fair”, that will focus on solutions to reducing and preventing health care errors and medication errors. That will occur in February 2000 at Rancho Mirage, CA. It is anticipated to be a 3-day conference. The other thing that the JCAHO is working on is the SCRIPTS project, which is a HCFA sponsor project to identify core medication use performance measures. These performance measures will go to the SCRIPTS steering committee meeting scheduled for July 20, 1999. They have established criteria against which the measures will be evaluated. About 40 measures have been identified. Jerrod Loeb specifically asked me to thank Bill Ellis publicly for his leadership.

APhA (Bill Ellis) – Marge Keyes from AHCPR is involved in the SCRIPTS steering committee and actually most of our work is done by conference call but the process is moving along. It is possible that medication errors may come under this group’s purview. We have to wait and see how things play out right now in dealing with the first couple of areas. We could possibly alpha and beta test some measures before the end of this year or at least start that process. Some of the NCC MERP organizations are working with this project. They also have a website underdevelopment at www.scriptproject.org for anyone interested. Talking about dissemination of results, Mr. Ellis noted that FIP (International Pharmacy Federation) recently had a meeting in the UK which focused on medication errors and they developed a series of recommendations a few of

which are adopted from the NCC MERP. They actually referenced the NCC MERP, which was great. They adopted the medication error index for categorizing errors and this is a starting point for them.

PhRMA (Michael Horan) – We too continue to partner with the NPSF, NPSP, which is Dr. Ken Kizer's group and I know that at least one of the Council members was attending the last meeting in February. There are really two points that look at this as a pharmaceutical safety chain that starts with the drug discovery development on one end and then all the way to the patient at the other end of the spectrum. In order to get a handle on medical error reporting the climate shouldn't be that if someone volunteers something they are liable to get their license revoked. We need to create an environment where it is to everybody's greater good to report things and not have to worry about getting into trouble. That family approach is what this Council is really about. One thing that we have been busy with is reanalyzing talking about safety in a vacuum. One point we made with GAO is the notion that you really have to talk about benefit and risk. The annual science and regulatory meeting has been held and it focused on balancing the benefits and the risk. We want to try as much as possible not to overlook adverse drug events that indeed could be attributable to the drug itself. We continue to operate in conjunction with other organizations.

•**Chairperson** (Deborah Nadzam) - The Cleveland Clinic Health System launched their medication use initiative and David Kvancz the pharmacy director was asked to observe this meeting. This initiative is something new for the Cleveland Clinics. As a new health system, it decided to attack with three different committees, David Kvancz will head the Pharmacy committee, which includes all the pharmacy directors from around the system, and Dr. Nadzam will facilitate the committee that deals with medication systems, which is predominately nurses and pharmacist. It will deal with how we are getting the drug to the patient in a timely manner and preventing errors and then a physician will facilitate the medication and therapeutics committee. This will be predominately physicians from across the Health System. We think we have the right players and will continue to report on our progress.

The Council is receiving e-mail messages from consumers asking about such things as getting a pharmacist to testify in a case against a retail pharmacy. Another we received asked about starting a database for consumers, so they could tap into it and learn about the drugs they are taking. We are making referrals and answering general questions. This raises the issue of whether the Council wants to communicate with the public differently than we have in the past. The downside is that consumers will start communicating with us and that raises the issue of whether we can handle it or not.

Presentations:

Focusing on Agency Sponsored Research:Where have we been?..Where are we currently?..Where are we going?..Relative to Health Care Errors and Patient Safety.

Marge Keyes – Agency for Health Care Policy and Research (AHCPR)

AHCPR has basically supported the early work of Dr. Lucian Leape and Dr. David Bates. No work in the area of medication errors has been done in the past in any organized fashion, but AHCPR does support the research focused on medication errors, diagnostic inaccuracies, and inaccurate information recall and system failures. AHCPR has done some work on improving patient safety and it looked at such things as, computerized ADE monitoring, computer-generated reminders for follow-up testing, standardized protocols, and computer-assisted decision making. Again these reflect work done between 1993 and 1998. AHCPR provided limited support to the President's Advisory Commission and one of the final chapters in that report was focused on reducing errors. In working with NCPIE, AHCPR promoted awareness of medication safety and co-sponsored a consumer guide (Prescription Medicines and You).

Medication errors are very important to the agency and it is very interested in the work of the Council, but it also wants to look at the broader issues of health care errors and improving patient safety. AHCPR is involved with the NPSF and has co-sponsored meetings to raise awareness and educate. The AHCPR administrator serves on the NPSF board. AHCPR is also in the process now of beginning the support of a cataloguing project that focuses on errors and patient safety research. It will be asked to go around the

country and interview research funders to see what type of research they are supporting and what their plans are for the future. This is all in anticipation of setting forth a comprehensive research agenda.
AHCPR is involved in VA's NPSP and it is co-sponsoring a grant, with the National Institute on Aging, dealing with ADE's in the ambulatory geriatric setting. This is being completed by Jerry Gerwitz at the University of Massachusetts Medical Center.
SCRIPT is a project that is contracted by JCAHO and funded by HCFA. It represents a 50-member coalition and it seems to be growing weekly. This group is looking at medication management issues. It wants to identify medication management measures that can be applied in the ambulatory setting. It is looking at six different diseases including: AMI, Atrial Fib, CHF, Hypertension, Dysllpidemia, and Diabetes. The steering committee has eight members.
The next area of interest is CERT's. AHCPR has set aside $2,000,000 to create centers of excellence and the purpose is to increase the understanding of ways to improve effective use of pharmaceuticals and other interventions, avoid ADE's, and add to knowledge of risks of new drugs and combinations of drugs in every day practice. Applications for CERT's, these are cooperative agreements, were due by the end of April and AHCPR anticipates awarding these grants before the end of this fiscal year. We expect that there will probably be three or four grants issued.
The Quality Interagency Coordinating (QuIC) task force, which was put into place approximately 13 months ago, is an outgrowth of the Presidents Advisory Commission. A recommendation has been made by the task force for the federal government to coalesce, coordinate, and cooperate on quality issues. QuIC represents 15 different federal agencies. It is working with IHI and will be looking at mis/underdiagnosis of depression. There is also a measures workgroup investigating the development of measures to address errors. These are in the very early stages.
AHCPR just created an internal agency task force on errors. Dr. Eisenberg created this committee in the middle of April and Ms. Keyes is the chair of that committee. AHCPR is developing a strategic plan and the participants represent all of the offices and centers, representative of clinicians, pharmacist, researchers, and policy oriented folks. The intent is to make sure that the effort in this arena is well coordinated, so that it can set forth a strong research agenda.
Future considerations for AHCPR include reauthorizing legislation. This sets forth a strong path in this arena. AHCPR had access to reauthorizing legislation in about the middle of May and it talks about doing a few things, such as, identifying causes of preventable health care errors and patient injury, to develop, demonstrate, and evaluate strategies for reducing errors, and improving patient safety. It is also talking about promoting the implementation of effective system strategies throughout the health care industry. It recognizes that this language is subject to change but regardless is highly certain that AHCPR's future mission will include a very strong emphasis on health care errors and improved safety.
AHCPR believes that errors are something the public and legislators can wrap their arms around rather than quality issues, which are harder for the public to understand. The role of AHCPR will include being a science partner. It wants to foster and support collaboration and partnerships and convene key external players, both domestic and international. It wants to provide information and be the point of contact for external groups interested in these issues and disseminate research findings. AHCPR also supports the Surgeon General on related initiatives. Specific activities may generally include funding of investigator-oriented research and targeted research agenda-setting meetings. AHCPR will probably co-sponsor conferences and emphasize forming and continuing strategic external partnerships.

The Council members posed numerous questions, including whether AHCPR was recreating itself to specifically look at medication errors. Ms. Keyes assured the group that quality was a major priority for the agency but that they were focusing on medication errors and not recreating. Ms. Keyes assured the Council that the entire AHCPR agency was not reauthorizing legislation toward medication errors or health care errors but that it is a big part of what they will be doing in the future. Reporting, collecting and tracking medication errors is being done in various ways and the Council is interested to know if AHCPR is also

proposing to do this type of work. Ms. Keyes noted that it is in the very early stages of formulating a strategic plan. Because AHCPR is a science based organization it wants to stay on the science side or evidence based side of the issues. The research agenda is only in the planning stages.

Update on NCC MERP website Activity
Meredith Tcherniavsky
The NCC MERP server software was updated recently for Y2K compliance. Summaries of hits etc., will be posted on the website. In April and May there were approximately 1,300 downloads of the Taxonomy. No problems were experienced from the users. The number of international users while not high is consistent with a couple of dozen each month. High on the list is normally the United Kingdom, Australia, and Canada. The average session lasts from 7 to 9 minutes, which is high compared to normal website standards, so people must be absorbing the information. The Council recommendations are normally in the top 3 most requested pages on the website, with About Medication Errors. Consumer questions are not significant. Direct requests for links to other sites is not high, however all the NCC MERP member organizations that have websites are linked. Meredith reminded the Council members that if they had any documents they wanted shared with other members they could be posted.

MedMARx™ Data Summary: The First Nine Months
Judy McMeekin and Fay Menacker, USP Practitioner and Product Experience Division
Data presented covers the period from August 1, 1998 through April 30, 1999. Nineteen facilities were reporting data during this time period. The facilities varied and its data was taken from inpatient and outpatient settings within the hospital. During that time period there were 1,307 records entered, with 98% of the errors not causing harm. 85% of the errors actually reached the patient and of those 4% actually resulted in harm.
The types of errors were analyzed and they included omission errors, improper dose, unauthorized drug, and extra dose. Most of these errors relate to medication administration which may actually indicate that error prevention efforts should be focused on the earlier parts of the medication use process that worked or prevented the error from occurring, such as pharmacist verification, computer generated medication administration records, and documentation efforts. The ten most frequently reported causes of error were examined and the top four are performance or human deficit, procedure/protocol not being followed, communication confusing/intimidating/lacking, and knowledge deficit. Systems issues stood out when the data were evaluated. Contributing factors will be reviewed and analyzed to establish improvement measures.
USP evaluated the top ten products captured in MedMARx and not surprising they included:

IV fluids (at least 16 of the 53 did include Potassium Chloride)
Insulin
Cephazolin
Warfarin
Heparin

It should be noted that these products are very similar to the top drugs reported through the USP/ISMP Medication Error Reporting Program. It may be that these drugs could be considered high alert drugs and facilities might want to take a careful look at the use of these products. USP continued to further delineate between the categories of errors, to see if anything particular could be seen with the most frequently reported products.
Now that we know the category, types, causes, etc., institutions can look at where in the medication use process the errors are occurring. One thing that is very helpful is looking at the action taken by facilities in response to a particular medication error. This is the real value in utilizing MedMARx across all the hospitals nationwide.
A poster was presented at ASHP and that is available for viewing after this presentation.

Facilities should be encouraged to report all medication errors. We know from our orientations to MedMARx that not all hospitals report unless the product reaches the patient. We as practitioner's l know that can be too late. Safety nets that are in place in hospitals should be promoted.
USP does plan to publish summary data to alert the hospital community at large about the medication error prevention strategies being observed in MedMARx.

Pharmacy Automation: Are the systems in hospitals safe?
Results of a survey of U.S. Hospitals – *Michael Cohen, ISMP*

Mike Cohen presented information on pharmacy automation that includes computer systems. Mr. Cohen and John Kessler presented this information at the ASHP Convention in Reno, Nevada. Many organizations are looking at the problems associated with medication errors and what is needed as far as creating a safe medical system. It is important to keep in mind that a lot has been learned especially from the reporting programs and a lot is not being put to use as yet. A study was done which Mr. Cohen separated into two parts, computerization in the medication use process, including the physician-ordering piece and second the pharmacy automation piece. There have been studies done on this subject and David Bates published a most recent one in JAMA. It showed a 55% reduction in preventable adverse drug events (ADR) due to prescribing of medications. This is obviously a good computer system that could prevent 55% of ADE's that were due to prescribing. They decided to look at not just prescribing errors but other uses dispensing and order screening with the hospital pharmacy computer systems.
Unfortunately, the current state of affairs with pharmacy automation is not encouraging. They asked a number of hospitals, which receive the ISMP Medication Safety Alert, to participate in the program. 320 hospitals agreed to send the data in. They were asked to process 10 medication orders that were known to have caused deaths or serious injuries during the previous years reported in various articles, through the USP Program, and through the ISMP Medication Safety Alert. They were asked to set up a test patient so that it would not interfere with any active patient. They were asked to enter the report as if it were a live patient. The results were as follows:

1. Antibiotic oral suspension that was actually given intravenously to a patient during 1998. When this order was processed 61% of the computer systems failed to pick up the fact that this was an oral suspension that they were actually entering for IV use. The labels printed out for IV use. Ten years ago this may not have been a problem but today we have a lot of substances that are not clear liquids and that in fact can be given appropriately IV. The old saying of only administering IV those liquids that are clear doesn't stand anymore. 36% of the computers when asked to override this order without documenting the reason for the override, were able to do so.
2. Pharmacists were asked to enter Ketorolac (a non-steroidal anti-inflammatory, which is available for IV use). There is a cross allergy between aspirin and this non-steroidal. In 12% of aspirin allergic patient, the systems did not detect the problem with the allergy. 64% were able to override.
3. 62% of the computer systems let the wrong dosage of Vincristine go directly to the patient. No maximum dose set that would prevent that from happening.
4. 66% of the computer systems let a massive ten-fold overdose of Colchicine go directly to the patient.
5. A physician in New Jersey ordered verbally for Cisplatin 20.4 mg. In the transcription process at the nursing unit the decimal point was left out and the child received 204 mg instead. 63% of the computer systems let this go through.

Mr. Cohen gave several more examples of the problems associated with computer system failures. He also noted that 69% of the respondents to the study said yes to the question "Your system allows you to build alerts for error prone situations such as look alike names." Indicating that 30% of the

respondents do not have such a system. 80% of the respondents noted that they had systems capable of providing management with regular reports of drug warning overrides by their staff. 74% responded that drug interaction alerts without clinical significance were either not present or easily eliminated. Only 13 % of American hospitals have physician order entry capability.
What is really interesting about all of this is when you look at the cost of adverse drug events in general, from the Johnson and Bootman studies, we are talking about $100 billion a year. If you were to divide the number of hospitals and pharmacies into that amount you would actually have about $1million per site. If we funded 1 million per site to either enhance the current system or provide a computer system that could provide the type of screening that is necessary we could go a long way in preventing the adverse drug events that we presently see.
Another interesting area was the response with regard to the vendor response and follow-up. Apparently, the vendors give very little follow-up support to the hospitals. They actually leave the programming, of the rules for detecting many of the issues we have addressed today, up to the facilities. One thing that Mr. Cohen would like for the NCC MERP to do is work with the pharmacy system vendors to create the best systems for preventing medication errors.
Bar coding is practically non-existent in hospitals in 1999. So another thing that Mr. Cohen would like to see NCC address is the issue of standardizing bar coding.
All the information, provided in this study, is available on the ISMP website at www.ismp.org.

Pharmacy automation was the next segment studied. Mr. Cohen presented some of the errors with automation systems (automated dispensing cabinets that are on the nursing units) reported through the USP MER Program. Approximately ½ of the US hospitals have these systems. Instead of floor stock there is limited access for the most part to certain medications that can be obtained by a nurse or other practitioner in many different areas of the hospital to administer medications. There should be a system whereby the pharmacy screens the orders before the drug is accessible. Unfortunately, our study shows that it is frequently not taking place and patients are sometimes at risk. Study results showed:

- More than one patient's medications can be accessed at a time.
- Items removed from the equipment but not ordered for the patient
- Problem with the return system
- Doses placed in the wrong slot or doses that fall into the wrong slot and are misplaced when returned
- Retrieving an incorrect medication due to misreading or an open access
- Wrong doses of medication or in larger quantity than ordered
- Careless reading of labels for various reasons.

On thing that you hear time and again are that people believe because it is a computerized system that it is unlikely those errors will actually occur. That is certainly could not be further from the truth.
Many studies have been published on automation and one of the best is by Dr. Kenneth Barker where he shows a three-fold increase in medication errors in practice. There are some studies that show lower error rates with the use of this equipment and John Kessler will cover this, but we have doubts about the results. Mr. Cohen described a survey done by ISMP of 453 US Acute Care Hospitals to evaluate the actual use of the automated equipment. He shared the partial results with the Council. This information is also on the ISMP website. One particularly scary practice is that only 12% of pharmacies screen the orders before drug removal. Safe practice recommendations for automated dispensing units have been established by ISMP and by Dr. Barker.

Current Research Involving Errors in Automation

Literature summary – *John Kessler, Duke University*

Dr. Kessler provided the Council members with copies of his slides from the ASHP Reno, Nevada presentation and presented a condensed version to the Council.
Dr. Kessler was struck by an article on automation that referred to a 1956 article in the *Financial Post* that stated since the advent of modern computers the practitioners have been promised the reduction of work, relief of tedium, elimination of error, etc., and if we look at the literature we get the same promises today. We need to go well beyond these promises and look and see what it is that is beneath the surface that is so alluring and that we can benefit from. Dr. Kessler took the group through a set of important lesson from the past and present and generalized where that might lead us in the future. He discussed the unit dose system and the research studies that have been completed on this topic. Dr. Kessler also discussed a computerized system that was integrated into the daily routine of rounds and clinical decision making in a particular hospital. He quoted Garibaldi, who noted that the human components of a system are much more difficult to transfer than the automated system itself. The point is that you cannot just buy a system off the shelf, plug it into your hospital and expect positive outcomes. Dr. Kessler pointed out that he was looking at the published literature and not the proprietary research or organizational research. Dr. Kessler summarized the past, present, and future and that in fact most of the literature has failed to describe what the role of management engineers have been in these systems in the implementation, design, and evaluation. Dr. Kessler noted that if we do not codevelop these things, bad things could happen. He noted that we couldn't have clinical decision support without effective drug delivery automation and vice versa.
Dr. Kessler described the parts of airline safety that struck him as relevant. The discipline found in airline safety and industry is not present in pharmacy or in most health care systems. The rigorous adherence to protocols, checklists, and redundancy in their practice is absent in ours. That absence of discipline has hindered the ability of healthcare to go back and measure and analyze error. We don't have a trail but only the memory of the people involved. The airline industry has accepted that tragic error will occur especially in a complex system. It does not reduce the drive to eliminate errors but it is accepted in the model.
Dr. Kessler also covered the sales and marketing, and engineering industries. Clinical Decision Support was evident in the research looking at diagnosis and preventive care, and other types of quality and error. There is not a lot of evidence to support that automation has a significant effect on physician performance and even less data on patient outcomes. We appear to be in the embryonic stages of measuring this and that automation probably has some effect, but looking at specific drugs and diseases it was difficult to show that automation had any effect.
Dr. Kessler reviewed the Bates study on electronic order entry. The end point of the study was non-intercepted, serious medication errors. They found that these decreased by about 55%. Preventable errors decreased about 17% and potential errors decreased 84% with the use of electronic order entry. What is important about the Bates research is that the observations and conclusions where based on the errors that remained in the system even after the automation, in contrast to other studies that look at what the system caught. The Bates study looked at what system errors were left after automation was in place. Richard Cook wrote an article on medication related failures after the year 2000. He noted that interesting future human failures that will take place in the new millennium would involve the following areas:

- Infusion devices
- Automated pharmacy dispensing systems will play a role in a grand disaster
- Prescribing by paraprofessionals
- Bar-coding systems
- Computer based order entry
- Coordination of care

Dr. Kessler referred the group to the White Paper by the Journal of the American Society of Consultant Pharmacists on pharmacy automation, which is an outstanding paper. Many excellent ideas for research have been addressed.
Discussion ensued regarding the possibility of inviting vendors of automated systems and bar coding to attend a NCC MERP meeting in the near future and whether the Council should consider issuing warnings about these systems so that hospitals know they are not failsafe.

ACTION ITEM: Form a small group to review the problem with bar coding and automation.
Bar-coding group: Mike Cohen (leader), Shawn Becker, Joe Deffenbaugh, Jerry Phillips, and Herb Carlin.
Automation group: Debbie Nadzam (leader), John Combes, David Keepnews, John Kessler, Diane Cousins, and Joe Cranston.

The Chairperson instructed the Council members to do their homework assignment on categorizing errors. The research agenda will be discussed at a later time. Steering committee will meet in closed session following adjournment.

The Chairperson made a motion for adjournment, and it was seconded. The motion carried and the meeting was adjourned at 5:00 P.M.

June 29 1999
Day two

The meeting reconvened on June 29, 1999, at 8:35 A.M.

Council delegates present:

Deborah Nadzam, Chairperson (Cleveland Clinic)	Diane Cousins, Secretary (USP)
John R. Combes (AHA)	Michael Horan (PhRMA)
Nancy Rapp Guilliom (ASHRM)	Jerry Phillips (FDA)
Jon R. May (NABP)	Joseph Cranston (AMA)
Joseph Deffenbaugh (ASHP)	Alice Till (GPIA)
Bill Ellis (APhA)	Linda Hanold (JCAHO)
John Kessler (USP Advisory Panel on Medication Errors)	

Alternates present:

David Keepnews (ANA)	Judy Smetzer (ISMP)

Other alternates that attended along with their delegates:

Shawn Becker (USP)	Herbert Carlin (GPIA)

Delegates absent:

Janet A. Myder (AHCA)	Michael Cohen (ISMP)
Andrew Smith (AARP)	

Observers present:

Jeff Ramirez (VA)	Russell Jenkins (ISMP)
David Kvancz (Cleveland Clinic)	Marge Keyes (AHCPR)

Jane Ward (APhA) Ken Barker (Auburn University) Fay Menacker (USP) Sue Zmuda (USP) Judy McMeekin (USP) Elizabeth Cowley (USP) Rita Calnan (USP) Sara Foer (USP) David Holmen (USP)

Debbie Nadzam announced the results of the executive session. She first welcomed the newly elected Department of Veterans Affairs as a Government Regular Member of the Council and acknowledged Jeff Ramirez as the delegate. She also announced that the Steering Committee voted to continue ASHRM's membership for another two years and know that we will have a new delegate chosen from ASHRM. Debbie Nadzam acknowledged the observers and newly arriving delegates. Michael Horan introduced himself as the new delegate representing PhRMA. He complimented Diane Cousins on her ability to construct a letter that the entire Council was comfortable in supporting and signing. He felt that if that ability was a judgement of the quality of the organization then he was very happy to be part of it.

Ms. Nadzam introduced Dr. Ken Barker for a presentation on the observation method and how it is being applied to hospital systems.

Guests Presentation:

Applying the Observation Method to a Hospital's Medication Error Reporting System
Kenneth N. Barker, Auburn University

Dr. Barker explained that he had recently attended a meeting of The Advisory Board Company, a consulting firm, and they have a new booklet out that summarizes the question of adverse drug events with recommendations to CEO's as to what they should do about them. He recommends that the Council review their presentation. Dr. Barker noted that the title of his presentation should be "The Observation Method in Detecting Errors and Preventing Adverse Drug Events." That is what he considers the observation method is all about.
Dr. Barker started with a definition of medication error that has historically been used in the development of the observation method for this purpose. It focuses on the drug distribution process and it excludes prescribing errors. He presented an outline of his presentation and described the basics of the observation method. The idea behind the observation method is that a hospital nurse or pharmacist is trained in the observation method and then this observer goes to a selected nursing unit, during a peak workload time to observe the medication administration. The observer witnesses the administration at the bedside. This method was designed to count those and only those that are actually medication errors as delivered to the patient. This method does not include potential errors. The observer then reads his/her notes and compares them against the patient's chart. In the last three years, the observer actually goes back on the same day and sits down with the nurse being observed and reviews the errors. This provides validation and discussion of the possible cause of the error. The error rate is calculated as the percent of total doses given plus those omitted which were in error. To make the rate as simple as possible each dose is considered either in error or error free.
In the past the observation method training lasted for six weeks, now we have it down to two days of intensive training followed by three days of extended clinical practice.

The rationale for the observation method is that this is an outcome measure of the quality of the drug distribution system itself or that process. We are questioned often as to the willingness of the nurse to report an error once it is known among the people involved. Dr. Barker reported that even in the instances when the nurse did not know the drug and gave it to the wrong patient less than ½ of these errors were reported via incident report.
Bates and Leape did a study to determine the clinical significance of errors and caused Auburn to look at the clinical significance of medication errors. Dr. Bates has come up with the estimate that using his method, including a chart review and interview with the health care practitioner, the best guest is that for every 100 errors detected by observation one will be associated with an adverse event. For 300 inpatients with one error per patient per day, where you have 100 errors, using Dr. Bates estimate that one of those will produce an adverse drug event (ADE) and for each ADE using Debbie Nadzam's estimate, approximating that the error costs $2000.00, excluding malpractice, you still come out with a situation that is costing $2+ million a year.

The accuracy rate in hospitals is approximately 90%. Lucian Leape points out how strange that must sound to people in other industries, where even the beleaguered post office system does not lose 16,000 letters per hour and banks do not lose 32,000 checks per hour.

Dr. Barker provided a history of the observation method, which began with an exploratory study back in 1961 at the University of Florida involving 9 RN's each observed for two 8-hour shifts. 93 errors were detected during a period of time when 607 opportunity for errors was identified. To determine an opportunity for error you simply add the doses that were given plus the doses that were supposed to be given. In 1966, Dr. Barker's group received a grant from the Hartford Foundation to find out what we could about the error problem which lead to a study of all 32 nurses giving medications in this same hospital. We followed each nurse for an 8-hour shift for 5 days in a row. We were able to look at a large number of errors and formed the basis for the unit dose concept. In 1969, we installed the unit dose concept at the University of Arkansas Medical Center and used the observation method before and afterwards. This was the only time that Dr. Barker is aware of that error rates were used as a way of evaluating an intervention for system changes. Since that time there have been eighteen studies in three different countries with comparable results conducted and we stopped counting them in 1990. People continue to use the observation method, primarily for the purpose of evaluating interventions and system changes.
During the period 1982-1984, HCFA approached Dr. Barker's group with a proposal for adapting this method to use for evaluating quality in long term care facilities as a condition for reimbursement under medicare/medicaid. A study of 68 small hospitals and nursing homes across the country was conducted. On the basis of that we found that we didn't have to use pharmacist as observers but make the definitions robust enough so they could be used with nursing observers and thereby lowering the cost. That is the system that HCFA uses today to regulate the nursing home industry.

A major hospital chain in Alabama requested Auburn to develop this system for use as an in-built quality improvement system for their hospital group. Their strategic plans predicted that within five years the rest of the country would be using hard measures of quality to make decisions and to compete with the other hospitals in the area. Their assessment was that this type of information would become public knowledge anyhow so they might as well be ready when this occurs.
Two hospitals had this system installed and Dr. Barker presented the methodology, description of sites, project origins and objectives, observer recruitment and specific sampling for this project.
Dr. Barker explained that it has been determined that in order for the observation method to succeed it does require 1 FTE to achieve the expected end result. They now accept that 1 FTE is the cost of the observation method. This system is now being used for performance evaluation and this required observing a 100 doses

a month on all nursing units. The results are from 20 months of observation and medication error tabulation. The observers identified 2027 errors and a total of 5000 opportunities for error. There was a high rate of wrong time errors and it was noted that excluding wrong time error the results were very similar to that of the past 20 years worth of research in this area. Dr. Barker described examples of the kinds of medication errors seen in these facilities and explored the trends. As a result of this database we saw a significant difference in the nursing units and found that there really are hospitals and units that have remarkably low error rates. If you are planning a quality improvement strategy you can put the areas with low error rates aside and concentrate resources on a much smaller group.

Performance evaluation was a major concern for the hospitals being evaluated. Dr. Barker and the researchers were not ready for this but apparently the hospitals were. They wanted to institute a performance evaluation system that has the following measures: any nursing personnel that want to participate in a 10% raise must be employed in a nursing unit whose error rate has been reduced by 10%. Dr. Barker noted that he was just reporting this information not necessarily in favor of it. He does however, stand behind the fact that this was not geared toward the individual nurses but was a recognition that this is a team effort.

Problem-based continuing education has proved very effective within these facilities. The nurses involved in the errors talked about the errors and determine appropriate measures to confront the causes of the errors being committed by their unit. Dr. Barker described a program in the State of Wisconsin. He noted that when HCFA started doing observations as part of its accreditation of nursing homes a for- profit seminar was put together and the nursing homes were invited to send their nurses to the seminar to learn how to avoid making medication errors. Thus doing a better job when the surveyors came around at the end of the year to do the observations. As a result the error rate went down in Wisconsin compared to the other states.

Dr. Barker summarized where he thought the observation method is useful and ready for general use. That is it is useful for the prevention of adverse drug events due to errors of drug distribution. The observation method allows one to narrow the focus earlier and faster than the other approaches that are available. Dr. Barker made several points regarding benchmarking. He offered that the definition of a medication error includes distribution and prescribing errors and that they are fundamentally different because they have two different denominators. The denominator for prescribing is orders and the denominator for distribution is doses. By lumping the two together it does a disservice to those of us attempting to do benchmarking. He would like to plead with the Council to give some attention, if you are going to proceed with benchmarking, to the problem of clearer operational definitions. Recognizing that politics are real and have to be done, the tough job of the Council is to reconcile them so the way can be found to benefit everyone's needs. Dr. Barker explained that he tried to come up with a successful benchmarking criteria and his follows:

1. Has to be easily understood, and if it immediately provokes an argument then you are already losing
2. Has to be believable
3. Has to be practical and has to be used for something
4. Needs to be objective so it cannot be one that leads to a particular profession using it to advance their causes
5. Needs to be economical
6. Widely used- calls for a massive effort

Numerous questions were posed by the Council members and Dr. Barker graciously provided answers, including:

1. Was there shock from the CEO when they saw that they had a 10% error rate at their facility? It certainly got their attention and the administrator called a meeting of the medical staff and that is how we got the 2 FTE's to be observers.
2. Has the observation method been used in pharmacy? The first observation was on prescriptions dispensed out of the pharmacy. It was Hartford study where two plants collected data. The pharmacy contribution was relatively low compared to the nursing units. The pharmacy situation did not leave a lot of unanswered questions. A study was done for *ABC's Prime Time Live Program* where a hidden camera was used and shoppers where four separate Rx's were made up and presented to pharmacies. We used 3 different states and learned that 4 our of every 100 prescriptions were wrong in some clinically significant way. Almost 40% were wrong if using state and federal standards, however we did not count these in the 4%. Dr. Barker feels that there is a major problem out there in the drugstores. That is not a surprise and the Chains and NABP are working on those issues.
3. About the methodology, how do the observers maintain independence from the process so that they wouldn't interfere and how do they maintain an ethical balance? This rarely comes up. For research purposes you do not want the observer to know what is suppose to be given because there is a natural inclination to write down what they think is suppose to be given. It was drummed into the observers that they should not look at charts, MAR's or anything on the unit. Just blindly write down what the nurse is giving. Writing down what the nurse does is physically demanding so they do not have time to worry about reading charts or gathering additional information. We caution the observers, to not do anything obtrusive, but not to hesitate in stopping the nurse if you see something that you are convinced is life threatening.
4. Does the smaller hospital have the kind of money necessary to engage the observation method? You are hard pressed to look at 20 doses in a smaller hospital and the bad news is they have serious problems in these smaller hospitals. It only takes looking at 20 to see a serious problem. If you look at the ones that HCFA closes based on the medication error rate they are typically in the small group.
5. What were the unusual characteristics of the units with the increased number of medication errors? That is the next logical next question to answer. All of the other methods being described are appropriate for answering that question. Trying to explain risk adjustment or anything else to someone outside our field and they only see that if things are this bad lets go in and clean up the mess. Get the error rates down now.
6. This method clearly identifies the person in error, do you have any problems with repercussions against those individuals. Do you have any agreement up front that the method is not being used to weed out people? Yes we do and frankly speaking that issue is probably the thorniest issue in the area. Management does have a responsibility to do something about someone who continues to make errors. What we have seen so far is that the group itself will provide pressure on the individual. That will not satisfy the attorneys. CE groups have addressed the person who leaves the hospital at risk. The issue of discoverability is a problem.
7. This is not developed to get a prescribing errors nor does it capture transcription errors is that correct? No it does not capture prescribing or transcription errors. You have a set of clues at the scene and it is like an automobile accident you have to investigate quickly.
8. In the study being done now are you observing the pharmacy technician administering the medication? Is the observer method been used with unlicensed personnel? In the study now the pharmacy technicians are being used as the observers and in the observer method the observers observe whoever is giving the medications.
9. The CE Groups sound like the quality circle concept. Could you comment on these groups? Dr. Barker does not want to take the credit for getting these groups together in giving them problem- based problems to deal with. It is an old idea and I suspect that one reason it falls out of favor is that the administration cannot be in on the meetings. How long they will allow this to continue with a facilitator saying "OK we are doing fine boss" remains to be seen.

10. How are the lesson shared out with the rest of the hospital? It comes from the facilitator to the QI committee of the hospital that is the committee we work with. They get put on the agenda to see what the hospital will do about it. Not much attention has been given on the information going out because there is a concern of not telling on each other. When the facilitator collects ideas those collected ideas for improvement go to the quality assurance committee and then they decide what to do.
11. How can you turn this into a practical solution for hospitals and other health care institutions to improve their performance in health care delivery? Do you have a program where you actually train observers to go out and talk to groups of hospitals to notify them about how to get a handle on this problem? Actually, people have been sent to Auburn to train and that is how a lot of studies got done. We are now going to talk with USP about setting up a group that would go out and actually install this in those places. Now that we know we can do it in a week or over two weekends.
12. Can the observation method be used in other settings besides the nursing unit? Presumably errors could be studied as long as the setting is schedulable. Errors could be studied and in fact physicians' errors have been studied in the OR by observation. Anesthesiology people have been way ahead of others in this respect. No we have not done these studies. These areas do seem to be harder, it can be done.
13. Does this study discount the errors of time? What is an appropriate time period for the routine administration of medications? This is something that varies by institution. We use a grace period of + or – 30 minutes. In one hospital that we studied, the nursing department debated this very subject for over one year and changed the criteria to be +or – 60 minutes. It is more important that everybody agree. We came up with 30 minutes based on real world experience. We looked at how long it took the average nurse to administer medications and we drew the line there. One thing to note is that the percent of drugs that are considered important relative to time has gone up so it may be important to take another look at the wrong time error and adjust it for different drugs.
14. Did you see in your observations, that the increase in time errors went up as the number of doses per day per patient went up? The real question here is there a workload effect and the answer to that is yes.
15. Was a severity of the outcome graded or captured at all? No.
16. As the error rate goes down is there some point, as that rate decreases, that it is possible that the observation method might be ineffective because errors are likely to be undetected due to a sampling process? Anytime you are involved in sampling you are subject to sampling error. If you use established sampling practices, for instance in the small institutions we are encountering now where 20 doses are being observed, we are observing the 20 doses that day. When asked what the rate of error on that unit is we are talking about the population not the sample.
17. Who are the facilitators for the continuing education sessions? The nurse observers act as the facilitators because the nurses trust them.

Measures of Comparison: A Discussion of Medication Error "Rates" and Comparisons.
Diane Cousins-USP, Judy Smetzer-ISMP, Linda Hanold-JCAHO, Jerry Phillips-FDA, and Ken Barker-Auburn University

Diane Cousins presented USP perspectives on this issue:

Hospitals are becoming very interested in comparing medication error rates data both between and among hospitals as well as inside their individual facilities. The report card concept for hospitals is really a measure of quality for patients selecting a health care facility. It's possible that error rates could play a role in this grading. HCFA supported this measure and suggested a 2% error rate in hospitals is acceptable.

Obvious questions center on this issue:

1. What are the appropriate and inappropriate denominators for calculating medication error rates? Is it 'number of doses administered', 'number of doses dispensed', 'number of orders written', 'number of doses given' vs. the 'number of doses omitted', 'number of patient days' in the inpatient setting.

USP has determined that the most common denominators used by hospitals are the 'number of doses administered' and 'number of doses dispensed'. Each of these aforementioned measures, however has shortcomings, for example the number of doses administered does not include the number of omissions that might result from error, systems such as Pyxis® and SurMed® might have improved the accountability of PRN medications but these are often not counted into those numbers. Doses prescribed may be overstated if it doesn't reflect the number of cancelled orders. Doses dispensed may be inflated if the dose is not given and returned for credit. If facilities use doses billed as a denominator, appropriate patient crediting presents a problematic issue.

2. Should rates be used at all to reflect medication errors? Three problems arise:
    - Individual facilities and organizations define medication error very differently. They may not include: potential errors, interceptions/near misses (pharmacy or nursing interventions), or prescribing errors often identified by voluntary reporting systems.
    - The number of medication error reports collected will be affected by the facility's culture (punitive vs. supportive) and the ease and convenience of reporting. Even the observational method could have built in biases.
    - Rather than collecting and comparing rates, perhaps measurement should involve comparison of raw numbers vs. time to measure incremental improvements? IHI may advocate this.

3. It may be that medication errors should not be expressed simply as a fraction but as an equation or formula, which might incorporate such things as severity of the outcome, acuity of the patient, or the age of the population affected.

4. What threshold, equation, or denominator is useful for regulatory purposes and the evaluation of risk by regulators?

Linda Hanold presented the JCAHO findings from the Oryx Initiative (integration of performance measurement into the medication process)

Ms. Hanold found 80 measures that addressed medication errors in the Oryx database and ran off 15 profiles from systems using medication error measurement tools. She noted considerable disparity in the measures collected. The denominators that were seen included:

- Total number of doses
- Total of inpatients, plus discharges, plus deaths for the designated reporting period
- Doses dispensed divided by 1000
- Patient admissions multiplied by the length of stay stated as 1000 inpatient days
- Doses dispensed
- All doses given
- All doses dispensed
- All doses administered
- Number of days patient received pharmacy services
- Number of patients on the census plus the number of discharged
- Total number of doses prescribed
- Inpatient population

- ♦ All patients taking medications

Bill Ellis described the Study of Clinically Relevant Indicators of Pharmacologic Therapy (SCRIPT) Coalition, which is 53 organizations defining relative measures of medication use quality improvement. SCRIPT is focusing on the disease state model and currently is looking at cardiovascular disease and diabetes. It is set up to identify and focus attention on medication use measures, but it is also focused on testing a process that allows a coalition to identify measures. The next generation of SCRIPT, may put medication errors on the table, but that is down the road a bit.

Jerry Phillips presented the FDA data:
Mr. Phillips noted that it might be a question about the numerators being used that needs to be addressed. Maybe we can have a common denominator and maybe we can't. What he found from FDA and the literature follows:

- Normal epidemiological rates require the number of outcomes of interest (numerator) divided by the number of exposures/procedures that could have resulted in that event (denominator)
- Most frequent denominator for med errors has been the number of prescriptions ordered in a particular setting
- The number of opportunities for error (total number of doses ordered plus any unordered doses given (Dean, Allen, and Barker. ASHP; 1995)
- Rate determined by the number of prescriptions containing 1 or more error divided by total number of prescriptions (Barker and Allen. ASHP, 1995)
- Denominator was hospital admissions (Bates, Cullen, and Laird. JAMA, 1995)
- Rate calculated as the number of actual errors divided by the total opportunity for error (sum of all doses ordered plus all the unordered doses given) (Allen and Barker. ASHP, 1990)
- Error rates per 1000 medication orders written, per 100 hospital admissions, and per 1000 patient days. (Lesar and Lomaestro. Arch Intern Med 1997)

FDA denominator for ADE's is the number of dosage units dispensed. FDA also uses IMS data, which is limited to retail pharmacy and has no hospital data. Jerry implied that HCFA's denominator was not specified. Furthermore, he is convinced that benchmarking will not have any impact on reducing or preventing medication errors and feels it should be discouraged. Mr. Phillips also feels that a standard denominator should be adopted that will reflect the best measure of risk that can be collected in all relevant settings. Because of the current limitations of data systems, it remains important to monitor each report and evaluate on a case-by-case basis.

Presentation of Dr. Ken Barker's HCFA Study

The proposed study is for 36 sites, where one week would be spent at each site. In the 36 sites, 1/3 would be SNIFS, 1/3 would be non-accredited by JCAHO, and 1/3 would be JCAHO accredited. The bed size of all the unaccredited facilities is small. The study needed to establish what kinds of observers would be needed. The best data collectors are pharmacists, but they are too expensive. The next best is some type of nurse and the third best observer is a pharmacy technician. Three different types of institutions and three different types of data collectors were established. Just to make it interesting we compared three different methods of data collection:

- Incident report method-any hospital recognized document that functions as an incident report (accident reports, event report, occurrence report)

- Chart review method-Leape and Bates were engaged as part of the study.
- Observation method-Barker

Geographically we picked two areas: Atlanta, GA and Denver, CO., with eighteen hospitals in each area. We tried to make the study as realistic for HCFA and for the local hospitals as possible, so we used the local papers for recruitment. We figured it would take approximately one month to talk to CEO's to arrange for the study. This actually took more than 3 months. Found out that approximately 1/4 of the hospitals identified by HCFA were no longer in business. Only found two hospitals that thought the study was too threatening.
The observation method uses the same denominators presented earlier in the agenda to the Council. The chart review method found that the observers could not identify prescribing errors. Denominators are difficult. Observing basic information from the charts was difficult. Chart review is done retrospectively, so even taking the last 7 days and trying to find a record of how many doses were ordered and given is difficult. Incident reports are a vast variety and being done for a number of different purposes. There is a lot more interest now in preventing medication errors but the focus is not there.

Judy Smetzer presented ISMP's impressions of this issue

Like the USP we receive calls requesting information on the national threshold for medication errors. Rates are not a valid measurement of medication errors. There is a problem with the methodology because of the variety of reporting mechanisms. Rates are being determined by the reporting systems in place in the hospital. It is so influenced by individual reporting that in the end a high error rate may signify an unsafe system or it could mean a system that has a culture where reporting is encouraged. More value is placed on knowing the problem than any perceived benefit. On the other hand you could have a low error rate signifying a safe process or improvement, or a very punitive culture where not a lot of effort is put into detecting errors and there is little incentive to report**.** What can be reported is an error detection rate? Errors are detected and reported in your organization.

A national measurement system is valuable if you have a consistent and accurate method of studying errors to drive at a rate. Simply comparing error rates without knowing what the hospital is measuring is not valid. Why are errors lower in one facility than in another?

Any national measurement system can only be effective if first you have an accurate measurement of errors, the ability to identify what makes facilities commit less errors, and the sharing of the information with other organizations to be proactive instead of reactive. Once best practices are identified that information should be shared with other hospitals. There should be oversight to that information by regulators and accrediting organizations. There are problems with all of these approaches so don't place as much emphasis on rates but on establishing a system for reporting and observing error rates.

Discussions:
Debbie Nadzam spurred the Council members by offering several suggestions.
The purpose of the discussions on comparison and denominators was to inform the membership about what is out there and to address the "R" for Reporting in the NCC MERP name. Promoting better reporting. Do we want to, or even better, can we come to consensus on what to do about rates and comparisons. I will offer two observations to get the discussion started. One relates to something we have talked about this morning. The denominator is different for dispensing,

administering, and even for prescribing. It makes me think about what has happened in the area of hospital infection control. There is acknowledgement now that a hospital infection rate is worthless. What you need to do when looking at nonsocomial infections is get to pneumonia, surgical site infection rates, blood stream rates, etc., and look at the different types and causes of infection individually. Maybe talking about a medication error rate is not the way to go. Maybe we should be talking about several different rates that better reflect what is happening when trying to get the right medication to the right patient at the right time. The other observation I would make, if we do come to some sort of consensus on how to report a measure, is that there is another whole quagmire regarding the adoption and implementation of this measure. We talked about how hospitals define rates differently and they are not working together**.** On the national level there are now several initiatives that focus on medication errors and the Council's organizations sit on a variety of those task forces. What our responsibility as a coordinating council, as we have accepted it, is to go back to these other efforts as well and try to minimize the dilution of effort that could be occurring? Because national groups, committees, and efforts are all trying to do the same thing maybe including the same organizations but not really working together. We need to consider this if we want to encourage the use of definitions and measures.

Bill Ellis— The Council came up with a valid definition for a medication error but now we are moving into areas of quality improvement and measurement I think it is only natural that you need to begin to separate those out. I think we need narrower definitions but not to replace the original definition. For research purposes we may need to look at other definitions. The ultimate measure does not exist but we may want to develop measure sets to take into account different practice sites or different aspects of an issue. We may want to come up with recommendations for measure sets.

Judy Smetzer— As a national committee, if we try to be more focused we could come up with some of the outcomes of medication use rather than promoting an overall medication error rate in ways that organizations can measure in more focused areas. A lot of that work is being done by IHI and other collaboratives where they offer organizations a totally different way of measuring med use outcomes. They identify and prove that their efforts were successful in reducing medication errors by offering them a different way of measuring that. For example, if you focus on a particular drug such as heparin, reducing heparin errors. Measures can be focused at potential adverse drug reactions and adverse drug events for example the measure for potential ADR could be any PTT that is over a certain level and your measure could be any bleeding episode. (Your totally removed from that action area you are looking at and the outcome of that medication which would indicate that an error either in prescribing, dispensing or administration has occurred. You want to measure before and after.)

Debbie Nadzam—had some efforts, which have tried to get at this kind of problem. JCAHO made an effort that tried to address the nodes in the system and measures that were patient focused, not error focused. ASHP developed guidelines.

John Combes—agrees with the discussion but would not sell short the movement in this country to develop comparative indicators for health care organizations to drive purchasers and consumers. Have to recognize that medical error rates are getting attention as one of those potential comparative factors. It may not be the best purpose for it and it does not necessarily mean that the science is there to help us compare our medical error rates. I think the role of this council is to monitor that situation particularly as it develops through the quorum for health care quality and reporting and to make sure that the science behind this really keeps up with our ability to draw conclusions from the data collected. Would hate for us to come out at this point in time with a standardized medical error rating because then you are almost endorsing that you can compare facilities on the basis of their error rates. Need to respond to those who do come up with error rates.

Michael Horan—alternatively, because of health care competitiveness, organizations competing in business are going to adopt this anyway and in spite of how difficult it is. We should perhaps be attempting to develop, if not perfect, error reporting rates. They need to be acceptable. If they start using something, we as a well-intentioned coordinating council will not have much authority.
John Combes—organizations will be using different rates and those organizations that will market their results will do so on good or bad indicators. We see it now. Decry a certain kind of report but advertise how well they do in comparison. As a Coordinating Council we should support the science and it would be good to develop something or support those who are developing something. However, I'm not sure this Council can come up with anything addressing such diverse interests, but it is important for us to endorse what appears to be the best. Concerned that the measure will become more important than what is actually being measured and that people will try to optimize that measure to market it. We should be careful what we endorse and come down on the side of science in whatever we endorse.
Bill Ellis— the medication use process is an inherently complex one so I think it's hard to get our hands around a measure of the medication use process unless we really boil it down and do it incrementally. We shift and use the terms without looking at the entire process**.** We need to narrow our focus.
Debbie Nadzam—we slip into the use of the term medical error when our purpose is medications.
John Kessler—the medication use process includes more than just prescribing through dispensing, it also includes monitoring. Let's not forget the monitoring piece. A recent study at Tufts Center for Development noted that drug monitoring plays a significant role in medication safety. Drug monitoring is one of the keys and should be part of our efforts.
Joe Deffenbaugh—this issue was discussed at ASHP House of Delegates in June
Debbie Nadzam—all of these things are in our definition including monitoring etc. I have to agree with Bill that there is something about our initial definition that is worth hanging onto.
Joe Cranston—this issue of error rates could be a pitfall. There could be a 1000-fold difference depending on what methodology is used. I see converging issues with certain pockets of improvement**.** DUR has gone this route. We have to look at a more narrow focus like lack of prescribing of beta-blockers.
Debbie Nadzam—think this strays from our mission. That is a treatment issue, which is medication related and prescribing related but different than the operations of getting the right drug to the right patient at the right time.
Judy Smetzer—on the other hand it could be considered an omission error in that science/medicine tells us that these drugs should be prescribed for certain patients then it is an error not to do so.
Debbie Nadzam—is it a medication error or a treatment error? What is a prescribing error? The wrong drug is picked, the wrong dose was picked, the wrong form? What's a prescribing error and what's an omission? What is the difference?
David Keepnews—it does raise yet more interesting issues in terms of how you describe a prescribing error. For that matter, when there is just an evolution in terms of what the understanding is of an appropriate drug. Something that may have been a perfectly good order at one point and then when there is a better understanding of side effect profile or dosage issue it could be clinically inappropriate. It does create an entirely new dimension. What is interesting to me is that as we are segmenting where appropriate rates are we can continue to break it up more and more. On the one hand I think it makes sense to be focused, however, it worries me that the more segmented we become what we do may not be used. Even if we break this up into five different kinds of rates, someone will come along and say, oh well sure, to come up with a medication error rate we will blend these rates into one. We have different pressures out there and recognize that people are going to be using rates as a matter of comparing performance for a number of reasons. What really strikes me is that in a number of the discussions today, we have

different definitions of error. Even though we have one from the Council, people will stick with their own. These are different approaches for determining numerators and denominators, and people are all over the map. This is almost as scary the information on the automated systems we heard about. For that matter, one thing that struck me is that as people are using rates to demonstrate their performance this is an incentive to under report and until there is some kind of standardization this whole thing is loaded with dangers. I think we have to address what is going to be the process for arriving at some kind of standard approach. What you are measuring and how you are measuring it and how you segment it. Try to reach some kind of consensus, not just around this table but circulating that to the world at large.

Debbie Nadzam—is there a definition for a prescribing error? Does the failure to prescribe something to a patient that science says you should, constitute a prescribing error.

Ken Barker—can't see how you can get out of it conceptually. I would like to comment on your strategic problem. I'm a USP historian and I can also reflect on the academic side of this issue**.** I think of how many times I have heard superior, mentally- prepared groups such as your Council, say that they need to measure everything and then I go home to the academics and they say ok but we can hardly measure anything. Both groups go home and nothing gets done. In the meantime, some consulting group comes up with a pretty simple measure somewhere in between and says it's not perfect but it works for a measure and they go out and sell the "who" out of it and everybody else plays catch up. So, I don't know if that is a true history of the world but it occurs to me that one way this group might find useful. Convene a two-day meeting, where you invite prominent researchers to attend and then the Council can tell them what you want to measure and they will tell you what can be measured practically and the problems associated with this tool. At the end try to come to a consensus of what can be measured now and what is most important to be measured now. If you leave it to the academics because of their particular focus, they will measure that which can be measured and it may not be important. The knowledge of what is most important lies with groups like this as far as setting priorities, however, the group may not have the methodological background to know operationally what can be done. I saw an article in the JCAHO Journal called collaborative use of informatics among hospitals to benchmark medication use processes. In spring 1995 pharmacist representing 23 member hospitals in Sinernet a hospital cooperative in Maine, decided to collaborate in developing a multi-hospital medication use evaluation program. They set up task forces for adverse drug reaction reporting prevention, MUE plans, and medication error reporting and prevention. They explored opportunities to eliminate duplication of efforts, compare performance and share the best practices. This group is doing exactly what you are talking about. This is what is going on. They want data so when they are competing for funds they want the hard measures of quality to justify. Given that this is the way things are going it seems logical to convene a meeting with researchers to determine what it is likely that people will come up with.

Linda Hanold—should this group deal with the definitions of what is meant by the term prescribing error etc. If we develop definitions then perhaps over a two-day meeting that will drive measure development off of a common set of definitions.

Judy Smetzer—agrees with Dr. Barker that we should get some researchers together. I would also recommend that maybe we need some experts such as Tom Noland to take medication use information and develop a white paper to set what the NCC MERP is going to do, or develop some sort of stand. We need to take a strong stand to effect change. As a national organization we do not need to lay down and accept what is being done.

ISMP observer-the Council has information that can make an impact. Need to get information out to the hospitals.

Debbie Nadzam—we have tried numerous mechanisms to get the work of the Council out to various groups and I don't think we are succeeding.

John Kessler—what a white paper conjures up in the minds of everyone around the table is to become a position paper that started as an education paper and could turn into a critique. At the very least we should develop a critique of what is out there and whether we can push this all the way to a position paper. If not we will depend on the determination of the committee and chair, but it would be a valuable thing for practitioners to have if it's the role of this group to educate. At least an educational document can often be referred to and developed from a beginning document for a conference that could lead to some level of consensus.
Michael Horan—with regard to dissemination, I'm sure AHCPR would want to support this. If through a white paper we ever do arrive at something we think is pretty acceptable and would be helpful we should disseminate the information. If a particular piece were too long, then I would suggest a synopsis that could go into JAMA because it would hit so many people. I would also suggest the progresses that we have already made get put in journals that get to hospital administrators. If we are trying to get to CEO's could we get it into a journal that deals with national health care problems? We need to consider disseminating in appropriate journals.
Debbie Nadzam— we currently have 5 recommendations and none that deal with monitoring. It may be a good time to package them all. It may be a good item for next meetings agenda. John Combs made an important point that DRG's were not developed to be used the way they are being used, so we have to be careful with what happens if we do come out with something.
John Combs—I think long before we come up with something somebody else will come up with something and I think that is what we need to be prepared for. I'm taking this forum on health care reporting very seriously and I think JCAHO is taking this very seriously thus their emphasis on core measures, because they don't want to be cut out of the picture either. I think the pressure given that presidential commission had an entire section on errors there will be an error measure coming out of that group and I think we have to be ready to respond to that.
Debbie Nadzam— I have heard a paper, an invitational conference, improved dissemination of NCC MERP work related to prevention strategies. The content for the paper is what is in question. How far do we go, do we split the definitions apart, do we need to refine prescribing error/dispensing error, etc. is that what we ask invitees of a conference to help us with and define a measure. We are walking right into the research agenda and we need to review the literature.
Bill Ellis—dissemination is important. Once we have the definitions then I think we may need to disseminate measures that people can use that then get incorporated into the very fabric of what we do organizationally then I think you will begin to see some movement. We will see changes in the institutions. How do we weave that into the fabric of those institutions and what they are all about and what they do on a daily basis? I think we need to give some more consideration on some activity here, like maybe a consensus conference to help define issues. May need to focus on the differences between prescribing and dispensing measures. Institutions should start to look at this. This would be in sync with what JCAHO requires. I know the last thing organizations want to do is to have to comply with another measure, but that is problematic.
Debbie Nadzam— Do we know specifically what the other national efforts are doing as far as identifying measures or medication errors or what they expect to do relative to definitions or rates. Developing measures is one thing; a measure at a time but that may be a starting point looking at what is being done. As a Coordinating Council how can we work with the other efforts as well as know what piece belongs to us.

Action Item:

1. Extract key points from the meeting summaries relative to rates, definitions, whether they contradict each other or not, elucidate what came out of the discussions.
2. Have another small group that that information and design a prototype invitational meeting with the types of individuals that would be invited, the topics for discussions, etc. Approximately 6-10 items that we want them to talk to us about.

3. Perhaps invite 10 different people to come to a meeting and talk about all of these points on which we need input. The small work group would bring the prototype plan for the meeting back to the Council membership and in an effort to get this onto our agenda, which may be difficult. It is possible to schedule a separate meeting either in December or January. From this meeting could come a white paper or position paper from the Council suggesting how to move beyond where we are today. If after hearing all of this we still want to offer a standardized way of reporting medication errors. Volunteers for this small group are:

- Diane Cousins
- Debbie Nadzam
- Bill Ellis
- Someone from ISMP
- Jerry Phillips

NCC MERP Medication Error Index for Categorizing Errors
Elizabeth Cowley and Rita Calnan – USP

Diane Cousins gave a brief background on what Elizabeth and Rita have been working on. The group has for some time recognized that there might be a need to reevaluate the index. USP has from time to time had difficulty interpreting that index and we have mentioned that we presented a paper. We would like to present the results of our findings. What Rita and Elizabeth did was to allow you to work with an interactive mechanism because it was felt that by working through these categories you might see some of the frustration that a user experiences in trying to apply it. They felt that it would make sense for you all to go through the application of the current index. The source of the reports actually are from the USP Medication Errors Reporting Program, the web reports, and USP experience in determining categories. USP may not categorize the reports accurately all the time but we are consistently inaccurate if we are not right. The consistency is important. From our experience we have tried to apply the index to more recent problems. The work product of the Council has already been adopted and absorbed into a large number of institutions, so we did not want to come up with something that was so new and different that it couldn't be useful with all the reports that have been previously coded.

Rita Calnan and Elizabeth Cowley reviewed the case studies and explained how they were categorized by USP. They also explained the areas of confusion for health care professionals who where trying to categorize the errors. It is apparent from the questions received at USP that the definition of harm is ambiguous. The reporters would also like the definitions to be clearer so they have a better understanding of where the errors fall within the index. Reports are coded at USP from the information provided and not on assumptions. The reporters and USP are trying to fit the error into the appropriate category with the limited amount of information available in a report. The C through F categories are areas where you get the most confusion about where it should be categorized. H (near death) seems to be very confusing and hard to define. USP made several suggestions for changes in the Index, which were presented along with the case studies.

After several case studies were addressed, the Council members offered their frustrations with the assignment and with how best to tackle the issue of ambiguous definitions and of the difficulty in making appropriate categorizations for errors. Does harm need to be further defined? Do the error category definitions need to be clarified? What is meant by an intervention? Should we use therapeutic

intervention? The discussions were extremely animated and lively which resulted in the Chairperson bringing the membership back to the point. She noted that the point of this discussion is that this is the categorization that the Council developed and the users of it, even though they may have more information than we have been dealing with, are having trouble using it. We need to clarify the index and possibly add a second page which may be a flow chart or decision tree or something to assist the users in its use. We may need to survey the users to see what they are doing with the Index.

Action Item: Create a work group to address the issues of clarification and assistance for users of the Categorization Index. Team members are Linda Hanold (Leader), Barbara Newman, Jerry Phillips, Judy Smetzer, and John Combes.

NCC MERP Research Agenda
Bill Ellis –APhA

Historically we have been struggling with the research agenda for the Council and what do we really know about medication error causes and prevention. We have been trying to figure out how best to tackle that job. A letter of intent has been drafted (distributed to the members) to allow for feedback from the Council members to establish the groundwork necessary to develop a research agenda. Based on discussions Bill feels that the following areas need to be addressed:

- Critical review of the existing literature on causes in and or prevention of medication errors. We stayed away from the concept of a meta-analysis.
- Review of the most commonly reported errors by severity or by type in the USP MER Program to do a GAP analysis

We need to address what we are attempting to do. We obviously need to go out and get some grant support to conduct a competitive bid process to see who we would award the contract to. It is important for the NCC MERP to do this because we can use the collective knowledge here at our level of understanding to really drive this and make sure we are getting at all the important issues. AHCPR may be a good group to go to for funding. The intent of the letter is to ask for funding and then it would be the job of the Coordinating Council to put it all together. What we are trying to do may fall into the other efforts that are ongoing.

Action Item: Create a work group to assist Bill Ellis in working through the issues surrounding the Research Agenda. Team members include: Bill Ellis (Leader), Debbie Nadzam, David Keepnews, and Judy Smetzer.

A few Council members had discussions during lunch where we tossed around a few ideas and we thought we should extract from the tapes and minutes the key points that we heard meshing from the discussions on rates and comparisons and establish another small group to design a prototype invitational meeting. We could possibly invite ten experts to address the Council at our next meeting of have an individual meeting after the 1st of the year. Out of this we should be able to develop a white paper or position paper to address how we move beyond where we are today with greater standardization.

Open Disscussions:

Barbara Newman suggested that we may need to revisit the dissemination of our recommendations and Bill Ellis noted that Council members can do more work in this area. All members should go back and see what

they are doing. Debbie Nadzam mentioned that another area for improved communication could be that if you know your organization is also involved in another related activity, if you are not the person on that, to make sure you talk to your colleague to keep the communications about what these National organizations are doing that may overlap, synchronize, or complement each other.

Diane Cousins mentioned that after reviewing the FIP recommendations, that were addressed earlier by Bill Ellis, that she noticed that they adopted all of the NCC recommendations without any citations. We want people to use things as much as possible however, we have put a lot of work into the recommendations and she feels the Council should protect the work so it is not presented as another's. We did not copyright the recommendations so we should not forget to do this in the future. We should definitely go back and copyright the recommendations now.

Action Item: Diane Cousins will address the copyright on all recommendations.

Debbie Nadzam summarized the meeting accomplishments:

- Elected a Chairperson and Vice Chairperson
- Voted in the VA as a government regular member
- Talked about offering ACHPR the third government seat which will have to be petitioned
- Reaffirmed ASHRM's 2 year membership
- Established five committees:
  - Bar-coding—Mike Cohen
  - Automation issues—Debbie Nadzam
  - Categorization Index—Linda Hanold
  - Planning for invitational meeting—Diane Cousins
  - Research agenda—Bill Ellis
- Need to educate the field about the concerns related to automation
- Need to revisit dissemination of activities in a more formal manner
- Medication error denominators, rates, and comparisons

Presuming we can get something planned for October the denominators, rates, and comparisons issue will be the primary agenda item. We want to invite guests to articulate the particulars on rates, comparisons, denominators, etc. We learned a lot from our speaker, Dr. Barker, but we also learned that there are areas we need even more information. Other agenda items for the next meeting include:

- Whether we should react or offer some kind of statement about the publishing of individuals names in State Board Bulletins
- Verbal orders
- Updates from all committees
- Dissemination
- Copyright issues
- Change in taxonomy
- Update on therapeutic equivalence codes

A motion for adjournment was made and seconded. The motion carried and the meeting adjourned at 2:55 PM.