February 16, 2000
Day One

Council delegates present:

Deborah Nadzam, Chair
Monica Berry (ASHRM)
John H. Combes (AHA)
Joseph Deffenbaugh (ASHP)
William Ellis (APhA))
Stacey FitzSimmons (PhRMA)
Linda Hanold (JCAHO)
Rita M. Gallagher (ANA) via teleconference
Jon May (NABP)
Janet Myder (AHCA)
Barbara Newman (NCSBN)
Jerry Phillips (FDA)
Jeff Ramirez (VA)
Andrew H. Smith (AARP)
Alice Till (GPIA)

Alternates present:

Shawn Becker (USP)

Alternates that attended with their delegates:

Alan Goldhammer (PhRMA)
Mary Gross (FDA)
Donna Nowakowski (NCSBN)
Jerod Loeb (JCAHO)
John Santell (ASHP)

Delegates absent:

Michael Cohen (ISMP)
Diane Cousins (USP)
Joseph Cranston (AMA)

Observers:

Marilyn Sue Bogner (Institute for the Study of Medical Error)
Sherrie Borden (USP)
Sharon Bohrer (USP)
Rita Calnan (USP)
Elizabeth Cowley (USP)
Sue Zmuda (USP)
Carol Holquist (FDA)
Judy McMeekin (USP)
Fay Menacker (USP)
Tia Morfessis (USP)
Marilyn Storch (USP)
Marge Keyes (AHRQ)
David Rodbard (Am Institute for Research)

Deborah Nadzam called the meeting to order at 12:17 p.m. Dr. Nadzam welcomed everyone and asked that they introduce themselves and state their affiliations. The Chair asked if there was an objection to switching the pre-break and post-break agendas due to Dr. Loeb's transportation arrangements. There being none, the Chair introduced Dr. Jerod Loeb.

Presentation

Dr. Jerod Loeb, JCAHO, thanked the Council for allowing him the opportunity to present JCAHO's issues and responses to the Institute of Medicine report. He stated that there is a modified Joint Commission mission statement that emphasizes safety as a separate component of quality care. JCAHO is in the process of building partnerships related to patient safety

The reported numbers of medical and medication errors leading to sentinel events have been going up steadily. But just because hospitals currently have the highest reported numbers of errors does not mean that hospitals make the most errors. JCAHO believes that an effective Sentinel Event Policy requires that procedures be in place to identify, report and remedy any and all medical and medication errors. Furthermore, any reporting program must contain system analysis, federal protection of information and sharing of information. Dr. Loeb reported that the SCRIPT project to develop methodology to identify evidence is almost completed. In addition, they are working on the Oryx initiative to establish data-driven accreditation processes.

National Comparisons of Medication Errors – Are Rates Necessary?

Discussion centered on the question of how to measure medication errors. Should there be a single denominator, or several measures, each with its own denominator. Even though facilities is still concerned with benchmark rates (their own and national), the consensus of the delegates feel that this concern should not be of primary focus. The CDC has gotten away from using rates for infection control. Data should be tracked with a systemic approach, but the focus should be on patient protection and the dissemination of information to correct problems. Currently facilities have to consider rates to show that they are making progress in reducing medication errors. The culture needs to be changed so that medication error rates will not be considered important by the hospital administrators. Rates may have some use, but first we must consider the incentives. What actually happens when a facility meets national or state averages? It was agreed that everyone sees the importance of increasing reporting and sharing data, but that error rates are not a true indicator. Whatever entity eventually is the repository of a national or state reporting system it must scientifically be able to analyze the data and make it available in a timely manner. Reporting was discussed at length. Who do we report to? Should reporting be mandatory or voluntary? We need to learn from the experiences of others so reporting is necessary and valuable. Protection for the data reported is extremely important.

ACTION ITEM: For the next meeting Shawn Becker will head a team of Deborah Nadzam, Jerry Phillips, and Joe Deffenbaugh, to draft a position paper on medication error rates.

ACTION ITEM: For the next meeting John Combes, Monica Berry, and Andrew Smith will draft a position paper on reporting errors, mandatory or voluntary.

Revision of Medication Error Definition

As a follow-up to the last meeting a request was made by David Bates for the Council to reevaluate its definition of a medication error because he had concerns with the use of the term "preventable." When the Council developed the definition they were aligning with the Bates/Leape definition of Preventable ADEs = Med errors. The converse is the idiosyncratic drug related reactions that are not predictable and therefore not preventable. Delegates were notified about the definition change request and asked to vote either by e-mail or phone prior to the meeting. The consensus of votes was that the definition should not be changed. There was no motion to change the definition at the meeting, therefore, the current definition stands.

ACTION ITEM: A letter will be sent to David Bates to inform him that NCC MERP will retain the current definition of a medication error and the reasons for this decision.

Activities Update

- **ANA** (Rita Munley Gallagher) - The ANA's activities have been centered on post IOM activities and on a report to their delegates on Building a Safer Health Care System. They have been focusing on five core issues, patient safety being predominate.
- **PhRMA** (Stacey FitzSimmons) – PhRMA is currently working towards a closer collaboration with the FDA in regard to toxicity issues, regulatory affairs and labeling issues. They have also been in contact with some state governments regarding the privacy issue. A clinical safety surveillance committee has been monitoring sentinel sites and a task force is working to improve the safe use of pharmaceuticals within the industry through drug names, packaging, barcoding, etc.
- **ASHP** (Joseph Deffenbaugh) – The ASHP has formally endorsed the NCC MERP recommendations. They passed a policy statement that supports mandatory reporting with seven specific characteristics. A memo that links medication errors to a nationwide shortage of pharmacists was sent to hospitals, pharmacies and CEO's. ASHP has endorsed the ISMP self-assessment tool.
- **JCAHO** (Linda Hanold) – Linda asked that everyone join in congratulating Mike Cohen on his recent recognition as pharmacist of the year. Jerod Loeb's presentation will suffice for JCAHO update.
- **AHA** (John Combes) – AHA has entered into a partnership with ISMP to develop a self-assessment tool for hospitals. Their quality advisory has been re-released and a whole section of their web-site is dedicated to prescription errors. The AHA has testified before the Senate HELP committee and has issued a position paper supporting a non-punitive reporting system. Do not see the need for a mandatory system when voluntary systems are available.
- **NABP (**Jon May) – In its leadership role for the safe and effective use of medications, NABP has its own Internet pharmacy program (VIPS). It is a voluntary program and the NABP is working to make this program part of a federal mandate. Legislation should be introduced within the next 60 days. NABP is very concerned about Internet pharmacy practices. This Spring there will be a public meeting, after the Keystone Report, about useful written information to be included with prescriptions.
- **ASHRM** (Monica Berry) – The annual conference is scheduled for November 2-10 in New Orleans, LA. ASHRM has been working closely with the ISMP on the hospital assessment tool. They were asked to endorse but had some questions about confidentiality. Changes were provided by ISMP and ASHRM will be voting on February 17.
- **USP** (Shawn Becker) **–** The quick turn-around response time for the survey on Amrinone was greatly appreciated. The survey was sent to practitioners and the outcome was to change the name of only one product. Therefore, to remedy confusion, as of July 1,2000, Amrinone will officially become Inamrinone. USP was mentioned several times in the Institute of Medicine report as an example of successful voluntary reporting programs. Diane Cousins testimony on February 9 before the House Commerce and Veterans Affairs Committees was highlighted by a modified MedMARx demonstration. USP has been working with Congresswoman Connie Morella drafting legislation to deal with the issue of protection for information reported through reporting programs such as MER and MedMARx. This

legislation will be submitted on February 17, followed by Congresswoman Morella's press conference.

- **VA** (Jeff Ramirez) – The VA has testified before various Congressional committees regarding medication errors and adverse drug events. They have developed a "Lessons Learned" website to disseminate information related to medication errors. The barcoding project has been introduced into 28 VA facilities so far. The time line has been extended, but all facilities should have started using barcoding by June.
- **AHCA** (Janet Myder) – No special projects on mediation errors at this time. Their organization is also concerned over confidentiality.
- **NCSBN** (Barbara Newman) – Medical error reporting is the top priority. The NCSBN is sending surveys to member boards to determine how to review data (forms, etc.) to be more effective and how best to communicate medication error reporting. There are no concrete conclusions from looking at disciplinary data, but the goal is for best nursing practices and patient care. State boards are being assessed. They have no initiatives of their own in regard to legislation, but they are participating with PhRMA initiative on labeling.
- **FDA (**Jerry Phillips) – The FDA is actively involved with answering the Institute of Medicine report. They are looking at a new initiative concerning trade names. They recently participated in a conference for "Healthy People 2010" and plan to be part of the March AHRQ symposium in Boston and the April PIAA symposium in Baltimore.
- **Cleveland Clinic Foundation** (Deborah Nadzam) – An integrated delivery system is now in use. They have been using the Advisory Board's best practices, but there needs to be an emphasis on identification and reporting.
- **AHRQ** (Marge Keyes) – AHRQ has a newly mandated name change. The task force is working on a number of issues in response to the IOM report.

Letter to the President of the United States

The Council determined that a one-page letter should be sent to the President profiling what the NCC has done. The purpose is to get publicity for the NCC and to offer whatever assistance possible.

ACTION ITEM: Deborah Nadzam will rework the draft letter to the President.

Response to the Institute of Medicine Report

NCC's response should be in the form of a position paper that applauds the IOM report and highlights recommended future directions. The paper should be something that will outlast IOM and have more than a one-time use. It was suggested that it might be time to reconstruct the communication directors committee.

ACTION ITEM: Deborah Nadzam will contact Sherrie Borden about a short press release, followed by the position paper.

Other Business

USP has received a request from JCAHO for permission to reprint the taxonomy for a series of seminars. The Council decided to grant permission for JCAHO to reprint the taxonomy as long as credit is given, there are no changes, and feedback is provided.

ACTION ITEM: Secretariat will write a letter to JCAHO to officially confirm this.

The meeting was adjourned at 4:07 p.m.

February 17, 2000
Day Two

Council delegates present:

Deborah Nadzam, Chair
Monica Berry (ASHRM)
Michael Cohen (ISMP)
John Combes (AHA)
Joseph Cranston (AMA)
Joseph Deffenbaugh (ASHP)
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Alan Goldhammer (PhRMA)
Mary Gross (FDA)
John Santell (ASHP)

Delegates absent:

William Ellis (APhA)
Diane Cousins (USP)

Observers present:

Margaret Coopey (AHRQ)
Carol Holquist (FDA)
Donna Nowakowski (NCSBN)
Paul Seelinger (PYXIS)
Roger Williams (USP)
Allen Vaida (ISMP)

Deborah Nadzam called the meeting to order at 8:35 a.m. The first order of business was a presentation by Paul M. Seelinger, RPh, of PYXIS.

Presentation:

Paul M. Seelinger, RPh, PYXIS, mentioned in passing that there is no reference to barcoding on the NCC website. Barcoding is not new for pharmacists, but it is new for bedside scanning. A hand-held scanner would reduce errors by confirming the identity of the healthcare worker, the patient's identity, and that the medication is correct while still in the original packaging. If medication is incorrect, the scanner would provide a reason (wrong medication, wrong dosage, etc.) This would be data captured in real-time – why medications were not given - and fed to an electronic charting system. There are several challenges to barcoding. Among them 1) not all barcodes are the same, 2) accessibility of all information to be scanned for each patient, 3)

memory limitations of the scanners, 4) keeping barcodes small enough to fit on medication labels, 5) keeping track of differing technology, 6) differentiating for safety, 7)

establishing a data standard and 8) anticipating workarounds. Ideally, there should be standard bar codes with standard data requirements. Several major groups, like the VA and FDA, are extremely interested in the use of bar codes; however, problems have been uncovered with older nurses being unable to read the scanners. Interested parties are mostly represented by the NCC, group purchasers and CEOs from healthcare organizations. The NCC could sponsor an invitational conference to deal with barcoding that would build consensus among users for what is needed. Attendees could be charged to a break-even point.

ACTION ITEM: Mary Gross will head up a group consisting of Diane Cousins, Linda Hanold, Alan Goldhammer, John Santell, Stacey FitzSimmons, Barbara Newman, Jeff Ramirez, John Combes and Mike Cohen to plan such a conference. Their mandate will include the invitation list, a statement of general purpose and objectives, an agenda and topics, a list of speakers and a financial plan to cover costs. This should be scheduled for the Summer.

NCC Incorporation

The pros and cons of incorporation were elucidated by Ken Alexander, an attorney at USP. It was stated that the major benefit of incorporation (obtaining a 501(c)3 status with the IRS) would be the relative ease of obtaining grant money as compared to an unincorporated group. This could be overcome by having one of the organization members act as custodian, maintaining records and accounting information. Roger Williams, Incoming CEO of USP, offered to make USP the custodian of any money for the NCC. The chair called for a motion for incorporation. There being none, the situation was left to do business as usual, without incorporation.

State Disciplinary Board Actions

Mike Cohen explained that hospitals and other organizations have been trying to develop non-punitive reporting programs internally to aid risk managers in improving their systems. However, when State Departments of Health or State Boards find out about errors, publicity usually ensues that can extend resolution for years. He referred to the Dana Farber case in Massachusetts and said that it had a very chilling effect on the profession, knowing that repercussions can take place years after an event. This encourages the non-reporting of errors and there has not been much discussion or understanding on the difference between error, incompetence, and negligence of malicious behavior. State boards of pharmacy should not spend time disciplining people. Rather, they should focus on getting information out to everyone. Barbara Newman countered that the state boards have to be watchdogs for incompetent personnel with patterns of repeated errors and this must be a component of their role. It was generally accepted that everyone needs to deal with media attention better. If there is a problem, it is better to go public sooner, rather than later, and educate the public with a definite proposal as to how the problem is being solved. Press releases should be sent out immediately after an incident is exposed. It was suggested that a conference be set up with

representatives from state boards of nursing and pharmacy to dialog about the dual aspect of pharmacy and public health.

ACTION ITEM: Mike Cohen will take the lead with Barbara Newman, Jon May, Rita Munley Gallagher and Monica Berry to set up a conference with representatives from state boards of nursing and pharmacy..

Automation White Paper

The white paper on automation will not be available until the next meeting.

Verbal Orders

Alice Till presented her committee's new draft recommendations for verbal orders. Joe Deffenbaugh suggested that a paragraph should be added requiring that a health care organization have verbal order policies and procedures in place that delineate the circumstances under which a verbal order can be processed. Are recommendations going too far, being too explicit and, therefore, not being followed? From a risk management position who should be taking verbal orders? The greater number of people involved, the greater chance there is for error. Discussion continued regarding the differences among verbal vs. oral vs. spoken vs. telephone orders. Organizations must determine when verbal orders are acceptable to be issued, who can send them and who can receive them. Once that is set, then NCC recommendations would go into effect for both verbal orders and verbal prescriptions.

ACTION ITEM: Alice Till will process feedback and work on a re-draft of recommendations to reduce medication errors associated with verbal orders and verbal prescriptions for the next meeting.

Index Categories Flow Diagram

The subcommittee selected to review the index categories using a flow diagram to help users categorize errors. Recommendations were made to clarify the definitions themselves and to expand the kinds of questions asked to elicit the kind of information needed. It was suggested that several categories be switched and that specific examples be given for each category. There is no way within the current system to know whether an institution is lacking data about a specific event it is reporting or if it has data and does not know what to do with it. It was determined that the categories will remain as is and the new wording will be adopted. The diagram and examples will be completed and presented at the next meeting.

ACTION ITEM: Subcommittee will continue to work on changes to the index in terms of providing examples. A finalized report and flow chart will be ready for the next meeting.

Miscellaneous

Mike Cohen described the multi-disciplinary, self-assessment tool for hospitals that ISMP is in the process of developing and testing in partnership with the AHA. It should be finished within the next few weeks. As soon as it is complete, he would be happy to e-mail it to anyone interested. Hospitals can send information to the ISMP for collection in a database for future comparisons.

The meeting was adjourned at 2:43 p.m.