October 14, 2008

Council members present:

Deborah Nadzam, Chair
Rita Munley Gallagher (ANA), Vice Chair
Diane Cousins (USP), Secretary
Ellen Quinn (ASHRM)
Carol Holquist (FDA)
Sal Peritore (GPhA)
Nancy Kupka (The JC)
Eleni Anagnostiadis (NABP)
Crystal Lennartz (NACDS)
Ray Bullman (NCPIE)
Rebecca Snead (NASPA) – by phone
Marjorie Shaw Phillips, Vice Chair USP Safe Medication Use Expert Committee

Organizations not represented:

AARP	IHI
AAHSA	NCSBN
AHA	NPSF
DoD	VA

Alternates attending as representatives of their organizations:

James Owen (APhA)
Tom Clark ASCP)
Michael Gaunt (ISMP)

Alternates attending with their delegates:

Shawn Becker (USP)

Presenter: Katharine Francis, RN, Founder & Chief Clinical Officer, InformMed

Observers:

Emily Leckwatch, NACDS Pharmacy Rotation Student
Michelle Bell, ISMP Safe Medication Management Fellow
USP Attendees: Colleen Brennan, Manager, Safe Medication Use Expert Committee
Mike Heath, HQS, Consultant
Marilyn Storch, Coordinator, Patient Safety Projects
Sue Thomson, Patient Safety Analyst

The Chair welcomed Council members, alternates, and guests and called the meeting to order at 8:45a.m. Congratulations were expressed on the Council's winning the 2008 Stuart M. Eisenberg Award and members responsible for the preparation of the application were profusely thanked for their efforts. It was moved, seconded, and unanimously approved to accept the June meeting summary. It was moved, seconded, and unanimously approved to accept the agenda for this October meeting.

Secretary's Report – *Diane Cousins*

– National Quality Forum (NQF) Common Formats Expert Panel

Ms. Cousins reported that she was invited to be a member of the Expert Panel and was able to furnish the Council with a report on the Panel's goals and current activities. The Common Formats Expert Panel is actually the third NQF committee to address the issue of a universal, in-patient hospital-based taxonomy. There have been two teleconferences to develop a

framework document that, so far, have produced (1) three generic paper forms that prompt responses in the areas of patient information, event description, and event follow-up and (2) nine event specific event forms to provide for the reporting of errors. The ultimate goal is that individual state reporting systems will map to this central system.

Membership

Applications for membership renewal were received from the follow organizations:

American Society for Healthcare Risk Management
American Society of Consultant Pharmacists
Department of Defense
Department of Veterans Affairs
Institute for Healthcare Improvement
Institute for Safe Medication Practices
National Alliance of Stat Pharmacy Associations
National Council on Patient Information and Education

The Council deemed no discussion was necessary prior to voting. Members whose renewal applications were being considered abstained from voting. The organizations were each renewed for two-year terms.

Action Item: The National Patient Safety Foundation will be informed that its membership is due to expire in February 2009 unless it takes steps to renew.

An appeal was made to member organizations to appoint designated alternates to attend meetings in lieu of their delegates as a way of maintaining a comprehensive perspective on Council decisions and work products. Members were reminded that there is an option to attend meetings telephonically.

Action Item: The Secretary will follow-up with member organizations lacking designated alternates to encourage the appointment of such alternates.

It was noted that the in the current structure of the Council only one medical organization is a member and no delegates or alternates are physicians. Cold calling of physician organizations was deemed as unproductive and inappropriate method of recruitment, members were encouraged to identify potential organizations and/or associations that may have an interest in the Council's work and membership. Member outreach will be directed to the following medical organizations: the American Academy of Family Physicians (AAFP), the American Academy of Pediatrics (AAP), the American Board of Medical Specialties (ABMS), the American College of Physicians Foundation (ACPF), the American Geriatrics Society (AGS), the American Medical Group Association (AMGA), the Alliance of Independent Academic Medical Centers, (AIAMC), the Society of Hospital Medicine (SHM), and individual patient safety officers.

Action Item: The following members will contact organizations to invite them to observe a Council meeting and, if interested, prepare a presentation as part of the membership application process: AAFP - Ms. Kupka, AAP - Dr. Cranston, ABMS -Dr. Gallagher, ACPF - Mr. Bullman, AGS - Mr. Clark, AIAMC –Ms. Phillips, Patient Safety Officer Society - Ms. Phillips, Society of Hospital Medicine - Ms. Benjamin.

FDA's Regulations and Labeling of Drug Samples - *Carol Holquist*

CPT Holquist was asked at the June meeting to provide the Council with the official position of the FDA in regard to drug samples. The FDA Office of Compliance provided this response:

> The labeling requirements for prescription drug samples are the same as for all prescription drugs, particularly, the requirement that the label is to bear only information authorized under the approved new drug application (21 CFR 201.100(c)(2)). The lot or control number is to appear on each sample label (and outer carton, if any) as defined at 201(k) of the FD&C Act (21 USC 321(k)) (21 CFR 203.38(a)). Any words that clearly designate a sample unit as a sample may be used, except the term, "starter." (21 CFR 203.38(c) and 64 FR 67720 at 67741). Stickers may be used on retail product that indicates that the products are samples. Such stickers should be difficult to remove; and if the stickers are removed, the removal should appear evident. The agency recommends other durable methods of identifying a sample product, such as overprinting, to be used (64 FR 67720 at 67742-67743).

CPT Holquist added that the FDA recommends only one tablet per blister and that medication guides must accompany all samples that have medication guides. The Council's recommendations are only slightly more extensive than those of the FDA.

Drug Suffixes Survey – *Michael Gaunt*

Dr. Gaunt reported that 5,697 individual responses to the drug suffixes surveys were received and later evaluated in a preliminary analysis by an ISMP student. The survey was distributed and publicized by Council members to practitioners nationwide. Pharmacists comprised the largest percentage of respondents, followed by nurses and physicians. Varying levels of experience in interpreting suffixes were evident in the responses; however, more than 60% of the respondents were aware that medication errors were occurring that were associated with drug name suffixes. It was resolved to publish the report as a copyrighted workproduct of the Council and have it posted on the Council's website. Several members will speak with identified persons within their organizations who may be responsive to publishing in their organizations journals.

Action Item: The preliminary authors (JC, ISMP, and USP) of the survey results will complete a first draft for the February meeting and a deliverables timeline for slide production and publication.

Action Item: A press release on the analysis of the survey and proposed publication will be developed for members to share in their internal communications.

ISMP's Consumer Website – *Michael Gaunt*

Dr. Gaunt introduced ISMP's new consumer website, www.consumermedsafety.com which is scheduled to go live by the end of.

Pediatric Medication Safety

Presentation: *Katharine Francis, RN, Founder & Chief Clinical Officer InformMed, Inc.*

Ms. Francis was cognizant of the fact that the Council does not endorse any products; however, she wanted the opportunity to raise the awareness of the Council in regard to the topic of handheld pediatric dosing devices. The handheld device features a drug library, includes clinical decision support with forcing functions, and can operate as a stand-alone system. This automated dose calculation system recognizes unsafe doses, calculates accurate doses, and records the calculated dose volume. Empirical evidence to date has shown that these devices can eliminate top areas of risk.

Not wanting to duplicate the efforts of other organizations, the Council questioned whether or not there has been a call for an invitational conference or stakeholder forum on the standardization of dosing and IV medications; and if not, should the Council take the initiative and host a summit with the goal of introducing recommended dosing measures. If the Council decides to proceed with a conference, it would have to be made evident that its purpose would be standardization, not fact-finding. ASHP indicated that it has several initiatives related to the standardization of dosing and IV medications under consideration. Conducting a survey would be another option that the Council could consider; but before that could commence, the Council would need to access current undertakings so as to assist, rather than duplicate efforts. Members reported that the topic has considerable interest but little coordination. However, it would be remiss for the Council not to issue a statement of support or promote recommendations to alleviate errors arising from dosing miscalculations. It was moved, seconded and unanimously approved that the Council develop a statement to be posted to its website that speaks to the concern for pediatric medication safety issues and the resources available.

Action Item: Dr, Nadzam and Ms. Phillips will develop a draft of a statement reflecting the Council's concern for pediatric medication safety and available resources.

Bar Coding

Dr. Goldhammer reported that his subgroup has held four conference calls. Currently, hospitals are under enormous cost pressures and bar coding has been delegated as a low priority area. Additionally, it has been difficult to identify issues that lead to steps that can be readily implemented. E-prescribing has become the hot item taking precedence over other initiatives. It was recommended that this issue be tabled and revisited at the June 2009 meeting. ASHP will examine the feasibility of doing a study next spring on informatics and technology that will be separate from its national survey. PhRMA indicated that it has funds available to support this effort.

ACTION ITEM: ASHP will circulate questions pertaining to a bar coding implementation survey in the spring of 2009.

Medication Error Rates and Medication Error Reporting Rates

Discussion of a medication error reporting rates statement was postponed until the February meeting, as the chair of this subcommittee was not available to participate at this meeting. The Council's statement on medication error rates was reviewed and will be posted to the website with

an updated review date. At a later time the Council may merge a medication error reporting rates and medication error rates statements into one cohesive document.

It was announced that Mike Cohen also received the John M. Eisenberg Award, which was met with vociferous congratulations from all delegates. It was suggested that a letter of congratulations be sent to Dr. Cohen.

ACTION ITEM: The Council will forward a letter of congratulations to Mike Cohen on his being presented the Stuart M. Eisenberg Award in the Individual Category.

The meeting was adjourned at 1:55 p.m.