

Report of the Task Force to Develop Recommendations to Best Reduce Medication Errors in Community Pharmacy Practice

Members Present:

Karen Ryle (MA), *Chair*; Philip P. Burgess (IL); Susan DelMonico (RI); Reginald B. Dilliard (TN); David Fong (CA); Linda McCoy (AZ); and Edward G. McGinley (NJ).

Ex Officio Members:

Michael Jarema (Project Director, Joint Commission of the Accreditation of Healthcare Organizations); and Allen Vaida (Executive Director, Institute for Safe Medication Practices).

Others Present:

Oren M. Peacock, *Executive Committee Liaison*; Carmen A. Catizone, Eleni Anagnostiadis, Charisse Johnson, *NABP Staff*.

Introduction:

The Task Force to Develop Recommendations to Best Reduce Medication Errors in Community Pharmacy Practice met on December 10, 2004, at the Hyatt Rosemont in Rosemont, IL. The appointment of this Task Force came at the direction of NABP President Donna M. Horn and the Executive Committee to move toward the development and implementation of initiatives that would specifically target the reduction of medication errors in the community pharmacy practice setting.

Review of the Task Force Charge

Task Force members reviewed their charge and, proposing no changes, accepted it as follows:

To examine information related to medication errors which occur in community practice and provide recommendations to the Executive Committee on what NABP and the state boards can do to reduce the incidence of medication errors in community practice.

Overview of Presentations:

Eleni Anagnostiadis, NABP staff member, presented the current initiatives of NABP in addressing patient safety. She first discussed the various programs and services NABP offers including the upcoming Pharmacist Self-assessment Mechanism™ (PSAM™) tool which will assist pharmacists in evaluating their practice skills against a number of predetermined competency standards. Through PSAM, NABP is working to promote the concepts of Continuing Professional Development (CPD). She also described the Verified Accredited Wholesale Distributors™ (VAWD™) program which is targeted to assist the state boards of pharmacy, other state agencies that regulate wholesale distribution, the industry, and the pharmacy profession to protect the public from the threat of counterfeit drugs infiltrating the United States' drug supply. The VAWD program will accredit wholesale distributors whose policies and operations meet the VAWD criteria and comply with state and federal laws. Lastly, she detailed NABP's involvement in efforts to develop and implement national electronic prescribing standards. NABP has submitted testimony to the National Committee on Vital Health Statistics (NCVHS), the organization responsible for recommending such standards to the United States Department of Health and Human Services.

Allen Vaida, executive director for the Institute for Safe Medication Practices (ISMP), highlighted his organization's initiatives in patient safety including the Medication Errors Reporting Program and various publications targeted to health care professionals and consumers. Dr Vaida talked about ISMP's Medication Safety Self Assessment tools for hospital and community/ambulatory pharmacies which are designed to heighten awareness of the distinguishing characteristics of safe pharmacy systems. In addition to providing background information about medication errors, Dr Vaida also presented some of the survey data collected by ISMP which highlighted the community pharmacies involvement in collecting medical histories, electronic prescribing transmission utilization, and the oral repetition of verbal telephone orders. Lastly, Dr Vaida conveyed a number of recommendations to the Task Force for consideration. Such recommendations included the requirement of state mandated medication safety continuing education, the establishment of a national system of referrals for the support of pharmacists who have made serious errors, and the establishment of quality improvement processes in all pharmacies.

Michael Jarema, project director, Division of Standards and Survey Methods, Joint Commission for the Accreditation of Healthcare Organizations (JCAHO), presented on JCAHO's Medication Management Standards, the 2005 National Patient Safety Goals, and Sentinel Event Alerts. From the data that JCAHO has collected, Mr Jarema presented some of the root causes of sentinel events. He highlighted that the "ordering" and "processing/dispensing" processes account for the majority of sentinel event root causes and therefore have become a focus of JCAHO standards. Mr Jarema explained the 2005 JCAHO National Patient Safety Goals which cover the areas of patient identification, communication among caregivers, and medication safety. Mr Jarema also discussed in depth the patient safety goal pertaining to reconciliation of medications (goal # 8). This goal requires that accredited institutions implement by 2006 a process for obtaining and documenting a complete list of the patient's current medications upon admission. Further, when the patient

is discharged or transferred to another institution, a process must be implemented whereby a complete list of the patient's medications is communicated to the next provider of service. Mr Jarema suggested that the Task Force recommendations focus on areas of improving the culture of safety and systems, the involvement of patients in their care, the education of health care professionals and consumers concerning safety and quality, and a special focus on high-alert medication errors (ie, insulin, anticoagulants, etc).

Charles W. Sauer, executive director of the National Pharmacists Association, submitted written comments to the Task Force. Recognizing the realities and practical concerns faced by community pharmacists, Mr. Sauer indicated factors that can influence the incidence of medication errors as workload, staffing issues, and volume based performance awards. Mr Sauer recommended that pharmacist staffing requirements be based upon volume of prescriptions, non-professional duties be delegated to sub-professional pharmacy personnel, and job performances be primarily based on the provision of pharmaceutical care.

Recommendation 1: To reflect NABP's continued initiatives to promote regulating for outcomes, the Task Force recommends the Executive Committee consider appointing a task force to analyze the NABP Model Pharmacy Practice Act and Rules; the Task Force further recommends that applicable patient safety standards from organizations like JCAHO and ISMP be evaluated and considered for incorporation in the NABP Model Pharmacy Practice Act and Rules.

Background:

In December 2002, the NABP Task Force on Transition of Pharmacy Regulation from the Dispensing Process to Outcomes convened and developed a number of recommendations. Recommendations included a stronger emphasis on the reporting of medication errors via the continuous quality improvement programs as outlined in the NABP Model Pharmacy Practice Act and Rules; and the continued support of NABP's commitment to improved patient outcomes through efforts designed to ensure continued professional competency.

To continue NABP's initiatives, the Task Force suggested that the Executive Committee consider appointing a task force that would evaluate and suggest amendments to the NABP Model Pharmacy Act and Rules in light of recent changes in various state regulations and the established patient safety guidelines from organizations like JCAHO and ISMP. The incorporation of such guidelines with the Model Act would further assist the boards in adopting the concept of regulating for outcomes.

Recommendation 2: The Task Force recommends to the Executive Committee that NABP continue to work with the boards to assess, develop, and implement best practices/non-punitive regulations and enforcement actions that are aimed to promote patient safety and medication error reduction.

Background:

The Task Force considered the action of states like California, Massachusetts, and Washington that have developed “best practice” recommendations and non-punitive approaches in response to patient safety and medication errors. According to the *2005 Survey of Pharmacy Law*, approximately 15 states require that pharmacies maintain a continuous quality improvement program to monitor and prevent quality-related events. The Task Force also recognized that the knowledge gained from continuous quality improvement programs is invaluable and should be shared not only within the pharmacy, but to others that are external to the pharmacy. In the case of community pharmacies, the information should be shared with other community pharmacies that may be under common control or within a retail chain.

The Task Force was very adamant about encouraging state boards to redirect their surveying focus to address patient outcomes. NABP can provide guidance to the boards through model language via the NABP Model Pharmacy Practice Act and Rules. Additionally, NABP can provide continuing education for board compliance officers that focus on the assessment of quality assurance and patient safety.

Recommendation 3: The Task Force recommends to the Executive Committee that NABP continue to work with states to enact “peer review programs and freedom from discovery protection” regulation and legislation to encourage the reporting, data collection, and analysis of medication errors.

Background:

The NABP Model Pharmacy Practice Act and Rules states that “all information, communications, or data maintained as a component of a pharmacy Continuous Quality Improvement Program are privileged and confidential.” The Institute of Medicine’s Report, *To Err is Human: Building a Safer Health System*, conveyed vulnerabilities in statutory law that may discourage voluntary reporting of medical errors because of fears of litigation. Although some states mandate the reporting of medical errors that result in serious harm, internal error reporting systems are primarily used to track “near misses”, or errors that have resulted in lesser harm. Subsequently, data from these reporting systems are used to identify and improve processes that are aimed to improve the quality of care.

The Task Force agreed that pharmacists are often hesitant to report errors because of fear that such information may be used against them in court proceedings or hearings. Therefore the Task Force agreed that NABP should continue to work with the state boards to

encourage regulations and legislation that provide certain protections of error data submitted by pharmacists and pharmacies.

Recommendation 4: The Task Force recommends to the Executive Committee that NABP aggressively pursue Food and Drug Administration (FDA) to prevent the use of product nomenclature, packaging, and labeling that may significantly contribute to medication errors. The Task Force further recommends that if warranted, NABP should commission a task force to identify such high risk error prone products and develop specific recommendations for reducing the risk of medication errors associated with such products.¹

Background:

The Task Force discussed a number of external causes of medication errors including products with similar names and/or pronunciations, packaging, and labeling. According to the ISMP-United States Pharmacopeia (USP) Medication Errors Reporting Program (MERP), one third of the medication errors reported were due to drugs with similar names.

The Task Force felt strongly that prior to product marketing, more proactive approaches be taken by the pharmaceutical manufactures and FDA to limit similarities between the nomenclature, packaging and labeling. Additionally, the Task Force agreed that strategies like separating similar sounding and/or looking products within the pharmacy that are commonly confused are helpful in reducing medication errors associated with these products.

Realizing the role of FDA's Center for Evaluation and Research's Office of Drug Safety to review and analyze product nomenclature, packaging, and labeling, the Task Force agreed that at times products are released to the market which are similar in nomenclature, packaging, and/or labeling to established products. The Task Force therefore recommended that the Executive Committee consider the establishment of a task force that would identify these particularly high risk error prone products and develop specific recommendations for minimizing errors associated with such products. Such recommendations could include revising the NABP Model Pharmacy Practice Act and Rules to recognize high risk error prone products.

Recommendation 5: The Task Force recommends to the Executive Committee that NABP continue to promote best practices recommendations to the profession established by organizations such as the American Society of Health-System Pharmacists and the American Pharmacists Association to encourage the maximum provision of pharmaceutical care.

Background:

The Task Force discussed the various initiatives and accomplishments of organizations like ISMP and JCAHO to improve quality and patient safety within the health care system. The Task Force conveyed that it was prudent for the profession to continue to recognize, incorporate, and apply established recommendations for reducing the incidence of medication errors through the provision of pharmaceutical care.

Although the Task Force recognized the role of product nomenclature, packaging, and labeling in the occurrence of medication errors, the Task Force also attributed other causes such as drug interactions, overdosing, sub therapeutic dosing, and other drug related problems that occur particularly in at risk patients such as the pediatric and geriatric populations. Therefore, the Task Force agreed that NABP and the state boards should continue to encourage the profession to prevent these types of events through the optimal delivery of pharmaceutical care.

Recommendation 6: The Task Force recommends to the Executive Committee that NABP explore the feasibility of incorporating specific competency statements regarding patient safety from a systems perspective into the North American Pharmacist Licensure Examination® (NAPLEX®). Further, the Task Force proposes that NABP submits a similar request to the Pharmacy Technician Certification Board (PTCB) regarding the Pharmacy Technician Certification Exam (PTCE).

Background:

Although the NAPLEX currently contains competency statements addressing (1) safe and effective pharmacotherapy and the optimization of therapeutic outcomes and (2) the safe and accurate preparation and dispensing of medications, the Task Force thought it was prudent for the Executive Committee to consider the inclusion of competency statements that specifically evaluate knowledge regarding patient safety and medical errors from a systems perspective. Similarly, since pharmacy technicians play a significant role in contributing to an environment that promotes patient safety and the minimization of medication errors, the integration of such competency statements within the PTCE should also be considered.

Recommendation 7: The Task Force recommends to the Executive Committee that NABP encourage the state boards and PTCB to incorporate patient safety and medication error continuing education requirements for licensure renewal and recertification for pharmacists and technicians, respectively.

Background:

According to the *NABP 2005 Survey of Pharmacy Law*, Florida and New York are the only states which require pharmacists to obtain continuing education (CE) specific to medication errors. Florida requires that at least two of the 30 mandated biennial CE hours be a Board-

approved course on medication errors. For its triennial registration period, New York requires that every pharmacist complete three hours of CE in the area of strategies used to reduce medication errors. Some state boards of pharmacy also require that pharmacy technicians obtain CE, although the requirements are not specific in mandating CE in the topics of patient safety or medication errors. However, a number of states require that pharmacy technician maintain PTCB certification, which includes obtaining at least twenty hours of CE every two years. Although one of the CE hours must be in the area of pharmacy law, PTCB does not require that CE pertaining to patient safety or medication errors.

In efforts to improve the awareness and knowledge of patient safety and reduction of medication errors, and particularly the integration of this knowledge into practice, the Task Force recommended that more states consider such mandates involving continuing education.

Recommendation 8: The Task Force recommends the Executive Committee encourages state boards to require pharmacies to document and report medication error incidences to national patient safety programs such as the ISMP-USP Medication Errors Reporting Program (MERP). Furthermore, the Task Force suggests that community pharmacies under common control or ownership be encouraged to periodically submit aggregate medication error data to USP MERP.

Background:

Currently, USP in conjunction with ISMP operates the MERP, which serves to collect voluntarily medication error data from health care professionals. Additionally, FDA also collects and analyzes medication error data through its Adverse Event Reporting System (AERS) database and the Med Watch Program.

The Task Force discussed various ways in which the state boards and NABP could help increase the reporting of medication errors. Suggestions included promoting a positive non-punitive culture, the incorporation of peer review programs, and the publication of state board Newsletter articles on patient safety and medication error reporting. The Task Force also expressed some of the hesitations for reporting such as fear on the part of pharmacists to be criminally or civilly liable if such information is legally discovered. Furthermore, some pharmacists are not able to realize the benefits of reporting to national patient safety programs such as the ISMP-USP MERP. However, programs that are available for purchase, such as MEDMARX, provide a mechanism for hospitals and health systems that collect, track, and analyze medication errors in a standardized format, to compare their medication error data with that of other institutions.

Historically, community pharmacies have reported only a small percentage of errors that actually occur to national error reporting databases. This has been evidenced by the amount of errors received from community pharmacies by entities such as USP MERP. The Task Force felt that improved medication error reporting could be achieved for community pharmacies specifically if these pharmacies could submit such data collectively. Often,

community pharmacies under common control or ownership have internal quality assurance programs which include the collection of data regarding medication errors which subsequently allows for the internal data analysis. Medication error reporting programs administered by ISMP-USP and FDA collect data on a per incident basis. The Task Force suggested that if ISMP-USP and FDA would accept data in aggregate, improvement in voluntary error reporting by community pharmacies could possibly be achieved.

Recommendation 9: The Task Force encourages NABP to continue its collaboration with the Centers for Medicare & Medicaid (CMS) and the National Council on Vital Health Care Statistics (NCVHS) on the standardization of electronic prescribing.

Background:

The Medicare and Modernization Act of 2003 signed by President George W. Bush requires that the United States Secretary of Health and Human Services develop and adopt uniform standards for electronic prescribing by September 1, 2005. Subsequently, the National Committee on Vital and Health Statistics (NCVHS) was delegated the task of recommending such standards and NABP has submitted testimony to NCVHS Subcommittee on Standards and Security in defining the electronic transmission of prescriptions, developing a national electronic prescribing standard, and creating an environment that fosters the safe and appropriate utilization of this technology. NABP is also collaborating with the Center for Medicare and Medicaid Services (CMS) and has provided CMS the laws and regulations from the states that have incorporated electronic transmission and/or electronic or digital signature language into their regulations. Such information will assist both CMS and NCVHS in determining which states allow for electronic transmission and which states continue to face barriers and challenges in implementing electronic transmission of prescriptions. In addition, NABP is a member of the SOS Rx Coalition, a national health care coalition promoting the safe use of medications. The coalition, managed by the National Consumers League, includes the participation of more than 60 consumer and patient safety organizations, physicians, pharmacists, caregivers, employer groups, and government. One of the initiatives that SOS RX has earmarked is “accelerating the adoption of e-prescribing by establishing guiding principles and a standard for e-prescribing. An ideal e-prescribing model will be developed and promoted to health care professionals.” A public education campaign will educate consumers about e-prescribing.

Realizing that a large percentage of medication errors are attributed to written miscommunication with prescriptions and prescription orders, the Task Force agreed that NABP should continue its efforts in working with federal regulators and agencies in moving forward to develop regulations and standards that would incorporate standardized processes for electronic prescribing such as uniform template for electronically transmitted prescriptions.

Recommendation 10: The Task Force recommends the Executive Committee encourage state pharmacy boards to collaborate with state medical boards and other stakeholders to advocate for the adoption and incorporation of patient safety regulations and other initiatives.

Background:

During the NABP Centennial Annual Meeting, delegates passed Resolution 100-7-04, Medication Indication on Prescriptions, which directed NABP to encourage national and state medical associations and other interested parties to support legislative and regulatory efforts in the states to require prescribers to include the indication for the medication on all prescriptions and medication orders issued orally, in writing, or transmitted electronically. The Task Force discussed instances in which medication errors could have been prevented if information such as indication were included on the prescription or prescription order.

The Task Force recognized that successes of patient safety initiatives are significantly dependent of joint efforts between the state boards of pharmacy and the medical boards. When feasible, state boards of pharmacy should work with the medical boards to advocate such efforts.

Recommendation 11: The Task Force suggests to the Executive Committee that NABP convene a stakeholders meeting inviting ISMP, USP, NACDS, NCPA, APhA, PhRMA, FDA, and other applicable organizations to explore ways to decrease medication errors in community practice settings through the creation and implementation of national patient safety goals targeted specifically for community pharmacy practice.

Background:

Although organizations such as ISMP and JCAHO have instituted criteria and standards that may be applicable to all types of pharmacy practice settings, the primary focus is on health system and institutional pharmacies. The Task Force agreed that the formation of similar patient safety goals specific to the community pharmacy practice setting through a multi-organizational undertaking could assist in the reduction of medication errors.

Recommendation 12: The Task Force recommends to the Executive Committee that NABP work with American Association of College of Pharmacy, the American Association of Colleges of Nursing, and the Association of American Medical Colleges to incorporate patient safety and quality into the curriculum of pharmacy, nursing, and medical schools, respectively.

Background:

The Task Force discussed the importance of the incorporation of patient safety and quality educational components into the health professions curriculum. For example, the Task Force agreed that health profession students would benefit from an early knowledge of confusing abbreviations, acronyms, and symbols to avoid in communication between health care providers.

¹Although the NABP Executive Committee supports the Association aggressively pursuing Food and Drug Administration (FDA) to prevent the use of product nomenclature, packaging, and labeling that may significantly contribute to medication errors, the Executive Committee does not endorse and will not appoint a NABP commissioned task force to identify such high risk error prone products and develop specific recommendations for reducing the risk of medication errors associated with such products.