

**The National Coordinating Council
for Medication Error Reporting and Prevention**

NCC MERP: The First Ten Years

"Defining the Problem and Developing Solutions"

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The National Coordinating Council for Medication Error Reporting and Prevention: The First Ten Years

NCC MERP History

Through its work as a drug standards-setting organization since 1820 and its experience with the nationwide USP-ISMP Medication Errors Reporting (MER) Program, the United States Pharmacopeia (USP) recognized that there were many causes for medication errors and no one organization was equipped to address this threat to patient safety. Therefore, the USP spearheaded an effort to convene a group of concerned national organizations that had the authority, mechanisms, and resources to confront the complexities of medication errors and seek solutions for those issues that adversely affected patient safety.

Fifteen interdisciplinary organizations and agencies met on July 19, 1995, for the first meeting of the National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP). The Council was formed to actively promote the reporting, understanding, and prevention of medication errors through the coordinated efforts of its member associations and agencies, and to focus on ways to enhance patient safety through a coordinated approach and a systems-based perspective.

Founding Council member organizations were the American Association of Retired Persons (now known as AARP), the American Health Care Association (AHCA), the American Hospital Association (AHA), the American Medical Association (AMA), the American Nurses Association (ANA), the American Pharmaceutical Association, now known as the American Pharmacists Association (APhA), the American Society of Health-System Pharmacists (ASHP), the Federation of State Medical Boards of the United States (FSMB), the Food and Drug Administration (FDA), the Generic Pharmaceutical Industry Association, now known as the Generic Pharmaceutical Association (GPhA), the Joint Commission on the Accreditation of Health Care Organizations (JCAHO), the National Council of State Boards of Nursing (NCSBN), the National Association of Boards of Pharmacy (NABP), the Pharmaceutical Research and Manufacturers of America (PhRMA), and the United States Pharmacopoeia (USP).

William Ellis, RPh, then Executive Director of the Pennsylvania Society of Health System Pharmacists, was selected by the USP to be the chairperson to lead the Council through its first year. He was then elected by the Council membership to serve another one-year term as chairperson. The USP agreed to serve as the Secretariat for the Council. Subsequent chairpersons for two-year terms each were: Deborah Nadzam, PhD, RN; Jerry Philips; John Coombs, M.D., and Linda Hanold, M.H.S.A.

At its first meeting the Council declared its purpose to mount a nationwide campaign for medication error reporting and prevention that will promote recommendations broadly to colleges, schools, and state associations of medicine, pharmacy, and nursing; national professional associations; managed care organizations; and third-party payers. Five goals were delineated, that continue to direct Council activities (see Table 1).

At its second meeting, the Council approved a definition of “medication error” and encouraged all stakeholders to use this definition to provide a uniform basis for medication error reporting and analysis. Standardized classification criteria (Taxonomy) and a severity grading system (Error Category Index) for medication errors were then developed by the Council, and health professionals and healthcare organizations were urged to report medication errors to national programs like the USP-ISMP Medication Errors Reporting (MER) Program and FDA’s MedWatch.

Over the past decade, the Council has grown to encompass 22 member organizations and two individual members (see Table 2). It has issued eleven sets of recommendations, standardized definitions, and hosted two national conferences. The first conference focused on bar coding with a resultant white paper urging standardization and adoption of bar codes on pharmaceuticals; the second one focused on the use of suffixes in drug nomenclature (recommendations pending). In addition, in concert with 93 state and national health-related associations, the Council signed on to a set of general principles supporting legislation to uphold as privileged that information submitted to error reporting programs. These General Principles were incorporated into the Patient Safety and Quality Improvement Act of 2005 which was passed by Congress and signed into law on July 29, 2005.

Definition of “medication error”

As one of its first actions, the Council defined a "medication error" as follows:

"A medication error is any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer. Such events may be related to professional practice, health care products, procedures, and systems, including prescribing; order communication; product labeling, packaging, and nomenclature; compounding; dispensing; distribution; administration; education; monitoring; and use."

The Council has urged all stakeholders to adopt this definition of a medication error to promote uniformity in the discussion of medication errors across the healthcare continuum. Among those adopting the NCC MERP definition are the FDA, Centers for Medicare and Medicaid Services (CMS), and the USP.

Index for Categorizing Medication Errors

Following closely on the promulgation of the definition of “medication error,” the Council moved on to develop the *Index for Categorizing Medication Errors*. The Council originally adopted the Index to classify an error according to the severity of the outcome. The Index was designed to help health care practitioners and institutions track medication errors in a consistent, systematic manner. The Index considers factors such as whether the error reached the patient and, if the patient was harmed, to what degree. The Council encouraged the use of the Index in all health care delivery settings and by researchers and vendors of medication error tracking software.

In 2001 a revised and expanded Index was developed by the Council to make it easier for health care professionals to categorize and report medication errors (see Figure 1). The Council created a new circular configuration for its Index, which attributes an equal area to each of the nine medication error categories. Initially, the Index had listed the categories in descending order. Medication error definitions within each category also were expanded. Although the nine Index categories remain the same (designated as Categories A-I), the definitions within each category were clarified so that practitioners can more easily apply the Index to individual reports of

medication errors. The revised Index expanded the definition of the harmful categories (E through I) so that the error "may have contributed to or resulted in" harm.

Another Index refinement included additional language for serious errors that result in an intervention necessary to sustain life. The definition of harm also was broadened to include pain. This was consistent with a movement within health care to routinely monitor a patient's pain as the "fifth" vital sign.

The Council also created the *NCC MERP Index for Categorizing Medication Errors Algorithm* that incorporated a series of "yes-no" questions to guide health care professionals in their determination of the appropriate medication error category for the error they are reporting or evaluating (see Figure 2).

Through its Taxonomy Subcommittee, the Council periodically reviews the Index and considers the need for refinement to assure continuing currency and ongoing relevance.

Taxonomy of medication errors

From 1996 to 1999, the Council developed an extensive "*Taxonomy of Medication Errors.*" Released in March 1999, this important tool provided a detailed structure and standardized language to report medication error-related data for use in developing databases to analyze medication error reports.

The Taxonomy's comprehensiveness reflects the complexity and system realities associated with medication errors. It consists of eight major categories: patient information, medication error event, patient outcome, product information, personnel involved, type of medication error, causes, and contributing factors.

Each category contains multiple fields and data choices. The Taxonomy, itself, is not intended to be a reporting system or form, but rather is a tool to categorize and analyze reports of medication errors for healthcare organizations with established reporting systems and forms. It can be used to analyze medication error reports and abstract data elements. The Taxonomy also can be used to design local or national medication error reporting forms and accompanying databases. A brief

user's questionnaire is included with the Taxonomy to aid in identifying the need for future revisions.

The Taxonomy Subcommittee has been charged with revising, maintaining, evaluating and improving the Taxonomy. It also considers requests for use of the Taxonomy by external individuals and organizations and makes recommendations to the Council. It is the intention of the Council that the Taxonomy be used widely. In that regard, the full, unaltered text of the Taxonomy may be reproduced without special permission by individual healthcare facilities for internal, non-commercial use. However, all other requests to use the Taxonomy must be approved by the Council. While the Council prefers that the Taxonomy be reproduced only in its entirety and without alteration, the Council realizes that, in some instances, an entity may have a valid reason to use only selected components of the Taxonomy. The Council has developed "Principles for Partial Use of the Taxonomy," and the Taxonomy Subcommittee evaluates requests for partial use of the Taxonomy against these principles, and makes its recommendation to the full Council for approval.

The Taxonomy has been widely used by healthcare organizations, including hospitals that participate in the USP's MEDMARX medication error reporting program. The Taxonomy also has been included in textbooks and numerous articles in scientific journals. It has formed the basis for development of assessment tools (both paper-and-pencil and electronic). Software vendors have included the Taxonomy in their products. The inclusion of the Taxonomy in healthcare organizational policy and procedures has served to improve patient safety and increase quality within healthcare settings.

NCC MERP Recommendations

Since its inception in 1995, the Council's mission has been to promote the reporting, understanding, and prevention of medication errors. To address its goals (see Table 1), the Council analyzed data from USP's two reporting programs (MER and MEDMARX) and identified areas in the medication use process that resulted in actual and potential medication errors. To help reduce such errors, the Council has periodically issued recommendations that span the medication use process. Recommendations issued to date are listed in Table 3.

Recommendations for Prescribing - <http://www.NCC MERP.org/council/council1996-09-04.html>

In 1996, the Council drafted its first set of recommendations to help reduce the potential for harmful errors in medication ordering and prescribing. “Recommendations to Correct Error-prone Aspects of Prescription Writing” were an important step in ensuring the five basic patient rights: the right drug in the right dose by the right route to the right patient at the right time. Recurring problems that led to the issuance of these recommendations included illegible handwriting on prescriptions and medication orders, the absence/presence of leading/trailing zeros, misinterpreted abbreviations, confusing Latin directions for use, and vague or incomplete instructions. It was hoped that these recommendations would be included in developing educational and orientation programs for health care staff and would promote the use of computerized order entry systems.

Recommendations for Labeling and Packaging - <http://www.NCCMERP.org/council/council1997-09-16b.html>; <http://www.NCCMERP.org/council/council1997-09-16.html>; <http://www.NCCMERP.org/council/council1998-07-17.html>

In an attempt to reduce medication errors in which product labeling and packaging were contributing factors, in 1997 the Council adopted two sets of recommendations, one for regulators and standards- setters and one for manufacturers of pharmaceuticals and devices. Suggested actions included restricting the use of any printing on caps and ferrules of injectables except to convey warnings; the use of innovative labeling, such as tall letters, to distinguish similar drug names; implementation of bar coding; the use of failure mode and effects analysis for the design of devices, and for the packaging and labeling of medications; and the continued partnership among members of the entire medication use spectrum to minimize labeling and packaging errors. Emphasis was placed on finding systems-based solutions to reduce errors, and on increasing awareness of product packaging and labeling that is associated with actual or potential errors.

In March 1998, additional recommendations on labeling and packaging were directed at health care professionals and health care organizations. When implemented, these recommendations would reduce those errors in which product labeling and packaging design had been identified as contributing factors to medication errors. The Council advocated for proper storage and location of medications within a healthcare facility; clear procedures for medication repackaging; education and training of healthcare professionals, technical support personnel, patients and caregivers for reducing and preventing medication errors; and for active participation and collaboration in reporting and investigating errors. The establishment of a systems approach to understanding and

reporting medication errors was endorsed, along with the establishment of a culture conducive to rectifying processes that contribute to errors.

Recommendations for Dispensing - <http://www.NCC MERP.org/council/council1999-03-19.html>

Patient harm is more likely to occur when there are no mechanisms in place to prevent medication errors from reaching patients. For example, poor environmental conditions, distractions, and excessive workload all act to undermine safe medication use practices. The Council believed that one of its roles was to make recommendations that were easily adoptable by all health care professionals to protect patients. Thus, in March 1999, the Council adopted recommendations aimed at preventing errors that occur during the dispensing phase of the medication use process. Emphasis was placed on checking and rechecking labels, arranging product inventory to visually differentiate medications, designing dispensing areas that are conducive to uninterrupted work, and encouraging pharmacists to take an active role in counseling patients.

Recommendations for Administration - <http://www.NCC MERP.org/council/council1999-06-29.html>

The Council also wanted to ensure that health care professionals who administer medications are knowledgeable about the drugs they administer and have easily-accessible product information. In June 1999, the Council adopted recommendations to reduce errors related to the administration of drugs in all areas of health care delivery, once again focusing on the five patient rights. Labels were to be checked three times and patients were to be continuously monitored for desired or adverse effects. The use of linked automated systems (i.e., direct order entry, computerized medication administration records, and bar coding) was encouraged to facilitate review of prescriptions, increase the accuracy of administration, and reduce transcription errors. The Council also recommended that data from actual or potential administration errors be continuously collected for quality improvement.

Recommendations for Verbal Orders - <http://www.NCC MERP.org/council/council2001-02-20.html>

In 2001, the Council developed recommendations to reduce medication errors associated with verbal medication orders and prescriptions. Errors resulting from verbal orders are an area of particular concern because confusion over similar drug names or other aspects of the medication

order are common. Developing organizational policies and procedures regarding verbal orders, limiting verbal orders to emergency situations, repeating the order back to the prescriber, immediately converting the order to writing, and fostering a culture where staff is encouraged to question prescribers about unclear verbal orders, were among the recommendations made at this time.

Recommendations for Standard Bar Codes on Medication Packages and Containers -

<http://www.NCCMERP.org/council/council2001-06-27.html>

Recommendations to standardize bar codes on medication packages and containers were adopted by the Council in June 2001, following an invitational conference sponsored by the Council (see below for full description of this activity). The recommendations describe the minimum requirements for the data elements of a bar code, the format and labeling parameters, and indicated that the bar code should be included on immediate container labels of all commercially available medications regardless of dosage form, the intermediate container or carton, and on the shelf-keeping unit.

Statement for Measuring Medication Errors - <http://www.NCCMERP.org/council/council2002-06-11.html>

In 2002, the Council issued a statement on medication error rates. The Council believes that there is no acceptable incidence rate for medication errors, and that the goal of every organization should be to continually improve systems to prevent harm to patients. On the other hand, the use of medication error rates to compare healthcare organizations is of no value because of differences among healthcare organizations in culture, the definition of a medication error, patient populations served, and the type(s) of reporting and detection systems used. Health care organizations should continuously monitor actual and potential errors and investigate the root causes of errors to identify ways of improving the medication use process to prevent future errors and patient harm. According to the Council, creating an open environment that encourages error reporting is more important than developing comparative error rates.

Recommendations to Reduce Medication Errors in Non-Health Care Settings - <http://www.NCCMERP.org/council/council2003-06-20.html>

In 2003, the Council issued recommendations to reduce medication errors in non-health care settings, such as schools, day care, assisted living, and prisons. In all of these settings, employees, many of whom are not licensed health care professionals, may lack adequate training in medication storage and/or administration, yet they are responsible for handling and administering prescription and over-the-counter medications. The Council recommended that non-health care settings have written policies and procedures on medication management, provide training to all personnel with responsibilities for medication management, provide safeguards to prevent and detect theft and diversion of controlled substances, and encourage the reporting of medication errors to appropriate state and national medication error reporting programs to identify significant trends that can lead to improved quality and safety of healthcare.

NCC MERP National Conferences

A key strength of the Council is to convene interested stakeholders on important issues that can be controversial. Two issues presented such opportunities for the Council's action: the use of bar codes on medication packages and containers; and the use of suffixes in drug nomenclature.

Standardization of Bar Codes

The use of machine-readable codes, such as bar codes, in a standardized format on all medication packages and containers was considered a promising technology to reduce medication errors and improve patient safety. In August 2000, the Council hosted a national conference to explore four specific areas relating to bar code technology: needs assessment, current standards, equipment manufacturers, and cost implications. Recommendations resulting from this conference called upon the USP and the FDA to collaborate with appropriate stakeholders to establish and implement uniform bar code standards at the unit-of-use package level. The recommendations, which were adopted by the Council in June 2001, described the minimum requirements for the data elements of a bar code, the format and labeling parameters, and indicated that the bar code should be included on immediate container labels of all commercially available medications regardless of dosage form, the intermediate container or carton, and on the shelf-keeping unit. Members of the pharmaceutical industry hailed the recommendations for providing a standard mechanism to efficiently implement bar coding onto pharmaceutical labels and advancing its commitment to the safe use of pharmaceutical products. Subsequently, the FDA proposed and then issued final rules on bar coding.

Drug Nomenclature and Suffix Use

The Council convened a group of interested stakeholders in October 2005, to review issues associated with drug nomenclature that includes suffixes. Currently, it is common practice to name a modified dosage formulation within a product line adding a suffix. Suffixes have also been used to describe unique characteristics of drug products such as “orally disintegrating” tablets. A suffix may be a letter, number or combination of letters and/or numbers attached to the end of a proprietary drug name. As an unintended consequence, the practice of adding suffixes to drug names has contributed to confusion among drug products and an increase in related medication errors. Also, there are currently no uniform standards or consistent definitions to guide what these suffixes mean or how they are used. The conference was held to: describe the wide array of issues associated with the use of non-standardized drug name suffixes from various stakeholder perspectives; quantify, to the extent possible, the underlying causes of medication errors arising from non-standardized use of drug name suffixes; and describe short and long-term solutions that will be encompassed in NCC MERP recommendations to reduce medication errors related to the disparate use of drug name suffixes. Results will be forthcoming.

Additional Council Actions

In addition to the major activities described in the preceding sections, NCC MERP has also undertaken many ancillary activities as follows:

- Developed and disseminated standardized definitions for terms such as adverse drug event, adverse drug reaction, harm, preventable event, etc.
- Established and launched a dedicated web site in August 1998 to facilitate reference and use of Council products (e.g., definitions recommendations, taxonomy) and to promote the Council’s mission, purpose and objectives regarding medication error reporting and prevention.
- Developed an article addressing solid oral dosage forms in 1998 for broad dissemination through the Council’s web site and through member organizations.
- Reviewed and endorsed the Institute for Safe Medication Practices (ISMP) “Safety Self-Assessment for Community/Ambulatory Pharmacy.” (2000)
- Added “Consumer Information for Safe Medication Use” to the NCC MERP web site.

- Broadly disseminated information about medical gas mix-ups through member organization web sites. (2001)
- Developed and disseminated a white paper in 2002 to assist front line users in the use of bar codes.

Impact of NCC MERP Activities

The National Coordinating Council for Medication Error Reporting and Prevention during its first ten years has had a significant national impact. The most important achievements include the following:

- The wide acceptance and adoption of the Council’s definition of “medication error,” its “Taxonomy of Medication Errors,” and its *Index for Categorizing of Medication Errors* by important public and private sector stakeholders has resulted in a much-needed standardization of medication error reporting and analysis.
- The Council’s national conference and subsequent recommendations on the standardization of bar codes provided the major impetus to the FDA and the pharmaceutical industry to agree on regulations in this area, with a final rule being published by the FDA in February.
- The Council’s practical recommendations on reducing medication errors related to prescribing, dispensing, administration, packaging and labeling, and other subjects has contributed to better practices by healthcare organizations and health professionals.
- The Council, in part because of the diversity and impact of its member organizations, has played a role in changing the national culture on how medication errors are perceived and on how systems-based solutions are necessary to address this problem.

A recent Internet search revealed more than 200 hundred national and international references to NCC MERP products and their new and ongoing use.

The Council’s work has been quickly embraced by the international community. Many countries including Canada, the United Kingdom, Australia, and others have embedded the Taxonomy, the definition for medication error, or other components of the Council’s work products into national reporting systems, patient safety best practices guidelines, error reporting/analysis systems, etc. In 2005, the Council submitted the Taxonomy to the World Health Organization for their unencumbered use in the World Alliance for Patient Safety project which is focused on building

international consensus on a high level taxonomy that will support analysis, aggregation, and learning from patient safety data within and across countries.

Council members have also noted NCC MERP's impact on their activities, as described below by the member organizations. Links to members' websites are provided in Table 2.

AARP (formerly the American Association of Retired Persons)

AARP is the leading nonprofit, nonpartisan membership organization of over 35 million persons age 50 and older. AARP is pleased to be a founding member of NCC MERP, for our participation has helped to inform our thinking on and understanding of patient safety medication issues, particularly those occurring in inpatient settings. We appreciate the valuable resource that NCC MERP provides to us and other organizations interested in improving safe medication use.

AARP's service on the NCC MERP has helped to inform our thinking on and understanding of patient safety medication issues, particularly those occurring in inpatient settings. Should AARP establish specific policy on medication errors and reporting systems, we are certain to look to the Council for guidance.

American Health Care Association (AHCA)

The American Health Care Association is committed to performance excellence and Quality First, a covenant for healthy, affordable and ethical long term care. AHCA represents more than 10,000 non-profit and for-profit providers dedicated to continuous improvement in the delivery of professional and compassionate care for our nation's frail, elderly and disabled citizens who live in nursing facilities, assisted living residences, subacute centers and homes for persons with mental retardation and developmental disabilities.

AHCA is pleased to have been a founding member of the National Coordinating Council for Medication Error Reporting and Prevention and an active participant in NCC MERP's development and activities during the past 10 years. AHCA has brought the perspective of the long term care resident and provider to the Council, and, in turn, has delivered NCC MERP's message to the long term care community. AHCA's initiatives toward improving quality care outcomes encompass the philosophy and elements behind NCC MERP's efforts directed at

identifying the cause of medication errors, modifying practices, and preventing errors. Patient safety is more than a regulatory compliance goal for long term care providers. It is a core principle that underlies their delivery of quality care and quality of life. AHCA and NCAL are committed to quality and performance excellence. We support Quality First.

American Medical Association (AMA)

The American Medical Association, our nation's largest physician professional association, helps doctors help patients by uniting physicians to work on the most important professional and public health issues.

The American Medical Association (AMA) congratulates the National Coordinating Council for Medication Error Reporting and Prevention on the celebration of its 10th anniversary. As a participating organization from the very beginning, the AMA believes that the NCC MERP has made a significant contribution to reducing medication errors in healthcare settings through a series of practical recommendations on the prescribing, dispensing, administration, packaging, and labeling of medications. In particular, the NCC MERP's recommendations on bar coding of commercial prescription drug products served as the impetus for subsequent Food and Drug Administration regulations for bar coding. Also, the NCC MERP's "Taxonomy of Medication Errors" has made a significant contribution in efforts to standardize the language and the structure for categorizing data from medication error reports.

American Nurses Association (ANA)

The American Nurses Association (ANA) is the largest full-service professional nursing organization representing the interests of the nation's 2.7 million Registered Nurses through its 54 constituent member associations and 13 organizational affiliate nursing organizations.

The American Nurses Association (ANA) is pleased to have been a founding member of the National Coordinating Council for Medication Error Reporting and Prevention. Over the ten plus years since NCC MERP's inception, ANA has disseminated information regarding the work of the Council electronically to its constituent member associations keeping them apprized of the actions and positions taken by NCC MERP. In addition, there is a link to the NCC MERP site on NursingWorld.org, ANA's website.

American Pharmaceutical Association (now known as American Pharmacists Association)

(APhA)

The American Pharmacists Association (APhA), founded in 1852 as the American Pharmaceutical Association, represents more than 56,000 practicing pharmacists, pharmaceutical scientists, student pharmacists, pharmacy technicians, and others interested in advancing the profession.

APhA congratulates the National Coordinating Council on Medication Error Reporting and Prevention (NCC MERP) on its 10th anniversary and is pleased to be a founding member of the Council. APhA's initiatives have focused on publishing safety and medication error-related articles and research, and highlighting the significant contribution the Council has made on preventing medication errors. Participation in NCC MERP activities has also influenced APhA policy development in a number of areas relating to medication errors and improving medication use. In addition, the APhA Foundation Pinnacle Awards recognizes contributions to health care quality through the medication use process. APhA commends NCC MERP's work on bar coding recommendations, the medication error taxonomy, medication error index for categorizing errors, and drug administration recommendation for reducing errors. These initiatives have helped the health care profession recognize the need for an increased focus on patient safety and preventing medication errors. APhA looks forward to continued collaboration with NCC MERP in improving medication use and advancing patient care.

American Society for Consultant Pharmacists (ASCP) – Joined Council in 2000

ASCP's 6,500+ members manage and improve drug therapy and improve the quality of life of geriatric patients and other individuals residing in a variety of environments, including nursing facilities, subacute care and assisted living facilities, psychiatric hospitals, hospice programs, and home and community-based care.

Since becoming a member of the National Coordinating Council for Medication Error Reporting and Prevention in 1997, the American Society of Consultant Pharmacists has utilized press releases and information produced by the Council in a variety of ways. All press releases have been released to our media contacts. In addition, summaries of the press releases have been published in our journal, *The Consultant Pharmacist*, which is also archived online. The Council's

definition of medication error and recommendations regarding administration of medications have been quoted in the Society's new publication, *The Consultant Pharmacist Handbook*. In addition, the Council's recommendations have been used to answer questions posed by individuals on the Society's online posting board called ConsultNet. For example, an inquirer searching for national medication error rates for benchmarking purposes was referred to the Council's statement on the potential dangers of using medication error rates to compare health care organizations.

Dissemination of information discussed at Council meetings occurs frequently. For instance, information about confusion and errors associated with suffixes presented at a Council meeting led to an article published on the subject in an edition of *The Consultant Pharmacist* this year. Also, the growing attention on patient safety and medication errors has influenced ASCP to form a leadership task force on this topic. We greatly appreciate the work of the Council and look forward to ongoing collaboration.

American Society of Health-System Pharmacists (ASHP)

The American Society of Health-System Pharmacists is the 30,000-member national professional and scientific association that represents pharmacists who practice in hospitals, health maintenance organizations, long-term care facilities, and other components of health systems.

The American Society of Health-System Pharmacists (ASHP) which represents more than 30,000 pharmacists who practice in hospitals and health systems has found great value in the Council as a neutral convening body for multiple stakeholders to work together to identify meaningful approaches to improving medication-use safety in multiple settings. The NCC MERP white paper on bar coding served as invaluable tool for ASHP to enhance its long-term advocacy efforts calling for the pharmaceutical industry to include machine-readable codes on all pharmaceutical product packages. The ASHP Board of Directors officially endorsed the NCC MERP recommendations for preventing medication errors, which included a list of dangerous abbreviations that ASHP, along with others, successfully advocated for the Joint Commission on Accreditation of Healthcare Organizations to prohibit the use of in accredited organizations. Most recently, the ASHP Research and Education Foundation helped fund the NCC MERP Conference on Errors Associated with Drug Suffixes, a topic in which ASHP has long been concerned. ASHP has committed itself to working with its partners on the Council, government, and industry, to find workable solutions to problems associated with suffixes. ASHP looks forward to another successful decade of

collaboration with NCC MERP in the interest in making medication-use safer and more effective for the patients we serve

American Society for Healthcare Risk Management (ASHRM) - Joined Council in 1997

The American Society of Healthcare Risk Management is a personal membership group of the American Hospital Association with more than 4,000 members representing healthcare, insurance, law and other related professions. ASHRM initiatives focus on developing and implementing safe and effective patient care practices, the preservation of financial resources, and the maintenance of safe working environments.

ASHRM is pleased and proud to be a member of the NCC MERP. Although ASHRM was not one of the original founding members of the Council, it has maintained an active membership and commitment to the Council since 1997.

NCC MERP has been referenced in many ASHRM publications including the “Risk Management Pearls” educational booklet on medication error reduction. Additionally, ASHRM also supports NCC MERP’s goals of promoting the reporting, understanding, and prevention of medication errors by providing a web link on ASHRM’s patient safety interest network Web page.

Department of Defense (DoD) – Joined Council in 2002

DoD has adopted MEDMARX (using the NCC MERP taxonomy) to report medication errors that occur in the military health system (143 facilities worldwide). USP has incorporated several NCC MERP resources including the Error Category Index and Algorithm into its formal training it provides to DoD. Additionally, the Council recommendation “*Use of Medication Error Rates to Compare Health Care Organizations is of No Value*” has also been incorporated into formal DoD/USP training and is one of the most frequently requested references by DoD healthcare facilities.

Food and Drug Administration (FDA)

FDA joined the National Council as a founding member in July 1995. NCC MERP is composed of a unique and important group of partners who bring specialized experience and expertise to the

Council. It has, in the past and continues today, to contribute significantly to reducing medication errors through a number of important public health initiatives. As a Council, NCC MERP developed a standardized definition of medication error that FDA adopted and codified as its own definition. In addition, FDA believes the use of the NCC MERP taxonomy to be an important asset in its effort to minimize medication errors. FDA also used the taxonomy as the basis to develop MedDRA terminology that has been used to classify medication error post-marketing events in AERS and global databases. NCC MERP was the first group to convene two patient safety workshops on issues of considerable interest to FDA. The first, an invitational workshop on bar coding technology and feasibility that brought technology, health professional and government experts together from around the country to discuss how best to implement this innovative tool. This meeting discussion proved to be an important first step that contributed greatly when FDA developed the final rule on bar code label requirements for human drug and biological products. The second, a meeting that explored the relationship and risks associated with drug name suffixes provided an important forum for the pharmaceutical industry, health practitioners and government experts to consider the complex safety issues resulting from adding suffixes to marketed drug names. FDA looks forward to continuing its relationship with NCC MERP to address issues of mutual concern regarding reduction of medication errors in the future.

Generic Pharmaceutical Association - (GPhA)

GPhA represents the manufacturers and distributors of finished generic pharmaceuticals, manufacturers and distributors of bulk active pharmaceutical chemicals, and suppliers of other goods and services to the generic drug industry. Generics represent 53% of the total prescriptions dispensed in the United States, but only 12% of all dollars spent on prescription drugs.

The Generic Pharmaceutical Association (GPhA) congratulates the National Coordinating Council on Medication Error Reporting and Prevention on its 10th anniversary. GPhA, an organization of nearly 140 members representing the generic pharmaceutical industry, is proud to have been a founding member and an active participant and contributor in the Council's vital work. The Council's work has greatly benefited patients and our nation's health care system.

GPhA shares the Council's goals and objectives to promote the proper and safe use of all drug products in the marketplace. The generic industry is pleased to provide manufacturing and

packaging expertise to assist in the overall identification of issues and formulation of recommendations to reduce the incidence of medication errors.

Institute for Safe Medication Practice (ISMP) - Joined Council in 1998

The Institute for Safe Medication Practices (ISMP) is the nation's only nonprofit organization devoted entirely to medication error prevention and safe medication use. ISMP represents more than 30 years of experience in helping healthcare practitioners keep patients safe, and continues to lead efforts to improve the medication use process. In 2004, the Institute celebrated the 10th anniversary of its official incorporation as a nonprofit organization. ISMP's highly effective efforts, which are built on a non-punitive approach and systems-based solutions, focus on improving the safety of medication distribution and use, naming, packaging, and labeling. For more information, visit ISMP online at www.ismp.org

The Institute for Safe Medication Practices (ISMP) wishes to congratulate the National Coordinating Council for Medication Error Reporting and Prevention on its 10 year anniversary. ISMP has supported the Council's important work since its inception and has disseminated NCC MERP statements on error prevention made by the council's multidisciplinary membership. The NCC MERP statement refuting the use of medication error rates to compare organizations in particular has had a major impact on the way healthcare organizations use error reporting data. ISMP looks forward to working with the NCC MERP on other key medication safety projects that involve all major stakeholders in the healthcare industry.

Joint Commission on Accreditation of Healthcare Organizations (JCAHO)

The Joint Commission evaluates and accredits more than 15,000 health care organizations and programs in the U.S. An independent, not-for-profit organization, the Joint Commission has maintained and applied state-of-the-art standards that focus on improving the quality and safety of care provided by health care organizations since 1951.

The Joint Commission on Accreditation of Healthcare Organizations is proud to have been one of the founding members of the National Coordinating Council for Medication Error Reporting and Prevention. The Joint Commission congratulates NCC MERP on the many significant

accomplishments achieved over the last decade and applauds the leadership role and progressive posture that NCC MERP has routinely demonstrated.

NCC MERP's influence and work products are reflected in many Joint Commission initiatives including the Patient Safety Event Taxonomy which builds upon several taxonomies including the NCC MERP Taxonomy, many NCC MERP recommendations are reflected in the Joint Commission's Patient Safety Goals, various patient safety activities and in standards related to patient safety. The work of NCC MERP is also often featured in various Joint Commission publications. Finally, the Joint Commission was pleased to host the highly successful bar-coding conference convened by NCC MERP in 2000 and will also host the upcoming Invitational Roundtable Meeting on the use of drug suffixes in October 2005.

The Joint Commission looks forward to its continued participation on NCC MERP and its ongoing efforts to address issues that potentially impact the safe use of medications by practitioners and consumers.

National Association of Boards of Pharmacy (NABP)

NABP is the independent, International, and impartial Association that assists its member boards and jurisdictions in developing, implementing, and enforcing uniform standards for the purpose of protecting the public health.

The National Association of Boards of Pharmacy (NABP) congratulates and extends warmest wishes to the National Coordinating Council for Medication Error Reporting and Prevention on the celebration of its 10th Anniversary. For a decade, NCC MERP has demonstrated a true commitment in working with the leading national health care organizations to address the interdisciplinary causes of errors and to promote the safe use of medications.

NCC MERP's philosophy of examining and evaluating the cause of medication errors, encouraging reporting of those errors, and heightening awareness of reporting systems has an underlying patient safety theme, which is consistent with NABP's mission of aiding its member boards of pharmacy in developing, implementing, and enforcing uniform standards in the interest of protecting the public health.

Patient safety is a priority that NCC MERP and NABP share. The Association commends NCC MERP for its commitment and dedication in developing many recommendations that have benefited patients and healthcare communities and its efforts to disseminate information to colleges, the medical and pharmacy profession, and professional associations. Examples include, but are not limited to, the Medication Error Index for Categorizing Errors, Taxonomy of Medication Errors, Council's Recommendations to Reduce Errors Related to Administration of Drugs, and their involvement in bar coding initiatives.

In closing, NCC MERP's targeted interest and focus on medication error prevention exemplifies just one of the many contributions NCC MERP has made to protect the public health. NABP looks forward to continued involvement with the Council on projects that aim to reduce medication errors and promote patient safety.

National Council of State Boards of Nursing (NCSBN)

The National Council of State Boards of Nursing (NCSBN) represents the 60 state and territorial boards of nursing who regulate the practice of nursing in the United States.

NCSBN has enjoyed being a founding member of, and valued contributor to, NCC MERP. Participation in issues that impact the regulation of nurses in medication-related practice has been very worthwhile. NCSBN, along with NCC MERP, is concerned with the safety of the public and strives to make nursing practice the safest it can be for all patients. Additionally, participation in the formation of the taxonomy of medication error has helped NCSBN with its own root cause analysis work and was a catalyst for a major project NCSBN is developing on nursing errors. We salute NCC MERP on this important milestone and a decade of hard work to make the public safer from medication errors.

National Council on Patient Information and Education (NCPIE) – Joined Council in 2002

The diverse, multidisciplinary coalition works to support the shared mission of stimulating and improving communication of information on appropriate medicine use to consumers and healthcare professionals.

Recognizing the value of multidisciplinary collaboration, the National Council on Patient Information and Education (NCPIE), a coalition of more than 100 organizations, is pleased to participate as a member of the National Coordinating Council on Medication Error Reporting and Prevention. A significant contribution by NCC MERP to advancing medication safety is its role as initiator and convener. By bringing together organizations with diverse constituencies (and perspectives) and sustaining a dynamic program of action, NCC MERP better ensures broad adoption and implementation of unique Council recommendations and programs.

Pharmaceutical Research and Manufacturers of America (PhRMA)

PhRMA represents the country's leading pharmaceutical research and biotechnology companies.

Pharmaceutical Research and Manufacturers of America (PhRMA) extends warmest congratulations to the National Coordinating Council on Medication Error Reporting and Prevention on the occasion of the Council's 10-year anniversary.

PhRMA is proud to be a founding member of the NCC MERP. PhRMA is committed to patient safety and served as a leader on the bar code initiative sponsored by NCC MERP. PhRMA actively worked with fellow Council member to successfully effect the requirement for linear bar code labels on drug and biological products, with the goal of reducing hospital-based medication errors by ensuring that patients receive the correct medicines as prescribed by their healthcare providers.

United States Pharmacopeia (USP)

The United States Pharmacopeia (USP) is the official public standards-setting authority for all prescription and over-the-counter medicines, dietary supplements, and other healthcare products manufactured and sold in the United States. USP sets standards for the quality of these products and works with healthcare providers to help them reach the standards. USP's standards are also recognized and used in many countries outside the United States. These standards have been helping to ensure good pharmaceutical care for people throughout the world for more than 185 years

Through its work as a standards-setting organization since 1820, the US Pharmacopeia (USP) recognized the need for national attention to the problem of medication errors through its medication errors reporting program. In 1995, it organized leading health care and consumer organizations to address challenges regarding the safe use of medications through its creation of the NCC MERP. Since the Council's inception, USP has acted as its Secretariat in the Council's activities addressing continuing concerns related to medication use and bringing the health care community together in a unified effort. USP adopted the Council's definition of "medication error" and its Index for Categorizing Medication Errors, incorporating both into USP's two nationwide reporting programs—the Medication Errors Reporting (MER) Program and MEDMARX[®]. USP has published and widely promoted these excellent work products. One of USP's on-going contributions to the Council is its administration and maintenance of the NCC MERP web site content and design. USP commends the Council's continued commitment to its original goals of evaluating the causes of medication errors and promoting development of strategies, practice standards, and guidelines to reduce, and ultimately prevent medication errors.

The Future

In the future the National Coordinating Council for Medication Error Reporting and Prevention will continue to focus on key issues impacting the safe use of medications. The Council has modified its structure to better support the accomplishment of multiple activities. Specifically, five sub-committees have been established to more efficiently manage inter-meeting work activities and to accelerate and facilitate accomplishment of objectives. Sub-committees are staffed by Council members and each has an explicitly defined charge. Active committees include the following:

- Strategic Planning Committee
- Practice-Related Issues Sub-Committee
- Promotion, Monitoring and Evaluation Sub-Committee
- Taxonomy Sub-Committee
- Technology Sub-Committee

The sub-committees will provide guidance for the completion of several activities already underway (expected to be completed within the next 6-12 months). These include:

- Review and revision of the Taxonomy to assure ongoing relevance and currency.

- Revision (Updating) of Recommendations to Reduce Medication Errors Associates with Labeling and Packaging of Medications.
- Definition of the scope of medication error issues associated with tubing interchangeability.
- Identification of the most common risk behaviors as determined through structured evaluation of more than 600 medication error cases; development and publication of identified risk behaviors and recommendations to obviate these behaviors.
- Development and dissemination of recommendations focused on the safe use of sample medications within various health care settings.
- Summary of the national conference on medication errors arising from the non-standardized use of drug suffixes in drug names and development of Council recommendations.
- Development of a database of taxonomy users and establishment of a process to routinely obtain input/feedback respecting the use of the taxonomy.

The Council currently is developing a strategic plan that will provide a roadmap for NCC MERP's work over the next five years. This will include a re-evaluation of NCC MERP's mission, vision, purpose and objectives to assure that they fully support and are consistent with projected work activities through 2010.

The strategic plan will focus on continuing to evolve NCC MERP's presence and role in the current patient safety environment, both nationally and internationally. As such, emphasis will be placed on identifying increased opportunities for publications and presentations, ongoing generation of relevant and timely work products designed to help reduce/prevent medication errors and increase/improve error reporting, greater presence and participation in various national patient safety activities, and increased communications.

The strategic plan also will identify and articulate potential Council projects and associated goals/objectives, potential areas that need to be monitored so that current and planned activities can be continuously informed and modified as needed, and potential project collaborators and funding sources to support planned activities.

Once the NCC MERP Strategic Plan through 2010 is finalized, it will be posted to NCC MERP's website. Current discussions indicate that future directions may include more focused attention on error-related issues in non-hospital settings such as long term care, home care and behavioral health care, predictive risk modeling, comprehensive analysis of the medication error literature over the past 10 years, initiation of a "campaign" for increased error reporting, development of a Research Agenda that targets critical error-reduction opportunities and enhanced error reporting incentives for further investigation, reliability and validity studies respecting the Index for Categorizing Medication Errors, expansion of Council membership, and the identification of collaborative opportunities with member organizations and others.

Objectives

1. Medication Error Reporting

- Heighten awareness of reporting systems available to or within health care organizations. Stimulate and encourage reporting of medication errors both nationally and locally.
- Develop standardization or classification systems for the collection of medication error reports so that databases will reflect reports and grading systems.
- Maintain systems to support and provide feedback to reporters so that appropriate prevention strategies can be developed in facilities.

2. Medication Error Understanding

- Assess current knowledge of medication errors through ongoing efforts (for example, literature searches) to gather data associated with the scope of problems, types of errors, causes and sources of errors, and impact on patients and health system costs.
- Develop a mechanism to identify gaps in research that hinder the understanding of medication errors.
- Sponsor research to expand knowledge regarding medication errors, their causes, and the effectiveness of interventions.

3. Medication Error Prevention

- Encourage standardization of error-prone aspects of drug prescribing, delivery, and administration.
- Encourage reliance on systems-based solutions to enhance the safety of medication use and to minimize the potential for human error.
- Explore the potential for computer-based information systems in the prevention of medication errors.
- Increase awareness of the need for distinctive packaging, labeling, and nomenclature of products associated with actual or potential medication errors.
- Educate consumers and patients regarding strategies to prevent medication errors for both prescription and nonprescription medications.
- Educate health care professionals regarding strategies to prevent medication errors.

Table 1: Goals Established at First Council Meeting

- Stimulate the development and use of reporting and evaluation systems by individual health care organizations;
- Stimulate reporting to a national system for review, analysis, and development of recommendations to reduce and ultimately prevent medication errors;
- Examine and evaluate the causes of medication errors;
- Increase awareness of medication errors and methods of prevention throughout the health care system; and
- Recommend strategies for system modifications, practice standards and guidelines, and changes in packaging and labeling.

Table 2: Organization and Individual Members (as of June 2005)

AARP www.aarp.org
American Health Care Association www.ahca.org
American Hospital Association www.aha.org
American Medical Association www.ama-assn.org
American Nurses Association www.nursingworld.org
American Pharmacists Association www.aphanet.org
American Society for Healthcare Risk Management www.ashrm.org
American Society of Consultant Pharmacists www.ascp.com
American Society of Health-System Pharmacists www.ashp.org
Department of Defense www.defenselink.mil
Department of Veterans Affairs www.va.gov
Food and Drug Administration www.fda.gov
Generic Pharmaceutical Association www.gphaonline.org
Healthcare Distribution Management Association www.healthcaredistribution.org
Institute for Safe Medication Practices www.ismp.org
Joint Commission on Accreditation of Healthcare Organizations www.jcaho.org
National Association of Boards of Pharmacy www.nabp.net
National Council of State Boards of Nursing, Inc. www.ncsbn.org
National Council on Patient Information & Education www.talkaboutrx.org
National Patient Safety Foundation www.npsf.org
Pharmaceutical Research and Manufacturers of America www.phrma.org
U.S. Pharmacopeia www.usp.org
Deborah Nadzam, Ph.D., FAAN - Individual member nadzamd@ccf.org
David Kotzin, R.Ph., BS, MS - Individual member dkotzin@terpsrxs.com

Table 3 - NCC MERP RECOMMENDATIONS

(Access these documents at www.nccmerp.org)

- Recommendations to Reduce Medication Errors in Non-Health Care Settings - *Adopted 6-20-2003*
- Use of Medication Error Rates to Compare Health Care Organizations is of No Value - *Adopted 6-11-2002*
- Promoting and Standardizing Bar Coding on Medication Packaging: Reducing Errors and Improving Care - *Adopted 6-27- 2001*
- Recommendations to Reduce Medication Errors Associated with Verbal Medication Orders and Prescriptions - *Adopted 2-20- 2001*
- Recommendations to Reduce Errors Related to Administration of Drugs - *Adopted 6-29-1999; Revised 6-2- 2005*
- Recommendations for Avoiding Error-Prone Aspects of Dispensing Medications-*Adopted 3-19-1999; Revised 6-2- 2005*
- Recommendations to Health Care Organizations to Reduce Errors Due to Labeling and Packaging of Drug Products and Related Devices - *Adopted 3-30-1998*
- Recommendations to Health Care Professionals to Reduce Errors Due to Labeling and Packaging of Drug Products and Related Devices - *Adopted 3-30-1998*
- Recommendations on Labeling and Packaging to Industry Manufacturers of Pharmaceuticals and Devices - *Adopted 5-12-1997*
- Recommendations on Labeling and Packaging to Regulators and Standards Setters - *Adopted 5-12-1997*
- Recommendations to Correct Error-Prone Aspects of Prescription Writing - *Adopted 9-4-1996; Revised 6-2-2005*

Figure 1 - NCC MERP Index for Categorizing Medication Errors

NCC MERP Index for Categorizing Medication Errors

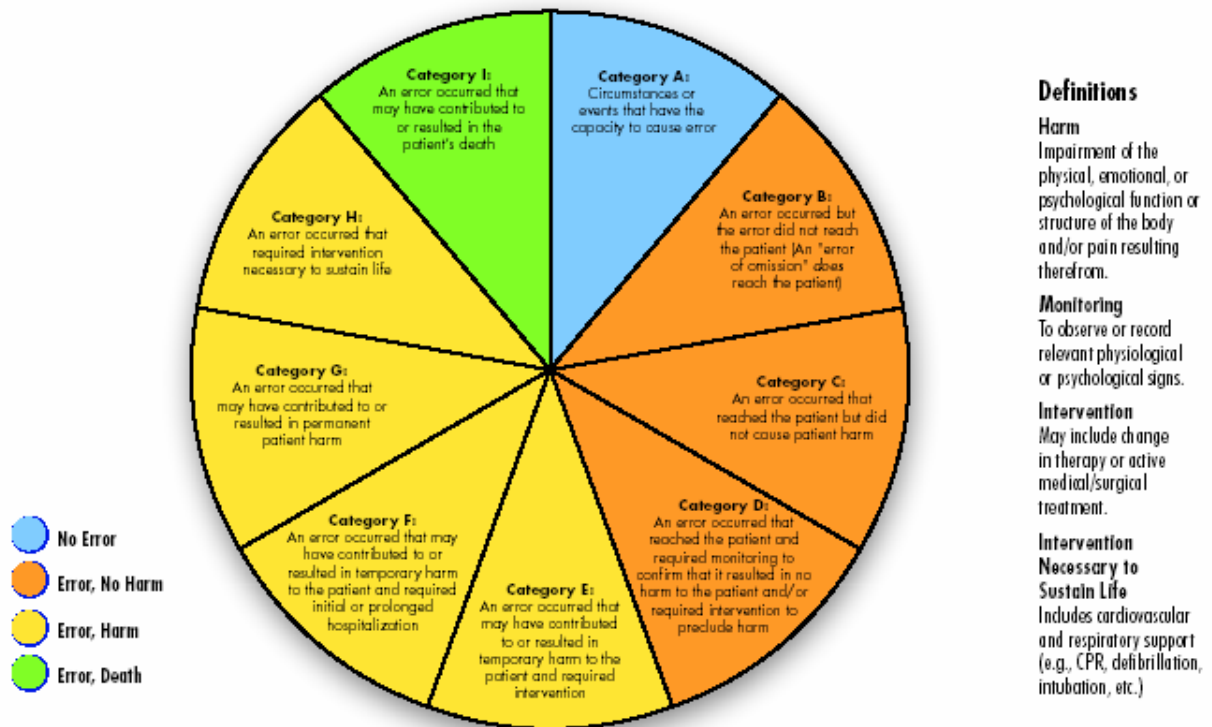
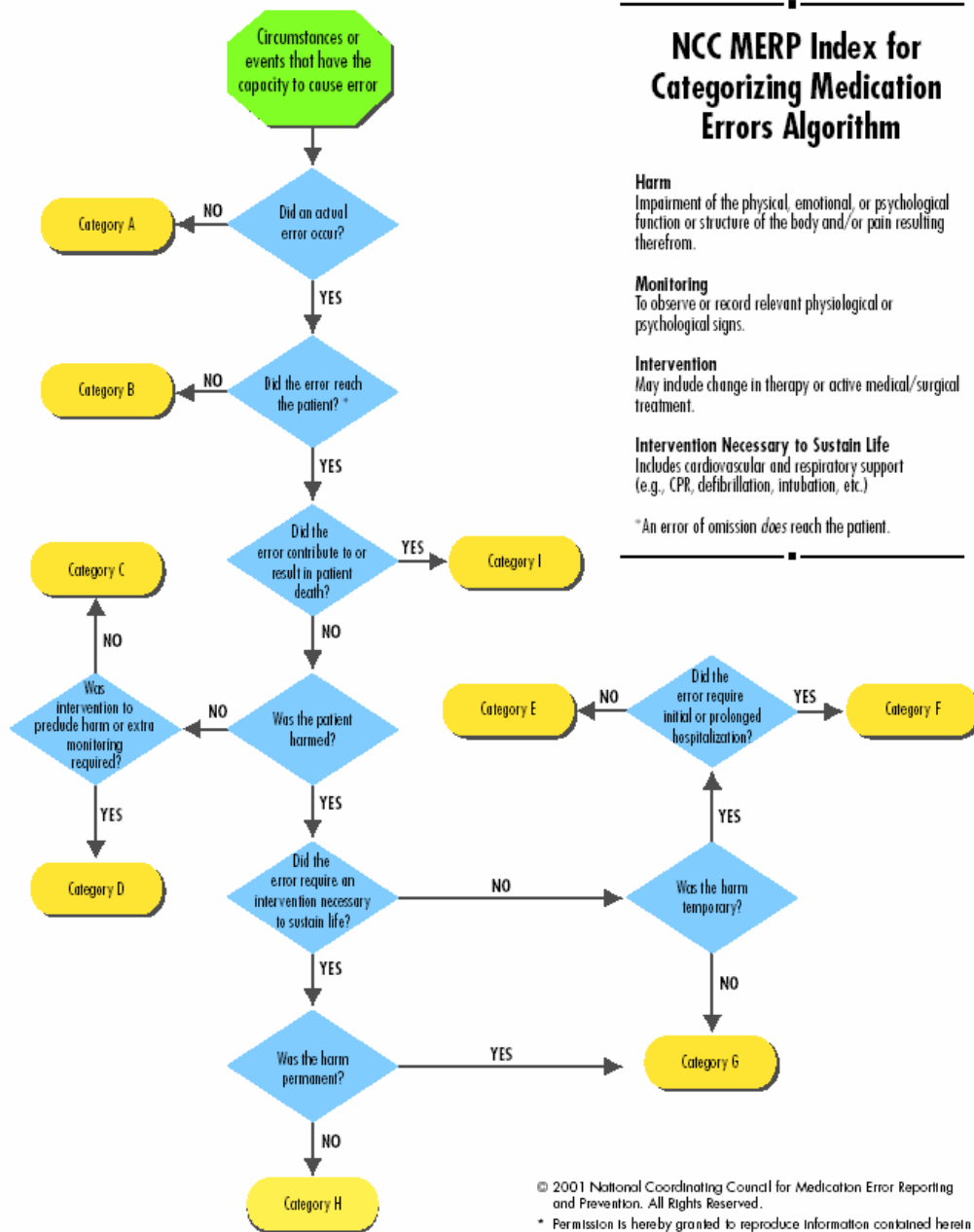


Figure 2: NCC MERP Index for Categorizing Medication Errors Algorithm



NCC MERP Index for Categorizing Medication Errors Algorithm

Harm
Impairment of the physical, emotional, or psychological function or structure of the body and/or pain resulting therefrom.

Monitoring
To observe or record relevant physiological or psychological signs.

Intervention
May include change in therapy or active medical/surgical treatment.

Intervention Necessary to Sustain Life
Includes cardiovascular and respiratory support (e.g., CPR, defibrillation, intubation, etc.)

*An error of omission *does* reach the patient.

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APPENDIX

Invitational Conference on the Use of Bar-coding with Pharmaceuticals

In 2000, the National Coordinating Council on Medication Error Reporting and Prevention co-sponsored with the FDA an invitational conference focused on the use of bar-coding to improve medication safety. Held at the Joint Commission in Oakbrook Terrace, Illinois, representatives from hospitals, software and hardware companies, regulatory agencies and the pharmaceutical industry discussed the advantages and challenges associated with standardizing bar-coding for drug identification and packaging, and medication administration.

The NCC MERP considered all presentations and ultimately issues the following document and set of recommendations.

Errors resulting in patient injury and death are occurring in hospitals at significantly high and unacceptable numbers. In 1999, the Institute of Medicine (IOM) published a report, *To Err Is Human: Building a Safer Health System*, calling public attention to the important issue of patient safety. According to the IOM, as many as 98,000 Americans may die annually because of medical mistakes made by health care professionals. A significant number of these deaths can be attributed to medication errors. The diversity of causes of errors will require many solutions. The most immediate and far-reaching may be in the area of technology implementation.

One way patient safety can be improved by information technology is through the use of machine-readable codes such as bar codes in a standardized format on all medication packages and containers. A scannable bar code can help guarantee that the right drug and dose are being administered to the correct patient.^{1,2,3} Technology developments allow for increased information to be imbedded within a bar code and makes coding of smaller packages possible.

The National Coordinating Council for Medication Error Reporting and Prevention organized a one-day conference on August 7, 2000, and invited individuals representing end users, the pharmaceutical industry, information systems vendors, regulators, and electronic standards-setting organizations. Four expert panels were organized to address specific areas relative to Bar Coding Technology: Needs Assessment, Current Standards, Equipment Manufacturers, and Cost Implications. While the Council's conference and literature review focused on the application and

use of bar codes in institutional settings, the Council believes these recommendations may have broader applicability to other settings, as well.

The Council proposes the expeditious implementation of the following recommendations:

1. FDA and USP should collaborate with pharmaceutical manufacturers and other appropriate stakeholders to establish and implement uniform bar code standards down to the immediate unit-of-use package* that are consistent with the critical elements listed in Recommendation Number Two below.

2. The data elements of a bar code should include:
 - National Drug Code (NDC)
The unique product identifier in the bar code should be a uniform NDC number. This number has regulatory standing with the Food and Drug Administration (21 CFR Section 207.20) and is currently used by the pharmaceutical industry and by health care organizations in automated tracking of drug products. The Council understands that both 11-digit and 10-digit NDC number formats exist today and strongly encourages key stakeholders to come to agreement on a single uniform format for the NDC number.

 - Lot/control/batch number and expiration date
The bar code should contain two secondary identifiers: the lot number and the expiration date. A unique lot number that is used in the event of a recall identifies each manufacturing batch. Inclusion of this lot number within the bar code will ensure that those lots subject to a recall can be readily identified. Inclusion of the expiration date within the bar code will ensure that the patient does not receive a medication that is beyond its expiration date.

3. Format parameters for the bar code should include:
 - The three data elements of a bar code (i.e., NDC, lot number, expiration date) should be uniformly ordered

- The three data elements should be bar coded using existing symbologies, such as reduced space symbology in the form of a composite bar code. For example, the NDC number can be encoded by a linear bar code with the lot number and expiration dates in the two-dimensional code.
 - The bar code print density should be sufficiently consistent to allow an accurate scan each time.
4. Labeling parameters should include:
- Standardized location of the bar code on the label
 - Only one bar code per label
 - Human readable drug name, strength/concentration, lot and expiration date per existing FDA regulation
5. The standard bar code should be included on:
- Immediate container labels of all commercially available prescription and non-prescription medications, in any dosage form (e.g., oral solids, oral liquids, injectables inhalers, nasal sprays, topicals, and other forms of specialized drug-product packaging)
 - Intermediate container or carton
 - Shelf Keeping Unit (SKU)
6. Bar code down to the unit-of-use package
- The standard bar code should be included on all immediate unit-of-use packaging which may include single-unit, single dose, unit-dose, unit-of-use, multiple-unit, and multiple dose containers.
7. Professional associations should develop relevant standards of practice including, but not limited to:
- Repackaging and labeling of extemporaneous preparations
 - Educating practitioners on the proper and optimal use of bar codes
 - Avoiding "work-around" processes

The recommendations contained in this report should not be seen as a mandate to health care providers but as a first step to the ultimate use of bar codes in the medication-use process. Before health care practitioners and organizations can benefit from machine-readable codes, the codes must be physically present in a standard format on unit-of-use medication packaging.

These recommendations will allow the development of systems to take advantage of the bar code; however, the Council recognizes that the development and implementation of such systems will be complex, costly, and will take a significant amount of time. All stakeholders in health care need to recognize these barriers and address how they will be overcome.

Further research is needed to quantify the safety and cost-effectiveness of bar coding in the medication-use process and should be undertaken before their universal incorporation into these processes. The use of bar coding technology as a mechanism to improve medication safety should be implemented incrementally with careful planning and given thoughtful deliberation for cost, cultural, and implementation issues.

** Terms as defined in General Notices, pg. 11, The United States Pharmacopeia and the National Formulary*

Single-Unit Container – A single-unit container is one that is designed to hold a quantity of drug product intended for administration as a single dose or a single finished device intended for use promptly after the container is opened. Preferably, the immediate container and/or the outer container or protective packaging shall be so designed as to show evidence of any tampering with the contents. Each single-unit container shall be labeled to indicate the identity, quantity and/or strength, name of the manufacturer, lot number, and expiration date of the article.

Single-Dose Container – A single-dose container is a single-unit container for articles intended for parenteral administration only. A single-dose container is labeled as such. Examples of single-dose containers include pre-filled syringes, cartridges, fusion-sealed containers, and closure-sealed containers when so labeled.

Unit-Dose Container – A unit-dose container is a single-unit container for articles intended for administration by other than the parenteral route as a single dose, direct from the container.

Unit-of-Use Container – A unit-of-use container is one that contains a specific quantity of a drug product and that is intended to be dispensed as such without further modification except for the addition of appropriate labeling. A unit-of-use container is labeled as such.

Multiple-Unit Container – A multiple-unit container is a container that permits withdrawal of successive portions of the contents without changing the strength, quality, or purity of the remaining portion.

Multiple-Dose Container -- A multiple-dose container is a multiple-unit container for articles intended for parenteral administration only.

1. Meyer GE, Brandell R, Smith JE, et al. Use of bar codes in inpatient drug distribution. *Am J Hosp Pharm.* 1991; 48: 953-66.
2. Hokanson JA, Keith MR, Guernsey BG, et al. Potential use of bar codes to implement automated dispensing quality assurance programs. *Hosp Pharm.* 1985; 20:327-37.
3. Puckett F. Medication-management component of a point-of-care information system. *Am J Health-Syst Pharm.* 1995; 52:1305-9.

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Invitational Conference on Drug Name Suffixes and Medication Errors: Exploring the Relationship and Minimizing the Risk

Currently, the existing practice of naming drug products within a product line is to add an appropriate suffix to the existing name to identify the modified dosage formulation rather than propose an entirely different name. Suffixes have also been used to describe unique characteristics of drug products such as “orally disintegrating” tablets. A suffix may be a letter, number, or combination of letters and/or numbers attached to the end of a proprietary drug name. As an unintended consequence, the use of non-standardized suffixes in drug product names has contributed to confusion among drug products and an increase in related medication errors. Also, there are currently no uniform standards or consistent definitions to guide what these suffixes mean or how they are used.

The use of suffixes in drug names is intended to:

- Distinguish the new modified dosage formulations from the currently marketed or original immediate release or modified release dosage formulation
- Differentiate drugs within a specific drug product line
- Identify certain product characteristics (e.g., orally disintegrating or extended-release tablet)
- Highlight dosing schedule (frequency or interval)
- Differentiate product strength
- Identify therapy duration
- Articulate the number of active ingredients
- Identify the total drug contents
- Articulate the strength of an active ingredient
- Identify the route of administration
- Distinguish between packaging configuration
- Distinguish indication for use
- Emphasize the absence of a preservative

For illustrative purposes, Attachment A provides a sample list of drug names that exemplify the aforementioned types of suffixes.

Numerous medication errors associated with the addition of suffixes to drug names have been reported to the Food and Drug Administration (FDA) through the *MedWatch Reporting Program* and through the United States Pharmacopeia/Institute for Safe Medications Practices (USP/ISMP) *Medication Errors Reporting (MER) Program*. Additionally, similar errors have been reported to USP’s MEDMARX[®] reporting program. These errors may be caused by:

- Confusion resulting from the introduction of a new modified release dosage formulation with an overlapping strength and dosing interval
- Knowledge deficit with respect to the introduction of the modified release product. Thus, prescriptions are being written with:
 - Incorrect dosing interval
 - Incorrect dosing frequency
 - Incorrect or non-existent modifier

- Omission of a modifier
- Incorrect spelling of the modifier
- Abbreviated name using the modifier alone rather than the drug name
- numerous extended-release terms used to describe the same dosing frequency or release rate
- Lack of uniformity and proliferation of different modifiers have also resulted in confusion in identifying the correct drug product.
- Suffixes LA, CR, CD, ER, XL, and SR have no standard interpretation that would give an unambiguous meaning to indicate release properties or dosing frequency. USP uses the single category, extended release, to denote any article designed to deliver the dose over a longer interval than what is seen in immediate release products.

In order to address the issue of confusion associated with the non-standardized use of drug suffixes, the National Coordinating Council for Error Reporting and Prevention (NCC MERP) will convene a Roundtable Meeting on October 20, 2005. The purpose of this meeting is to:

1. Describe the wide array of issues associated with the use of non-standardized drug name suffixes from various stakeholder perspectives,
2. Quantify and specify, to the extent possible, the underlying causes of medication errors arising from non-standardized use of drug name suffixes,
3. Describe short and long-term solutions that will be encompassed in NCC MERP recommendations to reduce medication errors related to the non- standardized use of drug name suffixes.

Attachment A

The use of suffixes in drug names is intended to:

- **Distinguish the new modified dosage formulations from the currently marketed or original dosage formulation**

- 1. Differentiate the original immediate release from the modified release dosage formulation**

Biaxin vs. Biaxin XL
Cardizem vs. Cardizem SR, CD, LA
Vicodin vs. Vicodin ES, HP
Voltaren vs. Voltaren XR
Wellbutrin vs. Wellbutrin SR, XL

- 2. Differentiate drugs within a specific drug product line**

Bactrim SS vs. Bactrim DS
Pred Forte vs. Pred Mild
Humulin N, R, U, L
Novolin N, R, U, L

- 3. Identify certain product characteristics (e.g., orally disintegrating tablet)**

Catapres-TTS (transdermal therapeutic system)
Pepcid RPD (rapid release)
Zyprexa Zydis (oral disintegrating tablet)

- **Highlight dosing schedule (frequency or interval)**

Covera HS (bedtime)
Estratest P.M. (evening)
Pilopine HS (bedtime)
Tofranil-PM (evening)
Verelan PM (evening)

- **Differentiate product strength**

Bactrim DS (double strength) vs. Bactrim SS (single strength)
Dilaudid-HP (high potency) vs. Dilaudid
Pred-Mild (mild strength) vs. Pred-Forte
Tranxene SD (single dose) vs. Tranxene T-tab
Vicodin ES (extra strength) vs. Vicodin

- **Identify therapy duration**

Monistat 3, Monistat 7
Levlen 21, Levlen 28
Tri-Levlen 21, Tri-Levlen 28

- **Articulate the number of active ingredients**

MVI-12

- **Identify the total drug contents**

Adderrall 12.5 (dextroamphetamine sulfate 3.125 mg, dextroamphetamine saccharate 3.125 mg, amphetamine aspartate 3.125 mg, amphetamine sulfate 3.125 mg)

- **Articulate the strength of an active ingredient**

Creon 5, 10, 20 (lipase 5,000 USP units, 10,000 USP units, 20,000 USP units)
Dilantin-125 (phenytoin 125 mg/5mL)
Darvocet N-100, A500 (propoxyphene napsylate 100 mg & acetaminophen 650 mg;
propoxyphene napsylate 100 mg & acetaminophen 500 mg)

- **Identify the route of administration**

Cipro I.V.
Cleocin-T (topical)
Primaxin I.M & Primaxin I.V.

- **Distinguish between packaging configuration**

EpiPen 2-Pak
Zithromax Z-Pak

- **Distinguish indication for use**

Betapace AF (antifibrillation)
Engerix-B, Recombivax HB (hepatitis B)

- **Intended patient population**

Aerolate JR (theophylline)
Aerolate SR
Extendryl JR (Chlorpheniramine, Phenylephrine, and Methscopolamine)
Extendryl SR

- **Articulate the active ingredient**

Adipex-P (phentermine)

Bontril PDM (phendimetrazine)

Carmol HC (hydrocortisone)

Sudafed-PE (phenylephrine)

- **Emphasize the absence of a preservative**

Adriamycin PFS (preservative free)

Astramorph PF (preservative free)

Vincasar PF (preservative free)

Xylocaine-MPF (methyl paraben free)