California State Board of Pharmacy
1625 N. Market Blvd, Suite N 219, Sacramento, CA 95834
Phone (916) 574-7900
Fax (916) 574-8618
www.pharmacy.ca.gov

STATE AND CONSUMERS AFFAIRS AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

Communication and Public Education Committee Report

Shirley Wheat, Chair and Board Member
Hank Hough, Board Member
Stan Goldenberg, Board Member
Bill Powers, Board Member

There was no meeting of the Communication and Public Education Committee this quarter. However, a committee meeting will be held in conjunction with this meeting. A separate agenda is provided at the back of the agenda for the Board Meeting.

As part of this Board Meeting, there will be a forum and discussion on preventing medication errors. Three prominent speakers will provide information on medication errors. The last two of these speakers will focus on principally on medication errors in the inpatient setting.

The board has taken a national leadership role in protecting patients from medication errors. In 2000, the board sponsored legislation that established the board's requirements for quality assurance programs for analyzing prescription errors requiring a pharmacy to perform a detailed analysis of why any prescription error occurred, and to implement changes as a way to prevent their reoccurrence. These requirements followed a 1999 Institute of Medicine report on medication errors, *To Err is Human*. An integral part of California's statutory requirements was immunity from discovery for civil actions for data generated for the quality assurance program, to ensure a through review by the pharmacy.

The board's requirements are provided in **Attachment 1**.

During routine inspections, the board checks the quality assurance program to ensure such reviews are routinely being done once an error occurs. The board does not initiate investigation of medication errors analyzed in the quality assurance programs when reviewing a pharmacy's documents as part of a routine inspection.

During investigation of medication errors reported to the board, review of the quality assurance program is a standard requirement.

Pharmacies and pharmacists that fail to have such programs are cited and fined.

Whereas the board supports the detailed review of medication errors during a quality assurance review, it also generally supports the belief that discipline for human errors is not beneficial to improving patient care. Specifically, unless gross negligence or reckless behavior is the cause of a medication error, formal discipline of a pharmacist or pharmacy is not initiated for medication errors. However, as a consumer protection agency, the board does use its citation and fine authority as a means to recognize that a medication error did occur, and as a means of redress for complainants to the board who have filed complaints about medication errors.

Hence, the board's philosophy is not entirely to hold the licensee "blameless," instead the board does emphasize with the quality assurance review of errors with pharmacy follow-up actions to maximize future changes to prevent recurrence of the errors.

During the presentations that will be made during this part of the meeting, the board will consider whether future actions are needed by the board to continue to improve the safety of patients against receiving a medication error.

As additional background, I am attaching a copy of executive summary the final Medication Errors Task Force -- SCR 49 Report, completed last year (**Attachment 2**). Dr. Ravnan was a member of this committee before she was appointed to the board.

Also, on April 11, 2008, the Joint Commission issued a report about an alarmingly high number of medication errors in the inpatient setting. To quote from the press release:

> Medication safety is a big problem for small children. Young patients are at greater risk for drug errors because most medications are formulated and packaged for adults and most health care settings are built around the needs of adults. A study in the April issue of *Pediatrics* says that medication mix-ups, accidental overdoses, and bad drug reactions harm roughly one out of 15 hospitalized children. This *Alert* covers the steps that are critical to reducing pediatric medication errors.

A copy of the "Sentinel Event Alert" is provided in **Attachment 3**.

Included in **Attachment 4** are some recent articles on medication errors that were provided to the board at the April Board Meeting.

A. FOR INFORMATION: Presentation by Michael Cohen, RPh, MS, ScD, Institute for Safe Medication Practices, on Medication Errors in the Pharmacy Setting

B. FOR INFORMATION: Presentation by John Keats, M.D., on the California Patient Safety Action Coalition (CAPSAC) and Its Efforts Toward "Fair and Just Culture" for Medication Errors in Health Care Facilities

Background: Information about CAPSAC and Fair and Just Culture are provided in **Attachment 5.**

C. FOR INFORMATION: Presentation by Loriann deMartini, PharmD, California Department of Public Health, Regarding California's Requirements for Reporting Adverse Events in California Hospitals

D. FOR DISCUSSION: RECOMMENDATIONS FOR FUTURE ACTION:

The board may want to discuss what direction or activities it wishes to pursue with respect to prescription errors.

E. FOR DISCUSSION AND ACTION: Future Meetings of the SB 472 Medication Label Subcommittee

At the request of Chairperson Wheat, the board will be asked to discuss what future meetings it envisions for this committee in the next few months.

Background:
Last fall, Governor Schwarzenegger signed SB 472 that directs the board to develop a patient-centered, standardized prescription container label for all medicine dispensed to California patients after January 1, 2011.

The board drafted the amendments that were ultimately enacted as SB 472, which requires the board to hold public meetings statewide that are separate from normally scheduled hearings to seek information from the public.

The timeline envisioned for this process was:
2008: conduct public hearings statewide – six meetings were envisioned
2009: develop regulations and adopt the requirements by the end of the year
2010: pharmacies implement requirements to be ready for 1/1/11 implementation
2011: requirements become effective and labels on prescription medicine are compliant

The Medication Label Subcommittee was formed as a subcommittee of the Communication and Public Education Committee to work on the labeling requirements. President Powers appointed the following individuals to this committee:
Ken Schell, Chair
Bill Powers

Rob Swart
Susan Ravnan
Shirley Wheat

The first meeting was held in Fremont on April 12. Senator Corbett asked that the first meeting be held in her district, and Senator Corbett attended the meeting to acknowledge the board's actions.

The board used a number of methods to encourage participation; however, while there were about 40 people present, only 3 of these attendees could be considered public. The rest were affiliated with pharmacies or were sponsors of the bill.

Recognizing that future public meetings where members of the public would get up and publicly admit what they do not understand about prescription container labels (or how to improve them) would be difficult for most individuals, new plans were generated to collect information from patients. Staff began identifying health fairs where the board could interview patients one-on-one to collect information about what they liked about labels and what they would like changed. This approach has been far more productive.

In the future, the board will seek auxiliary labels that are used on containers to see an array of what is in use in California pharmacies.

Currently the next planned public meeting of the SB 472 Medication Label Subcommittee is planned for November 20, during the Department's Professionals Achieving Consumer Trust Summit. The board may wish to direct additional meetings in advance of this date.

Attachment 1

California's Requirements for Quality Assurance Review of Medication Errors

California's Quality Assurance Program Requirements for Review of Prescription Errors

4125. (a) Every pharmacy shall establish a quality assurance program that shall, at a minimum, document medication errors attributable, in whole or in part, to the pharmacy or its personnel. The purpose of the quality assurance program shall be to assess errors that occur in the pharmacy in dispensing or furnishing prescription medications so that the pharmacy may take appropriate action to prevent a recurrence.

(b) Records generated for and maintained as a component of a pharmacy's ongoing quality assurance program shall be considered peer review documents and not subject to discovery in any arbitration, civil, or other proceeding, except as provided hereafter. That privilege shall not prevent review of a pharmacy's quality assurance program and records maintained as part of that system by the board as necessary to protect the public health and safety or if fraud is alleged by a government agency with jurisdiction over the pharmacy. Nothing in this section shall be construed to prohibit a patient from accessing his or her own prescription records. Nothing in this section shall affect the discoverability of any records not solely generated for and maintained as a component of a pharmacy's ongoing quality assurance program.

(c) This section shall become operative on January 1, 2002.

§1711. Quality Assurance Programs.

(a) Each pharmacy shall establish or participate in an established quality assurance program which documents and assesses medication errors to determine cause and an appropriate response as part of a mission to improve the quality of pharmacy service and prevent errors.

(b) For purposes of this section, "medication error" means any variation from a prescription or drug order not authorized by the prescriber, as described in Section 1716. Medication error, as defined in the section, does not include any variation that is corrected prior to furnishing the drug to the patient or patient's agent or any variation allowed by law.

(c) (1) Each quality assurance program shall be managed in accordance with written policies and procedures maintained in the pharmacy in an immediately retrievable form.

(2) When a pharmacist determines that a medication error has occurred, a pharmacist shall as soon as possible:

(A) Communicate to the patient or the patient's agent the fact that a medication error has occurred and the steps required to avoid injury or mitigate the error.

(B) Communicate to the prescriber the fact that a medication error has occurred.

(3) The communication requirement in paragraph (2) of this subdivision shall only apply to medication errors if the drug was administered to or by the patient, or if the medication error resulted in a clinically significant delay in therapy.

(4) If a pharmacist is notified of a prescription error by the patient, the patient's agent, or a prescriber, the pharmacist is not required to communicate with that individual as required in paragraph (2) of this subdivision.

(d) Each pharmacy shall use the findings of its quality assurance program to develop pharmacy systems and workflow processes designed to prevent medication errors. An investigation of each medication error shall commence as soon as is reasonably possible, but no later than 2 business days from the date the medication error is discovered. All medication errors discovered shall be subject to a quality assurance review.

(d) The primary purpose of the quality assurance review shall be to advance error prevention by analyzing, individually and collectively, investigative and other pertinent data

collected in response to a medication error to assess the cause and any contributing factors such as system or process failures. A record of the quality assurance review shall be immediately retrievable in the pharmacy. The record shall contain at least the following:

1. the date, location, and participants in the quality assurance review;
2. the pertinent data and other information relating to the medication error(s) reviewed and documentation of any patient contact required by subdivision (c);
3. the findings and determinations generated by the quality assurance review; and,
4. recommend changes to pharmacy policy, procedure, systems, or processes, if any. The pharmacy shall inform pharmacy personnel of changes to pharmacy policy, procedure, systems, or processes made as a result of recommendations generated in the quality assurance program.

(f) The record of the quality assurance review, as provided in subdivision (e) shall be immediately retrievable in the pharmacy for at least one year from the date the record was created.

(g) The pharmacy's compliance with this section will be considered by the board as a mitigating factor in the investigation and evaluation of a medication error.

(h) Nothing in this section shall be construed to prevent a pharmacy from contracting or otherwise arranging for the provision of personnel or other resources, by a third party or administrative offices, with such skill or expertise as the pharmacy believes to be necessary to satisfy the requirements of this section.

Authority cited: Section 4005, Business and Professions Code; and Section 2 of Chapter 677, Statutes of 2000.
Reference: Section 4125, Business and Professions Code.

Attachment 2

Medication Errors Panel
SCR 49 Report
Executive Summary

Prescription for Improving Patient Safety: Addressing Medication Errors

An Executive Summary of the The Medication Errors Panel Report

Pursuant to California Senate Concurrent Resolution 49 (2005)

About the Medication Errors Panel:

Recognizing the significant and growing public health concern of medication errors, in 2005 Senator Jackie Speier authored Senate Concurrent Resolution (SCR) 49, sponsored by the California Pharmacists Association. This resolution, adopted September 14, 2005, called for the creation of an expert panel to study the causes of medication errors in the outpatient setting and to recommend changes to the healthcare system that would reduce errors associated with prescription and over-the-counter medication use.

The Medication Errors Panel, assembled in 2006, consisted of two Senators, two Assembly members and 13 persons representing academia, consumer advocacy groups, health professions (medicine, nursing, public health and pharmacy), health plans, the pharmaceutical industry, and community pharmacies. Throughout 2006, Panel members gave a tremendous effort to this study and met at the state capitol 12 times to hear and discuss testimony from 32 invited speakers who included many widely respected state and national leaders in the fields of pharmacy practice, medicine, medical technology, healthcare regulation, academia, and the pharmaceutical industry.

The following is the Executive Summary of the Panel's report complete with its consensus recommendations.

The Problem of Medication Errors

A medication error is any preventable event occurring in the medication-use process, including prescribing[1], transcribing, dispensing, using and monitoring, that results in inappropriate medication use or patient harm. These errors and their consequences present a significant public health threat to Californians.

While most consumers and healthcare providers do not often associate poor health outcomes with adverse drug events – frequently the result of medication errors – the human and financial costs of the problem are staggering.

The most recent estimate of costs associated with drug-related morbidity and mortality in the US exceeds $177 billion per year.[2] Amazingly, this amount is significantly greater than the amount actually spent on prescription drugs during the same year. In terms of patient harm, the Institute of Medicine projects that at least 1.5 million Americans are sickened, injured or killed each year by medication errors.[3] Extrapolating these figures to California suggests that on an annual basis, the problem costs our state $17.7 billion and causes harm to 150,000 Californians.

Perhaps the most concerning aspect of these errors is that the tremendous human and financial costs are not the result of some serious disease, but rather, well-intentioned attempts to treat or prevent illness.

Reducing Errors through a "Systems Approach"

Testimony provided to the Panel indicated that efforts to address errors are best targeted not at a particular group of individual "wrong doers," but rather at faulty systems, processes, and conditions that either lead people to make mistakes or fail to prevent them. Consequently the Panel took a "systems approach" for studying the problem and developing its recommendations.

After spending considerable time examining each part of the medication-use process – prescribing, dispensing, using (administering/self-administering) and monitoring – and the inter-relationships of each component, the Panel identified four key medication-use systems/ processes and three key stakeholder groups which served as the focus of its recommendations.

Key Processes and Stakeholders

The four key processes which the Panel believes could be better designed to reduce and prevent medication errors are those related to:

1) **The transcription and transmission of prescriptions** (i.e. the methods prescribers use to document a prescription order and communicate that order to the pharmacy where it will be filled).
2) **The education of the consumer** regarding the purpose of the treatment, the effective use of the medication, and the monitoring of signs and symptoms that may indicate efficacy or toxicity.
3) **Healthcare provider payments and incentives** which can directly or indirectly influence providers to pursue behaviors designed to reduce medication errors.
4) **Healthcare provider training and licensure** which could foster a better understanding among providers about the seriousness of medication errors and the behaviors to adopt that will reduce them.

The three key stakeholder groups which the Panel believes will be critical in affecting the necessary changes to these processes are:

1) **Consumers and consumer oriented organizations** such as the California Department of Consumer Affairs; advocacy organizations (e.g. AARP, American Heart Association); community-based organizations; and private and public foundations.
2) **Healthcare providers and related organizations** such as academic institutions, professional societies and advocacy groups, and provider licensing/oversight Boards.
3) **Healthcare purchasers, payers, regulators and related organizations** such as the State of California, its Department of Health Services and the Medi-Cal program; private purchasers of health care such as employers; commercial insurance companies which administer health benefits for both public and private sector purchasers; the California Departments of Insurance and Managed Health Care which regulate these insurance companies; pharmacy benefit managers which focus specifically on the administration of pharmacy benefits; and of course, the Legislature and Administration of the State of California which possess the potential to influence and/or establish accountability for these groups.

Based on the analysis of these four key processes and three key stakeholder groups, the Panel developed 11 consensus recommendations within five subject areas, and a twelfth recommendation to further consider and address issues that went beyond the scope of the Panel's purpose.

Recommendations

A. **Communication Improvements,** with an emphasis on improving the quality and accuracy of communications between prescribers, pharmacists and patients. Specific recommendations are:

   1) *Improve legibility of handwritten prescriptions, and establish a deadline for prescribers and pharmacies to use electronic prescribing.*
   2) *Require that the intended use of the medication be included on all prescriptions and require that the intended use of the medication be included on the medication label unless disapproved by the prescriber or patient.*
   3) *Improve access to and awareness of language translation services by pharmacists at community pharmacies and encourage consumers to seek out pharmacists who speak their language and understand their cultural needs.*
   4) *Promote development and use of medication packaging, dispensing systems, prescription container labels and written supplemental materials that effectively communicate to consumers accurate, easy-to-understand information about the risks and benefits of their medication, and how and where to obtain medication consultation from a pharmacist.*

B. **Consumer Education** to increase consumer awareness regarding the proper use – and dangers of misuse – of prescription and over-the-counter medications. Specific recommendations are:

   5) *Identify and disseminate information about best practices and effective methods for educating consumers about their role in reducing medication errors.*
   6) *Establish an on-going public education campaign to prevent medication errors,*

targeting outpatients and persons in community settings.

7) *Develop and implement strategies to increase the involvement of public and private sector entities in educating consumers about improving medication safety and effectiveness.*

C. **Pharmacy Standards and Incentives,** with a focus on information and medication consultations given by pharmacists to their patients as a means of educating consumers about drug safety. Specific recommendations are:

8) *Help ensure quality and consistency of medication consultation provided by pharmacists within and among pharmacies.*

9) *Establish standards for Medication Therapy Management (MTM) programs and create incentives for their implementation and ongoing use by pharmacists and other healthcare providers.*

D. **Training and Education for Healthcare Providers** on various medication safety practices. The specific recommendation is:

10) *Create training requirements for pharmacists and other healthcare professionals that address medication safety practices and related programs, including medication consultation and medication therapy management programs.*

E. **Research,** with a focus on obtaining information about the incidence, nature, and frequency of medication errors in the community setting. The specific recommendation is:

11) *Establish and support efforts to collect data regarding the nature and prevalence of medication errors and prevention methods for reducing errors, especially focused on persons at high risk for medication errors and on community, ambulatory and outpatient settings.*

In addition to these five subject areas, the Panel identified a sixth that needs to be addressed but which it determined was beyond its scope. This issue relates to the many obstacles that pharmacists face in providing drug consultation to their patients which encompasses a variety of factors such as manpower shortages and the lack of payment systems to cover the time and expense associated with these tasks. Before additional duties can be imposed on pharmacists practicing in outpatient settings, the Panel recognizes that these issues must be addressed. Therefore the Panel put forth a twelfth recommendation:

12) *Convene a panel of stakeholders to identify and propose specific actions and strategies to overcome barriers to qualified pharmacists being recognized and paid as healthcare providers.*

Acknowledgements

This project has benefited from the generous contributions of many individuals and organizations. In particular the Panel would like to thank former Senator Jackie Speier who authored the resolution; Lynn Rolston of the California Pharmacists Association which sponsored SCR 49 (2005); Judith Babcock of the Pharmacy Foundation of California which managed funding for the Panel and arranged for administrative support; the Kaiser Family Foundation and California HealthCare Foundation which funded the Panel; Sandra Bauer, Michael Negrete and Ronald Spingarn who provided staff support for the Panel; and of course all of the Panel members listed on the following page with special thanks to Carey Cotterell for helping to write this report.

End Notes and References

[1]While the Panel identified drug and dose selection as a process (i.e. prescribing) where errors can occur, its analysis and recommendations were focused on the areas of the medication-use process that occur *after* the point where prescribers consciously make such decisions.

[2] Ernst FR, Grizzle AJ. Drug-related morbidity and mortality: updating the cost-of-illness model. J Am Pharm Assoc 2001;41:192-9.

[3] Institute of Medicine (IOM). (2007). *Preventing medication errors: Quality chasm series.* P. Aspden, J. Wolcott, J. L. Bootman, & L. R. Cronenwett (Eds.). Washington, DC: The National Academies Press.

MEDICATION ERRORS PANEL MEMBERS

Senate Appointees

Senator Jackie Speier, Chair

Senator Sam Aanestad

Dorothy (De) Calvert, RN
Kaiser Permanente Medical Group (representing California Nurses Association*)

Robert Friis, PhD
Professor and Chair, Health Sciences Department, California State University Long Beach (representing a public health organization*)

John Gallapaga
(representing AARP*)

Gil Preston, JD
Watson Pharmaceuticals (representing Generic Pharmaceutical Association*)

Susan Ravnan, Pharm.D., FCSHP
Associate Professor, University of the Pacific, Thomas J. Long School of Pharmacy and Health Sciences (representing CA Society of Health System Pharmacists*)

Lorie Rice, M.P.H.
Associate Dean, School of Pharmacy, University of California San Francisco (representing Consumer Healthcare Products Association*)

Debbie Veale, R.Ph
Director, Managed Care, CVS/pharmacy (representing California Retailers Association*)

Assembly Appointees

Assemblymember Wilma Chan

Assemblymember Greg Aghazarian

Brian Alldredge, Pharm.D.
Professor, Department of Clinical Pharmacy, University of California, San Francisco (representing pharmacy school faculty*)

Ramon Castellblanch, PhD
Assistant Professor, Health Education Department, San Francisco State University (representing a consumer organization*)

Carey Cotterell, R.Ph.
Pharmacy Quality & Patient Safety Leader, Kaiser Permanente Medical Care Program (representing California Association of Health Plans*)

Merrill Jacobs
Deputy Vice President, State Government Affairs, Pharmaceutical Research and Manufacturers of America*

Carlo Michelotti, R.Ph.
CEO (retired), California Pharmacists Association*

Gurbinder Sadana, MD, FCCP
Director of Critical Care Services, Pomona Valley Hospital Medical Center (representing California Medical Association*)

Panel Staff

Sandra K. Bauer
Arthur Bauer & Associates, Inc.

Ronald Spingarn
Office of Senator Jackie Speier

Michael J. Negrete, Pharm.D.
Pharmacy Foundation of California

*Organizations required to be represented per Senate Concurrent Resolution 49 (2005)

Attachment 3

Sentinel Event Alert

Advisory Group
Forms and Tools
Policy and Procedures
Reporting Alternatives
Sentinel Event Alert
Statistics

Sentinel Event Alert

Issue 39, April 11, 2008

Preventing pediatric medication errors

Errors associated with medications are believed to be the most common type of medical error anc significant cause of preventable adverse events. Experts agree that medication errors have the pc cause harm within the pediatric population at a higher rate than in the adult population. For examp medication dosing errors are more common in pediatrics than adults because of weight-based do calculations, fractional dosing (e.g., mg vs. Gm), and the need for decimal points.

"Research shows that the potential for adverse drug events within the pediatric inpatient populatic about three times as high as among hospitalized adults," (1) says Stu Levine, PharmD, informatic pediatric specialist, Institute for Safe Medication Practices, an organization which serves as a resc information on how to improve medication practices. "For this reason, health care providers must special attention to the specific challenges relating to the pediatric population."

A new study—the first to develop and evaluate a trigger tool to detect adverse drug events in an i pediatric population—identified an 11.1 percent rate of adverse drug events in pediatric patients. more than described in previous studies. The study also showed that 22 percent of those adverse events were preventable, 17.8 percent could have been identified earlier, and 16.8 percent could been mitigated more effectively. (2)

Children are more prone to medication errors and resulting harm because of the following:

- Most medications used in the care of children are formulated and packaged primarily for adult Therefore, medications often must be prepared in different volumes or concentrations within tl care setting before being administered to children. The need to alter the original medication dc requires a series of pediatric-specific calculations and tasks, each significantly increasing the of error.
- Most health care settings are primarily built around the needs of adults. Many settings lack tra oriented to pediatric care, pediatric care protocols and safeguards, and/or up-to-date and easi accessible pediatric reference materials, especially with regard to medications. Emergency de may be particularly risk-prone environments for children. (3)
- Children—especially young, small and sick children—are usually less able to physiologically tc medication error due to still developing renal, immune and hepatic functions.
- Many children, especially very young children, cannot communicate effectively to providers re adverse effects that medications may be causing.

During calendar years 2006-2007, USP's MEDMARX® database shows nearly 2.5 percent of ped medication errors led to patient harm. The most common types of harmful pediatric medication er were: improper dose/quantity (37.5 percent), omission error (19.9 percent), unauthorized/wrong c percent), and prescribing error (9.4 percent), followed by wrong administration technique, wrong ti prepared incorrectly, wrong dosage form, and wrong route. Medication errors involving pediatric p were most often caused by: performance deficit (43.0 percent), knowledge deficit (29.9 percent), procedure/protocol not followed (20.7 percent), and miscommunication (16.8 percent), followed b calculation error, computer entry error, inadequate or lack of monitoring, improper use of pumps, documentation errors. The MEDMARX Data Report (4) reveals that approximately 32.4 percent o errors in the operating room involve an improper dose/quantity compared with 14.6 percent in the population and 15.4 percent in the geriatric population. A recent study indicates that children are particularly at risk for chemotherapy medication errors. (5)

Risk reduction strategies

Pediatric-specific strategies for reducing medication errors include:

Standardize and identify medications effectively, as well as the processes for drug administration.

- Establish and maintain a functional pediatric formulary system with policies for drug evaluatior and therapeutic use. (6)
- To prevent timing errors in medication administration, standardize how days are counted in all by deciding upon a protocol start date (e.g., Day 0 or Day 1).
- Limit the number of concentrations and dose strengths of high alert medications to the minimu to provide safe care.
- For pediatric patients who are receiving compounded oral medications and total parenteral nu home, ensure that the doses are equivalent to those prepared in the hospital (i.e., the volume home dose should be the same as the volume of the hospital prepared products).
- Use oral syringes to administer oral medications. The pharmacy should use oral syringes whe oral liquid medications. Make oral syringes available on patient care units when "as needed" n are prepared. Educate staff about the benefits of oral syringes in preventing inadvertent intrav administration of oral medications.

Ensure full pharmacy oversight—as well as the involvement of other appropriate staff—in the veri dispensing and administering of both neonatal and pediatric medications.

- Assign a practitioner trained in pediatrics to any committee that is responsible for the oversigh medication management.
- Provide ready access, including website access, to up-to-date pediatric-specific information fo hospital staff. This information should include pediatric research study data, pediatric growth c normal vital sign ranges for children, emergency dosage calculations, and drug reference mat information about minimum effective doses and maximum dose limits.
- Orient all pharmacy staff to specialized neonatal/pediatric pharmacy services in your organiza
- Provide a dosage calculation sheet for each pediatric critical care patient, (8), (9) including bo emergency and commonly used medications. (7)
- Develop preprinted medication order forms and clinical pathways or protocols to reflect a stan approach to care. Include reminders and information about monitoring parameters.
- Create pediatric satellite pharmacies or assign pharmacists and technicians with pediatric exp areas or services such as neonatal/pediatric critical care units and pediatric oncology units. (1 minimum, pediatric medications should be stored and prepared in areas separate from those medications are stored and prepared.

Use technology judiciously.

- Use methods to ensure the accuracy of technology that measures and delivers additives for ir solutions, such as for total parenteral nutrition.
- If dose and dose range checking software programs are available in hospital or pharmacy info systems, enable them to provide alerts for potentially incorrect doses.
- Medications in automated dispensing cabinets that do not undergo appropriate pharmacist re be limited to those needed for emergency use and/or to those medications under the control o independent prescriber, as specified in Joint Commission standard MM 4.10.
- Recognize that the use of infusion pumps, or smart pumps, is not a guarantee against medica Appropriate education for nurses, pharmacists and other caregivers regarding these technolo important for all institutions caring for pediatric patients.
- To prevent adverse outcomes or oversedation, use consistent physiological monitoring – parti pulse oximetry (10) – while children are under sedation during office-based procedures. Use a size-appropriate monitoring equipment and follow uniform procedures under the guidance of s appropriately trained in sedation, monitoring and resuscitation.
- Providers are encouraged to develop bar-coding technology with pediatric capability. Potentia should be carefully considered while adapting this technology to pediatric processes and syst example, a pediatric bar-coding solution must be able to provide readable code for small-volu specific dose labels.

Existing Joint Commission requirements

As part of National Patient Safety Goal 2B, Joint Commission accredited organizations are require follow The Joint Commission's Official "Do Not Use" Abbreviations List. In addition, Goal 3 (Impro safety of using medications) and Goal 8 (Accurately and completely reconcile medications across continuum of care) establish several medication standardization, identification and communicatior requirements that are especially important in pediatrics and neonatology. Three Sentinel Event Al address specific issues relating to pediatric medication errors. (11), (12), (13)

Other Joint Commission suggested actions

The Joint Commission offers the following suggested actions to prevent pediatric medication error their related adverse events in pediatric care settings:

1. Since patient weight is used to calculate most dosing (either as weight-based dosing, bod area calculation, or other age-appropriate dose determination), all pediatric patients shoul weighed in kilograms at the time of admission (including outpatient and ambulatory clinics four hours of admission in an emergency situation. Kilograms should be the standard nom for weight on prescriptions, medical records and staff communications.
2. No high risk drug should be dispensed or administered if the pediatric patient has not beer unless it is an emergency.
3. On inpatient medication orders and outpatient prescriptions, require prescribers to include calculated dose and the dosing determination, such as the dose per weight (e.g., milligram kilogram) or body surface area, to facilitate an independent double-check of the calculatio pharmacist, nurse or both. (7) Exceptions to this are medications that do not lend themsel weight-based dosing, such as topicals, ophthalmics, and vitamins.
4. Whenever possible, use commercially available pediatric-specific formulations and concer When this is not possible, prepare and dispense all pediatric medications in patient-specifi dose" or "unit of use" containers, rather than in commercially available adult unit doses. (7 liquid preparation medications, use oral syringes to ensure correct dosage.
5. Clearly differentiate from adult formulations all products that have been repackaged for us pediatric populations. (14) Use clear, highly visible warning labels. To prevent overdoses, concentrated adult medications away from pediatric care units. Avoid storing adult and pe concentrations in the same automated dispensing machine/cabinet drawer.
6. Ensure comprehensive specialty training for all practitioners involved in the care of infants children, as well as continuing education programs on pediatric medications for all health providers. Training and education should include information on how adverse effects shou reported. (6), (15)
7. Communicate verbally and in writing information about the child's medication to the child, and parents/guardians, including information about potential side effects. Ask the caregiver/parent/guardian to repeat back their understanding of the drug and how it is to b administered. Encourage the asking of questions about medications.
8. Have a pharmacist with pediatric expertise available or on-call at all times.
9. Establish and implement medication procedures that include pediatric prescribing and adn practices.

Should a serious error or adverse event occur, the organization should conduct a root cause anal develop and implement a corrective action plan which should be monitored to assure that it is effe The Joint Commission also encourages apology and transparency about the error with both staff families involved.

In addition, The Joint Commission encourages pharmaceutical manufacturers to develop pediatric formulations as well as to standardize the labeling and packaging for all types of medications. (14 Researchers are encouraged to conduct additional research on interventions to reduce pediatric medication errors, especially in emergency departments, ambulatory clinics and home environme

In conclusion, since parents and caregivers play an extremely important role in the health care of The Joint Commission encourages parents and caregivers to seek out information and ask questi their child's medications and to repeat back instructions to clinicians in order to ensure understan about the drug, dosages, timing and routes of administration. This is done both to reassure staff t parents or caregivers have a true understanding of the medications the child is taking and, most importantly, to ensure that everyone involved can safely administer medications to this most vulne population.

References

1 Kaushal R, et al: Medication errors and adverse drug events in pediatric inpatients. *Journal of t American Medical Association*, 2001, 285:2114-2120

2 Takata, GS, et al: Development, Testing, and Findings of a Pediatric-Focused Trigger Tool to I Medication-Related Harm in US Children's Hospitals. *Pediatrics*, 2008, 121:e927-3935. Available http://www.pediatrics.org/cgi/content/full/121/4/e927 (accessed 4/8/08)

3 Committee on the Future of Emergency Healthcare in the United States; the Institute of Medicin Emergency Care for Children: *Growing Pains*. Available for purchase online: http://www.nap.edu/catalog/11655.html (accessed 4/4/08)

4 Hicks RW, Becker SC, Cousins DD: *MEDMARX® Data Report: a Chartbook of Medication Err Findings from the Perioperative Settings from 1998-2005*, 2006, Rockville, MD, United States Pharmacopeia Center for the Advancement of Patient Safety

5 Rinke ML, Shore AD, Morlock L, Hicks RW, Miller MR: Characteristics of pediatric chemotherap medication errors in a national error reporting database. *Cancer*, May 25, 2007, 110(1):186-195

6 Committee on Drugs and Committee on Hospital Care, American Academy of Pediatrics: Polic statement—Prevention of medication errors in the pediatric inpatient setting. *Pediatrics*, 2003, 11

7 Levine SL, Cohen MR: Preventing medication errors in pediatric and neonatal patients. *Medica Errors*, 2007, Washington DC, American Pharmacists Association

8 Potts MJ, Phelan KW: Deficiencies in calculation and applied mathematics skills in pediatrics a primary care interns. *Archives of Pediatrics & Adolescent Medicine*, 1996, 150:748-52

9 Hazinski MF: Reducing calculation errors in drug dosages: the pediatric critical information she *Pediatric Nursing*, 1986, 12:138-40

10 Cote, et al: Sedation disasters in pediatrics and concerns for office based practice, *Canadian Anesthesiology*, 2002, 49:R10

11 The Joint Commission: Tubing misconnections—a persistent and potentially deadly occurrenc *Sentinel Event Alert* #36, April 3, 2006. Available online: http://www.jointcommission.org/SentinelEvents/SentinelEventAlert/sea_36.htm (accessed 4/4/08)

12 The Joint Commission: Using medication reconciliation to prevent errors. *Sentinel Event Alert* January 25, 2006. Available online: http://www.jointcommission.org/SentinelEvents/SentinelEventAlert/sea_35.htm (accessed 4/4/08)

13 The Joint Commission: Preventing vincristine administration errors. *Sentinel Event Alert* #34, 2005. Available online: http://www.jointcommission.org/SentinelEvents/SentinelEventAlert/sea_3 (accessed 4/4/08)

14 United States Pharmacopeia: Error-Avoidance Recommendations for Medications used in Pe Populations. Available online: www.usp.org/hqi/patientSafety/resources/pedRecommnds2003-01 (accessed 4/7/08)

15 Fortescue EB, et al: Prioritizing strategies for preventing medication errors and adverse drug pediatric inpatients. *Pediatrics*, 2003, 111:722-729

Other resources

Hardmeier B, et al: Adverse drug events caused by medication errors in medical inpatients. *Swis Weekly*, 2004, 134:664-670

Bates DW, et al: Incidence of adverse drug events and potential adverse drug events, Implicatior prevention, ADE Prevention Study Group. *Journal of the American Medical Association*, 1995, 27

Nebeker JR, et al: High rates of adverse drug events in a highly computerized hospital. *Archives*

Medicine, 2005, 165:1111-1116

Cordero L, et al: Impact of computerized physician order entry on clinical practice in a newborn ir care unit. *Journal of Perinatology*, 2004, 24:88-93

Lehmann CU, et al: Preventing provider errors: Online total parenteral nutrition calculator. *Pediat* 2004, 113:748-753

Kozer E, et al: Variables associated with medication errors in pediatric emergency medicine. *Ped* 2002, 110:737-742

Larsen GY, et al: Standard drug concentrations and smart-pump technology reduce continuous-medication-infusion errors in pediatric patients. *Pediatrics*, 2005, 116:21-25

Losek JD: Acetaminophen dose accuracy and pediatric emergency care. *Pediatric Emergency C* 20:285-28

Potts AL, et al: Computerized physician order entry and medication errors in a pediatric critical ca *Pediatrics*, 2004, 113:59-63

McPhillips HA, et al: Potential medication dosing errors in outpatient pediatrics. *Journal of Pediat* 2005, 147:761-767

Fontan JE, et al: Medication errors in hospitals: Computerized unit dose drug dispensing systems ward stock distribution system. *Pharmacy World and Science*, 2003, 25:112-117

Cable G, Croft J: Agreement between pediatric medication orders and medication cardex. *Journa Healthcare Quality*, 2004, 26:14-19

Holdsworth MT, et al: Incidence and impact of adverse drug events in pediatric inpatients. *Archiv Pediatrics & Adolescent Medicine*, 2003, 157:60-65

Pichon R, et al: Analysis and quantification of prescribing and transcription errors in a pediatric o service. *Pharmacy World & Science*, 2002, 24:12-15

Lesar TS: Tenfold medication dose prescribing errors. *The Annals of Pharmacotherapy*, 2002, 36 1839

Romano MJ, Dinh A: A 1,000-fold overdose of clonidine caused by a compounding error in a 5-y child with attention-deficit/hyperactivity disorder. *Pediatrics*, 2001, 108(2):471-472

Suresh G, et al: Voluntary anonymous reporting of medical errors for neonatal intensive care. *Pe* 2004, 113:1609-1618

Taylor JA, et al: Use of incident reports by physicians and nurses to document medical errors in p patients. *Pediatrics*, 2004, 114:729-735

Aspden P, et al: *Preventing Medication Errors*. Institute of Medicine of the National Academies, 2

National Coordinating Council for Medication Error Reporting and Prevention: Recommendations Enhance Accuracy of Dispensing Medications. Available online: http://www.nccmerp.org/council/council1999-03-19.html (accessed 4/4/08)

Cote, et al: Guidelines for Monitoring and Management of Pediatric Patients During and After Se Diagnostic and Therapeutic Procedures: An Update. *Pediatrics*, December 2006, 118(6)

Strang S: Creating a culture to prevent medical errors. *Children's Hospitals Today*, National Asso Children's Hospitals and Related Institutions, Summer 2004. Available online: (accessed 4/4/08)

American Society of Health-System Pharmacists: Guidelines on Preventing Medication Errors wi Antineoplastic Agents. *American Journal of Health-System Pharmacy*, 2002, 59:1648-68

Goldmann D, Kaushal R: Time to Tackle the Tough Issues in Patient Safety. *Pediatrics*, October 110(4):823-826

Accreditation Programs | Certification Programs | Quality Check | Achieve the Gold Seal | Libr
Standards | Patient Safety | Performance Measurement | Sentinel Event | Public Policy | Sear
Contact Us | Site Map | Careers | Newsroom | About Us © 2008 The Joint Commission, All Ri

Attachment 4

Medication Errors Articles

Los Angeles Times

http://www.latimes.com/features/health/la-he-survey28jan28,1,6537721.story?track=rss
From the Los Angeles Times

What consumers say

January 28, 2008

American medical consumers are aware of the medical error problem and are concerned about it, a 2004 survey showed. Many people are also taking steps to protect themselves by checking on results of medical tests. Of those surveyed:

* 48% said they were concerned about the safety of medical care.

* 34% had experienced a medical error or said a family member had.

* 92% said serious medical errors should be reported.

* 63% said medical error reports should be made public.

* 69% have checked that a drug they got from a pharmacy is the same as their doctor prescribed.

* 48% have brought a list of medications to their doctors.

* 69% have called to check results of medical tests.

* 43% have brought a support person to a medical appointment.

Source: Telephone survey of 2,012 randomly selected adults in 2004. National Survey on Consumers' Experiences with Patient Safety and Quality Information, a joint project of the Kaiser Family Foundation, the Agency for Healthcare Research and Quality and the Harvard School of Public Health; www.kff.org/kaiserpolls/pomr111704nr.cfm.

If you want other stories on this topic, search the Archives at latimes.com/archives.
TMSReprints
Article licensing and reprint options

Copyright 2008 Los Angeles Times | Privacy Policy | Terms of Service
Home Delivery | Advertise | Archives | Contact | Site Map | Help
partners: ktla5cw Hoy

Subject New York Daily News: Drugstore slipups a prescription for death

DAILY NEWS

DRUGSTORE SLIPUPS A PRESCRIPTION FOR DEATH

BY JORDAN LITE
NEW YORK DAILY NEWS STAFF WRITER
Sunday, July 13th 2008, 9:23 PM

New York pharmacists filled an estimated 210,000 prescriptions with the wrong drug or dose in 2006, putting patients at risk of illness and even death, a new analysis shows.

The problem is worst at chain stores that fill more than 200 prescriptions every day - some at a clip of one every two minutes, said Sen. Jeff Klein (D-Bronx, Westchester).

"Something as important as [filling] someone's lifesaving drug shouldn't be rushed," Klein said.

New York doesn't track prescription errors - something Klein has proposed changing.

Few patients report the errors, and only a small fraction of pharmacies are punished by the state, he said.

Between 2005 and 2007, 1,275 such complaints were made to the state Office of the Professions, which disciplined pharmacies in 106 of those cases, Klein said.

Klein's error rates are estimates, extrapolated from 2003 findings by Auburn University.

He applied the Auburn University results to the 210 million prescriptions processed in New York in 2006 to come up with the estimated error rate.

The Auburn study found that pharmacies that process more than 250 prescriptions daily make four mistakes every day, and that one in 1,000 are health-threatening.

Research by Ohio State University has estimated that 2.2 million dispensing errors occur nationally each year.

Lawrence Mokhiber, executive secretary of the state Board of Pharmacy, which disciplines pharmacies, did not respond to a call and an e-mail seeking comment.

Representatives of the Pharmacists Society of the State of New York and the American Pharmacists Association could not be reached yesterday.

A spokeswoman for Rite Aid, Cheryl Slavinsky, said the company has an eight-point procedure to ensure prescriptions are accurate and that it supports electronic prescribing - a proposal of Klein's.

"Safety is the No. 1 priority of any pharmacy, and one error is too many," said Chrissy Kopple, a spokeswoman for the National Association of Chain Drug Stores.

jlite@nydailynews.com

Preventing Name Confusion Errors

The Institute for Safe Medication Practices (ISMP) has received numerous reports of mix-ups between **OxyContin** (oxycodone HCl controlled-release tablets) and **oxycodone HCl** immediate-release tablets. Look-alike drug name issues often contribute to these errors. In one case, a handwritten prescription for "oxycodone 10 mg q2h prn pain" was presented at a community pharmacy for an oncology patient. It was misinterpreted and dispensed as OxyContin 10 mg, despite the instructions to take 1 tablet every two hours as needed for pain. After taking the medication as directed for four days, the patient returned to the oncology center due to excessive drowsiness. The error was discovered when an oncology nurse noticed the "OxyContin" name on the prescription bottle. Fortunately, the patient recovered with supportive treatment and intravenous fluids.

In other cases, the generic name, oxycodone, was used to prescribe OxyContin, but "controlled-release" was not specified. Thus, patients have accidentally received the immediate-release product in a dose appropriate for controlled-release OxyContin. In one report, a physician noted that when he looked up "OxyContin" in an electronic database on his hand-held device, "oxycodone" appeared in the description with no mention that OxyContin was a controlled-release product. Based on this information, he wrote a prescription for what he thought was the generic OxyContin, "oxycodone 60 mg PO q12h," in an effort to reduce costs for his patient. In a similar report, a prescription generated from a physician's computer system (below) nearly led to an error. Although the description "OXYCODONE HCL TBCR 10 MG" is intended to describe OxyContin 10 mg, the immediate-release product was almost dispensed because the "CR" portion of the description was initially overlooked and newly available generic versions of OxyContin were unavailable at the time.

Now, with their recent release, be prepared for more opportunities for mix-ups between the immediate- and controlled-release products (e.g., "oxycodone" product selection errors from prescriber, pharmacy, and wholesaler computer order entry screens).

ISMP RECOMMENDATIONS

Consider the following measures to reduce the likelihood of mix-ups between immediate- and controlled-release oxycodone products:

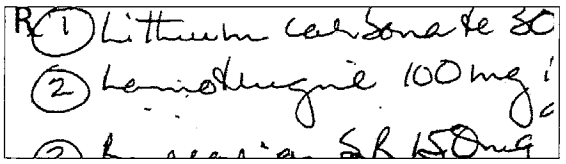
- Ensure that "oxycodone" prescriptions clearly specify the release rate. Clarify orders where this is not indicated or if the dosing frequency does not seem to correspond to the release rate.
- Avoid using the abbreviations "IR" and "CR" as they may look similar on some handwritten prescriptions. Instead write out the appropriate release rate.
- Clearly differentiate oxycodone release rates on prescriber and pharmacy computer order entry screens.
- Use caution when referencing "oxycodone" in wholesaler computers as order entry screens may not clearly differentiate release rates. Alert wholesalers if problems are recognized.
- Store immediate- and controlled-release products in completely separate locations. Differentiate the products using auxiliary labeling or highlighting the release rate.
- Incorporate an independent double check into the verification process for opiate products. ap

---

This article has been provided by the Institute for Safe Medication Practices (ISMP). Errors, near misses, or hazardous conditions may be reported on the ISMP (www.ismp.org) or U.S. Pharmacopeia (www.usp.org) Web sites. ISMP can be reached at 215-947-7797 or ismpinfo@ismp.org.

Avoid Lamotrigine, Levothyroxine Mix-Ups

A physician wrote a prescription for lamotrigine (**Lamictal**) 100 mg (see image). Subsequently, a pharmacist misread the handwritten order as levothyroxine 100 mcg. Lamotrigine is indicated for bipolar disorder and seizures, while levothyroxine is used to treat hypothyroidism. The drugs have overlapping dosage strength numbers (25, 100, 150, and 200) and are administered orally once daily, increasing the risk of mix-ups. Although the pharmacist dispensed levothyroxine, the error was detected by the patient after reading the patient information leaflet.



Warn practitioners about the potential for mix-ups with these products. Prescribers should include the indication for use on prescriptions for these drugs. Also, write only one medication order per prescription blank. Including more than one order, or three as in this case above, can make it difficult to interpret the orders and lead to mix-ups. For pharmacists, counseling patients on all new prescriptions always helps to avoid mix-ups.

AVOID "USE AS DIRECTED"

A prescriber called and left a prescription on a pharmacy's voice mail system for **Clindesse** (clindamycin vaginal gel) with instructions, "use as directed." Upon playback the order sounded like **Clindets** (clindamycin pledgets) and was processed and dispensed as such.

Later that day, the patient called back to the pharmacy wondering how she was supposed to use the pledgets vaginally. The pharmacist contacted the prescriber and found that the order was actually for Clindesse. The correct prescription was then dispensed and there was no delay in treatment. Since these two names sound so much alike, practitioners need to take action to minimize the risk of confusion. Clear and specific instructions should be provided on each prescription. Avoid "use as directed." Include the medication's indication as well as route of administration on the prescription. If possible, prescribers should avoid leaving prescriptions on voice mail systems as there is no opportunity for interaction with the pharmacist nor ability to read back the prescription.

SEASONAL MIX-UPS

In reviewing medication errors over the years, mix-ups between Pfizer's antihistamine **Zyrtec** (cetirizine) and Eli Lilly's antipsychotic **Zyprexa** (olanzapine) seem to spike in the winter months. We have noticed a similar spike during the spring allergy season. Mix-ups between these two medications have caused serious patient harm.

Patients who receive Zyprexa in error have reported dizziness, sometimes leading to fall-related injuries, and patients on Zyprexa for a behavioral health illness have relapsed when given Zyrtec in error. Therefore, we recommend that you take time this month to notify prescribers, nurses, pharmacists, and patients about the risk of mix-ups when either drug is prescribed. Including on a prescription the purpose of the drug may help avoid mix-ups, as would storing the containers of these products apart from one another and adding reminders on containers and computer screens about the potential for error. ap

---

This article has been provided by the Institute for Safe Medication Practices (ISMP). The reports described in this column were received through the USP-ISMP Medication Errors Reporting Program (MERP). Errors, near misses, or hazardous conditions may be reported on the ISMP (www.ismp.org) or U.S. Pharmacopeia (www.usp.org) Web sites. ISMP can be reached at 215-947-7797 or ismpinfo@ismp.org.

Educating the Healthcare Community
About Safe Medication Practices

ISMP
Medication Safety Alert!®

E-mail: ismpinfo@ismp.org
Hotline: 1 800 FAIL SAF(E)

Community/Ambulatory Care Edition
Volume 7, Issue 6 ■ June 2008

Fatal Overdose: Rethink where pediatric IV medications are *dispensed* and *administered*

PROBLEM: In October 2007, Florida news media reported a tragic, fatal medication error involving a 3-year-old boy who received a 10-fold overdose of arginine (**R-GENE 10**, 10% arginine hydrochloride injection) during an outpatient growth hormone stimulation test.[1-3] Even though the child's mother had questioned the dose, and his father had asked that the procedure be stopped when his son exhibited symptoms of distress, the error was not detected until the next day, after the child was hospitalized and declared brain dead.

Before the test, the child's parents had taken him to a physician because he was small for his age. He was subsequently scheduled for a diagnostic test at a pediatric clinic to assess his pituitary function. The test involved the IV administration of the amino acid arginine, which stimulates pituitary release of growth hormone and prolactin through origins in the hypothalamus. Patients with impaired pituitary function will exhibit no increase or a lower than expected increase in plasma concentrations of growth hormone after administration of arginine. The test is a useful diagnostic aid in such conditions as craniopharyngioma, pituitary trauma, hypophysectomy, acromegaly, gigantism, and problems of growth and stature.

The child's physician had prescribed 5.75 g of arginine (500 mg/kg/dose for the 11.5 kg child) to be administered IV over 30 minutes, but the child received 60 g in error. An outpatient pharmacy had dispensed the drug. R-Gene 10, the only brand of arginine available in the US, is supplied in 300 mL bottles containing 30 g each—the recommended dose for an adult undergoing testing. Smaller containers are not available for pediatric patients.

The child's parents had been given a prescription for arginine to take to a community pharmacy to be filled. The pharmacy did not carry the drug, so the parents returned to the clinic to find out how to obtain the drug. The clinic nurse phoned in a prescription for arginine to an outpatient pharmacy associated with the clinic. The product was not in stock in this pharmacy either, so the pharmacist wrote a note on the prescription that said "2 bottles" to remind her to order 2 bottles of the drug.
cont'd on page 2

Safety Briefs

■ **Child dies from misuse of fentanyl patch.** We've often stressed the importance of patient education when dispensing fentanyl transdermal system patches. Another tragic event in which a 6-year-old girl died and her foster mother is charged with criminal gross negligence in her accidental death reinforces this imperative. When the child complained of neck pain late one evening, her foster mother gave her an appropriate dose of ibuprofen but also placed a leftover fentanyl patch on the child's neck to help treat the pain. The next day, the child was found unconscious in bed and was pronounced dead by the time she arrived in the emergency department. The child's foster mother had been given a prescription for fentanyl patches several years earlier to treat chronic pain after an accident. The patch she placed on the child was leftover from that prescription. The criminal charges against the foster mother were based on the severity of the error, called "gross negligence" in legal terms. This tragedy may have been avoided had the foster mother received adequate education when the fentanyl patches were prescribed and dispensed.

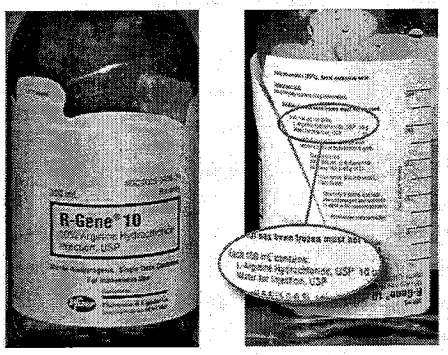
■ **Dangerous prescribing of propylthiouracil as "PTU."** Our May 2008 newsletter included an article about a tragic medication error involving a propylthiouracil prescription written as "PTU 50 mg" that was improperly dispensed. A pregnant woman who was supposed to receive propylthiouracil for long-standing hyperthyroidism instead received **PURINETHOL** (mercaptopurine) from her pharmacy. After 5 weeks, she developed fever, a painful anal fissure, and vaginal bleeding. She was admitted to the hospital with sepsis and spontaneously aborted the fetus at 16 weeks gestation. The patient was taken to the OR to deliver the placenta, where she coded multiple times and died. At the end of May, a local New York City television station broadcast a nearly identical incident in which another woman was mistakenly given mercaptopurine instead of "PTU" to treat a thyroid condition. This woman developed liver toxicity and was hospitalized for a week, but she
cont'd on page 2

Fatal Overdose *(cont'd from page 1)*

The use of arginine to test pituitary function had increased recently, and she wanted to keep a bottle in reserve for the next scheduled test. Later, the prescription was entered into the computer by a second pharmacist who misinterpreted the notation of "2 bottles" on the prescription to mean that the test was going to be performed on one day and repeated on another day. The second pharmacist thought the parents wanted to pick up both bottles at the same time.

On the day of the test, both bottles were dispensed to the parents, each labeled, "Take to clinic and infuse 5.75 gm." The pharmacist had also marked each bottle on the corner of the label as "1 of 2" and "2 of 2" to identify that more than a single container was to be picked up by the parents. However, the clinic staff thought that both bottle # 1 and bottle # 2 were required to administer the prescribed dose.

The nurse who administered the drug read the pharmacy labels on the bottles and thought that, together, the dose would equal 5.75 g. (The nurse had made a similar error before, believing that the entire bottle dispensed from the pharmacy contained the patient-specific dose; in that case, the child experienced adverse effects but recovered without permanent harm. This prior error was detected while investigating the more recent event.) The manufacturer's labeling on the front of the bottle prominently displays the brand name, generic name, and percent concentration of 10% (see Figure). However, the strength (10 g/100 mL) only appears in very small print on the back of the bottle, which the nurse failed to see. The nurse did not recognize that each bottle contained 30 g of arginine, nor was she alerted to the error by the extremely rapid rate of infusion (1,200 mL/hour) required to administer the drug over 30 minutes, as prescribed.



Only the percent strength is listed on the front panel (L); the mg strength appears in very small print, embedded in text on the back of the bottle (R).

Before the infusion, the child's mother asked the staff to check the dose; she was assured it was correct. When the child developed signs of distress, including a severe headache, the father asked to halt the procedure. A physician checked the child's medical records for the prescribed dose and asked the nurse

cont'd on page 3

Safety Briefs *(cont'd from page 1)*

survived. As we explained in our May 2008 article, both drugs are available only in a 50 mg tablet strength, and the "your" sound present in both "purine" and "uracil" further increases the risk of an error. Another issue often associated with mix-ups, including the most recent errors, is use of the abbreviation "PTU" for propylthiouracil. Each name shares the letters P, T, and U, so misinterpretation is easy. PTU is an error-prone abbreviation that has been on ISMP's error-prone abbreviation list for many years. Again, we are asking you to share this information with colleagues who might prescribe, dispense, or administer these drugs. The abbreviation "PTU" is dangerous and should never be used. See our May 2008 article for more suggestions to prevent mix-ups.

■ **Caution regarding color-coded eye meds.** Color-code schemes used for ophthalmic products have posed look-alike problems for nurses and pharmacists for many years. At the request of ophthalmologists seeking a method to help differentiate eye products on their office trays, the American Academy of Ophthalmology (AAO) endorsed a color-code scheme in 1996 that was later approved by FDA for use by manufacturers. The scheme is based on therapeutic class and used voluntarily by the manufacturer. For example, anti-infective ophthalmic containers and carton labels have a tan background on most of the label. Mydriatics and cycloplegics use a red background, miotics use green, betablockers use yellow or blue, and so on. (For details, visit: www.aao.org/about/policy/upload/Color_Codes_for_Topical_Ocular_Medications.pdf.) Despite the Academy's intention to reduce errors, the downside of color-coding products in this manner is that items within each therapeutic class become much more difficult to differentiate. When similar highly-stylized corporate logos, fonts, package sizes, and color combinations are factored in, what may work well in an office setting or in the patient's home does not necessarily work well in pharmacies or other clinical locations. Thus, the USP-ISMP Medication Errors Reporting Program has a long history of receiving reports of mix-ups between items within each class. Errors have happened when dispensing and administering these products both on nursing units, in ophthalmology clinics, and in hospital and ambulatory care pharmacies. Surprisingly, ophthalmologists continue to

cont'd on page 3

Fatal Overdose *(cont'd from page 2)*

how much medication he had received. The nurse responded that "75%" of the medication had infused, never mentioning the actual dose. Finding no reason to stop the test, the physician ordered the continuation of the infusion without visualizing the actual bottle(s) of medication. Upon completion of the infusion, the child was discharged. That night, he was brought to the emergency department, disoriented and vomiting, and admitted to the hospital for dehydration. The next day, the parents continued to report that their child was not "acting normally." That evening, after a witnessed seizure, the child was transferred to a pediatric ICU at another hospital. He was later declared brain dead, and his parents were informed about the medication error.

Under the WARNINGS section of the package insert for R-Gene 10, the manufacturer, Pfizer, acknowledges that two reports of possible overdoses in children were reported before this event occurred. The warning states: Extreme caution must be exercised when infusing R-Gene 10 into pediatric patients. Overdosage of R-Gene 10 in pediatric patients can result in hyperchloremic metabolic acidosis, cerebral edema, or possibly death.

Safe Practice Recommendations: This tragic error might have been avoided or detected earlier had any one of seven key error-reduction strategies been in place: 1) standardizing methods of communication between practitioners, 2) dispensing patient-specific doses of pediatric IV medications, 3) providing patient education, 4) dispensing and administering IV drugs to children according to established protocols in dedicated infusion centers, 5) requiring an independent double-check of IV pediatric medications, 6) maintaining a heightened index of suspicion of error when patient/family expresses concerns, and 7) changing the manufacturer's label on the product to place the strength (30 g/300 mL) on the front panel.

Standardizing methods of communication. The first pharmacist's notation of "2 bottles," which did not relate to the patient's dose, on the original prescription was misinterpreted and contributed to the error. Alternative methods of communicating information not pertinent to the prescription should be established to avoid unnecessary notes on the prescription.

Dispensing patient-specific doses. Pfizer does not offer R-Gene 10 in smaller volumes for pediatric doses; the drug is only available in a unit-dose container for adults. Thus, arginine prescriptions for pediatric patients should be dispensed from pharmacies that are: 1) staffed with pharmacists who are experi-

cont'd on page 4

Safety Briefs *(cont'd from page 2)*

endorse the system because, in an AAO spokesperson's words, "The system results in a time saver for the physician who can read the label on the drugs once a day—at the beginning of the day" (www.fda.gov/cder/meeting/part15_3_2005/Transcript.pdf). This "grab and go" when selecting medications without fully reading the label is an at-risk behavior that can lead to medication errors. Despite ISMP's efforts over the years to convince AAO, FDA, and manufacturers that color-coding leads to errors, no changes have been made to improve safety. Errors continue, including a recently reported mix-up between Bausch and Lomb's cyclopentolate 1% and atropine sulfate 1% vials (see Figure). Incidentally, all manufacturers color-code their eye products, not just Bausch and Lomb. Possibly the best way to prevent problems is for pharmacy purchasers to avoid awarding contracts to one vendor for an entire product line or purchase drugs within a class from different manufacturers. We'll continue our efforts toward safer labeling of these products.

A patient recently received atropine instead of cyclopentolate.

■ **FDA meeting on drug name testing.** On June 5-6, FDA hosted a public workshop to discuss a concept paper (www.fda.gov/cder/drug/MedErrors/meeting_names.pdf) about a pilot program to address look- and sound-alike brand names. The pilot, called for in the FDA Amendments Act of 2007, would allow drug companies (or outside contractors) to evaluate proposed brand names and submit the data to FDA for review. Currently, FDA's Division of Medication Error Prevention screens drug names, in consultation with other divisions responsible for product approval. The concept paper outlines the types of studies that should be conducted. Based on discussions during the meeting and submitted comments (go to www.regulations.gov, type "FDA-2008-N-0281" in the search window, and submit comments by July 6), FDA will revise the concept paper and present testing methods to the pharmaceutical industry.

Fatal Overdose *(cont'd from page 3)*

enced in preparing pediatric IV infusions, 2) furnished with the equipment necessary to prepare patient-specific sterile IV doses, and 3) able to dispense the drug to the infusion area immediately before use. Full bottles from the manufacturer should never be dispensed for pediatric patients, even with directions for use on the label. Pfizer has been contacted several times for information about stability of the drug once it is removed from its original container, as there is no information about this in the package insert. A company representative informed us that stability has not been tested, but he referred the question to another department. We have not yet received a call back.

Providing patient education. Prescribers, pharmacists and nurses should provide patient education prior to tests and procedures. It is important that patients and/or caregivers understand the dose of any medication to be administered and be able to verbalize who will administer the medication and when this will occur. The patient also should learn the intended and adverse effects of the drug.

Dedicated infusion centers and protocols. The organization where the event occurred now restricts the administration of IV pediatric solutions/medications to dedicated infusion centers rather than clinic areas. While the outpatient pediatric clinic where this error happened was likely staffed with well-qualified practitioners, an additional level of safety might be attainable in a setting where: 1) standardized practices for IV infusions are well integrated and consistently carried out, 2) pharmacy and nursing staff are more familiar with the types of medications commonly administered, 3) pharmacy staff possess the experience and equipment to prepare and dispense IV infusions, and 4) protocols have been established and are referenced during testing and drug administration.

Independent double-checks. It is uncertain whether an independent double-check in the pharmacy prior to dispensing the drug would have detected the dispensing error. However, patient counseling at the point of sale may have brought attention to the fact that the child was scheduled for only one test. The dispensing error also might have been detected if the nurse who administered the medication had asked another nurse to check the drug and dose/infusion rate. Arginine should always be independently double-checked before dispensing and administration, particularly since it is hypertonic (950 mOsmol/L) and contains 47.5 mEq of chloride ion per 100 mL of solution (compared to 308 mOsmols/L and 15.4 mEq of chloride per 100 mL of 0.9% isotonic sodium chloride).

Heightened suspicion of an error. One of the most regrettable aspects of this tragedy is that the concerns expressed by the child's parents about the dose, and their son's reaction to the test, did not lead to early detection of the error. Without knowing all the facts in this case, we assume that the nurse who administered the medication and the physician who later examined the patient during the test took the parents' expressed concerns seriously and rechecked the testing procedure. Nevertheless, this case clearly illustrates that our index of suspicion of an error should be very high when patients or family members speak up about medication safety concerns.

Manufacturer labeling. We have contacted Pfizer and FDA to express our concerns about the labeling of the product's strength. We suggested listing the product's strength (30 g/300 mL) directly under the product name on the front panel. We are awaiting a response from the company.

We applaud the leaders in the facility where this error happened for their honest disclosure of the event to the child's parents and support of the family. The child's family also has publicly expressed appreciation for the organization's ethical and thorough investigation of the event. The family has established a charitable foundation (www.sebastianferrero.org/) to support the establishment of a free-standing, state-of-the-art children's hospital in Gainesville, FL.

References: 1) Chun D. ...apologizes for death of boy. The Gainesville Sun, Oct. 26, 2007. 2) Tasker F. Toddler's death leads to stricter medical safeguards. Miami Herald, Oct. 27, 2007:A1. 3) Associated Press. Medication error causes death of boy, 3. Florida Today, Oct.25, 2007.

The Institute for Safe Medication Practices is an independent nonprofit agency. ISMP accepts no advertising. The contents of this newsletter are copyrighted. ©2008 Institute for Safe Medication Practices. Law strictly prohibits redistribution, reproduction, or republication by recipients through any means, including print, e-mail, or fax, without written permission by ISMP. Individual subscription rates are $48 per year for 12 monthly issues. Discounts are available for organizations with multiple sites or multiple users. For more information, contact ISMP at 215-947-7797 or e-mail to community@ismp.org.

ISMP Medication Safety Alert! Community/Ambulatory Care Edition (ISSN 1550-6290) **©2008 Institute for Safe Medication Practices (ISMP).** ISMP® is an FDA MEDWATCH partner. Call 1-800-FAIL-SAF(E) to report medication errors to the USP-ISMP Medication Errors Reporting Program (MERP) or report on-line at www.ismp.org or www.usp.org. Unless noted, published errors were received through the MERP. ISMP guarantees confidentiality and security of information received and respects reporters' wishes as to the level of detail included in publications. Editors: Michael J. Gaunt, PharmD; Michael R. Cohen, RPh, MS, ScD; Judy Smetzer, RN, BSN. Reviewers: ISMP staff and Tabitha Carreon, PharmD, RPh; Eddie Dunn, PharmD; Richard A. Feifer, MD; Alan S. Fox, RPh; Stan Illich, RPh, MHA; Amanda G. Kennedy, PharmD; Crystal Lennartz, PharmD, MBA; Patrick McDonnell, PharmD; Andrew Seger, PharmD; Kelly J. Stanforth, PharmD, FISMP; Kimberly Tallian, PharmD, FCSHP, FASHP; Larry Wolfe, RPh; Chuck Young, RPh, CFE. Institute for Safe Medication Practices, 200 Lakeside Drive, Suite 200, Horsham, PA 19044. Tel. 215-947-7797; Fax 215-914-1492; E-MAIL: community@ismp.org. This is a peer-reviewed publication.

Copyright © 2008 ISMP. Duplication is permitted only for internal distribution ***at your practice site.*** Duplication by any means for distribution outside your site is strictly prohibited.

PR Newswire
United Business Media

News & Information
We tell your story to the world.

Home | Send Release | Today's News | Multimedia | Industry & Markets | International | Investor News | RSS | Our Services | About Us | Contact Us

Industry News

print e-mail link RSS Technorati Blog Search bookmark it blog it

First DataBank Launches Campaign to Focus Public and Industry Attention on Medication Error Prevention

Company will donate money to non-profit organizations supporting medication error prevention outreach and education for HIMSS attendees wearing custom wristband

SAN BRUNO, Calif., Feb. 19 /PRNewswire/ -- First DataBank, a leading provider of drug information databases, today announced the launch of a new brand awareness campaign to focus public and industry attention on the prevention of medication errors. The campaign will be unveiled at the Healthcare Information and Management Systems Society (HIMSS) 2008 Annual Conference & Exhibition to be held February 24-28, in Orlando, Florida.

First DataBank's campaign theme, "A World Free of Medication Errors," is intended to focus industry and public attention on how the intended use of the company's medication information at the point of care may play a key role in the prevention of medication errors. The company is a pioneer in the development of drug information databases used throughout healthcare in clinical decision support. Experts estimate that as many as 98,000 people die each year from medical errors that occur in hospitals and a significant number of those deaths are due to medication-related errors.

A key component of the public awareness effort is a tie-in to two non-profit organizations that share First DataBank's mission of medication error prevention. At the HIMSS 2008 Annual Conference, attendees visiting the First DataBank booth will receive a custom-designed wristband and a brochure describing the "A World Free of Medication Errors" campaign mission. Throughout every public event in which First DataBank participates in 2008, the company will set aside five dollars toward each wristband distributed that will be shared equally by two non-profit organizations. The two organizations chosen by First DataBank to share in the funds raised throughout the campaign year are: FLAAME: Families Launching Action Against Medication Errors and the Josie King Foundation.

"The employees at First DataBank are passionately committed to improving patient safety and healthcare quality in everything we do," said Don Nielsen, M.D., President, First DataBank. "The knowledge that our drug information plays a significant role in the prevention of harmful medication errors was our inspiration for this campaign and our hope is that it motivates others to join with us," he continued.

"On behalf of the Josie King Foundation, we are honored to have been selected to be part of First DataBank's campaign to raise public and industry awareness of medication errors," said Sorrel King, co-founder of

the Josie King Foundation named to honor of her young daughter, Josie, who died from a medical error. "I speak to hundreds of clinicians working in hospitals around this country on this subject every year since Josie's death and there is always more information to share, and more teaching to be done. The donation from First DataBank's campaign will support these ongoing educational efforts," she stated.

About FLAAME: Families Launching Action Against Medication Errors

FLAAME was founded in 2007 to heighten public and health care industry awareness of errors made on both sides of the prescription counter. Co-founded by Cathy Horton, whose career, family life and health were thrown into turmoil following a medication error. FLAAME'S mission is to eliminate instances of prescription errors, medication use errors and negative drug interactions through awareness programs, education, lobbying and web-based resources. For more information about FLAAME visit http://www.flaame.org.

About The Josie King Foundation

The Josie King Foundation was founded in 2001 by Sorrel and Tony King, after their young daughter, Josie, died of medical errors at Johns Hopkins University Hospital. The Josie King Foundation's mission is to prevent others from dying or being harmed by medical errors. By uniting healthcare providers and consumers, and funding innovative safety programs, the foundation's hope is to create a culture of patient safety, together. For more information about the Josie King Foundation visit http://www.josieking.org.

About First DataBank

First DataBank, a subsidiary of Hearst Corporation, drives patient safety and healthcare quality by providing drug databases that are used within information systems that touch every aspect of healthcare. For 30 years, we have partnered with system developers to integrate and optimize our drug information to improve user workflow and enhance clinical decision making by those entrusted with treating patients at the point-of-need. For more information about First DataBank, call 800-633-3453 or visit http://www.firstdatabank.com.

(C) 2008 First DataBank, Inc. A subsidiary of Hearst Corporation. All trademarks mentioned herein are the properties of their respective owners.

SOURCE First DataBank

back to top

Related links:
- http://www.firstdatabank.com
- http://www.josieking.org
- http://www.flaame.org

Technorati Blogs Discussing This News Release

AbbeKitty@cs.com
03/05/2008 11:10 AM

To Virginia_Herold@dca.ca.gov
cc
bcc
Subject WSJ: Hospitals Tackle High-Risk Drugs to Reduce Errors

HOSPITALS TACKLE HIGH-RISK DRUGS TO REDUCE ERRORS

March 5, 2008; Page D1
WALL STREET JOURNAL

Hospitals are taking steps to prevent errors in the use of so-called high-alert medications -- those that, when given in the wrong dose or used incorrectly, have the highest risk of seriously harming or even killing a patient.

Many of the high-alert medications are the most essential to hospitals. Among them are drugs to prevent blood clots, sedate patients, relieve pain and stabilize diabetics. But incorrect use of these drugs can lead to disasters, such as the accidental overdoses of heparin, an anticlotting drug, that killed three infants at an Indiana hospital in 2006 and threatened the newborn twins of actor Dennis Quaid this past November.

High-dose heparin was repackaged (right) to make errors less likely.

While there are 19 categories of high-alert medications, according to the Institute for Safe Medication Practices, studies show that about eight medications, including heparin, account for 31% of all medication errors that harm patients.

Now, amid growing awareness of medication mistakes and pressure from safety groups, hospitals are scrambling to overhaul their safety practices. They are working with drug makers to redesign confusing packages and eliminating multiple concentrations of the same drug from supply cabinets. They are also investing in bar coding and systems that let staffers check the accuracy of medication orders at patients' bedsides and see other information, such as allergies, that could cause adverse reactions.

In perhaps the most challenging step, hospitals are tackling the "grab and go" culture in busy hospitals that evidence increasingly shows causes errors. Doctors, nurses and pharmacy staffers often give out medications without fully reading the labels, evaluating patients' risks, or checking one another's work. "For each one of these errors to reach a patient, six to eight slip-ups have occurred somewhere in the system, and each one of those steps is an opportunity for someone to intervene," says Kerry Butler, quality and medication-safety officer at Saint Thomas Health Services in Nashville, Tenn., a unit of nonprofit health-care system Ascension Health.

Saint Thomas is one of a number of hospitals establishing "behavioral accountability" standards for staffers, with acronyms like STAR -- for Stop, Think, Act, Review. Hospitals are also adding strict new policies, such as requiring two staffers to check before certain drugs are given to patients and creating new training programs to help staffers intercept errors and respond faster when mistakes do occur.

The Institute for Healthcare Improvement, a Cambridge, Mass., nonprofit that sponsors health-care quality programs, has created a guide for hospitals on how to prevent harm from high-alert medications, focusing on four categories

of medications that it says are most frequently used and have the greatest potential for harm: anticoagulants, narcotics, insulin and sedatives.

The Joint Commission, which accredits hospitals, is requiring that hospitals have programs in place by the end of this year to reduce the likelihood of harm from anticoagulation therapy using drugs like heparin.

But Mike Cohen, president of the Institute for Safe Medication Practices, which monitors and analyzes errors and maintains an updated list of high-alert medications, says that safety efforts are largely voluntary and that too few hospitals have invested in technologies such as bar coding that could sharply reduce errors.

Hospitals are also calling on patients and families to act as a final line of defense, keeping a watchful eye on medications and asking nurses to verify their accuracy -- especially when infants and children are involved. "Kids are changing every day, and administering medications in doses according to size and weight adds a new level of complexity," says Charles Homer, a professor at Harvard University and chief executive of the National Initiative for Children's Healthcare Quality.

While hospitals have always had to deal with potentially dangerous medications, the introduction of thousands of new drugs in a growing range of doses, concentrations and packages has increased the likelihood of error, Mr. Cohen says.

For example, nurses often flush the tubes used to deliver intravenous medications to infants with a low-dose heparin product to keep the catheters from clotting. But at Methodist Hospital in Indianapolis, three infants that were treated in the neonatal intensive-care unit died in 2006 after a technician accidentally replaced 10-unit-per-milliliter vials in a medicine dispenser with vials containing 10,000 units per milliliter. Six different nurses took out the medications, assuming them to be the correct dose because of their placement in the cabinet, and flushed the infant's catheters. By the time the mistake was discovered, it was too late.

Methodist, facing investigations and lawsuits tied to the deaths, acted quickly to publicly disclose the errors and retrained its staff in rigorous prevention policies. It installed a system to bar-code medications, as well as an automated refilling system for medication storage cabinets and a scanner for verifying medication at the bedside. It also replaced the 10,000-unit heparin vial with a heparin-filled syringe that can't be confused with the smaller dose, and two health-care workers must now look at a dose of heparin before it is administered to a newborn.

The hospital is sharing its strategy for dealing with the errors with other hospitals, including a teleconference March 10 sponsored by IHI. Says Valerie Shahriari, director of risk management and patient safety for Methodist parent Clarian Health: "If this happened to us, it can happen to other hospitals, and we think people can learn from our experience."

In the case of the Quaid twins, who survived a heparin overdose at Cedars-Sinai Medical Center in Los Angeles in November, the family is suing heparin marketer Baxter International Inc., saying that the error was a result of confusion by hospital staffers over similar packaging used for its low-dose Hep-Lock IV flushing product and a 10,000-unit vial.

Baxter says it hopes to resolve the lawsuit and work with patients and hospitals to further improve safety. In February 2007, the company sent out a safety alert to its customers, warning of the potential for error; in October, it changed its packaging to more sharply set apart different heparin

concentrations, adding snap-off caps so that nurses must take an extra step when opening it. It also varied the colors, enlarged the font size, and stamped "Not for Lock Flush," referring to the low-dose flushing product, on large-dose vials. But hospital staffers "still have to read the labels, no matter what we do," says Debra Bello, senior director of global medical and clinical affairs for Baxter's medication-delivery business.

(In an unrelated development, Baxter is recalling heparin vials amid a Food and Drug Administration investigation of reports of allergic reactions and deaths that appear to be linked to manufacturing problems.)

Cedars-Sinai has also taken steps to overhaul safety practices, after an internal investigation concluded that staffers failed to follow any of its policies on verifying medication before dispensing and administering the heparin in the case of the Quaid twins. About 1,800 nurses and all its pharmacy technicians were required to undergo retraining on high-alert-medication policies and pass a written test. It also has replaced heparin with a saline solution for flushing catheters.

Other hospitals are taking steps now to prevent such errors. Duke University Hospital is using "mistake-proofing" strategies such as stocking standardized concentrations of medicines and premixed doses and using "smart pumps" that deliver an alert if a mistake is made in entering a dose. It has also adopted the Six Sigma methodology, used by manufacturers to minimize errors, to identify what could go wrong with high-alert medications and develop prevention plans. The hospital, which already has a computerized system used by doctors to enter medication orders, is now adding a medication-administration system that will let nurses view all the information about a patient and make it easier to avoid errors at the bedside, according to Judy Prewitt, chief nursing officer.

Write to Laura Landro at laura.landro@wsj.com1

URL for this article:
http://online.wsj.com/article/SB120467987732012017.html
Copyright 2008 Dow Jones & Company, Inc. All Rights Reserved

Prescribing Errors

Angie S. Graham, PharmD, FCSHP
Drug Information Coordinator, Department of Pharmacy, Stanford Hospital & Clinics
Assistant Clinical Professor of Pharmacy, University of California, San Francisco
Please address correspondence to Angie Graham at AnGraham@stanfordmed.org.

Continuing Education

Learning Objectives

At the completion of this article, the reader should be able to:

1. Identify the incidence of prescribing errors in various care settings
2. Recognize the types of prescribing errors reported most commonly in the literature
3. List the interventions that have been recommended for reducing prescribing errors during hospital care, ambulatory care, and long-term care
4. State the opportunities for pharmacists to reduce medication errors in hospitals
5. Recognize potential barriers to reducing medication errors

The Institute of Medicine estimates that 1 million preventable adverse drug events occur annually in the United States. Although the best data come from studies conducted in hospitals, the problem of medication errors is probably larger in other settings. Every stage of the medication-use process is vulnerable to errors, but the steps most frequently associated with errors are prescribing and administration.[1] This article will review the literature on prescribing errors in different settings with a focus on the Institute of Medicine's (IOM) Preventing Medication Errors report. Pharmacists can serve not only as the first line of defense against individual prescribing errors but also as leaders in systems approaches to preventing prescribing errors.

The National Coordinating Council for Medication Error Reporting and Prevention defines a medication error as 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.[2] A definition of prescribing errors has also been developed by a group of practitioners using a 2-stage Delphi technique: "A clinically meaningful prescribing error occurs when, as a result of a prescribing decision or prescription writing process, there is an unintentional significant (1) reduction in the probability of treatment being timely and effective or (2) increase in the risk of harm when compared with generally accepted practice."[3]

Although many medication errors do originate with prescribers, determining who made the error is ultimately less important than determining why. Targeting the underlying causes supports a systems approach to medication errors. Michael Cohen, president of The Institute for Safe Medication Practice, identified 10 key system elements as having the greatest impact on medication use:

1. Patient information
2. Drug information
3. Medication-related communication
4. Drug labeling, packaging, and nomenclature
5. Drug standardization, storage, and distribution
6. Medication delivery device selection, use, and monitoring
7. Environmental factors
8. Staff competency and education
9. Patient education
10. Quality improvement processes and risk management.[4]

In keeping with these 10 key system elements, the IOM recommended the following in all settings to reduce medication errors: reference information accessible at the point of care, prescribing managed electronically, technologies effectively used and well designed, patient-specific medication information communicated at all hand-offs of care, error monitoring, and a safety culture.[1]

Hospital Care

Among the IOM's findings in their *Preventing Medication Errors* report was that, on average, each hospitalized patient in America experiences 1 medication error every day. Studies show that the average preventable adverse drug event rate in United States (U.S.) hospitals ranges from 3.7 to 84.1 per 1,000 admissions. Between 380,000 and 450,000 preventable adverse drug events are thought to occur each year in U.S. hospitals, resulting in total annual costs of $3.5 billion and average extra inpatient costs of $5,857 per patient.[1]

Error Rates – Hospital Care

Rates of prescribing errors in hospital studies vary widely, but for the most part, the studies that found the highest rates were the ones with the most comprehensive detection methods, suggesting that the higher estimates are probably more accurate. Across various studies, the rates have been found to be 12.3 – 1,400 prescribing errors per 1,000 admissions, 0.61 – 53 prescribing errors per 1,000 orders, and 1.5 – 9.9 prescribing errors per 100 opportunities for errors. Prescribing errors for hospitalized pediatric

patients have been detected in 4.2% to 30% of all orders, depending on the study. In an investigation of pediatric emergency departments, 10% of all children experienced a prescribing error.[1]

Key Findings – Hospital Care

In one study of 4,768 medication errors occurring over 5 years in hospital cardiology wards, 1,102 could be attributed to a particular health-care discipline. Of these, 692 (62.8%) were associated with prescribers, including physicians and physician assistants. Three hundred seventy-four (54%) of the errors attributed to prescribers were classified as admission errors, defined as errors related to unintended changes in drugs or doses from what the patient was taking before admission. Another 284 (41%) were attributed to lack of drug knowledge, and 28 (4%) were related to errors at discharge.[5]

In another study of 264 preventable adverse drug events and 334 errors among adult admissions to 11 medical and surgical units in 2 tertiary hospitals over 6 months, most errors occurred in the physician ordering stage of the medication use process (39%). The most common error types were wrong dose (28%), wrong choice (9%), and wrong drug (9%). The underlying causes of the prescribing errors were most often lack of knowledge of the drug (36%), lack of information about the patient (24%), rule violations (19%), and slips and memory lapses (11%).[6]

A systematic evaluation of every third prescribing error detected and averted by pharmacists in a large teaching hospital over 1 year found an error rate of 3.99 per 1000 orders. Dosing errors accounted for the largest proportion of all errors and included both overdoses (41.8% of all errors) and under doses (16.5% of all errors). Prescribing medications to which the patient was allergic (12.9%) and prescribing inappropriate dosage forms were the next most common error types. The drug classes most frequently involved with prescribing errors were antimicrobials (39.7%), cardiovascular drugs (17.5%), and gastrointestinal drugs (7.3%). The patient factors typically associated with drug or dose errors were advanced age, renal impairment, and patient weight. Underlying factors thought to contribute to the prescribing errors were lack of knowledge of the drug (30%), lack of knowledge of the patient (29.2%), and problems with calculations and rate/unit expressions (17.5%). Among 43 severe errors, 83.7% involved prescribing a drug to which the patient was allergic and 17.7% involved dose calculation problems.[7]

A study of 10-fold dosing errors in a large tertiary teaching hospital detected 0.51 10-fold prescribing errors per 100 total admissions and 0.83 10-fold dose prescribing errors per 1,000 total patient days. For adults, the rate was 0.52 per 100 admissions and 0.77 per 1,000 patient days. Among pediatric patients, 0.53 10-fold dosing errors were found per 100 admissions and 0.98 were found per 1,000 patient care days. Errors were potentially severe in 45% of cases and were overdoses 61% of the time.[8]

Lack of training on prescribing safety may contribute to the high rate of prescribing errors observed to date. In one study, 82% of medical students and house staff at a large teaching institution said they learned about safe prescribing simply by copying orders written by other physicians. In questionnaires of medical residents, interns, and students, the conditions they thought contributed to prescribing errors were being in a hurry (84%), being interrupted (66%), excessive workload (55%), fatigue (43%), incomplete knowledge of the medication (34%), and incomplete knowledge of the patient (29%).[9] Despite these questionnaire results, no correlation was detected between the prescribing error rate and number of hours worked or between the prescribing error significance and number of hours worked in a study of 43 medical residents and 45,366 orders.[10] These findings are in contrast to studies in pharmacists, in whom the risk of dispensing errors has been shown to increase with increased workload.[11,12,13]

Finally, although much of the literature on prescribing errors in hospitals has focused on errors of commission, a growing body of evidence suggests that there is a considerable problem with errors of omission and specifically with underutilization of appropriate therapies. Significant findings cited in the IOM's *Preventing Medication Errors* report were that, for patients admitted for a myocardial infarction, only 85-93% were given aspirin within 24 hours of hospitalization; only 53-93% were discharged with an aspirin prescription; only 66-78% were given a beta-blocker within 24 hours of hospitalization; only 53-83% were discharged with a beta blocker; and only 51-73% were discharged with an ACE inhibitor. Appropriate prophylactic antibiotics for surgery were prescribed when indicated in 70-98% of patients, and thromboembolic prophylaxis was carried out when indicated for procedures in 5-90% of cases.[1]

Improvement Strategies – Hospital Care

The first and most important approach that hospital pharmacy leadership can take to reduce the medication error problem in general is to offer evidence-based clinical pharmacy services associated with error reductions. In Bond's survey of approximately 1,000 hospitals and 400,000 medication errors, the clinical pharmacy services associated with decreased medication errors were managing drug protocols, managing adverse drug reactions, participating in medical rounds, providing a formal drug information service, and taking drug admission histories. Hospitals providing these services had reductions in their medication error rates of 13% to 51%, depending on the service. Increased staffing of clinical pharmacists per occupied bed was also associated with decreased medication errors. The authors advocated the use of their results as a template for restructuring hospital pharmacies to reduce medication errors and improve patient safety.[14]

Pharmacists and pharmacy services are a component of the IOM's medication error prevention strategies. The *Preventing Medication Errors* report concluded that there was good evidence to support pharmacist participation on hospital rounds. Good evidence was also found to support the effectiveness of stand-alone clinical decision support systems and of computerized physician order entry with built-in clinical decision support systems, based on reductions in medication errors of 13-86% and in preventable adverse drug events of 17-62% across various studies. Interventions that were characterized as promising were smart intravenous pumps and bar coding.[1]

Although quality study data supporting efficacy in the hospital setting are available only for a handful of medication-safety interventions like clinical decision support, a variety of other recommendations have been made based on preliminary data or expert opinion. These include computerized physician order entry, unit dosing, standardized

prescription writing, prescribing rules, elimination of dangerous abbreviations, written protocols for high-alert medications, and verbal order standards and limits. Beyond these interventions, most organizations recommended a systems approach to medication safety, a culture of safety, and improved error identification and reporting.[1]

Several non-pharmacy national organizations offer recommendations for clinical pharmacy services to reduce medication errors in the hospital setting. A selected list is available in Table 1.[1] The endorsement of specific pharmacy services by these national organizations can be used to justify new or expanded pharmacy roles to hospital administration.

The Agency for Healthcare Research and Quality is a division of the federal government's Department of Health & Human Services. Their report, *Making Health Care Safer: A Critical Analysis of Patient Safety Practices,* identified 2 pharmacy services as having a high potential impact on reducing medication errors and adverse drug events: pharmacist consultation services and information transfer between inpatient and outpatient pharmacies. High impact interventions were defined as those that targeted either a patient population of greater than 1% of hospitalized patients (about 300,000 patients per year) or a patient safety problem that could result in death or disability. Anticoagulation services and clinics for warfarin, which are often managed by pharmacists, were also categorized as high-impact interventions. Several other interventions that were classified as high impact are either components of the medication distribution process or present opportunities for pharmacists to develop new clinical services. These include: implementing computerized physician order entry with clinical decision support and automated medication dispensing devices; limiting antibiotic use; improving perioperative glucose control, perioperative beta-blocker use, and venous thromboembolism prophylaxis; and providing geriatric consult services and pain services. Medium impact interventions were defined as those that targeted 0.01% to 1% of hospitalized patients (about 3,000 to <300,000 patients per year) or a patient safety problem that might result in reversible adverse effects if an effective prevention strategy were not available. Within this category, possible opportunities for pharmacists were developing computer monitoring for adverse drug reactions, heparin nomograms, and unit-dose distribution systems, and improving pneumococcal vaccination and antibiotic prophylaxis for surgeries.[15]

The Institute for Healthcare Improvement (IHI) advocated three specific pharmacy services to improve the core processes for ordering medication in hospitals. First, they supported the implementation of pharmacy-based dosing for certain medications, starting with one high-risk medication, demonstrating benefits, and then expanding to physician-approved protocols or guidelines for other medications as appropriate. The IHI recognized that pharmacists could interpret patient-specific information such as age, weight, and laboratory test results that could affect dose selection; save both pharmacist and physician time by managing dosing themselves; and decrease certain types of errors. Second, the Institute recommended assigning pharmacists to patient care units. Activities at the unit level would include assisting physicians with new orders, educating other health-care professionals and patients, and participating in all patient safety activities, including rounds and safety briefings. The recommendations noted, however, that pharmacists should be assigned to as few units as staffing resources would allow so that unit-based activities could be implemented effectively. The third pharmacy service recommended by the IHI was pharmacy-based dosing for renal patients. Similar to the recommendations for pharmacy-based dosing of high-risk medications, IHI acknowledged that pharmacists have adequate training to interpret renal function studies and apply findings when determining appropriate doses. Again, the IHI recommended pharmacy-based dosing not only to allow prescribers more time for other clinical activities and reduce pharmacist time spent contacting physicians for dose adjustment requests, but also to reduce the risk of adverse events. The use of physician-supported protocols or guidelines wa recommended, as well as ensuring the availability to pharmacists of all renal function information in real time.[16]

Beyond the inclusion of pharmacists in hospital rounds, which was characterized as an intervention supported by good evidence, the IOM recognized several pharmacy-specific services that have been promoted as reducing medication errors during hospital care. A medium strength recommendation was to have a pharmacist available on call after hours of pharmacy operation. Recommendations that were acknowledged but that were characterized as having limited evidence were having a central pharmacist supply high-risk intravenous medications and pharmacy-based admixture systems, pharmacist counseling of hospitalized patients, and pharmacist review of all medication orders before first doses are given.[1]

The Institute for Safe Medication Practices (ISMP) advocates a leadership role for pharmacists in developing medication-related communication tools.[17] At a minimum, the ISMP states that all prescription orders should include the following required elements: the patient's full name and location, the patient's clinical information (weight, age, allergies), the drug name, the drug strength in metric units by weight for solids and by concentration for liquids, the dosage form, the dispensing amount in metric units, the directions for use (route, frequency), the drug's purpose or indication, and the number of refills or duration of therapy.[18] Specific recommendations for the safe design and use of preprinted order sets have been published and are summarized in Table 2.[18] The IOM further recommends that pharmacists work in cooperation with information technology departments and others to develop safe electronic communications

Table 1. Organizations with Published Clinical Pharmacy Service Recommendations to Reduce Medication Errors in Hospitals[1]

Agency for Healthcare Research and Quality
Institute for Healthcare Improvement
Institute of Medicine
Institute for Safe Medication Practices
National Quality Forum
Pathways for Medication Safety

Table 2. Recommendations for the Safe Design and Use of Preprinted Order Sets[18]

Involve an interdisciplinary team of individuals involved in the medication use process to develop the order sets
Ensure consistency with organizational policy
Use generic names for drugs
Avoid jargon and nicknames for drugs (banana bag)
Avoid use of common allergens whenever possible
Avoid use of dangerous abbreviations and dose designations
Express doses in metric weight (mg)
List doses per square meter or area under the curve for chemotherapy orders when a calculated dose must be entered. Include daily dose and number of days for multi-day chemo regimens
List the dose by weight for pediatric orders when dose must be calculated
Spell drug names correctly, and include a space between names and doses and between doses and units
Specify the purpose of the drug whenever possible
Use professional quality fonts and print styles to improve readability
When multiple medication choices are listed, develop a consistent system for indicating that a choice was not selected
Omit lines on the backs of order forms
Include a tracking number and revision date on the form
Do not use preprinted orders prepared by pharmaceutical companies
Ensure that order forms are easily accessible
Review preprinted order forms every 2 or 3 years or when protocols change

Table 3. Safe Expression of Drug Names and Doses in Electronic Orders[17]

List products by the FDA-approved generic name using lower case letters, unless "tall-man" letters are specifically recommended.
Only specify the drug salt if multiple salts are on the market. If the salt is part of the name, list the generic name first and salt second (eg, "phenytoin sodium" or "phenytoin Na" instead of "sodium phenytoin" or "Na phenytoin)
When appropriate, list brand names in a second field using all upper case letters. Do not include trademark symbols.
List suffixes that are part of the brand name in both the generic name and brand name fields (eg, bupropion XL and Wellbutrin XL).
Exclude dangerous abbreviations and dose designations.
Avoid abbreviations for drug names.
Use "tall-man" letters to help distinguish between look-alike names in order lists.
If the drug name, strength, dosage form, and dosage units will appear together, express them in this order: Generic name, brand name, strength, dose (if different from strength), and dosage form.
If the drug name, strength, dosage form, and dosage units appear together, always insert a space between them for ease of reading.

standards for medication orders. They have issued guidelines for safe expression of drug names and doses in electronic medication orders, as shown in Table 3.[17] A checklist of computerized physician order entry system requirements for supporting safe order communications is provided in Table 4.[17]

In the National Quality Forum's *Safe Practices for Better Healthcare, 2006 Update,* key practices are recommended that have been proven effective and of potential benefit in improving health-care safety. Among these is a minimum standard for pharmacist participating in medication management systems, which would include working with other disciplines to establish and maintain a drug formulary, being available for consultation by prescribers at the point of medication ordering, reviewing medication orders, preparing and dispensing medications, assuring safe storage, and monitoring medication use. Beyond the minimum standard, the National Quality Forum recommended that pharmacists offer recommendations for and promote medication safety throughout their organizations, review all medication orders except in select cases outlined by the Joint Commission, oversee all medication preparation and storage, ensure a safe working environment throughout the medication use process, provide 24-hour telephone access to a pharmacist even if the pharmacy is closed, and lead safety initiatives around look-alike/sound-alike medications and concentrated electrolytes.[19]

The Pathways for Medication Safety, a joint effort of the American Hospital Association, the Health Research and Educational Trust, and the IOM, with financial support from the Commonwealth Fund, offered numerous detailed recommendations for the basic pharmacy functions within the medication use process, such as product purchasing, storage, labeling, and dispensing. Of interest was the number of clinical pharmacy services endorsed by the Pathways evaluation tools for administrators/managers, physicians, and risk-management professionals. Recommendations included: having pharmacists routinely adjust medication doses for patients with hepatic or renal impairment; making pharmacists available on patient care units to assist prescribers with drug selection, to answer questions from nurses, to counsel patients on their medications, and to track high-risk patients or patients on

high-risk medications; involving pharmacists in the provision of in-services to medical staff; and having pharmacists provide in-service programs on new medications to nurses.[20]

Ambulatory Care

The IOM estimated that 530,000 preventable adverse drug events occur each year in the U.S. in the ambulatory care setting. The annual cost of these adverse drug events was estimated at $887 million nationally or $1,983 per event.[1]

Error Rates and Key Findings – Ambulatory Care

When *Preventing Medication Errors* was released in 2006, it was estimated that 21% of all ambulatory care prescriptions contained at least 1 prescription writing error.[1] In a recent systematic review of all types of preventable adverse drug events in ambulatory care, the largest proportion of errors originated in the prescribing stage, accounting for 64.7% of all preventable adverse drug events and 56% of all preventable adverse drug events causing hospital admission.[21]

In a retrospective review of 1,411 handwritten prescriptions over 5 months from an internal medicine clinic, 386 (27.4%) contained 1 or more errors or potential errors. Because some prescriptions had more than 1 error, the total error number was 463 and the rate was 32.8%. Ninety percent were considered potential errors, representing circumstances with the capacity to cause an error, such as missing information or illegible writing. The percentage of errors that reached the patient was 6.9%, and the percentage that caused harm was 0.2%. Only 21% of errors were categorized as clinical errors. Most commonly, these involved prescribing a contraindicated drug for a patient 65 years of age or older, according to the Beers criteria. The most severe clinical errors involved drug-disease interactions and lack of appropriate laboratory monitoring.[22]

Among ambulatory Medicare patients aged 65 or older and being cared for by a multispecialty group practice, 13.8 preventable adverse drug events occurred per 1,000 person-years. Of the preventable adverse events, the error originated in the prescribing stage in 58.4% of cases. The most common prescribing error types included wrong drug or wrong therapeutic choice (27.1%), wrong dose (24%), and drug interaction (13.3%).[23]

In a study of 4 adult primary care practices affiliated with an academic medical center, 7.6% of 1,879 prescriptions had a prescribing error. The most common types of errors were incorrect or missing dose (54%) or frequency (18%). In total, 19% of all prescriptions contained a prescribing error or rule violation, defined as a failure to follow preset prescribing guidelines, such as including a route of administration. Error rates were similar to those observed at sites with basic computerized order entry, but a physician review panel judged that up to 97% of the errors could have been prevented by a computerized order entry system that included decision support.[24]

Information on prescribing errors for ambulatory pediatric patients is limited. In one study, 15% of children seen in a pediatric outpatient clinic were given a prescription that contained a potential dosing error for a common medication.[1]

Improvement Strategies – Ambulatory Care

Medication reconciliation, medication education programs, prescribing aids, practice guidelines, physician-pharmacist collaborative services, patient medication management reports, error reporting programs, and electronic prescribing with alerting functions and field limits have all been proposed as interventions to reduce prescribing errors in the ambulatory care setting.[1] Data on the impact of these interventions is limited, however.

Long-Term Care

About 1.6 million Americans reside in the nation's 18,000 nursing homes, where 800,000 preventable adverse drug events are estimated to occur each year.[1,25] An estimated 0.01-0.04 preventable adverse drug events occur per patient per month, equivalent to 0.02-0.1 adverse drug events per 100 admissions.[1]

Table 4. CPOE System Requirements that Support Safe Order Communications[17]

Data fields have ample space so that abbreviations for drug names, units, administration routes, and frequencies do not have to be abbreviated.
A data field is included that requires the prescriber to enter the drug indication for PRN medications, look-alike name medications, and medications with multiple uses.
The system provides a way to alert prescribers of specific warnings or to provide clinical notes for medications.
Searches can be performed by generic name, brand name, common synonyms, and mnemonics, all of which link to a list organized by generic name. Within generic name listings, drugs are further categorized by dosage form.
The system allows a clear way to communicate a desired deviation from standard administration times.
A data field is included that requires the prescriber to enter the desired dosage form.
The system links drugs to appropriate administration routes only (eg, the system does not allow an intrathecal route selection for vincristine).
A dose selection field is provided in addition to a field for selecting product strength.
All labels and reports, including medication administration records, print the generic name of the drug with brand name as an optional choice.
The system allows for safe ordering of complex dosing regimens, such as tapering schedules, and expresses these orders in a way that is easy to understand for the purposes of dispensing and administering the medication.
The prescriber can specify a time or date to start a drug that is different from the time the order was entered.
The system links ancillary drug therapies to the primary drug therapy (eg, opioids are linked with laxatives) and allows for automatic discontinuation of the ancillary drugs when the primary drug is discontinued.
The system makes it possible to put medication orders on hold for specified conditions and to communicate when a drug is being held.
The system allows for complete access to free texting in the pharmacy and nursing systems but only limited access in CPOE.

Error Rates and Key Findings – Long-Term Care

In a 4-month study of 631 errors among 2,731 incident reports submitted by nurses from 23 nursing homes, the most common error types were dose omission (32%), overdose (14%), underdose (7%), wrong patient (6%), wrong product (6%), and wrong strength (6%). The error types with the most serious outcomes were wrong patient errors, dose omissions, and overdoses. Of all incidents, only 2% occurred during the prescribing phase of the medication use process.[26]

Errors of omission in the long-term care setting may be particularly problematic. The IOM found that 62-75% of assisted-living facility residents with congestive heart failure were not receiving an angiotensin-converting enzyme inhibitor. Seventy-six percent with a past history of myocardial infarction were not receiving beta-blockers, and 60.5% were not receiving aspirin. Of patients in assisted living facilities with a history of stroke, 37.5% had no anticoagulant or antiplatelet agent. Sixty-one percent with osteoporosis were not receiving calcium. Only 53% of ideal candidates with atrial fibrillation were receiving warfarin. Between 45% and 80% of patients had unrelieved pain. Only 15% on nonsteroidal anti-inflammatory drugs were receiving gastroprotective agents.[1]

Improvement Strategies – Long-Term Care

Educational visits appear to be a promising intervention for improving prescribing practices and patient outcomes in long-term care, as well as involving pharmacists in medication management. The best evidence to date is for pharmacist involvement in managing specific conditions like diabetes. Interventions to reduce medication errors in the long-term care setting include regulation, educational initiatives, physician feedback, medication management programs, and implementation of technology.[1]

General Recommendations for Good Prescribing

In addition to the specific recommendations for reducing medication errors that have been provided by the Institute of Medicine, Institute for Safe Medication Practices and others, the World Health Organization issued a practical manual on good prescribing practices. The Guide to Good Prescribing aimed to improve the overall quality of prescribing, addressing both medication safety and rational use of therapeutics.[27] A modified version was recently published by the American Academy of Family Physicians.[28]

Although geared toward undergraduate medical students entering clinical rotations, the World Health Organization's *Guide to Good Prescribing* can serve as a practice model for interdisciplinary safety teams, who could potentially incorporate the recommendations into systems initiatives, and can be useful for any prescriber interested in best practices. The contents were field tested in a sample of over 200 medical students at 7 universities around the world, from Kathmandu to San Francisco, and shown to significantly improve students' performance in tackling complex patient medication problems. The *Guide to Good*

Prescribing advocates developing a personal repertoire of medications, following a systematic 6-step approach to treating patients, and keeping up-to-date on drug therapy.[27]

Selecting a Personal Drug List

One of the basic foundations of the *Guide to Good Prescribing* is the concept of personal drugs or "P-drugs." P-drugs represent a physician's predetermined drugs of first choice for particular indications, much like a drug formulary within a health system or hospital. The routine use of selected medications allows for improved familiarity and potentially reduced errors.[27]

The first step in selecting a P-drug is to define the diagnosis. Next, the prescriber should determine the ultimate therapeutic goal. Goals may include disease prevention, symptom management, disease modification, or cure. The ideal therapeutic goal should always be kept in mind. For example, although many oncology drugs are initially approved for marketing based on studies of surrogate endpoints like tumor response, the ultimate goal is usually prolonged survival.[27]

The prescriber can then consider the entire universe of potential drug therapy options and narrow the choices, primarily by considering the drug's proven efficacy in achieving the ultimate goal of therapy. For some conditions, the time to onset of efficacy can be relevant. The next criteria to consider are safety, suitability, and cost. Although suitability can be patient-specific, a general preference for oral dosage forms and drugs that require fewer doses per day will likely accommodate more patients than injectable products, for example, or drugs with complex dosing schedules.[27]

Based on these factors, it is then possible to choose an active substance and dosage form, a standard schedule for administration, and a standard treatment duration that will meet the needs of most patients. An advantage of this level of forethought is that, in working through the best choices for the average patient, the clinician will encounter and consider the choices that may be important for more unusual patients.[27] In hospital or long-term-care settings with closed formularies, many of these steps may have already been completed for the prescriber, narrowing the range of therapy options requiring exploration.

Treating Patients

The World Health Organization (WHO) advocated a 6-step approach to treating patients: defining the patient's problem, setting the therapeutic objective, determining whether the usual P-drug is appropriate for a specific patient, starting therapy, providing relevant information to the patient, and monitoring or stopping the therapy. New practitioners were cautioned not to merely copy the prescriptions written by more senior prescribers but to work through the steps themselves.[27]

Step 1: Define the problem. The patient's problem can be determined by listening to the patient's chief complaints or questions, taking a thorough history, observing the patient, and conducting physical examinations and lab tests. In addition to a symptom or disease requiring treatment, the underlying problem could also be an adverse drug effect, evidence of poor compliance, the need for a drug refill, a psychological prob-

Table 5. Potential Drug Information Sources and Factors to Consider[27]

Reference books	Frequency of new editions, comparative therapeutic data, expense
Drug compendia	Completeness, frequency of new editions, comparative therapeutic data, and expense
National drug lists and guidelines	Availability within the U.S., currency
Drug formularies	Comparative therapeutic data, cost information
Drug bulletins	Funding source, inclusion of practical recommendations
Medical journals	General versus specialized scope, peer review, funding source
Verbal information from specialists, colleagues, or pharmacists	Availability of the individual, application to practice
Drug information centers	Resources available to the center, center affiliation
Computerized information sources	Update frequency, hardware and software requirements
Pharmaceutical industry information sources	Inherent bias, time costs, need for critical evaluation

Table 6. National Organizations that Track Medication Errors[29]

The Food and Drug Administration 5600 Fishers Lane Rockville MD 20857-0001 1-800-332-1088 www.fda.gov/medwatch/how.htm	The Food and Drug Administration accepts reports from consumers and health professionals about the products it regulates through MedWatch, a safety information and adverse event reporting program.
Institute for Safe Medication Practices 1800 Byberry Rd., Suite 810 Huntingdon Valley, PA 19006-3520 215-947-7797 www.ismp.org/Pages/Consumer.html	The Institute for Safe Medication Practices accepts reports from consumers and health professionals related to medication and publishes newsletters on medication errors and patient safety.
U.S. Pharmacopeia www.medmarx.com 12601 Twinbrook Parkway Rockville, MD 20852 1-800-822-8772 www.usp.org	The Medication Errors Reporting (MER) Program is a voluntary national medication error reporting program.

Pharmacists in work settings without routine reporting systems should consider sharing medication error experiences with national organizations that can use the data to its best effect.

lem, an interest in disease prevention, or some combination of these. Many problems will not require drug therapy at all.[27]

Step 2: Set the goal of therapy. Goals should be obtainable and should match the underlying problem. When the patient is engaged in a discussion of the therapeutic goals, compliance can improve.[27]

Step 3: Determine whether the P-drug is appropriate. This step allows for tailoring of drug therapy beyond the prescriber's usual drugs of choice. Considerations include whether the drug can be expected to be effective for the particular patient's situation, whether convenience or other factors are likely to affect compliance, and whether safety concerns specific to the particular patient, such as drug-drug or drug-disease interactions, are a barrier to use. Even if the P-drug is appropriate, this step should include an assessment of the standard dose and duration of treatment, which might need adjustment. If the P-drug would be effective only with a difficult dosing regimen or extended duration of treatment, selecting an alternative agent might be warranted.[27]

Step 4: Initiate therapy by writing the prescription or order. The WHO mandates the inclusion on the prescription of the patient's age if the patient is a child or senior adult. The use of the generic name instead of the brand name and of the local language instead of Latin is encouraged, and the use of decimals, abbreviations, and vague instructions like "as directed" or "as before" is discouraged.[27]

Step 5: Provide information, instructions, and warnings. The WHO supports patient education as a method for ensuring optimal drug use. A patient who understands the expected benefits of a medication, its adverse effects, how to use it, safety precautions, and monitoring requirements is more likely to comply with therapy, to avoid medication errors, and to appropriately seek help if problems arise.[27]

Step 6: Monitor or stop treatment. Some therapies will require specific laboratory or other monitoring; in other cases, monitoring can be accomplished passively, by having the patient call if the drug does

not appear to be working, or actively, at a routine follow-up visit. If the patient's problem has been solved, such as when an infection is cured, drug therapy can be stopped. Effective and well-tolerated treatments for ongoing medical problems can be continued, while ineffective therapies should prompt a reassessment of the original diagnosis, therapeutic objective, drug selection, prescription, patient instructions, and monitoring plan.[27]

Staying Current on Drug Therapies

Similar to the strategy for selecting a list of P-drugs, the WHO recommended that all prescribers make an inventory of the drug information resources available to them, weigh their advantages and disadvantages, and establish a repertoire of reliable and familiar sources. The guidelines identified the potential information sources and factors to consider when evaluating their utility, as shown in Table 5. For the average practitioner, regular use of at least 1 journal, 1 book, and 1 bulletin, supplemented with information from therapeutics committees or specialists, was promoted as a way to stay up-to-date on drug therapies. Additional resources could be tapped for specific patient care dilemmas.[27]

Barriers to Reducing Prescribing Errors

Reporting Limitations

The less a problem is understood, the more difficult it can be to solve. Underreporting of prescribing errors is probably significant. In a study of 3,875 incident reports from 2 hospitals, only 1.9% of all reports were filed by physicians, even though physicians were the providers involved in potentially preventable incidents 16% of the time. Two theories were advanced for why hospital incident reports likely underestimate errors involving physician care: (1) Traditionally, hospitals have addressed issues with physician care through peer review, credentialing, and morbidity and mortality conferences, and (2) physicians are thought to be the most likely to identify a physician error, and their participation in reporting is consistently low.[29]

Based on surveys of 120 internal medicine physicians at an academic medical center, Schectman and Plews-Ogan reported that only 65% and 52% of physicians and medical residents, respectively, had filed an adverse event or near-miss report in the past year, even though 60% and 75% of them, respectively, had witnessed at least 3 events or near misses during that time period. Only 39% said they knew how to report an adverse event or near miss. The top 3 barriers to reporting cited by physicians were uncertainty about the reporting mechanism, lack of actual harm to the patient, and reporting being too difficult or too time consuming.[30]

Reporting is universally endorsed as a way to improve awareness and understanding of the medication error problem. Pharmacists in work settings without routine reporting systems should consider sharing medication error experiences with national organizations that can use the data to its best effect. National organizations that track medication error reports are listed in Table 6.[31]

Technology Limitations

A recent systematic review comparing prescribing errors with hand-written and computerized physician orders showed that the rates of prescribing the wrong drug did not decrease after implementing computerized physician order entry.[32] Although basic computerized physician order entry can decrease errors downstream from the prescriber, order entry systems without clinical decision support may have limited benefits in the prescribing stage of the medication use process.

An important distinction that is emerging for clinical decision support systems is basic versus advanced systems. Basic clinical support usually provides a checking system for doses, interactions, allergies, formulary status, and therapy duplication. More advanced clinical decision support systems can guide dose selection for patients with advanced age or renal dysfunction, check for drug-pregnancy or drug-disease interactions, and prompt appropriate laboratory test ordering.[33]

Focus groups have shown that physicians were skeptical about the ability of clinical information technologies in general to reduce medication errors. They believed that the solutions offered by current technologies did not fit the underlying problems leading to medication errors, that current software and hardware applications had significant limitations, and that new technologies brought new and different error risks. Many physicians had negative impressions of the impact of information technologies on their time. They were particularly concerned that computerized physician order entry systems take more time to use than manual systems and that computerized physician order entry shifted the burden of data entry to them from ancillary staff such as unit clerks.[34]

Knowledge Limitations

The *Preventing Medication Errors* report identified knowledge deficits among both patients and providers as a major barrier to safe and effective medication use. It further pointed out that attitudes could be a barrier, giving the example of patients' and providers' different beliefs about medication use. The report advocated sweeping changes to strengthen patients' ability to self manage their medications. The IOM called upon government agencies to provide resources for patient drug information and medication self-management, including standardized and widely available drug information leaflets, internet-based health information resources, national drug information telephone help lines, and community-based health resource centers.[1]

Practical Limitations

Practical problems, such as patients' inability to pay for their medications and the burdens imposed on prescribers by third party payers, were also cited in the *Preventing Medication Errors* report as barriers to optimal medication use. Health-care organizations were encouraged to provide complete patient information and decision support tools to patients and providers. The government, industry, and regulatory bodies were encouraged to improve drug product labeling, medication information communication, and standards for health information technology and to motivate the adoption of medication safety technologies and safe practice standards. Finally, the IOM recommended increased funding for the government to fully research medication errors across the various care settings.[1]

Summary/Conclusion

Medication errors are a source of considerable mortality, morbidity, and health-care costs in the U.S. today. Many of these errors originate in the prescribing stage of the medication use process. Opportunities exist for pharmacists to intercept prescribing errors and to lead systems-based approaches to reducing their incidence. Strategies for tackling the problem of medication errors are available from The Institute of Medicine and other national and international organizations. ◆

References

1. Institute of Medicine. Preventing medication errors. Available at http://www.nap.edu/catalog.php?record_id=11623 (accessed 2007 November 1).
2. National Coordinating Council for Medication Error Reporting and Prevention. What is a medication error? Available at http://www.nccmerp.org/aboutMedErrors.html (accessed 2007 November 8).
3. Dean B, Barber N, Schachter M. What is a prescribing error? *Qual Health Care* 2000;9:232-7.
4. Cohen MR. Causes of medication errors. In: Cohen MR (Ed.). *Medication Errors, 2nd edition*. American Pharmacists Association; 2007:55-66.
5. LaPointe NM, Jollis JG. Medication errors in hospitalized cardiovascular patients. *Arch Intern Med* 2003;163:1461-6.
6. Leape LL, Bates DW, Cullen DJ, et al. Systems analysis of adverse drug events. *JAMA* 1995;274(1):35-43.
7. Lesar TS, Briceland L, Stein DS. Factors related to errors in medication prescribing. *JAMA* 1997;277(4):312-7.
8. Lesar TS. Tenfold medication dose prescribing errors. *Ann Pharmacother* 2002;36:1833-9.
9. Garbutt JM, Highstein G, Jelle DB, et al. Safe medication prescribing: training and experience of medical students and housestaff at a large teaching hospital. *Acad Med* 2005;80:594-9.
10. Davydov L, Caliendo G, Mehl B, Smith LG. Investigation of correlation between house-staff work hours and prescribing errors. *Am J Health-Syst Pharm* 2004;61:1130-4.
11. Malone DC, Abarca J, Skrepnek GH, et al. Pharmacist workload and pharmacy characteristics associated with dispensing of potentially clinically important drug-drug interactions. *Med Care* 2007;45:456-62.
12. Hoia ET, Patel M, Mathis AS. Effects of 16-hour shifts on order-verification medication errors by hospital pharmacists. *Am J Health-Syst Pharm* 2007;64:1467-8.
13. Kistner UA, Keith MR, Sergeant KA, et al. Accuracy of dispensing in a high-volume, hospital-based outpatient pharmacy. *Am J Hosp Pharm* 1994;51:2793-7.
14. Bond CA, Raehl CL, Franke T. Clinical pharmacy services, hospital pharmacy staffing, and medication errors in United States hospitals. *Pharmacother* 2002;22(2):134-47.
15. Agency for Healthcare Research and Quality. Making Health Care Safer: A Critical Analysis of Patient Safety Practices. Evidence Report/Technology Assessment: Number 43. AHRQ Publication No. 01-E058, July 2001; Rockville, MD. Available at http://www.ahrq.gov/clinic/ptsafety/ (accessed 2007 November 26).
16. Institute for Healthcare Improvement. Improve Core Processes for Ordering Medications. Available at http://www.ihi.org/IHI/Topics/PatientSafety/MedicationSystems/Changes/Improve+Core+Processes+for+Ordering+Medications.htm (accessed 2007 November 26).
17. Institute for Safe Medication Practices. It's time for standards to improve safety with electronic communication of medication orders. Available at http://www.ismp.org/Newsletters/acutecare/articles/20030220.asp (accessed 2007 November 7).
18. Cohen MR. Preventing prescribing errors. In: Cohen MR (Ed.). Medication Errors, 2nd edition. American Pharmacists Association; 2007:175-203.
19. National Quality Forum. Safe practices for better healthcare, 2006 update. A consensus report. Available at http://www.qualityforum.org/publications/reports/safe_practices_2006.asp (accessed 2007 November 26).
20. Pathways for Medication Safety. Use of the ten key elements to assess risk. Available at http://www.medpathways.info/medpathways/tools/tools.html (accessed 2007 November 26).
21. Thomsen LA, Winterstein AG, Sondergaard B, et al. Systematic review of the incidence and characteristics of preventable adverse drug events in ambulatory care. *Ann Pharmacother* 2007;41(9):1411-26.
22. Devine EB, Wilson-Norton JL, Lawless NM, et al. Characterization of prescribing errors in an internal medicine clinic. *Am J Health-Syst Pharm* 2007;64(10):1062-70.
23. Gurwitz JH, Field TS, Harrold LR, et al. Incidence and preventability of adverse drug events among older persons in the ambulatory setting. *JAMA* 2003;289(9):1107-16.
24. Gandhi TK, Weingart SN, Seger AC, et al. Outpatient prescribing errors and the impact of computerized prescribing. *J Gen Intern Med* 2005;20:837-41.
25. Jones A. The National Nursing Home Survey: 1999 summary. National Center for Health Statistics. *Vital Health Stat* 13(152). 2002.
26. Pierson S, Hansen R, Greene S, et al. Preventing medication errors in long-term care: results and evaluation of a large scale web-based error reporting system. *Qual Saf Health Care* 2007;16:297-302.
27. de Vries TP, Henning RH, Hogerzeil HV, et al. Guide to good prescribing. A practical manual. World Health Organization Action Programme on Essential Drugs. Available at http://whqlibdoc.who.int/hq/1994/WHO_DAP_94.11.pdf (accessed 2007 November 16).
28. Pollock M, Bazaldua OV, Dobbie AE. Appropriate prescribing of medications: an eight-step approach. *Am Fam Physician* 2007;75:231-6, 239-40.
29. Nuckols TK, Bell DS, Liu H, et al. Rates and types of events reported to established incident reporting systems in two U.S. hospitals. *Qual Saf Health Care* 2007;16:164-8.
30. Schectman JM, Plews-Ogan ML. Physician perception of hospital safety and barriers to incident reporting. *J Qual Patient Saf* 2006;32(6):337-43.
31. Food and Drug Administration. Strategies to Reduce Medication Errors: Working to Improve Patient Safety. Available at http://www.fda.gov/fdac/special/testtubetopatient/safety.html (accessed 2007 November 10).
32. Shamliyan TA, Duval S, Du J, Kane RL. Just what the doctor ordered. review of the evidence of the impact of computerized physician order entry system on medication errors. Health Serv Res 2007; available at http://www.blackwell-synergy.com/doi/abs/10.1111/j.1475-6773.2007.00751.x.
33. Kuperman GJ, Bobb A, Payne TH, et al. Medication-related clinical decision support in computerized provider order entry systems: a review. *J Am Med Inform Assoc* 2007;14:29-40.
34. McAlearney AS, Chisolm DJ, Schweikhart S, et al. The story behind the story Physician skepticism about relying on clinical information technologies to reduce medical errors. *Int J Med Inform* 2007;76:836-42.

Attachment 5

Background Information on "Just Culture"

Benefits of a Just Culture

Background:

The term "Just Culture" refers to a safety-supportive system of shared accountability where health care organizations are accountable for the systems they have designed and for responding to the behaviors of their staffs in fair and just manners. Staff, in turn, are accountable for the quality of their choices and for reporting both their errors and system vulnerabilities.

This model is designed to help change an organization's culture by placing less focus on events, errors, and outcomes, and more focus on risk, system design, and the management of behavioral choices. In this model, errors and outcomes are the outputs to be monitored; system design and behavioral choices are the inputs to be managed.

Benefits for Patients and Families:

- Safer care – Patients receive care from organizations with a learning culture, organizations that treat all providers and staff in an open and fair manner, organizations that design safe systems and manage the behavioral choices of everyone in the organization.
- Clear expectations of what should happen when things go wrong, and an understanding of how best to hold organizations accountable (for individual patients and to the public).

Benefits for Employees and Staff:

- Employees work in a just system that is neither punitive nor blame free – but a system of shared accountability between individual providers, employee, health care institutions, and regulators.
- Employees and staff have an objective framework for fair and constructive response to errors and events.
- Managers have a practical tool to guide consistent, objective, and fair evaluations of behavior leading to errors or events.
- Individuals have a framework to evaluate their own behavioral choices.

Benefits for the Organization:

- An environment of internal transparency around risk;
- Reduced risk and prioritized interventions – this is possible in organizations with open, fair and learning cultures, and in organizations that design safe systems and manage the behavioral choices of everyone working in and for the organization;
- A framework for *proactive* management of system design and management of behavioral choices, and
- When adverse events occur, the organization has an objective framework for a fair and constructive response to errors and events.

"Fair and Just Culture" Fact Sheet

CAPSAC promotes a "fair and just culture." What does this mean?

The "fair and just culture" principle that CAPSAC advocates is an approach to medical event reporting that emphasizes learning and accountability over blame and punishment. It is built on the recognition that ***to err is human*** and that simply forbidding errors ***or penalizing individual(s)*** cannot prevent errors. However, by learning from errors through better event reporting, health care providers can improve safeguards and reduce the chance of future errors.

Where does the idea of a "fair and just culture" come from?

The principles of a fair and just culture are based on research by human behavior and management experts such as James Reason, Ph.D., and David Marx, J.D. Their work has shown that how an organization responds to errors can make a critical difference in preventing future errors from occurring. The most effective way of preventing errors, they find, is to accept that humans will act in unpredictable ways that may lead to mistakes. By understanding how each error occurred, the system can make changes to prevent errors or mitigate their effects.

Will non-punitive reporting lead to a loss of individual accountability?

It seems counterintuitive that reducing blame would reduce errors, but blame and accountability are not necessarily connected. Adopting a fair and just culture does not mean throwing out an organization's disciplinary system. Instead, it means changing that system to focus on future error prevention rather than individual punishment. Dr. Reason's work, in particular, addresses how to do this. He developed an "unsafe acts algorithm" for deciding when an individual's error should be managed through a system change – like a change in staff training, the work environment or a process – or a traditional disciplinary action such as firing the employee. In a fair and just culture, an individual is accountable to the system, and the greatest error is to not report a mistake, and thereby, prevent the system and others from learning.

How do we know this approach works?

Other safety-conscious industries, such as the airline industry, and health care providers in other states have been able to reduce system problems that lead to errors by adopting the principles of a fair and just culture. When these principles are adopted, health care organizations and regulatory agencies investigate all reports to identify and correct the systems and processes of care that contributed to the medical error or near miss; they do not assign blame. By feeling protected by this non-punitive culture of medical error reporting, health care organizations and providers report more errors and near misses, which further allow patient safety improvements.

Why is it important to focus on a "fair and just culture" now?

In recent years, health care providers, consumers, regulators and legislators have become increasingly focused on reducing medical errors. However, there has not been an advocacy organization in place to help all these parties learn about best practices from other systems. Through promoting a fair and just culture in medical event reporting, we can make current efforts to improve patient safety more effective and prevent potential problems associated with punitive regulatory and legislative changes.

California Patient Safety Action Coalition Fact Sheet

What is CAPSAC?

The California Patient Safety Action Coalition (CAPSAC) is a group of representatives from more than 20 of the state's leading public and private health care industry organizations who share the common goal of enhancing patient safety and increasing reporting of near misses and medical errors.

Who are the members of CAPSAC?

Representatives from a diverse group of health care industry stakeholders guide the coalition.

- Association of California Nurse Leaders
- Brightline/Beacon
- California Children's Hospital Association
- California Department of Managed Health Care
- California Department of Public Health
- California Hospital Association
- California Leaders Network Alumni-Patient Safety Task Force
- California Medical Association
- California Primary Care Association
- Catholic Healthcare West
- Cedar Sinai Medical Center
- Center for Patient Safety, School of Nursing, UCSF
- Community Clinics of Santa Clara and Contra Costa Counties
- Community Medical Centers
- County and Safety-Net Provider Organizations
- The Doctor's Company
- HealthCare Partners
- Hospital Association of Southern California
- Hospital Council of Northern and Central California
- Kaiser Permanente
- Los Angeles County Department of Health Services
- Lumetra
- Marsh Risk and Insurance Services
- Palo Alto Medical Foundation
- Sutter Health
- The Woodland Clinic

In addition, ad hoc members include: the California Association of Physician Groups, domain experts, and representatives of similar organizations in other states.

What makes CAPSAC's approach to increasing patient safety different from others?

Many institutions assume medical errors are caused by negligent individuals and organizations, and as such, can and should be prevented by assigning blame and punishment. This creates a culture in which health care providers are afraid to report errors and near misses. In contrast, CAPSAC members believe that a strictly punitive approach to the handling of medical errors can actually make things more unsafe by creating an incentive to not report possible safety concerns and errors. The CAPSAC approach to protecting the public from medical errors is to focus on making systems better and not on punishing individuals.

What is CAPSAC's goal?

CAPSAC wants to change the current culture of blame and punishment to one of trust and accountability by promoting the principles of a "fair and just culture" medical event reporting system. A "fair and just culture" in health care organizations is characterized by everyone throughout the organization being aware that medical errors are inevitable, but by reporting all errors and unintended events – even when the events may not cause patient injury – they can make the system safer.

California
Patient Safety Action Coalition
CAPSAC

California Statement of Support for a Statewide Culture of Learning, Justice and Accountability

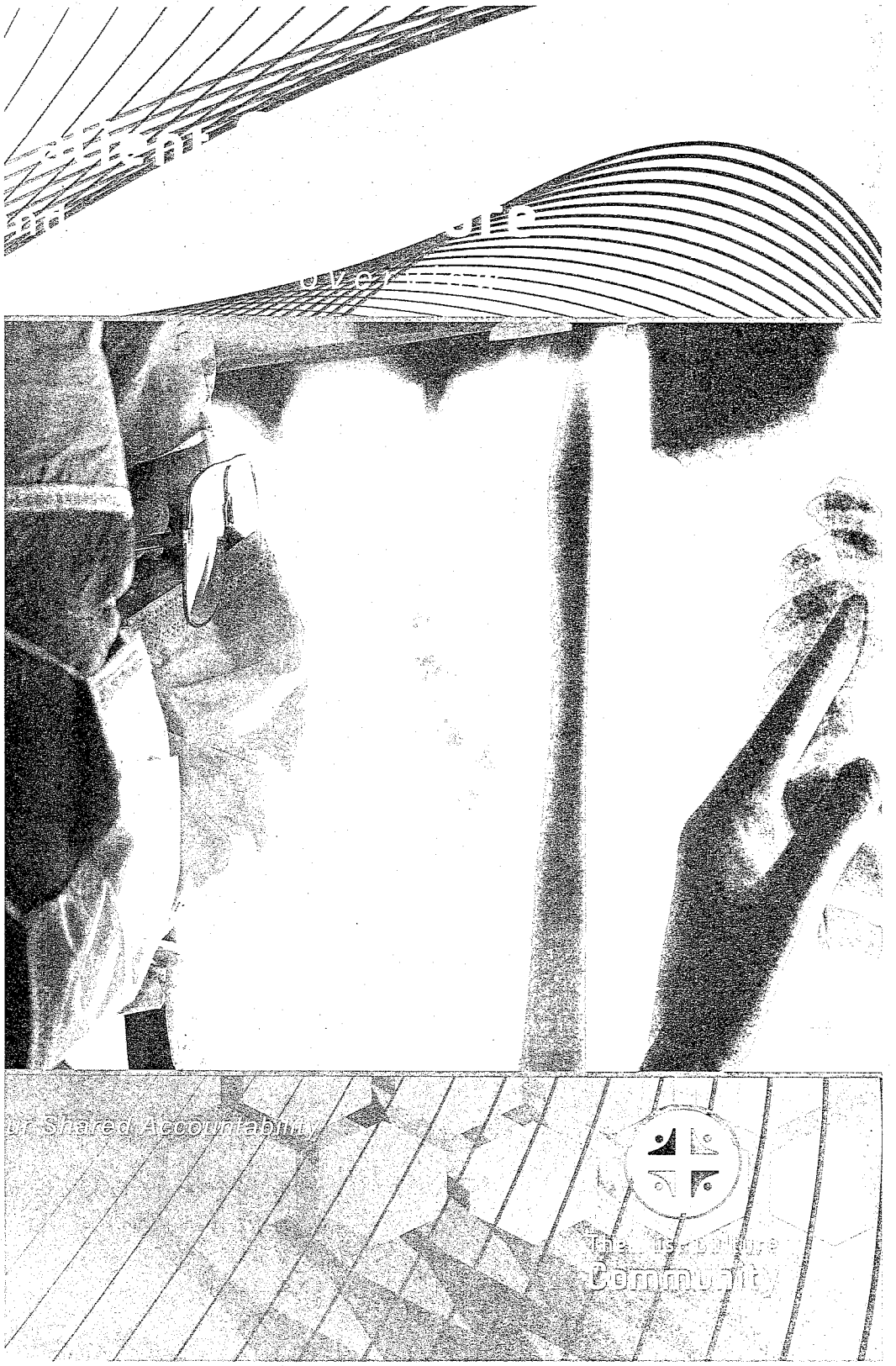
Given that:

- Medical errors and patient safety are a national concern to all involved in health care delivery.
- We are legally and ethically obligated to hold individuals accountable for their competency and behaviors that impact patient care.
- A punitive environment does not fully take into account systems issues, and a blame-free environment does not hold individuals appropriately accountable.

We resolve that our organization will:

- Strive for a culture that balances the need for a non-punitive learning environment with the equally important need to hold persons accountable for their actions.
- Seek to distinguish between human error, at-risk behavior and reckless behavior, without regard to the severity of the error.
- Foster a learning environment that encourages the identification and review of all errors, near-misses, adverse events and system weaknesses.
- Promote the use of a wide range of responses to safety-related events caused by lapses in human behavior, including coaching, non-disciplinary counseling, additional education or training, demonstration of competency, additional supervision and oversight, and disciplinary action when appropriate, to address performance issues.
- Support and implement systems that enable and sustain safe behavior to prevent harm.
- Work to share information across organizations to promote continuous improvement and ensure the highest level of patient and staff safety.
- Collaborate in efforts to establish a statewide culture of learning, justice and accountability to provide the safest possible environment for patients.

(signature)	*(date)*
(printed name)	*(title)*
(organization)	*(city and state)*


Shared Accountability
Community

A patient does not recognize the signs of a heart attack…

A nurse delivers the correct medication, but to the wrong patient…

A unit clerk misreads an order…

A pharmacist pulls the wrong drug from the shelf...

A physician does not detect a rare life-threatening illness…

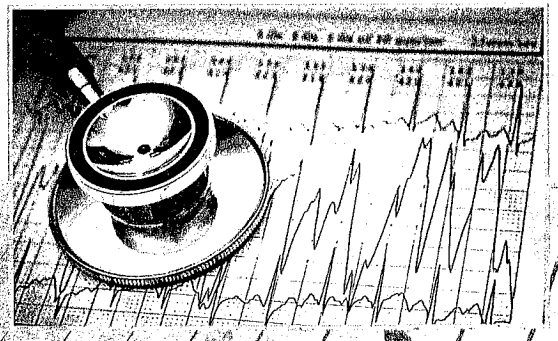
A unit manager cannot find nurses to provide adequate coverage...

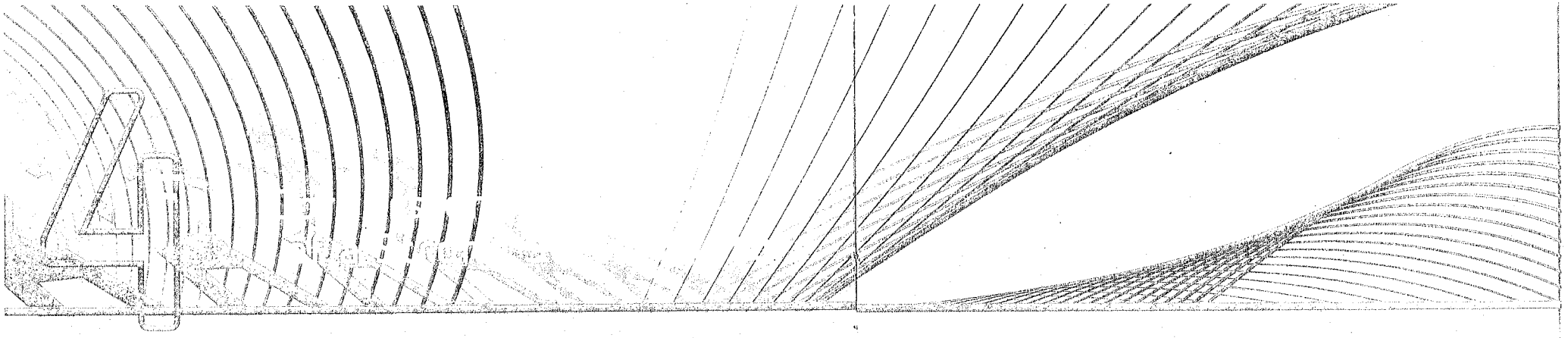
An IV pump designer does not recognize how her design might be misused…

A CFO underestimates the actual cost of the new electronic health record…

There is arguably no more complex business than that of healthcare. At bedside, healthcare providers must tend to the safety, dignity, privacy, comfort, and medical needs of their patient – all within an ever-changing environment of care.

To take the next steps, we must change our health-care culture – not by demanding perfection, but instead by designing safer systems and being more critical of our everyday choices within those systems. As healthcare providers, we are entrusted with the care of a nation. It is our safety culture that will influence how well we fulfill that trust.





one Create a Learning Culture...

A learning culture is the foundation of patient safety. It is a culture that is hungry for knowledge - in the case of patient safety, it is a culture that is eager to understand risk at both the individual and organizational level. We can see risk through events and near misses. We can see risk by observing the design of the systems in which we work, our behaviors, and the behaviors of those around us. We must all be willing to learn from our mistakes and to share this learning in a manner that supports system design and continued safe choices.

two Create an Open and Fair Culture...

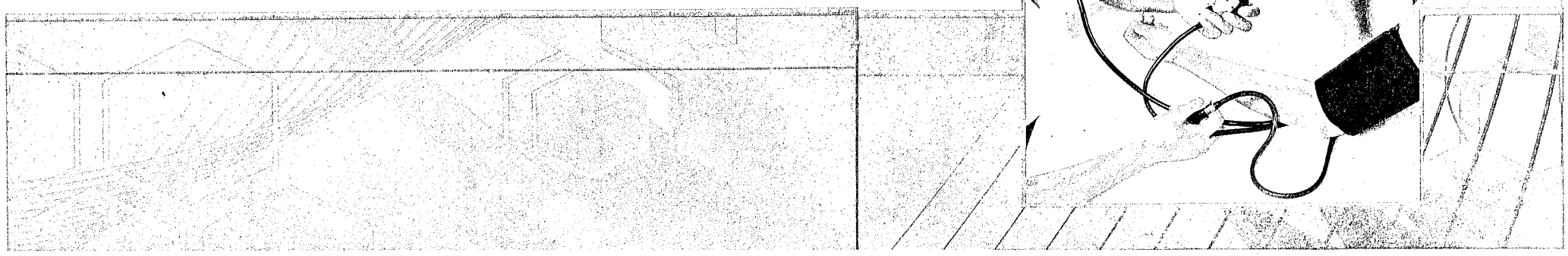
To create a learning environment, organizations must move away from an overly-punitive reaction to events and errors. We must ask the erring provider to report the event so that others may not be denied the learning opportunity. That being said, a strong safety culture is one that reinforces accountability for safety across all levels of the organization from CEO to staff. It is a system of accountability that does not focus on the human error or the unintended consequences but rather focuses on the quality of our decisions as components of the healthcare system. From CEO to staff, we must be accountable to our patients for the choices we make as their caregivers.

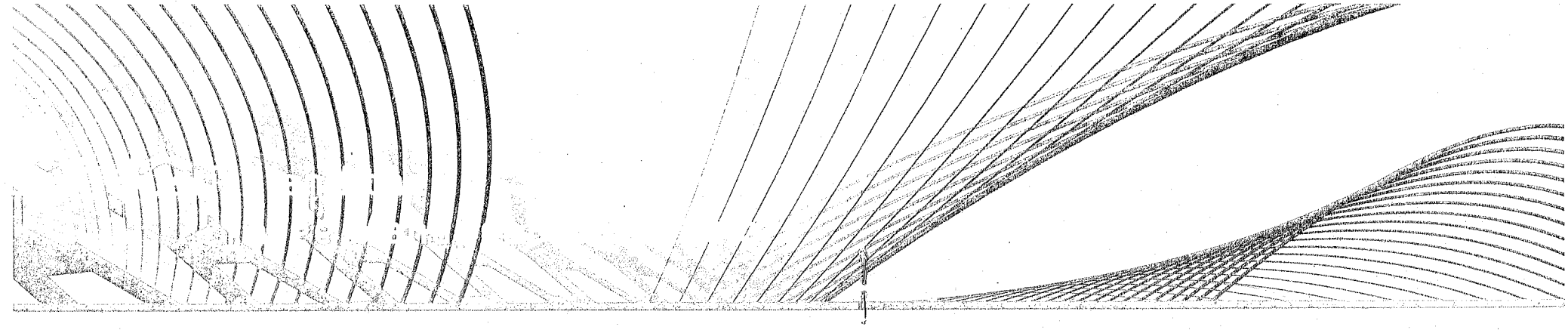
three Design Safe Systems...

It is the system in which we work that has the greatest overall influence on the safety of the patient. We must design healthcare delivery systems that anticipate human error, capture errors before they become critical, and permit recovery when errors do reach the patient.

four Manage Behavioral Choices...

While we must anticipate that we as humans will make mistakes, it is our management of behavioral choices that will allow us to achieve the safety outcomes we desire. A strong safety-culture puts a premium on critical decision making skills – and asks every healthcare provider to continuously evaluate the risks inherent in the choices they make.





The term, "Just Culture," refers to a safety-supportive system of shared accountability where healthcare institutions are accountable for the systems they have designed and for supporting the safe choices of patients, visitors, and staff. Staff, in turn, are accountable for the quality of their choices - knowing that we cannot will ourselves to be perfect, but we can strive to make the best possible choices available.

To err is human ...

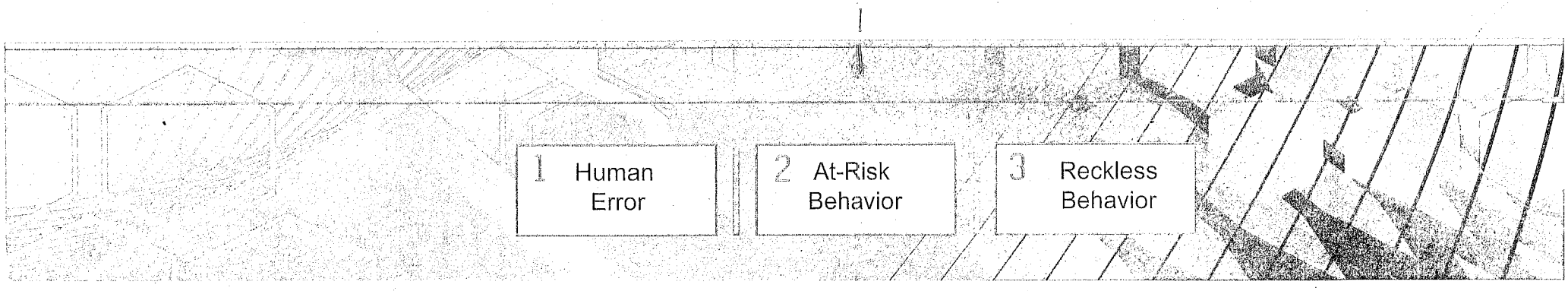
As healthcare providers, we all make mistakes even when trying our best. When they do occur, we must learn to see these errors in the context of the system we are in, and of the systems we have created to manage the individual errors in that system. Knowing that "to err is human," a strong safety culture is one that designs its systems anticipating that healthcare providers will be susceptible to slips, lapses, and mistakes. A strong safety culture is one that sees the single failure path (one human error or one equipment failure away from harm) as a sign of system vulnerability.

To drift is human ...

While we may not like to admit it, not only do humans err, but we drift away from safe behaviors as well. As our perceptions of risk fade and we try to accomplish more with fewer resources and less time, we all begin to drift away from the behaviors we have been taught. A strong patient safety culture is one that anticipates these at-risk behaviors and designs barriers and controls to keep healthcare providers on the safest possible path.

Occasionally, the reckless act...

While we like for it to be rare, we can also anticipate that humans will put their own self-interest ahead of those they serve. Reckless behavior, where practitioners know they have put patients into an unsafe place, must be addressed through a strong disciplinary or punitive response. In this third behavior, accountability rests wholly with the individual who chooses the reckless act.



Management

For managers of a healthcare institution, the task in developing a strong safety culture involves:

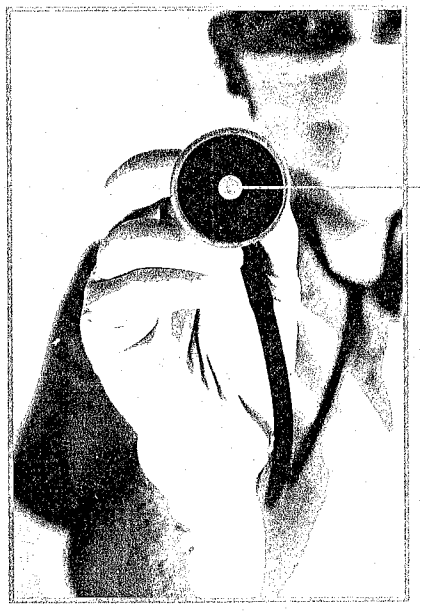
- Creating an open learning environment
- Learning when to console and when to coach employees
- Committing to the limited use of warnings and punitive actions in the narrow circumstances where it will benefit system safety
- Striving to understand why human errors occur within the organization
- Striving to understand why at-risk behaviors occur within the organization
- Learning to see common threads – to prioritize risk and interventions
- Working with staff to design systems that reduce the rate of human error and at-risk behavior, or mitigate their effects
- Learning to measure patient safety risk, at both the unit and organizational level

Providers and Staff

For providers and staff, the patient safety tasks involve:

- Looking for risks in the systems in which we work
- Looking for risk in our own behavioral choices
- Evaluating risk versus benefit – looking for the risks that do not provide value to those we serve
- Reporting hazards and adverse events
- Participating in the learning culture – being open and honest about what happened
- Always making safe choices

No human endeavor can be risk-free. Healthcare is no exception. We are fallible human beings – we design imperfect systems and make imperfect choices.

Patient safety is not about willing ourselves to be perfect; rather, it is about designing robust systems around the healthcare provider and relying on them to make safe choices within those systems.

We cannot guarantee perfect outcomes for our patients, but we can commit to being the best stewards of the limited resources we have to meet the demands put on the healthcare system.