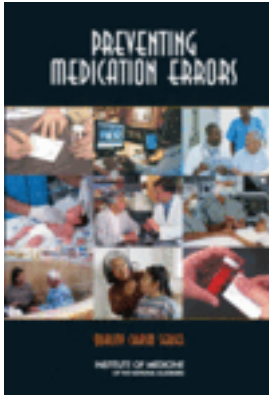


Free Executive Summary



Preventing Medication Errors: Quality Chasm Series

Committee on Identifying and Preventing Medication Errors, Philip Aspden, Julie Wolcott, J. Lyle Bootman, Linda R. Cronenwett, Editors

ISBN: 0-309-10147-6, 544 pages, 6 x 9, hardback (2007)

This free executive summary is provided by the National Academies as part of our mission to educate the world on issues of science, engineering, and health. If you are interested in reading the full book, please visit us online at <http://www.nap.edu/catalog/11623.html>. You may browse and search the full, authoritative version for free; you may also purchase a print or electronic version of the book. If you have questions or just want more information about the books published by the National Academies Press, please contact our customer service department toll-free at 888-624-8373.

In 1996 the Institute of Medicine launched the Quality Chasm Series, a series of reports focused on assessing and improving the nation's quality of health care. Preventing Medication Errors is the newest volume in the series. Responding to the key messages in earlier volumes of the series—To Err Is Human (2000), Crossing the Quality Chasm (2001), and Patient Safety (2004)—this book sets forth an agenda for improving the safety of medication use. It begins by providing an overview of the system for drug development, regulation, distribution, and use. Preventing Medication Errors also examines the peer-reviewed literature on the incidence and the cost of medication errors and the effectiveness of error prevention strategies. Presenting data that will foster the reduction of medication errors, the book provides action agendas detailing the measures needed to improve the safety of medication use in both the short- and long-term. Patients, primary health care providers, health care organizations, purchasers of group health care, legislators, and those affiliated with providing medications and medication-related products and services will benefit from this guide to reducing medication errors.

This executive summary plus thousands more available at www.nap.edu.

Copyright © National Academy of Sciences. Permission is granted for this material to be shared for noncommercial, educational purposes, provided that this notice appears on the reproduced materials, the Web address of the online, full authoritative version is retained, and copies are not altered. To disseminate otherwise or to republish requires written permission from the National Academies Press.

Summary

ABSTRACT

The use of medications is ubiquitous. In any given week, more than four of five U.S. adults take at least one medication (prescription or over-the-counter [OTC] drug, vitamin/mineral, or herbal supplement), and almost a third take at least five different medications.¹ Errors can occur with any of these products at any point in the medication use process and in any care setting. The frequency of medication errors and preventable medication-related injuries represents a very serious cause for concern.

The Centers for Medicare and Medicaid Services sponsored this study by the Institute of Medicine with the aim of developing a national agenda for reducing medication errors based on estimates of the incidence of such errors and evidence on the efficacy of various prevention strategies. The study focused on the safe, effective, and appropriate use of medications in the major components of the medication use system, addressing the use of prescription drugs, OTC drugs, and complementary and alternative medications, in a wide range of care settings—hospital, long-term, and community.

The committee estimates that on average a hospital patient is subject to at least one medication error per day, with considerable variation in error rates across facilities. The few existing studies of the costs associated with medication errors are limited to the health care costs associated with preventable injuries, and these are substantial.

At least a quarter of all medication-related injuries are preventable. Many efficacious error prevention strategies are available especially for hospital care; examples are electronic prescribing and clinical decision-support systems that check dosages and monitor for harmful drug-drug interactions. This report provides guidance on how to implement error prevention strategies in hospitals, long-term care, and ambulatory care.

Establishing and maintaining a strong provider-patient partnership is a key approach for reducing medication errors. The report outlines how such a partnership can be achieved and what roles providers, patients and third parties must play. For example, consumers should maintain careful records of their medications, providers should review a patient's list of medications at each encounter and at times of transition between care settings (for example, hospital to outpatient care), and the federal government should seek ways to improve the quality of pharmacy leaflets and medication-related information on the Internet for consumers.

Health care providers in all settings should seek to create high-reliability organizations that constantly improve the safety and quality of medication use. To this end, they should implement active internal monitoring programs so that progress toward improved medication safety can be accurately demonstrated. The report offers guidance on appropriate monitoring systems for each major care setting.

In carrying out this study the IOM committee identified enormous gaps in the knowledge base with regard to medication errors. Current methods for generating and communicating information about medications are inadequate and contribute to the incidence of errors. Likewise, incidence rates of medication errors in many care settings, the costs of such errors, and the efficacy of prevention strategies are not well-understood. The report proposes a research agenda to address these and other knowledge gaps.

¹ In this report, the terms "medication" and "drug" are used interchangeably.

STUDY SCOPE

The Institute of Medicine (IOM) report *To Err Is Human: Building a Safer Health System* (IOM, 2000) accelerated existing efforts to prevent medication errors and improve the quality of health care, efforts that are just now gaining acceptance as a discipline requiring investment in individuals who specialize in error prevention and quality improvement. Against this background, at the urging of the Senate Finance Committee, the United States Congress directed the Centers for Medicare and Medicaid Services (CMS) to contract with the IOM for a study to formulate a national agenda for reducing medication errors by developing estimates of the incidence of such errors and determining the efficacy of prevention strategies (see Box S-1).

BOX S-1 Scope of the Study

Congress through the Medicare Modernization Act of 2003 (Section 107(c)), mandated the Centers for Medicare and Medicaid Services to sponsor the Institute of Medicine to carry out a study:

- To develop a fuller understanding of drug safety and quality issues through the conduct of an evidence-based review of the literature, case studies and analysis. This review will consider the nature and causes of medication errors; their impact on patients; and the differences in causation, impact and prevention across multiple dimensions of health care delivery including patient populations, care settings, clinicians, and institutional cultures.
- If possible, to develop estimates of the incidence, severity and costs of medication errors that can be useful in prioritizing resources for national quality improvement efforts and influencing national health care policy.
- To evaluate alternative approaches to reducing medication errors in terms of their efficacy, cost-effectiveness, appropriateness in different settings and circumstances, feasibility, institutional barriers to implementation, associated risk, and quality of evidence supporting the approach.
- To provide guidance to consumers, providers, payers, and other key stakeholders on high-priority strategies to achieve both short-term and long-term drug safety goals, to elucidate the goals and expected results of such initiatives and support the business case for them, and to identify critical success factors and key levers for achieving success.
- To assess opportunities and key impediments to broad nationwide implementation of medication error reductions, and to provide guidance to policy-makers and government agencies in promoting a national agenda for medication error reduction.
- To develop an applied research agenda to evaluate the health and cost impacts of alternative interventions, and to assess collaborative public and private strategies for implementing the research agenda through the Agency for Healthcare Research and Quality and other government agencies.

PREPUBLICATION COPY: UNCORRECTED PROOFS

THE LEVEL AND CONSEQUENCES OF MEDICATION ERRORS ARE UNACCEPTABLE

Rates of Errors and Preventable Harmful Events Are High

The frequency of medication errors and preventable adverse drug events (ADEs) (defined in Box S-2) is a very serious cause for concern. In hospitals, errors are common during all steps of the medication-use process—procuring the drug, prescribing, dispensing, administering and monitoring the patient’s response. In hospitals, they occur most frequently at the prescribing and administration stages.

Published error rates depend on the intensity and specifics of the error detection methods used. In particular, some methods are better suited to certain stages of the medication-use process. Detection methods addressing all stages but not including direct observation of administration found a rate of 0.1 prescribing errors per patient per day in a study of hospital pediatric units (Kaushal et al., 2001) and a rate of 0.3 prescribing errors per patient per day in a study of hospital medical units (Bates et al., 1995a). A major study using direct observation of administration (Barker et al., 2002) carried out at 36 different health care facilities, found an administration error rate of 11 percent, excluding doses administered outside the scheduled time (“wrong-time” errors). Since a hospital patient receives on average at least ten medication doses per day, this figure suggests that on average, a hospital patient is subject to one administration error per day. Further, since prescribing and administration errors account for about three-fourths of medication errors (Leape et al., 1995), the committee conservatively estimates that on average, a hospital patient is subject to at least one medication error per day. Substantial variations in error rates are found, however. For the 36 facilities in the study mentioned above, the administration error rate (excluding wrong-time errors) ranged from 0 to 26 percent, with a median value of 8.3 percent (Barker et al., 2002).

A preventable ADE is a serious type of medication error. ADEs, defined as any injury due to medication (Bates et al., 1995b), are common in hospitals, nursing homes, and the outpatient setting. ADEs associated with a medication error are considered preventable. The committee estimates that at least 1.5 million preventable ADEs occur each year in the United States:

- Hospital care—Classen and colleagues (1997) projected 380,000 preventable ADEs occurring annually and Bates and colleagues (1995b) 450,000. These are likely underestimates given the higher preventable ADE rate of another study using more comprehensive ADE identification methods (Jha et al., 1998).
- Long-term care—Gurwitz and colleagues (2005) projected 800,000 preventable ADEs, again likely an underestimate given the higher ADEs rates of other studies.
- Ambulatory care—Among outpatient Medicare patients alone, Gurwitz and colleagues (2003) projected 530,000 preventable ADEs. Their approach was conservative, however, because it did not involve direct contact with patients, which yields much higher rates (Gandhi et al., 2003).

The above data exclude errors of omission—failure to prescribe medications for which there is an evidence base for the ability to reduce morbidity and mortality. With respect to such errors, the committee found well-documented evidence of inadequate treatments for acute coronary syndromes, heart failure, chronic coronary disease, and atrial fibrillation, as well as inadequate antibiotic and thrombosis prophylaxis in hospitals.

PREPUBLICATION COPY: UNCORRECTED PROOFS

BOX S-2 Key Definitions

Error: The failure of a planned action to be completed as intended (error of execution) or the use of a wrong plan to achieve an aim (error of planning). An error may be an act of commission or an act of omission (IOM, 2004).

Medication error: Any error occurring in the medication use process (Bates et al., 1995a).

Adverse drug event: Any injury due to medication (Bates et al., 1995b).

Morbidity Due to Medication Errors Is Costly

Current understanding of the costs of medication errors is highly incomplete. Most of what is known relates to additional health care costs associated with a preventable ADEs, which represent the injuries caused by errors:

For hospital care, there is one estimate of the extra costs of inpatient care for a preventable ADE incurred while in the hospital—\$5,857 (Bates et al., 1997). This figure excludes health care costs outside the hospital and was derived from 1993 cost data. Assuming conservatively an annual incidence of 400,000 in-hospital preventable ADEs, each incurring extra hospital costs of \$5,857, yields an annual cost of \$2.3 billion in 1993 dollars or \$3.5 billion in 2006 dollars.

For long-term care, as noted earlier, Gurwitz and colleagues (2005) projected an annual incidence of 800,000 preventable ADEs. However, there is no estimate of the associated health care costs for this group of preventable ADEs.

For ambulatory care, the best estimate derives from a study (Field et al., 2005) that calculated the annual cost of preventable ADEs for all Medicare enrollees aged 65 and. The cost in 2000 per preventable ADE was estimated at \$1,983, while national annual costs were estimated at \$887 million.

In addition to the likelihood of underestimation, the above estimates are characterized by some important omissions. First, the costs of some highly common medication errors, such as drug use without a medically valid indication and failure to receive drugs that should have been prescribed, were excluded from the Medicare study of ambulatory ADEs, (Field et al., 2005). Moreover, the costs of morbidity and mortality arising from the failure of patients to comply with prescribed medication regimens were not assessed. Second, all the studies omitted some important costs: lost earnings, costs of not being able to carry out household duties (lost household production), and compensation for pain and suffering. Third, few data are available for any setting regarding the costs of medication errors that do not result in harm. While no injury is involved, these errors often create extra work, and the costs involved may be substantial.

Effective Error Prevention Strategies Are Available

According to most studies, at least a quarter of all harmful ADEs are preventable. Moreover, many efficacious error prevention strategies are available, especially for hospital care. In the hospital setting, there is good evidence for the effectiveness of computerized order entry with clinical decision-support systems (Bates et al., 1998), for clinical decision-support systems themselves (Evans et al., 1994), and for pharmacist participation on hospital rounds (Leape et al., 1999). Barcoding and smart intravenous (IV) pumps show promise for the hospital setting, but their efficacy has not yet been clearly demonstrated.

PREPUBLICATION COPY: UNCORRECTED PROOFS

Interventions consisting of educational visits appear to hold promise for improving prescribing practices and patient outcomes in nursing homes. Involving pharmacists in the management of medications in nursing homes and ambulatory care also shows promise, but requires additional study. This intervention has been most successful to date in populations with certain conditions, such as diabetes.

IMPROVED PROVIDER–PATIENT COMMUNICATION IS VITAL

Achieving the patient-centered model of care envisioned in the IOM report *Crossing the Quality Chasm: A New Health System for the 21st Century* (IOM, 2001) will require a paradigm shift away from a paternalistic, provider-centric model of care. Consumers (and their surrogates) should be empowered as partners in their care, with appropriate communication, information, and resources in place to support them. For medication safety, consumers and providers (including physicians, nurses, and pharmacists) should know and act on patients' rights; providers should engage in meaningful communication about the safe and effective use of medications and at multiple points along the medication-use process; and government and other participants should improve consumer-oriented written and electronic information resources.

Patient Rights

Patient rights are the foundation for the safe and ethical use of medications (see Box S-3). Ignoring these rights can have lethal consequences. Millions of Americans take prescription drugs each year without being fully informed by their providers about associated risks, contraindications, and side effects. When clinically significant medication errors do occur, they usually are not disclosed to patients or their surrogates unless injury or death results.

Many but not all of patient rights relating to medical care have been established broadly in the U.S. Constitution (Amendments I and XIV) and articulated by the courts through common law. Certain states have instituted a patient bill of rights relating to particular providers or care settings. One important point not specifically addressed by these laws is the right for a patient to be told when an adverse event occurs. Establishing a comprehensive set of patient rights in one document would facilitate patient and provider understanding and exercise of these rights and improve the safety and quality of medication use.

BOX S-3 Patient Rights

Patients have the right to:

- Be the source of control for all medication management decisions that affect them (that is, the right to self-determination).
- Accept or reject medication therapy on the basis of their personal values.
- Be adequately informed about their medication therapy and alternative treatments.
- Ask questions to better understand their medication regimen.
- Receive consultation about their medication regimen in all health settings and at all points along the medication use process.
- Designate a surrogate to assist them with all aspects of their medication management.
- Expect providers to tell them when a clinically significant error has occurred, what the effects of the event on their health (short- and long-term) will be, and what care they will receive to restore their health.
- Ask their provider to report an adverse event and give them information about how they can report the event themselves.

SOURCE: Committee on Identifying and Preventing Medication Errors

Actions for Consumers

For sound medication management, providers and consumers² should maintain an up-to-date record of medications being administered, including prescription medications, OTCs, and dietary supplements, as well as all known drug and/or food allergies. Such records are especially important for patients who have chronic conditions, see multiple providers, or take multiple medications.

By becoming more informed and engaged, consumers (and their surrogates) may decrease the probability of experiencing a medication error (Cohen, 2000). Such actions can range from the simple and routine, such as double-checking their prescription when dropping it off and picking it up from the pharmacy, to the more involved, such as forming an active partnership with providers in managing their health care. When using OTC medications, herbal remedies, and dietary supplements, consumers should seek the information they need to make informed decisions. When obtaining medical care, consumers should ask questions and insist on answers from providers to guide their decision making based on their personal values and preferences. They should ensure that their provider explains their medication regimen clearly and speak up if they do not understand. In addition, they should ensure that providers give them written information about their medications, as well as tell them where to obtain information from other sources. Finally, consumers should communicate with their providers if they experience any unexpected changes in the way they feel after initiating a new medication. Some specific actions consumers can take are outlined in Box S-4.

² In this report, the term “consumers” is often used in referring to patients to emphasize the active role individuals need to take in ensuring the quality of the health care services they are purchasing.

BOX S-4 Consumer Actions to Enhance Medication Safety

Personal/Home

- Maintain a list of the prescription drugs, nonprescription drugs and other products, such as vitamins and minerals, you are taking.
- Take the list with you when you visit any medical practitioner and have him or her review it.
- Be aware of where to find educational material in your local community and at reliable Internet sites.

Ambulatory Care/Outpatient Clinic

- Have the prescriber provide in writing the name of the drug (brand and generic names, if available), what it is for, its dosage, and how often to take it, or provide other written material with this information.
- Have the prescriber explain how to use the drug properly.
- Ask about the side effects of the drug and what to do if you experience a side effect.

Pharmacy

- Make sure the name of the drug (brand or generic) and the directions for use received at the pharmacy are the same as that written down by the prescriber.
- Know that you can review your list of medications with the pharmacist for additional safety.
- Know that you have the right to counseling by the pharmacist if you have any questions; you can ask the pharmacist to explain how to properly take the drug, the side effects of the drug and what to do if you experience them (just as you did with your prescriber)
- Ask for written literature about the drug.

Hospital Inpatient (Patient or Surrogate)

- Ask the doctor or nurse what drugs you are being given at the hospital.
- Do not take a drug without being told the reason for doing so.
- Exercise your right to have a surrogate present whenever you are receiving medication and are unable to monitor the medication-use process yourself.
- Prior to surgery, ask whether there are medications, especially prescription antibiotics, that you should take or any you should stop taking preoperatively.
- Prior to discharge, ask for a list of the medications you should be taking at home, have a provider review them with you, and be sure you understand how the medications should be taken.

SOURCE: Committee on Identifying and Preventing Medication Errors

Actions for Providers

Providers can take several specific actions to improve medication safety (see Box S-5). First, they can verify the patient's current medication list for appropriateness at each encounter, and at times of transition between care settings, they can ensure that this list is accurate. They can educate their patients about the medication regimen, understanding that patients need different kinds

PREPUBLICATION COPY: UNCORRECTED PROOFS

of information at different times and for different purposes. Providers can also respect patients' wishes and inform them of their rights, including the right to have a surrogate present and involved in their medication management whenever they are unable to monitor their own medication use.

BOX S-5 Issues for Discussion with Patients by Providers (includes Physicians, Nurses, and Pharmacists)

- Review the patient's medication list routinely and during care transitions.
- Review different treatment options.
- Review the name and purpose of the selected medication.
- Discuss when and how to take the medication.
- Discuss important and likely side effects and what to do about them.
- Discuss drug–drug, drug–food, and drug–disease interactions.
- Review the patient's or surrogate's role in achieving appropriate medication use.
- Review the role of medications in the overall context of the patient's health.

When communicating about medication errors that occur with the potential for or actual harm, providers can tell patients how the error may affect their health and what is being done to correct it. The vast majority of patients want and expect to be told about errors, particularly those that cause them harm.

Barriers Experienced by Consumers and Providers

In the current system, however, there are a number of barriers that affect the ability of consumers to engage in safe and effective use of medications and the ability of providers to change their day-to-day practices to support new consumer-oriented activities (Cohen, 2000). These barriers include (1) knowledge deficits, such as, patients lacking sufficient education about their medications, and providers lacking the latest pharmacological knowledge about particular medications; (2) practical barriers, such as patients being unable to pay for their medications, and providers having to operate burdensome prescribing arrangements required by payers; and (3) attitudinal factors, such as the patient and provider having different cultural and belief systems about the use of medications. These barriers often result in errors, such as taking the wrong dose, taking a medication at the wrong time, or taking someone else's medication. Many of these barriers can be overcome by improved consumer-oriented drug information; providers responding to the factors challenging their patients; and health care organizations adopting a culture of safety and more extensive use information technology systems.

Recommendation 1: To improve the quality and safety of the medication-use process, specific measures should be instituted to strengthen patients' capacities for sound medication self-management. Specifically:

- **Patients' rights regarding safety and quality in health care and medication use should be formalized at the state and/or federal levels and ensured at every point of care.**

PREPUBLICATION COPY: UNCORRECTED PROOFS

- **Patients (or their surrogates) should maintain an active list of all prescription drugs, over-the-counter (OTC) drugs, and dietary supplements they are taking; the reasons for taking them; and any known drug allergies. Every provider involved in the medication-use process for a patient should have access to this list.**
- **Providers should take definitive action to educate patients (or their surrogates) about the safe and effective use of medications. They should provide information about side effects, contraindications, and how to handle adverse reactions, as well as where to obtain additional objective, high-quality information.**
- **Consultation on their medications should be available to patients at key points along the medication use process (during clinical decision making in ambulatory and inpatient care, at hospital discharge, and at the pharmacy).**

Actions for Government and Other Stakeholders

Consumers should be able to obtain high-quality information about medications not only from their provider, but also from the pharmacy, Internet resources, and community-based resources. However, these resources need significant improvement in two overarching areas.

First, current materials (e.g., pharmacy information sheets [leaflets], Internet-based information) are inadequately designed to facilitate consumers' ability to read, comprehend, and act on medication information. Pharmacy leaflets are the source of such information most relied upon by consumers. Yet a number of studies have revealed the inadequate quality of pharmacy leaflets, as well as the variability in their quality from one pharmacy to another and from one drug to another (Svarstad and Mount, 2001). Internet-based health information has proliferated over the last decade, providing consumers with immediate access to valuable resources such as medical journals and libraries, but most consumers are unfamiliar with how to access this information since it usually does not figure prominently during online searches. Rather, consumers are directed to a multitude of other sources of information with differing standards for providing content. The federal government should develop mechanisms for improving pharmacy leaflets and the quality of Internet information for consumers.

Second, there is a need for additional resources beyond pharmacy leaflets and Internet information that can be provided on a national scale. In particular, a national drug information telephone helpline and community-based health resource centers should be developed to promote consumer education. Further, communication networks already in place, such as those associated with the public health infrastructure (e.g., the Centers for Disease Control and Prevention's National Center for Health Marketing) and consumer networks should be used for broad dissemination of national medication safety initiatives.

Recommendation 2: Government agencies (i.e., the Agency for Healthcare Research and Quality [AHRQ], the Centers for Medicare and Medicaid Services [CMS], the Food and Drug Administration [FDA], and the National Library of Medicine [NLM]) should enhance the resource base for consumer-oriented drug information and medication self-management support. Such efforts require standardization of pharmacy medication information leaflets, improvement of online medication resources, establishment of a national drug information telephone helpline, the development of personal health records, and the development of a national medication safety dissemination plan.

PREPUBLICATION COPY: UNCORRECTED PROOFS

- **Pharmacy medication information leaflets should be standardized to a format designed for readability, comprehensibility, and usefulness to consumers. The leaflets should be made available to consumers in a manner that accommodates their individual needs, such as those associated with variations in literacy, language, age, and visual acuity.**
- **NLM should be designated as the chief agency responsible for Internet health information resources for consumers. Drug information should be provided through a consumers' version of the DailyMed program, with links to NLM's Medline Plus program for general health and additional drug information.**
- **FDA, CMS, and NLM working together, should undertake a full evaluation of various methods for building and funding a national network of drug information helplines.**
- **CMS, FDA, and NLM should collaborate to confirm a minimum data set for personal health records and develop requirements for vendor self-certification of compliance. Vendors should take the initiative to improve the use and functionality of personal health records by incorporating basic tools to support consumers' medication self management.**
- **A national plan should be developed for widespread distribution and promotion of medication safety information. Health care provider, community-based, consumer, and government organizations should serve as the foundation for such efforts.**

ELECTRONIC PRESCRIBING AND MONITORING FOR ERRORS IN ALL CARE SETTINGS ARE ESSENTIAL

Safe medication use requires that clinicians synthesize several types of information, including knowledge of the medication itself, as well as understanding of how the medication may interact with coexisting illnesses and medications and how its use might be monitored. Several electronic supports can help providers absorb and apply the necessary information.

Access to Automated Point-of-Care Reference Information

The underlying knowledge base is constantly changing, creating a situation in which it is almost impossible for health care providers to have current knowledge of every medication they prescribe. Clinicians therefore need access to critical syntheses of the evidence base. The Cochrane Collaboration (CC, 2005) is one such resource. In addition, many software applications are being developed that provide decision support for prescribing clinicians (Epocrates, 2005). Applications of this type are typically available via the Internet or on personal digital assistants (PDAs). All prescribers should use point-of-care reference information.

Electronic-Prescribing

Paper-based prescribing is associated with high error rates (Kaushal et al., 2003). Electronic prescribing is safer (Bates et al., 1998) because it eliminates handwriting and ensures that the key fields (for example, drug name, dose, route, and frequency) include meaningful data. More important, as noted above, computerization enables the delivery of clinical decision support (Evans et al., 1998), including checks for allergies, drug–drug interactions, overly high doses, and clini-

PREPUBLICATION COPY: UNCORRECTED PROOFS

cal conditions, as well as suggestions for appropriate dosages given the patient's level of renal function and age. Recent studies have identified implementation problems and the unintended occurrence of new types of errors with these computerization strategies (for example, pharmacy inventory displays of available drug doses being mistaken for the usual or minimally effective doses). Avoiding these problems requires addressing business and cultural issues prior to implementation and aggressively fixing technological problems during implementation.

In addition, all pharmacies receiving prescriptions electronically will lead to fewer errors than occur with current paper or oral approaches (Bates, 2001). A number of issues must be addressed, however, many of which are regulatory, for electronic transmission of prescriptions to be practical.

Effective Use of Well-Designed Technologies

To deliver safe drug care, health care organizations should make effective use of well-designed technologies, which will vary by setting. Although the evidence for this assertion is strongest in the inpatient setting (AHRQ, 2005), the use of technology will undoubtedly lead to major improvements in all settings. In acute care, the technology should target prescribing by including computerized provider order entry with clinical decision support. Administration is also an especially vulnerable stage in the process, and several technologies are likely to be especially important. These include electronic medication administration records which can improve documentation regarding which medications have been given and when, and will likely also include machine-readable identification, such as bar coding, and smart IV infusion pumps. All these technologies should be electronically linked.

In nursing homes, computerized prescribing with decision support will likely be important, although there has been little research on its efficacy (Gurwitz et al., 2005). Moreover, implementation of computerized prescribing in this setting will be challenging since most nursing homes have very limited resources.

Limited evidence suggests that computerized prescribing will be important in the outpatient setting as well (Gandhi et al., 2003), although it may not result in significant safety benefit without added decision support. Equally important are likely to be approaches that improve communication between patients and providers.

Communication of Patient-Specific Medication-Related Information

The delivery of care often involves moving the locus of care among sites and providers. These "handoffs" are fraught with errors. One strategy for reducing errors during these care transitions is to reconcile medication orders between transition points, especially between care settings such as the hospital and outpatient setting, but also between points within organizations, such as the intensive care unit and a general care unit. This reconciliation involves comparing what a patient is taking in one setting with what is being provided in another to avoid errors of transcription, omission, duplication of therapy, and drug-drug and drug-disease interactions. This process typically reveals many discrepancies (Pronovost et al., 2003).

Reconciliation is facilitated when medication data are transmitted electronically among providers, with confirmation by the patient. Three important steps are required. First, a complete and accurate medication list must be compiled. Second, the data must be structured into components such as the medication name, dose, route, frequency, duration, start date, and so on. Third, these data must be formatted in a way that allows disparate computer systems to understand both their structure and the content.

PREPUBLICATION COPY: UNCORRECTED PROOFS

The power of interoperable health care data was demonstrated after the devastation of Hurricane Katrina. Pharmacy chains were able to make patients' medication lists available quickly to care providers, and states with immunizations registries were able to retrieve immunization records, enabling the enrollment of children in new schools.

Monitoring for Errors

All health care provider groups should seek to be high-reliability organizations preoccupied with the possibility of failure (Reason, 2000). They should implement active internal monitoring programs so that progress toward improved medication safety can be accurately demonstrated. Voluntary internal reporting systems have recognized limitations for evaluating the true frequency of medication errors and ADEs (Flynn et al., 2002). Error detection methods that complement such systems should be used in all care settings. These include computerized detection of ADEs, observation of medication passes in hospitals to assess administration errors, and audits of filled prescriptions in community pharmacies to monitor dispensing errors.

Many external programs exist to which patients and providers can report a medication error or hazardous situation (IOM, 2004). Voluntary practitioner reporting to an external program will continue to be important, as it is often the only way practitioners can effect change outside their organization. Errors need to be reported and analyzed if improvements in care are to be achieved.

Adopting a Safety Culture

Patient safety can best be achieved through the adoption of a culture of safety – organizational commitment to continually seeking to improve safety. To achieve high levels of safety culture senior management of health care organizations must devote sufficient attention to safety and also make sufficient resources available for quality improvement and safety teams (IOM, 2004). Senior management must also authorize the investment of resources in technologies that have been demonstrated to be effective but are not yet widely implemented in most organizations, such as computerized provider order entry systems and electronic health records. It has become increasingly clear that the introduction of any of these technologies requires close attention to business processes and ongoing maintenance. As noted above, studies have shown that these tools can have unintended and adverse consequences, and that avoiding these consequences requires addressing both business and cultural issues.

Recommendation 3: All health care organizations should immediately make complete patient-information and decision-support tools available to clinicians and patients. Health care systems should capture information on medication safety and use this information to improve the safety of their care delivery systems. Health care organizations should implement the appropriate systems to enable providers to:

- **Have access to comprehensive reference information concerning medications and related health data.**
- **Communicate patient-specific medication-related information in an interoperable format.**
- **Assess the safety of medication use through active monitoring and use these monitoring data to inform the implementation of prevention strategies.**
- **Write prescriptions electronically by 2010 and all pharmacies to be able to receive them electronically, also by 2010. All prescribers should have plans in place by 2008 to implement electronic prescribing.**

PREPUBLICATION COPY: UNCORRECTED PROOFS

- **Subject prescriptions to evidence-based, current clinical decision support.**
- **Have the appropriate competencies for each step of the medication use process.**
- **Make effective use of well-designed technologies, which will vary by setting.**

ENORMOUS KNOWLEDGE DEFICITS MUST BE ADDRESSED

Current methods for generating and communicating information about medications are inadequate and contribute to a growing rate of medication errors. Likewise, error incidence rates, costs to the health system, and prevention strategies are not well understood. As a result, there are enormous gaps in the knowledge required to implement a safe medication-use system.

Risk/Benefit Information for Prescription Drugs

Being able to determine whether a medication error has been made depends on knowing the correct dose of the drug for that patient at that time and whether the indication for that drug is correct in comparison with alternative approaches to treatment. Over the past several decades, however, drug evaluations have not been sufficiently comprehensive. As a result, the balance of risk and benefit for a drug often is not known for a given population. Such gaps in therapeutic knowledge often result in devastating effects on clinical practice and patient health, as exemplified by adverse events involving hormone replacement therapy, cyclooxygenase-2 (COX-2) inhibitors, and non-steroidal anti-inflammatory drugs that resulted in increased morbidity and mortality.

These issues are magnified in specific patient populations. For example, the majority of prescriptions written for children are off label, not based on empirical demonstration of safety and efficacy. Among those over 80 years old, the fastest-growing segment of the population, almost nothing is known about the balance of risks and benefits. Patients with renal dysfunction are another large and growing group for whom more comprehensive studies are needed. And patients with multiple comorbidities are typically excluded from premarketing clinical trials, yet many of the major problems with drug toxicity have occurred in those taking multiple medications because of multiple diseases. Thus the numbers and types of patients for whom clinical outcomes are measured must be greatly increased to elucidate the proper dosing of drugs in individuals and within subgroups.

Of critical concern is the need for transparency through the publication of clinical studies in a national repository to advance medication safety, error prevention, and public knowledge. The studies that should be published in such a repository include postmarket studies. The goal of postmarket studies is to generate new data about a drug's effects in the population; often, however, these studies give insufficient emphasis to safety information. There is a need for comprehensive redesign and expansion of the mechanisms for undertaking clinical studies to improve understanding of the risks and benefits of drug therapies, prevent errors and ADEs, and meet the health needs of the population.

Communication of Drug Information

How information about a drug is communicated to providers and consumers can directly affect the frequency of medication errors and ADEs (see Box S-6). Drug information is communicated through labeling and packaging, marketing practices, and advertisements. Poorly designed materials and inadequate representation of the risks and benefits to providers and consumers

PREPUBLICATION COPY: UNCORRECTED PROOFS

have led to many errors, including inappropriate prescribing; confusion among products, affecting dispensing and administration; and compromised ability to monitor the effects of drugs adequately.

BOX S-6 Drug Naming, Labeling, and Packaging Problems

- Brand names and generic names that look or sound alike
- Different formulations of the same brand or generic drug
- Multiple abbreviations to represent the same concept
- Confusing word derivatives, abbreviations, and symbols
- Unclear dose concentration/strength designations
- Cluttered labeling—small fonts, poor typefaces, no background contrast, overemphasis on company logos
- Inadequate prominence of warnings and reminders
- Lack of standardized terminology

In particular, drug names that look or sound alike increase the risk of medication errors. Abbreviations, acronyms, certain dose designations, and other symbols used for labeling also have caused errors. Even the layout and presentation of drug information on the drug container or package label can be visually confusing, particularly if it is designed for marketing rather than clinical purposes.

Unit-of-use packaging – containers that provide enough medication for a particular period, for example, blister packs containing 30 individually wrapped doses – is not widely used in the United States but is extensively used elsewhere. This form of packaging brings important safety and usage benefits. The committee believes that the expanded implementation of unit-of-use packaging in the United States warrants further investigation.

Free samples of prescription drugs are widely distributed to patients by prescribers to start patients quickly on their medications, to adjust prescribed doses before the full prescription is filled, and to offset medication costs for indigent and underinsured patients. However, there has been growing unease among providers about the way free samples are distributed – particularly, the resulting lack of documentation of medication use, and the bypassing of the standard prescribing and dispensing services which incorporate drug-interaction checking and pharmacy counseling services. More investigation is needed on the impact of differing free sample distribution methods on medication safety.

Recommendation 4: Enhancing the safety and quality of the medication-use process and reducing errors requires improved methods for labeling drug products and communicating medication information to providers and consumers. For such improvements to occur, materials should be designed according to designated standards to meet the needs of the end user. Industry, AHRQ, the FDA, and others as appropriate (e.g., U.S. Pharmacopeia, Institute for Safe Medication Practices) should work together to undertake the following actions to address labeling, packaging, and the distribution of free samples:

- **The FDA should develop two guidance documents for industry: one for drug naming and another for labeling and packaging. The FDA and industry should collaborate to develop (1) a common drug nomenclature that standardizes abbrevia-**

PREPUBLICATION COPY: UNCORRECTED PROOFS

tions, acronyms, and terms to the extent possible, and (2) methods of applying failure modes and effects analysis to labeling and packaging.

- **Additional study of optimum designs for all drug labeling and information sheets to reflect human and cognitive factors should be undertaken. Methods for testing and measuring the effect of the materials on providers and consumers should also be established including methods to field test materials. The FDA, NLM, and industry should work with consumer and patient safety organizations to improve the nomenclature used in consumer materials.**

- **The FDA, the pharmaceutical industry, and other stakeholders should collaborate to develop a strategy for expansion of unit-of-use packaging for consumers to new therapeutic areas. Studies should be undertaken to evaluate different methods of presenting unit-of-use packaging and designs that best support different consumer groups in their medication self management**

- **The Agency for Health Care Research and Quality should fund studies that evaluate the impact of free samples on overall patient safety, provider prescribing practices, and consumer behavior (for example, adherence), as well as alternative methods of distribution that can improve safety, quality, and effectiveness.**

Health Information Technology

Realization of the full benefits of many health information technologies (such as decision-support systems, smart IV pumps, bar-code administration systems, and pharmacy database systems) is hampered by the lack of common data standards for system integration and well-designed interfaces for end users.

Problems with data standards for drug information are threefold. First, there is no complete, standardized set of terms, concepts, and codes to represent drug information. Second, there is no standardized method for presenting safety alerts according to severity and/or clinical importance. Instead, providers are sometimes inundated with too many alerts, which can result in “alert fatigue”. Third, many systems lack intelligent mechanisms for relating patient-specific data to allowable overrides, such as those associated with a particular patient and drug allergy alert or duplicate therapy request.

The ability of clinicians to use health information technologies successfully depends on how well the technologies have been designed at the level of human–machine interaction (i.e., user interface). Displaying information in a cluttered, illogical, or confusing manner leads to decreased user performance and satisfaction. Moreover, a poorly designed user interface can contribute to medication errors. Addressing user interface issues requires greater attention to the cognitive and social factors influencing clinicians in their daily workflow and interaction with technologies (van Bommel and Musen, 1997).

Recommendation 5: Industry and government should collaborate to establish standards affecting drug-related health information technologies, specifically:

- **The NLM should take the lead in developing a common drug nomenclature for use in all clinical information technology systems based on the standards for the national health information infrastructure.**

- **AHRQ should take the lead in organizing safety alert mechanisms by severity, frequency, and clinical importance to improve clinical value and acceptance.**

PREPUBLICATION COPY: UNCORRECTED PROOFS

- **AHRQ should take the lead in developing intelligent prompting mechanisms specific to a patient's unique characteristics and needs; provider prescribing, ordering, and error patterns; and evidence-based best-practice guidelines.**
- **AHRQ should take the lead in developing user interface designs based on the principles of cognitive and human factors and the context of the clinical environment.**
- **AHRQ should support additional research to determine specifications for alert mechanisms and intelligent prompting, and optimum designs for user interfaces.**

Research on Medication Errors: Incidence Rates, Costs, and Prevention Strategies

In reviewing the research literature, the committee concluded that large gaps exist in our understanding of medication error incidence rates, costs, and prevention strategies. The committee believes the nation should invest annually about \$100 million in the research proposed below.

The primary focus of research on medication errors in the next decade should be prevention strategies, recognizing that to plan an error prevention study, it is essential to be able to measure the baseline rate of errors. Evidence on the efficacy of prevention strategies for improving medication safety is badly needed in a number of settings, including care transitions, ambulatory care (particularly home care, self-care, and medication use in schools), pediatric care, psychiatric care, and the use of OTC and complementary and alternative medications. For hospitals, key areas are further investigation of some prevention strategies (particularly bar coding and smart pumps) and how to integrate electronic health records with computerized provider order entry, clinical decision support, bar coding, and smart pumps.

Overall, most data about medication error incidence rates come from the inpatient setting, but the magnitude of the problem is likely to be greater outside the hospital. Areas of priority for research on medication error and ADE incidence rates are care transitions, specialty ambulatory clinics, psychiatric care, the administering of medications in schools, and the use of OTC and complementary and alternative medications. Much more research is needed as well on the patient's role in the prevention of errors, specifically, what systems provide the most cost-effective support for safe and effective medication self-management or for surrogate participation in medication use when a patient is unable to self-manage.

Most studies of the costs of medication errors relate to hospitals, and some report data more than 10 years old (Bates et al., 1997). A better understanding of the costs and consequences of medication errors in all care settings is needed to help inform decisions about investing in medication error prevention strategies.

Recommendation 6: Congress should allocate the necessary funds and AHRQ should take the lead, working with other government agencies such as CMS, FDA and NLM, in coordinating for a broad research agenda on the safe and appropriate use of medications across all care settings, covering research methodologies, incidence rates by type and severity, costs of medication errors, reporting systems, and in particular, further testing of error prevention strategies.

OVERSIGHT, REGULATION AND PAYMENT

Improving medication safety will require key changes in oversight, regulation, and payment. Accordingly, the following recommendation is addressed to the stakeholders that shape the environment in which care is delivered, including legislators, regulators, accreditors, payers, and patient safety organizations.³

Recommendation 7: Oversight and regulatory organizations and payers should use legislation, regulation, accreditation, and payment mechanisms and the media to motivate the adoption of practices and technologies that can reduce medication errors, and to ensure that that professionals have the competencies required to deliver medications safely.

- **Payers and purchasers should continue to motivate improvement in the medication-use process through explicit financial incentives.**
- **CMS should evaluate a variety of strategies for delivering medication therapy management.**
- **Regulators, accreditors, and legislators should set minimum functionality standards for error prevention technologies.**
- **States should enact legislation consistent with and complementary to the Medicare Modernization Act's e-prescribing provisions and remove existing barriers to e-prescribing.**
- **All state boards of pharmacy should undertake quality improvement initiatives related to community pharmacy practice.**
- **Medication error reporting should be promoted more aggressively by all stakeholders (with a single national taxonomy used for data storage and analysis).**
- **Accreditation bodies responsible for the oversight of professional education should require more training in improving medication management practices and clinical pharmacology.**

MOVING FORWARD

The American people expect safe medication care. In this report, the committee proposes an ambitious agenda for making the use of medications safer. This agenda requires that all stakeholders—patients, care providers, payers, industry, and government, working together—commit to preventing medication errors. Given that a large proportion of injurious drug events are preventable, this proposed agenda should deliver early and measurable benefits.

REFERENCES

AHRQ (Agency for Healthcare Research and Quality). 2005. *Advances in Patient Safety: From Research to Implementation*. Vols. 1–4. Rockville, MD: AHRQ.

Barker KN, Flynn EA, Pepper GA, Bates DW, Mikeal RL. 2002b. Medication errors observed in 36 health care facilities. *Archives of Internal Medicine* 162(16):1897–1903.

³ Patient safety organizations are regulated through the Patient Safety and Quality Improvement Act of 2005 (P.L. 109-41). Broadly, they are organizations separate from health care providers that collect, manage, and analyze patient safety data, and advocate safety improvements on the basis of analysis of the patient safety data they receive.

- Bates DW. 2001. A 40-year-old woman who noticed a medication error. *Journal of the American Medical Association* 285(24):3134–3140.
- Bates DW, Boyle DL, Vander Vliet MB, Schneider J, Leape L. 1995a. Relationship between medication errors and adverse drug events. *Journal of General Internal Medicine* 10(4):100–205.
- Bates DW, Cullen DJ, Laird N, Petersen LA, Small SD, Servi D, Laffel G, Sweitzer BJ, Shea BF, Hallisey R, Vander Vliet M, Nemeskal R, Leape LL. 1995b. Incidence of adverse drug events and potential adverse drug events. Implications for prevention. ADE Prevention Study Group. *Journal of the American Medical Association* 274:29–34.
- Bates DW, Spell N, Cullen DJ, Burdick E, Laird N, Petersen LA, Small SD, Sweitzer BJ, Leape L. 1997. The costs of adverse drug events in hospitalized patients. Adverse Drug Events Prevention Study Group. *Journal of the American Medical Association* 277(4):307–311.
- Bates DW, Leape LL, Cullen DJ, Laird N, Petersen LA, Teich JM, Burdick E, Hickey M, Kleefield S, Shea B, Vander Vliet M. 1998. Effect of computerized physician order entry and a team intervention on prevention of serious medication errors. *Journal of the American Medical Association* 280(15):1311–1316.
- CC (Cochrane Collaboration). 2005. *What is The Cochrane Collaboration?* [Online]. Available: <http://www.cochrane.org/docs/descrip.htm> [accessed October 6, 2005].
- Classen DC, Pestotnik SL, Evans RS, Lloyd JF, Burke JP. 1997. Adverse drug events in hospitalized patients. Excess length of stay, extra costs, and attributable mortality. *Journal of the American Medical Association* 277(4):301–306.
- Cohen MR. 2000. *Medication Errors: Causes, Prevention, and Risk Management*. Sudbury, MA: Jones and Bartlett Publishers.
- Epocrates. 2005. *All-One-Guide to Drugs, Diseases and Diagnostics*. [Online]. Available: <http://www2.epocrates.com> [accessed October 6, 2005].
- Evans RS, Classen DC, Pestotnik SL, Lundsgaarde HP, Burke JP. 1994. Improving empiric antibiotic selection using computer decision support. *Archives of Internal Medicine* 154(8):878–884.
- Evans RS, Pestotnik SL, Classen DC, Clemmer TP, Weaver LK, Orme JF, Lloyd JF, Burke JP. 1998. A computer-assisted management program for antibiotics and other anti-infective agents. *New England Journal of Medicine* 338(4):232–238.
- Field TS, Gilman BH, Subramanian S, Fuller JC, Bates DW, Gurwitz JH. 2005. The costs associated with adverse drug events among older adults in the ambulatory setting. *Medical Care* 43(12):1171–1176.
- Flynn EA, Barker KN, Pepper GA, Bates DW, Mikeal RL. 2002. Comparison of methods for detecting medication errors in 36 hospitals and skilled-nursing facilities. *American Journal of Health-System Pharmacy* 59(5):436–446.
- Gandhi TK, Weingart SN, Borus J, Seger AC, Peterson J, Burdick E, Seger DL, Shu K, Federico F, Leape LL, Bates DW. 2003. Adverse drug events in ambulatory care. *New England Journal of Medicine* 348(16):1556–1564.
- Gurwitz JH, Field TS, Harrold LR, Rothschild J, Debellis K, Seger AC, Cadoret C, Garber L, Fish LS, Kelleher M, Bates DW. 2003. Incidence and preventability of adverse drug events among older person in the ambulatory setting. *Journal of the American Medical Association* 289(94):1107–1116.
- Gurwitz JH, Field TS, Judge J, Rochon P, Harrold LR, Cadoret C, Lee M, White K, LaPrino J, Mainard JF, DeFlorio M, Gavendo L, Auger J, Bates DW. 2005. The incidence of adverse

PREPUBLICATION COPY: UNCORRECTED PROOFS

drug events in two large academic long-term care facilities. *American Journal of Medicine* 118(3):251–258.

IOM (Institute of Medicine). 2000. *To Err Is Human: Building a Safer Health System*. Washington, DC: National Academy Press.

IOM. 2001. *Crossing the Quality Chasm: A New Health System for the 21st Century*. Washington, DC: National Academy Press.

IOM. 2004. *Patient Safety: Achieving a New Standard for Care*. Washington, DC: The National Academy Press.

Jha AK, Kuperman GJ, Teich JM, Leape L, Shea B, Rittenberg E, Burdick E, Seger DL, Vander Vliet M, Bates DW. 1998. Identifying adverse drug events: Development of a computer-based monitor and comparison with chart review and stimulated voluntary report. *Journal of the American Medical Informatics Association* 5(3):305–314.

Kaushal R, Bates DW, Landrigan C, McKenna KJ, Clapp MD, Federico F, Goldmann DA. 2001. Medication errors and adverse drug events in pediatric inpatients. *Journal of the American Medical Association* 285(16):2114–2120.

Kaushal R, Shojania KG, Bates DW. 2003. Effects of computerized physician order entry and clinical decision support systems on medication safety: A systematic review. *Archives of Internal Medicine* 163(12):1409–1416.

Leape LL, Cullen DJ, Clapp MD, Burdick E, Demonaco HJ, Erickson JI, Bates DW. 1999. Pharmacists participation on physician rounds and adverse drug events in the intensive care unit. *Journal of the American Medical Association* 282(3):267–270.

Leape LL, Bates DW, Cullen DJ, Cooper J, Demonaco HJ, Gallivan T, Hallisey R, Ives J, Laird N, Laffel G, Nemeskal R, Petersen L, Porter K, Servi D, Shea B, Small S, weitzer B, Thompson B, Vander Vleit M. 1995. Systems analysis of adverse drug events. *Journal of the American Medical Association* 274(1): 35-43.

Pronovost P, Weast B, Schwarz M, Wyskiel RM, Prow D, Milanovich SN, Berenholtz S, Dorman T, Lipsett P. 2003. Medication reconciliation: A practical tool to reduce the risk of medication errors. *American Journal of Critical Care* 18(4):201–205.

Reason J. 2000. Human error: Models of management. *British Medical Journal* 320(7237):768–770.

Svarstad BL, Mount JK. 2001. *Evaluation of Written Prescription Information Provided in Community Pharmacies, 2001*. Rockville, MD: U.S. FDA.

van Bommel JH, Musen MA. 1997. *Handbook of Medical Informatics*. Heidelberg, Germany: Springer-Verlag.

Preventing Medication Errors

Committee on Identifying and Preventing Medication Errors
Board on Health Care Services

Philip Aspden, Julie Wolcott, J. Lyle Bootman, Linda R. Cronenwett, *Editors*

INSTITUTE OF MEDICINE
OF THE NATIONAL ACADEMIES

THE NATIONAL ACADEMIES PRESS
Washington, D.C.
www.nap.edu

PREPUBLICATION COPY: UNCORRECTED PROOFS

Copyright © National Academy of Sciences. All rights reserved.
This executive summary plus thousands more available at <http://www.nap.edu>

THE NATIONAL ACADEMIES PRESS 500 Fifth Street, N.W. Washington, DC 20001

NOTICE: The project that is the subject of this report was approved by the Governing Board of the National Research Council, whose members are drawn from the councils of the National Academy of Sciences, the National Academy of Engineering, and the Institute of Medicine. The members of the committee responsible for the report were chosen for their special competences and with regard for appropriate balance.

This study was supported by Contract No. HHSM-500-2004-00020C between the National Academy of Sciences and Department of Health and Human Services (Centers for Medicare and Medicaid Services). Any opinions, findings, conclusions, or recommendations expressed in this publication are those of the author(s) and do not necessarily reflect the view of the organizations or agencies that provided support for this project.

International Standard Book Number 0-309-XXXXX-X (Book)
International Standard Book Number 0-309-XXXXX -X (PDF)
Library of Congress Control Number: 00 XXXXXX

Additional copies of this report are available from the National Academies Press, 500 Fifth Street, N.W., Lockbox 285, Washington, DC 20055; (800) 624-6242 or (202) 334-3313 (in the Washington metropolitan area); Internet, <http://www.nap.edu>.

For more information about the Institute of Medicine, visit the IOM home page at: www.iom.edu.

Copyright 2006 by the National Academy of Sciences. All rights reserved.

Printed in the United States of America.

The serpent has been a symbol of long life, healing, and knowledge among almost all cultures and religions since the beginning of recorded history. The serpent adopted as a logotype by the Institute of Medicine is a relief carving from ancient Greece, now held by the Staatliche Museen in Berlin.

PREPUBLICATION COPY: UNCORRECTED PROOFS

Copyright © National Academy of Sciences. All rights reserved.
This executive summary plus thousands more available at <http://www.nap.edu>

*“Knowing is not enough; we must apply.
Willing is not enough; we must do.”*
—Goethe



INSTITUTE OF MEDICINE
OF THE NATIONAL ACADEMIES

Advising the Nation. Improving Health.

PREPUBLICATION COPY: UNCORRECTED PROOFS

Copyright © National Academy of Sciences. All rights reserved.
This executive summary plus thousands more available at <http://www.nap.edu>

THE NATIONAL ACADEMIES

Advisers to the Nation on Science, Engineering, and Medicine

The **National Academy of Sciences** is a private, nonprofit, self-perpetuating society of distinguished scholars engaged in scientific and engineering research, dedicated to the furtherance of science and technology and to their use for the general welfare. Upon the authority of the charter granted to it by the Congress in 1863, the Academy has a mandate that requires it to advise the federal government on scientific and technical matters. Dr. Ralph J. Cicerone is president of the National Academy of Sciences.

The **National Academy of Engineering** was established in 1964, under the charter of the National Academy of Sciences, as a parallel organization of outstanding engineers. It is autonomous in its administration and in the selection of its members, sharing with the National Academy of Sciences the responsibility for advising the federal government. The National Academy of Engineering also sponsors engineering programs aimed at meeting national needs, encourages education and research, and recognizes the superior achievements of engineers. Dr. Wm. A. Wulf is president of the National Academy of Engineering.

The **Institute of Medicine** was established in 1970 by the National Academy of Sciences to secure the services of eminent members of appropriate professions in the examination of policy matters pertaining to the health of the public. The Institute acts under the responsibility given to the National Academy of Sciences by its congressional charter to be an adviser to the federal government and, upon its own initiative, to identify issues of medical care, research, and education. Dr. Harvey V. Fineberg is president of the Institute of Medicine.

The **National Research Council** was organized by the National Academy of Sciences in 1916 to associate the broad community of science and technology with the Academy's purposes of furthering knowledge and advising the federal government. Functioning in accordance with general policies determined by the Academy, the Council has become the principal operating agency of both the National Academy of Sciences and the National Academy of Engineering in providing services to the government, the public, and the scientific and engineering communities. The Council is administered jointly by both Academies and the Institute of Medicine. Dr. Ralph J. Cicerone and Dr. Wm. A. Wulf are chair and vice chair, respectively, of the National Research Council.

www.national-academies.org

PREPUBLICATION COPY: UNCORRECTED PROOFS

Copyright © National Academy of Sciences. All rights reserved.
This executive summary plus thousands more available at <http://www.nap.edu>

COMMITTEE ON IDENTIFYING AND PREVENTING MEDICATION ERRORS

- J. LYLE BOOTMAN** (*Co-chair*), Dean and Professor, University of Arizona College of Pharmacy; Founding and Executive Director, University of Arizona Center for Health Outcomes and PharmacoEconomic (HOPE) Research
- LINDA R. CRONENWETT** (*Co-chair*), Professor and Dean, School of Nursing, University of North Carolina at Chapel Hill
- DAVID W. BATES**, Chief, Division of General Medicine, Brigham and Women's Hospital; Medical Director of Clinical and Quality Analysis, Partners Healthcare System; Professor of Medicine, Harvard Medical School
- ROBERT M. CALIFF**, Associate Vice Chancellor for Clinical Research, Director of the Duke Clinical Research Institute, and Professor of Medicine, Division of Cardiology, Duke University Medical Center
- H. ERIC CANNON**, Director of Pharmacy Services and Health and Wellness, IHC Health Plans, Intermountain Health Care
- REBECCA W. CHATER**, Director of Clinical Services, Kerr Drugs, Inc./KDI Clinical Services
- MICHAEL R. COHEN**, President, Institute for Safe Medication Practices
- JAMES B. CONWAY**, Senior Fellow, Institute for Healthcare Improvement; Senior Consultant, Dana-Farber Cancer Institute; Adjunct Lecturer on Health Care Management, Department of Health Policy and Management, Harvard School of Public Health
- R. SCOTT EVANS**, Senior Medical Informaticist, Department of Medical Informatics, LDS Hospital and Intermountain Health Care; Professor, Department of Medical Informatics, and Adjunct Professor, Department of Medicine, University of Utah
- ELIZABETH A. FLYNN**, Associate Research Professor, Department of Pharmacy Care Systems, Harrison School of Pharmacy, Auburn University
- JERRY H. GURWITZ**, Chief, Division of Geriatric Medicine and Dr. John Meyers Professor of Primary Care Medicine, University of Massachusetts Medical School; and Executive Director, Meyers Primary Care Institute, University of Massachusetts Medical School, Fallon Foundation, and Fallon Community Health Plan
- CHARLES B. INLANDER**, President, People's Medical Society
- KEVIN B. JOHNSON**, Associate Professor and Vice Chair, Department of Biomedical Informatics, and Associate Professor, Department of Pediatrics, Vanderbilt University Medical School
- WILSON D. PACE**, Professor of Family Medicine and Green-Edelman Chair for Practice-based Research, University of Colorado; Director, American Academy of Family Physicians National Research Network
- KATHLEEN R. STEVENS**, Professor and Director, Academic Center for Evidence-Based Practice, The University of Texas Health Science Center at San Antonio
- EDWARD WESTRICK**, Vice President of Medical Management, University of Massachusetts Memorial Health Care
- ALBERT W. WU**, Professor of Health Policy and Management and Internal Medicine, The Johns Hopkins University

PREPUBLICATION COPY: UNCORRECTED PROOFS

Health Care Services Board

JOHN C. RING, Director (from December 2005 to May 2006)

CLYDE J. BEHNEY, Acting Director (June 2005 to December 2005 and from May 2006)

JANET M. CORRIGAN, Director (September 2004 to May 2005)

ANTHONY BURTON, Administrative Assistant

Study Staff

PHILIP ASPDEN, Study Director

JULIE A. WOLCOTT, Program Officer (to April 2006)

RYAN L. PALUGOD, Senior Program Assistant (from December 2005)

TASHARA BASTIEN, Senior Program Assistant (to January 2006)

WILLIAM B. MCLEOD, Senior Librarian

GARY J. WALKER, Senior Financial Officer (from December 2005)

TERESA REDD, Financial Advisor (to December 2005)

BETH E. LAFALCE, Intern (April to May, 2005)

PREPUBLICATION COPY: UNCORRECTED PROOFS

REVIEWERS

This report has been reviewed in draft form by individuals chosen for their diverse perspectives and technical expertise, in accordance with procedures approved by the NRC's Report Review Committee. The purpose of this independent review is to provide candid and critical comments that will assist the institution in making its published report as sound as possible and to ensure that the report meets institutional standards for objectivity, evidence, and responsiveness to the study charge. The review comments and draft manuscript remain confidential to protect the integrity of the deliberative process. We wish to thank the following individuals for their review of this report:

LOWELL ANDERSON, Watauga Corporation
MARGE BOWMAN, University of Pennsylvania Health System
PATRICIA FLATLEY BRENNAN, School of Nursing and College of Engineering, University of Wisconsin-Madison
DAVID COUSINS, National Patient Safety Organization, London
DON E. DETMER, American Medical Informatics Association and The University of Virginia
WILLIAM EVANS, St. Jude Children's Research Hospital, Memphis
ANN HENDRICH, Ascension Health, St. Louis, MO
CRAIG HOESLEY, University Hospital, University of Alabama at Birmingham
WILLIAM J. KOOPMAN, Department of Medicine, University of Alabama at Birmingham
GERALD D. LAUBACH, Pfizer Inc., Past President
LUCIAN LEAPE, Department of Health Policy and Management, Harvard School of Public Health
ART LEVIN, Center for Medical Consumers, New York, NY
G. STEVE REBAGLIATI, Department of Emergency Medicine, Oregon Health and Sciences University
HUGH TILSON, School of Public Health, University of North Carolina

Although the reviewers listed above have provided many constructive comments and suggestions, they were not asked to endorse the conclusions or recommendations nor did they see the final draft of the report before its release. The review of this report was overseen by **Paul F. Griner**, University of Rochester, Professor Emeritus and **Charles E. Phelps**, University of Rochester. Appointed by the National Research Council and Institute of Medicine, they were responsible for making certain that an independent examination of this report was carried out in accordance with institutional procedures and that all review comments were carefully considered. Responsibility for the final content of this report rests entirely with the authoring committee and the institution.

PREPUBLICATION COPY: UNCORRECTED PROOFS

Preface

In 2000, the Institute of Medicine (IOM) report *To Err Is Human: Building a Safer Health System* raised awareness about medical errors and accelerated existing efforts to prevent such errors. The present report makes clear that with regard to medication errors, we still have a long way to go. The current medication use process, which encompasses prescribing, dispensing, administering, and monitoring, is characterized by many serious problems and issues that threaten both the safety and positive outcomes of the process. Each of the steps in the process needs improvement and further study.

At the beginning of the medication use process, prescribers often lack sufficient knowledge about how the drugs they are prescribing will work in specific patient populations. If the balance of medication risks and benefits is not known (as is common, for example, with children and the elderly), it is impossible to say whether medication use is safe. Improving medication use and reducing errors, therefore, requires improving the quality of information generated by the pharmaceutical industry and other researchers regarding drug products and their use in clinical practice. We also need to better understand how to communicate such information to clinicians and patients via packaging, leaflets, and health information technology systems. Lastly, we need to understand how better to prevent medication errors in all care settings and in transitions between care settings. In this report, the IOM Committee on Identifying and Preventing Medication Errors proposes a research agenda for industry and government that can help meet these critical needs.

Despite the lack of data regarding many interventions that might improve the quality and safety of medication use, the committee offers recommendations for change that should be implemented and evaluated. People who use medications to meet their health care needs have a huge stake in that effort. The most powerful strategy for improving safety may be motivating providers and organizations to support the full engagement of patients and surrogates in improving the safety of medication use. In addition, providers and leaders of health care organizations must create the climate and infrastructure necessary to continuously learn about and improve the safety of all steps in the medication use process. This report provides guidance on the type of error prevention strategies that should be implemented in each care setting. It also presents the committee's recommendations for the pharmaceutical industry, government, and regulatory, certification, and accreditation bodies, each of which has a role to play in improving the quality and safety of medication use.

This report represents the culmination of the dedicated efforts of three groups of people. We would like to thank our fellow committee members who have worked long and diligently on this challenging study, the many experts who provided formal testimony to the committee and informal advice throughout the study, and the staff of the Health Care Services Board who managed the study and coordinated the writing of the final report.

J. Lyle Bootman, Ph.D., Sc.D.
Linda R. Cronenwett, Ph.D., M.A., R.N.
Cochairs
July 2006

PREPUBLICATION COPY: UNCORRECTED PROOFS

Acknowledgments

The Committee on Identifying and Preventing Medication Errors wishes to acknowledge the many people whose contributions and support made this report possible. The committee benefited from presentations made by a number of experts over the past 2 years. The following individuals shared their research, experience, and perspectives with the committee: Tom Abrams, Food and Drug Administration; Bruce Bagley, American Academy of Family Physicians; Robert Ball, Food and Drug Administration; Jim Battles, Agency for Healthcare Research and Quality; Karen Bell, Centers for Medicare and Medicaid Services; Douglas Bierer, Consumer Healthcare Products Association; David Bowen, Office of Senator Edward Kennedy; Bill Braithwaite, eHealth Initiative; Dan Budnitz, Centers for Disease Control and Prevention; Betsy Chrischilles, University of Iowa; John Clarke, ECRI; David Classen, First Consulting Group; Ilene Corina, Patients United Limiting Substandards and Errors in Healthcare; Diane Cousins, U.S. Pharmacopeial Convention; Loriann De Martini, California Department of Health Services; Noel Eldridge, Veterans Health Administration; Frank Federico, Institute for Healthcare Improvement; Susan Frampton, Planetree; David Gustafson, University of Wisconsin; Ed Hammond, Duke University; Mark Hayes, Office of Senator Chuck Grassley; Carol Holquist, Food and Drug Administration; David Hunt, Centers for Medicare and Medicaid Services; Gordon Hunt, Sutter Health; John Jenkins, Food and Drug Administration; Mike Kafrisen, Johnson & Johnson; Ken Kizer, National Quality Forum; Richard Moore, Massachusetts State Senator; Bill Munier, Agency for Healthcare Research and Quality; Dianne Murphy, Food and Drug Administration; Steve Northrop, Office of Senator Chuck Grassley; Jerry Osheroff, Micromedex; Emily Patterson, Ohio State University; John Reiling, Synergy Health and St. Joseph's Hospital; Lisa Robin, Federation of State Medical Boards; William Rollow, Centers for Medicare and Medicaid Services; Jeffrey Rothschild, Brigham and Women's Hospital Partners Healthcare; Lee Rucker, American Association of Retired Persons; Luke Sato, Harvard Risk Management Foundation; Stephen Schondelmeyer, University of Minnesota; David Schulke, American Health Quality Association; Paul Schyve, Joint Commission on Accreditation of Healthcare Organizations; Paul Seligman, Food and Drug Administration; Vickie Sheets, National Council of State Boards of Nursing; Pat Sodomka, Medical College of Georgia; Scott Stanley, University Health System Consortium; Jonathan Teich, Health Vision; Anne Trontell, Food and Drug Administration; Tim Vanderveen, Alaris & Cardinal Health; and Ed Weisbart, Express Scripts.

The following individuals were important sources of information, generously giving their time and knowledge to further the committee's efforts: Michele Boisse, American Society for Clinical Pharmacology and Therapeutics; Anne Burns, American Pharmacists Association; Francis Dobscha, Advance Med; Melody Eble, Johnson & Johnson; Atheer Kaddis, Blue Cross and Blue Shield of Michigan; Lucinda Maine, American Association of Colleges of Pharmacy; Gary Merica, York Hospital; Joseph Morris, Health Care Improvement Foundation; Richard Park, *IVD Technology* magazine; Ken Reid, Washington Information Source Co.; Ed Staffa, National Association of Chain Drug Stores; Kasey Thompson, American Society of Health-system Pharmacists; Marissa Schlaifer, Academy of Managed Care Pharmacy; Junelle Speller, American Academy of Pediatrics; Sharon Wilson, Center for Nursing Practice; and Charles Young, Massachusetts Board of Registration in Pharmacy.

The committee commissioned eight papers that provided important background information for the report, and would like to thank all the authors for their dedicated work and helpful insights: Harvey J. Murff, Vanderbilt University; Ginette A. Pepper, University of Utah College of Nursing; Grace M. Kuo, Baylor College of Medicine; Marlene R. Miller, Karen A. Robinson, Lisa H. Lubomski, Michael L. Rinke, and Peter J. Pronovost, The Johns Hopkins University; Benjamin C. Grasso, The Institute for Self-Directed Care; Albert I. Wertheimer and Thomas M. Santella, Temple University; Eta Berner, University of Alabama at Birmingham, and Richard

PREPUBLICATION COPY: UNCORRECTED PROOFS

Maisiak, consultant; Brent Petty, The Johns Hopkins University; and Lorri Zipperer, Zipperer Project Management.

The committee also benefited from the work of other committees and staff of the Institute of Medicine that conducted studies relevant to this report, particularly the Committee on Quality of Health Care in America and the Committee on Identifying Priority Areas for Quality Improvement. The Committee on Quality of Health Care in America produced the 2000 report *To Err Is Human: Building a Safer Health System* and the 2001 report *Crossing the Quality Chasm: A New Health System for the 21st Century*. The committee on Identifying Priority Areas for Quality Improvement produced the 2003 report *Priority Areas for National Action: Transforming Health Care Quality*.

Finally, funding for this project was provided by the Centers for Medicare and Medicaid Services. The committee extends special thanks for that support.

PREPUBLICATION COPY: UNCORRECTED PROOFS

Contents

SUMMARY	1
1. INTRODUCTION	21
PART I: UNDERSTANDING THE CAUSES AND COSTS OF MEDICATION ERRORS	37
2. OVERVIEW OF THE DRUG DEVELOPMENT, REGULATION, DISTRIBUTION, AND USE SYSTEM	45
3. MEDICATION ERRORS: INCIDENCE AND COST	95
PART II: MOVING TOWARD A PATIENT-CENTERED, INTEGRATED MEDICATION USE SYSTEM	127
4. ACTION AGENDA TO SUPPORT CONSUMER-PROVIDER PARTNERSHIP	135
5. ACTION AGENDA FOR HEALTH CARE ORGANIZATIONS	195
6. ACTION AGENDA FOR THE PHARMACEUTICAL, MEDICAL DEVICE, AND HEALTH INFORMATION TECHNOLOGY INDUSTRIES	235
7. APPLIED RESEARCH AGENDA FOR SAFE MEDICATION USE	277
8. ACTION AGENDAS FOR OVERSIGHT, REGULATION AND PAYMENT	291
APPENDIXES	
A BIOGRAPHICAL SKETCHES OF COMMITTEE MEMBERS	309
B GLOSSARY AND ACRONYM LIST	317

PREPUBLICATION COPY: UNCORRECTED PROOFS

C	MEDICATION ERRORS: INCIDENCE RATES	325
D	MEDICATION ERRORS: PREVENTION STRATEGIES	361

PREPUBLICATION COPY: UNCORRECTED PROOFS