A Call to Action:

Protecting U.S. Citizens from Inappropriate Medication Use

A WHITE PAPER ON MEDICATION SAFETY IN THE U.S. AND THE ROLE OF COMMUNITY PHARMACISTS

Institute for Safe Medication Practices

a nonprofit organization

Prepared by the Institute for Safe Medication Practices through a grant from The Community Pharmacy Foundation

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About the Institute for Safe Medication Practices

The nonprofit Institute for Safe Medication Practices (ISMP) is recognized worldwide as the premier education resource for understanding and preventing medication errors. ISMP represents more than 30 years of experience in helping healthcare practitioners keep patients safe, and continues to lead efforts to improve the medication use process.

The Institute provides independent expert review of medication errors reported through the US Pharmacopeia (USP)-ISMP Medication Errors Reporting Program. Working with healthcare practitioners and institutions, regulatory and accrediting agencies, consumers, professional organizations, the pharmaceutical industry, and others, ISMP also provides timely, accurate medication safety information to the healthcare community, policy makers, and the general public.

As an independent watchdog organization, ISMP receives no advertising revenue and depends entirely on charitable donations, educational grants, newsletter subscriptions, and volunteer efforts to pursue its lifesaving work. For more information, visit ISMP online at **www.ismp.org**.

Executive Summary

Two out of every three patients who visit a doctor leave with at least one prescription for medication, leading to a record volume of nearly 3.4 billion prescriptions dispensed in 2005 alone. This is an increase of almost 60% since 1995. Two-thirds of the U.S. population receive at least one prescription per year, and close to 40% receive prescriptions for four or more medications. Unfortunately, half of the prescriptions taken each year in the United States (U.S.) are used improperly, and 96% of patients nationwide fail to ask questions about how to use their medications. This increasing misuse of medications is due to many contributing factors.

There has been considerable growth in the number of medications available to American consumers. Currently more than 10,000 prescription drugs and 300,000 over-the-counter (OTC) medications are on the market, and that number is growing. Brand name extension in the OTC marketplace, with products having a common brand name but completely different ingredients, also is increasing. At least 1.5 million preventable adverse drug events occur in the U.S. each year; these costly and sometimes fatal incidents include cases of drug mix-ups and unintentional overdoses.

In recent years, direct-to-consumer (DTC) advertising has become a leading form of marketing practiced by pharmaceutical companies. Many new drugs advertised through DTC may not be appropriate for a consumer's specific condition or illness and can lead to inappropriate or excessive medication use. Results of a survey published in the February 2007 issue of *Consumer Reports* magazine show that 78% of primary care physicians are asked by their patients for specific drugs they have seen advertised on television, and 67% concede that they sometimes grant patients' requests for medications that are not clinically indicated.

Another factor contributing to medication misuse is that alternative medicines continue to gain in popularity. More than 40% of all Americans and half of people aged 35-49 have tried alternative medicines, which are not scientifically reviewed by the U.S. Food and Drug Administration (FDA) for safety. Almost one-fourth of the 44 million people using these products experience adverse reactions.

Low health literacy is a relevant problem that is not fully appreciated by healthcare professionals and consumers. Many healthcare consumers may not be able to read, understand, and act on the instructions found on prescription medication labels and in prescription information pamphlets, which may lead to inappropriate and unsafe medication use. Adults with low health literacy levels are less likely to adhere to prescribed treatment, make more medication errors, and are at higher risk for hospitalization.

Children represent another patient population particularly vulnerable to medication misuse. Approximately 6% of school-age children (nearly 13 million) receive required prescriptions, many of which need to be administered during the school day. Eighty percent of reported school-related medication errors are due to missed doses, which can have a dramatic effect on a child's disease state as well as his or her learning ability.

Limited use of electronic prescribing and electronic healthcare records presents an additional challenge to safe medication use. These technologies can help prevent errors and give healthcare professionals access to more complete patient information, but they have not been fully implemented in most U.S. healthcare settings.

Community pharmacists are uniquely positioned to provide solutions to the problem of medication misuse, in conjunction with other members of the healthcare team. They are widely accessible and have the ability to improve care, enhance communication among healthcare providers, and optimize medication use, resulting in better patient outcomes. They also can help eliminate unnecessary healthcare costs through medication therapy management, which involves reviewing and monitoring medication use, counseling patients, and conducting wellness and disease-prevention programs. Engaging the community pharmacist as a resource for ensuring safe medication use will greatly improve the health of the nation.

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ISMP believes that community pharmacists are the healthcare professionals most qualified to assume responsibility for the medication management of appropriate outpatients who take prescription and non-prescription medications. The further expansion of community pharmacists' role from traditional dispensers of drugs to disease-state managers and providers of direct patient education will help prevent medication misuse, reduce costs, and improve patients' overall health.

ISMP urges Congress, healthcare policy-makers, employers, healthcare insurers, and the public at large to ensure that adequate funding is available for pharmacists to provide additional medication-related services to patients throughout the U.S. These services include medication therapy management and collaborative drug therapy management, which allow pharmacists to provide crucial medication review, monitoring, counseling, education, and disease prevention screenings for patients. More research must be done to determine the best ways to optimize use of community pharmacist services.

The expansion of community **pharmacists' role** from dispensers of drugs to disease-state managers will **help prevent medication misuse**, reduce costs, and improve patients' overall health.

In community pharmacies, pharmacists must be given the time and resources to assist healthcare consumers directly with medication-use issues, particularly with the selection of over-the-counter (OTC) medications. Electronic healthcare records that include the ability of pharmacists to view prescription and OTC medications that patients are currently obtaining from any source must be developed for patients who desire that option, so that pharmacists can check for drug interactions and ingredient duplications that can be lethal to the unsuspecting consumer.

A recent study found that pharmacists would like to devote more of their time to consultation and drug use management activities in community pharmacy settings, but have not yet had the opportunity to engage in these activities to the extent that they desire. As funding, resources, and time are made available, pharmacists must assess their own professional competency skills to determine any potential areas for improvement and enhance their comfort level with providing medication management services.

ISMP applauds healthcare organizations that have adopted electronic prescribing and electronic healthcare records, but more widespread implementation of these medication safety technologies needs to occur. Barriers to adoption must be addressed in order to provide community pharmacists and other healthcare professionals with the information and tools necessary to improve communication and ensure appropriate medication use.

U.S. school systems also should utilize pharmacists' expertise. Research should be conducted to determine if adding consultant pharmacists to the medication management process for school systems would decrease medication misuse, increase adherence to medication regimens, and result in better healthcare outcomes for the nation's children.

Healthcare consumers may be able to help prevent medication misuse by developing relationships with their community pharmacists, which will provide more opportunities for individualized medication counseling and monitoring. Additional study is needed on consumers' attitudes toward medication use—for example, the possible link between patients' concerns regarding unknown and suspected adverse reactions to medications and subsequent non-adherence to prescribed therapy.

The FDA or other appropriate agency must work with manufacturers of pharmaceutical products to provide uniform labeling of ingredients that is prominent on the front package label and limit confusing brand name extension of OTC products. Clearly labeled measuring devices should be provided with all liquids and any other products that require consumers to measure a specific dose from a multi-dose container. Finally, the risks versus benefits of direct-to-consumer (DTC) advertising for prescription medications should be studied more thoroughly to determine the impact on appropriate medication use.

The Problem

An increasing number of U.S. consumers are taking medications. Two out of every three patients who visit a doctor leave with at least one prescription for medication, leading to a record volume of nearly 3.4 billion prescriptions dispensed in 2005. This is an increase of nearly 60% since 1995.[1] In fact, 81% of adults in the U.S. take at least one medication during a given week and 27% take at least five.[2]

When used safely, medications contribute to better health and to a longer and greater quality of life. However, a vast number of Americans take prescription medications without being fully informed about the associated risks, contraindications, and adverse effects.[3] Misuse of medications can interfere with desired treatment and cause harmful reactions. In the year 2000, the annual costs of drug-related illness and death in ambulatory care settings alone were estimated at more than $177 billion.[4] The most common types of medication misuse include:[5]

- Taking the incorrect dose
- Taking a dose at the wrong time
- Forgetting to take a dose
- Stopping medicine too soon

According to research published by the California Board of Pharmacy and others, half of the prescriptions taken each year in the United States are used improperly, and 96% of patients nationwide fail to ask questions about how to use their medications.[6] When patients do not take medication that has been prescribed, unnecessary disease progression, disease complications, reduced functional abilities, a lower quality of life, and even death can result.

In a 2007 report, the National Council on Patient Information and Education (NCPIE) listed lack of awareness among clinicians about basic medication management principles, poor communication between patients and clinicians, operational aspects of pharmacy and medical practice, and professional barriers as some of the contributing factors to U.S. patients not taking prescriptions as directed.[7]

At least 1.5 million preventable adverse drug events occur in the United States each year; these costly and sometimes fatal incidents include cases of drug mix-ups and unintentional overdoses.[3] One study estimates that more than 700,000 complications from medications are experienced nationwide each year.[8]

For every:	There are:
1,000 outpatients who are taking a prescription drug	90 who seek medical attention because of drug complications
1,000 prescriptions written	40 that involve medical errors[9]

A survey by Harris Interactive® found that a patient's previous experiences with adverse reactions to prescribed medications can lead to subsequent non-adherence to medication therapy. This includes not taking prescription medications as directed (non-adherence) and not filling prescriptions over time (lack of persistence). The poll found:

- Thirty-five percent of people who have ever taken a prescription medication reported they had decided not to take a prescription drug because they had a concern about a potential adverse reaction
- Twenty-seven percent of people who have ever taken a prescription medication reported they had decided not to obtain a prescription because of concern about a potential adverse reaction
- Ninety-four percent of people who have had an adverse reaction reported they had stopped taking a medication due to an adverse reaction[10]

There are five key pieces of information that must be conveyed to patients when prescription medication therapy is to be initiated to ensure proper medication use:

- The name of the medication
- The purpose of the medication

- The length of time the medication should be taken
- Amount of medication per dose and how frequently it should be taken
- Information on possible adverse effects and what to do if they occur

If patients do not receive all of this information, they may not take their medication appropriately, leading to medication errors and unnecessary hospitalizations.[11] The 2006 Institute of Medicine (IOM) report *Preventing Medication Errors* estimates that more than 1.5 million people are injured by medication errors each year, with an estimated cost of $3.5 billion.[3]

Contributing Factors to Medication Misuse

Growth in the Number of Medications Readily Available to American Consumers

There are currently more than 10,000 prescription drugs and biologics and more than 300,000 over-the-counter (OTC) medications on the market.[3] Increased growth in the number of available medications may be contributing to increased consumption and potentially greater risk for medication misuse.

Direct to consumer (DTC) advertising has become a leading form of marketing practiced by pharmaceutical companies to promote new prescription medications. Overwhelmingly positive advertising claims presented on the television and in magazine advertisements often result in inappropriate demands for new drugs by consumers. This can lead to improper or excessive medication use, since many drugs advertised through DTC may not be right for a consumer's specific condition or illness.

Survey results published in the February 2007 issue of *Consumer Reports* magazine reveal that 78% of primary care physicians are asked by their patients for specific drugs they have seen advertised on television. The survey, which involved 335 doctors and more than 39,000 healthcare consumers around the nation, found 67% of doctors concede that they sometimes grant their patients' requests for medications.[12] However, the advertised medications may or may not be clinically indicated for these patients. Overmedicating can lead to significant complications such as drug-resistant infections and even death. Despite that fact, expenditures on DTC advertising have grown 50% per year since 1997, totaling $2.3 billion in 2005.[13]

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The aging of America's baby-boomer generation has created a stronger demand for access to state-of-the-art pharmaceuticals, treatments, and other aids to enhance and prolong quality of life. Spending on 'specialty' drugs, a category that includes many biotech treatments for chronic conditions, such as rheumatoid arthritis, cancer, hemophilia, hepatitis, anemia, cystic fibrosis, and growth hormone deficiency, increased by 17.5% from 2004 to 2005. In addition:

- Spending on specialty drugs accounted for 19%, or $40 billion, of all prescription drug spending in 2005
- Spending on specialty drugs is projected to reach $90 billion by 2009 and account for 28% of the projected $316 billion in total spending on all medications
- The greatest increase in specialty drug spending in 2005 was for treatments used for inflammatory diseases, which increased 35%; hemophilia, which increased 25%; and cancer drugs, which increased by 19.2%[14]

The development of new specialty medications offers hope for patients who may previously have had few pharmaceutical options, but also raises significant challenges in medication oversight and management. Many of these medications require significant expertise and training to prepare the exact dose of medication to be administered, monitor side effects and reactions, and adjust the dose throughout treatment.

The Expanding OTC Market

Presently, drugstore and supermarket shelves are filled with complicated, confusing brand-extension OTC products. There are now more than 50 Tylenol brand products that contain varying strengths of acetaminophen, and many have different ingredients. For example, regular-strength Tylenol contains 325 mg of acetaminophen in each tablet, but Tylenol Extra Strength with 500 mg of acetaminophen per tablet also exists, as well as Tylenol Arthritis Pain with 650 mg of acetaminophen per tablet. Tylenol PM with 500 mg of acetaminophen also contains a sedating antihistamine (diphenhydramine).

A wide variety of other Tylenol products with similar-sounding names are also available.[15] Acetaminophen overdose and toxicity is very plausible if more than one Tylenol product is being taken simultaneously by an unsuspecting, uninformed consumer. In fact, patients may take these products not realizing that they contain acetaminophen at all, since the Tylenol brand name is emphasized and not the ingredient.

A recent study indicates that acetaminophen-induced liver toxicity is a growing problem that now accounts for more than 40% of U.S. cases of acute liver failure. During the six-year study period, nearly half of the reported cases of acetaminophen-induced acute liver failure were due to unintentional overdoses. In addition, 63% of patients in this group used prescription narcotic-acetaminophen combinations such as Percocet (oxycodone and acetaminophen) or Vicodin (hydrocodone and acetaminophen) and 38% reported using two or more acetaminophen-containing products simultaneously.[16]

The presentation of drug and dosing information on the labels of OTC products also can be confusing to consumers and lead to misuse. Missing or hidden side effect information may mislead the consumer into thinking the product is safe. Drug facts labels, intended to be clear and easy to read, are actually printed in a small type size and can be spread out over three panels (top, back and bottom) as well as on 'hidden' back panels.

The use of OTC drug products and dietary supplements in the elderly is of particular concern, since this population uses more prescription medicine and is at higher potential risk of harmful prescription and OTC medication-related duplication, interactions, and side effects than are younger adults. The elderly (aged 65 and older) make up 13% of the U.S. population—however, they account for 34% of all prescription medicines dispensed.[17] Research shows that 40% to 87% of community-dwelling adults aged 65 and older use at least one OTC product regularly, and one study reports that 5.7% take five or more nonprescription medications and/or dietary supplements daily.[18]

The conversion by the FDA of prescription medications to OTC status, known as 'Rx-to-OTC switch,' is a growing trend that could lead to increased medication misuse. More than 700 products that once required a prescription can be purchased in pharmacies, supermarkets and other retail outlets today without a prescription, and many new OTC conversions are on the horizon.

The expansion of the OTC market is placing more responsibility on the consumer to make correct clinical decisions and appropriate product selections. Many educated consumers are now using diagnostic home testing kits, which can potentially lead to medication misuse. Safe use of OTC products requires accurate diagnosis of the patient's conditions and optimally should be done by the physician or other appropriate healthcare professional in conjunction with the patient. An incorrect self-diagnosis, such as mistaking chest pain as heartburn rather than an impending heart attack, may lead to an adverse event, hospitalization, and possible death.

Increased Use of 'Natural' Medicines

The use of dietary supplements and alternative medicines continues to gain popularity among health-seeking consumers. More than 40% of all Americans and 50% of people aged 35-49 have tried alternative medicines.[19] It has been reported that:

- 106 million people use vitamins and minerals
- 44.6 million people use herbal remedies
- 24.2 million people use specialty dietary supplements[20]

The FDA has not evaluated scientific data concerning the safety or benefits of most dietary supplements.[21] Estimates show that 11.9 million people have experienced a side effect or an adverse reaction from using herbal remedies. That means almost one-fourth of the 44 million people using such products experience adverse reactions.[20]

Low Health Literacy

Physicians, nurses, pharmacists, and other healthcare professionals may assume that their patients can read, understand, and act on the brief instructions found on prescription medication labels and on medication information pamphlets. Ninety million Americans read below the 5th grade level,[22] while 98% of the consumer medication information sheets accompanying dispensed prescriptions are written between a 9th and 12th grade level or higher.[23]

A study published in the *American Journal of Health-System Pharmacy* showed that there is a high level of misunderstanding of prescription drug warning labels among adults with low literacy. In fact, the majority of patients misinterpreted all of the labels tested with exception of the most simple, "Take with food."[24]

Poor health literacy can lead to consumers misusing their medications. For example, adults with low health literacy:

- Are less likely to adhere to prescribed treatment and self-care regimens[25]
- Make more medication or treatment errors[20]
- Often fail to seek preventive care[26]
- Are at a higher risk for hospitalization[18]
- Remain in the hospital on average nearly two days longer than individuals with adequate health literacy.[22]

Other effects of low health literacy include poor health outcomes, unnecessary health expenditures, higher patient dissatisfaction with treatment, and higher provider frustration.

Parents are often confused by measurements for liquid medications… and give their children an incorrect dose of OTC fever medicine **47%** of the time.

Vulnerability of Children to Medication Misuse

Children are particularly vulnerable to medication misuse. One study demonstrated that parents give their children an incorrect dose of OTC fever medicine 47% of the time.[3] Recent studies have shown that educating parents on how to measure and administer the correct dose of medication for their children can prevent errors.

Parents are often confused by the measurements used to administer liquid medications as well as the measuring devices—they often do not understand the difference between a teaspoon and a tablespoon, or the proper use of metric measurements such as milliliters (mL).[27]

Safe and correct medication administration during school hours is another challenge for school systems. Approximately 6% of school-age children (nearly 13 million) receive medication while in school and 80% of school-related medication errors reported were due to missed doses.[28]

In addition, many medications are not indicated for use in children. A study by Medco Health Solutions found an 85% increase from 2002 to 2004 in the use of sleeping pills among children and young adults. Approximately 15% of the children who took sleeping pills were concurrently taking drugs to treat attention deficit and hyperactivity disorder. Since those drugs may cause insomnia, the sleeping pills were most likely being used to counteract the side effect,[29] although the use of sleep medications for children under the age of 18 has not been approved by the FDA.

Student attendance in school (and corresponding parent absenteeism from work), attention span, performance, and safety are all affected by improper disease management.

The Solution

Who's Minding the Medicine Cabinet?

The ambulatory healthcare community has very few quality indicators to monitor appropriateness and safety in medication delivery. This is alarming considering the complexity of medication therapy and the dangers patients face when taking medications. However, as the medication-use process has become increasingly complex, pharmacists are more and more seen as key healthcare professionals who can interact directly with the patient, caregivers, and the prescriber. They have patients' trust and respect (see sidebar), and are in a position to know exactly what medications are being taken and to identify problems.

Pharmacists have the skills needed to evaluate patients' medication regimens relative to their disease status. They can make suggestions to prescribers about additional or different medications that patients might benefit from, eliminate duplication in therapy caused by patients taking more than one drug with the same ingredients, screen for drug-drug interactions, and assess patient adherence to medication regimens. Pharmacists also can provide valuable education about prescription and OTC medications as well as alternative, herbal, and natural medications that may be available without a prescription but are not necessarily benign or safe. In addition, pharmacists can support school health services by sharing their expertise on medication safety and by facilitating the continuity of information between parents, students, school healthcare professionals, and the patients' primary healthcare providers.

Pharmacists Working as Key Members of the Healthcare Team

Effective management of medication therapy requires cooperation by all members of the healthcare team. Physicians, pharmacists, nurses, and other healthcare providers need to collaborate to ensure that patients understand their health conditions, the risks versus benefits of suggested treatments, results of their diagnostic tests, treatment goals, and the need to take an active role in managing their condition. Establishing and maintaining strong partnerships between healthcare providers and patients is crucial to reducing the risk of medication errors and medication misuse.

It is possible that if patients develop a relationship with their community and other pharmacists, they may be less likely to use drugs inappropriately, because their pharmacists then have enhanced opportunities to provide medication counseling.[31] "We as healthcare professionals need to create an environment that allows patients to ask questions and makes them feel more comfortable with taking an active role in the health care process," states Eric Cannon, PharmD, a member of the 2006 IOM report committee and director of pharmacy services and health and wellness at SelectHealth/Intermountain Healthcare in Salt Lake City.[32] Pharmacists are in a position to ensure that patients understand why they are taking medications and know how to take them properly.

A recent study shows that "pharmacists would like to devote more of their time to consultation and drug use management activities in community pharmacy settings, but have not yet been afforded a full opportunity to engage in these activities to the extent that they desire."[33] Pharmacists have a role to play in meeting the primary care needs of patients by providing patient education, advice to prescribers, medication therapy management, and in states where it is authorized, collaborative drug therapy management. But to do this, pharmacists must shift from a dispensing-centered focus to a focus on patient services. Pharmacy leaders point out that pharmacists' expertise can be used to help patients maximize the benefits of medications by reducing adverse reactions, increasing adherence with medication regimens, and reducing overall spending on healthcare.[34]

Collaborative drug therapy management—a multidisciplinary process that involves selecting appropriate drug therapies, educating patients, providing drug therapy monitoring, and continually assessing outcomes of therapy—is one way pharmacists' expertise could be better utilized. Pharmacists participate in collaborative drug therapy management for patients who have a confirmed diagnosis from

Patient Trust in Pharmacists

Top 10 Professions Rated by Americans as Having 'Very High' or 'High' Ethical Standards

1. Nurses (84%)
2. Pharmacists (73%)
3. Veterinarians (71%)
4. Medical doctors (69%)
5. Dentists (62%)
6. Engineers (61%)
7. Clergy (55%)
8. College teachers (55%)
9. Policemen (54%)
10. Psychiatrists (38%)

Source: 2006 Gallup Poll[30]

Establishing and maintaining **strong partnerships** between healthcare providers and patients **reduces the risk** of medication errors and medication misuse.

an authorized prescriber. The activities of a pharmacist in collaborative drug therapy management may include, but are not limited, to: initiating, modifying, and monitoring a patient's drug therapy; ordering and performing laboratory and related tests; assessing patient response to therapy; and counseling and educating patients on medications and administering medications. For example, studies have shown that patients taking blood thinning medications while being followed in an anticoagulation clinic managed by pharmacists have better treatment outcomes and experience fewer adverse events because the pharmacist monitors their international normalized ratio (INR), an important number that indicates blood thinning levels.[35]

Certainly financial challenges exist for this type of model, in which the community pharmacist is considered an active member of the patient's healthcare team. Cuts in spending for Medicare and Medicaid as well as overall healthcare cost containment makes initial funding for these services difficult, but in the long run this model can show an overall decrease in healthcare costs, especially if databases are synchronized within and between these government plans. Americans spend more than $75 billion per year on prescription and nonprescription drugs; the following statistics illustrate the high price of medication misuse:[36]

- Improper use of prescription medicines due to lack of knowledge costs the economy an estimated $20-100 billion per year
- American businesses lose an estimated 20 million workdays per year due to incorrect use of medicines prescribed for heart and circulatory diseases alone
- Failure to have prescriptions dispensed and/or renewed has resulted in an estimated cost of $8.5 billion per year due to increased hospital admissions and physician visits—nearly 1% of U.S. total healthcare expenditures

Intervention by the pharmacist as a member of the healthcare team can be of significant help in eliminating unnecessary costs by improving medication use.

Medication Therapy Management by Pharmacists

While collaborative drug therapy management is a multidisciplinary process, medication therapy management (MTM) describes services that many pharmacists already provide. MTM is a platform that has launched pharmacy practice into a new era. The mission of MTM is to optimize therapeutic outcomes through improved medication use and to reduce the risk of adverse events. A 1995 study estimated that $76 billion in healthcare expenditures could be saved and 120,000 deaths per year could be prevented if pharmacists were more fully utilized in community healthcare.[37]

Through the MTM provisions of the Medicare Part D benefit, pharmacists for the first time are being recognized for the value they bring to healthcare. Payers, both private and public, are starting to see that patients need assistance to better manage their medications, and that pharmacists have an important role to play in medication management.[36] This is an opportunity to demonstrate that pharmacists can provide help specifically in the community setting; pharmacist interaction with patients is the missing link to providing better continuity of care. The local community pharmacist has the expertise, as well as the trust of, access to, and relationships with patients, their caregivers, and physicians to ensure safe, appropriate medication therapy.

MTM services describe what pharmacists are already doing or should be doing—helping patients manage their medications by ensuring that they are taking the right drug, the right strength, and the right dose in the right combination with other medications if necessary, at the right time.[38] MTM includes managing and monitoring drug therapy in patients receiving treatment for a variety of conditions, consulting with patients and their families on the proper use of medication, conducting wellness and disease prevention programs to improve public health, and overseeing medication use. These services are provided across the entire healthcare system, including home care settings, hospitals, ambulatory settings, long term care facilities, clinics, and intensive care units.[39]

Community pharmacies already are integral parts of neighborhoods across the U.S. and provide important services and benefits to their patients and to their local neighborhoods. Currently, many

pharmacies offer preventive services, such as blood pressure screenings, bone density screenings, pulmonary function testing, cholesterol testing, diabetes education, and flu shots. Pharmacists also offer a variety of professional services such as counseling on new and refill medication, assistance with selection of OTC products (see sidebar), take-home patient literature on prescribed medications, compliance/persistency reminder programs, health condition information, and advice on non-prescription and herbal products. In many cases, they are able to coordinate care with the patient's other healthcare providers.

Guidelines for Choosing and Using Over-the-Counter (OTC) Drugs[40]

- Make sure that the self-diagnosis is as accurate as possible. Do not assume the problem is "something that is going around"
- Choose a product because the ingredients are appropriate for the condition, not because the product has a familiar brand name
- Choose a product with the fewest appropriate ingredients. Products that attempt to relieve every possible symptom are likely to expose people to unnecessary drugs, pose additional risks, and cost more
- Read the label carefully to determine the correct dose and precautions, including what conditions would make the drug a poor choice
- When in doubt, ask a pharmacist or doctor what the most appropriate ingredient or product is
- Ask a pharmacist to check for potential interactions with other drugs used
- Ask a pharmacist to identify possible side effects
- Do not take more than the recommended dose
- Do not take an OTC drug longer than the maximum time suggested on the label. Stop taking the drug if symptoms worsen
- Keep all drugs, including OTC drugs, out of the reach of children

Pharmacists in community pharmacy practice also are uniquely positioned to assist patients in choosing home diagnostic testing solutions based on ease of use and reliability of results. Using the test kit results, the pharmacist and the consumer can select the most appropriate OTC product available for the desired treatment, or discuss possible prescription solutions with both the patient and their primary care provider. For example, the best way to prevent diabetes or the complications of diabetes is active self-monitoring of blood glucose levels. This can be accomplished by the patient at home, using the glucose monitoring kit with which they feel most comfortable.

Much of the community pharmacist's time is spent interacting with patients, identifying possible drug interactions, and advising how to best use OTC products. But given the opportunity and resources, they are well-positioned and willing to do more—MTM programs go one step further by offering pharmacist services that optimize therapeutic outcomes for an individual patient, usually in conjunction with the dispensing of a prescribed medication.

MTM usually includes:

- A medication therapy review of all the medications currently being taken by an individual
- A medication action plan to address safety issues, inconsistencies, duplicate therapy, and omissions
- An intervention and referral plan to make necessary changes
- Documentation and follow up to ensure consistent levels of pharmacy service and positive patient outcomes

Anticipated outcomes of MTM include:

- Improved patient satisfaction with their healthcare plan
- Increased cost effectiveness for the insurance plans—drug costs may not go down, but overall health care spending will
- Decreased emergency room visits, hospitalizations, and doctor office visits
- Improved quality of life
- Fewer missed work days (due to their own medication mismanagement or that of their children's medication misuse)

$76 billion in healthcare expenditures could be saved and 120,000 deaths per year could be prevented **if pharmacists were more fully utilized** in community healthcare.

The benefits of pharmacists providing MTM services are gaining recognition; however, only a fraction of the potential savings and positive outcomes are being realized.

There are well-documented community pharmacist/patient partnership success stories for MTM. The Asheville experience is one such success story. In Asheville, NC, seven self-insured employers representing 12,000 covered lives were eligible to receive face-to-face chronic disease 'coaching.' In fact, 1,100 people with diabetes, asthma, high blood pressure, or high cholesterol met with their pharmacist more than 5,000 times in a year as part of the program. The results are staggering.

Significant outcomes included:[41]

- ***Net*** decrease in total healthcare costs averaged greater than $2,000/patient/year for patients with diabetes
- ***Net*** decrease in total healthcare costs averaged $725/patient/year for patients with asthma
- Missed work hours due to diabetes decreased by 50%
- Missed work hours due to asthma decreased by 400%
- No diabetes program participant went on dialysis during the program, resulting in savings of $100,000 per year (cost of dialysis per year)
- Total health plan costs for the largest employer (Mission Hospital) rose only 0.1% in 2004 and decreased 1% in 2005

In another pharmacy care intervention program, researchers studied 174 patients, average age 78, taking an average of nine different medications a day.[42] The study found that the program, which included education about medications, regular patient follow-up by pharmacists, and dispensing of medications using time-specified blister packs, increased patient medication adherence by more than 30%. The average adherence rate—the rate of patients taking their medications in the amounts and at the frequencies prescribed by their physician—was 61% at the start of the study, but after six months of pharmacist interventions it increased to 97%.

Pharmacists partnering with patients in these MTM programs is a key factor in their success, largely due to the fact that pharmacists are readily accessible in the community. Patients struggle to adjust their daily habits in order to comply with their treatment regimens. Often they have numerous questions that are not viewed as justifying an appointment with their doctor, and may not be covered by their insurer. Obtaining the answers to those questions from their pharmacist(s) can aid in the success of their treatment. Enabling patients to be healthier through proper medication use and patient monitoring is an important role that pharmacists can play to help control the high cost of healthcare. New reimbursement models that include paying the pharmacist for managing medication therapy need to be expanded to enable growth of these important services.

The benefits of pharmacists providing MTM services are gaining recognition; however, only a fraction of the potential savings and positive outcomes are being realized. Enormous additional value could be brought to healthcare if programs such as the Asheville program are expanded to other communities.

For MTM services to be fully utilized, the following is necessary:

- Monetary reimbursement for cognitive pharmacy services, with national recognition of pharmacist treatment billing codes
- Increased number of pharmacy school graduates and their training on cognitive services
- Increased level of pharmacist confidence in providing these services, gained through continuing individual professional development
- Patients and healthcare policy makers realizing the importance of services offered by pharmacists and value of return visits to the pharmacy
- Physicians and other healthcare providers referring and maintaining patients within the MTM services
- Expanded use of technology in order to lower costs and improve efficiency

Supporting Continuity of Care and Greater Pharmacist Role through Technology

One important contributor to continuity of care is medication reconciliation. Medication reconciliation, the process of comparing a patient's current medications with those being ordered after

admittance to the emergency department (ED) or other entry point to healthcare, begins with an accurate home medication list. When a patient is admitted to a hospital or treated in any ambulatory setting, including their physician's office, it is imperative that the most accurate list of the medications that the patient is taking is available to the medical staff so that potential medication errors can be avoided and the best decisions about patient care can be made.

The community pharmacist is the key source for this up-to-date information. The community pharmacist can also let the healthcare team know which medications the patient has been taking regularly by checking their refill history. To improve communication between the community pharmacy, patient, physician office, and hospital staff, the local pharmacist can provide each patient with an updated computer printout listing their medications and dates of dispensing.

To ensure better continuity of care, a coordinated, interdisciplinary team-based care model is necessary, in which all healthcare professionals, patients, and family members work together to initiate an electronic healthcare record (EHR). The EHR has the ability to enrich communications between pharmacists and physicians, resulting in better patient outcomes.

An EHR also can enable an additional layer of patient safety by providing software with clinical decision support tools that can support medication ordering. Clinical decision support tools screen orders for contraindications, drug-drug interactions, indications, and potential errors in dosing. Effective contraindication screening can be facilitated by tools that are supported by standardized vocabularies for describing medication, allergies, and indications. Pharmacists as well as other providers need access to these clinical decision support tools.

Pharmacy and individual pharmacists also must focus on taking professional responsibility for ensuring continuity of pharmaceutical care as patients move from one healthcare setting to another. Upon discharge or transfer from one provider of care to another, medication information, including the medication list, allergy information, new allergies identified during hospitalization, medication-use instructions, and new prescriptions, must be communicated to the patient, family members, patient advocate, next provider of care, and the patient's community pharmacy. If there is no pharmacy care partnership with patients and providers, the potential for incorrect dosing, drug interactions, treatment failures, drug use without indication, and failure to receive medications increases.[43]

The 2006 Institute of Medicine (IOM) report *Preventing Medication Errors* emphasized the necessity for finding solutions to ensure safe medication use, and recommended a series of actions for patients, healthcare organizations, and pharmaceutical companies. One key area of focus was the increased use of medication-safety technology in the healthcare workplace. The 2006 IOM report presents two technology-related recommendations that can help improve the prescription delivery process when applied in the community pharmacy setting.

The first technology is electronic prescribing, or 'e-prescribing,' and the report's specific recommendation is that all prescriptions be written and received electronically by 2010. This was a recommendation that ISMP had hoped would be achieved by the year 2003.[44] Combined with EHRs, e-prescribing opens up the lines of communication between all members of the healthcare team and gives pharmacists and physicians the information needed to improve patients' adherence to their medication therapy and identify potential problems. It can improve accuracy of prescriptions and give pharmacists more time with the patient.

Today, more than 90% of the nation's pharmacies are certified to receive prescriptions electronically.[38] This is a great achievement, but certification to receive electronic prescriptions alone does not improve safety. Only a limited number of providers are actually transmitting prescriptions directly from the prescriber's computer system to the information system at the pharmacy. Many additional changes and solutions will be required for maximum use of this new technology in community pharmacies. The IOM's goal of 100% adoption and utilization of electronic prescribing by 2010 will require rapid and massive support from prescribers, payers, government agencies, pharmacists, and patients.

Community pharmacy also has been focusing its efforts on a second technology recommendation from the IOM report—giving healthcare providers a patient's medication history across all prescribers as

The **electronic healthcare record** (EHR) has the ability to enrich communications between pharmacists and physicians, resulting in **better patient outcomes**.

part of an EHR. This service would be created by connecting data from the nation's community pharmacies, regardless of retail brand or physical location, combining it with medication data from payer sources, and presenting that data to physicians through software certified by several network providers to provide a more complete, timely, and clinically sound view of a patient's medication record. This capability was first tested as part of community pharmacy's response to helping victims of hurricane Katrina. Those displaced and in need of medication were often without any prescription information. Shortly after the disaster, caregivers were able to access patient medication histories from community pharmacies via KatrinaHealth.org, an online information source established by a collaboration of private companies, public agencies, and national organizations.[38]

The IOM's **goal of 100%** adoption and utilization of **electronic prescribing** by 2010 will require **rapid and massive support** from prescribers, payers, pharmacists, and others.

Summary

Medication misuse is a growing problem in the U.S. due in part to the increasing use of prescription and OTC medications by an aging population. Growth in the number of available medications, rise of DTC advertising, gaining popularity of alternative medicines, and low health literacy among healthcare consumers are additional contributing factors.

The healthcare system faces many challenges to ensuring safe medication use, including limited use of electronic prescribing and other technology that can improve the prescription delivery process. Collaboration by all members of the healthcare team also needs to be enhanced in order to ensure optimal medication use education and monitoring.

ISMP believes that mounting evidence points to the fact that community pharmacists are a crucial part of the healthcare team and an underutilized resource for protecting patients from inappropriate medication use. Community pharmacy is designed to improve care, enhance communication among patients and other healthcare providers, improve collaboration among providers, and optimize medication use that leads to improved patient outcomes.

Through the MTM provisions of the Medicare Part D benefit, pharmacists for the first time are being acknowledged for their value in healthcare. Payers, both private and public, are starting to see that patients need to manage their medications better and that pharmacists have an important role to play in medication management. The U.S. government also has recognized the value of community pharmacy—the Department of Health & Human Services national health goals state that by 2010, 95% of patients should receive verbal counseling from their prescribers and pharmacists on appropriate use and potential risks of medications.[45]

This trend needs to continue. Healthcare policymakers, the healthcare community, and patients need to recognize that community pharmacists can help meet the American public's increasing need for patient care services related to medication use and wellness promotion. Community pharmacists are among the most widely accessible healthcare professionals, and need to be utilized not only as the traditional dispensers of drugs, but also as disease state managers providing patient education, counseling, and monitoring of drug therapy.

In addition, the healthcare system model needs to include community pharmacists partnering with other members of the healthcare team to share clinical data and work from the same medical records. This collaboration and access to resources will help provide an advanced level of care, enhance the patient's understanding of appropriate drug use, increase adherence with medication therapy, and improve detection of adverse drug events.

Community pharmacists have the ability to impact the management of patients' chronic disease and contribute substantially to improved outcomes and lowered healthcare costs. Supporting and engaging the community pharmacist as a resource for safe medication use and early detection and management of adverse drug reactions is an important step toward improving the health of the nation.

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