Best Practices in Medication Safety: Areas for Improvement in the Primary Care Physician's Office

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Abstract

This research describes a medication safety framework for primary care office-based practices and evaluates how offices manage the medication use process within this framework. The conceptual model supporting the safety framework integrates structure, process, and outcome quality concepts relevant to medication safety. Medication safety domains were identified through a review of published literature; the Agency for Healthcare Research and Quality (AHRQ) patient safety agenda; research portfolios, reports, guidelines, and standards from private and public organizations; and an onsite evaluation of the medication use process in two primary care offices. Domains identified include the medication use process, technology and safety, the office environment, error management, workplace conditions, safety education. safety perceptions, and patient education. Based upon these domains, a 154-item written survey was developed to assess medication safety in office practice. It was administered to 31 primary care office-based practices in the Nebraska and Iowa region, using the interviewer-assisted technique. A direct observation study, onsite technology readiness survey, and accessibility of drug information sources were conducted concurrently. Results provide evidence that a medication safety framework is lacking in office-based practice. Suboptimal—and sometimes unacceptable—practices related to medication safety in primary care offices are identified and described. Results may be used to describe the medication safety framework and to identify best practices for office-based medication safety.

Introduction

The Institute of Medicine suggests that hospitalized patients represent a fraction of the total population at risk of experiencing a medication-related error, as the majority of medication prescribing and use occurs in the ambulatory environment (2.5 billion prescriptions dispensed by U.S. pharmacies in 1998).[1] Forty percent of consumers in a recent survey reported they were very concerned about serious errors or mistakes from care received at the doctor's office.[2] A study of 89 community pharmacists in five States revealed 1.9 percent of 33,011 new prescription orders required a pharmacist to resolve a prescription-related problem. Expert evaluators concluded that 28.3 percent of the prescribing problems identified during the study could have caused patient harm if the pharmacist had not intervened to correct the problem.[3] Legibility of prescriptions

has also been cited as a common reason for error.[4] Although a large contingency believe that electronic prescribing will solve these problems, early evidence suggests that new ones may also be created.[5] Distribution of medication samples in physicians' offices also contributes to the safety problem in the United States. Although the quantity of sample medications distributed each year is not widely known, two examples provide an indication of the high volume. In 1999, Schering Plough distributed 35.7 million samples of Claritin® and SmithKline Beecham distributed 18.5 million samples of Augmentin®.[6] Medication samples are received, stored, and provided to patients with limited regulatory requirements governing their use. They are given to patients without the benefit of a drug regimen review by a pharmacist, and, unlike prescriptions handled in the traditional pharmacy system, maintenance of the records is not required by law. These examples illustrate the medication safety gap in our system of ambulatory-care delivery in primary care office-based practices in the United States.

Much time and energy and many resources have been spent improving the medication safety practices for the inpatient environment. In the Agency for Healthcare Research and Quality (AHRQ) publication, *Making Health Care Safer: A Critical Analysis of Patient Safety Practices*, all 79 evidence-based best practices described were in the hospital setting.[7] The time has come to address these safety issues in the primary care office-based environment. Office-based practices are literally devoid of the safety systems that parallel those developed for inpatient care. A recent review by Galt summarizes the needs for further medication safety research in the primary care office setting.[8]

Objective

This research describes a comprehensive evaluation of medication safety problems identified in primary care office-based practices. Findings may be useful in developing a recommended set of best medication safety practices for adoption by offices in the United States. Specific aims of this work are to (1) identify patient medication safety domains in office-based practice, and (2) assess medication safety practices of primary care offices through survey research combined with direct observation field work that incorporates patient medication safety domains.

Methods

A field study of 31 primary care office-based practices was conducted in May 2003. Each office completed a written survey, an onsite interview, and participated in a concurrent observational study by a field researcher.

Study population

A convenience sample of 31 primary care office-based practices enrolled in an AHRQ-sponsored study of potential office-based prescribing errors was studied.[9] The offices were predominantly family medicine primary care practices (85

percent family medicine, 15 percent internal medicine), with an average of 2.1 practitioners per office (range: 1–7 physicians per office). Seventy-eight physicians were in these practices located in the region of eastern Nebraska and western Iowa. The physician gender distribution was three-fourths male, with a mean age of 42. These Midwestern offices were typical of independent primary care offices nationally—all were urban, with the exception of one rural practice.[10]

Medication safety domain identification

Medication safety domains have previously not been identified in the ambulatory setting. The domains were identified by reviewing the areas of safety emphasis from the Institute of Medicine report, *To Err Is Human*; the AHRQ patient safety agenda and portfolio; the scientific literature, reports, guidelines, and standards from public and private organizations; and a preliminary onsite evaluation of medication use processes that take place in primary care physicians offices.[1, 7, 11–19] Medication safety domains were further evaluated by physicians and pharmacists who are experts in the medication use process. The results of this review yielded the following domains: (1) medication use process; (2) patient interactions and medication safety; (3) office environment; (4) error management; (5) work place conditions and safety perceptions; (6) safety education; and (7) technology and medication safety.

Medication use process in office-based practice

The medication use process in the primary care office-based practice is complex, due to the various communication pathways between the patient, prescriber, and the pharmacist. The five-step medication use process model (prescribing, documenting, dispensing, administering, and monitoring) generally used to represent the inpatient setting does not accurately describe the complex process in the outpatient setting. To improve our identification of safety improvement opportunities, we described specific process steps and key points of communication that take place in the office-based environment and between physician's office, patient, and pharmacy. Figure 1 depicts the general outpatient medication use process in the physician's office and the pharmacy, and outlines communication pathways common to the two entities.

Data collection

The written, 154-item survey was piloted on two primary care offices before administration to all participating offices. Specific items were developed based upon the same sources used to develop the safety domains. This survey was completed by the primary care office managers using the self-administration, interview-assisted technique.[20]

Direct observation was conducted at each office to evaluate the environment, facilities, and office behaviors related to medication safety and use, and to prescription transmission. A technology-readiness survey and accessibility of drug information sources survey developed by the investigators were conducted concurrently. These data and observations were triangulated with an onsite

interview of office management staff (usually a nurse) to learn of the approaches and experiences with medication safety in these practices. Office practices were evaluated for any observations that might suggest increased risk of medication errors or unsafe practices.

Analysis

Survey items were grouped within relevant domains and analyzed using descriptive statistics (Statistical Package for the Social Sciences or SPSS).[21] The research team conducted a group review process to determine those findings warranting attention from a medication safety perspective.

Results

All 31 offices completed the surveys, interviews, and direct observation visits. Overarching findings are described in the text of the results discussed here. A detailed itemization of results is described in Table 1, organized according to the large safety domain categories. Survey results indicate a wide range of medication safety practices and issues requiring attention. Almost all survey items reflect areas where improvement is achievable.

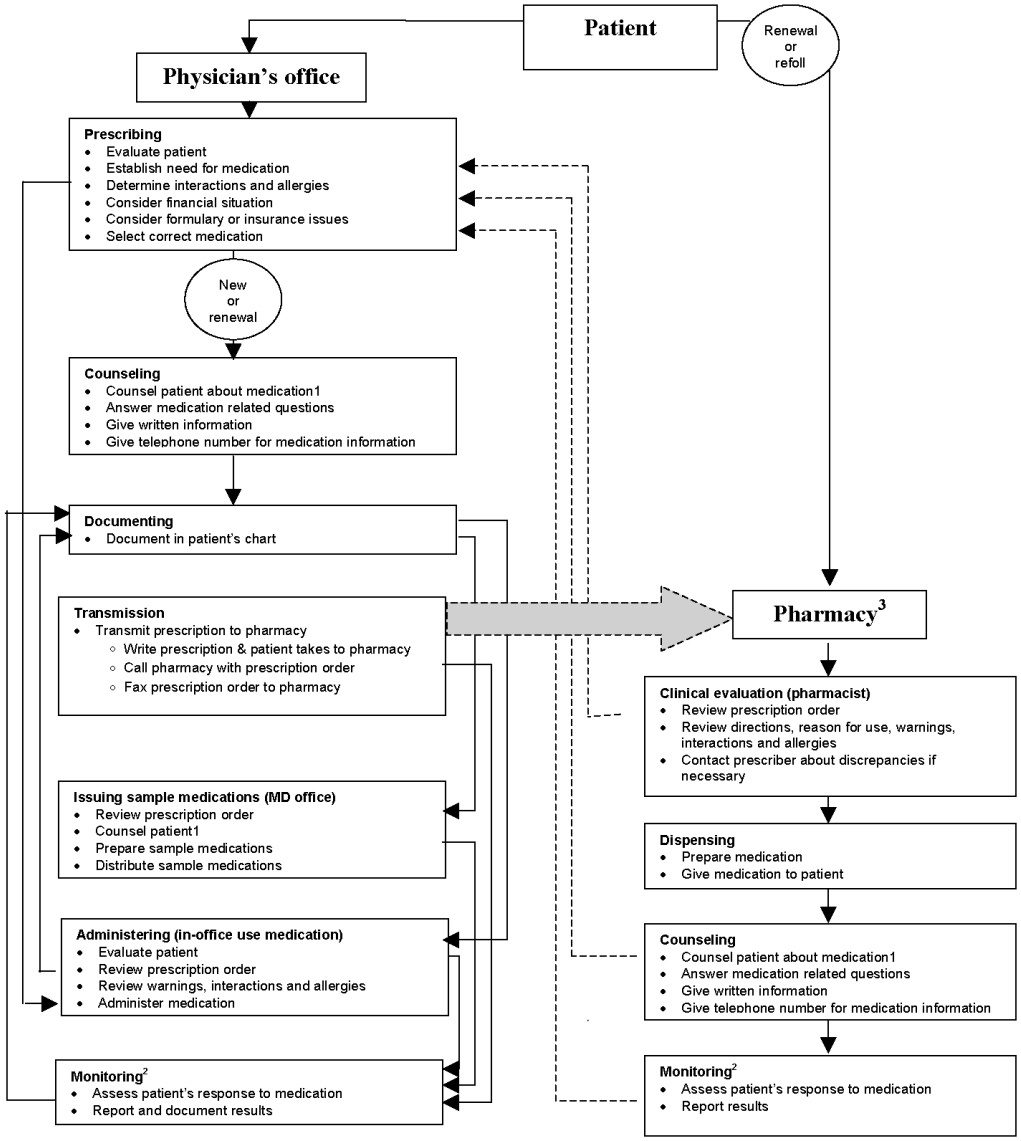
Medication use process

Findings about medication safety and the medication use process are organized by key structure and process elements: chart documentation practices and prescribing practices.

Chart documentation practices

Chart documentation practices were highly variable. The most consistent practices included updating the patient health history annually and documenting prescription medications, allergies, and body weight with each patient visit. Offices were inconsistent about updating the chart for patient demographic data other than basic information about the patient (i.e., name, address, telephone number, birth date, gender). The chart was not updated as a matter of practice when prescriptions were renewed by telephone. Medication histories were highly variable with inconsistent inclusion of self-treatments, over-the-counter products, alternative products, herbal remedies, and homeopathic remedies between office sites.

Figure 1. Medication use process and care communication in the outpatient setting



Legend: Solid Line (——) = Process; Dashed line (- - -) = Communication

[1] Counsel patient includes medication name, directions for use, reason for use, warnings, length of therapy, what to do if a dose is missed; includes assessing ability to adhere, allergy info, meds from other physicians

[2] Monitoring includes adherence, effectiveness, adverse events, proper medication use. It may also include educating patients about devices to monitor disease (i.e., glucose monitor)

[3] Pharmacy is intended to be a local community pharmacy. However, the pharmacy could be mail order, home care, etc.

Table 1. Results of primary care office survey

Medication use process	**Percent frequency of offices reporting "yes" for the following areas (n = 31)**					
Chart documentation practices						
Patient comprehensive health history is updated	81% — annually	6% — each visit				
Specific health information updated at each encounter/visit	90% — weight	84% — allergies	50% — chronic conditions and co-morbidities	32% — smoking status	17% — renal and hepatic function	17% — alcohol consumption
	100% — is updated annually	100% — is updated each visit	32% — is updated when prescriptions are renewed by phone	Contains: 100% — Rx 97% — OTC 77% — herbals 61% — diet suppl 45% — alternative medicines 36% — homeopathic remedies		
Method of collecting patient medication history information	39% — self reported on a standard form	81% — documented by provider in progress note				

Table 1. Results of primary care office survey, cont.

Medication use process	**Percent frequency of offices reporting "yes" for the following areas (n = 31)**					
Prescribing practices						
Routine office practices related to prescribing	48% — screen contraindications/ precautions to medications *prior to* writing new or renewal prescriptions	58% — confirm patient address, telephone number, birth date, gender *prior to* prescribing	100% — consider lifestyle, cost, and frequency of medication use when prescribing			
Routine office practices related to prescription renewal	12% — review the chart *prior to* prescription renewal	87% — the physician is consulted *prior to* renewing a prescription	32% — when therapeutically indicated, medications are given a renewal time period until the patient's next visit	94% — *after renewal* the medication name, strength amount filled, number of refills, date renewed and the person authorizing is recorded in the patient's chart.	71% — there is a method for prescription renewal after hours/when office is closed	48% — on call physicians are allowed to renew medications 47% — office is notified when a prescription renewal has occurred after hours/when office is closed
Methods of prescription transmission to pharmacies	0% — Prescriptions are transmitted to pharmacies electronically by hand-held device or computer.	87% — Prescriptions are transmitted to pharmacies electronically via facsimile.				

Table 1. Results of primary care office survey, cont.

Medication use process	**Percent frequency of offices reporting "yes" for the following areas (n = 31)**					
Routine practices related to telephoning prescriptions to pharmacies	81% — office requires that either a physician or nurse telephone in prescriptions, not office staff.	87% — The process of telephoning in prescriptions includes informing the pharmacist of the patient's birthdate /age.	36% — the indication for a prescription is included when telephoning in a prescription to a pharmacist	32% — provide patient allergies, 3% comorbid conditions, 3% body weight when telephoning prescriptions	12% — request to speak to a pharmacist when telephoning prescriptions.	36% — pharmacists are reported to read back telephoned prescriptions to assure correctness.
Methods of prescription renewal requests experienced by primary care offices	67% — Patients request pharmacies to send fax request to renew medication to the physician's office.	61% — Patients call to a telephone medication renewal line at the physician's office.	7% — Patients e-mail prescription renewal requests to the physician's office.	87% — Most prescription renewals take place by the pharmacy faxing a request to the office on behalf of the patient.	88% — *patients encouraged to have the pharmacy contact us* when prescription renewals are needed, rather than the other way around	

Table 1. Results of primary care office survey, cont.

Medication use process	Percent frequency of offices reporting "yes" for the following areas (n = 31)					
Patient interactions and safety						
Routine office practices related to medication counseling	77% — patients provided with the office telephone number for follow-up support after receiving a prescription	97% — patients are encouraged to call with any concerns about their drug therapy after they leave the office.	65% — patients are encouraged to speak with the pharmacist for further information about medications	97% — drug name, purpose and directions for use are routinely included in medication counseling given to the patient/caregiver.	90% — The dose of medication is routinely included in medication counseling given to the patient/ caregiver.	
Routine office practices related to medication counseling (continued)	18%— written information about prescribed drugs is provided	35%— language-appropriate written information about prescribed drugs to non-English speaking patients is provided	74%— The risks with each medication is routinely included in medication counseling given to the patient or caregiver.			
Routine method of device distribution and counseling in primary care offices (e.g. home blood glucose monitor, insulin pumps)	68% — When patients are given a device they are provided with written information that comes with the device.	39% — When patients are given a device a separate appointment is scheduled for education.	19% — When patients are given a device they are instructed to speak with their pharmacist for further education.			

Table 1. Results of primary care office survey, cont.

Medication use process	**Percent frequency of offices reporting "yes" for the following areas (n = 31)**					
Office environment and safety						
Drug information sources *Discuss in text below based upon other survey questions asked of physicians:* *74% — Time is a barrier to my use of drug information resources. 52% — Accessibility is a barrier to my use of drug information resources. 30% — Drug information resources are either out of date or inadequate to answer my questions* *This shows difference in office staff/MD percept.*	90% — Drug information resources are kept in a centrally accessible location outside the patient exam room.	0% — Drug information resources are kept in each patient encounter room.	84% — Our physicians have easy access to drug references so that they can use them while seeing patients.	26% — Drug information resources are available in the main office via computer.	0% — Clinical computers are located in the patient exam rooms where patients are seen.	

Table 1. Results of primary care office survey, cont.

Medication use process	**Percent frequency of offices reporting "yes" for the following areas (n = 31)**					
Medication sample storage and safety management	94% — The office has adequate space for storage of drugs and drug supplies.	97% — The current sample inventory is reviewed to remove expired products: 45%— monthly 29%— q 2 mo. 13%— q 3 mo. 10% — q 6 mo.	3% — The current medication sample inventory is not reviewed to remove expired products.	81% — Samples with different routes of administration are routinely stored together.	52% — Medication samples are stored in a locked cabinet or room.	84% — The office has a separate refrigerator for medication storage.
When a new sample item is added to the office's drug inventory we check to see if:	16% — its name looks or sounds like other products it might be confused with	13% — its packaging looks similar to other products it might be confused with	32% — the storage location we are choosing is away from products it might be confused with	94% — they are shelved so that their labels face forward and are readable		
Medication sample patient care process						
	55% — there is an established procedure for giving samples to patients to take home.	24% assess sample process for areas of improvement at least annually	6% — A prescription label for medication samples is prepared each time a sample is give to the patient to take home.	94% — When a medication sample is given to a patient, the medication name, strength of medication and instructions for use are documented in the patient's chart.	90% — When a medication sample is given to a patient, the quantity or duration of medication use are documented in the patient's chart.	

Table 1. Results of primary care office survey, cont.

Medication use process	**Percent frequency of offices reporting "yes" for the following areas (n = 31)**					
Medications for office use						
	100% — To remove expired products, the medication inventory is reviewed 71% — q 1 mo. 13% — q 2 mo. 13% — q 3 mo. 3% — q 6 mo.	91% — medications are stored in a locked cabinet or room.				
Pharmaceutical representatives						
When new drug products are FDA approved, pharmaceutical representatives provide education about:	97% — effectiveness relative to other agents for the same indication.	87% — dose, duration of therapy, warnings and contra-indications	81% — place in therapy (e.g., drug of choice, 2nd line therapy)	29% — other products that have a name that looks or sounds similar	23% — other products that have a packaging that looks similar.	

Table 1. Results of primary care office survey, cont.

Medication use process	Percent frequency of offices reporting "yes" for the following areas (n = 31)					
Error management and safety						
Error reporting	45% — Prescribers and nurses receive ongoing information regarding medication errors occurring within the organization.	32% — Prescribers and nurses receive ongoing information regarding error prone situations in the office.	23% — Prescribers and nurses receive ongoing information regarding errors occurring in other offices.	41% — Management provides positive incentives for individuals to report errors.	65% — Prescribers and office staff are thanked and praised for detecting and reporting errors.	53% — Clear definitions and examples of medication errors and hazardous situations that should be reported have been established for use in this office.
Error reporting (continued)	88% — A formal system is in place for reporting actual errors.	59% — Prescribers support practitioner reporting to external voluntary reporting programs (e.g. USP, FDA, and CDC)				

Table 1. Results of primary care office survey, cont.

Medication use process	Percent frequency of offices reporting "yes" for the following areas (n = 31)					
Event Management	68% — An outlined procedure for responding to a serious medication error exists for the office.	68% — Prescribers and office staff involved in serious errors that caused a patient harm are emotionally supported by their colleagues.	23% — Prescribers and office staff involved in serious errors that caused a patient harm are offered psychological counseling.	7% — Prescribers and office staff involved in serious errors that caused a patient harm are expected to cope with it as part of the work life.		
System Improvement	39% — There is no integrated plan to detect, analyze and reduce medication errors at this time.	45% — Staff who are directly involved in a serious or potentially serious medication error participate in analyzing those failures in the system that allowed the error to happen.	58% — Staff who are directly involved in a serious or potentially serious medication error are encouraged to recommend system enhancements to reduce the potential for errors.	71% — A formal system is in place for reporting hazardous situations that could lead to an error.	94% — "Near misses" that have potential to cause harm are given the same high priority for analysis and error prevention strategies as errors that actually cause patient harm	41% — Prescribers use published error experiences from their organization to proactively target improvement in the prescribing process.

Table 1. Results of primary care office survey, cont.

Medication use process	Percent frequency of offices reporting "yes" for the following areas (n = 31)					
Education	26% — At least annually, an educational program on ways to avoid medication errors is provided to physicians, physician assistants, nurse practitioners, nursing staff and office assistants.	52% — Office staff review education about important drug safety issues when an event triggers such a review.	87% — When medication errors occur, educational efforts are directed toward all office staff who may make a similar error.	35% — The patient care process is evaluated for opportunities to reduce errors at least annually.		
Patients and medication safety						
	82% — if an error has led to improper medication prescribing regardless of the level of harm that results, the error is disclosed to the patient, caregiver/family.					

Table 1. Results of primary care office survey, cont.

Medication use process	**Percent frequency of offices reporting "yes" for the following areas (n = 31)**					
Workplace conditions and safety						
	90% — Communication in this office is very good to excellent.	90% — Patient care areas in the office are clean and orderly.	55% — Patient care areas in the office are free from distractions.	65% — Patient care areas in the office are free from excessive noise.	32% — Schedules and workload permit prescribers to take at least one 15-minute break per shift of work each day.	58% — Schedules and workload permit prescribers to take one 30-minute break per shift of work each day.
	100% — Lighting is adequate for your work needs in the office.	71% — The office staff perceives the temperature and humidity in the office to be comfortable.	82% — There is a specific effort made in the office environment to reduce work related stress.	65% — Reference to errors is made in employee personnel files.	71% — Errors are considered as a performance measure during either annual performance appraisals or during competency assessments.	

Table 1. Results of primary care office survey, cont.

Medication use process	**Percent frequency of offices reporting "yes" for the following areas (n = 31)**					
Safety perceptions						
	100% — Management actively demonstrates its commitment to patient safety	65% — A management approved safety plan is in place.	88% — Practitioners and other staff report and openly discuss errors without undo embarrassment or fear of reprisal from office management.	65% — medication errors and ways to avoid them are openly discussed between prescribers and office staff.	. 24% — Individuals have been dismissed from employment because of a medication error in this office.	
Safety education						
29% — Temporary agency staff are utilized in this office.	7% — The offices who utilize temporary agency staff have a training program in place for these individuals.	16% — A brief orientation program is provided for temporary agency staff.	47% — Those who train new staff have their workload reduced in other areas so they can accomplish the goals of orientation.	82% — The length of time for orienting new office staff is individualized and based on an ongoing assessment of their needs.	65% — During orientation, office staff are taught strategies designed to reduce the risk of errors.	59% — Each staff member is assessed on safe medication practices skills and knowledge at least annually.
Technology and medication safety						
	41% — The routine physician practice in this office throughout the day depends on access to a computer.	0% — Personal computers are located in the patient exam rooms.	100% — The office computers are networked to each other.	94% — The office computers are networked to a printer.	3% — The office maintains an electronic medical record.	

Prescribing practices

Almost all offices confirmed a patient's drug allergy status prior to issuing a prescription. It was not routine for offices to proactively identify and screen for contraindications and precautions to medications, or to confirm the core identifiers for patients when either prescribing a new medication or renewing a medication for a patient. Offices generally did not include the medication indication for the prescription when calling in a new or renewal prescription to the pharmacy. Only one-third of the offices consider the time interval between the patients' visits when authorizing the number of medication refills on prescriptions used for non-acute treatment. Usually the office nurse telephoned new prescriptions to pharmacies, but some offices allowed a nonhealth-care professional to perform this function. Similar patterns were observed for both new and renewal prescriptions. When giving prescription orders over the telephone, practices varied regarding the routine inclusion of information such as the patient's birth date, indication for medication use, and allergies. It was not part of telephone processes in any of the practices to include the patient's weight or comorbid conditions. Similarly, pharmacists varied greatly in their practices about repeating back telephone orders for verification, with 36 percent of office staff indicating that pharmacists almost always, or always, repeat back the order.

Two-thirds of the offices reported communicating with between 10 and 50 different pharmacies in any workweek via fax or telephone. When patients received prescriptions for new treatments while at the office, the most common method of prescription transmission from offices to pharmacies was facsimile. No offices in this study used a hand-held device or desktop computer either for prescribing or for transmitting prescriptions to pharmacies.

Prescribers generally welcomed input from pharmacists with concerns about prescriptions, and no offices allowed nonhealth-care professionals to handle these concerns. The most common concerns that pharmacists contacted prescribers about were to clarify details about a prescription, discuss drug interactions and allergies, or follow up on patients reporting that they have had a previous adverse drug reaction to the medication prescribed.

Offices encouraged patients to request medication renewals by asking their pharmacist to send a fax request to the physician's office. This was the dominant communication method that patients used to request refills. Telephone renewal request from patient to office staff was the second most common. Many offices reported that when this occurred, they still referred the patient to the pharmacy to initiate the renewal request to the prescriber's office. One-half of the offices had a dedicated medication renewal voice-messaging system where patients can leave their renewal requests, and a few indicated that some patients e-mail requests for prescription renewals. On-call physicians authorized renewal of prescriptions after hours; it was not the practice to notify the office of the renewal or provide documentation when such a renewal had occurred.

Counseling: patient interactions and safety

It was a routine practice to include the drug name, purpose, and directions for use in medication counseling given to patients and caregivers. Risks were discussed less often, and only two-thirds encouraged patients to communicate with pharmacists about further details and information about medications.

A minority of practices addressed educational needs about medications by providing written information and language-appropriate information to non-English speaking patients. Several different methods were described that some offices employed to handle hearing, speech, and visually impaired patients. Counseling practices related to devices were less prevalent than practices related to medications.

Office environment

Drug information resources

Physicians in these practices were interviewed about their access to drug information sources. Physicians believed that the support for drug information needs was inadequate. Identified barriers to the use of information sources were time (74 percent of the physicians) and accessibility (52 percent of the physicians). One-third indicated that they did not believe the references they had were adequate for their needs. Traditional print-form drug information resources were kept either in the physician's office or a central location. Most practices kept drug information resources in a centrally accessible location outside patient exam rooms; no practices kept them in the patient encounter rooms. Only 26 percent reported accessibility for drug information resources via computer with no real-time access to clinical references in exam rooms. Some physicians indicated they do not take the time to look up needed drug information because the information is not readily accessible during the patient visit. Further study should be conducted to determine how this need is best met.

Sample medication

Almost all of the offices reported documenting the issuance of medication samples to patients, including name, strength, instructions for use, and duration of therapy in the patient's chart, yet procedures for safety upon issuance were lacking. Only 2 of the 31 offices reported that they prepare a prescription label for samples prior to giving them to the patient to take home. Offices did not have policies and procedures for the proper acquisition, storage, and inventory management of medication samples. Several offices did indicate an interest in developing such a policy and procedure, and requested information on how they might accomplish this. Offices had standard practices of checking expiration dates periodically. When new samples were added to the inventory, the universal practice was to shelve the medication so that the label faced forward and was readable. However, the unsafe practice of storing medications with different routes of administration mixed together was reported in 81 percent of offices.

Less than 15 percent of the offices separated “look or sound alike” and/or “similar packaging products” from other products in the sample inventory area.

Medications for office use

Offices generally kept drug products away from patients in the examination rooms. However, safe storage of refrigerated medications and keeping medications under lock and key was not done in most offices. Offices had no standard method for organizing medication inventories and often mixed sample medication with office-use medication.

Manufacturers’ representatives

Offices received education about use and effectiveness of new medications from the manufacturers’ representatives. However, less than one-third of the offices reported that the industry representatives educated them about confusing names or packaging that looked or sounded similar to other medications already commercially available.

Drug sample inventory was primarily managed by pharmaceutical representatives. The representatives checked in at the front desk, then went to the drug sample area and stocked their samples. The offices reported that representatives are asked to remove expired samples. Many offices admitted that representative management of the drug samples and subsequent monitoring by office staff were not consistent. Only three offices escorted representatives to the sample area. The other offices allowed representatives to go through the private patient care areas to the sample area to stock and remove samples without supervision. Drug samples were stored in a variety of areas, from open shelves to closed cabinets to sample rooms. Most sample areas were organized by therapeutic category. Some offices had inadequate space to store the large volume of sample medications.

Error management

Most offices had a formal system in place for reporting an actual error in the employment site, and indicated they report hazardous situations that could lead to an error. A minority of offices reported using published error experiences (e.g., case reports) from other sources to proactively target improvement in the prescribing process, while a majority report receiving information about strategies to prevent errors (newsletters, trade journals and other services). More than half of the offices supported voluntary practitioner external reporting programs, such as the United States Pharmacopoeia Medication Errors Reporting Program; Food and Drug Administration MedWatch; or the Centers for Disease Control Vaccine Adverse Reaction Reporting Program.

A majority of practices had a management-approved safety plan in place to detect, analyze, and reduce medication errors in office practice, yet the majority did not have open discussions on an ongoing basis about medication errors and close calls. Even fewer acknowledged the existence of circumstances that may

increase the risk of error in the office. A full one-third of the offices had no outlined procedure for responding to a serious medication error.

Support for health professionals or office staff members involved in a serious error varied. Offices reported emotional support from colleagues as the primary method of support. One-quarter of the offices reported they offer psychological counseling, and a couple expected the involved health care workers to cope with an error as part of the job.

Error disclosure to patients was the general practice reported by these offices. If the prescriber discovered that an error had led to improper medication prescribing, regardless of the level of resultant harm, the error was reported as disclosed to the patient, caregiver, and/or family by 82 percent of the office practices.

Workplace conditions and safety perceptions

Perceptions about communication within the office and physical conditions (cleanliness, orderliness, and lighting) were positive, but became less positive when noise and distractions were considered. The workload was heavy enough that only half of the offices could accommodate at least one 30-minute break per shift of work each day. Reference to errors was made in employee personnel files, and these were considered in annual performance appraisals or competency assessments. One-quarter of these offices indicated individuals have been dismissed from employment because of a medication error in the office.

Safety education

Most offices reported that staff are trained before they are allowed to participate in patient care. However, only two-thirds taught strategies designed to reduce the risk of error and assess safe medication practice skills and knowledge on an annual basis. The most common reason why education takes place about a medication safety issue was an event "trigger." The large majority of offices reported that remedial educational efforts are directed toward all clinical staff after an error has occurred, not just toward the staff person who was involved. Only 26 percent of offices reported annual educational programming designed to assist clinical and office staff in avoiding medication errors. Temporary agency staff was used by 29 percent of the offices, but only 7 percent indicated a training program was in place to assist these professionals.

Technology and medication safety

Technology readiness varied greatly in offices. At the time of this survey (March 2003), half of the offices used Microsoft Windows® 95 (which does not support hand-held synchronization) as an operating system, with Windows® 2000 being a standard for the nation. One-third had dial-up Internet connections, with none reporting wireless connectivity. The office support computers were networked and the network supported printers. Only two reported that they have infrared-enabled printers, and some reported owning printer models so out-of-date

that they have been discontinued by the manufacturer. Figure 2 displays the variation in technology readiness of these primary care office-based practices.

Fewer than half of the physicians reported use of a computer in their routine daily practice. The most frequent uses of the office-based computers by clinicians were communication, word processing, and information access. Literature searches performed on the office-based computers via the Internet occurred in the central area of the office after the patient was seen, rather than at the point of care (clinical computers in exam rooms). Our observations affirmed that the present clinical information-support model in these offices was suboptimal for real-time access to clinical support information. Only one practice reported the use of an early-phase electronic medical record system that allowed access to lab information, progress notes, and demographic information about patients. However, such information was not accessible in real time; a staff member input data from the paper chart after the patient visit was completed.

Physicians emphasized concern about time constraints with regard to technology in their office-based practice. They expected technology implementation to prolong the amount of time it takes to complete common tasks. Further research is needed on the actual impact of time constraints and implementation of new technology.

Discussion

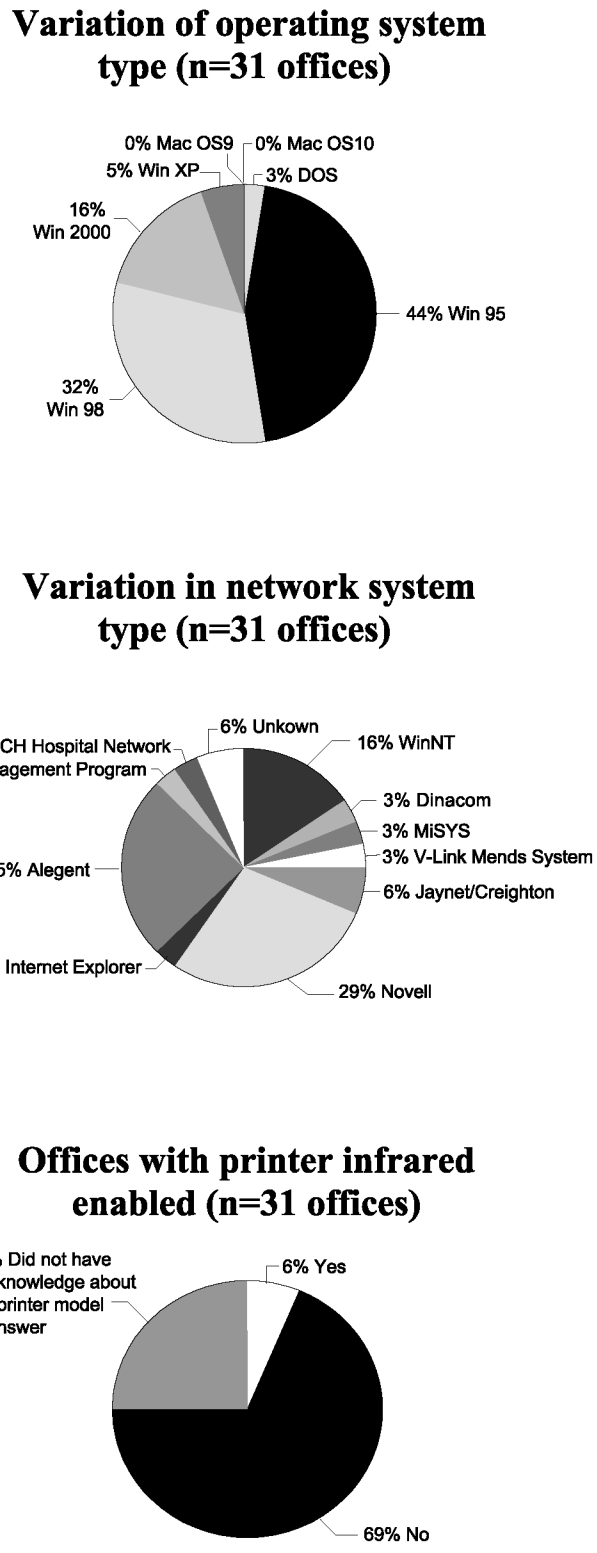
Survey results reveal some activities that promote patient safety throughout all of the offices, as well as other suboptimal—and sometimes unacceptable—practices related to medication safety. Study results indicate both qualitative and quantitative variation between offices in the collection and documentation of essential clinical information from patients. There is a lack of consistency in the data elements that are collected (e.g., allergies, body weight, current medications) and in the thoroughness of their collection. This variation and inconsistency can lead to suboptimal quality in therapeutic decisions in office-based practice.

Medication use process

Chart documentation practices

Incomplete documentation of patients' medication histories, including prescription changes and renewals via telephone, is problematic. Without the benefit of a complete medication profile, safe prescribing is difficult to accomplish. A current and accurate list optimizes prescribing through proactive screening for potential allergies, drug-drug interactions or drug-disease interactions. Two office sites updated demographic and health-related information at every visit, which is also necessary to ensure patient safety when prescribing medications. These are improvements that each practitioner can make at no additional cost.

Figure 2. Technology readiness of primary care office-based practices



Prescribing practices

The large number of pharmacies interacting with a physician's office complicates communication about prescriptions. The receptivity to pharmacists' efforts to clarify and correct prescribing problems is positive and necessary to safe medication practices. A major area for improvement is the real-time interaction between the prescriber or office nurse and pharmacist when telephoning new prescriptions. In the current environment, there was little systematic exchange of patient-specific information that would improve medication safety evaluation at the time of prescribing. Further, those offices that allowed a nonhealth-care professional to handle these tasks were promoting an unsafe practice. The gaps in communication that occur because of an incomplete medication use process can only be compensated by interactions between professionals who have expert knowledge of the patient's conditions, circumstances, and care needs. Limiting communication to health care professions is a minimal to no-cost improvement.

Facsimile and telephoned prescription transmission was the dominant model. This is suboptimal because of auditory misinterpretation or illegibility. The low number of medication indications included on written prescriptions or telephoned prescriptions represents a significant area for improvement at no cost by providing the pharmacist with information necessary to detect potential errors before the prescription is dispensed to the patient. In one study, prescription-writing errors would not have been discovered without the addition of the patient's diagnosis.[22] Another study in the community pharmacy setting demonstrated that 89 percent of pharmacists' errors related to safe medication dispensing and use were caught during pharmacist counseling of patients at the time patients received their medications.[23]

Lack of screening for contraindications and precautions to medications is a major safety gap in outpatient medication prescribing. The multiplicity of prescribers, medications, and pharmacies that are used by patients increases the opportunities for these to go unnoticed. Routine pharmacist screening for contraindications and precautions is an activity complementary to the office practice that helps to reduce errors. It is not sufficient, however, because pharmacists lack access to all necessary patient data (e.g., patient chart information). Similarly, physicians encounter a similar problem in not having access to all prescription data (e.g., medications initiated by other prescribers). Patients' safety is best served by screening by all health professionals involved in their care.

Counseling: patient interactions and safety education

A positive patient safety finding of this work is the extent of routine basic patient education about medication names, purposes, and proper dosing. This is an excellent practice that promotes communication about medication with patients. Areas not routinely addressed by office-based counseling included cautions, risks, possible adverse reactions, and how to manage these. These results suggest that pharmacists should continue comprehensive patient counseling at the time of

medication dispensing. Because counseling by pharmacists can result in identification of gaps in patient knowledge, the finding that two-thirds of physicians encouraged pharmacist-patient communication is encouraging, but also indicates room for no-cost improvement. The finding that only one in five offices recommended that patients speak to pharmacists about selection and proper use of medical devices indicates an even more dramatic underutilization of an important resource for safety, and this is an area for improvement. Physicians and pharmacists must continue to work together to keep the patient informed.

Office environment

Primary care offices have not developed systems for ready access to drug information at the point of care. Lack of access to and adequate breadth of drug information resources at the point of care was evident and may lead to medication errors. Access to current information is necessary to enhance safety and requires some investment in resources. An inexpensive electronic method involves use of drug information software on hand-held devices updated by one desktop computer with Internet connectivity.

Offices did an excellent job of keeping drug products away from patients in the examination rooms, thereby avoiding injury—particularly to small children—via accidental exposure. Improvements are needed in product sample management. Strictly enforced office policies are needed to manage acquisition, storage, dispensing, and disposal of medication samples because these items represent an often-unrecognized potential for medication error and liability. A documented quality-control system can reduce liability exposure.

Most offices did not label samples with adequate directions for use and did not provide written drug information—lapses that may be detrimental to patient safety. While some argue it is a benevolent pharmaceutical industry practice, a myriad of problems is created by wide dissemination of samples.[24] The American College of Physicians recognizes the importance of safe sample management and has recently published basic guidelines for this purpose.[25] Responsibility for medication samples should lie with a designated staff member; reliance on the pharmaceutical representative for examining and removing expired products is risky at best. Despite their best efforts, office practices are inherently limited in their ability to ensure medication safety.

Substantial investment is needed for offices to meet minimal pharmacy practice standards that are designed to protect the public when medications are dispensed. Given that this type of investment may not be fiscally possible for offices, a change in federal law prohibiting possession of samples by pharmacies (the Prescription Drug Marketing Act) may be necessary to improve safety. Pharmacists dispensing samples is one solution to providing professional services consistent with current pharmacy practice standards. Such a change would provide the same levels of continuity of care and safety currently required for all prescriptions dispensed in community pharmacies.

Error management

A vast majority of offices reacted to an error event by educating everyone on staff, whether involved in the incident or not. This is a sound practice. However, the findings indicate that very few offices provided minimal preventive education to clinical and office staff through annual programming focused on the avoidance of medication errors. Offices need to improve their preventive education to reduce the number of errors that actually occur.

One-third of offices had no outlined procedure for responding to serious medication errors—a critical and essential best practice and a no-cost area for improvement. However, it is encouraging that when a staff member actually experienced a medication error, 45 percent of offices indicate that they involve that staff member in planning and improvement efforts to reduce the potential for that error to occur again.

Workplace conditions

Preventive education could be further optimized by learning more from the errors that actually occur. Open communication is necessary to expose and understand the sources of error and facilitate systematic improvement. At a societal level, the culture of error issues blame and exacts penalties, which stifles the open exchange of information that could contribute to future error prevention. The investigators found that the majority of offices reported referring to errors in employee personnel files and considering them in annual performance appraisals. Personnel policies that use such data in a punitive manner may decrease error disclosure; the policies must be changed to improve office error-reduction practices. This is a no-cost improvement dependent upon change in professional and local cultures.

Offices reported positive work environments as evaluated from the point of view of work flow and lighting. However, reported areas for improvement included reduction of distractions and excessive noise—a problem that employees can solve through cooperation.

Safety education

Safety education is essential and should be incorporated for all employees in office-based work. The offices did not indicate much of a commitment toward education of either permanent or temporary staff related to medication safety. This is a system improvement that requires little to no overhead investment.

Technology and medication safety

Many technological solutions to error reduction would best be accomplished through integration of systems to a common electronic patient medical record. The finding that only 3 percent of the offices reported using electronic medical records is an indication of their lack of preparedness to incorporate technological solutions. As offices place electronic medical records online, we need standardization of platforms and software to facilitate information exchange.

Study limitations

There are recognized limitations to this study. The written survey was self-administered at the study site by respondents. Although the investigator was available onsite to clarify questions, self-administered surveys are associated with potential misinterpretation of questions, which may introduce artificial variation in responses. Combining self-administration with interviewer assistance, as was done in this study, has been shown to reduce response variation when compared to self-administration alone.[20]

Another limitation is response bias. Some respondents might perceive some item responses as potentially self-indicting, i.e., indicating that the office practice is in some way deficient in relationship to medication safety. This could lead to an inflation of self-reported activities within offices, leading us to a more positive view of office-based safety than is actually present. Even if this bias is present, the findings are still substantive.

A final limitation is the regional sample. Variations in technology infrastructure between States (wireless, high-speed cable access or inadequate bandwidth), particularly in rural areas, may preclude technology support in some areas but not others, making survey results of some areas less reflective of the nation as a whole. Overall, however, the characteristics of the sample are reflective of typical primary care office-based practices in the country.[26, 27] Further, the variation by region regarding the lack of using some of these best practices in no way devalues the need to bring these improvements into daily patient care.

Conclusion

Improving the medication use process initiated in primary care offices is an important step to improving medication safety for the public. This research contributes new knowledge to our understanding of outpatient medication safety, supports evidence-based decisions about improvement practices, and reveals that most of these safety practices may be implemented without additional financial resources.

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