

Mail-Order Prescriptions Requiring Clarification Contact With the Prescriber: Prevalence, Reasons, and Implications

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ABSTRACT

BACKGROUND: Prescription review by pharmacists prior to dispensing is an important step in an overall strategy for preventing medication errors. Contacts with prescribers may be required to clarify missing, unclear, or inconsistent information. While essential to reduce the likelihood of potential patient harm, clarification contacts are time-consuming for pharmacists and prescribers. The scope of the issue and the factors that contribute to it are not well understood.

OBJECTIVE: To quantify the frequency of contacts with prescribers that were necessary to obtain clarification of prescriptions and to identify the factors that made these prescriber contacts necessary.

METHODS: An analysis was conducted involving new prescriptions received by a national mail-order pharmacy that required clarification contacts with prescribers for quality reasons (i.e., those potentially impacting the accuracy of dispensing). Excluding refills and renewals, the percentage of new prescriptions requiring clarification contacts was calculated and categorized by incoming delivery channel (mail, fax, telephone, etc.). The quality problems that prompted these contacts were categorized according to the problem identified.

RESULTS: Among the total of 295,378 new prescription orders received during the 1-week study period (from April 7 to April 13, 2002), 8.7% contained quality problems that necessitated clarification contact with prescribers. Prescriptions received by fax transmission and mail were most likely to require clarification as compared with direct telephone conversation and miscellaneous (including electronic) channels. Among prescriptions that required a clarification contact for quality problems, an average of 2.4 problems per prescription was observed. The most common problems were: directions unclear or missing (24.3%); refill quantity unclear, missing, or incorrect (24.3%); dosage unclear (20.2%); drug name or strength unclear (13.2%); missing physician or patient data (11.4%); and missing prescriber signature (3.2%).

CONCLUSION: Prescriber clarification contacts are frequently needed to reduce the potential for medication error in the current prescription fulfillment process. While these contacts are necessary to clarify data elements essential to accurate medication dispensing, they are time- and resource-intensive. These study results suggest that alternate prescription order channels, including electronic, could reduce the sizable burden of prescription order clarification in mail-order pharmacy.

KEYWORDS: Pharmacy benefit management, PBM, Prescriber contacts, Clarification contacts, Mail-order pharmacy, Prescription dispensing, Prescription order channels

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In its 2000 report, the U.S. government's Quality Interagency Coordination Task Force (QuIC) responded to the issues raised by the Institute of Medicine in 1999 regarding the scope and prevalence of medical errors in the health care system. The QuIC stated in its report, *Doing What Counts for Patient Safety: Federal Actions to Reduce Medical Errors and Their Impact*, that the estimated total cost of medical errors resulting in injury was between \$17 billion and \$29 billion annually (in 1996 dollars), including lost income, disability, and health care costs.¹ Inpatient and outpatient medication errors are major contributors to the total number of medical errors.^{2,3} While prior studies and reports have provided some insights into the potential causes of medication errors, identifying the root causes and potential solutions remains a challenge.²

Although limited data are available on the full scope and nature of ambulatory medication errors, 2 recent studies have quantified ambulatory drug-related morbidity and mortality and the associated costs in the United States.^{4,5} In considering such information, it is important to recognize that medication errors and drug-related morbidity or mortality reflect distinct but overlapping concepts. Not all medication errors cause morbidity or mortality, and drug-related morbidity or mortality can occur even when no error was involved.

Ambulatory drug-related morbidity and mortality costs rose to an estimated \$177.4 billion in 2000 from an estimated \$76.6 billion in 1995, much of which is attributable to errors.⁶ Increases in prescription volume may account for some, but not all, of the increases in drug-related morbidity and mortality. During the period 1983 to 1993, deaths from medication errors increased 2.57-fold, while the number of prescriptions only increased 1.39-fold.³

The types and causes of medication errors are varied and include incorrect medication choice, dosing regimen, and route (e.g., oral, nasal, topical).⁷ Some of the contributing factors include failure to account for contraindications, unappreciated allergy history, transcription errors, missing patient information, illegible handwriting, and interruptions during the dispensing process.^{8,9}

Any aspect of the medication prescribing, dispensing, or administration process may be a potential contributor to medication errors,⁷ a fact emphasized by the National Coordinating Council for Medication Error Reporting and Prevention in its definition:

A medication error is any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer. Such events may be related

to professional practice, health care products, procedures, and systems, including prescribing; order communication; product labeling, packaging, and nomenclature; compounding; dispensing; distribution; administration; education; monitoring; and use.¹⁰

In this context, the pharmacist's review of each prescription continues to play an integral role in preventing medication errors. Pharmacists are uniquely positioned to identify potential quality and safety issues before the medication is dispensed.⁵ Pharmacy practice standards exist to ensure quality along the entire spectrum of pharmacy tasks and responsibilities, including, but not limited to, training, prescription review, dispensing, patient counseling, drug utilization review, and record keeping.¹¹ Encompassed within the prescription review standard is the requirement to clarify any missing or ambiguous elements of the prescription.¹¹

If information on a prescription order is unclear or missing, pharmacists typically contact the prescriber via telephone or fax for clarification.⁴ These clarification contacts are distinct from other types of contacts related to pharmacy practice. Clarification contacts focus on the completeness and accuracy of the prescription order (i.e., that it contains all the required elements and the dosage is appropriate for the drug administration route). Other types of reviews performed by the pharmacist, which differ from clarification contacts, include drug utilization review (checking for drug interactions, potentially dangerous usage patterns, and other contraindications), therapeutic interchange (promoting compliance with the formulary of the patient's pharmacy benefit plan), and prior authorization (requesting coverage approval from the patient's pharmacy benefit plan).

The necessity for clarification contacts with prescribers affects the entire prescription fulfillment process.⁷ Inefficiencies produced may include rework (faxing copies of prescriptions to prescribers for completion or correction), data reentry, and telephone calls to the prescriber to obtain the correct information. These activities may lead to dispensing delays, poor customer service, and increased staffing costs.⁷ Additionally, distractions and interruptions have been shown to increase dispensing errors.⁹

While the cost of the pharmacist's time may be offset by the medical savings associated with the avoidance of adverse drug events (ADEs), an opportunity clearly exists for improving the efficiency of the entire system.¹² Managing quality by downstream inspection (such as evaluating the quality of prescriptions *after* they reach the dispensing stage) creates the potential for mistakes, and this may be more costly overall than managing quality earlier in the prescribing-dispensing process.¹³

There is little published data on the frequency with which prescriptions require clarification contacts in the outpatient setting. In a 1988 study of 9 community pharmacies in Indiana, 2.6% of new prescriptions were found to contain prescribing

errors.¹⁴ The cost of the pharmacists' interventions, including labor and operations costs, was estimated to be \$1.75 per prescription. The average savings in avoided medical care was estimated to be the \$7.15 per prescription from the potential drug-related complications that were presumed to have been avoided by making the interventions. In a larger study of 89 community pharmacies in 5 states, 1.9% of new prescriptions required a pharmacist's intervention (including clarification of unclear or missing data as well as discussion of potential drug-drug interactions and patient allergies).⁵

The extant study was undertaken to quantify the prescriber clarification contacts made by a large home delivery (mail-order) pharmacy service operated by a nationwide pharmacy benefit management (PBM) company. The primary objective was to assess the types and frequency of prescription issues requiring clarification contacts with prescribers. Such data can then be leveraged to serve as a basis for process improvement initiatives, to ultimately reduce the likelihood of medication errors.

Methods

Study Sample

The data sample was drawn from prescriptions processed by a national home-delivery pharmacy service operated by a PBM company with dispensing operations involving 12 mail-order pharmacies located throughout the United States. Prescriptions were processed and dispensed from these pharmacies for patients nationwide who had been provided with prescription benefit plans by their employers, unions, managed care organizations, insurance plans, and government employee programs.

The sampling interval for this study was the 7-day period from April 7 to April 13, 2002. The sampling interval was chosen to exclude major holidays and other significant events that might have affected the submission or processing of prescription orders. During this time frame, a total of 1,732,389 prescriptions were received.

From this total number of prescriptions, a subset was identified that reflected all *new* prescriptions, excluding refills or renewals. For the purpose of this study, new prescriptions were defined as those for which there was no history of the same medication at the same strength being dispensed for the same patient within the prior 365 days. Aside from prescriptions that did not satisfy this definition of being new, no other exclusion criteria were applied.

Analysis of Clarification Contacts

Throughout the process for new prescription dispensing from this PBM network, information is recorded electronically in a proprietary, comprehensive, system-wide prescription fulfillment database at each of the various process steps. Such information includes data on the incoming delivery channel (mail, fax, telephone, etc.), the initial prescription review, clarification contacts (if needed), outcomes of the contacts, and final dispo-

FIGURE 1 Example of Unclear Drug Name

This prescription is an example of those requiring clarification of the drug name in order to avoid potential adverse drug events. The prescription was initially read by the pharmacist as "Darvocet N 100 mg" (a narcotic analgesic), but upon careful review, the pharmacist realized that the prescriber might have intended Docusate (a laxative). A clarification call was made to the prescribing physician, who confirmed the intent as "Docusate Na 100 mg." The correct prescription was ultimately dispensed.

sition of the prescription. Upon reviewing each prescription prior to dispensing, the pharmacist renders a professional judgment as to whether the prescription requires clarification of any component with the prescriber. If a clarification contact is required, the pharmacist reviewing the prescription documents the reason(s) for the contact in the same database described above. Some clarification contacts are prompted by factors related to the drug being prescribed (e.g., unclear or missing drug name, strength, or directions). Contacts are also prompted by unclear or missing prescriber information, patient information, or signature. For certain prescriptions, multiple issues exist that necessitate a clarification contact.

Two different analyses were conducted on the set of new prescriptions identified. The first assessed the percentage of prescriptions that required clarification contacts. This was com-

puted in aggregate as well as for each of the delivery channels through which the mail-order pharmacy received the prescription (e.g., mail, fax, telephone, voice message). *Mail* includes hard-copy prescriptions received by standard post or express service, and are almost entirely handwritten (data on file). *Fax* includes prescription facsimiles sent by prescribers. *Telephone* prescriptions are verbal orders called in directly to a pharmacist. *Voice-message* orders are prescriptions communicated via telephone with an audio recording device for prescription data elements. A *Miscellaneous* category was also created, which includes a variety of delivery channels that were infrequently used during this time period, such as file transfers from electronic prescribing devices. This final Miscellaneous category was collected and reported in aggregate because of the relatively small numbers of prescription flowing through each of these channels and because data limitations prevented confident subgroup analysis within it.

The second evaluation assessed the types of issues requiring clarification contacts. For all contacts, the reasons were tabulated and issues categorized by frequency of occurrence. The relative frequency of each issue was computed as a percentage of the total issue count among the sampled prescriptions.

As discussed above, the quantification and analysis of these clarification contacts were distinct from, and exclusive of, other prescriber contacts related to pharmacy practice, such as drug utilization review, therapeutic interchange, and prior authorization.

Results

During the period of this study, a total of 295,378 prescriptions met the criteria for inclusion in the study sample of *new* prescriptions, as defined above. Among these, 8.7% contained quality problems that required clarification contacts with prescribers. Examples of the types of prescriptions that required clarification can be found in Figures 1, 2, and 3. The prevalence of prescriptions having such issues varied, depending on the delivery channel (Table 1). Prescriptions received by fax and mail required relatively high rates of clarification as compared with direct telephone conversation and miscellaneous (including electronic) channels.

Prescriptions necessitating a clarification contact contained an average of 2.4 issues per prescription. The relative frequency of each type of issue is summarized in Table 2. The most common issues requiring clarification were related to *directions for use and administration* (directions unclear or missing), *prescribed number of refills* (refill quantity unclear or missing), *dosage* (dosage unclear), and *drug identity and strength* (drug name or strength unclear).

Discussion

Clarification contacts with prescribers play an important role as part of a comprehensive patient-safety program.⁵ Clarification contacts can help to ensure the accuracy and safety of the medications dispensed, but these important benefits require signifi-

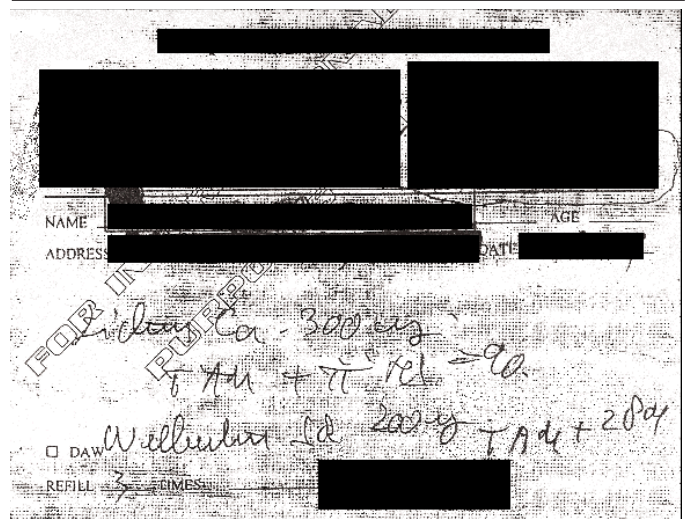
cant investments in time and impact a pharmacy's operational efficiency.⁹ In this study, a significant percentage of new prescription orders (8.7%) contained issues that required follow-up with prescribers for clarification. While these follow-up contacts place additional workload on both pharmacists and prescribers, they are critical for achieving safety objectives and satisfying legal requirements for dispensing. In fact, some of the most frequently identified issues in this study have a significant potential to affect patient health and safety. Those issues, which include lack of clarity in drug name or drug strength, dosage, and instructions for use, account for 57.7% of all issues identified in this study.

Efforts by individual pharmacies to improve the quality and safety of prescription dispensing fit within a broader set of initiatives that have been proposed and, in some cases, developed at the national and local levels, with the goal of reducing medication errors. In 2000, the U.S. government funded the Center for Quality Improvement and Patient Safety to serve as a clearinghouse for medical error reporting within the Agency for Healthcare Research and Quality. The federal government also instituted mandatory and voluntary reporting systems for medical errors, promulgated safety performance standards for the Medicare program, and funded premarketing and postmarketing surveillance by the U. S. Food and Drug Administration. In U.S. Veterans Health Administration facilities, medication safety has been improved through the use of automated order-entry systems.¹ Similar systems are in place in other large and small hospitals, spurred in part by organizations like the Leapfrog Group that have placed computer order-entry near the top of their quality improvement agendas.^{15,16} The pharmaceutical industry is also developing drug names, labels, and packages to reduce the likelihood of dispensing errors associated with human factors (e.g., confusion, inattention, forgetfulness).^{1,17,18}

Many of the efforts to reduce medication errors focus on the roles of the prescriber and pharmacist. For the prescriber, educational sessions are employed to improve awareness of potential errors during the prescribing process and to recommend ways to avoid them, such as printing clearly and using abbreviations with great caution. For the pharmacist, increasing emphasis is placed on clinical consultations with prescribers.¹² Other changes include computerized pharmacy systems to identify questionable prescriptions, check for drug allergies, and flag potential drug-drug interactions; electronic prescribing systems; unit dose dispensing and distribution; standardization of processes and equipment; bar-coding of medication bottles; and automated dispensing systems.¹²

In the context of these activities and initiatives, clarification contacts by pharmacists with prescribers play a key role in promoting patient safety. This study found an overall clarification contact rate of 8.7% for new prescriptions received by a national home-delivery pharmacy, which is higher than the rates reported in earlier studies of community-based pharmacies. The exact reasons for this disparity are unclear, although a vari-

FIGURE 2 Example of Unclear Dosing Instructions



This prescription is an example of those requiring clarification of the instructions in order to avoid potential adverse drug events. The second prescribed medication here is Wellbutrin SR 200 mg. The instructions, which include apothecary symbols and numerals, could be interpreted 1 of 2 ways: either "1 every morning and 2 every evening" or "1 in the morning and 1 at 2:00 p.m." No quantity is indicated. Aside from the differences in timing of administration, these 2 possibilities result in significantly different daily dosings. A clarification call was made to the prescribing physician, who confirmed the intent as "1 in the morning and 1 at 2:00 p.m. each day."

FIGURE 3 Example of Unclear Patient Name



This prescription is an example of those requiring clarification of the patient's name. The patient's first name is visible in the figure above, and is somewhat unclearly written. (For confidentiality reasons, the patient's last name is not shown.) When this prescription was received by the mail-order pharmacy, it was determined that both a Marilyn and a Mark were patients who had the same last name and address. Although name clarification may seem like a simple administrative matter, this example also raises an important medication safety concern. Filling a prescription under an incorrect name, even if ultimately delivered to the correct address, would circumvent a variety of safety-related processes and systems, such as those that identify potential drug-drug interactions. In this case, a clarification call was made to the prescribing physician, who identified the patient as Marilyn.

ety of factors likely contribute. Many potential differences between the 2 settings could affect clarification contact rates, including the demographics of the customers served, the types

TABLE 1 New Prescriptions in Mail-Order Pharmacy Requiring Clarification Contact With the Prescriber

Prescription Delivery Channel	Number of New Prescriptions	% of Total New Prescriptions	Prescriptions Requiring Clarification	% Requiring Clarification (95% CI)
Mail	234,590	79.4	19,851	8.5 (8.4-8.6)
Fax	49,983	16.9	5,731	11.4 (11.1-11.7)
Telephone	2,809	1.0	11	0.4 (0.2-0.6)
Voice message	73	< 0.1	6	8.2 (1.8-14.6)
Miscellaneous sources (including electronic)	7,923	2.7	166	4.0 (3.6-4.4)
Totals	295,378		25,765	8.7 (8.6-8.8)

TABLE 2 Relative Frequency of Types of Prescription Issues Requiring Clarification Contact With the Prescriber

Subject	Relative Frequency* (%)
Directions unclear or missing	24.3
Refill quantity unclear or missing	24.3
Dosage unclear	20.2
Drug name/strength unclear	13.2
Missing prescriber data	6.0
Missing patient data	5.4
Prescriber signature missing	3.2
Prescribed drug no longer available or manufactured	2.0
Issue date missing	1.2
Prescription appears altered	<0.1

* Frequency of each issue as a percentage of all issues reported. Total is less than 100% due to rounding.

of prescriptions filled (maintenance medications versus medications for acute illness or injury), and differences in pharmacy operations related to pharmacy size. The relative frequency of certain delivery channels for prescription orders is another significant variable, with mail-order pharmacies receiving relatively few prescriptions by telephone (1% in this study) versus retail pharmacies where the percentage may be considerably higher. Furthermore, in a community setting, the pharmacist may have experience with a local prescriber's practice style, handwriting, and prescription drug preferences that enable res-

olution of an issue through professional judgment without a clarification contact. A community pharmacist also may be able to obtain clarification of some information such as patient demographics directly from the patient or his or her proxy at the pharmacy counter, whereas this option is not as readily available to a home-delivery pharmacist. Recognizing all of these issues, mail-service pharmacists may tend to clarify prescriptions more often than their retail counterparts in order to assure safe and accurate dispensing.

Clarification contacts are time consuming for both pharmacists and prescribers.⁵ For pharmacists, these contacts may interrupt and delay dispensing and may also reduce the pharmacist's availability to counsel patients. These contacts also introduce new opportunities for errors in dispensing, especially when issues on multiple prescriptions are being pursued and documented simultaneously. For prescribers, clarification contacts may interrupt face-to-face patient care and reduce the time they have available for other responsibilities. These contacts also increase demands on office staff and reduce overall office efficiency.

The workload associated with clarification contacts is a significant contributor to pharmacy staffing requirements and operating costs.⁵ As prescription volumes continue to increase (from 3 billion prescriptions dispensed in 2000, projected to reach 4 billion by 2004),¹⁹ the magnitude of this impact will only grow. A related concern is that staffing shortages, overwork, and job stress may further contribute to increased medication errors.^{20,21}

This study found that the need for prescription clarification contacts varies considerably based on the incoming delivery channel of the new prescription order, and the subgroup that included electronic channels demonstrated significantly less need for clarification. In this context, electronic prescribing may provide a means to reduce the inefficiencies associated with the current prescription ordering and fulfillment processes.^{22,23}

While this study did not specifically measure the comparative difference between electronic prescribing and other channels of prescription orders, this study did identify the potential need for a method of prescription ordering that requires less clarification contacts with prescribers. An electronic tool would permit a prescriber to transmit a legible prescription electronically to a pharmacy without the inherent opportunities for unclear, confusing, and missing information that is related to handwritten prescriptions. Electronic prescribing technology provides the potential to review and check the prescription against a variety of drug safety criteria (e.g., allergies or interactions), prompt the prescriber with appropriate warnings and options, and present clarification request to the prescriber *before* being transmitted to the pharmacy. Other advantages include the ability to handle renewal requests, support interactive messaging with pharmacists, maintain a history log on prescription processing, and provide dose calculators for specific medical conditions or age groups. Optimal integration of this technology requires immediate access to a wide range of patient data, including demographic information, lab results, allergies,

prescription benefit plan formulary, and current medications.²⁴ It also requires access to detailed information on available drugs and formulations, dosage and administration guidelines, interactions, and contraindications. Many of these functions have already become available for electronic prescribing systems or are being tested in the marketplace.^{13,22}

Opportunities also exist to educate prescribers about the prevalence of the prescription issues described here and the associated risk of ADEs associated with them. As the total number of U.S. prescriptions continues to increase by approximately 150 million each year,²³ efforts to inform prescribers about the critical elements of safe prescribing become even more important. Through direct outreach efforts to prescribers as well as initiatives involving medical organizations and health care delivery systems, opportunities exist to reduce the number of prescription issues that pharmacists are required to clarify.

Limitations

One limitation of this study is its exclusive focus on new home-delivery (mail-order) prescriptions, so the results cannot be generalized to home-delivery refill or renewal prescriptions or to prescription fulfillment in other settings such as community pharmacies or hospitals.

A second limitation is that this is a descriptive study that was not designed to quantify clinical outcomes. We did not study the relationship between clarification contacts and the ADEs that may have been avoided and did not quantify the types and frequency of ADEs that are averted by clarification contacts with prescribers. Some of the issues identified in the extant study (e.g., unclear drug name, strength, or dosage) have the potential to cause dispensing errors and adverse events unless they are first clarified with prescribers. Based on pharmacy data alone, the likelihood, type, and severity of avoided ADEs could not be quantified.

A third limitation relates to the relatively small number of electronic prescriptions that were received during the analysis period. The clarification rate for the miscellaneous category (which included electronic prescriptions) was considerably less than most other channels and about one half the incidence of clarification contacts needed for mail-prescription orders, the most common channel for new orders to mail-order pharmacy. However, a more-detailed analysis of the issues related to the electronic subgroup of prescriptions requires a significantly larger sample, which may be more likely in a future period when electronic prescribing becomes more prevalent.

Finally, study design and limited data availability prevented the inclusion of the specific costs of performing the requisite clarifications with prescribers. Therefore, the overall economic impact of these activities was not quantified and provides an opportunity for future analysis.

Conclusion

Traditional prescription-ordering processes offer many opportunities for miscommunication and mistakes and may con-

tribute to the high rates of outpatient medication errors that have previously been reported. At a national home-delivery pharmacy, 8.7% of prescriptions had incomplete, unclear, or missing information related to elements that are essential to accurate medication dispensing. Although clarification contacts with prescribers can help avoid these potential dispensing errors, these contacts are time consuming and reduce operational efficiency.

Future efforts might be directed toward improving the quality of prescription communication for those prescription order channels that are currently associated with higher rates of clarification contacts as well as shifting prescription communication away from these channels and toward those that require fewer clarification contacts.

Emerging electronic prescribing technologies may offer a better long-term approach to the problem of unclear or incomplete prescription orders.²⁴ Electronic prescribing would presumably include electronic edits to verify the prescribed drug name, strength, dosage, etc., against valid data elements for these and other prescription order fields. Electronic edits can also help to ensure that prescription orders are populated completely and that the data are consistent with patient information and available medications. These technologies can also provide a more efficient means for pharmacists to receive and process prescriptions. Improving the quality of the initial prescription order will improve pharmacy and physician office efficiency by reducing the need for clarification contacts with prescribers.

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