

An assessment of pharmacists' readiness for paperless labeling: a national survey

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ABSTRACT

Objective To assess the state of readiness for the adoption of paperless labeling among a nationally representative sample of pharmacies, including chain pharmacies, independent retail pharmacies, hospitals, and other rural or urban dispensing sites.

Methods Both quantitative and qualitative analyses were used to analyze responses to a cross-sectional survey disseminated to American Pharmacists Association pharmacists nationwide. The survey assessed factors related to pharmacists' attitudinal readiness (ie, perceptions of impact) and pharmacies' structural readiness (eg, availability of electronic resources, internet access) for the paperless labeling initiative.

Results We received a total of 436 survey responses (6% response rate) from pharmacists representing 44 US states and territories. Across the spectrum of settings we studied, pharmacists had work access to computers, printers, fax machines and access to the internet or intranet. Approximately 79% of respondents believed that the initiative would improve the adequacy of drug information available in their work site and 95% believed it would either not change (33%) or would improve (62%) communication to patients. Overall, respondents' comments supported advancing the initiative; however, some comments revealed reservations regarding corporate or pharmacy buy-in, success of implementation, and ease of adoption.

Conclusions This is the first nationwide study to report about pharmacists' perspectives on paperless labeling. In general, pharmacists believe they are ready and that their pharmacies are well equipped for the transition to paperless labeling. Further exploration of perspectives from product label manufacturers and corporate pharmacy offices is needed to understand fully what will be necessary to complete this transition.

BACKGROUND AND SIGNIFICANCE

According to the Institute of Medicine's 'Preventing medication errors' report in 2006,¹ in any given week, four out of five Americans use prescription drugs, over-the-counter drugs, or dietary supplements. At least 1.6 million preventable medication errors occur every year. Given the statistics about increasing trends in prescription medication use among Americans² and the prevalence of medication errors,¹ improving medication safety has become a primary goal in healthcare reform and research over the past several years.^{3–6}

One approach (or strategy) for reducing medication errors that has been proposed by the Institute of Medicine is to improve timely access to medication product labeling. Traditional paper product labels, or package inserts, have been the standard format of prescribing information for decades.⁷

The format of these inserts has remained virtually unchanged during that time, despite the increasing information content making them lengthy, complex, and hard to use.⁸ Misleading product labeling for high-alert drugs can cause confusion in drug administration resulting in fatal consequences. For example, in 2006, similar labeling and packaging of two different concentrations of heparin led to an overdose and eventual death of three infants.⁹ While the US pharmacopeia proposed modifications to product labeling features such as font size and color for high-alert drugs like heparin to help healthcare professionals, caregivers, and patients more readily distinguish between differing drug doses, the consequences of mislabeling continue to serve as an example of the importance of timely and unambiguous package inserts.

In response to a desire to address this longstanding concern, the Health Level 7 community formed the structured product label (SPL) working group to create a standard XML schema for paperless labeling. This schema was adopted by the US Food and Drug Administration (FDA) in 2005,¹⁰ and it is now required for all prescription and non-prescription medication labeling to be submitted to the FDA's Center for Drug Evaluation and Research.¹¹ Since the FDA's adoption of the SPL standard, the National Library of Medicine has maintained a repository of FDA-approved product labels, known as DailyMed (<http://dailymed.nlm.nih.gov>). These SPL documents contain not just product labeling information (ie, text, tables, and figures), but also product description (eg, brand and generic names, ingredients, ingredient strengths, dosage forms, routes of administration, appearance, Drug Enforcement Agency schedule for controlled substances) and packaging information (ie, package quantity, type). The SPL standard was designed to promote a shift to a paperless labeling system that would no longer rely on paper package inserts attached to stock supplies of medication. The FDA sends updates through this mechanism daily, making it the most up-to-date repository of labeling information.

The continued development of the SPL program over recent years has sparked renewed interest and effort in integrating a paperless labeling system into the current pharmacy workflow. Ideally, the next generation of pharmacy and prescribing systems would access an electronic copy of the US prescribing information label that would allow advantages such as the availability of more frequently updated and accurate drug information, unlimited copies, widespread access and dissemination, and opportunities to improve readability (eg, font size). However, while the FDA has taken measures to

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facilitate the transition to paperless labeling such as making SPL information freely available, it is unclear whether healthcare professionals are ready and willing to embrace a paperless labeling system fully. A proof-of-concept study showed that pharmacists in community pharmacy practice settings perceived the paperless labeling system to be accessible and user friendly, but found package insert information hard to read and onerous to print.¹² Although these problems have largely been remedied over time, many questions remain about implementation issues at other dispensing sites. Namely, are all types of pharmacies nationwide equipped to adopt a paperless labeling system? Do pharmacists feel prepared to implement a new system? The goal of this study was to assess the state of readiness for a national scale paperless labeling pilot among chain and independent retail pharmacies, hospitals, and other dispensing sites both urban and rural.

METHODS

Our study design was composed of two phases. First, we conducted brief interviews with pharmacists to collect general information about the current state of practice. Second, using the feedback collected in the preceding phase, we developed and administered a survey to a larger national population. All study methods were approved by the Vanderbilt University Institutional Review Board.

Setting and study population

Interviews were conducted with a convenience sample of pharmacists in the Davidson County, Tennessee metropolitan area, which represents a variety of different practices. Our survey study population consisted of pharmacists who are members of the American Pharmacists Association (APhA)—a national organization comprised of over 62 000 members from all US states and territories.

Survey design

For the first phase of this study, a trained research assistant conducted semistructured interviews either over the phone or in person with pharmacists. Each interview lasted approximately 15–30 min. On providing verbal consent, interviewees were asked open-ended questions that were grouped into three areas of impact—structure, process, and outcomes of paperless labeling. Structural questions included the following: ‘What kinds of hardware do you have available in your facility and how many of each do you have? Do you have access to the Internet?’ Process questions included the following: ‘How many prescriptions do you fill per day? If labeling is electronic, in that paper package inserts will no longer be necessary, how will this change affect your workflow?’ Questions related to outcomes of use included the following: ‘What advantages do you foresee if package inserts are only available electronically? Disadvantages?’

A total of 12 pharmacists was interviewed, representing the following settings (numbers of pharmacists are shown in parentheses): chain (3), independent urban (2), independent rural (2), hospital (2), and supermarket pharmacies (2). Pharmacy volumes in this sample ranged from 60 to 200 prescriptions fulfilled per day. Interview responses were reviewed by two of the authors (YXH and KBJ) and were used to refine and develop subsequent survey items (see supplementary appendix, available online only). We assessed content validity of the survey items by consulting with a panel of eight content experts (Pharmaceutical Research and Manufacturers of America and APhA board members) and using an iterative process of reviewing and refining the survey items based on expert feedback before final

consensus was reached. Our online survey consisted of multiple-choice items designed to collect information about pharmacy attributes (eg, prescription volume, pharmacy setting, geographical location) and to assess structural and attitudinal readiness. We defined structural readiness for paperless labeling as the availability or use of electronic resources for retrieving labeling information. We defined attitudinal readiness as perceptions of the impact of paperless labeling. Attitudinal readiness items were scored on a five-point Likert scale and were statements related to issues of quality and communication of information as well as issues of environment and resources. The survey included open-ended items to probe additional perceived advantages and disadvantages that may not have been included in the attitudinal items. The survey was managed by APhA using Qualtrics (<http://aphanet.qualtrics.com>), commercially available online survey software.

Survey data collection

Survey responses were collected for a period of approximately 3 weeks (mid-October to early November 2011). A link to the online survey was sent to a random sample of 7426 (out of 109 780) pharmacists on the listserv, which includes APhA members in and outside of the USA who had previously agreed to receive surveys distributed through APhA. This sample was based on previous experience on the sample size needed to receive an adequate response rate. Survey respondents received a chance to win one of five US\$150 American Express gift cards as compensation for their participation. An email reminder was sent to pharmacists 10 days after the initial email.

Data analysis

Descriptive statistics were used to describe our study sample. Pearson's χ^2 or Kruskal–Wallis tests were used to examine relationships between pharmacy characteristics and readiness factors. Spearman's correlation coefficient was used to examine the relationship between pharmacy volume and attitudinal factors. Cronbach's α was used to determine the degree of internal consistency between attitudinal factors. Confidence intervals for Cronbach's α estimates were obtained using a bootstrap approach with 1000 resamples in order to evaluate the reliability of the measurement. All statistical analyses were performed using R 2.15.0 (<http://www.r-project.org>). Free-text responses were categorized thematically by two of the authors (KBJ and YXH.)

RESULTS

We collected 436 responses to our survey out of 7426 invited, yielding an overall response rate of 6%. Out of the 436 survey responses, seven pharmacists identified themselves as ‘currently not working’ and were thus excluded from analyses. We received complete responses from 76% of the remaining 429 pharmacists, while 24% completed only part of the survey. Both complete and partial responses were included in analyses and are reported here collectively. Respondents represented 44 of the 50 states, as well as Puerto Rico. Response rates for US regions were as follows: northeast, 4.8% (60/1259); midwest, 7.7% (135/1754); south, 4.8% (132/2730); and west 5.4% (80/1495). Figure 1 shows the survey response rate by state for 408 respondents with state information.

Respondent profile

Table 1 shows the types of pharmacy settings represented in our sample. Pharmacists reported 15 years of experience on average since receiving a pharmacy degree (N=401). The median

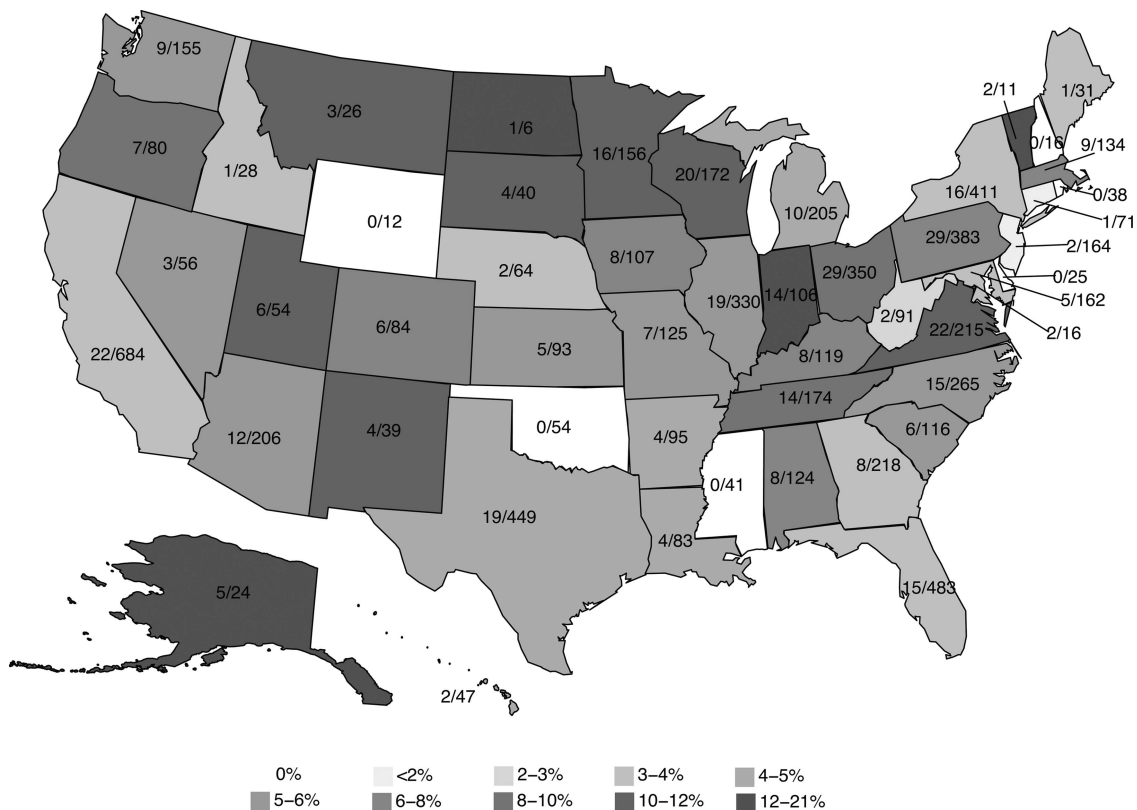


Figure 1 Survey response by state. Shading indicates response rate (percentage of survey respondents out of survey recipients) and actual numbers of respondents per state are shown on the map. (One respondent was located in Puerto Rico and is not shown here.)

number of prescriptions fulfilled at pharmacies as reported by our respondents was 250 prescriptions per day ($N=384$, between 150 and 400 prescriptions in the 25th percentile and 75th percentile, respectively).

Almost all pharmacists in our sample reported using prescribing information ‘sometimes to often’ (376/407, 92%). Pharmacists reported using prescribing information for other activities as well as being a professional resource (see table 2). Over 80% of pharmacists reported using prescribing information when educating or counseling patients (348/429, 81%) and verifying dose information (348/429, 81%).

Structural readiness

Out of 407 pharmacists, 6% reported using exclusively paper resources to retrieve label information, while 93% reported using either an electronic resource or both electronic and paper resources (1% of pharmacists did not know what kind of resource they used). The majority of pharmacists (62% or more respondents per state) from each of the states represented in our sample reported the use of a computer in their pharmacy—with the exception of Maine (0/1, 0% computer use), Connecticut (0/1, 0%) and South Dakota (2/4, 50%). The availability of

Table 1 Pharmacy practice setting

Type of pharmacy	No of pharmacists
Chain	175 (41%)
Independent	72 (17%)
Hospital/institutional (inpatient)	62 (14%)
Supermarket	44 (10%)
Clinic (outpatient)	35 (8%)
Mass-merchandise	16 (4%)
College (academia)	3 (1%)
Other*	8 (1%)
Federal/military/Department of Defense	4 (1%)
Pharmaceutical industry	4 (1%)
Mail-service	3 (1%)
Managed care	3 (1%)

Types of pharmacies represented by study respondents are shown from largest to smallest representation ($N=429$).

*Includes: consultant, hospice, ambulatory, home infusion, central fill, clinical pharmacist specialist.

Table 2 Other uses for prescribing information

Activity	No of pharmacists
Educating/counseling the patient	348 (81%)
Verifying dosing information	348 (81%)
Educating/counseling healthcare professionals (eg, physicians, nurses, physician assistants, nurse practitioners)	306 (71%)
Educating/counseling patients' families/caretakers	305 (71%)
Assessing the potential for drug interactions	295 (69%)
Educating/counseling employees	207 (48%)
Educating/counseling insurers	33 (8%)
Dispensing information (eg, ingredients for compounding)*	6 (1%)
Assessing possible unintended consequences (eg, adverse effects)*	6 (1%)
General education (eg, manufacturer information)*	2 (<1%)
Educating students*	2 (<1%)

Various activities pharmacists reported using prescribing information for shown from most to least popular activities ($N=429$).

*Categories created by study authors based on free-text responses entered by pharmacists in the ‘other’ category.

computers, printers, and fax machines ranged from 80% to 94%, 64% to 89%, and 60% to 88%, respectively, across different types of practice settings. There was no significant association between the type of practice setting and the availability of any of these three devices ($p=0.20$, 0.12 , and 0.08 , respectively), but the availability of mobile devices was significantly different across settings ($p=0.002$), with pharmacists of independent pharmacies reporting the highest rate of mobile device availability (51%) and those of clinic outpatient pharmacies reporting the lowest rate (14%).

Pharmacists in all settings, except chain pharmacies, reported relying on manufacturer web sites for online label information. Pharmacists of chain pharmacies reported using corporately curated label information. As for internet access, 61% (230/380) of pharmacists reported using a corporate intranet to access the web, while 35% reported having direct internet connection. A total of 4% reported no internet access. Internet access patterns were significantly different between practice settings ($p < 0.001$). Notably, most pharmacists operating at independent pharmacies reported direct internet connection (95% of 72 independent pharmacists), while a majority of pharmacists operating at chain and supermarket pharmacies reported internet access via corporate intranet to selected sites (75% of 175 chain and 56% of 44 supermarket).

When asked about their preferred means of accessing electronic label information, 53% of pharmacists (199/377) indicated that they would prefer that label information be accessed from the same computer and printer used to process prescriptions. Pharmacists also specified that the two most preferred methods for obtaining label information would be through a pharmacy operating/dispensing program (171/375 or 46%) or through a direct link (118/375 or 31%) versus through a corporate intranet site (59/375 or 16%) or from an offline electronic resource (27/375 or 7%).

Attitudinal readiness

Overall, pharmacists responded favorably to the impact of online availability of label information. There was a weak but significant positive correlation between pharmacy volume and pharmacists' attitudes towards paperless labeling ($r=0.131$, $p=0.017$). Table 3 shows the distribution of scores from 1 to 5 (greatly worsen to greatly improve) for each of the 11 items.

Items were grouped into two predefined categories: Content and communication and environment and resources and Cronbach's α coefficients for these two categories were 0.86 (95% CI 0.82 to 0.89) and 0.74 (95% CI 0.68 to 0.79), respectively, indicating good internal consistency within each category. Most pharmacists believed that electronic prescribing information would produce no change in communication to insurers, need for print information, and need to repair equipment. In contrast, pharmacists believed that the speed of retrieving information and the degree to which information retrieved would be up to date would greatly improve. One pharmacist commented, 'quick access is always better than having to go look for a package insert'. Another pharmacist remarked that paperless labeling would achieve 'speed and efficiency in a world where the need for information is rapid and often urgent'. Nonetheless, some pharmacists also raised concerns about delays in the process due to technical limitations noting, 'I (sic) may delay information, due to slow computers!' In fact, one pharmacist believed that it is actually 'hard to get exactly the information you need' and it is 'faster to skim a book'.

The majority of pharmacists noted that both the impact on the environment and the need to print information would improve. According to supporting comments, one pharmacist believed that one 'would only need to print occasionally' resulting in 'a lot of paper saved'. Another pharmacist agreed and added that the existing paper inserts are problematic, 'not only are the current package inserts an unnecessary waste paper, they are difficult to read due to small print and nearly impossible to keep organized with the medication once unfolded'.

Most pharmacists believed that issues such as the adequacy of drug information, level of patient safety, and communication to patients and prescribers would all improve. For instance, there would be 'greater availability (of information) to all health professionals'. Furthermore, patient safety could be improved because 'updated information would be readily accessible' and thus, 'any recall, or other important dosing instructions that were changed after the drug info sheet was printed, would be obtainable'. In fact, one pharmacist perceived paperless labeling would provide more opportunities for pharmacists to consult with patients, 'time saver so retail pharmacists may spend more time with patients'. Four pharmacists expressed concerns about patient safety. One pharmacist believed that patient safety could potentially be negatively impacted because 'non-professionals

Table 3 Attitudinal readiness

Impact of online availability of prescribing information on...	1 Greatly worsen	2 Worsen	3 No change	4 Improve	5 Greatly improve	Mean (SD)
Content and communication						
Adequacy of drug information	1 (<1%)	3 (1%)	69 (20%)	<i>161 (46%)</i>	114 (33%)	4.10 (0.76)
Level of patient safety	1 (<1%)	5 (1%)	53 (15%)	<i>181 (52%)</i>	108 (31%)	4.12 (0.73)
Communication to patients	3 (1%)	13 (4%)	116 (33%)	<i>139 (40%)</i>	77 (22%)	3.79 (0.86)
Communication to prescribers	1 (<1%)	5 (1%)	98 (28%)	<i>154 (44%)</i>	90 (26%)	3.94 (0.79)
Communication to insurers	4 (1%)	8 (2%)	201 (58%)	84 (24%)	51 (15%)	3.49 (0.81)
Environment and resources						
On the environment	0 (0%)	2 (1%)	62 (18%)	<i>139 (40%)</i>	145 (42%)	4.23 (0.75)
Speed of information retrieval	3 (1%)	13 (4%)	54 (16%)	<i>142 (41%)</i>	<i>136 (39%)</i>	4.14 (0.87)
Up-to-dateness	0 (0%)	3 (1%)	33 (9%)	<i>144 (41%)</i>	<i>168 (48%)</i>	4.37 (0.69)
The need to print information	13 (4%)	33 (9%)	118 (34%)	<i>131 (38%)</i>	53 (15%)	3.51 (0.99)
The need to repair equipment	7 (2%)	61 (18%)	208 (60%)	46 (13%)	26 (7%)	3.07 (0.83)
Other financial costs	9 (3%)	47 (14%)	203 (58%)	61 (18%)	28 (8%)	3.15 (0.85)

The average score (and SD) for each survey item and actual number of responses in each response category are shown with percentage of total responses in parentheses (N=350). Values in *italics* indicate modes for each item.

could have access and then use it to further their drug seeking habit'. Another pharmacist was wary of the online availability of drug information in general stating, 'the availability to patients has made some of them hesitant to take their medication'. Yet another pharmacist remarked that more responsibility is placed on the pharmacist to uphold levels of patient safety; although paperless labeling is a 'good idea, mandatory (sic) requirement for accessibility is needed' because the 'availability of unlimited amount of information from the pharmaceutical company regarding a particular drug will place the pharmacist in the position of having a mountain of data available, but with limited time to review the latest data'. According to this pharmacist, the need to review the latest data would 'place greater liability for failure to notify patient of information on the pharmacist (sic) at the dispensing end'. Despite a few comments suggesting some reservation about paperless labeling, fewer than 20% of pharmacists believed that paperless labeling would produce a negative impact for any one of the attitudinal readiness items addressed here.

Other issues that were revealed by pharmacists' comments included concerns about corporate or pharmacy buy-in, the value of prescribing information in current practice, and dependence on familiarity with or ease of using technology. Themes and corresponding supporting comments are shown in table 4.

DISCUSSION

Our results suggest that most pharmacists nationwide across pharmacy settings and sizes are attitudinally ready, and report that their pharmacies are structurally ready to adopt a paperless labeling system. Most pharmacists reported that electronic resources considered necessary for product label management were either in active use or were currently available in their pharmacies. Regarding the potential impact of the online availability of prescribing information, most pharmacists predicted no change in communication to insurers or issues related to resources such as the need to repair equipment and other financial costs. In general, pharmacists perceived that online availability of prescribing information would improve the communication and quality of prescribing information as well as environmental and resource needs.

Nonetheless, a few barriers remain. Pharmacists suggested that the effectiveness of the paperless labeling system would

depend on its usability. Furthermore, accessibility to the internet remains an issue for a handful of pharmacies. Given the rapid expansion of electronic prescribing, or e-prescribing, this accessibility is likely to improve. A more focused investigation of pharmacies with limited resources, particularly those lacking the critical infrastructure such as internet access, might be helpful in determining the best solution to address this barrier. For example, even in pharmacies without internet access, there may be ways to enhance their internal information systems to support the National Library of Medicine DailyMed web services.

Although our study sample included pharmacists representing a variety of settings nationwide, our study was not without its limitations. We recognize the low response rate; however, this is not unusual compared to other APhA surveys distributed in the past. Another limitation was that our sampling frame consisted of only APhA members with valid email addresses who had opted to receive surveys electronically, thus excluding pharmacists with no email and/or a preference for postal mail. As a result, perspectives of pharmacists captured here may not necessarily be representative of all pharmacists nationwide. Furthermore, due to the survey method and topic of this study, our sample may have been subject to a selection bias. However, it is reassuring that despite the potential bias towards respondents who may be more technologically inclined, our sample did not just consist of pharmacists representing pharmacies fully equipped with current technologies, for example, internet access; our sample also included pharmacists from a number of pharmacies that reported no internet use. Finally, we did not collect information to determine which franchised pharmacies were represented in this study; therefore, there may be an overrepresentation of specific franchised pharmacies, which could falsely skew perceptions of this population.

Respondents provided valuable suggestions that address real or perceived barriers to embracing paperless labeling, including the importance of considering the readiness of larger corporate pharmacy chains, addressing the need to provide up-to-date product label data to manufacturers who currently provide product label information on their own websites, and the critical step of creating a 'guiding coalition' of affected stakeholders to lead this transformation.¹³

While this report provides reassurance about the technical feasibility of migrating to paperless labeling, it does not address the as-yet unimproved overall readability of labeling information.¹⁴ There is a clear need to address the challenges patients with low literacy have in understanding labeling information,¹⁵ which has been associated with adverse drug events,¹⁶ incorrect self-administration,¹⁷ and potentially medication adherence.¹⁸ Additional work will need to continue to improve the utility of labeling information—work that should be catalyzed by the increasing migration towards e-prescribing and paperless labeling.

CONCLUSION

We assessed pharmacists nationwide for readiness to adopt a paperless labeling system and found that most pharmacies are equipped with at least computers, printers, fax machines, and access or potential access to online package insert information. Pharmacists perceived the impact of paperless labeling favorably and recognize its value; however, some reservations about corporate buy-in and internet accessibility were expressed. Future studies probing the readiness of larger corporate pharmacy chains and product label manufacturers may help address

Table 4 Other themes that emerged from pharmacists' comments about online availability of prescription drug labeling information

Theme (n)	Example comment
Corporate or pharmacy buy-in (6)	'Many corporations do not allow automatic internet accessibility from the store level' 'Some companies do not allow internet access and therefore it would not be available to those providers (RiteAid, Walgreens)' 'If this is only available with internet connectivity, some pharmacies may not 'buy into' this program, leaving some pharmacists without access'
Value of prescribing information in current practice (7)	'Its time has come' 'Not a bad idea, just unsure of how to implement it, as internet can go out due to system issues'
Dependence on familiarity with or ease of using technology (7)	'Must be quick and easily retrievable—user friendly.' 'Younger employees/patients have more confidence in on-line access'

pharmacists' concerns and provide a more complete picture of nationwide readiness for paperless labeling.

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