

Prescription Labeling and Language Barriers

According to the U.S. Census Bureau, almost 50 million Americans speak a primary language other than English at home. Among those, 22.3 million have limited English proficiency (LEP), defined as the self-rated ability to speak English “less than very well”. Over the past ten years, the number of LEP individuals in the United States has dramatically increased by 53% (Bradshaw et al. 2007). According to a U.S. Census Bureau survey in 2005, ethnic or racial minority groups comprise one-third of the total U.S. population. Among minority populations, Hispanics are the largest and fastest growing group, followed by African Americans and Caribbean African Americans, and Asian Americans (Bernstein 2006). With continued growth in LEP populations, there is a great emphasis on the need to overcome language barriers in order to maintain quality health care.

The Importance of Language

Although, in the past, the medical field did not pay appropriate attention to the importance of language barriers, recent studies indicate that language problems should not be ignored (Brewer 2006). In an interview by Medscape, Linda Weiss, senior research associate at the New York Academy of Medicine stated, “Research suggests that patients with limited English proficiency do have poorer knowledge of medication and dosing instructions, and that they have significantly greater problems with medication adherence. The provision of oral and written medication information in the patient’s language has been linked to improved health outcomes” (Barclay 2007).

Language barriers can have serious adverse consequences on the health care of individuals with limited English language skills. Since the FDA does not require approval in languages other than English for medications marketed in the United States, manufacturing labels and inserts are primarily in English. Moreover, pharmacies are not required to provide labels and information in other languages. Despite the potential risks to patients, nearly half of LEP patients who need a medical interpreter do not get one (Flores 2006). As a result, many LEP patients do not fully understand their discharge instructions and prescription information. Frequently, they are unclear about dosage, potential side effects, timing, and other important specifications such as “do not operate heavy machinery” or “do not drink alcoholic beverages” when taking their medications.

Potential Risks

One of the biggest challenges in translating medication labels is that unlike manufacturing labels, each prescription must be tailored to each patient’s case. Furthermore, many hospitals and pharmacies may not have sufficient bilingual staff to ensure that patients are given instructions in their native language. The benefits of providing language-appropriate prescription labels along with interpreters for LEP patients, however, greatly outweigh the risks.

In clinical settings, ad hoc interpreters are sometimes used in the absence of bilingual staff or medical interpreters, despite the fact that they are unqualified because of their own limited English language skills or medical backgrounds. Parents commonly rely on their children to interpret, and children often misinterpret or omit relevant information to avoid embarrassment. In the case of young children, frequently family members or friends are used to interpret despite the fact that they are not adequate as medical interpreters. As a result of the language barriers, parents are afraid they will administer their child’s prescription medication at the wrong dose. When

interviewed through an interpreter by the *Gotham Gazette* in a New York City (NYC) pharmacy, one mother expressed her discomfort at giving her son his medication. She explained that she preferred to give him low doses because she was unsure of the actual prescribed dose (Gross 2008).

There are several examples in which language barriers have resulted in medical errors, particularly among pediatric cases.

One case reported a 10 month old girl with iron-deficiency anemia who experienced a 12.5-fold overdose of iron and was hospitalized for iron intoxication after her parents who received instructions in English reported giving 15 mL of iron elixir rather than the prescribed dosage of 15 mg per 0.6 mL, 1.2mL daily. Despite the fact that the parents clearly spoke primarily Spanish, no bilingual staff or interpreters were present at the time of the visit. Furthermore, all instructions and labels were provided solely in English by the pharmacist. (Flores 2006).

Requirements for Pharmacies Differ

Current legislation mandates all health care providers that receive federal funds offer language services to LEP patients. These laws have largely been enforced in hospitals, clinics, nursing homes, and Medicaid agencies. For example, many emergency rooms employ interpreters, especially for languages common in the community that they serve, and in the absence of an interpreter, use telephone interpreter services.

However, efforts to improve communication with LEP patients must continue to evolve. Recently, there has been an emphasis on pharmacies meeting language requirements, especially pharmacies located in metropolitan areas or serving minority communities. In NYC, where large immigrant populations reside, new legislature is being proposed that will require pharmacies to provide translation services. “Giving New Yorkers access to the information they need starts with simple, commonsense steps, like providing translation services and extra medical instruction for those with limited English proficiency who are filling prescriptions,” said public advocate Betsy Gotbaum in a prepared statement for the *Gotham Gazette*. Betsy maintains that this proposed legislature will help eliminate uncertainty regarding prescriptions resulting from language barriers (Gross 2008).

Surveys of U.S. Pharmacies

Several studies on the practice of providing prescription labels and inserts in languages other than English and the availability of bilingual staff in pharmacies many non-English speaking customers have been conducted. Results indicate that pharmacies do not adequately meet the language requirements for LEP individuals.

Of 200 randomly selected pharmacies in NYC, 26% report that they do not provide non-English language labels despite the fact that they serve many non-English speaking patients on a daily basis.

Some 25% of the NYC population does not speak English well; however, more than 80% of the NYC pharmacists surveyed report that they do not have the ability to identify which patients need translations. (Barclay 2007).

A recent study of all 161 pharmacies in the Bronx, (a NYC borough with a predominantly Spanish-speaking population) reveals that 31% of the pharmacies cannot provide

prescription labels in Spanish. Of the pharmacies that do provide translated labels, such labels are given only on the patient's request (Sharif 2006).

In the United States, the most common method for translating prescription labels and inserts is computer translation. However, the quality and accuracy of translating prescription labels and information packets using the available software varies. According to the Bronx study, computer translation software is not always adequate. An analysis of the translation software used by one particular chain pharmacy shows incorrect Spanish translations for common expressions such as “dropperful” and “for 30 days” (Sharif 2006). In addition, many pharmacists do not feel sufficiently confident in using available commercial translation software because they have poor methods of checking for readability and accuracy. The Bronx study indicates that only one bilingual Spanish employee is available to adequately check for translation errors.

Given that immigrant populations have increased in over 45 states between 1990 and 2000, this is becoming a national problem (Barclay 2007). LEP individuals who live in communities less densely populated by immigrants may face even more difficult barriers. One study in Michigan indicates that 47% of pharmacies never or only sometimes provide non-English prescription labels. More than half the pharmacies surveyed also indicate that they never or only sometimes provide a non-English version of information packets. Two-thirds of the pharmacies report that verbal communication is conducted primarily in English. Those who do communicate in non-English languages use bilingual staff (approximately two-thirds), telephone interpretation services, or family members and friends to interpret (Bradshaw 2007).

Identifying Problems

New York City has the largest immigrant population in the United States. Thus, NYC pharmacies best reflect the challenges of providing language services for immigrants with inadequate English skills. The NYC pharmacists surveyed cite the following barriers to improved language access:

- a need for additional translation tools
- lack of bilingual personnel
- time
- cost constraints
- multiple labels (see below)

In NYC, new legislature may require pharmacies to provide translation services, including the hiring of bilingual staff. This alternative may not always be feasible, so other options such as telephone language services should be improved. Another common issue involves the logistics of printing labels in more than one language. Since the United States requires that prescription labels be printed in the country's official language, English, pharmacists would need to print a separate label for each additional language, because more than one language cannot be accommodated on a single label.

Solutions

Inform patients about language services Providing an interpreter during clinical visits when no bilingual staff is available can ensure that LEP patients receive all relevant information in their native language. In addition, health care providers should inform their patients about the availability of translated materials when they prescribe medication in order to assist pharmacists in determining which customers require translated labels. Physicians can also help patients to identify which local pharmacies have translation services for their particular language needs.

Improve translation quality of labels and inserts In 2006, the FDA made significant changes to the formatting guidelines for drug labels and inserts in an attempt to lessen potential confusion and decrease medical errors due to language inaccuracies on drug labels (Rabkin 2007). The stricter FDA regulations improved the comprehension of English-speaking patients and increased the translation quality into other languages. Some manufacturers took the opportunity to print translated labels and inserts for their international markets. These should be made readily available for LEP patients in the United States

Increase distribution of multilingual materials Many pharmaceutical companies do provide printed or Web-based product information in other languages, particularly Spanish. For example, due to the prevalence of diabetes among Hispanics in the United States, some brand-name diabetes medication information is available in Spanish. Although this has improved communication with Hispanic diabetic patients, it does not eliminate the need for translating prescriptions and interpreters. Furthermore, physicians and pharmacists need to make their patients aware of the availability of these materials.

Improve prescription translation software Expanding software for other commonly spoken second languages, as well as improving the existing Spanish software may be useful. Software for the Spanish language has been established to a greater extent than other secondary languages since the largest LEP population in the United States is comprised of Spanish speakers. Finally, in order to eliminate lesser quality translations, standardized software for translating prescription labels should be made universal.

Apply other multilingual labeling models Other international guidelines for labeling may be used as a model to help overcome language barriers in the United States. For example, in the European Union, additional languages (other than the official language of the member state) may be included in labeling and inserts provided the information is the same in all languages and does not have an adverse impact on the legibility, clarity, and comprehensibility of the text. In countries such as Switzerland where there are three official languages-French, German, and Italian-three labels must be printed for each medication. Once a system has been established for pharmacies, the logistics of using multiple labels may not be as challenging.

Conclusions

Although health care providers are best equipped to accurately inform and ensure their patient's understanding of medicine prescribed to them, it is the role of the pharmacists to confirm that instructions have been adequately understood. Thus, counseling during medical care in the presence of an interpreter, an indication on the prescription that the patient requires a translated label, and providing language services in pharmacies are all ways which can significantly improve communication with LEP patient populations and ultimately ensure better health care.

References:

Bradshaw, Michael, et al. 2007. "Language Barriers to Prescriptions for Patients with Limited English Proficiency: Survey of Pharmacies." *Pediatrics*, Vol. 120(2) August: e225-e235. <http://pediatrics.aappublications.org/cgi/content/abstract/120/2/e225?rss=1>

Bernstein, Robert. 2006. "Minority Groups Now One-Third of the U.S. Population". U.S. Census Bureau News: Press Release. May 10. <http://www.census.gov/Press-Release/www/releases/archives/population/006808.html>

Brewer, Mike "Prescription Label Translations Could Help Prevent Medical Errors". Pharmacy Choice. February 2, 2006. http://www.pharmacychoice.com/news/article.cfm?Article_ID=21399

Barclay, Laurie. 2007. "Pharmacies May Not Always Translate Prescription Labels for Non-English Speaking Patients." *Medscape Today*. Web MD. April 27. <http://www.medscape.com/viewarticle/555840>

Flores, Glenn. 2006. "Language Barriers Are More Than an Inconvenience." *AHRQ Case & Commentary*, Web M&M. *Pediatrics*. April. <http://www.webmm.ahrq.gov/case.aspx?caseID=123>

Gross, Courtney. 2008. "Language Barriers at the Drugstore" *Gotham Gazette*. February. <http://www.gothamgazette.com/article/health/20080204/9/2420>

Sharif, Iman, et al. 2006. "Availability of Spanish Prescription Labels." *Journal of Health Care for the Poor and Underserved*. 17(1), February: 65-69. http://muse.jhu.edu/login?uri=/journals/journal_of_health_care_for_the_poor_and_underserved/v017/17.1sharif.html

Rabkin, Bill. 2007. "SPL, Electronic Labeling and 'Right First Time' Patient Information." *PharmaManufacturing.com*. <http://www.pharmamanufacturing.com/articles/2007/053.html>

2001 Beacon Street, Suite 103 Boston, MA 02135 USA
web: www.LanguageConnections.com **tel:** 617.731.3510
toll-free: 877.731.6332 **fax:** 617-731-3700
e-mail: translate@languageconnections.com