http://www.afb.org/info/programs-and-services/public-policy-center/health-and-safety/rx-label-enable-campaign/access-to-drug-labels-survey-report/12345

AMERICAN FOUNDATION FOR THE BLIND

Access to Drug Labels Survey Report

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Summary: The Access to Drug Labels Survey explored the personal stories of people who had trouble reading prescription or over-the-counter medication information. Approximately 100 individuals completed the online survey and, in nearly every instance, respondents explained serious negative consequences of unreadable drug labeling information including illness, emergency room visits, hospitalization, additional expense, and increased anxiety.

Introduction

According to the 2006 National Health Interview Survey (NHIS)1, approximately 21.2 million Americans reported that they have difficulty seeing, even when wearing eyeglasses or contact lenses, or that they are blind or unable to see at all. For many of these more than 20 million Americans with vision loss, reading drug container labels, such as those on prescription medications, and package inserts about the medication is difficult, or even impossible. Given that the incidence of vision loss is expected to continue to dramatically increase, this poses a significant public health challenge.

The American Foundation for the Blind (AFB) has launched Rx Label Enable, a campaign to improve access to drug labeling information for people with vision loss. The campaign aims to ensure that people with vision loss have access to the vital information available to all consumers via prescription labeling and related documentation, enabling them to take medications safely, effectively, and independently. To achieve this goal, AFB is reaching out to consumers experiencing vision loss, policymakers, federal regulators, doctors, the pharmaceutical industry, retailers, assistive technology providers, and public and private insurers to promote solutions, build consensus and take action. The Access to Drug Labels Survey was one component of the Rx Label Enable campaign.

Methodology

The Access to Drug Labels Survey explored the personal stories of people who had trouble reading prescription or over-the-counter medication information. Respondents voluntarily completed the online questionnaire. This informal online questionnaire consisted of four open ended questions that asked about the extent of vision loss, descriptions of why drug labeling information was unreadable, negative consequences of the unreadable drug information, and strategies or techniques that were used to properly identify and take medications.

Results

Approximately 100 individuals completed the Access to Drug Labels Survey. Respondents included people of all ages with vision loss, people with all degrees of vision loss, people who have vision loss and may have additional disabilities, and family

members of people with vision loss as well as professionals with substantial experience and expertise in this area of vision rehabilitation.Data indicated that the inability to access necessary instructions supplied with prescription and over-the-counter medications often resulted in people with vision loss not taking a proper dose of necessary medication.

People with vision loss frequently reported that they have mistakenly taken expired medications or incorrect doses of medication because they were unable to see the expiration dates or dosage information. People with vision loss also reported that they have taken incorrect medication because they were unable to visually tell the difference between medicine containers. In some instances, people with vision loss explained that they were victims of pharmacy errors due to the fact that they could not read the prescription numbers to verify they were given the correct medicine. In other instances, people with vision loss were unable to read the refill instructions. They did not know it was necessary to refill their prescriptions nor did they know the drug number necessary to refill. Nearly every one of the approximately 100 respondents explained that they were dependent either on trusted sighted companions or complete strangers to convey necessary drug information.

Respondents consistently reported serious negative consequences of the unreadable drug labeling information including illness, emergency room or hospital visits, additional expense, and increased anxiety. Many of the personal stories respondents shared are provided to further emphasize the critical situation.
Inability to detect pharmacy errors involving an infant
A husband and wife who are both legally blind shared their story. They are parents of an infant. They are unable to read drug labeling information because it is not available in braille. They must manage several prescriptions. They have been given the wrong medication by a pharmacy and told the medication was the prescription they had intended. The only reason they figured this out was because they had the medication on a previous occasion and the packaging was so different that they asked a sighted neighbor who happened to be visiting. The mistake made by the pharmacy could have been lethal. Because they could not read the label, they had no way to ensure they were provided the correct medication.

Dependence on complete strangers to convey necessary drug information for two young children
A mother of two young children explained her story. This woman is totally blind. Reading prescription labels has always been a problem. There are no braille instructions. Doctors often forget to mention necessary drug information that is provided in the drug labels. She is unable to double check that the pharmacist gave her the correct bottle of medication. There are no after hours number that she can telephone for verbal instructions. To properly identify medications, she has been forced to seek out sighted assistance. She tries to memorize instructions verbally explained by sighted people. Sometimes she has had to ask strangers for sighted assistance. She does not know if she can always trust complete strangers with medicine information. This makes her feel like her family's privacy is being invaded.

Total lack of access
A respondent who has very little functional sight explained that he is on several prescriptions due to other medical conditions. He is the only person in his household.

He is unable to read print. The pharmacy does not provide braille. He can call the pharmacy to ask for directions, but that only works if he knows exactly which bottle he is holding. He relies on the size, shape, and texture of the pills or bottles to properly identify and take medications. At times he has taken the wrong medication. Other times he has taken the incorrect dosage.

Taking the incorrect medicine
A respondent who has low vision regularly takes prescriptions with labels that have very small print. She often confuses blood pressure medicine with stomach medication or antidepressant medication. She uses different rubber bands on each of her pill bottles in an effort to avoid further confusion.

Hospitalization
A respondent who has low vision explained that he cannot read the prescriptions on his medicine bottles and he cannot tell the difference between insulin bottles. He has given himself the wrong insulin and ended up in the hospital.

Emergency room visit
A respondent explained he has received the wrong dosage of insulin due to not being able to read the label. The prescription was for 50 unit insulin syringes and the pharmacy filled it with 100 unit syringes. He passed out from hypoglycemia and ended up in the hospital.

Inability to detect pharmacy errors and other serious difficulties
A respondent who is legally blind indicated that the regular print drug information is too small for him to read. The prescription number is also only available in regular print. The warnings on the sides of the vial or box are even smaller print that he is unable to read as well. One of the negative consequences he faces is that sometimes he misses taking one of his medications. He has also been the victim of pharmacy errors due to the fact that he cannot read the prescription numbers. He explained the strategies and techniques he uses to properly identify and take medications. He keeps his medications organized in a box with the eye drops on the bottom half of the box and the pills vials on the top end of the box, using rote memory to determine what he has to take. To tell how full or empty his prescription medicine containers are, he shakes the medicine containers.

Expired medication and illness
A respondent who was diagnosed with multiple sclerosis had to start taking several prescriptions. Shortly after her diagnosis with multiple sclerosis she experienced vision loss and had to manage several more prescriptions. At one point, she had a daily medication in prefilled syringes that expired. Not being able to verify that the medicine had expired, she continued to take the expired medicine and it resulted in a relapse of multiple sclerosis. The medication was unable to do what it is prescribed to do because it was expired. She was hospitalized for three weeks and then spent two weeks in rehabilitation followed by an additional three months before she was well enough to return to work.

Refill problems and additional expenses
A respondent who is a totally blind braille reader explained that labeling information such as the prescription number, pharmacy phone number to order refills, number of refills that remain, dosage, and side effects are not available in braille. One of her prescriptions has a fill by date. Unable to access the refill information, she forgot what that date was and was not able to refill the prescription on time. This resulted in an unnecessary delay and her having to pay for another doctor visit to obtain the necessary refill.

Anxiety
A respondent who is totally blind explained that she cannot read medicine bottles or medicine package print. She further explained that medication errors are constantly possible and something that is quite anxiety provoking. She makes her own braille labels for the containers but still requires sighted assistance to obtain the information for the braille labels. Braille labels only provide the name of the medication, not the dosage, frequency, or warnings.

Inability to maintain confidentiality and dependence on others
A respondent who has low vision shared her story. All the labels on her prescription bottles are too small for her to read. She has had to put her drugs in special places in a cardboard box so that she knows which medicine she is taking. She has managed to find a friend who tells her what she gets when she has prescriptions refilled. The pharmacists refuse to print the medication in larger print for her. She is left with no choice but to have her friend help her manage the situation. She further explained how embarrassing and degrading it is for her to be dependent on sighted assistance.

Dependence on sighted assistance
A respondent with recent vision loss explained that the printed drug labeling information is too small for his vision. He has experienced errors when attempting to organize and take his medication. If he could access the printed drug information, he would be capable of managing the situation. Due to the inaccessible drug labels, someone must assist him in organizing and taking his medication.

In summary, data indicated that the inability to read medication labels and instructions has resulted in serious negative consequences for people with vision loss. The most commonly reported negative consequences of unreadable drug labeling information included:
taking the wrong medication
taking an incorrect dosage of medication
taking expired medications
inability to access the necessary information to refill medications on time
illness due to taking the wrong medication or incorrect dosage of medication
emergency room visits or hospitalization
additional expenses
increased anxiety
inability to maintain confidentiality
inability to detect pharmacy errors
dependence on either trusted sighted companions or complete strangers to convey necessary drug information

The fourth and final item on the survey asked respondents to share strategies or techniques used by people with vision loss to properly identify and take medications. The suggestions included strategies such as tactually labeling medicine bottles, differentiating between medicines by their smell, size, texture, or shape as well as asking for sighted assistance. The obvious shortcoming of identifying medication by pill texture, shape, or size clues, for example, was a great matter of concern discussed by many of the participants.

Assistive technology devices that use smart-label and speech synthesis technologies to verbalize prescription information can enable people with vision loss to more effectively identify and take medications. There were only a few respondents who addressed the use of these assistive technology devices. The use of this sort of assistive technology can allow those who cannot read their prescription labels, a better way to manage their own medication. Nearly all those who addressed the use of such assistive technology devices explained that these devices were not affordable.

Another trend in the response to this fourth and final item was that people who experienced the challenge of vision loss also often experienced the challenge of other disabilities in addition to their vision loss. The presence of additional disabilities can further limit the ability of people with vision loss to effectively manage their medications while also increasing the need for more types of medication. This complicated their ability to devise effective strategies or techniques for properly identifying and taking medications.

Discussion

Overall results from this informal online questionnaire demonstrated that people with vision loss find themselves unable to take prescription and over-the-counter medicines safely, effectively, and independently due to inaccessible printed drug labeling information. Open ended questions gave respondents the opportunity to share their personal stories. Data indicated that the inability to access necessary instructions supplied with prescription and over-the-counter medicines often resulted in people with vision loss not taking a proper dose of necessary medication. In nearly every instance, respondents explained the serious negative consequences of unreadable drug labeling information and that they were dependent either on trusted sighted companions or complete strangers to convey necessary drug information.

There were only a few personal stories that addressed the use of assistive technology devices that can allow those who cannot read their prescription labels, a better way to manage their own medication. The few respondents who did address the use of such assistive technology devices explained that these devices were not affordable. The findings of this survey indicated that the lack of awareness and affordability were two substantial barriers people with vision loss experienced in accessing these high-tech devices.

No single currently available assistive technology or modality can meet the needs of all of the growing population of people with vision loss. This population of people with vision loss is not homogenous and, therefore, multiple means of communicating drug information are necessary. Increasing age, additional disabilities, socioeconomic status, severity of vision loss, and skill in the use of computer and/or assistive technologies should be taken into consideration when researching or developing assistive

technologies or modalities for use by people with vision loss to access prescription drug information.

Thus, assistive technology devices that use smart-label and speech synthesis technologies to verbalize prescription information seem to have not yet reached their full potential. To be most effective, an assistive technology or modality that allows those with vision loss a better way to manage their own medication should have certain features. The assistive technology device should:
provide essential drug information that is understandable and readily comprehensible to consumers, as well as the most current labeling information, as it becomes available;
have the ability to reach the majority of individuals with vision loss;
be easy to use; and
be affordable.

Policy Implications

Even though people of all ages with all degrees of vision loss are affected by the negative consequences of inaccessible drug labeling information, there are essentially no federal guidelines for pharmacists to follow in making prescription labels accessible.

The Food and Drug Administration (FDA) implements laws and regulations that govern prescription drug information. However, the FDA has never issued specific regulations or guidelines to guarantee that prescription drug information intended for patients is accessible for people with vision loss. In general, states are the primary regulators of the content and format provided directly on a prescription bottle and/or pharmacy-provided packaging. Nearly all of the states in the union have statutory requirements pertaining to prescription labeling. However, no state law ensures that prescription labeling is accessible to persons with vision loss. Even the state of Massachusetts, which attempts to establish such requirements, merely provides: "upon the request of-a person visually impaired [sic], directions on the label affixed by the pharmacist to a container of a prescription drug shall be typed in a print size allowing no more than ten characters per inch (Mass. Gen. Laws Ch. 94C, §21)." Few states have ever considered adopting a clear accessibility requirement-the California legislature is currently considering such a proposal, AB 1399, which provides: "upon the request of a customer who is blind or visually impaired, a pharmacist shall provide a prescription drug label that is readable by an assistive technology device for the blind or visually impaired".

Some pharmacies are beginning to experiment with different ways to offer their customers alternate means of identifying prescription medications. However, while such efforts are well-intentioned, they do not amount to a national trend and are not based on any reliable standards or evidence of their effectiveness. Nationally, few pharmacies are voluntarily providing their customers with meaningful access to the labeling and other information related to prescription medications they dispense. Moreover, those pharmacies that have begun to try to provide their customers with vision loss with prescription information they can use are doing so in a vacuum without standards that ensure complete and consistent presentation of information.

Recent Actions

As part of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Congress called upon the FDA to investigate solutions addressing the problem of inaccessible prescription drug labeling. Unfortunately, the report issued to Congress in

May 2005 failed to describe specific processes, regulatory changes, or other solutions ensuring access. Nevertheless, the report does affirm that "all Americans, whether visually impaired or not, should have equal access to essential prescription drug information". In essence the FDA missed an opportunity to offer meaningful answers to the challenge of inaccessible labeling and related information. Since the study's release in May 2005, some effort has been made to convene expert panels to begin to formulate questions for future research and the development/communication of stopgap solutions. Even though the Secretary of Health and Human Services, Mike Leavitt, in announcing the introduction of FDA's new packaging insert format requirements, recognized that "clear and concise information about prescriptions will help ensure safe and optimal use of drugs", this language is limited only to package inserts and fails to consider accessibility for people with disabilities.

Action Needed Now

Congress should grant the FDA clear authority to regulate this area and develop standards to ensure that prescription labeling is accessible to individuals with vision loss. A number of existing solutions demonstrate the feasibility of providing access to prescription drug labeling and pharmacies should be prepared to provide prescription labeling in multiple modalities.

1 Data source: National Center for Health Statistics, National Health Interview Survey, 2006, www.cdc.gov/nchs/nhis.htm . For further information, see "Pleis J.R., Lethbridge-Çejku M. (2007). Summary health statistics for U.S. adults: National Health Interview Survey, 2006. National Center for Health Statistics. Vital Health Stat 10 (235)."