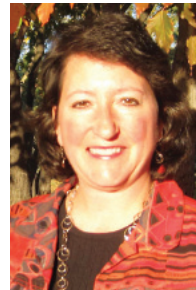


Study Shows Patient Confusion with Rx Labels

Medication labeling and medication adherence are often subjects at the American Society for Automation in Pharmacy's semiannual conferences. The recent midyear conference was no exception, with industry veterans Dan Ramirez and Bruce Briggs discussing proper labeling on acetaminophen prescriptions to address toxicity issues and tapping pharmaceutical manufacturer dollars to deliver messages to patients to address adherence. So I should not be surprised that labeling made news this week with an article discussing how confusing prescription drug labeling can be for the "everyday" patient.

The July 4, 2011, *New York Times* article, titled "When Take as Directed Poses a Challenge" and written by Paula Span, showcased results of a study recently conducted by Dr. Michael Wolf, an associate professor of medicine at Northwestern University who studies drug safety. As part of the study, the research team interviewed 464 adults between 55 and 74 years of age who were patients at several Chicago medical practices and clinics. The research team gave each patient seven amber-colored vials with different dosing instructions. They also provided the patients with a slotted tray that was marked with different times of the day. Patients were then instructed by the researchers to show them how they would take these medications over 24 hours.

Regardless of the instructions, Wolf said, "There was no reason to take these medications more than four times a day." Patients, however, had a difficult time putting the medication doses into the slotted tray. One-third of the patients did not think to take two of the drugs at the same time, although the labeled instructions were the same. In another case, when one drug was labeled to take with food and water and another was not labeled that way, 50% of the patients were going to take them at different times, even though they could have been taken together. When one drug was labeled "Take one tablet every 12 hours" and another labeled, "Take one tablet twice daily," two-thirds of the patients would not take them together.



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All told, less than 15% of those patients who participated were successful in organizing the doses to be taken the most efficient way each day. Rather, participants said they would take the tablets an average of six times a day, with some setting up as many as 14 doses a day. As the number of medications rises and the medication regimen schedule becomes more complicated, adherence becomes more of an issue. Wolf noted that the need for more simplified dosing instructions has been demonstrated in many studies, and said in the article that 90% of all prescription medications can be taken no more than four times a day. The lack of standardized or universal dosing instructions is attributed to the differing state board of pharmacy regulations. The article does note that a bill requiring a universal medication schedule has been introduced in New York and that one has become law in California.

Addressing the Problem

The study seems to support efforts to address prescription labeling. ASAP has been consulted

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by the United States Pharmacopeia (USP) in its proposed set of universal standards to guide the content, language, format, and appearance of prescription medication labels to reflect how patients read and understand medication instructions.

The USP's proposed standards carry several principles for prescription labeling (see box at right).

Well-Rounded Program

Speaking of future developments, the ASAP midyear conference in Palm Beach, Fla., featured a fantastic lineup of updates and new information, including the creation of accurate prescriber data, HIPAA transaction and code set changes, plans for the National Health Plan ID, pharmacy performance and quality tools, telepharmacy trends, institutional barcode scanning implementation tips, the latest news about health information exchange, and activities related to the interorganizational Pharmacy e-Health Information Technology Collaborative.

My Contribution I was delighted to be asked to provide the participants with a look at the major points featured in the President's Council of Advisors on Science and Technology (PCAST) report on health information technology (see my May/June 2011 column for the details). The reaction from participants was swift and strong. Few had been aware of the report. The report's major cornerstone calls for the creation, dissemination, and use of a "universal exchange language" for health information that enables it to be shared through a network infrastructure that allows a patient's data to be located and accessed with

USP convened a group of independent experts to put together the standards, which state that prescription labels should:

- Be organized in a patient-centered manner, to reflect how most patients understand medication instructions, and featuring the most important information for safe and effective understanding and use.
- Emphasize instructions and other important information (such as patient's name, drug name and strength, and clear directions for use), with less critical but important content such as the pharmacy name and number not taking precedence.
- Give explicit instructions that separate the dose from the timing of each dose, and use numbers in these instructions — for example, "Take 2 tablets in the morning and 2 tablets in the evening" rather than "Take two tablets twice daily."
- Include the purpose of the medication's use, unless the patient prefers that this information not appear.
- Improve readability by using high-contrast print and a large font size.
- Limit auxiliary information. Labels, stickers, or other supplemental information should be expressed in simple and explicit language that is minimized to avoid distracting patients.

Stay tuned for further developments.

strong, persistent, privacy preferences. The language would be based on some kind of extensible markup language syntax. The strategy represents an "evolutionary" transformation from traditional EHR systems to a "tagged data element" model, in keeping with managing and storing data using advanced data-mining techniques that break down data into the smallest individual pieces that can be exchanged or aggregated. PCAST uses the analogy of people today using their computer to access a webpage where various parts of the page are dynamically aggregated in real time from many different computers.

Most attendees felt the approach would be very difficult to implement, especially in tandem with CMS's rules for meaningful use requirements to be implemented in 2013 and 2015. Sources tell me the report generated similar, swift reaction earlier this year,

but things have been quiet since then. Among the first steps if the report's recommendation moves ahead would be HHS issuing a notice of proposed rulemaking (NPRM) to develop the universal exchange language. Keep your eyes open, and I will keep you up-to-date in future columns.

And mark your calendars now for the ASAP annual conference slated for Jan. 19 to 21, 2012, at the Don CeSar in Clearwater, Fla. If it is anything like June's meeting, you will walk away with actionable items from every presentation. Hope to see you there! **CT**

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