Healthcare Provider Preferences for Medical Device Labeling

Toni Stifano, Maggie Fu, Jennifer P. Alexander, Stacey A. Weger, Brian G. Southwell, Michael F. Burke, and Samruddhi Thaker

About the Authors

Toni Stifano, MT, CPH, is consumer safety officer at the U.S. Food and Drug Administration (FDA/CDRH). E-mail: toni.stifano@fda.hhs.gov

Maggie Fu, BS, is program analyst at the FDA/CDRH. E-mail: maggie.fu@fda.hhs.gov

Jennifer P. Alexander, MPH, MSW, is public health researcher at RTI International. E-mail: jalexander@rti.org

Stacey A. Weger, MA, is survey manager at RTI International. E-mail: sweger@rti.org

Brian G. Southwell, Ph.D., is senior research scientist at RTI International. E-mail: bsouthwell@rti.org

Michael F. Burke, Ph.D., is former senior research scientist at RTI International. E-mail: mburke@rti.org

Samruddhi Thaker, Ph.D., is senior research scientist at RTI International. E-mail: sthaker@rti.org

Communicating information about the use of medical products, including medical devices, has become increasingly important. One of the most critical means employed by the U.S. Food and Drug Administration (FDA) and the device industry is medical device labeling. However, there is currently insufficient empirical evidence on how practitioners utilize and view labeling.[1] In order to understand how or if healthcare practitioners use medical device labeling and to assess provider preferences for the content and format of labeling, we conducted two studies: a series of focus groups and a survey of healthcare providers.

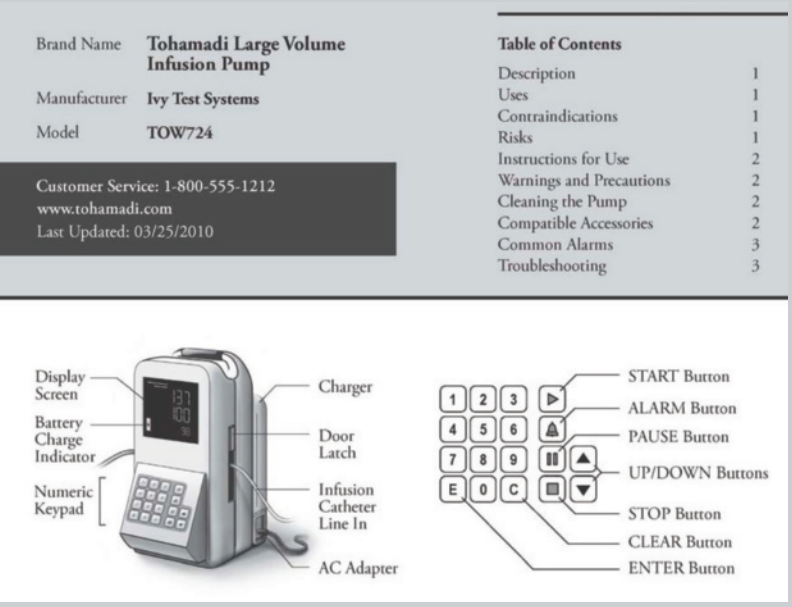

Figure 1. Portion of sample labeling developed for hypothetical device.

Focus Groups

In 2011, we conducted a series of nine focus groups in three cities with a variety of different healthcare practitioners (n=77). Participants were asked if they were aware of or referred to medical device labeling, which sections and what information they believed were the most important in device labeling, and their level of satisfaction with existing labeling. We also requested participant feedback about possible changes to device labeling.

Results suggested that several sections of labeling are crucial in drawing provider attention and satisfying their needs. The most important sections identified by practitioners were instructions for use, warnings, precautions, contraindications, troubleshooting, and manufacturer's contact information (e.g., phone number for 24-hour technical support), along with the device name, serial number, and expiration date.

Providers expressed a need for concise, clear and less technical language accompanied by a clear graphical depiction of the device. Respondents also generally wanted to have access to both short and long versions of the labeling. Figure 1 illustrates an example of the labeling we generated in response to focus group results.

Practitioner Survey

In 2012, we conducted a web-based survey of healthcare practitioners, including doctors and other prescribers, nurses, therapists, and technicians. Participants (n=411) were randomly assigned to comment on one of three sample versions of abbreviated (shortened) device labeling and asked to assess their usefulness. Data collection continued through fall 2012; data collected through October 19, 2012, was used for the present analysis. All of the versions reflected design suggestions from formative research and differed only in format and section ordering.

Results confirmed that the iterative design process was successful, as most respondents viewed the proposed labeling favorably, regardless of which version of the labeling they viewed. Approximately 82% of participants (335 of 410), across all versions, found the headings in the labeling they viewed to be "very easy" to understand. Approximately 90% of respondents (368 of 411), across all versions, were "satisfied" with the order of the information presented in the labeling they viewed. Of the participants who identified their primary work area as "home health," 90% said the headings were "very easy" to understand, and 95% were "satisfied" with the order in which the information was presented. We also found no significant differences between job categories in perceived ease in understanding the labeling headers ($p > .05$ for an ANOVA comparing prescribers, RNs and LPNs, and technicians and therapists).

In summary, these results suggest that practitioners want concise and informative labeling. Example labeling developed through this study shows promise in improving efforts to educate users about device safety and use.