Draft Report on Medical Device Labeling:

Patients' and Lay Caregivers' Medical Device Information and Labeling Needs

Results of Qualitative Research

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Executive Summary of Testing Findings

The Division of Device User Programs and Systems Analysis, CDRH, FDA conducted a limited series of focus groups and individual interviews to gain information on lay user (patient) preferences for the content and formatting of the patient labeling of medical devices. The information gained in this qualitative research is intended to be combined with research by the Center for Drug Evaluation and Research (CDER), the National Cancer Institute (NCI) and others, as well as literature findings, to provide a basis for recommendations to manufacturers on the development of effective patient labeling.

Participants preferred that their physician be the principal source of device and related procedure information. Labeling is just one part of an information system from which patients draw what they need and want to know. The participants made it clear that there is no single right approach to developing patient labeling. Their needs for device and procedure information depend on where they are in the decision making and treatment process and on their personal learning preferences. These same variables also affect whether written information, either in the form of labeling or health care provider developed information, is useful to them.

There were those who wanted everything there was to know, notably a statistician and an attorney who wanted all the clinical study results. Most others wanted just the basic information. When asked to reconcile these disparate preferences in one patient labeling document, the participants offered two primary solutions, with some variations. The first was to arrange the information in one document with the basics up front and the additional information, such as clinical studies and full lists of adverse events, as appendices. One group suggested a refinement to the first option. Patient labeling prepared according to this option would be skillfully segmented with clear headers and some tool, such as a Table of Contents or flow chart, to guide the reader to the desired information. The second suggested solution was to produce the primary patient labeling with the basic, plain language information and make the rest available to those who requested it through a manufacturer's customer assistance number, the physician, or an Internet site. Participants also discussed an approach that some manufacturers already use. That approach is to distribute with the device three different forms of the patient labeling, to be used at different times or by users of different skill or knowledge levels. One form would include complete device information. At the other end of the spectrum would be a very brief "cheater card" of important reminder information for the experienced user. The intermediate form would be an expansion of the important information in the cheater card, especially key use instructions. The groups (and research literature) referred to this form as a mini manual.

The groups provided a descriptive list of the types of information they need for decision making about and use of medical devices. As noted, they expected the physician to be the primary source of this information. They described a model for written information/labeling, based on this list, that they would find most useful as an adjunct to discussions with their health care provider. However, they exhibited no strong preference for the source of this written information as long as they got it. Most assumed that

manufacturers developed written information about their devices. Several participants had contacted manufacturers for information when they did not get it from their health care provider. Although the patient labeling may not be their first source of device information, they expect to be able to get it if they want it and expect it to be useful once they get it.

The principle items on the information list included: risk/benefit information, including warnings, adverse events and alternatives for both the device and the associated procedure; what to expect before, during and after the surgical procedure and/or the use of the device; clear, concise directions for use, including troubleshooting and maintenance; some way to contact the manufacturer (customer assistance number); and, comparative information on costs, success rates, etc. There was extensive discussion throughout the testing about the inclusion of clinical study information. Most wanted it available, but not included in the basic information. The participants did not agree on the depth of what they termed "scary stuff", such as risks, warnings, and adverse events. They did agree, however, that it should be available to the person who wanted it, either through the physician or the manufacturer, if it was not detailed in the patient labeling. Some participants felt that a third party should develop this information. While the participants indicated that they would expect to get most of this information from their health care provider, they would like to have all of it repeated in the patient labeling.

During the discussions, the participants repeatedly cited a number of formatting approaches that they preferred in information of this type. They strongly prefer simple, plain language with large print and well-labeled graphics. They object to vague terms. A consistent order was not as important as a logical flow and highlighting techniques to guide the reader. Preferred highlighting included a Table of Contents, bullets and numbers, short segments with clear headings, and lots of white space.

Introduction

The Food and Drug Administration (FDA) has undertaken a number of efforts to improve the labeling of medical devices. While a certain amount of information exists concerning the needs and preferences of health care professionals with respect to the labeling of medical devices, there is little information available to guide the development of labeling for patients and lay users. Much of the available research on consumer needs and preferences from labeling is focused on products other than medical devices. The agency did some investigations as background for the development of the 1993 publication *Write It Right: Recommendations for Developing User Instruction Manuals for Medical Devices Used in Home Health Care.* That work, however, focused on user instructions and did not encompass the full range of information that may be part of labeling for patients and lay users of medical devices.

The Center for Drug Evaluation and Research (CDER) has done research to determine needs and preferences of consumers of pharmaceuticals[1]. Some of the information gained from that research may or may not be applicable to the patient labeling of medical devices. Also relevant is the research conducted by the Office of Cancer Communications of the National Cancer Institute (NCI) on public perception and interpretation of risk information[2]. In order to develop sound recommendations for the development of patient and lay user information for medical device labeling, it is important for the agency to verify that assumptions derived from CDER and NCI research and other sources are, in fact, applicable to the patient labeling of medical devices. It is also essential to explore patient labeling issues unique to medical devices. For that reason, the CDRH, FDA conducted a limited series of focus groups to address issues associated with patient labeling for medical devices.

Purpose of the Study

The purpose of this project was to determine the perceptions, opinions, beliefs and attitudes of patients and lay users of medical devices about the written information for those devices. Specifically, we were seeking information on:

- what device information they need, want and don't want in writing,
- what determines when the information presented is "enough",
- potential differences in preferences when the information presents risk/benefit information versus user instructions,
- preferred order, if any, for information presentation, and
- effects of text enhancers, such as graphics and highlighting techniques on usefulness of written information.

Our ultimate goal is to make patient labeling for medical devices as useful as possible to patients. This research explored patients' basic informational needs as well as the roles that the various sources of device information play.

For purposes of this research, we considered all information that is intended to advise patients or their caregivers about proper use, risks and benefits of medical devices. In its written form, this information is usually supplied as patient brochures, leaflets and instruction manuals. Device manufacturers develop written device information, as "patient labeling", as appropriate for the particular device. Written information may also be developed by other sources, such as health care professionals, professional groups and educational groups. While these contribute to the information that patients have available, they are not usually considered "labeling" in the regulatory sense. The focus of this research was on the informational needs of patients as opposed to a specific critique of existing patient labeling. Therefore, we included the full range of possible written information in our exploration of the issues, while attempting to focus participant discussion on what they want from patient labeling.

Patient information/labeling may also be in the form of video- or audiotapes or Internet-based documents. These forms were not the focus of this research.

For purposes of this study, we categorized patient labeling as either:

(a) risk/benefit information or
(b) use instructions.

"Risk/benefit information" might also be described as selection information or the information a person needs to decide to use a device or have it used on them. It might include, as appropriate to the device:

- sufficient descriptive information to tell what the device is and what it is used for,
- types of people and situations for whom the device would not be a good choice,
- risks and benefits associated with the use of the device,
- alternative therapeutic and diagnostic choices available,
- other information to enable the person to make an informed decision about the device.

It does not include directions or instructions on how to use the device.

Devices that would have patient labeling that would be categorized as risk/benefit information might be: implants that have no external patient interface once they are implanted, or prescription diagnostic or therapeutic devices which the patient is actively involved in choosing (e.g., laser eye surgery, lithotripsy, intraocular lenses).

"Use instructions" are the procedural steps to follow in setting up, using, cleaning, troubleshooting and storing a device. This information constitutes the "how to" for the device.

Devices that might have patient labeling that would be categorized as "use instructions" would be those the patient or lay care giver has to set up, operate, clean, etc. They might include such devices as suction equipment, intravenous infusion pumps, physical therapy equipment, and transdermal electrical nerve stimulation (TENS) devices.

There are many types of devices for which the patient labeling would have both risk/benefit and use instruction information.

Methodology

We planned to conduct a total of six focus groups of users with recent device experience. The first four were intended to address the five goal issues, discussed in the Purpose section, as thoroughly as possible. These four groups were held in October 1998. House Market Research, Inc. of Potomac, Maryland recruited the participants. The groups were moderated by Paula Silberberg and Jay Crowley from the Division of Device User Programs and Systems Analysis, Office of Health and Industry Programs, CDRH, FDA.

As noted, we considered patient labeling to fall into two categories: risk/benefit information and use instructions. There are a number of ways that the different kinds of information in patient labeling could be categorized. However, we are aware, from the literature and previous research, that patients have different needs for and reactions to these two types of information. In this research, we wanted to determine the answers to our goal issues for both types of information. For this reason, we divided the first four groups into two groups of users of devices needing primarily risk/benefit information and two groups of users of devices with complex instructions/directions for use. Although the moderators addressed both types of information in all of the groups, they spent more time on one or the other, depending on group composition.

- Group 1 had six (6) participants, half of whom had, or were spouses of individuals who had, pacemakers. The other half were diabetics who used blood glucose meters. One participant also had intra-ocular lenses. Another had a rod implanted in her leg to stabilize a fracture. The primary, though not exclusive, focus of this group was on risk/benefit information. The participants had strong opinions about their needs from device patient labeling.

- Group 2 had eight (8) participants. Two had had laser eye surgery; three had hearing aids; one had a knee replacement; and, two had dental implants. During the course of the discussion, it became clear that some members had used other devices as well. Again, the primary focus of this group was on risk/benefit information and members of the group had definite, sometimes contradictory, opinions about what they wanted from device patient labeling.

- Group 3 comprised nine (9) individuals with experience with a variety of devices requiring instructions for use, the primary focus of this group. The devices they used included apnea monitors, continuous positive airway pressure (CPAP) devices, ventilators, oxygen equipment, infusion pumps, and peritoneal dialysis equipment. There was a combination of patients and caregivers in the group.

- Group 4 had nine (9) participants who had experience with blood glucose monitors TENS devices, orthopedic braces, and over-the-counter (OTC) test in vitro diagnostic (IVD) kits. The primary focus of this group was also on instructions for use.

To address the five goal issues listed in the Purpose section, moderators' guides for this study (see Attachment A) presented participants with the following questions:

- What parts of the patient labeling did they read and why?
- What didn't they read and why?
- What do they expect and need from patient labeling?
- Where else do they get this information?
- What topics are most/least important to them?
- What gets their attention and motivates them to read something?
- In what order should information be presented?
- How should the information be laid out?
- Is consistency important?
- When and from whom should they get this information?

The questions were addressed through a series of approaches designed to elicit participant reactions while introducing as little bias as possible. First, participants were asked to discuss these issues based on their own experience with device labeling.

As a framework for the discussion of what topic areas should and should not be included in patient labeling, the Division of Device User Programs and Systems Analysis developed a list of 21 topics. The list is Attachment B. The list was drawn from current labeling practices, risk communication and health education literature, and patient labeling testing done by the CDER. It was presented to each of the groups after the initial discussion described above. Participants' reactions were elicited and comparisons were drawn with the points raised in the initial discussion.

At this point in each group, participants were asked to develop "ideal labeling" from the topics they had thus far determined to be important. Their important topic areas and the preferred order for this information is presented in the tables in Attachment C. They were then asked to react to model labeling for an intraocular lens (risk/benefit groups) or a home use cholesterol test kit (use instructions groups). In each phase of the discussion, the five goal issues, as framed in the above questions, were the basis for the discussion.

From the information gained in these groups, we developed a template for patient labeling from which we designed a series of four patient labeling models for specific but fictitious products. Fictitious products were used for the model labeling to avoid a focused critique of the patient labeling of one product and to give us the opportunity to incorporate the preferred characteristics expressed by the first four groups. We planned to present these models to follow up groups to get their reactions and to readdress some of the issues from the initial groups. Recruiting problems caused us to conduct this phase of the testing as two individual interviews and one mini group of four participants.

Statement of Limitations

In qualitative research, the focus group and individual interview methods attempt to gain insight and develop direction rather than obtain quantitatively precise or absolute measures. Because of the small number of participants, the restrictions of recruiting, and the limitations of the sample this research must be considered only in a qualitative frame of reference. This study cannot be considered reliable or valid statistically since the recruiting of participants cannot be exactly replicated, identical questions cannot be asked in each group or of each individual, nor can the results of one group or interview be compared precisely with other groups or interviews.

This type of study has inherent biases. Participants self-select to join the group. They tend to be risk takers who may be more assertive than non-participants. Those who participate in focus groups may be more articulate and willing to express opinions in a group than non-participants. Participants are not selected randomly. In addition, people asked a question in a group setting may respond differently than if individually asked that same question.

An additional potential limitation deserves consideration in interpreting the findings of this research. Respondents repeatedly stated that they do not consistently get or use the patient labeling for the devices they use. They do not consider nor do they prefer that patient labeling be a primary source of the device information they need. Therefore, their preferences and projections of effective content and format may be influenced by present habit of information gathering and knowledge of patient labeling.

The findings presented here provide perceptions, opinions, beliefs and attitudes about the way patients use patient labeling of medical devices and their preferences concerning the information and its presentation in that labeling. They can be used by the CDRH in determining future activities in device labeling research and recommendations.

Main Findings – Phase 1

General Impressions

The participants with implants wanted risk/benefit information associated with the surgery and the device as well as the life expectancy of the device. They would like to have gotten this information before surgery to better prepare them. Long term device users, such as the diabetic participants, were no longer interested in risk/benefit or general disease related information. They, as well as other participants using devices needing use instructions, wanted easy to follow instructions and troubleshooting information. While they had read the patient labeling that came with their devices, their focus was on skimming for the information they needed, such as battery information and operating instructions. They were most receptive to material that was formatted as an easy reference. They read the patient labeling to compare products. In general, they found the patient labeling of their devices met their needs. The participants with TENS devices were not so positive about the information provided with their devices. One individual requested and got physician labeling for the device from the manufacturer. These participants felt that hands-on training, rather than the labeling, was the key to safe and effective use of these devices. The groups felt the best time to get the information is when the physician tells you that you need the device.

There was disagreement among the participants as to the length and depth of information that was ideal. A few wanted everything there was to know, complete with statistical information from the clinical trails. Most participants wanted condensed, plain English, predigested information that focused on the most important issues. The group seemed to agree that all of the known information about a device should be available to the patient, who could decide for himself how much and what he wanted to read. However, "available" could mean a number of different things, not just everything in one piece of labeling. The most important feature of the patient labeling should be a logical flow.

Most participants had identified alternative sources for the information they thought they needed and had not gotten. Some group members had contacted the device manufacturer for labeling when they did not get it from durable medical equipment suppliers or health care professionals.

Each of the groups had participants that were troubled by discrepancies between the labeling and the verbal instructions they had received. These users tended to trust the written instructions over the verbal ones, if the written instructions were for that particular device rather than generic to the type of device. Still other users had gotten no written information on the devices they were using and wished they had some, particularly for troubleshooting, for assurance that they were using the devices properly, and for reference material. One of the participants had a frightening experience when his device had functioned in an unexpected manner and he had no troubleshooting information to help him deal with it. A number of the participants who had gotten written instructions admitted that they had not read them or had given them only cursory perusal, because they felt the verbal instructions adequate for their needs. One group

raised the issue of international travel with devices and the attendant problems, such as battery and parts replacement while abroad. The pregnancy test kit users complained about labeling that mixed several languages throughout the brochure. Group members felt that small print interfered with ease of labeling use. Other participants did not like labeling that combined information for several models in one manual. Participants cited simplicity as critical to useful patient labeling.

Sources of Information

Participants had gotten information from various sources, but verbal information was the primary source. There was discussion about the lack of written information that they had experienced. Some had to insist in order to get written information from physicians. Others sought it from other sources. The groups, in general, thought such information was necessary and were glad when they got it. Participants cited the Internet, manufacturers, health magazines, health care professionals, and other users as other sources for information on devices. They considered the physicians and other health care providers to be their most important source. Participants experienced with devices for which use instructions were necessary considered manufacturer advertising and labeling, personally testing a device before selecting it, and displays at diabetes meetings important sources to them. Two participants get monthly calls from the device supplier, which they like. The remark was made that most users need more than a written instruction manual to properly use a device.

They discussed how they dealt with patient labeling that provided information different from what the physician told them. Most trusted the physician, but questioned him or her when this situation arose. Those who had patient labeling on a specific device tended to trust the technical information in the written labeling if it conflicted with what they heard from the health care provider. It increases their comfort when the written information reflects what they have heard from the health care provider.

Topics of Importance

The moderators used a number of approaches to determine which topics were most important to the participants and which of these should be addressed in the device patient labeling. They first asked the groups to list topics important to their own device experiences. The four lists were similar to each other and to the list of topics developed by CDRH.

In determining the most important *risk/benefit information*, study participants addressed a number of topics, including: interaction between the device and an ongoing disease process, comparisons with alternative therapies, thorough information on what to expect, procedure success rates, cost information, and references for further information. The groups acknowledged the possibility that inclusion of negative risk information could be a disincentive for the patient faced with a difficult decision.

When asked what they considered to be the most important information to be included in written *use instructions*, the groups identified warnings and precautions, troubleshooting information, "how to's" including care and maintenance, use and installation, replacement parts and customer assistance number.

Participants indicated a strong preference for information on how to contact the manufacturer for more information and assistance. They expect to see a customer assistance number (e.g., 1-800#) on the back of the patient labeling booklet, and perhaps in the front and on the bottom of each page as well.

When the moderators asked what topics were NOT important and should not be included in patient labeling, the participants could not identify any. However, in later discussions of the scope of information, each group did express a preference for brevity in the basic information and for the inclusion of clinical studies, full lists of adverse events, and some other topics as appendices or separate documents available on demand.

As noted earlier, each group was asked to review and react to a model of device patient labeling. The groups with a risk benefit focus were provided with a model of patient labeling for an intra-ocular lens. The groups with a use instruction focus were given a model of patient labeling for an OTC cholesterol test kit. These models sparked discussion of the appropriateness of including such topics as who could benefit from the device, new technologies under research, controversy concerning the device, or the risks and benefits of other options. There was some agreement, however, that the burden for the presentation of this kind of information was on the health care provider rather than on patient labeling developed by the manufacturer. The participants, on reflection, agreed that manufacturers were not the appropriate source of some of these kinds of information. They grouped this kind of information with detailed scientific/clinical trial information, printing date, warranty information, and Internet address as interesting but not necessary to have or read. Such information appealed to some and not others. For that reason, they want what they consider to be the "important stuff" up front where it can be read quickly. They agreed that what would be considered "important" could vary with the criticality of the device. For example, in a less critical device, some of the warnings might come later in the document. One point of discussions focused on the provision of complete information in warnings. Some participants felt that failing to provide consequences of the hazard might reduce the likelihood that users would follow the directions carefully. Participants agreed that scientific information may be useful but could be available through the customer assistance number rather than in the basic patient labeling. However, to be useful, information from the clinical trials should be available to them <u>before</u> they selected the device.

Some items that had not been included on the FDA list of topics were discussed as potentially useful. These included the life of the device and its accessories and storage information when the device would not be used for an extended period.

There was an apparent distinction between the primary interests of participants, depending upon the type of device they were talking about. Those with implants focused

their attention on risk/benefit information, what to expect and follow up care. Those with glucose monitors, TENS devices, OTC test kits, and other devices requiring instructions for use stressed the need for clear instructions with well labeled graphics, good troubleshooting sections, and useful warnings.

Each of the four groups developed an ideal patient labeling document by listing, in the preferred order of presentation, the topics that they would like to see in the labeling. The groups developed the "ideal" patient labeling by selecting and arranging topics from the CDRH list of 21 topics and adding topics from their own lists. These "ideal" lists are attached at Attachment C. The "ideal" lists were again similar to each other. They served as a basis for the development of a model-patient labeling template, which was presented in the Phase 2 testing discussed below.

Format Preferences

When asked what approaches to presentation and formatting would make patient labeling most effective, participants felt we should not generalize one format to all devices. However, they noted certain elements that they felt were helpful, such as clear graphics, large print, descriptive headers, highlighting techniques such as different size print for headings, and a Table of Contents. Well-located graphics were cited as good guides to finding information. Although they wanted the patient labeling to be simple and straightforward, they objected to material they characterized as being "written for kids". They expressed a need for information in "plain English" that told them what to expect, what they could and couldn't do, and how long the device would last. They want specific rather than vague terminology (e.g., "100 beats per minute" rather than "higher heart rate"). They were not interested in promotional information in patient labeling.

Some participants asked that information be condensed, presenting just the "important" information. They suggested a brief overview or executive summary up front to give the reader the highlights of the important information. While they were not wedded to any specific order for the information, they want to see it in some logical order. The most useful information has just the facts, nothing extra. There is no one ideal length. They agreed that a good Table of Contents near the beginning and an index and glossary near the end were important. They cited the consumer information now given with prescription drugs as a good model.

They identified some formatting approaches that would make patient labeling most appealing and readable. They prefer: bullets rather than lengthy text; plenty of white space; well-labeled graphics; clear warnings and precautions; instructions broken out into small segments and accompanied by diagrams; color, as an attention-getting tool; careful use of highlighting techniques, such as bolding; consistent use of terms; and large print. Manuals should not be written in technical language, but for the general public. Warnings should be kept to a minimum, with the obvious ones excluded. For complex devices, they suggested a brief checklist of important information to know before selecting or using the device be placed up front. They admitted that labeling is often read only "when all else fails" or as a reference, e.g., for battery replacement. They would

like to see the labeling as attractive as the sales brochures. Some liked the Question and Answer format; others did not. Some found dealing with multiple language patient labeling difficult. There was a request to provide separate booklets, or completely separate sections for different languages.

They suggested using warranty registration as a method to track users for updated patient labeling distribution. Some members of the group felt that the distribution of the patient labeling with the device should be mandatory. Although the groups discussed alternative media for device information, such as videotapes, they continue to want written information and instructions.

Meeting Varied User Needs

Because it was apparent that different users could have very different informational, and, therefore, patient labeling needs, the moderators asked participants to reconcile these differences. The groups came up with two primary options. The first was for the manufacturer to provide the basic information with directions for getting more comprehensive information from a customer assistance number or the Internet or a similar, easy to use, source. The second suggestion was to provide the basics up front with the more extensive information as an appendix. A variation of the second option was to skillfully "segment" the information with clear headers and some tool, such as a Table of Contents or a flow chart to guide, the reader to the desired information. The groups explored different vehicles for presentation of information from a quick and dirty "cheat card", that was characterized as a business card sized list of the most important information, particularly troubleshooting assistance, to general brochures on the full range of information. While they generally preferred a brief presentation of the "important" information, they felt that full information about a device should be easily accessible to those who wanted it. They also explored the role of alternative delivery mechanisms, such as videos, CDs, and Internet formats.

Background for Phase 2 Testing

Purpose

The first four groups had given us information on what patients want in written patient information/labeling, including a proposed content and order for the presentation of that information. Our purpose in conducting follow up groups was to clarify some issues raised in the initial groups, to address some of the specifics of patients' informational needs, and to get respondents' reaction to patient labeling developed according to the model suggested by the first four groups. We hoped to take what we learned in the first groups a step further in order to more clearly define the purpose, content and format of effective patient labeling. We intended to refine the model and our recommendations to patient labeling developers in response to feedback from this phase of testing. In addition, we intended to identify issues in need of further research.

Group Composition

After conducting the four groups in Phase 1, we determined that four mini-groups of 3 to 4 participants each would better serve our needs than the two full groups originally planned. We recruited for participants who had recent device experience or were in the process of deciding to use or not use a particular device. We believed that individuals with recent or current experience could more accurately pinpoint their device information needs. We had selected cardiovascular implants, orthopedic implants, infusion devices and OTC IVD kits as the subject devices for the four groups. We believed that these types of devices would present a reasonable representation of the available devices. We felt that feedback on patient labeling needs for these devices would provide us with a basis for generalizing both risk/benefit and instructions for use informational needs across most device types. We had chosen the mini group format to be able to focus on specifics with a smaller, more intimate group without losing the group dynamic that can be sacrificed in an individual interview.

During the initial recruiting period, it became apparent that we would not have the response necessary to constitute the four groups. We had no cardiovascular implant respondents. There was one respondent each for the orthopedic implant group and the infusion device group. We elected to conduct individual interviews with these respondents rather than lose the opportunity to gain the information from them. We had four respondents for the OTC IVD group and conducted that group as planned. Jay Crowley and Paula Silberberg conducted the interviews and mini-group on January 5, 1999.

Model Patient Labeling Development

The first four groups provided us with information, which, combined with information from the research discussed in the Introduction, enabled us to develop a model for patient labeling content and format. The following is the outline for that model:

- Descriptive information
  - Name, other specific identifiers
  - Purpose, description
  - Risk/benefit information
  - Expectations of device and procedure associated with device
  - General warnings
- Operating information – as applicable
  - Set up +
  - Instructions for operation
  - Maintenance
  - Etc.
- Troubleshooting
- Additional information for interested readers (could be provided separately)
  - Scientific info/clinical studies
  - Self care, disease information…
- Customer assistance number (1-800#)

We developed mock patient labeling for four fictitious products, based on the model, one to present to each of the originally planned mini-groups[Note]. The model patient labeling generally followed the outline, as applicable to the device. The implantable devices chosen for these models (cardiovascular and orthopedic) do not have instructions for use. Therefore, the model patient labeling for these devices does not contain that section. The Additional Information section could contain a number of other items, such as warranty information or information on traveling with the device. In the interest of model simplicity, we did not include this information.

[Note:] The four models were developed before recruiting problems limited the testing to three devices.

Main Findings – Phase 2

Sources of information

Both interviewees had gotten most their information from their physicians. However, both had sought information from a number of other sources, including support groups, other health professionals, libraries, the Internet and friends. The written information that they got was dependent on the personal research that each had done. Neither had been given any written information by the physician. They used their reading and discussions with other device users to generate questions for their physicians.

Although one OTC user had been directed to the product by her physician, most of the participants in the mini-group had relied on their own choice and on the labeling of the device.

Topics of Importance

The risk/benefit information that the interviewees described needing was similar to that discussed in the focus groups. It was a combination of some basic device information with a preponderance of information about procedures associated with devices and what to expect in each stage. Although they felt they needed risk information to make an informed decision, they wondered if most people would want a full presentation of all the "scary stuff". On reflection, both felt it should be easily available to those who wanted it. Although they were interested in alternative treatments, they left the choice of device largely to the physician. They differed in whether they would want the clinical study results included in the patient labeling, but agreed that it would be too technical for most readers and should be at the end of the patient labeling or as a document available on demand.

Both an interviewee thinking about an insulin pump and the OTC kit users wanted to know the physical characteristics of the device, how it operates, how one would troubleshoot problems, if the device had to be calibrated, and signs or symptoms of problems. The OTC kit users did not have strong risk/benefit informational needs. They did, however, have suggestions for labeling that they would find most useful. They wanted to know what the test could do (scope), how accurate it was, and what the results meant. They liked, and some had used, the manufacturer's customer assistance number to get more information. They wanted as much information as possible about the problem or disease process for which they were using the test, but did not want complex clinical study or statistical information.

As with previous groups, all preferred simple, clear information.

Format Preferences

All participants in this phase were asked to react to model patient labeling for one fictitious product as described earlier. They reacted positively to short, simple

discussions of risks/benefits and what to expect. They objected to lengthy and technical discussions. They thought the sections in the model were, for the most part, useful, as long as they were brief and targeted to the likely candidate for the device.

The formatting tools they felt most useful were simple language, some color and good graphics. They objected to vague terms.

They responded positively to the possibility of a consistent patient labeling format across devices, saying that it would assist individual users to find critical information quickly. They did not, however, make this suggestion spontaneously. They agreed that the model could be cut off after the basic information, feeling that the Additional Information section (e.g., clinical studies, disease-oriented information) was interesting but not necessary.

Participants had a number of formatting recommendations. They like to see a Table of Contents and a list of device or kit contents. All members preferred large print, objecting to the small print that they had seen in package inserts. In addition, they want important information highlighted, suggesting a number of techniques that appealed to them. These included: bolding of section headings, plenty of white space around sections, section topic sentences that provided the most important information of the section, and highlighting the manufacturer's customer assistance number.

Meeting Varied User Needs

When asked how written patient labeling could effectively present information to meet the needs of patients who wanted little or lots of information, these participants had similar suggestions to the groups in the initial phase. A primary suggestion was for two separate documents. The first would be a simply written, basic discussion of the primary risks and benefits and patient education on what to expect. This should be given to everyone who is considering the procedure or product. The information would not be exhaustive, but would touch on all of the important topics. The presentation of these topics would serve as triggers for questions to ask the physician. Participants in this phase expressed a limited capacity for what they termed "scary information", wanting just enough to trigger them to ask their physician about it. The second document would detail the technical information, including complete device description, clinical studies, full list of adverse events and so on. This could be supplied to those who requested it from the physician or the manufacturer.

Another recommendation was for one document with all of the information, with clear headings to guide the reader to what he wanted to read. It would be up to him to read as much as he wanted of it and ask questions of his physician.

Conclusions and Recommendations

Conclusions

Information provided by study participants has led us to a number of conclusions that, within the confines of the study limitations, can serve as a basis for some assumptions about patients' labeling needs and for recommendations for preparing medical device patient labeling as well as for future research. Patients have extensive and varied needs for information about the medical devices they will be using or will have used on them. The device specific information they want is integrally intertwined with information about the condition that necessitates the use of the device and any procedure (e.g., surgery) that will accompany the use of the device. The content, scope, depth and presentation of information that they need will vary depending on where they are in the decision making process and their own learning preferences. Their preferred source for all of this information is the physician or other health care provider. When they find inadequacies in this source, for whatever reason, they are not, in general, averse to seeking what they need from a variety of other sources. They consider patient labeling a useful source, though not the primary one, for this information. Labeling can serve as a reinforcement or reminder of the information from the health care provider, as well as a trigger for questions and seeking more information. They consider reading the labeling to be part of and a reference source for a total information gathering process. As such, it has different value and use to different patients.

Participants in this study did not feel that there was a single best approach to presentation of information in patient labeling. In this study, users of similar devices with similar levels of experience tended to express the same informational and labeling needs. The novice user tends to focus on the risk/benefit information first, while the experienced user is more interested in procedural instructions and troubleshooting information. While it would be impossible for patient labeling to meet the needs of all users equally, there are some commonalties in the needs expressed by these study participants that can serve as a basis for developing patient labeling.

Because they use labeling as an adjunct to other sources of information, patients want it to be an easy-to-use reference. Although a consistent format might prove useful, most important to them was a **logical flow** in plain language with highlighting that would guide them to the desired information for their needs at the moment. They suggested a number of approaches to meeting varied informational needs. One document could suffice if it was well segmented and highlighted, with a Table of Contents and the most-desired, basic information up front. Clinical study results, complete adverse event listing, additional self care information and other information desired by a smaller segment of the affected target population could be appendices to the primary document. Another approach would be to create separate documents with the additional information, available on demand. There were other approaches that were appealing to study participants, all based on the idea that the simpler the better.

It is of interest to note that participants in this study wanted sufficient information to assist them in deciding upon the use of a device as one of the alternatives in their treatment (e.g., the implantation of an insulin pump as an alternative to an external insulin pump or continued insulin injections). However, they depended upon the physician to make the final choice of specific device (e.g., which manufacturer's pump or which model of several made by a manufacturer). For this reason, few of them were interested in complex technical information about the specific device, other than the use instructions. This points to the need for effective *general* risk/benefit information and the necessity to reconcile this need with the role of patient labeling developed by the manufacturer for a specific device.

There remain two unanswered questions regarding the labeling model developed and refined during this study. First, while group participants reacted positively to the idea of consistent patient labeling content and format and could devise an approach they felt would be useful to them, is it really necessary or desirable? Secondly, is this model the most effective approach? Although we could not completely answer these questions with the mini groups, we plan to address the issues in future research.

Recommendations

We have a number of recommendations based on the findings from this research. We suggest that these recommendations be captured in guidance to manufacturers, patient labeling developers and reviewers about ways to make medical device patient labeling most useful.

1. Current research does not indicate that there is a single best way to present all written medical device information to patients. The key is to know the target audience for the particular device, to determine their needs and to test the patient labeling on a sample of that audience.

2. The following model reflects the preferences of the study participants and is suggested as a basis for development of patient labeling. It addresses the important issue of logical flow, clear descriptive headings, and discrete sections that can be concise and still provide the important information. It groups, or chunks related information, making it easier for the reader to follow and remember.

    - Table of Contents
    - Descriptive Information
        - Name, other specific identifiers
        - Purpose
        - Description
        - Risk/benefit information
        - Expectations of device and procedure(s) associated with the device
        - General (major) warnings
    - Operating Information (Use Instructions) – as applicable
        - Set up (including calibration and other preparation)

    - Instructions for operation
    - Maintenance/storage
    - Other applicable topics associated with operating the device
  - Troubleshooting (could be part of Operating Information or a separate section)
  - Additional Information for interested readers (could be provided separately)
    - Scientific information/clinical studies
    - Self care, disease information
    - Full listing of adverse events
    - Comparative information, e.g., success rates
    - Warranty information
    - Travel/international use information
  - Index/glossary (as appropriate to the length and complexity)
  - Customer assistance number (800#)

  The model could provide a framework for patient labeling for almost any device. The sections used in a particular patient labeling document and the precise order chosen for presentation of the information should be based on the needs of the users of the particular device. Testing proposed patient labeling on members of the targeted audience best assesses the most effective approach. Patient labeling designers might also consider whether their target audience could benefit from the alternative approaches suggested by the study participants.

3. We recommend that patient labeling developers give consideration to the formatting tools that study participants indicated make written device and health care information most useful to them. These included: simple language that avoids vague terms, a Table of Contents or other "roadmap" to the document, informative headings, plenty of white space, large print, well-labeled graphics, and judicious use of highlighting for important information. The highlighting techniques cited by the study participants included bolding, bullets, numbering, and a summary of important information.

4. We heard in this study, as we have heard in other venues, that health care practitioners are not always the effective sources of device information that patients depend on them to be. Effective patient labeling can serve part of the informational needs of patients making decisions about and using medical devices, but cannot replace the health care practitioner as the preferred primary source of information. We recommend that both the manufacturing community and the agency take steps to engage health professional organizations in developing an effective model of complete medical device information. This model would encourage practitioners to be effective gatekeepers of all the information, including device labeling, that a patient needs to participate in the safe and effective use of a device. Device labeling developed for the health care practitioner may serve an important role in this model by providing effective patient counseling information.

5. This study points to the need for further research to answer a number of questions.

- Since patients look to their health care providers as a primary source of information for devices, do they have different labeling needs for OTC devices where there is no learned intermediary?
- Are the informational needs of novice patient users significantly different from those of experienced patient users, necessitating tailoring the information?
- Will medical device patient labeling, developed according to the preference model from this study, effectively serve patients' medical device informational needs?
- Might format consistency, which does not seem to be a critical issue for infrequent device users, improve the effectiveness of labeling for devices whose users are exposed to a number of devices and/or use one or more types of devices frequently?
- How should the various sources of device information be coordinated to assure that the patient gets the information necessary to make informed choices about the safe and effective use of medical devices?

We recommend that the agency, manufacturers, academia and health care providers work together to conduct the research to answer these questions.

References

[1] Aiken A. Consumer Comprehension and Preference for Variations in the Proposed Over-the-Counter Drug Labeling Format. Center for Drug Evaluation and Research, FDA 1998.

[2]Office of Cancer Communications. June 1998. How the Public Perceives, Processes, and Interprets Risk Information: Findings from Focus Group research with the General Public. National Cancer Institute, Bethesda, Maryland.

Attachment A

Moderators Guides

Discussion Questions

Start off with show and tell of various samples of medical device labeling:

(1) What written medical device information have you used?

Where did you get this information – and from whom?

Did you receive it when you needed it (timely, not timely)?

(2) What topics did you read about in the information?

When did you read it?

Why did you read it?

Was there anything that specifically got your attention and motivated you to read this information (formatting/wording/graphics)?

What didn't you read?

(3) What did you expect/need from the written information?

Did you get what you expected/needed?

What didn't you get?

Did you get this information somewhere else?

(4) If not from the labeling, where did you get information you used?

What was your most important source of information?

Least important source?

Who did you most believe (how credible was the source)? Least believe?

(5) What was the most important information to you?
FLIPCHART

Why? (What about _____ made it important to you?)

Least important? Why?

Handout device labeling (R/B then IFU)
– look over example of written information, and we'll discuss it.

(1) Is there any information that you expected to see or would need to know, but wasn't there?

(2) What information was the most important to you? *FLIPCHART*

Why? (What about _____ made it important to you?)

Least important? Why?

Topic Chart

Show chart -- compare what they wrote and all of the possibilities.

Order and Layout

(1) What order would you like the information presented so it makes the most sense to you?

How does the order affect your use of the information?

Probe for whether order actually matters to them or is important?

How do you feel about the information being presented consistently in the same order for every device?

(2) What type of layout makes the most sense to you? -- Need to explain layout!

Layout is the format, type, size, graphics, icons,

How does the layout affect your use of the information?

Probe for whether the layout matters to them or is important?

Are there certain layout attributes (e.g., format, graphics) that help you focus on and understand the information?

Wrap-up question – may not be necessary:

In your opinion, what should ideal written information about medical devices be like?

When is the best time to get this information? From what source?

What is the ideal length of the information for you (enough/too much)?

Is there a difference for you between the ideal written information for over-the-counter medical devices vs. the ideal for prescription medical devices?

Closure:

1. Is there anything else you want to say about written information about medical devices?

2. Thank you for your time and opinions.

Patient Labeling Mini Groups
Moderator's Guide

Introduction

Hi. My name is Jay. I'm your moderator today. We'll be here for about 45 minutes and the purpose of today's group is to talk about:

your experience with information and instructions about OTC test kits.

Self Disclosure

I'm a focus group moderator and I also work for the Food and Drug Administration (FDA). My role here is to understand you and your opinions. Feel free to make any negative or positive comments about any of the things we will be discussing today. What you say today does not affect my job.

Ground Rules

Before we get going, let me explain some things about this session:

1. We are audio-taping this research so that we can write an accurate report of what you said. Your anonymity will be protected. We'll use only your first names in conducting this group and any reports resulting from it will not use your names.

2. Some of our project team is present behind the one-way mirror.

3. Today you are being paid for three things: your **time**, your **opinions**, and your **courage** in voicing your point of view. There are no wrong answers, just different opinions. I'm looking for different points of view.

4. If need to leave the room, please, one person out at a time. (Bathroom location)

Self Intros

Let's introduce ourselves to each other → your first name, where you were born and where you grew up.

Moderator's Purpose for the Session

We're here today to talk about your opinions about written information that you saw when you were selecting or using the OTC test kit. I don't want to focus on anyone's particular medical condition or medical device, but about your experiences with written material about a medical device.

Discussion Questions:

1. Remembering your most recent experience selecting and using an OTC test kit -- what did you **need** to know about your device?

   Chart the topics.

   Probes: Needs when you had to make a decision.
   Needs after you got the device.
   Needs when you had to use the device.

   Probe: What was your **source** of information?

   Probe: What did you want to know, but didn't/couldn't find out?

   Probes: If written source:
   What other topics of information did you read about in [that source]?
   What did you read in-depth about your device? When? How much detail do you prefer for each of these categories of information?

2. Looking at what you said you needed to know about your medical device, let's list those topics you would want to receive as written information **(rechart)**.

3. **SHOW MODEL. [This is fictitious medical device patient information. It is not technically accurate for any specific device.]** How does this compare with what you said you needed in written patient information? (refer to recharted information)

   Probe: Are there types of information here that you haven't listed?

   Which of these types of information would you want to add to your list?

   Which wouldn't you add? Tell me more about that.

4. Use model to discuss topics not mentioned – get reaction to specific parts of model.
   - Do you want to know about controversy about a device? Adverse events?
     If so, what's the best way for you to get this information? (in PL, other?)
- Alternatives – therapies + devices of the same type???

5. Let's look at each category of information. (Refer to written flipchart.) Tell us your reasons or circumstances when each category of information would be important or not important to you?
   - How would you sequence these categories of information? (Explore subheadings within each chunk, and reasons for placement.)
   - Is the consistent arrangement of this information important to you? (Would you want it arranged in the same sequence for all the devices you use?
   - Would you want to receive any of this information in another way? (e.g., doctor, Internet)

6. Different types of patients have different information needs because they are at different phases of device use (e.g., new vs. experienced user.) Should/can one patient information piece do it all? What would you use, where and when?

7. What makes you want to read something in written patient information? What makes it easiest to read? (Probe: formatting, language, graphics)

Closure:

Check with observers for additional questions…

1. Is there anything else you want to say about written information about medical devices?

2. Thank you for your time and opinions.

Attachment B

CDRH Proposed Headings for Patient Labeling Testing

- User assistance information (toll-free number)
- Description of the device, its parts and accessories
- Purpose of the device (indications for use)
- Importance of the need to adhere to a care regimen
- Conditions under which the device should and should not be used (contraindications)
- Risks and benefits
- Alternatives to the device and treatment
- Any controversy about the device and its use
- Setup instructions
- Check-out procedures
- Operating instructions
- Cleaning instructions
- Maintenance description, who should do it, and its cost
- Explain need to monitor the activity of the device
- Expected failure time and mode and its effect on the patient
- Storage instructions
- Troubleshooting section
- Date of printing
- Instructions on accessories
- Warnings and precautions
- Scientific information (how device works, clinical study data, process or basis of FDA approval)

Attachment C

"Ideal" Labeling Models Designed by Phase 1 Focus Groups

Group 1	Group 2	Group 3	Group 4
Alternatives	Purpose	Customer assistance information	Purpose
Description (with costs)	Description	Purpose	Customer assistance information
Purpose	Contraindications	Risks/benefits	Risks/benefits
Surgery/time frames (with risks)	Risks/benefits/side effects[1]	Warnings/precautions	Warnings/precautions
Contraindications	Warnings/precautions[1]	Contraindications	Contraindications
Scientific information[2]	Alternatives	Care regimen adherence	Care regimen adherence
Controversy	Controversy	Description (including parts and model number)	Description
Warnings and precautions	Operating instructions	Setup	Setup
Risks and benefits	Setup	Checkout	Checkout
Set up	Instructions on accessories	Instructions on accessories	Instructions on accessories
Operating instructions/ Accessories	Monitoring	Operating instructions	Operating instructions
Check out	Cleaning	Maintenance	Maintenance
Device monitoring information	Care regimen adherence	Device monitoring information	Device monitoring information

[1] Alternative breakout: "Purpose/benefits" and "Risks/warnings/side effects"
[2] Some wanted, most did not

Group 1 (cont.)	Group 2 (cont.)	Group 3 (cont.)	Group 4 (cont.)
Failure time and effect	Storage	Troubleshooting	Troubleshooting
Maintenance	Checkout	Cleaning	Cleaning
Cleaning	Failure time and mode	Storage	Storage
Storage	Maintenance	Failure time and mode	Failure time and mode
Troubleshooting	Troubleshooting	Controversy	Controversy
Date of Printing	Scientific information	Scientific information	Scientific information/ FDA approval information
Care regimen adherence[3]	Date of Printing	Alternatives	Alternatives
Customer assistance information	Customer assistance information	Date of Printing	Date of Printing
	Author of information	Warranty	Warranty
		Travel information	Travel information
		Internet site	Frequently asked questions/ most used features
		Index	Internet site
			Index

[3] Not all were interested in this