Draft Initial Report on Medical Device Labeling:

Health Care Practitioners' Medical Device Information and Labeling Needs

Results of Qualitative Research

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Executive Summary

Purpose

The Center for Devices and Radiological Health has identified the need to determine what, if any, changes to device labeling would make that labeling most useful to health care practitioners. This research was conducted to assess the decision making process used by health care practitioners for the selection of medical devices, the role of device labeling in that process, and potential approaches to improving medical device labeling to more effectively assist practitioners in selecting and using devices.

Findings

1. Physicians and nurses, in the facilities represented, had little direct selection power for medical devices. Their recommendations are considered, but often they simply use what is selected by the facility.

2. Practitioners rely on personal knowledge and knowledge gained from colleagues in making recommendations for device selection and in device use. Labeling is not an important source of this information.

3. Current device labeling is not seen by these practitioners as a useful tool either for selection decision making or for device use for a number of reasons. Participants cited poor distribution, cost of device manuals, the way labeling is written, the availability of more appealing sources for the information, and skepticism about the validity of some labeling. The lack of cost and comparative information was particularly important to them.

4. Suggestions for making device labeling more useful in decision making included the inclusion of cost and comparative information,

development of a compendium of comparative information, and electronic access to improved summary prescribing information.

5. Practitioners want shortened, simplified**user** instructions.

Actions Suggested by Findings

1. Consider an alternative to the original plan for implementing summary prescribing information for medical devices. With the strong request for concise operating instructions, the weak reaction to including summary prescribing information in device labeling and the complexities of properly addressing the presentation of the cost and comparison information that the physicians are asking for, we recommend addressing the operating instruction issue immediately with a continued study of the effective presentation of prescribing information.

2. Investigate validity of the results of this research for implantables and home care devices.

3. Consider engaging manufacturers and perhaps others to continue exploring the value of summary prescribing information.

4. Present detailed findings of this study to industry and the health care community to encourage further study of the issues raised, particularly those that are outside the main mission of the Food and Drug Administration, i.e., cost and comparative information.

Introduction

Purpose of Research

The purpose of this qualitative research was to solicit the perceptions, opinions, beliefs and attitudes of a sample of health care practitioners on the decision making process for the selection of medical devices, the role of device labeling in that process, and approaches to improving medical device labeling to more effectively assist health care practitioners in the selection and use of medical devices.

The Food and Drug Administration, with regulatory responsibility for product labeling, has been concerned that drug, device and biologic labeling may not meet the needs of the health care professionals who must select and use these products for patient diagnosis and care. The Center for Drugs Evaluation and Research (CDER) has conducted focus groups and a survey of physicians to examine this issue. In response to what they learned from the physicians, CDER has developed a prototype for an abbreviated summary of the information currently contained in the full drug labeling. The intention is that this piece of labeling, developed by the manufacturer, would accompany the full labeling, succinctly highlighting the critical information that the practitioner would need to make a prescription decision and assisting the reader to find more comprehensive information in the full labeling. This prototype and its implementation are still under study.

Consideration has been given to extending the standardization of labeling to include medical devices and biologics, providing practitioners with familiar format and content for the essential prescribing information for the range of the products they use to diagnose and treat patients.
In the Center for Devices and Radiological Health (CDRH), a prototype Essential Prescribing Information (EPI) label for medical devices was developed, based on the CDER prototype. During the process of getting

preliminary review and comment on the prototype, discussions with CDRH staff and external health care providers revealed three critical pieces of information. First, physicians are not the sole or necessarily the principal prescribers/selectors of medical devices, particularly in the hospital setting. Secondly, the concept of prescribing medical devices is very different from that of prescribing drugs. Finally, practitioners use medical device labeling in a very different manner from the way they use drug labeling and, therefore, device labeling may not play the same role in prescription decision making as does drug labeling. This possibility raises the concern that a summary prescribing information label for devices may not serve the needs of the health care practitioner.

It had originally been planned that the CDRH prototype would be focus tested with physicians, following the process used by CDER. Given the concern about the utility of the document, the goal for this qualitative research was expanded to include examination of the decision making process used by health care professionals to select medical devices and the role that the device labeling plays in this process as well as testing the format and content of the prototype. While nurses and physicians have different professional responsibilities associated with the care of patients, they have a great deal of overlap in the decision making associated with and the use of medical devices. As noted earlier, the prescription/selection/purchase process is not as clear cut with medical devices as it is with drugs. Physicians are not as exclusively involved in this process as they are with drugs. In addition, it is well known that nurses are the largest medical device user group. Their input was felt to be important to an examination of the decision making process associated with the selection and use of medical devices, so the study plan was expanded to include nurses.

Methodology

Because of the complexity of the issue and the difficult logistics

associated with recruiting health care professionals, particularly physicians, two different methods of qualitative research were used to examine the medical device decision making process and the use of labeling by health care practitioners in this process: focus groups and individual interviews. Two focus groups were conducted with nurses and individual interviews were conducted with physicians at a professional meeting. The information gained in the interviews reinforced the information from the focus groups.

Focus Groups

Two focus groups, each approximately 90 minutes in length, were conducted on May 18 and 30, 1995. Group #1 (May 18, 6:30 p.m.) consisted of eleven operating room nurses from seven Baltimore/Washington area hospitals. Ten females and one male participated in this group, representing a range of practice experience from 5 to more than 20 years. Group #2 (May 30, 6:00 p.m.) consisted of nine critical care nurses from three Baltimore/Washington area hospitals This group was all female with a practice experience concentrated in the 5 to 10 year range. A primary criteria for recruitment was experience in selection and purchase of medical devices, to ensure that participants had knowledge and understanding of the decision making process that goes into device selection.

The groups were recruited by Macro International, Inc. for FDA under Contract 223-94-2273, Task Order 5. Macro used a nurse consultant as a principal contact for these groups, tapping both her network and her knowledge of how to reach nurses who met the criteria of the research. This approach facilitated recruitment of an appropriate number of participants but may have limited the number of facilities from which the nurses were drawn. It is not likely that this limitation adversely affected the outcome of the groups.

The moderators for both groups were Paula Silberberg and Jay Crowley

from the Division of User Programs and Systems Analysis, Office of Health and Industry Programs, Center for Devices and Radiological Health, Food and Drug Administration.

Individual Interviews

Individual interviews were conducted with attendees at the annual Scientific Assembly of the American College of Emergency Physicians in Washington DC on September 11 and 12, 1995.

Attempts had been made, at the time that the nurse focus groups were held, to recruit physicians for similar groups. These attempts were not successful in getting a sufficient number of participants to conduct the groups. In searching for a reasonable alternative approach to get the necessary information from physicians, we contacted a number of medical professional organizations. The Center had previously been successful at working with such organizations to elicit information from their membership at their meetings. A number of the organizations were once again willing to assist us. We selected the American College of Emergency Physicians because their membership deals with a broad range of medical devices on a regular basis, their constituency is large enough to provide us with a reasonable size population to recruit from, and their meeting was in the Washington area.

A one page flyer was sent to each registered participant of the meeting ten days before the commencement of the meeting. The flyer announced that FDA would be at the meeting for the purpose of holding brief discussions about medical devices and invited them to participate. Posters were mounted near the registration booth and outside the hospitality room announcing our purpose and inviting participation. In addition, CDRH staff members spoke with meeting attendees who stopped to read the poster, reinforcing the invitation to be interviewed.

Two tools were developed to facilitate the interviews. A background information screener was constructed to gather some demographic information about participants and to explore the information sources that they use to make medical device decisions. The second tool was an interview guide constructed to clarify the entries on the screener and to solicit reaction to the model labeling that the participants were shown during the interview.

The American College of Emergency Physicians provided us with a large room for the first two mornings of the meeting. A CDRH staff member greeted interested individuals at the door and explained our purpose. The participants were then invited to help themselves to breakfast and fill out the background information screener, a two page information sheet that would provide us with a sense of how these practitioners gather the information they think is important to make medical device selection decisions. They were asked what kind of devices they use, how involved they are in the selection process for devices in their facility and what they consider the most important sources of device information for selection and use. They were also asked some general demographic information on their profession, years in practice, and type and size of their home facility. The responses to these questions provided us with background for evaluating the comments made in the individual discussions.

Once they had completed the screener, participants were directed to one of four CDRH staff members conducting interviews. A sixth staff member assisted participants, greeter and interviewers as necessary, assuring that things moved efficiently. CDRH staff participating in this phase of the research were Carol Clayton, Jay Crowley, Jack McCracken, Mary Lou Pijar, Paula Silberberg, and Pat Kingsley.

The interview started with a few questions asked to clarify answers on the screener and to invite further comment on the screener questions. Early on the first day of interviewing, all four interviewers found that there was little additional information to be gained from these questions. By mutual

consent of the interviewers, that part of the interview was kept very brief for the remainder of the interviews.

In the second part of the interview, the participant was shown a model for medical device labeling that would contain essential information for prescribing in a very concise format. A number of questions were asked to elicit reaction to the model format, contents and potential utility. Responses to the interview questions were recorded for each participant and clipped to the screener completed by that participant for later review and analysis.

There were a total of 97 useable response sheets. As with the focus groups, the criteria for interview were that the participant be a health care practitioner with medical device experience. A physician's wife, a marketing professional and two publishing professionals were excused as not meeting the criteria. Ninety-two (92) of the respondents were physicians, four (4) were nurses, and one (1) was an emergency medical technician. They represented hospitals from 44 to over 1000 beds, over half of which the respondents classified as teaching hospitals. The respondents dealt principally with hospital based, surgical and disposable equipment. They did not work with implantables or a significant number of home care devices.

Statement of Limitations

In qualitative research, the investigator attempts to gain insight and develop direction rather than to obtain the precise or absolute measures sought in quantitative research. Because of the small number of participants, the restrictions of recruiting, and the limitations of the sample to two of several potential target health care provider specialties, this research must be considered only in a qualitative frame of reference. This study cannot be considered statistically reliable or valid since the recruiting of participants cannot be exactly replicated, identical questions cannot be asked in each group or interview, nor can the results of one

group or interview be compared precisely with other groups or interviews.

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

There are a number of additional points to consider in interpreting the information gained in the interviewing process. The open ended questions asked in the interviews encouraged interpretation and subjective grouping of answers by the analyst. The short time for review of the labeling model by participants may have led to some confusion about the purpose of the document, therefore affecting answers to subsequent questions. Interviewers were not necessarily consistent in pursuing answers to all questions and respondents may have been selective as to which questions they focused on. No question was answered by all respondents and some questions were answered by few of the respondents. The rapid interaction of the interviews precluded interviewers from recording all possible remarks and reactions, restricting subsequent analysis to written responses. Interviewers' recollection of interactions was taken into account but could not be given significant weight vis a vis recorded encounters. Overlap of responses between questions (interpreting and recording respondent's thought process) may have led to subjective grouping by the analyst of responses that seemed to fit another category.

An additional potential limitation deserves consideration in interpreting the findings of this research. Participants in both the focus groups and the interviews repeatedly stated that they do not routinely see or use the labeling for the devices they select and use. Since labeling is not

currently a primary source of device information for these health care providers, their preferences and projections of use of the prototype that was tested here may be influenced by their present habit and knowledge of labeling.

The findings presented here provide perceptions, opinions, beliefs and attitudes about the decision making process used in the prescription or selection of medical devices and the effect that device labeling has on that process. They can be used to assist the Center in determining future activities in device labeling research and recommendations.

Main Findings/Detailed Findings

Note: Transcripts were provided for the focus groups, allowing the inclusion in the report of individual quotes to support the findings. No recordings or transcripts were made of the interviews. Findings were drawn from the screener and the interviewers recordings of comments.

Nurse Focus Groups

The introductory discussions of both nurse participant groups was centered on what they considered to be medical devices. It had been determined by the project personnel, in anecdotal discussions with health care professionals, that many nurses and physicians have a very narrow view of what is considered a medical device. This perception was verified in the initial portions of the focus group discussions.

> "...I was sort of surprised at the--how simple a device gets included as far as a medical device,..."
>
> "You don't mean equipment, you mean implants, devices."

> "I think we all thought of medical device as being much more narrow."

Although it was not a goal of the testing to educate the participants on what the FDA defines as a medical device, it was deemed necessary to do so in order to assure that all participants were operating from the same mental model in answering the subsequent questions about medical device decision making.

Once this groundwork was laid, a number of main finding emerged.

1. Hospital facilities acquire devices in three basic ways:
- a) bid contracts for high volume/usually low cost items
- b) some method of "committee review" for special purchases and capital equipment with a cost greater than ~$500
- c) local/unit budget for items costing less than ~ $500

> "...urinary catheters that are considered almost a commodity item. It really doesn't matter. The vendor. And it can be put out on bid."

> "...we had what we called a prime vendor. If we bought outside the prime vendor, then it will cost more."

> "...things that would cost a great deal of money out of the capital budget, greater than $500, has to go to a standardization committee."

> "But under $500, then we don't go to the extent of, you know, it has to go through this person, this person, and this person. It goes through the nurses and we look at it. The doctor wants to use it...And if we like it, fine, we'll go ahead and get it."

"We use a lot of bedside, or the lab tests and that's something I'm responsible for and make sure it comes in under costs in whatever I'm doing with patient care, I'm being held responsible for that."

"...because we are a multi-hospital system, the ultimate in many of the capital equipment purchases have to go through the helix level which is the highest governing level for all five hospitals."

2. A number of factors had impact on the acquisition processes and the health care professionals' decisions within these acquisition approaches.

A. The acquisition process is influenced by the hospital nurses' preference and particularly by surgeon preference, since they bring in patients/revenue.

"...physicians, nurses might specify a range of sizes (for a commodity item)..."

"You can have all that process...But there's always --" "Way to get around it." "A surgeon."

"It varies by individual, too, how strong a surgeon."

"And I asked him (rep) some very pointed questions. He did not give a satisfactory answer...it was not a closed system which is what I wanted. He left and I turned it down."

"And if it was something that nursing had to sterilize or wash, we had -- that's what the nurses got their input on. If you had to assemble it, how many pieces. Is it easy to clean."

"I look at what the staff can use...if there's a learning curve...someone still has to take care of the patients..."

"the clin[ical] specs, the managers of the areas, the staff nurses really do the majority of the data collection."

Regarding a decision to purchase IV pumps: "Basically the staff nurses made that decision."

"...we are able to, between myself, the nurse manager, and the staff on the unit, decide what we are going to purchase, and we were able to get a completely different IV pump than the whole system because --"

"Yes (nurses are focal points of information for a lot of equipment). Especially in a critical care setting. They're very concerned about how this is going to benefit the patient."

B. **Sales representatives had a significant impact on health care professional preference for specific devices.**

"A salesperson is going to tell you, as I was told, oh, trust us, everything you currently have in your old system we have an alternate for."

"They give you demos and then they'll let the equipment stay on your unit and let you trial it and see how well you like it and give feedback on that."

"I mean with the monitoring system we had two companies side by side coming in every day, one was trying to sell -- it was who was bringing the most food to bribe the nurses."

"-- sales representatives that come into the hospital with certain products. It just seems like there are certain ones you see more often than others."

"They contact the doctor."

"Not only do they see them at work, they see them outside of work."

"If you have a persuasive rep, and you have a person that's a go getter, he's going to visit."

"The sales rep helped the team put instruments in the autoclave. They're like a part of the team..."

"He contacted the doctor. He went over to his office. He was visible when the surgeon was there. And his product was used."

"And depending on what the chemistry is between the doctor and the rep, that's when you get the pressure brought to bear.

C. Cost concerns are a major factor that nurses take into consideration when determining their preferences.

"We do a price comparison, and then we evaluate it."

"It's on price and availability, and quantity."

"I would say managers are being held much more accountable for their budgets than they used to be and there's not as much free floating money out there."

"Nothing could go through without being trialed and whether we're saving money or not saving money...this group was the one that made the decision whether it was cost effective..."

Recognizing cost considerations, manufacturers may negotiate packages:

"...they had two competitors come in and we trialed both of the chest tubes. One chest tube was slightly higher than the other manufacturer, but if we would keep their new model, they would lower the price, just so we wouldn't change to a different distributor."

"And what they do is, if you buy these, these are the fringe benefits that go with it."

"Right now they don't just have a blanket way of selling something to a hospital. You can barter for better maintenance warranties. You can barter for better training. You can barter for little freebies that they throw in. You don't get anything you don't ask for."

"I did look at how much it would cost to have some of the stuff repaired."

"...those little pieces add up to be a lot of money."

"...they contract into the purchase price the amount of training that we're going to get from them. Training is no longer free and when you're talking about something that you're going to switch brands, there's a fair amount of training that has to occur."

"And because we have so many ORs, we could get a reasonable contract with this company, but also have them repair and refurnish them as needed. So that saves hassle and money with repair and replacement, and we know it's a reliable product."

In response to a question on the barriers to making effective medical device decisions: "Money."

A number of participants acknowledged that the political component of the acquisition process exists to varying degrees in their institution. However, they are seeing a shift away from that pressure, which they feel will continue. See discussion of cost issues, below.

> "Well, at one time I would say yes (that the surgeon has strong control of the device purchase process). But with the present world and the dollar, I think you're going to see less of that. We're seeing less of that in our hospital now."

> "It's starting to change because everyone wants the one thing, one product."

> "Our surgeons are fighting because they're not happy about it but they('re) -- coming around slowly."

In an effort to determine where the device labeling fits into this decision process, the moderators asked the participants where they get the information they need to decide what devices they want to purchase or recommend for purchase.

3. Health care professionals use a number of approaches to gather information with which to make medical device decisions.

a) experience from trial use of device
b) information from data services
c) networking with other professionals
d) promotional materials from manufacturers

Labeling was not mentioned by the participants as a source of this information. When they were prompted to consider how they use labeling, they did not consider it a principal source of information.

> "So, now we have different companies coming in and we're doing -- we're looking at various OR tables. Each week we have a

different OR table."

"We'll have a trial evaluation with input from the surgeons post procedure, et cetera."

"...if it's going to decrease the length of stay by two days or a day, then sure, bring it in, and even look at it to see what it does."

In response to questioning on how products are compared: "By trial evaluation."

"Basically we have so many things come and the reps come in initially to show us how it works and we have an in-service course. We basically just go from there."

"...we have one other step that, particularly in the capital process, that we contract with a company called MD Byline. And so, when we're looking at a particular device, they've done an analysis and looked at it, and their information is taken into consideration and presented at the capital subcommittee that makes decisions on equipment."

"MD Byline has been very helpful to me."

"Our bio-medical department uses services like ECRI."

"...actually I found an e-mail network where you can look and compare products..."

"Then this is something that might be brought in by one of the nurses who has been to a conference."

"I just got back from New Orleans, National Teaching Institute of Critical Care and you have a tremendously huge building with every

vendor there and the vendors were kind of mad this time because AACM was actually putting two different bed vendors together and they didn't like that. They want them all spread out so you make it a little more difficult to compare."

"If you can find people who have used an item or a product, they've used it over a period of time, and you can get their input."

"Many of our nurses will contact nurses at other hospitals of similar size, say we're looking at such and so."

"Journals, nursing journals."

"You always know when the orthopedic (meeting) is because they always come back with new and great ideas."

"Again, from journals or from the reps, or from a meeting...Or from actual experience with use."

"I like to read -- if they have research articles related to their products, if they've done some kind of actual study, I like to read that. Even though it still may be somewhat biased, I take that into consideration."

"...our education department has a lot (of promotional material). They come along and show us a lot of new things that are out and that might be beneficial."

"A lot of stuff comes in the mail. I'm always getting a lot in the mail."

When the participants were specifically asked what labeling information they get from the manufacturers and how they use it, they referred again to in-service training or other sources of information than the device

labeling. The latter was mentioned only in a minor role, even with this prompting.

> "They in-service it, the company."
>
> "One of the latest things, too,...many of the companies are either providing your own little competency checklist that you can go through..."
>
> "We said, without having the literature in front of us, what does the product need to do. And then that was our evaluation tool."

4. Current device labeling is not seen by nurses as a useful tool either for acquisition decision making or for device use for a number of reasons:

a) poor distribution
b) cost of sufficient number of copies
c) way it is written
d) other, more appealing sources
e) skepticism about validity of some labeling

> "We usually don't see the user manual or maintenance manual for purchasing a piece of equipment."
>
> "Even the physician's brochures and the patient brochures, I don't think you see those until after you purchase -- they don't offer out -- "
>
> "Biomed doesn't even (inform) us that they have the user manuals. We usually get a little thing from the sales rep."
>
> "You want something there in the unit that they can troubleshoot

and figure this out themselves and it's very frustrating when the information isn't available. Why it's being withheld I don't know, whether they think we're not capable of reading the user manual, you know, and figuring it out."

"I would disagree...I've been able to get the manuals because Biomed holds the manuals because they have to approve and check all the equipment that comes in...But I mean I've had the use of those manuals prior to purchasing."

"We have shelves and shelves of policies in our department. No one ever reads them...why not put some user information in there, some hard copy print material on how to use the monitors, something you could go to and open up the book."

"The problem is, they only give you one copy and, if you don't keep it in your office, it walks."

"...I've had a lot of hard time trying to find information about those little things (e.g., the internal diameter of a catheter) than I have finding information about the big $10,000, $15,000 pieces of equipment that we purchased."

"When I purchased three of them, bringing up the new unit, I only got one user manual and for the rest I had to pay $50 apiece for, so therefore, I only purchased one because I wanted to buy other medical equipment for my unit, but I only bought one and granted, that book is in my closet, my office, because I need that for the Sunday afternoons or Friday nights at 11 o'clock and somebody calls me."

"Well, you're in a crisis, you want to get things going and you're trying to hook it up and here's the card and you're reading it and it doesn't make any sense and then 'Marcie, come here, come here!

Hook this up for me.’ You pretty much troubleshoot with other staff members.”

“Availability is really an important thing, but also the instructions need to be, I mean, we’re not rocket scientists, but we’re not stupid either.”

“The terminology, I think, is not familiar terminology that we would use, you know and it may be just lingo that we use in critical care nursing, but you would think this monitor is supposed to function adequately in this environment. It should have terminology that everyone is kind of used to.”

“More computer-assisted training. I’ve gotten, I’d say, about four different floppy disks in the last year that are presenting some product and it really -- it catches your senses better.”

“One of the things I’m often given is copies of journal articles. Oftentimes they’re not as relevant to the actual piece of equipment as the manufacturer would like you to believe...perhaps suggest their product and it’s used in research, but it isn’t really clearly there...”

“...I’ll get articles handed to me...if they have actually done research, we do our own little research projects all the time to compare data on different pieces of equipment and devices, but we don’t see a whole lot of that in truthful context.”

“I’ve experienced many sales people who really don’t know their products and will tell you one thing and you’re going to find out by reading it’s something else...I’ve gotten so much information about a product...”

5. There are some additional factors that preclude the use of the current labeling:

a) competing organizational requirements such as lowest cost or general use across the facility
b) presence of sales representative when device is used
c) personal information needs of users, e.g., hands on learners
d) staff and managers looking for new information technology, e.g., electronic database

"So, ultimately, they (the hospital governing body) could still come down and say you're all going to buy Hewlett-Packard monitors..."

"...standardization is when they wanted one pump in the whole house, the standardization committee had to sit back and listen to the anesthesiologist, listen to the nurses, listen to the administrators of the hospital...and try to decide what was the best issue in cost and what the pump could do..."

Referring to sales representative presence in the OR: "...it is getting essential for them to be there to ensure the smoothness because we're getting such a wide variety of stuff to keep our OR nurses extremely alert...They're providing technical assistance...they'll say this is -- this next, this next. So you just follow and put the stuff together."

"Each one of the people who are trying to make a decision have a different way of learning. They can take a book...a little pamphlet, sit down and can run a machine right away. But you have another person who has to have somebody stand beside them and go through each one of the steps..."

"I would say most of the ICU nurses are going to be the show me, let me do it and then I'll be ready to teach it. But there's always a

few people that want to take something and digest it."

"Or the specialist is instructed and then responsible for training each department."

"One of the latest things, too, and I think it's based on the Joint Commission and their requirements for competency, many of the companies are providing your own little competency checklist..."

"They're building their balloon pumps now with actually you can plug the phone line right in. They can diagnose, they can troubleshoot with you over the phone. And some other medical devices are coming out with that too. It's very reassuring to staff that you're getting an expert right then."

"I think there will be a lot more medical information being provided on the computer..."

The nurses were shown a model of essential prescribing information that could be included with the full medical device labeling. They were asked for their reactions to the model's format, contents and potential utility to them and their colleagues in selecting and using medical devices. Their reaction was positive, although not overwhelmingly so. They felt that this could be a useful tool, provided it was effectively distributed and focused on the information that they needed most. The importance of good user instructions, particularly trouble shooting information was a strong theme.

6. A number of suggestions for improving device labeling were made:

a) include a standardized "brief summary" in promotional material,
b) develop a compendium of comparative information,
c) shorten and simplify user instructions,
d) make summary prescribing information available for facility database, and
e) some specific instructions for improving the model labeling

"The best place seems to be with the promotional."

"If the FDA could have some kind of consumer report on some of these products...an unbiased type of survey."

"Almost like a catalogue or something purchasing agents could get a book of these, of all the..."

"If you had just one sheet, you could look real quickly and decide what the differences would be between the equipment."

"This would be great like a PDR where you flip through and find out what's there and update it."

"If they keep it short and sweet, that's what you need. It's right there and you're not searching for it somewhere."

"I would just say make sure the reading levels -- make them down for us too when we're stressed and running around --"

"So don't give them a lot of senseless directions."

"I only want to know what buttons to push."

"Keep it simple and direct and informative."

"Do you think the physicians read? They always go running for the nurses."

"Maybe like a picture, some things -- a little black and white picture of the product."

"...the date...the model number...interactions with other devices...who can use it...whether there is a patient booklet...where the patient can get help with this device when they go home..."

Physician Interviews

Several main themes emerged in the physician background information screeners and interviews.

1. These physicians have little direct control over device purchase for their facility. They may recommend specific devices to selection committees or prescribe devices.

In the emergency room environment, physicians primarily use what is there. They may be able to recommend something that they have seen at a meeting or heard about from a colleague, but most have little control in the selection and purchasing process. The comment recurred that they often did not know how to find unbiased information on alternatives to what they were using. This echos the complaint noted earlier in the focus groups that there is a large gap in the readily available comparative information. This was a strong theme that will be discussed in more detail later. It has clear impact on the clinicians' ability to make sound recommendations for selection and purchase. It also has an impact on the format and content changes of labeling information that they may find most useful.

2. They rely on information from colleagues and their own experience in selecting medical devices. There are some additional sources that are important to them. Labeling was rarely mentioned as a source of device selection information.

On the Screener/Demographic Information form (see Appendix C), participants were asked to rank their three most important sources of information for the selection of devices for purchase from a list of ten (10) possible sources and a choice for "other". Colleagues experience/recommendations and personal experience/judgement ranked as the top choices, drawing close to equal votes. Professional meetings fell somewhat behind these choices, followed by sales representatives, manufacturer in-service materials, and journal articles. Labeling and advertising were rarely mentioned as important sources for this decision process.

A second ranking exercise on the screening form asked participants to use the same list to choose the three most important information sources for determining if a specific devices was appropriate for a patient in a certain situation. Personal experience was the first choice, followed fairly closely by colleagues' recommendations. Professional meetings again fell considerably behind the first two with journal articles, sales representatives and in service materials grouped somewhat lower. As in the previous response, labeling and advertising got little interest.

The third ranking question on the screening form sought to determine sources for medical device use/operation information. Respondents ranked colleagues' experience, in service materials and sales representatives close together at the top. These written responses are interesting in light of the comments made during the interviews that complained about the lack of in service access to physicians with a subsequent dependence on nurses to help them operate the equipment.

Their own experience was the next source they relied upon. This choice was followed at some distance by the operator's manual with the labeling in or on the device ranking a little better in this response category than the previous two. Neither form of labeling could be considered a significant source of information to this sample of practitioners.

Most respondents, who stated a preference for when they would like to receive device information, would like to have this information provided early in the decision process. The suggestions supporting this preference voiced most often were: from the sales representative when the device is presented or demonstrated, when they are thinking about buying, and in advertising. A number of respondents asked that it be provided as a hang tag on the device. The interviewers indicated that most often this response referred to operational information, such as the troubleshooting assistance often requested during the discussions. Respondents saw possibilities for summary information as part of the full labeling provided when a device is purchased or a handout for the in service on a device.

It is clear that there is currently little primary reliance on labeling except for device operation, but there may be possibilities for addressing this problem.

3. Respondents felt that a deficit exists in the information available to clinicians about medical devices. Cost and comparative information were primary deficits.

The comments made in the interviews pointed to both content and distribution deficits in device information. As noted earlier, the interview started with a few questions meant to clarify and probe the answers recorded on the screener. The most prevalent comment made during this part of the discussion was that there is no good source for comparative information on devices. They feel that they are missing critical cost and comparative information and that what is out there is hard to get in a timely fashion. These are critical pieces of information to them. A significant number of respondents brought this up spontaneously and re-

emphasized it a number of times in their comments.

A large number of the respondents felt that some form of compendium would be the most effective way to provide this information. The comment was made a number of times that respondents did not know how to find out "what else is out there" or had difficulty getting information on alternatives. Although some felt that they could make the appropriate decisions from their own comparison of basic device information, others wanted a comparative "Consumer Reports" approach to the presentation of device information. Although a PDR-like volume was the model most often mentioned, respondents were aware of the difficulties with keeping such information up to date. Suggestions were made to have the compendium computerized, either in a CD ROM format or an on line service. A FAX availability approach as well as some form of periodical were also mentioned by a few respondents. Some respondents also voiced a concern with getting unbiased information, recommending that information provided by the FDA or a third party would be seen as more reliable than that from manufacturers.

4. Physicians reacted positively to the model but not strongly so. They had a number of suggestions for making it more useful to them, principally a need for concise operating instructions.

The interviews explored respondents reactions to a possible approach to remedy the information deficit identified by the physicians, a model for essential prescribing information. As noted earlier, the model presented to the participants was based on a labeling model being tested for the presentation of prescription drug information. Reaction to the device labeling was positive but not strongly so. Those few respondents who said they liked it would use it or at least try it. A number of participants responded to one or more specific things that they liked about the format or intended content rather than to the entire document. From the

additional information requested, as noted below, it is clear that there is an interest in having some sort of concise operating instructions as part of the labeling in addition to, or perhaps instead of, essential prescribing information. As requested during the nurse focus groups, the physicians were looking for something quick and simple to assist them in using the device.

Items on the model that were liked by several respondents were: single page/summary approach/concise presentation; the boxed warning; and, the concept of a standardized format across devices. Additional items mentioned positively but with less frequency were: easy to read; contains the necessary information; familiar looking (resembles drug information); could be used for patient information sheet; may be helpful with unfamiliar device.

A large number of respondents suggested headings that they would like to see added. However, no one topic area was suggested more than a few times. The topics most frequently suggested were: performance measures and limits, outcome measures/safety-effectiveness data, and device reliability/history. Additional topics mentioned included: special features, skill level required, shelf life/durability, and troubleshooting information.

There were a number of headers that respondents felt were inappropriate for medical device labeling or for the stated purpose of this labeling. "Dosage and administration" was the principal example cited. Although there were a couple of recommended replacements for this header, and most respondents discussing the issues felt that it should not be completely deleted, there was no consensus on what would be more appropriate. Some headings that respondents felt may be unnecessary were: patient counseling, indications, special populations and description. Some respondents felt that the terms "Special Considerations" and "Side Effects" were not strong enough. In addition, some respondents suggested that not all headers would be needed for all devices.

A few respondents voiced the concern that the existence of a short summary could encourage a practitioner not to read the full information and therefore miss important information. One respondent wanted to see a prominent warning to read the full label added. While these comments reinforce information and suggestions found in the literature on constructing product information, this concern conflicts with comments from other respondents that the labeling is often not available with the device and the preponderance of respondents who indicated in their screening information that they relied on colleagues and personal knowledge for device selection information and very little on labeling. An additional few respondents felt that this summary would have limited use, perhaps verifying the lack of reliance on labeling by this population. A small number of respondents actually discredited such a document as a legal disclaimer for the manufacturer.

There were some formatting recommendations, such as bolding/highlighting headers and other critical information (e.g., warnings). In the interest of brevity, participants wanted special considerations limited to the most important issues and ranked.

Most respondents felt that the order of information on the model was reasonable or that the order did not really matter. The only other comment on order that recurred was a suggestion to group what several respondents referred to as “good stuff” (positive information such as description, indications for use, and some form of dosage and administration) and “bad stuff” (contraindications, special considerations, and common side effects). This is a comment that was also heard in focus testing conducted by the Center for Drug Evaluation and Research on model labeling for essential prescribing information. There was no agreement among our respondents on which group should appear first.

Most respondents felt that the information covered in the model was appropriate. Several indicated specific categories, such as indications, contraindications, and warnings, that they felt most important to them. A

number also voiced the opinion that they would like to see the scientific evidence for manufacturers' claims and information, particularly for adverse events.

The horizontal orientation was a problem for some readers. They were uncertain as to what sequence to follow when reading the document, e.g., down the entire first column before reading the second or back and forth between the columns. Most who had a preference liked the two column format.

When directly questioned as to whether the model would provide them with enough information, more respondents answered positively than negatively. However, if the number of respondents asking for cost and comparative information is factored in, the model is seen as lacking in critical information that practitioners do not feel that they now have. A small number felt that this would be a start or a reference. Comments made by those who, on direct questioning, did not find the model sufficiently focused on the need for comparative information, more specific information, hands on experience with the device, and operational rather than selection information. These responses prompt further investigation of the value to be added by providing Essential Prescribing Information, particularly given the complaint by some respondents that they are in information overload and that the labeling that they do see is too long and complex.

There were some additional suggestions on ways the physicians would like to see the information that they get improved. These included more and better dialogue with the sales representatives and the manufacturers. Some also recommended more meeting presentations and journal articles focused specifically on devices. Better physician access to in service presentations, training videos and device manuals was also suggested. A number would like to see more feedback from patients and other users on effectiveness of devices.

Actions Suggested by Findings

1. Consider an alternative plan for implementing some form of summary labeling for medical devices.

   The current plan has been to follow the CDER lead in developing and implementing essential prescribing information (EPI) for physicians in an effort to provide clinicians with similar labeling for all of the products that they use to diagnose and treat patients. This plan was based on the assumption that what was determined appropriate for drug labeling would also hold for device labeling. The results of the focus groups and interviews clearly indicate that:

   - clinicians have a level of comfort, whether it is well founded or not, with their current sources of device information,
   - labeling is not a primary source of selection information,
   - there is poor distribution of labeling to health care providers, particularly prior to any selection process and
   - clinicians surveyed expressed only mild interest in the concept of an EPI for devices.

   These are not insurmountable obstacles to implementing an EPI if there was clear indication that it would have value. Clinicians could be educated to use labeling, particularly if the distribution was improved. It would require overcoming the current comfort with their reliance upon themselves and their colleagues for the information that they need. Changing habits through education is a slow process, requiring careful planning, time and perseverance. The value to them would have to be clear and considerable to motivate them to invest the necessary time and effort.

However, a critical piece of information that came through very clearly in both the focus groups and the interviews was that they feel they are missing cost and device comparison information. Without that information, the EPI would not be likely to be considered any more valuable to them than current labeling. The respondents admitted problems with collecting and publishing this information. It would be very difficult to collect the necessary information in one place, given the number of devices, the protection of proprietary information, the rapidly changing technology and the importance of the information being accurate. It would be very difficult for the responsible entity to keep the information current. In addition, the physicians were very strong in their request that any such information be from an unbiased source. While some respondents felt that this was a government responsibility, most who addressed the issue wanted some third party to be the repository of this information. Positive experience with organizations such as ECRI and MD Buyline engendered some of these responses.

It is clear that developing the kind of cost and comparative information that clinicians are asking for in an EPI will involve considerably more than a simplified format for current information and manufacturer cooperation in the program. While it may be an important program to pursue over the long run, there is no quick approach to what physicians appear to be asking for in this area. It requires further study across a broader sample of responsible practitioners for most effective content, format and distribution, with attention to the re-education of practitioners in the use of medical device labeling.

Information that was clearly imparted by participants in both the focus groups and the interviews indicated that what they really wanted was clear, concise operating instructions. Participants in both the groups and the interviews repeatedly asserted the need for "hang tags" with critical operational information, particularly

troubleshooting information. The indication is that there is an immediate need for this kind of information with the probability that, if it was properly provided, it would be used. Respondents commented on constructing their own "hang tags" and summary operating documents and repeatedly referred to their dependence upon each other for critical information on how to operate and troubleshoot a device.

With the strong request for concise operating instructions, the weak reaction to the EPI and the complexities of properly addressing the presentation of the "prescribing" information that the physicians are asking for, we recommend addressing the operating instruction issue immediately with a continued study of the effective presentation of prescribing information.

2. Investigate validity of these results for implantables and home care devices.

Because, as noted earlier, the sample tested in both the focus groups and the interviews did not deal with implantables and home care devices to an appreciable extent, it is important that these device areas be further investigated to assure that the results of the current tests do, in fact, reflect practitioners' opinions concerning implantable and home care devices. There is some anecdotal evidence that implantables and home care devices may have a greater need for Essential Prescribing Information than do the devices that the practitioners that we surveyed deal with. Practitioners who deal with these devices were not well enough represented in the test sample to make a clear determination. In addition, comments made in both the focus groups and the interviews indicate that there may be more clinician control in selection of these devices than with the general hospital, surgical or disposable devices.

For the above reasons, it is recommended that further interviews and/or focus tests be conducted with a sample of the target audience that deals with implantables and home care devices, for example, cardiovascular and/or orthopedic surgeons and internists/pediatricians. This research would attempt to capture the necessary information to determine if an EPI would be an effective tool for conveying device prescription information to this group of physicians and should be pursued for these types of devices.

3. Consider engaging manufacturers and perhaps others to continue exploring the value of the EPI.

   Since there was mild interest in the EPI on the part of the physicians and nurses participating in these discussions and groups, some effort should probably be continued to explore its value and to attempt to satisfy the stated need for cost and comparative information. Because of the nature of the information that practitioners have requested as well as the limited resources that the Center has to devote to assisting manufacturers in improving labeling, the continued effort with the EPI might best be managed by a cooperative effort of manufacturers and third party information sources such as ECRI and MD Buyline. The Center could act as a catalyst to engage this activity and as a resource if a serious effort is undertaken.

4. Present the findings of these groups and interviews to encourage further study of some of the issues raised.

   There are some very complex issues raised by the practitioners in this study that need further discussion and investigation. Some of these are: the complex problem of poor use of labeling by clinicians, the apparently inadequate distribution of device labeling to users and throughout facilities, the need for better access to in service training and the need for cost and comparative information. These

and other issues noted by our participants may have a critical impact on device use, misuse and error. The Center has some role to play in a number of these issues, but is far from the sole or even principal player in a number of them. It is recommended that the Center share the information gained in this study, through articles, presentations, or some appropriate forum in an effort to generate discussion and encourage solution identification and implementation.